

VIRGINIA ECONOMIC DEVELOPMENT PARTNERSHIP P.O. Box 798 . 901 East Cary Street Richmond, Virginia 23218-0798 804.545.5600 . www.YesVirginia.org

November 1, 2017

The Honorable Terence R. McAuliffe Governor of the Commonwealth of Virginia Patrick Henry Building, 3rd Floor 1111 East Broad Street Richmond, Virginia 23219

The Honorable Thomas K. Norment, Jr. Co-Chair, Senate Committee on Finance 14<sup>th</sup> Floor, Pocahontas Building 900 East Main Street Richmond, Virginia 23219

The Honorable S. Chris Jones Chair, House Committee on Appropriations 13<sup>th</sup> Floor, Pocahontas Building 900 East Main Street Richmond, Virginia 23218 The Honorable Emmett W. Hanger, Jr. Co-Chair, Senate Committee on Finance 14<sup>th</sup> Floor, Pocahontas Building 900 East Main Street Richmond, Virginia 23219

Re: Virginia Biosciences Health Research Corporation

Dear Governor McAuliffe, Senator Norment, Senator Hanger, and Delegate Jones:

Chapter 836, Item 106:I of the 2017 Acts of Assembly includes funding for the Virginia Biosciences Health Research Corporation (VBHRC), a 501(c)(3) non-stock corporation, to serve as a catalyst to accelerate and focus life science research momentum at Virginia's universities. VBHRC uses the name "Virginia Catalyst."

Chapter 836, Item 106:I.6 requires that you be provided by, November 1 of each year, a written report summarizing the activities of the consortium, including, but not limited to, a summary of how any funds disbursed to the consortium during the previous fiscal year were spent, and the consortium's progress during the fiscal year in expanding upon existing research opportunities and stimulating new research opportunities in the Commonwealth.

Earlier this fall, representatives of Virginia Catalyst met with staff from the Senate Finance Committee and the House Appropriations Committee. At that time, Virginia Catalyst delivered a comprehensive report detailing the mission, funding, initiatives and progress of Virginia Catalyst. A copy of that comprehensive report is attached.

At the time of that comprehensive report, the audited financial statements for the fiscal year ended December 31, 2016 were still in draft form. A final copy of the audited financial statements for the fiscal year ended December 31, 2016 are attached to this letter. Virginia Catalyst has recently changed its fiscal year end to June 30. Accordingly, also attached to this

The Honorable Terence R. McAuliffe The Honorable Thomas K. Norment, Jr. The Honorable Emmett W. Hanger, Jr. The Honorable S. Chris Jones November 1, 2017

letter are the audited financial statements for Virginia Catalyst for the six months ended June 30, 2017.

On behalf of VBHRC and its Board of Directors, thank you for your continued support of these important and innovative efforts to transform Virginia's economy. As always, please do not hesitate to contact Mike Grisham, the Chief Executive Officer of VBHRC, or me, if we can be of any assistance.

Very truly yours,

Sandra Jones McNinch

General Counsel

cc: The Honorable Todd P. Haymore, Secretary of Commerce & Trade

Mr. Mike Grisham, Chief Executive Office, Virginia Biosciences Health Research Corporation

# VBHRC 4-CATALYST

**Briefing Book - 2017** 



**Virginia Catalyst** is a not-for-profit 501(c)(3) corporation created by the Virginia General Assembly and funded by the Commonwealth's General Fund and seven Virginia public research universities: EVMS, GMU, ODU, UVA, VCU, VT and W&M.

**Our Mission** is to advance economic development by creating competitive critical mass for Virginia life sciences through collaborations with our research universities and industry, to attract research and commercialization capital to Virginia and to catalyze the commercialization of Virginia's innovations that meet large, unmet medical needs, improve human health and to create many more high-paying life science jobs in Virginia.

Our Programs. We provide competitive, non-dilutive, milestone-based grant funding where two or more of Virginia's research universities collaborate with an industry partner on significant translational research and commercialization opportunities to improve human health and create jobs. All Virginia Catalyst funding is disbursed to the prime university, not the industry partner. Disbursements are spread out over the project period based on the achievement of measurable milestones.

We also lead strategic initiatives in areas Virginia can be a national and global leader, and support this with investments creating research tools and infrastructure that provide our research universities, healthcare systems and companies a competitive advantage over other regions in the country.

Actions and Results. Virginia Catalyst awards have resulted in a 10-to-1 return on investment. We have awarded grants totaling \$10.2 million to advance 24 collaborative projects of great scientific and commercial promise through meaningful developmental milestones. These projects have attracted an additional \$100 million in matching funds and follow-on funding. We are just completing our seventh round of grant funding for an additional \$1.4 million in awards to 3 projects focused on the neurosciences including a game-changing project to significantly improve the standard of care for the treatment of opioid addiction.

We have helped our research universities and healthcare systems build a breakthrough *statewide* system of research tools and infrastructure to support the neurosciences with 1) a directory of Virginia's impressive assets in the neurosciences, including our top researchers and core facilities; 2) a registry of all neuro patients, and 3) a clinical trial and research network. This will attract increased funding from industry, private equity, philanthropy and the federal government. Our plans include expanding this model to other clinical and research fields.



## **Introduction and Executive Summary**



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Increasing impact by expanding collaborative grant programs and building shared research capabilities to support next generation collaborations in Virginia to compete globally



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24 projects in 6 rounds of funding, over 4 years7 Virginia research universities and 19 industry partners

Over \$10 million in grants awarded brings in...

## \$100 million in additional capital

including \$20 million in matching funds + \$80 million in follow-on funding

+ Jobs

Virginia Catalyst (a non-profit corporation of the Commonwealth) awards competitive matching grants to collaborations involving two or more of Virginia's public research universities and industry partners with matching funds to accelerate commercialization of innovative projects that have outstanding potential to impact human health and economic development, attract investment, and grow jobs.

## **Industry Partners**

BioTherapeutics (Blacksburg) • BrightSpec (Charlottesville) • Cavion (Charlottesville) • Ceres Nanosciences (Manassas) • Embody LLC (Norfolk) • First String Research (Roanoke and Mt. Pleasant, SC) • HemoShear (Charlottesville) • Gencia (Charlottesville) • Neoantigenics (Charlottesville) • SphynKx Therapeutics (Charlottesville) • LifeNet Health (Virginia Beach) • PhenoCHIP (Blacksburg) • Propagenix (Rockville, MD) • Pulse Biosciences (Burlingame, CA) • OncoSec Medical (San Diego, CA) • US Probe (Glen Allen) • Sanyal Biotechnology (Virginia Beach) • Serpin Pharma (Manassas) • VoltMed (Blacksburg)



## **University Partners**

Eastern Virginia Medical School • George Mason University • University of Virginia • Virginia Commonwealth University • Virginia Tech • Old Dominion University • William & Mary

For more information, contact: Mike Grisham, President and CEO mgrisham@virginiacatalyst.org 804.545.5799 | 804.543.5200



### **Project Results to Date**

	Collaborators	Date	Amount of Grant	Matching Funds	Follow on Funding	Initial Job Creation	Net Job Creation	Additional Funding – Next 18 Months	Job Creation – Next 18 Months
VT, VCU	BioTherapeutics Inc. Blacksburg, VA	12-2013	\$400,000	\$400,000	\$10,000,000	15	15	\$35,000,000*	7
UVA, GMU	Tau Therapeutics (Cavion LLC) Charlottesville, VA	12-2013	\$200,000	\$238,000	\$26,100,000	2.5	2.5		4
VT, UVA	First String Research Roanoke, VA and Mt. Pleasant, SC	12-2013	\$200,000	\$1,000,000	\$3,000,000	10	10	\$15,000,000*	0
UVA, VCU	HemoShear LLC Charlottesville, VA	12-2013	\$450,000	\$800,000	\$1,900,000	5	5	\$15,000,000	10
	Subtotal Round 1		\$1,250,000	\$2,438,000	\$41,000,000	32.5	32.5	\$65,000,000	21
VCU, UVA	Gencia, LLC Charlottesville, VA	03-2014	\$400,000	\$400,000	\$8,800,000	2	2		
UVA, VCU	Neoantigenics LLC** Charlottesville, VA	03-2014	\$348,729	\$2,000,000	\$3,000,000	1	0	\$0	0
VT, UVA	SphynKx Therapeutics*** Charlottesville, VA	03-2014	\$400,000	\$400,000	\$150,000	4	4	\$0	0
EVMS, UVA	LifeNet Health Virginia Beach, VA	03-2014	\$255,000	\$255,000	\$5,000	3	1		
	Subtotal Round 2		\$1,789,479	\$2,825,657	\$11,955,000	10	7		
VT, UVA	PhenoCHIP Blacksburg, VA	08-2014	\$270,000	\$386,000	\$450,000	5	4	\$1,000,000	7
ODU, EVMS	OncoSec Medical San Diego, CA	08-2014	\$585,000	\$2,750,000	\$8,700,000	3.5	3.5	. , , ,	3
VCU, ODU	US Probe Glen Allen, VA	08-2014	\$536,000	\$536,000	\$450,000	5.5	5.5	\$500,000	2.5
	Subtotal Round 3		\$1,391,000	\$3,672,000	\$9,600,000	14	13	\$1,500,000	12.5

<sup>\*</sup>Confidential Information – These companies have commitments expecting to be actualized in October 2017. \*\*Principal Investigator, Josh Hare, died of heart attack, and project ended. \*\*\*SphynKx returned Intellectual Property to Virginia Tech, where they are continuing to collect additional data from animal models.

		-							
4	eres Nanosciences Janassas, VA	08-2015	\$500,000	\$500,000	\$5,000,000	13	11	\$ 6,000,000	7
Ro	rst String Research Danoke, VA and Mt. easant, SC	08-2015	\$290,000	\$500,000					
No	mbody LLC orfolk, VA	08-2015	\$634,500	\$725,000	\$3,600,000	5	9	\$9,000,000	10
	oTherapeutics Inc. acksburg, VA	08-2015	\$400,000	\$400,000					
	rightSpec, Inc narlottesville, VA	08-2015	\$400,000	\$400,000	\$2,150,000	6	6	\$4,000,000*	15
Su	ubtotal Round 4		\$2,224,500	\$2,525,000	\$10,750,000	24	26	\$19,000,000	32
	avion narlottesville, VA	12-2015	\$307,057	\$352,862					
/A Vo	oltMed, Inc. acksburg, VA	12-2015	\$380,000	\$1,200,000	\$2,000,000	12	10	\$4,000,000	8
DESCRIPTION OF THE PARTY.	ubtotal Round 5		\$687,057	\$1,552,862	\$2,000,000	12	10	\$4,000,000	8
	oltMed, Inc. acksburg, VA	10-2016	\$800,000	\$800,000					
:U Bio	oTherapeutics Inc. acksburg, VA	10-2016	\$800,000	\$800,000					
Ma	erpin Pharma Janassas, VA	10-2016	\$400,000	\$3,400,000	\$550,000	4.5	6.5	\$6,750,000	10
	anyal Biotechnology rginia Beach, VA	10-2016	\$100,000	\$100,000	\$580,000	3	3		8
I I	ulse Biosciences urlingame, CA	10-2016	\$300,000	\$300,000	\$0	2	2		2
Pro	opagenix ockville, MD	10-2016	\$425,000	\$1,200,000	\$500,000	1	1	\$12,900,000	4
The state of	ubtotal Round 6		\$2,825,000	\$6,600,000	\$1,600,000	10.5	12.5	\$19,650,000	24
	otal Rounds 1-6		\$2,825,000	\$6,600,000	\$1,600,000	10.5	12.5	\$19,650,000 \$109,150,000	



#### FOR IMMEDIATE RELEASE

#### **Media Contact:**

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#### Seven Virginia Universities Sign Groundbreaking Agreement to Share Resources to Enhance Collaborative Research

Institutions focus on more advanced collaboration to drive solutions to the world's most pressing human health challenges

RICHMOND, VA – July 11, 2017 – Seven academic research institutions in Virginia have signed a memorandum of understanding (MOU) to share core facilities and resources in an effort to advance life sciences and other areas of research in the Commonwealth. This initiative will accelerate the commercialization of Virginia's innovations, creating more high potential start-up companies, producing many more high-paying jobs, and growing the Commonwealth's biosciences economy. The Vice Presidents for Research from the University of Virginia, Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Old Dominion University, Virginia Tech and William & Mary, working together with Virginia Catalyst, have achieved a breakthrough in collaborations that will greatly increase Virginia's competitiveness nationally and globally.

The universities have agreed to provide reciprocal access to shared R&D resources. The institutions have individually made significant investments to acquire specialized equipment and establish unique research laboratories to support basic, translational and clinical research. To further enhance the availability of these existing resources, the institutions seek to share, in an economical manner, specialized technical services and access to equipment and expertise for research purposes.

The memorandum will be reviewed biannually and could be amended at those times. Other state institutions are also encouraged to become signatories of the MOU.

Virginia Biosciences Health Research Corporation, now known as the Virginia Catalyst, is a not-for-profit 501(c)(3) corporation funded by the Virginia General Assembly's general fund and seven of Virginia's research universities. The organization has now awarded 24 grants totaling \$10 million, combined with \$20 million in matching funds, which financed the achievement of meaningful milestones. This then resulted in follow-on funding of an additional \$80 million and the creation of high-paying jobs throughout the Commonwealth.

#### Supporting Quotes

"Virginia's institutions of higher education are committed to working together to enhance the competitiveness of research in the Commonwealth, while sharing resources to improve efficiency. This MOU enables us to achieve both of those goals by formalizing our collaboration." — University of Virginia President Teresa A. Sullivan

"The research officers of VCU and our sister institutions have crafted an unprecedented agreement that will enhance research across the Commonwealth's universities. In doing so, it effectively leverages state resources that are frequently used to create and maintain these shared resource core facilities." – Michael Rao, President of Virginia Commonwealth University

"Eastern Virginia Medical School has a history of collaborative research that addresses healthcare disparities and the medical priorities of our community and the Commonwealth. We welcome this opportunity to expand collaboration in biomedical research with our partner universities." — Richard V. Homan, President and Provost, Dean of the School of Medicine, Eastern Virginia Medical School

"George Mason University is delighted to join with its sibling institutions to share research facilities and expertise that will advance the Commonwealth's leadership in the knowledge economy. This agreement reflects our deep commitment to work together to advance our shared mission and goals." – **President Ángel Cabrera of George Mason University** 

"Old Dominion University has long been a proponent of collaboration, in disciplines from flooding resiliency to cybersecurity. We are happy to be part of this effort, which will maximize the ability of all institutions to conduct cutting-edge research to address the Commonwealth's most important priorities." — Old Dominion University President John R. Broderick

"Virginia Tech is proud to be part of this unique research agreement and we applaud the spirit of cooperation and collaboration it represents. Virginia's research institutions are doing remarkable things to improve lives and energize the Commonwealth's economy, and when we work together, the sky's the limit." – Virginia Tech President Tim Sands

"William & Mary hopes and expects this agreement to share resources will heighten the efficiency of each participant's efforts and the excellence of research done in the Commonwealth. Effective collaboration can bear rich fruit for us all." – William & Mary President Taylor Reveley

#### **About the Virginia Catalyst**

The mission of Virginia Biosciences Health Research Corporation (VBHRC), known as Virginia Catalyst, is to advance life sciences throughout Virginia as a means of addressing large unmet medical needs to improve human health and to create high-paying jobs throughout the Commonwealth. Funded by the Virginia General Assembly's General fund, the University of Virginia, Virginia Commonwealth University, Virginia Tech, Eastern Virginia Medical School, George Mason University, Old Dominion University, and William and Mary, Virginia Catalyst has funding opportunities to support collaborative projects in the Commonwealth and is home to the Virginia Neuroscience Initiative. For more information, visit www.virginiacatalyst.org.

###

### **Memorandum of Understanding**

Seven Virginia Research Universities Sign MOU to Share Core Research Facilities



## MEMORANDUM OF UNDERSTANDING AMONG ACADEMIC RESEARCH INSTITUTIONS REGARDING RECIPROCAL ACCESS TO SHARED RESOURCES

#### **BACKGROUND**

This Memorandum of Understanding ("MOU") is entered into by and between the seven undersigned academic research institutions: Virginia Commonwealth University, College of William & Mary, George Mason University, University of Virginia, Eastern Virginia Medical School, Old Dominion University, and Virginia Polytechnic Institute and State University (individually an "Institution" and collectively, the "Institutions"). The Institutions have been encouraged by the Virginia Biosciences Health Research Corporation ("VBHRC") to consider ways to enhance collaboration, cooperation and interaction between institutions of higher education within the Commonwealth of Virginia in a manner that effectively and efficiently uses existing resources at each Institution. The Institutions believe that such collaboration will be facilitated by execution of this MOU.

The Institutions have individually made significant investments to acquire specialized equipment and establish unique research cores supporting basic and clinical research. To further enhance the availability of these existing resources, the Institutions seek to share, in an economical manner, specialized technical services and access to equipment and expertise for research purposes.

This MOU sets forth the understanding of the Institutions concerning reciprocal access to shared resources. The purpose of the MOU is to document (a) the intent of each Institution to provide reasonable access, as capacity will permit, to its specifically identified shared resources and (b) the policies and conditions governing such access. For purposes of this MOU, "Shared Resources" means the research equipment and expertise, cores, facilities and/or services specifically identified by an Institution that shall be made available to the other Institutions pursuant to this MOU.

#### I. General Understanding:

- A. The Institutions shall cooperate in good faith to encourage access to each Institution's respective Shared Resources, for research purposes. Pursuant to the MOU, an Institution may designate investigators as those faculty members of an Institution who seek to use Shared Resources in support of research ("Investigators").
  - 1. Each Investigator must be a member of the faculty, or under the direct supervision of such a faculty member, at his/her respective

Institution. Each Institution is encouraged to send to the other Institutions quarterly updated lists of its Investigators and available Shared Resources. Each Institution shall appoint a Shared Resource Director who will serve as an Institutional point of contact for requests to use Shared Resources.

- 2. Investigators desiring to use a Shared Resource at another Institution must first contact the appropriate Shared Resource Director at the other Institution to confirm availability of access and learn of any specific policies governing access. Once this is done, the point of contact at both Institutions should be notified that samples and/or data will be sent and to arrange for billing information to be provided.
- 3. Fees charged to an Institution by another Institution shall equal the fees charged to the Investigators at their own Institution for internally funded activity. Further, the fees charged shall not include, and shall be in addition to, any expense properly allocated by the providing Institution as an indirect cost on Subawards or Subcontracts, in accordance with the providing Institution's indirect cost rate agreement.
- 4. Each Institution shall invoice for use of a Shared Resource as requested by each Investigator, with the requesting Investigator providing appropriate billing information to the Investigator before the Shared Resource is provided, as set forth in this MOU.
- 5. The Institutions shall review performance under this MOU biannually, and based on such review shall propose appropriate amendments to the MOU, including but not limited to soliciting other higher education institutions within the Commonwealth of Virginia to become signatories to this MOU. Any amendments to this MOU shall be binding as to an Institution only upon the execution of such amendment by a duly authorized signatory of the Institution.
- B. Each Institution shall give priority for use of Shared Resources to Investigators at their home Institution. An Investigator at an Institution wishing to use a Shared Resource at another Institution may do so on an 'as available' basis. Investigators shall have priority for Shared Resource access at their home Institution. As availability permits, Investigators shall have access to the Shared Resources of other Institutions. In special recognition of the frequently irreplaceable nature of samples

housed within a Shared Resource primarily concerned with acquisition and distribution of clinical tissue samples (i.e., a biorepository), access to tissue samples from an Institution will require a determination by the respective scientific director of such resources at such Institution that granting access will not disruptively impact the potential future needs of investigators at the home Institution.

C. This MOU extends to the Shared Resources at the respective Institutions as indicated on Exhibit B.

#### II. Term; Renewal; Termination

- A. This MOU shall be effective as of June 22, 2017 (the "Effective Date"), and shall remain in full force and effect until the 5th anniversary of the Effective Date, unless terminated earlier in accordance with this MOU. Unless terminated earlier, this MOU shall automatically renew for additional five year terms.
- B. An Institution may terminate this MOU at will solely with respect to such Institution by providing 60 days advance written notice to the other Institutions.

#### III. Administration:

- A. Investigators who seek to use a Shared Resource shall contact the specific Shared Resource Director and the Administrator at their home Institution as set forth on <a href="Exhibit A">Exhibit A</a> attached hereto. Before services are provided, the ordering Institution will provide order information to the supplying Institution. The point of contact at the supplying Institution will be responsible for submitting an invoice for payment for services provided to Investigators and for providing copies of the invoices to the point of contact at the ordering Institution. Shared Resource Directors will keep a log of all reciprocal users. Shared Resource Directors will submit a monthly report to the Shared Resource Directors who oversee all Shared Resources at their respective Institutions.
- B. Each Institution will have an oversight committee to review usage capacity. If an Institution determines, in its sole discretion, that another Institution is making excessive use of Shared Resources, that Institution shall notify the relevant Administrator and the two Institutions shall work

in good faith to reach an understanding about future usage of Shared Resources. Such understanding may include a temporary or permanent moratorium on such usage of Shared Resources. If the relevant Institutions cannot reach an understanding, the Institution providing the Shared Resources may terminate this MOU with respect to the relevant Institution only, and/or with respect to specific Shared Resources. Such termination of access rights shall be made in a writing delivered to the Administrator of the Institution being denied access rights.

C. Investigators from the Institutions will be invited to attend annual Shared Resource Retreats to be held at times and locations to be mutually agreed upon by the Institutions.

#### **IV.** Intellectual Property:

- A. Except in making the Shared Resources known to faculty, no Institution may use the other Institutions' names, logos or marks, or any derivative thereof, without the prior written permission of the Institution whose name, logo or marks, or derivative thereof, are proposed to be used.
- B. Ownership and other rights in and to intellectual property of the Institutions shall not be affected by this MOU. The Institutions intend for ownership of intellectual property rights to vest in the employer of the individual inventors and/or authors according to the intellectual property policy of the Investigator's institution. Unless otherwise agreed to in a writing signed by duly authorized representatives of an Institution, mere usage of a Shared Resources shall not entitle the provider of the Shared Resource to any ownership or usage rights of intellectual property belonging to another Institution.
- C. All right, title and interest in and to any data generated by the provider of the Shared Resources in performance of work for another Institution shall vest exclusively in the Institution paying for or receiving such Shared Resources (the "Requesting Institution"). Unless otherwise expressly agreed to by the Requesting Institution, any data generated by the provider of the Shared Resources as a result of performing work for the Requesting Institution shall not be retained by the provider Institution, but shall instead either be sent to the Requesting Institution or destroyed per the instructions of the Requesting Institution.

#### V. Liability and Insurance:

- A. No Institution is, by virtue of this MOU, the agent of any of the other parties to this MOU, and no Institution shall be liable for the wrongful acts or negligence of the other parties to this MOU. Each Institution understands that use of the other Institutions' Shared Resources may involve exposure to potentially hazardous conditions.
- B. IN NO EVENT SHALL ANY PARTY TO THIS MOU BE LIABLE TO ANOTHER PARTY HERETO FOR INCIDENTAL, SPECIAL, INDIRECT, LOST PROFITS, LOST REVENUE, LOST OPPORTUNITY OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE ARISING FROM OR IN RELATION TO THIS MOU.

#### VI. Confidentiality:

- A. Each Institution agrees not to disclose, except as required by law, to any third party or to use, directly or indirectly, for a period of five years after disclosure, any proprietary and confidential research data or other similar information of which the Institution may become aware as a result of using Shared Resources of the other Institutions, or as a result of having other institutions use its Shared Resources. For the avoidance of doubt, such information shall be marked "confidential" and "proprietary" at the time of disclosure.
- B. Notwithstanding the preceding provision, the obligations of the Institution receiving confidential information (the "Receiving Institution") from another Institution do not include: (i) information that, at the time of disclosure, was published, known publicly, or otherwise in the public domain; (ii) information that, after disclosure, is published, becomes known publicly, or otherwise becomes part of the public domain through no fault of the Receiving Institution; (iii) information that, prior to the time of disclosure, is known to the Receiving Institution as evidenced by its written records and is not then subject to an obligation of confidentiality to any third party; or (iv) information that, after disclosure, is made available to the Receiving Institution in good faith by a third party under no obligation of confidentiality and without restriction on its further disclosure by the Receiving Institution.

#### **VII.** Conduct Compliance:

- A. Each Institution shall require all employees, agents and students (if applicable) who use Shared Resources provided under this MOU to observe all applicable policies, rules and regulations of the Institution providing the Shared Resources.
- B. Each Institution shall comply with all applicable laws and legal requirements in connection with the activities contemplated by this MOU.
- C. This MOU shall be governed in all respects by the laws of the Commonwealth of Virginia without regard to its rules regarding conflict of laws. Any action to enforce the obligations of this Agreement shall be brought and maintained exclusively in the state courts of the Commonwealth of Virginia.

[Signature Page Follows]

## VIRGINIA COMMONWEALTH UNIVERSITY [NAME] **COLLEGE OF WILLIAM AND MARY** [NAME] GEORGE MASON UNIVERSITY [NAME] UNIVERSITY OF VIRGINIA Dr. Phillip A. Parrish, Interim Vice President for Research **AVP for Commercialization** EASTERN VIRGINIA MEDICAL SCHOOL [NAME] **OLD DOMINION UNIVERSITY** [NAME] VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY [NAME]

#### **EXHIBIT A**

Shared Resource Directors for University of Virginia:

Jay W. Fox, Ph.D.; Professor of Microbiology, Immunology and Cancer Biology and Director of Shared Resources

#### **EXHIBIT B**

#### SHARED RESOURCES AVAILABLE AT University of Virginia

University of Virginia (https://med.virginia.edu/core-facilities/cores-2/)

Advanced Microscopy Facility

Antibody Engineering and Technology Core

**Bioinformatics Core** 

Biomolecular Analysis Facility

**BioNMR Facility** 

Biorepository and Tissue Research Facility

Exercise Physiology Core

**DNA Sciences Core** 

Flow Cytometry Core

Genetically Engineered Murine Model Core

Molecular Electron Microscopy Core

Molecular Imaging and Radiochemistry Core

Research Histology Core

Stem Cell Core

Tissue Culture Facility

VIRGINIA COMMONWEALTH UNIVERSITY
[NAME]
COLLEGE OF WILLIAM AND MARY
[NAME]
GEORGE MASON UNIVERSITY
Deborah Crawford, Ph.D., Vice President for Research
UNIVERSITY OF VIRGINIA
[NAME]
EASTERN VIRGINIA MEDICAL SCHOOL
[NAME]
OLD DOMINION UNIVERSITY
[NAME]
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
[NAME]

#### **EXHIBIT A**

Shared Resource Directors for each Institution:

#### **GEORGE MASON UNIVERSITY**

Michael Laskofski, Associate Vice President of Research Operations George Mason University Office of Sponsored Programs 4400 University Drive, MSN: 4C6 Fairfax, Virginia 22030

Phone: (703) 993-4573 Email: mlaskofs@gmu.edu

## EXHIBIT B SHARED RESOURCES AVAILABLE AT EACH INSTITUTION

#### **GEORGE MASON UNIVERSITY**

Core Laboratories at George Mason University

#### **ANIMAL CARE AND USE:**

George Mason University manages two state-of-the-art vivarium facilities that have capacity for rodents through primates up to BSL-3, one on the Fairfax Campus and one of the Science and Tech Campus. The contact for these core facilities is David Myers; Animal Care Program Manager, Research Development, Integrity, and Assurance; <a href="mailto:iacuc@gmu.edu">iacuc@gmu.edu</a>; 703-993-6118; <a href="http://oria.gmu.edu/research-with-humans-or-animals/animal-care-and-use/">http://oria.gmu.edu/research-with-humans-or-animals/animal-care-and-use/</a>

#### **RESEARCH COMPUTING:**

The Office of Research Computing offers the following on-campus research computation options are:

- The ARGO cluster which has been installed in the Aquia Data Center for large scale computation needs of researchers in the university.
- Requesting a virtual computer for research from ITU. This is for research related computations that cannot be done on university researchers' desktops or laptops.

The contact for these resources is: Jayshree Sarma; Interim Director of Research Computing; <u>jsarma@gmu.edu</u>; 703-993-4397; <u>http://orc.gmu.edu/</u>.

#### MICROSCOPY:

There are two confocals--one upright, one inverted a Zeiss AxioObserver with AxioCam and a Nikon C1si D-eclipse. Also, an Olympus/Provis with Neruolucida software. The contact for these resources is: Nadine Kabbani, Assistant Professor, Molecular Neuroscience, 703-993-4406 or nkabbani@gmu.edu.

#### **MAGNETIC RESONANCE IMAGING:**

The Mason 3T MRI Facility houses a Siemens Prisma 3T Magnetom for human brain and whole body MRI. This facility is equipped with 32 channel phased array head coil, 16 channel shoulder coil, and multiple other head/neck/ spine, body, and flex coils. Applications include sequences for neuro, angio, cardiac, body, onco, breast, ortho, 2D and 3D ASL, SWI, and spectroscopy imaging. A 64 channel, MR compatible EEG system is also available. Visual displays include an Eiki projector. An ARRT certified MR Technologist is available for scanner operation.

#### Contact:

James Thompson Department of Pychology jthompsz@gmu.edu (703)993-9356

#### **PROTEOMICS:**

#### Center for Applied Proteomics and Molecular Medicine Laboratory

The Protein Microarray and Molecular Characterization Laboratory houses Aushon 2470 Automated, High-Throughput Protein Arrayers and Dako robotic autostainers utilized to generate protein arrays for analysis of tissue and cellular samples for biomarker discovery. The **Molecular Characterization Laboratory** is equipped with an Illumina Bead Array Reader for high density DNA single nucleotide polymorphism (SNP) analysis. The SNP analysis is used to assess genomic copy number variation and can be used to create a molecular karyotype.

The **Tissue Processing and Imaging Laboratory** is equipped with histology equipment to embed and cut paraffin and frozen tissue sections with a Tissue Tek VIP Tissue Processor, Thermo microtome MH325, Harvard Apparatus vibratome, and Leica CM1850UV cryostat. Five laser capture microdissection systems in the laboratory are used to isolate enriched cell populations under direct microscopic visualization (2 Arcturus XT Automated Laser Capture Microdissection Systems, and 3 Arcturus PixCell II/IIe Laser Capture Microdissection Systems). A cytospin centrifuge and RoboSep magnetic cell sorting instrument are also available for processing biological fluids.

Imaging capabilities include an Olympus BX51 microscope outfitted with a digital camera, phase contrast and fluorescence, as well as an Olympus BX51 dual head, light microscope with a digital camera.

The Mass Spectrometry Laboratory uses specialized chromatography, electrophoresis, and cell fractionation systems, combined with high-performance mass spectrometers (Orbitrap Fusion, LTQ-Orbitrap, Triple Quadrupole, and MALDI- TOF-TOF), to separate and analyze components of tissue, serum and other physiological samples, resulting in protein characterization, identification and biomarker discovery. The laboratory is equipped with 4 mass spectrometers that are capable of identifying and quantitating femtomole levels of biomolecules such as peptides and proteins.

The Nanofabrication Laboratory is equipped to manufacture hydrogel nanoparticles used for biomarker discovery and the development of diagnostic tests. A novel protein painting technology developed in the lab identifies hot spots of protein-protein interaction.

The CAP/CLIA Clinical Proteomics Laboratory, the first in the United States to be dedicated solely to proteomics translational research, operates under the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) guidelines to:

- Provide a unique opportunity to assess and evaluate new proteomic technologies under rigorous clinical guidelines
- Accelerate the verification and validation of promising candidate biomarkers in a clinical diagnostic setting
- Implement unique clinical trials and diagnostic tests

The CAP Clinical Proteomics Laboratory uses an Aushon 2470 Automated, High-Throughput Protein Arrayer, and a Dako robotic autostainer to generate protein arrays and perform immunohistochemistry for analysis of tissue and cellular samples for biomarker discovery. An

Immulite 1000 Immunoassay instrument is also available to measure protein analytes and perform clinical tests.

#### Contact:

Amy Adams
Center for Applied Proteomics and Molecular Medicine
<a href="mailto:avanmete@gmu.edu">avanmete@gmu.edu</a>
(703)993-2672

#### **METABOLOMICS SEQUENCING:**

The Metabolomics Laboratory houses several chromatography instruments, including a GC-FID, GC-NPD, and semi-preparative and preparative HPLCs. The metabolomics platform is centered on an Agilent 7890A Gas Chromatograph with 5975C Mass Spectrometer, an Agilent 1290 Infinity LC with a 6530 QToF (MS/MS), and an Agilent 1100 LC-MSD (with interchangeable ESI, APPI, and APCI sources). Coupled with custom designed software algorithms and the commercially purchased Agilent Mass Profiler Professional software package, these instruments enable a comprehensive examination of volatile and non-volatile metabolites present in biological samples

#### Contact:

Robin Couch, PhD
Department of Chemistry & Biochemistry
rcouch@gmu.edu
(703)993-4770

#### **GENOMIC SEQUENCING:**

The MicoBiome Analysis Center has a separate PCR room with 10 PCR machines, an ABI 3130xl sequencer, a Life Technology RT PCR instrument, an Ion Torrent PGM sequencer (4 million reads/run), an Ion Torrent S5 (80 million reads/run), and high-end computational facilities. The computational facilities include 10 iMac computers, a 48 processor HP workstation, two development HP servers, and access to a 640 node SGI cluster. A wide array of bioinformatics software is accessible through networked computers within the DNA research labs.

#### Contact:

Pat Gillevet, PhD Microbiome Analysis Center pgilleve@gmu.edu (703)993-1057

#### MACROMOLECULAR/SMALL MOLECULE ENGINEERING AND SPECTROSCOPY:

The Small Molecule, Peptide, and Protein Engineering Spectroscopy Laboratory is equipped for small molecule, protein, and peptide synthesis. Computational chemistry experiments are performed using a variety of available software on the Mason Argo cluster. Proteins are expressed in either bacterial or mammalian cells. Molecular characterizations are performed using a Bruker AVANCE III HD 400 MHz NMR.

The NMR Laboratory is equipped with a Bruker AVANCE III HD 400 MHz NMR instrument for multi-dimensional magnetic resonance spectroscopy experiments, including structure determination/confirmation of small molecules. It's Diffusion Ordered Spectroscopy (DOSY) capabilities enable investigation of intermolecular interactions. The instrument is equipped with Bruker's SMART Probe technology for enhanced resolution and an automatic sample changer for processing up to 24 samples.

The **Spectroscopy Laboratory** is also equipped with 1) Jasco FP-8300 Spectrofluorometer w/ Peltier temperature control and polarizers, 2) Jasco FTIR4100 Infrared Spectrometer w/ Peltier temperature control and protein secondary structure prediction software, 3) Bio-Tek Eon Microplate Spectrophotometer, 4) Molecular Devices SpectraMax Gemini EM Microplate Spectrofluorometer, 5) Tecan Spark 10M Spectrophotometer w/ AlphaScreen and chemiluminescence, 6) Rudolph AUTOPOL IV Polarimeter, 7) Rudolph J357 Automatic Refractometer, and 8) Jasco J-1500 Spectropolarimeter.

#### Contact:

Mikell Paige, PhD

Expertise: Small molecule design/synthesis and spectroscopy

Department of Chemistry & Biochemistry

mpaige3@gmu.edu (703)993-1075

Barney Bishop, PhD
Expertise: Peptide engineering and macromolecular spectroscopy
Department of Chemistry & Biochemistry
bbishop1@gmu.edu
(703) 993-8302

Young-Ok You, PhD Expertise: Protein engineering/enzymology Department of Chemistry & Biochemistry yyou@gmu.edu (703) 993-7141

VIRGINIA COMMONWEALTH UNIVERSITY
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EASTERN VIRGINIA MEDICAL SCHOOL
[NAME]
OLD DOMINION UNIVERSITY
[Morris Foster, Vice President for Research]
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
[NAME]

#### **EXHIBIT A**

#### Shared Resource Directors for each Institution:

Karen Eck, PhD
Assistant Vice President for Research
Office of Research
Old Dominion University
4111 Monarch Way, Suite 203
Norfolk, VA 23508
(757) 683-3707
keck@odu.edu

## EXHIBIT B SHARED RESOURCES AVAILABLE AT EACH INSTITUTION

#### OLD DOMINION UNIVERSITY

Account Code	Project Director	Account Title	Account Short Title	Status	PI Home Department Code
956200- 010	BRITCHER, C.	VIPER DYNAMOMETER / INSTRU LAB	VIPER LAB	A	MECHANICAL AND AEROSPACE ENGINEERING
956500- 010	ELSAYED- ALI, H.	ARC EQUIPMENT USAGE	ARC EQUIPMENT	A	APPLIED RESEARCH CENT
957300- 010	CATRAVAS, J.	FLOW CYTOMETRY FACILITY	FACS-ARIA	A	FRANK REIDY CENTER FO BIOELECTRICS
958100- 010	PLATSOUCAS, C.	CENTER- ISOTOPE*TRACE ELEMENTS	CENTER- ISOTOPE*	Α	BIOLOGICAL SCIENCES
958100- 020	DAINES, D.	ELECTRON MICROSCOPY LAB	ELECTRON MICROS	A	BIOLOGICAL SCIENCES
958100- 021	DAINES, D.	DNA SEQUENCER	DNA SEQUENCER	A	BIOLOGICAL SCIENCES
958100- 022	DAINES, D.	BIOLOGY VEHICLE USAGE	BIOLOGY VEHICLE	A	BIOLOGICAL SCIENCES
958110- 001	DAINES, D.	RESEARCH FACULTY- MARSHALL, H.	RES FAC- MARSHAL	A	BIOLOGICAL SCIENCES
958200- 010	DONAT, J.	CBP WQL-CC AUTOANALYZER	CBP WQL-CC AUTO	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 011	DONAT, J.	CBP WQL-CC C/N ANALYZER	CBP WQL-CC C/N	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 012	DONAT, J.	CBP WQL-CC SPECTROPHOTO	CBP WQL-CC SPEC	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 013	DONAT, J.	CBP WQL-CC STD ANALYSES	CBP WQL-CC STD	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 014	DONAT, J.	CBP WQL-CC FIELD EQUIPMENT	CBP WQL-CC FIEL	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 015	DONAT, J.	CBP WQL-CC R/V BAYRUNNER	CBP WQL-CC R/V	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 020	HATCHER, P.	MAJOR INSTRUMENTATION CLUSTER	COSMIC	A	CHEMISTRY & BIOCHEMISTRY DEPT
958200- 021	HATCHER, P.	CENTER-IRMS	IRMS	A	CHEMISTRY & BIOCHEMISTRY DEPT
958500- 010	HARVEY, R.	R/V FAY SLOVER	R/V FAY SLOVER	Α	OCEAN, EARTH & ATMOSPHERIC SCIENCE
958500- 011	HARVEY, R.	RESEARCH VESSEL- SMALL BOATS	RESEARCH VESSEL	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE
958500- 012	HARVEY, R.	ELECTRONIC SUPPORT	ELECTRONIC SUPP	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE

958500- 020	DARBY, D.	ELECTRON PROBE MICROANALYZER	EPMA- ELECTRON	A	OCEAN, EARTH & ATMOSPHERIC SCIENCE
958600- 010	PLATSOUCAS, C.	VIRTUAL ENVIRONMENTS LABS	VIRTUAL ENVIRON	A	CTR FOR COASTAL PHYSICAL OCEAN
958600- 011	ATKINSON, L.	CCPO PROFILER COST CTR	CCPO PROFILER C	A	CTR FOR COASTAL PHYSICAL OCEAN
958600- 012	SEDWICK, P.	ICP - MS FACILITY	ICP - MS CC	A	CTR FOR COASTAL PHYSICAL OCEAN
958800- 010	FOSTER, M.	ANIMAL CARE FACILITY	ANIMAL CARE FAC	A	OFFICE OF RESEARCH
958800- 011	FOSTER, M.	ANIMAL CARE OPERATIONS	ANIMAL CARE OPS	A	OFFICE OF RESEARCH
959300- 010	RANJAN, D.	CS COST CENTER	CS COST CENTER	A	COMPUTER SCIENCES

VIRGINIA COMMONWEALTH UNIVERSITY  Susan E. Robb, Sr. Assoc. VP for Research Administration and Compliance	
COLLEGE OF WILLIAM AND MARY	
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OLD DOMINION UNIVERSITY	
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VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY	
[NAME]	

#### **EXHIBIT A**

Shared Resource Directors for each Institution:

Virginia Commonwealth University
Paul Fawcett, Ph.D.
Assistant Professor of Internal Medicine and
Director of Research Infrastructure
paul.fawcett@vcuhealth.org
(804) 827-0975

# EXHIBIT B SHARED RESOURCES AVAILABLE AT EACH INSTITUTION

- Center for Molecular Imaging (http://www.molecularimaging.vcu.edu/)
- Chemical and Proteomic Mass Spectrometry Core Facility (<a href="https://chemistry.vcu.edu/research/facilities/chemical-and-proteomic-mass-spectrometry-core-facility/">https://chemistry.vcu.edu/research/facilities/chemical-and-proteomic-mass-spectrometry-core-facility/</a>)
- Cancer Mouse Models Shared Resource (https://www.massey.vcu.edu/research/cores/cmmc/)
- Flow Cytometry Core Facility (<u>https://www.massey.vcu.edu/research/cores/flow-cytometry/</u>)
- Lipidomics & Metabolomics Core Facility (http://www.biochemistry.vcu.edu/Research/lipidomics\_core.html)
- Microscopy Core Facility (<a href="http://www.anatomy.vcu.edu/microscopy/">http://www.anatomy.vcu.edu/microscopy/</a>)
- Nanomaterials Characterization Core: (http://nano.vcu.edu/)
- Nucleic Acid Research Facilities / Genomics Core Facility (http://www.narf.vcu.edu/)
- Structural Biology Core Facility (<a href="https://www.massey.vcu.edu/research/cores/structural-biology/">https://www.massey.vcu.edu/research/cores/structural-biology/</a>)
- Tissue and Data Acquisition and Analysis Core Facility (https://www.massey.vcu.edu/research/cores/tdaac/)
- Transgenic and Knock-out Mouse Core Facility (https://www.massey.vcu.edu/research/cores/tmf/)

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EASTERN VIRGINIA MEDICAL SCHOOL
Vala 1/2/2017
Richard V. Homan, MD Date President & Provost, Dean of the School of Medicine
OLD DOMINION UNIVERSITY
[NAME]
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
[NAME]

#### **EXHIBIT A**

#### Shared Resource Directors for each Institution:

EVMS Biorepository and Histology Core

Flow Cytometry Core

Microscopy and Imaging Core

**Proteomics Core** 

Molecular Core Facility

Bioinformatics and Bioanalytic Core

Laurie Wellman PhD. wellmall@evms.edu

Woong-Ki Kim PhD kimw@evms.edu

Frank Lattanzio PhD Lattanfa@evms.edu

Julius Nywalwidhe PhD Nyalwijo@evms.edu

Julia Sharp PhD molecularcore@evms.edu

Patric Lundburg PhD <u>lundbeps@evms.edu</u>

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#### Exhibit A

Shared Resource Director for Each Institution

#### William and Mary

Director: Christopher A. Del Negro, Ph.D.; Professor of Applied Science, Coordinator Core Resources Deputy Director: Eric L. Bradley, Ph.D.; Professor of Biology, Science Precinct Coordinator and EMT Liaison

#### **Exhibit B**

#### William and Mary

(name is faculty contact for high-level advisory)

Bioengineering Core Lab (Saha)

Cellular and Cytometry (Saha)

Cellular Analytical Core (Bradley)

Imaging laboratories hard matter - non-ionizing methods (Cooke)

Biomaterial imaging Core (Cotton)

Imaging Laboratories soft matter - ionizing methods (Bradley)

Live-cell, in vitro, and in vivo multi-photon neuroscience neuroimaging lab (Del Negro)

Laser-scanning confocal (fixed tissue) imaging core lab (Del Negro)

Surface characterization core lab (Cooke)

Magnetic studies Core - 17.6T solid state NMR, Squid magnetometry,

liquid NMR (Cotten) Living Human subjects neurophysiology Lab (Burk)

Marine Biology Seawater Lab 1 (Luckenbach)

Marine seawater lab 2 (Luckenbach)

Marine cytometry center core (Luckenbach)

Marine research vessel core operations (Luckenbach)

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[NAME]
VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
John S. Mayor

[Theresa S. Mayer, Vice President for Research and Innovation]

#### **EXHIBIT A**

Shared Resource Directors for each Institution:

#### 1) VTCRI Fluorescence Assisted Cell Sorting (FACS) Core Facility

The facility is equipped with instruments to separate cells of interest from tissue and from a heterogeneous population of cultured cells. The facility houses a fully equipped SH800 cell sorter (SONY). This cell sorter contains four laser lines (405, 488, 561 and 638 nm), 6 photomultipliers and a variety of filters to allow for the detection of most fluorescence signals. The facility houses a BD Accuri C6 flow cytometer equipped with a blue and red laser and four fluorescence detectors to count, phenotype and determine cytokines and growth factor levels in specific cells. The facility is also equipped with an automated cell fractionator that allows the separation of subcellular organelles, a SpeedVac to concentrate nucleic and protein samples (Fisher Scientific) and a the QX200 digital PCR reader equipped with a droplet generator (BioRad) to examine the transcriptome of single or subpopulations of cells.

#### 2) VTCRI Super Resolution Core Microscopy Facility

The super-resolution microscopy facilities is located in a BSL-2 certified imaging suite. Equipment available includes a Bruker Vutara 350 super-resolution microscope with Okolab Bold Line incubation system, both of which are controlled by a high-end computer workstation for data acquisition and analysis. The Vutara 350 combines 1000 mW lasers and a sCMOS detector to enable researchers to undertake multi-color video-rate 3D particle tracking in living cells and tissues at a resolution within 20 nm lateral and 50 nm axial. Significant depth (>15 μm) of penetration can be achieved in both live and fixed specimens, which is enhanced, and scatter reduced, when utilizing the near infra-red 750 nm laser excitation. A sCMOS Hamamatsu ORCA Flash 4.0 camera permits frame rates necessary for dynamic super-resolution imaging, and an additional Interline CCD camera provides wide-field image acquisition. Experiments on live preparations can be performed in physiological oxygen levels in addition to automated initiation of insults such as hypoxia.

#### 3) VTCRI animal behavioral core

The core provides resources for comprehensive behavioral and sensory-motor analyses in rodents. The facility includes a staging area and four independent testing rooms, which allow simultaneous work by up to four investigators. Available tests include those for learning and memory, depression and anxiety-related behaviors, social behaviors, operant tasks, sensory-motor gating, motor functions, circadian rhythm analysis, pain and analgesia. The facility equipment includes a custom built Morris water maze, a fear conditioning system, open field and AnyMaze video tracking systems, a three chamber social interaction apparatus, a rodent touch screen chambers, startle response and Gemini avoidance systems, a rotarod and 26 voluntary running wheel systems.

#### 4) VTCRI Optical imaging core

The institute has a state-of-the-art light-based imaging facility staffed with expert support personnel. This facility was specifically designed to provide researchers with all major types of imaging modalities necessary for standard cell and molecular biology at

multiple imaging scales. The core is directed by two faculty members (Dr. Michael Fox – Associate Professor and Dr. Greg Valdez- an Assistant Professor) who provide training and support for other labs to use the facility and who manage the facility. Facility access is managed by a web based sign up system that allows investigators access. For relatively low magnification image analysis the imaging core is equipped with a Zeiss V20 fluorescent dissecting microscope (with MRc camera and computer) and numerous standard (non-fluorescence) dissecting microscopes. For higher magnification imaging, the facility is equipped with a Zeiss AxioVert epi-fluorescence microscope, a Zeiss Apotome with a Neurolucida package from MicroSystems Devices, and a Zeiss AxioImager A2 (with an AxioCam MRm camera and PC work station with ZEN imaging software). The facility is equipped with 2 Zeiss laser confocal microscopes: a Zeiss 710 confocal microscope with an AxioExaminer upright stage (4 laser lines – 488 / 555 / 594 / 633) and a Zeiss 700 confocal microscope with an AxioVert inverted stage (4 laser lines – 405 / 488 / 555 / 647). The imaging core is equipped with a Zeiss/Coherent 2 photon scanning upright microscope. The core also offers a Zeiss multi-photon optical imaging system with attached brain slice, in vivo and isolated cell electrophysiology systems.

#### 5) VTCRI Core Human Neuroimaging Lab (HNL)

The VTCRI HNL houses two research-dedicated 3T Siemens MR scanners in Roanoke of hich one is a Trio and the other is a Prizma. A third scanner, also a 3.0 Tesla Siemnes Trio is located on the VT Blacksburg campus. Each scanner is 100% research-dedicated. Each scanner bay is equipped for 1) behavioral response acquisition: two-hand, four-button optical response pads with USB, serial, and TTL output (Current Designs, Inc.); 2) video stimulation: rear-projection video display (NEC GT2150) and corrective lenses for use with video stimulation (MR-compatible frames with insertable polycarbonate lenses by Solo Bambini); 3) eye-tracking: IR-illuminated CCD system. ViewPoint software (Arrington Research); 4) audio stimulation: dynamic and piezoelectric headphones (MR Confon, GmbH); 5) gustatory stimulation: dualsyringe pump (Harvard Apparatus HA33)); 6) real-time image reconstruction and online neurofeedback (LaConte et al., 2007). HNL director, Dr. P. Read Montague and his team of developers have designed, coded, and implemented a unique imaging technique for simultaneous scanner image acquisition from multiple scanners as behavioral data are also being acquired. The open-source software package allows for the simultaneous presentation of stimuli, acquisition of behavioral responses, and synchronized acquisition of functional imaging data from multiple scanners. The use of the internet as a communication channel between client and server computers allows for the study of realtime social interactions and for such interactions to be implemented across institutions. The freely available software is currently deployed at imaging facilities in hospitals, universities and health centers across the U.S. and on three continents. Critically, this technology allows for the direct measurement of multiple brains engaged in social and economic interactions and relies on straightforward multisite synchronization of image acquisition. The hyperscan system, implemented with Network Experiment Management Objects (NEMO) includes 1) a client, 2) an application server, and 3) a public domain, SQL server database (called PostgreSQL). There is a separate authentication system for HIPAA compliant secure interactions. In addition to NEMO, Dr. Montague's team has also developed an easy-to-use scripting language so that scientists can specify experiments without detailed knowledge of how

the hyperscan system functions. The software is available for public download through VTCRI. The CPU combines state-of-the-art technology with neuroscience, economics, and behavioral methods to understand the neural computations involved in human cognition and psychiatric illness. In addition to the computer workstations and analysis tools in the PIs' independent laboratories, the VTCRI Human Neuroimaging Laboratory includes the following computing resources: 2 Penguin Computing servers (each with 4 dual core processors) available for image and data analysis; 26 Dell servers (dual processor Xeons) available for image and data analysis; 32 node, 64 processor Linux IBM cluster; 2 Gbit storage area network; 30 terabyte fast disk storage; 60 terabyte digital tape backup; daily backups with weekly off-site data storage at secure facility; 54 Mbit secure, encrypted, wireless network; 1Gbit Ethernet computer network (64 drops); MR stimulation software: NEMO: synchronized, multi-subject, multi-institution generalized stimulation presentation and data management framework; MR image retrieval software: Experiment Browser: secure web-based image retrieval using NEMO client with proper authorization; MR Analysis Tools: MATLAB with statistics and signal processing toolboxes, SPM8, AFNI, FSL, MRIcro, xjView, R, SAS; Productivity Tools: Adobe Suite, Microsoft Office Suite, OpenOffice.

6) VTCRI Cryo-electron microscopy facility





#### **About the Virginia Neuroscience Initiative**

Virginia Catalyst instituted the Virginia Neuroscience Initiative (VNI), an innovative, statewide collaborative approach that brings together experienced scientists, medical providers, and industry partners. The mission of the VNI is to accelerate clinical and translational research in neuroscience and related fields, and provide economic opportunities and benefits for the Commonwealth through expanded state and federal government funding, private equity funding, philanthropy funding, new company formation, and corporate sponsored research.

#### **Neuroscience Directory**

Members of the Neuroscience Directory include researchers and scientists in the Commonwealth of Virginia who are involved in basic or translational research on the nervous system and related fields, along with clinicians who provide care for individuals with neurological disorders. This searchable database includes contact information for each member and descriptions of their research interests and expertise.

#### **Neurological Disorders Directory**

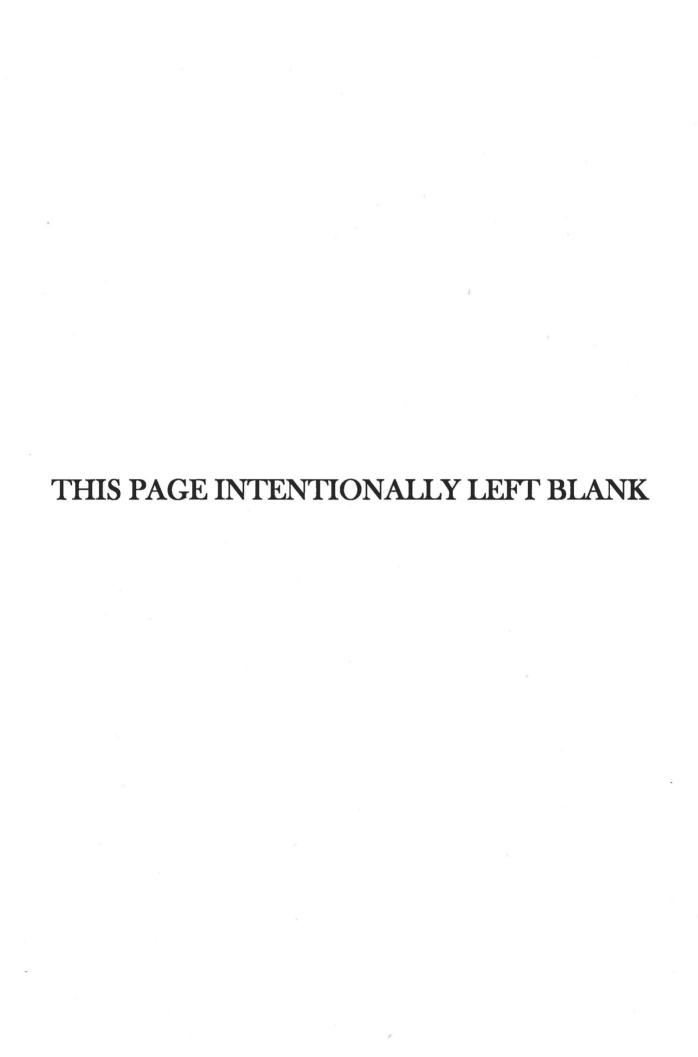
The Neurological Disorders Registry consists of nearly half a million individuals diagnosed with one or more neurological conditions. The Neurological Disorders Registry is derived from the active electronic medical records (EMRs) of the five participating medical centers and thus, contains the current personal health information (PHI) of more than six million individuals. While the EMRs remain under the complete control of each respective medical center, the internal utilization of these records for a common purpose creates a HIPAA-compliant, de facto registry. Our collaborative research team has access to this searchable database to rapidly quantify the number of patients who meet specific eligibility. Once a clinical trial is in place, the database can be used to recruit those patients.

#### **Clinical Trials Network**

Physicians from our five clinical sites and researchers from our affiliated universities bring exceptional expertise to all aspects of human subjects research, clinical research, and clinical trials. Functioning as a single clinical research site, the Clinical Trials Network is capable of rapidly screening and enrolling participants for clinical trials.

#### **Core Facilities**

Seven academic research institutions in Virginia have signed a memorandum of understanding (MOU) to share core facilities and resources in an effort to advance life sciences and other areas of research in the Commonwealth. The University of Virginia, Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Old Dominion University, Virginia Tech and William & Mary have all agreed to provide reciprocal access to shared R&D resources, which will accelerate the commercialization of Virginia's innovations, creating more high potential start-up companies, producing many more high-paying jobs, and growing the Commonwealth's biosciences economy. Over 60 core facilities are currently listed on the VNI website in an effort to encourage collaboration among scientists and researchers throughout the Commonwealth.





#### **About Covance**

Covance Inc., a global clinical research organization (CRO), is the world's most comprehensive drug development company.

A clinical research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

We're dedicated to advancing healthcare and delivering Solutions Made Real® by providing high-quality nonclinical, preclinical, clinical and commercialization services to pharmaceutical and biotechnology companies to help reduce the time and costs associated with drug development. Because of our broad experience and deep knowledge, we're in a unique position to provide insights to our client partners that go above and beyond testing.

We also offer laboratory testing services to the chemical, agrochemical and food industries and are a market leader in toxicology services, central laboratory services, discovery services and a top global provider of Phase III clinical trial management services.

#### About LabCorp®

In 2015, LabCorp® (NYSE: LH) acquired Covance Inc., creating the world's leading healthcare diagnostics company, providing comprehensive clinical laboratory services and end-to-end solutions for drug and diagnostics development and commercialization. Laboratory Corporation of America® Holdings (NYSE: LH), an S&P 500 company, is a world leading life sciences company, providing comprehensive clinical laboratory and end-to-end drug development services. With net revenue in excess of \$8.5 billion in 2015, LabCorp's 50,000 employees serve clients in 60 countries.

#### **Our Mission**

Our mission is to bring new and innovative medicine to patients sooner.

#### **Our Vision**

Our vision is to be recognized by clients as:

- The undisputed leader in providing drug development services
- A trusted partner whose hallmarks are
- Great people
- High-quality data
- A proven track record of integrating and streamlining the development process

#### **Our Values**

Our values are to strive for operational and service excellence through a relentless focus on People, Process and Clients.





The Lists: June 05, 2017

## **Top 10 U.S. Biopharma Clusters**

## GEN's Annual Ranking Counts Down the Nation's Most Nurturing Regions

Alex Philippidis

Bruce Booth, D.Phil., a partner at Atlas Venture, astutely observed earlier this year that two key resources fueling the growth of biopharma were until recently somewhat geographically spread among the 10 or so regions of the nation where the industry began to arise a generation ago.

"In recent years, this has changed—Boston and San Francisco are now the preeminent biotech clusters. And their gravity in the ecosystem is only getting stronger," Dr. Booth concluded in a March 21 post on his Life Sci VC blog. "Beyond having great science and the right 'pixie dust' in the local environment, two fundamentally important ingredients to the success of any cluster are capital and talent—and both are aggregating into the two key clusters."

So it's no surprise that Boston/Cambridge, MA, and the San Francisco Bay Area again top this year's GEN List of the nation's top 10 biopharma clusters, as they did last year and in 2015. Yet that's not to say the other eight clusters rounding out the list are the proverbial chopped liver; they too have significant assets that make them attractive to biopharma researchers, executives, and investors, often drawing upon heritages that include the presence of big pharmas or home-grown biotech giants.

And while the regions making the list this year will be very familiar to biopharma industry watchers, the regions just below the top 10 also continue to build clusters that may someday propel them to future GEN lists. Highest among those remains Denver at No. 11, which ranked higher on two criteria—ninth in lab space (4 million square feet) and 10th in jobs (27,666, according to JLL).

GEN ranks regions based on five criteria:

- NIH funding—Taken from the publicly available NIH RePORT database, for the current federal fiscal year, from its start on October 1, 2016, through May 23, 2017.
- Venture Capital (VC) funding—Taken from 2016 and Q1 2017 figures furnished by the publicly available MoneyTree Report.

- Patents—Based on the number of patents containing the word "biotechnology" awarded since 1976 in namesake cities and suburbs where key companies are located.
- Lab space—Based on total-size-of-market figures, in millions of square feet, furnished by the commercial real estate brokerage JLL in its U.S. Life Sciences Outlook report for 2016.
- Jobs—Based on JLL's report. While job numbers are ranked this year compared with last year's Top 10 US Clusters list, less weight had to be given to job totals in regions where GEN has found widespread discrepancies in job figures. However, workforce size was factored in when deciding the ultimate position of a region.

#### #10. Chicagoland

The region rounds out the Top 10 in NIH funding (713 awards totaling about \$252.5 million), lab space (3.5 million square feet), and VC funding (five deals totaling \$69 million in 2016), but fares better in patents (1,143) and best on employment (53,054 jobs, including 29,230 within Chicago's Illinois Medical District). This year's VC numbers should be much better; while MoneyTree Report recorded no biotech VC deals in Q1, a single company nearly equaled last year's deal volume in May. Iterum Therapeutics closed a \$65 million Series B-financing whose proceeds will help it develop its first product candidate sulopenem, an antibiotic designed to treat Gram-negative multidrug-resistant infections.

Improving the region's biopharma ecosystem will be among the priorities of James E. Audia, CSO of Constellation Pharmaceuticals, who on May 25 was named the new executive director of the Chicago Biomedical Consortium, effective August 1. The consortium was formed to stoke collaboration among researchers at Northwestern University, The University of Chicago, the University of Illinois at Chicago, and other institutions.

In March, Rosalind Franklin University of Medicine and Science said it will build a \$50 million Innovation and Research Park with labs and an incubator for biopharma startups, and space for larger global life sciences companies. Ground for the 100,000 square-foot addition to the campus' north side is set to be broken in September, with the project completed by summer 2019.

## #9. Los Angeles / Orange County

A milestone in the cluster-building effort of the City of Angels and surrounding Southland region is set to occur soon: Site clearing has begun for a 20,000-square-foot incubator on the campus of the Los Angeles Biomedical Research Institute (LABioMed), funded by a \$3 million county grant spearheaded by L.A. County Board of Supervisors Chairman Mark RidleyThomas. The incubator is set to open next year. Lab space remains the L.A. region's biggest challenge, as it ranks 11th among top U.S. clusters with just over 2 million square feet, less than the other nine regions on this list and the Denver region. Also in May, LABioMed since it joined with UCLA to sell royalty rights to Allergan's Kybella®

(deoxycholic acid), the first and only FDA-approved injectable drug for submental fullness, for an undisclosed price.

Basic research is among strengths of the region, which ranks seventh in patents (1,479), and ninth in NIH funding (806 awards totaling \$337.4 million). Those numbers can be expected to grow, as startup accelerator Make in LA joined LabLaunch last year to create a new bioscience-focused lab at Make in LA's Chatsworth, CA, campus, with plans to create the first early-stage biotechnology incubator in the City of L.A. Where the region shines is in number of jobs, where it ranks second with 120,688, according to JLL—though regional life science industry group Biocom counts 117,879, consisting of 69,830 in L.A. County and 48,049 in Orange County.

#8. Raleigh-Durham, NC (includes Research Triangle Park, NC) North Carolina's mecca of biopharma yo-yoed in VC funding, finishing ninth in Q1 (seven deals totaling \$14 million) after placing fourth in 2016 with 10 deals totaling \$211 million. That figure includes the \$47 million Series C financing won last year by Research Triangle Park (RTP)-based, small-molecule cancer therapy developer G1 Therapeutics. On May 16, G1 raised \$105 million in gross proceeds through an initial public offering. Ten days later, RTP saw one of its largest real estate deals ever when GlaxoSmithKline sold 20 buildings totaling 1.1 million square feet within the campus for an undisclosed price to Parmer Innovation Centers; GSK will instead lease four buildings totaling 700,000 square feet. Also in May, Durham-based Parion Sciences licensed exclusive global rights for its Phase II dry eye treatment candidate P-321 to Shire for up to \$535 million.

The region also ranks eighth in NIH funding (749 awards totaling \$349 million) and 10th in patents (928)—but fared a little better in jobs, ranking ninth with 35,073 according to JLL, though the North Carolina Biotechnology Center counted 62,937 jobs statewide in 2016. The Center faces either a budget freeze at \$13.6 million each year during 2017–19, or a 5% cut, in the approximately \$23 billion biennial spending plan under discussion by state lawmakers at deadline.

#### #7. Seattle

If the region's biopharma leaders needed another reason for worry, it came in April when advertisements emerged in Seattle urging life sciences companies to move their businesses and jobs to New York City. It was the latest affront to a region that has worked to bounce back from setbacks such as the departure of Amgen and state budget cuts that wiped out the R&D tax credit. Industry advocates are trying to restore the credit, but a bill to that effect hasn't advanced beyond referral to committee. More positive news has emerged from a few growing companies: Nohla Therapeutics, spun out in 2015 from the Fred Hutchinson Cancer Research Center, opened a new lab in Seattle's Eastlake neighborhood in February, two months after winning \$43.5 million in Series A financing, while Seattle Genetics in January disclosed plans to add 200 employees this year, bringing its workforce to 1,100-plus.

The region ranked fifth in VC (eight deals totaling \$169 million in 2016), dipping in Q1 (two deals totaling \$31 million) to sixth, same as its ranking for NIH funding (621 awards totaling \$374.4 million) and patents (1,887). However, the Seattle area has already more than doubled its VC dollars this quarter, as Genoa Pharmaceuticals closed on a \$62 million Series A financing in May. The region fares worse, however, in lab space (eighth with 4.6 million square feet) and especially jobs (11th with 24,320, according to JLL). A report released in February by Washington state's Life Science & Global Health Advisory Council showed the life sciences industry has lost 3% of its jobs since 2011.

#### #6. Greater Philadelphia

The birthplace of American independence is increasingly a nurturing spot for early-stage biopharmas. Over the past year, the University of Pennsylvania opened the office-labproduction space Pennovation Center, whose tenants include tissue engineering and disease modeling startup BioBots; while in suburban Buckingham Township, the Pennsylvania Biotechnology Center of Bucks County broke ground in April on a \$13 million expansion expected to create 100 jobs. The University City Science Center, the nation's oldest research campus, welcomed Chondrial Therapeutics to its Port incubator. University City is part of an "innovation district" that could attract more jobs in part by focusing on precision medicine, a Brookings Institution initiative concluded in May.

Yet during this year's Philly Tech Week, according to Technically Philly, Barbara Schilberg, CEO of VC firm Bioadvance, said investors remain concerned about getting startups past their seed stage: "The thing to watch is if they can get to a Series A." VC funding is among challenges for the region, which ranked eighth both last year (11 deals totaling \$125 million) and in Q1 (two deals totaling \$29 million). The region also ranked eighth in patents (1,365), but fared better in lab space (seventh with nearly 6.4 million square feet), employment (sixth with 53,614 jobs, according to JLL) and notably NIH funding (fifth with 671 awards totaling \$389 million).

#### #5. Maryland / Virginia / DC Metro

Area biopharma leaders have committed to growing their "BioHealth Capital Region" cluster into one of the nation's top three by 2023, building on anchors ranging from the NIH and FDA, to the nation's top academic recipient of research grant funding, the Johns Hopkins University. Hopkins accounts for 64.5% of the region's NIH funding (556 awards totaling \$271.4 million), placing fourth with 880 awards totaling nearly \$420.7 million. The region is close to meeting its goal in patents (fourth with 4,108), but further back in employment (eighth with 39,145 jobs, according to JLL) and lab space (sixth with 9.5 million square feet).

Vaccine developers continue to grow: In May, Gaithersburg-based Emergent BioSciences opened an \$80 million expanded medical countermeasures plant in East Baltimore, while GlaxoSmithKline announced a \$139 million capacity

expansion at its API plant in Rockville, MD, due to growing demand for its lupus erythematosus treatment Benlysta® (belimumab).

The region finished sixth in VC funding last year (\$146 million), but climbed to fourth during Q1 (seven awards totaling \$71 million). Courting the industry eagerly are both Virginia Gov. Terry McAuliffe (D) and Maryland Gov. Larry Hogan (R), a non-Hodgkin's lymphoma survivor who calls the cluster-building effort a personal mission.

#### #4. San Diego

"America's Finest City" will be the center of the biopharma industry in June, when the Biotechnology Innovation Organization holds its annual BIO International Convention at the San Diego Convention Center, expected to draw 16,000 attendees. The "Plymouth of the West" and vicinity remain third in VC funding with 28 deals totaling \$650 million last year. Nearly one-third of that total came from a single deal, the "in excess of" \$220 million Series B financing of Human Longevity Inc. HLI and its executive chairman J. Craig Venter, Ph.D., who stepped down as CEO earlier this year, are among anchors of the region's cluster-within-a cluster focused on genomics, which according to the San Diego Regional Economic Development Corporation encompasses some 100 of the 1,200-plus companies and institutions. Another anchor, Illumina, in January opened the \$40 million, 293,000-square-foot "Building 6" manufacturing facility, built for the sequencing giant by Alexandria Real Estate Equities.

Illumina's roughly 3,000 employees help made the region fifth in jobs (63,730 according to JLL, compared with 49,763 counted by Biocom). The region ranks fourth in lab space (11.9 million square feet plus 1.1 million square feet under construction) and third in patents (4,383), but seventh in NIH funding (741 awards totaling \$352.9 million).

#### #3. New York-New Jersey

The region's biopharma industry may emerge as winners in the ongoing political rivalry between New York Gov. Andrew Cuomo (D) and New York City Mayor Bill de Blasio (D), who is seeking re-election this year. Both have advanced big-money cluster-building efforts: In April, Cuomo and legislative leaders agreed to include \$620 million for life sciences programs in the state's \$153.1 billion budget for 2017–18, while de Blasio used a meeting with Seattle Mayor Ed Murray to restate the city's commitment to the industry. Back in December, de Blasio announced \$500 million in incentives designed to help create 16,000 life sciences jobs. Across the Hudson River, New Jersey in April launched a smaller incentive, the NJ CoVest Fund, designed to provide seed funding to Garden State-based early-stage life sciences and other technology companies.

New Jersey accounts for nearly 61% of the region's jobs, helping catapult the Empire State—Garden State tandem to number-one in jobs (127,308, according to JLL). Among growing companies is Tarrytown, NY-based Regeneron Pharmaceuticals, which in January said it will purchase its headquarters site for \$720 million—a month after shelling out \$50 million for an office property in nearby Sleepy Hollow, NY. Despite being home to Wall Street and the financial

industry, the region ranks only seventh in VC funding (11 deals totaling \$132 million in 2016; two deals totaling \$29 million in Q1). NY–NJ fares better in patents (fifth with 3,208), and especially in lab space (12.7 million square feet) and NIH funding (third with 1,835 awards totaling about \$787.3 million).

#### #2. San Francisco Bay Area

The Bay Area leads the nation in patents (10,312), and is close behind Boston/Cambridge in lab space with 19.3 million square feet. The lab market may be peaking; developer Oyster Point Development in January halved the lab R&D space it proposes to build at The Landing at Oyster Point in South San Francisco, from the 2.25 million square feet submitted to City officials last year, to 1 million square feet, replacing the lab space with 1,191 residential units. However, on May 4, the "Birthplace of Biotechnology" saw another developer, BioMed Realty, break ground on the first phase of Gateway of Pacific, a 1.3 million square foot lab-office campus.

In VC funding, the Bay Area finished 2016 second with \$2.2 billion in 80 deals, and narrowly edged Boston/Cambridge in Q1 2017 with \$1.435 billion in 20 deals. The region finished third in NIH funding (1,283 awards totaling about \$520.6 million), and fourth in jobs with 67,738 according to JLL, though the California Life Sciences Association offers a slightly higher count of 68,313 as of 2015. That number can be expected to grow in coming months, with Juno Therapeutics in April confirming plans for a Bay Area office, saying it "puts us in the best position to continue to hire world-class talent." Not all the region's job news has been good; OncoMed halved its workforce in April.

#### #1. Boston / Cambridge, MA

A decade after then-Gov. Deval Patrick (D) enacted the Massachusetts Life Sciences Initiative, his successor has yet to announce what support the state will offer the industry when the \$1 billion, ten-year measure expires next year. However, Gov. Charlie Baker (R) has committed the state to growing life sciences companies through workforce development programs and funding for drug R&D. Supporting biopharma is also the goal of the region's incubators and accelerators—including the first Chinese-owned bioincubator, the Qilu Boston Innovation Center (QBIC), which opened May 19. QBIC was founded by Qilu Pharmaceuticals, a \$2 billion-a-year Chinese drug developer that opened within the incubator its first branch company, cancer immunotherapy developer QLB Biotherapeutics.

Not surprisingly, the region leads the nation in NIH funding (2,169 awards totaling nearly \$1.055 billion), lab space (19.9 million square feet), and 2016 VC funding (78 deals totaling \$3.06 billion), though Boston/Cambridge finished second to the San Francisco Bay Area in Q1 with 19 deals totaling \$534 million. Biopharma growth is fueling a wave of speculative lab space development in and around Boston and Cambridge; King Street Properties, for example, is building the \$200 million, 145,000-square-foot 828 Winter Street adjacent to an

existing lab building owned by the developer, and slated for completion in 2018. The region is also second in patents (6,496), but third in jobs with 86,235 according to JLL, though industry group Massachusetts Biotechnology Council (MassBio) reported 63,026 last year.

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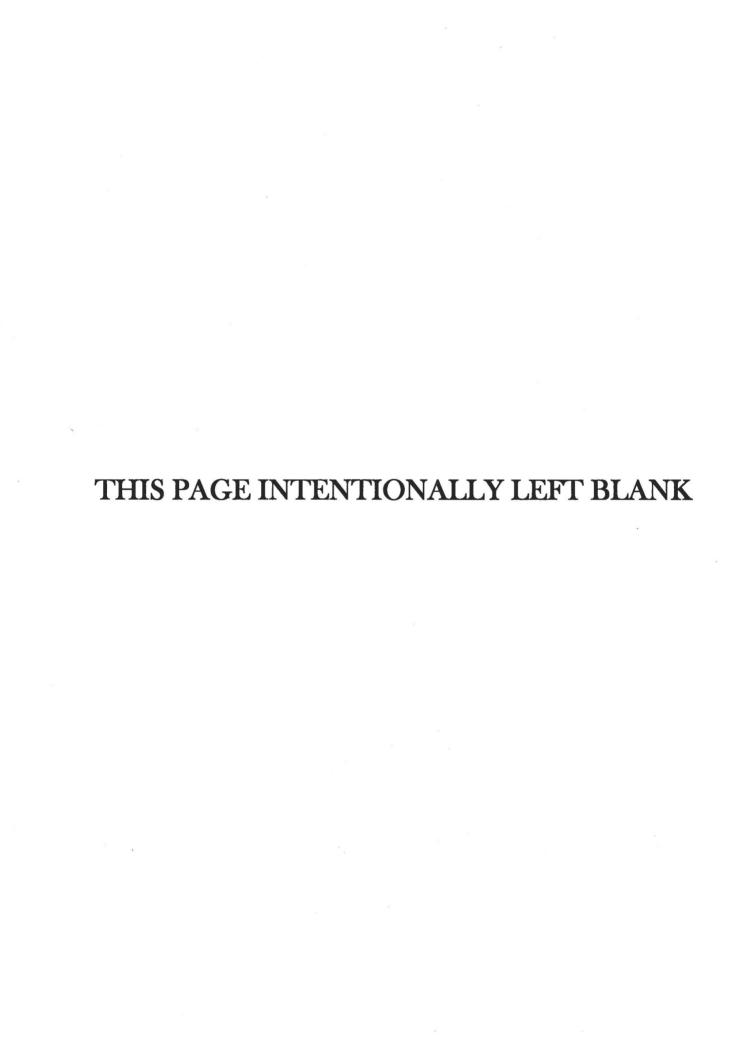
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# **Funding Initiative**



# **Project Results to Date**

	Collaborators	Date	Amount of Grant	Matching Funds	Follow on Funding	Initial Job Creation	Net Job Creation	Additional Funding – Next 18 Months	Job Creation – Next 18 Months
VT, VCU	BioTherapeutics Inc. Blacksburg, VA	12-2013	\$400,000	\$400,000	\$10,000,000	15	15	\$35,000,000*	7
UVA, GMU	Tau Therapeutics (Cavion LLC) Charlottesville, VA	12-2013	\$200,000	\$238,000	\$26,100,000	2.5	2.5		4
VT, UVA	First String Research Roanoke, VA and Mt. Pleasant, SC	12-2013	\$200,000	\$1,000,000	\$3,000,000	10	10	\$15,000,000*	0
UVA, VCU	HemoShear LLC Charlottesville, VA	12-2013	\$450,000	\$800,000	\$1,900,000	5	5	\$15,000,000	10
	Subtotal Round 1		\$1,250,000	\$2,438,000	\$41,000,000	32.5	32.5	\$65,000,000	21
VCU, UVA	Gencia, LLC Charlottesville, VA	03-2014	\$400,000	\$400,000	\$8,800,000	2	2		
UVA, VCU	Neoantigenics LLC** Charlottesville, VA	03-2014	\$348,729	\$2,000,000	\$3,000,000	1	0	\$0	0
VT, UVA	SphynKx Therapeutics*** Charlottesville, VA	03-2014	\$400,000	\$400,000	\$150,000	4	4	\$0	0
EVMS, UVA	LifeNet Health Virginia Beach, VA	03-2014	\$255,000	\$255,000	\$5,000	3	1		
	Subtotal Round 2		\$1,789,479	\$2,825,657	\$11,955,000	10	7		
VT, UVA	PhenoCHIP Blacksburg, VA	08-2014	\$270,000	\$386,000	\$450,000	5	4	\$1,000,000	7
ODU, EVMS	OncoSec Medical San Diego, CA	08-2014	\$585,000	\$2,750,000	\$8,700,000	3.5	3.5	<del>+</del> 2,-2 <b>3,000</b>	3
VCU, ODU	US Probe Glen Allen, VA	08-2014	\$536,000	\$536,000	\$450,000	5.5	5.5	\$500,000	2.5
	Subtotal Round 3		\$1,391,000	\$3,672,000	\$9,600,000	14	13	\$1,500,000	12.5

<sup>\*</sup>Confidential Information – These companies have commitments expecting to be actualized in October 2017. \*\*Principal Investigator, Josh Hare, died of heart attack, and project ended. \*\*\*SphynKx returned Intellectual Property to Virginia Tech, where they are continuing to collect additional data from animal models.

	Subtotal Round 6		\$2,825,000	\$6,600,000	\$1,600,000	10.5	12.5	\$19,650,000	24
/CU, JVA	Propagenix Rockville, MD	10-2016	\$425,000	\$1,200,000	\$500,000	1	1	\$12,900,000	4
ODU, EVMS	Pulse Biosciences Burlingame, CA	10-2016	\$300,000	\$300,000	\$0	2	2		2
EVMS, GMU	Sanyal Biotechnology Virginia Beach, VA	10-2016	\$100,000	\$100,000	\$580,000	3	3		8
GMU, VCU	Serpin Pharma Manassas, VA	10-2016	\$400,000	\$3,400,000	\$550,000	4.5	6.5	\$6,750,000	10
VT, VCU	BioTherapeutics Inc. Blacksburg, VA	10-2016	\$800,000	\$800,000					
VT, UVA	VoltMed, Inc. Blacksburg, VA	10-2016	\$800,000	\$800,000					
	Subtotal Round 5		\$687,057	\$1,552,862	\$2,000,000	12	10	\$4,000,000	8
VT, UVA	VoltMed, Inc. Blacksburg, VA	12-2015	\$380,000	\$1,200,000	\$2,000,000	12	10	\$4,000,000	8
UVA, GMU	Cavion Charlottesville, VA	12-2015	\$307,057	\$352,862					
	Subtotal Round 4		\$2,224,500	\$2,525,000	\$10,750,000	24	26	\$19,000,000	32
GMU, VT	BrightSpec, Inc Charlottesville, VA	08-2015	\$400,000	\$400,000	\$2,150,000	6	6	\$4,000,000*	15
VT, VCU	BioTherapeutics Inc. Blacksburg, VA	08-2015	\$400,000	\$400,000				,	
ODU, EVMS	Embody LLC Norfolk, VA	08-2015	\$634,500	\$725,000	\$3,600,000	5	9	\$9,000,000	10
VT, UVA	First String Research Roanoke, VA and Mt. Pleasant, SC	08-2015	\$290,000	\$500,000					
GMU, VT	Ceres Nanosciences Manassas, VA	08-2015	\$500,000	\$500,000	\$5,000,000	13	11	\$ 6,000,000	7

# **Previously Awarded Projects**

Project Title	Date Awarded	Award Amount	Prime University	Partner University	Industry Partner
Development of Novel Anti-Inflammatory Drugs	12-2013	\$400,000	Virginia Polytechnic Institute and State University	Virginia Commonwealth University	BioTherapeutics
Commercialization of a Human Tumor Microenvironment System for Pharmaceutical Cancer Drug Discovery and Development	12-2013	\$450,000	University of Virginia	George Mason University	HemoShear, LLC
Novel Regenerative Drug	12-2013	\$200,000	Virginia Polytechnic Institute and State University	University of Virginia	FirstString Research, Inc.
Determining the Optimal Dosing Schedule for the Commercialization of Mibefradil in Front-Line Glioblastoma	12-2013	\$200,000	University of Virginia	Virginia Commonwealth University	Cavion
UVA-VCU Partnership to Develop Radioimmunotherapeutic and Imaging Agents to a Unique Cell-Surface Target Relevant for Multiple Human Cancers	03-2014	\$348,729	University of Virginia	Virginia Commonwealth University	Neoantigenics LLC
Reversing Bioenergetic Deficits and Improving Cognitive Function in Alzheimer's Disease	03-2014	\$400,000	Virginia Commonwealth University	University of Virginia	Gencia Corporation, LLC
Lead Optimization of a SphK2 Inhibitor for the Treatment of CKD	03-2014	\$400,000	Virginia Polytechnic Institute and State University	University of Virginia	SphynKx
Enhancement of Healing in Diabetic Wounds Using a Decellularized Dermal Matrix	03-2014	\$255,000	Eastern Virginia Medical School	University of Virginia	LifeNet Health
Ultrasonographic Probe	08-2014	\$536,000	Virginia Commonwealth University	Old Dominion University	Ultrasonic Probe LLC
PhenoCHIP-phenotype-based Cell Hierarchy and Isolation Platform	08-2014	\$270,000	Virginia Polytechnic Institute and State University	University of Virginia	Proteo Biosciences
Biomarker-driven Optimization of IL-12 Gene Electrotransfer for the Treatment of Melanoma	08-2014	\$585,000	Old Dominion University	Eastern Virginia Medical School	Onosec Medical Inc.

Clinical Trial of New Drug in Dogs to Treat Brain Cancer in Humans	08-2015	\$290,000	Virginia Polytechnic Institute and State University	University of Virginia	FirstString Research, Inc.
Nanofabrication of Tissue Scaffolds	08-2015	\$634,500	Old Dominion University	Eastern Virginia Medical School	Embody
Optimizing Oral Delivery of BT-11 as a Clinical Candidate for Treating Inflammatory Bowel Disease	08-2015	\$400,000	Virginia Polytechnic Institute and State University	Virginia Commonwealth University	BioTherapeutics
Three Wave Mixing Technique for Chiral Analysis in Continuous Process Manufacturing	08-2015	\$400,000	University of Virginia	Virginia Commonwealth University	BrightSpec, Inc.
Nanotrap® Tick-Panel Test Development	11-2015	\$500,000	George Mason University	Virginia Polytechnic Institute and State University	Ceres Nanosciences, Inc.
Development of a Biomarker Assay and Protocol for the Commercialization of Mibefradil Dihydrochloride as a First-Line Treatment for Glioblastoma	11-2015	\$307,057	University of Virginia	George Mason University	Cavion
INSPIRE To Fight Brain Cancer	12-2015	\$380,000	Virginia Polytechnic Institute and State University	University of Virginia	VoltMed Inc.
Commercialization of INSPIRE Brain Cancer Treatment	10-2016	\$800,000	Virginia Polytechnic Institute and State University	University of Virginia	VoltMed Inc.
BT-11: First-in-class Oral Therapeutic for IBD	10-2016	\$800,000	Virginia Polytechnic Institute and State University	Virginia Commonwealth University	BioTherapeutics
Novel and potent anti-inflammatory drug with cardio-protective effects to treat myocardial injury and prevent heart failure	10-2016	\$400,000	George Mason University	Virginia Commonwealth University	Serpin Pharma
Accelerating the commercialization of the Diamond™ mouse model of NASH	10-2016	\$100,000	Eastern Virginia Medical School	George Mason University	Sanyal Biotechnology
Translational Research with Nanosecond Pulsed Electric Fields for Immuno- Oncology Applications	10-2016	\$300,000	Old Dominion University	Eastern Virginia Medical School	Pulse Biosciences
Bioengineering for the Therapeutic Delivery of Massively Expanded Islet- Derived Human Beta-Cells	10-2016	\$425,000	Virginia Commonwealth University	University of Virginia	Propagenix

# **Project Budgets, Payments to Date, and Outstanding Commitments**

As of August 31, 2017 Prime Partner				Payments to	Outstanding
University Round 1	University	Industry Partner	Budget	Date	Commitment
VT	VCU	BioTherapeutics	\$400,000	\$400,000	-
UVA	GMU	Hemoshear	\$450,000	\$450,000	-
VT	UVA	FirstString	\$200,000	\$200,000	-
UVA	VCU	Cavion	\$200,000	\$200,000	
Total			\$1,250,000	\$1,250,000	-
Round 2					
VT	UVA	SphynKx	\$400,000	\$400,000	_
VCU	UVA	Gencia	\$400,000	\$400,000	_
UVA	VCU	Neoantigenics	\$348,729	\$348,729	_
EVMS	UVA	LifeNet Health	\$255,000	\$255,000	_
Total	0171	Ziiortot rioditir	\$1,403,729	\$1,403,729	_
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Round 3					
VCU	ODU	US Probe	\$536,000	\$406,000	\$130,000
VT	UVA	PhenoCHIP	\$270,000	\$270,000	-
ODU	EVMS	OncoSec	\$585,000	\$585,000	-
Total			\$1,391,000	\$1,261,000	\$130,000
Round 4					
VT	VCU 1	BioTherapeutics	\$400,000	\$400,000	-
GMU	VT	Ceres	\$500,000	\$356,528	\$143,472
UVA	VCU	BrightSpec	\$400,000	\$400,000	-
ODU	EVMS	Embody	\$634,500	\$475,875	\$158,625
VT	UVA	FirstString	\$290,000	\$290,000	
Total			\$2,224,500	\$1,922,403	\$302,097
Round 5					
VT	UVA	VoltMed	\$380,000	\$380,000	_
UVA	GMU	Cavion	\$307,057	\$293,537	\$13,520
Total	Civio	Guvion	\$687,057	\$673,537	\$13,520
			<del>-</del>	<del></del>	<b>V.0,0</b>
Round 6					
VT	UVA	VoltMed	\$800,000	\$260,000	\$540,000
VT	VCU	BioTherapeutics	\$800,000	\$442,000	\$358,000
GMU	VCU	Serpin	\$400,000	\$90,000	\$310,000
EVMS	GMU	Sanyal	\$100,000	\$33,000	\$67,000
ODU	EVMS	Pulse	\$300,000	\$75,000	\$225,000
VCU	UVA	Propagenix	\$425,000	\$225,000	\$200,000
Total			\$2,825,000	\$1,125,000	\$1,700,000





### FOR IMMEDIATE RELEASE

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Virginia Catalyst Awards \$2,825,000 to Fund Bioscience Research Initiatives

Six winning projects to address human health issues such as brain cancer, heart failure and immune-oncology

RICHMOND, VA – June 19, 2017 – The Virginia Biosciences Health Research Corporation, known as Virginia Catalyst, today announced that it has awarded \$2.825 million in grants to six collaborative bioscience commercialization projects between Virginia's research universities and private companies. Round six of funding is intended to catalyze the development and commercialization of life science projects that address major unmet needs for improving human health, while also contributing to Virginia's economic growth.

"Virginia's research universities are providing leadership on a national and global level in the life sciences by combining their intellectual and scientific prowess through collaborations to achieve critical mass. This competitive critical mass is attracting significant outside capital and industry participation to commercialize Virginia's innovations, while creating high-paying jobs for Virginia," said Mike Grisham, CEO, Virginia Catalyst. "Bioscience continues to be a vital part of Virginia's economy and we are excited to help fuel innovation, collaboration and economic growth in our state. Virginia, Maryland and the D.C. metro area are now nationally ranked by Genetic Engineering & Biotechnology News (GEN) as a top five biopharma cluster."

The six winning projects for this current round of funding include:

### **Project Focus: INSPIRE Brain Cancer Treatment**

- Company: VoltMed, Inc. (Blacksburg, VA)
- · University collaborators: Virginia Tech and University of Virginia
- Funding amount: \$800,000
- Matching funds: \$1.7 million provided by the National Institutes of Health

### Project Focus: BT-11: First-in-class Oral Therapeutic for Inflammatory Bowel Disease

- Company: BioTherapeutics, Inc. (Blacksburg, VA)
- University collaborators: Virginia Tech and Virginia Commonwealth University
- Funding amount: \$800,000
- Matching funds: \$800,000 provided by BioTherapeutics, Inc.

# <u>Project Focus: Novel and Potent Anti-inflammatory Drug with Cardio-protective Effects to Treat Myocardial Injury and Prevent Heart Failure</u>

- Company: Serpin Pharma (Manassas, VA)
- University collaborators: George Mason University and Virginia Commonwealth University
- Funding amount: \$400,000
- Matching funds: \$400,000 provided by Serpin Pharma

# <u>Project Focus: Accelerating the Commercialization of the Diamond™ Mouse Model of Nonalcoholic Steatohepatitis</u>

- Company: Sanyal Biotechnology (Richmond, VA)
- University collaborators: Eastern Virginia Medical School and George Mason University
- Funding amount: \$100,000
- Matching funds: \$100,000 provided by Sanyal Biotechnology

### <u>Project Focus: Translational Research and Nanosecond Pulsed Electric Fields for Immuno-</u> Oncology Applications

- Company: Pulse Biosciences, Inc. (Burlingame, CA)
- University collaborators: Old Dominion University and Eastern Virginia Medical School
- Funding amount: \$300,000
- Matching funds: \$300,000 provided by Pulse Biosciences, Inc.

### <u>Project Focus: Bioengineering for the Therapeutic Delivery of Massively Expanded Islet-Derived</u> Human Beta-Cells

- Company: Propagenix, Inc. (Rockville, MD)
- University collaborators: Virginia Commonwealth University and University of Virginia
- Funding amount: \$425,000
- Matching funds: \$1.04 million provided by the National Institutes of Health and Propagenix, Inc.

Virginia Catalyst is a not-for-profit 501(c)(3) corporation funded by the Virginia General Assembly's general fund and seven of Virginia's research universities. The organization has now awarded 24 grants totaling \$10 million, combined with \$20 million in matching funds, which financed the achievement of meaningful milestones. This then resulted in follow-on funding of an additional \$80 million and the creation of high-paying jobs throughout the Commonwealth.

### Supporting Quotes

"This Virginia Catalyst research award will propel deployment of a unique combination of capabilities at Virginia Commonwealth University, the University of Virginia and Propagenix to discover new approaches to improve islet transplantation for Type 1 diabetes," said Brian Pollok, CEO of Propagenix. "The merger of bioengineering and material sciences expertise at these universities, with our proprietary cell expansion technology, has the promise of significantly changing the current equation of human islet cell therapy for patients suffering

from this disease."

"Virginia Tech, spin-out company VoltMed, Inc. and the University of Virginia are developing a tumor treatment platform that selectively destroys brain cancer cells, including malignant glioma," said Chris Arena, Vice President of VoltMed. "The therapy utilizes minimally invasive electrodes placed into the tumor under medical imaging guidance, followed by a series of brief, but intense electric pulses. Funding from the Virginia Catalyst will be instrumental in clinical translation of the technology by supporting compliance with regulatory manufacturing and testing."

"Inflammatory bowel disease (IBD) afflicts over four million people worldwide. This Virginia Catalyst award offers an accelerated path toward addressing an unmet clinical need for safer, more effective drugs for four million IBD patients and a \$9 billion per year market growing at a 25% rate annually," said Josep Bassaganya-Riera, President and CEO of BioTherapeutics. "Our lead compound, BT-11, is an oral first-in-class therapeutic for moderate to severe Crohn's disease and ulcerative colitis. We anticipate filing an investigational new drug (IND) for BT-11 and entering Phase 1 and 2 clinical testing in 2018."

"Sanyal Bio is committed to developing cures for liver diseases like fatty liver and NASH that result from the twin epidemics of diabetes and obesity," said Rebecca Caffrey, Founder and CEO, Sanyal Biotechnology LLC. "This funding will help in the development of a tissue bank and provide some R&D into mechanisms driving the development of these diseases in our model. This funding allows us to answer some key questions for our pharmaceutical company clients, so that we can grow our business faster. State-funded programs that support commercialization and new product development for small biotechnology companies like ours are so important. I hope that the Virginia Catalyst will be fully funded by the General Assembly so that it will be able to support the growth of other deserving new biotech companies in Virginia in the future."

### **About the Virginia Catalyst**

Virginia Biosciences Health Research Corporation (VBHRC), known as Virginia Catalyst, has a vision of advancing life sciences throughout Virginia as a means of addressing large unmet medical needs to improve human health and to create high-paying jobs throughout the Commonwealth. Funded by the Virginia General Assembly's General fund, the University of Virginia, Virginia Commonwealth University, Virginia Tech, Eastern Virginia Medical School, George Mason University, Old Dominion University, and William and Mary, Virginia Catalyst has funding opportunities to support collaborative projects in the Commonwealth and is home to the Virginia Neuroscience Initiative. For more information, visit <a href="https://www.virginiacatalyst.org">www.virginiacatalyst.org</a>.

###



### **Award Guidelines**

# **Description of Funding Opportunity**

Virginia Catalyst provides grants of \$200,000 to \$800,000 per project to accelerate translational research and commercialization of breakthrough technologies in the life sciences. The purpose of funding is to:

- Fund innovative, collaborative, translational research projects that elevate the level of sponsored research and have the potential to significantly improve human health and create high value jobs in the Commonwealth.
- Develop a process which is robust, objective, and defendable in design and execution, and which yields powerful collaborations that produce world class technologies, products and services.

# Eligible Applicants

Proposals must come from active and significant collaboration between at least two Virginia research universities that are members of VBHRC and one industry partner in the biosciences field. These universities include the University of Virginia, Virginia Commonwealth University, Virginia Tech, Eastern Virginia Medical School, George Mason University, Old Dominion University, and William and Mary. Universities outside of Virginia may participate in the project provided that there are still at least two qualifying Virginia universities involved.

# Type of Proposals

### Proposals must:

- Clearly identify large unmet need(s) in the market
- Demonstrate a positive impact on human health and/or patient care
- Delineate a competitive advantage and/or clinical utility
- Define commercialization pathways
- Hold potential for high impact near-term success in generating other sponsored research, creating spin-off companies or otherwise creating new jobs

# **Funding Cycles**

Our timeline for grant rounds is determined based on budget decisions made by the Virginia General Assembly. Generally, we have one or two grant rounds per year. Virginia Catalyst offers a neuroscience-specific funding opportunity every other grant round, where projects are intended to focus around the development, validation and application of new approaches to diagnosing, preventing and treating neurological conditions, including brain injuries, brain developmental disorders, neurodegenerative disorders, neuropsychiatric and behavioral disorders, addiction and substance abuse. In non-neuroscience rounds, we invite project teams involved in all areas of translational research with commercial potential to apply.

# Award Type and Amount

Grant awards are made in the range of \$200-\$800K. Companies receiving awards will be required to prepare semi-annual progress reports and a final report for Virginia Catalyst. Approvals for animal and/or human subjects (if needed) will be required "in just time" after awards are announced.

# Matching Funds Required

Proposals have a matching funding requirement, beginning at 1:1 and rising to up to a 6:1 for major projects.

### Period of Performance

Grants are awarded annually and can cover expenses over a 12 to 18 month time frame. Follow-on grants may be renewed on a competitive basis with new applications. Grants may be terminated and remaining funds recalled at mid-year if progress reports are not acceptable. Competitive renewal applications must have a comparison of milestones achieved versus those planned in the original submission.

### **Budget**

Eligible budget items include faculty and non-faculty salary support, clinical trial costs, operating supplies, minor equipment items, prototyping expenses, licensing fees, imaging/core equipment time, and travel directly associated with the research activity. The indirect overhead rate to be paid to universities in connection with Virginia Catalyst-funded projects is 30%. The indirect rate is only applied to funds utilized by the universities; it is not applied to funds utilized by the industry partner.

# **Funding Criteria**

### **Market Need**

- This translational research project addresses a large unmet need and it can lead to significantly improving human health
- Medical/life science need
- Innovative/breakthrough technology
- Competitive advantage over other approaches
- Size of market

### Level of Collaboration

- This project encompasses substantive real collaboration between and among Virginia research universities and industry
- There is a defined process to manage the collaboration including clear accountabilities, an internal communication plan and a methodology to declare and solve breakdowns
- The collaboration has true synergies that will ensure creative debate, innovation, and the achievement of critical mass

### Scientific Merit

- Scientific and technical feasibility
- Stage of technical development
- Scientific and technical expertise/credibility
- The project technology is superior to competing approaches
- Scientific and product development milestones and timelines are clearly defined
- There is adequate evidence that resources (financial and human) are adequate to achieve the timelines

### Commercialization

- There is a clear understanding of who is the targeted customer, what the unmet need is, the size of the market (patients) and what the pathway to commercialization is
- The commercialization value proposition is clear, robust, and compelling
- There is a clear collaborative pathway to transfer know-how and technology from inventors to the commercialization or industry partner

### Intellectual Property

- The intellectual property portfolio and patent strategy are adequate to provide barriers to entry and to obtain freedom to operate
- The applicable technology transfer office of the universities are aligned with the goals of the project and the proposed licensing terms will not be a barrier to commercialization

# Management and Leadership

- The management and scientific team have the expertise and will allocate the necessary time to achieve the goals
- If there is a gap in the management or scientific team, there is a milestone plant to recruit the talent needed

# Follow-on Funding and Economic Development

- The project is well positioned to attract follow on funding for the next stage of development and ultimately funding for commercialization
- Economic impact and job creation for Virginia

# **Proposal Process**

### Letter of Intent

A letter of intent is required in advance of application submission. These will be reviewed by the Project Management and Oversight Panel, and appropriate submissions will be solicited for full applications.

### Requirements:

- 2-page maximum
- Single-spaced
- 12 pt font
- 1" margins
- Saved as a .pdf

- Project title in heading
- References can be submitted as a supplement to the LOI and will not count towards the 2-page limit

### Criteria to be Addressed

- **Description and Nature of the Project**. Provide a brief overview of the project plan including an analysis of its strengths as well as the gaps and requirements for progressing the idea
- Scientific and Clinical Impact. Explain the novel insight, target, compound, biomarker, screen, assay, or technology and clearly outline the project's potential for translation, impact in life sciences, and achievability
- **Economic Impact for Virginia**. Describe how this project will create a positive impact for Virginia through increased revenues, job creation, and/or follow on funding
- Plan for Commercialization. Clearly articulate a plan for moving the project from idea into commercialization
- **Significant Collaboration**. Describe the capabilities of each project team member to perform the project, and include their contact information.
- Matching Funds. List the source of the matching funds for the project. Proposals have a
  matching funding requirement, beginning at 1:1 and rising to up to a 6:1 for major
  projects.

LOIs should be submitted by email to Mike Grisham at <a href="mailto:mgrisham@vbhrc.com">mgrisham@vbhrc.com</a>.

Inclusion of proprietary information in LOIs or full applications is discouraged unless absolutely necessary for evaluation. When proprietary information is provided, it should be clearly marked and submitted as an appendix to the proposal.

# **Full Application**

Detailed guidelines for full applications will be provided in response to appropriate LOIs. Applicants will be given a username and password to securely upload their application to the online grant application portal. Full applications should not exceed the 13-page PowerPoint presentation template. The proposal should clearly address the scientific/technical importance and commercialization potential of the project and how the funding will be used. Also, specific milestones and timelines to achieve objectives should be clearly defined. Appropriate grant administrators at each applicant's university will be identified and notified of the proposal's consideration for funding by Virginia Catalyst at this time.

The top applicants will be invited to present in person to the Project Management and Oversight Panel. Project teams are allocated 20 minutes for the presentation, followed by 10 minutes of Q&A with the panel.

### Matching Funds Guidelines

Proposals have a matching funding requirement, beginning at 1:1 and rising to up to a 6:1 for major projects. Grants from sources such as federal and state governments as well as foundations may be used as matching funds as long as the dollars are not yet spent and the granting authority allows their funds to be counted as a match. Equity capital can also be used as matching funds. Matching funds must be hard-dollar matches. Neither In-kind services nor the waiver of overhead funds can contribute towards the matching funds requirement. Documentation in support of matching funds will be reviewed by Virginia Catalyst's accounting firm, RealTime Accounting Solutions, and the CEO of Virginia Catalyst. Matching funds documentation must be approved before funds can be released for the project.

The documentation criteria may be met by one or a combination of the following:

- A current accrual basis balance sheet that shows the company's assets, liabilities and equity. The match will be considered supported if current assets less current liabilities exceeds the pledge of matching funds;
- A grant award from a third party (NIH, STTR, SBIR) where the project to be funded is specified as an allowable grant expenditure; and/or
- A commitment of private funding for the project from angel investors, venture capital, or other private equity or corporate sponsorship.
- We ask that the CEO and CFO sign off on the documentation indicating that the information provided is true and correct to the best of their knowledge.

# Application Processing and Review

Project teams whose Letters of Intent meet criteria will be invited to submit a draft of their project presentation to obtain feedback and guidance from the Project Management and Oversight Panel prior to the in-person presentations at Virginia Catalyst. Projects will be scored and ranked by the Panel. The Panel will then make funding recommendations to the Board of Directors. The Board of Directors makes all funding decisions. Project teams will be notified of the decisions of the Board. If awarded a grant, award contracts will be executed and subsequently, initial disbursements will be made.

# **Proposal Scoring Elements**

Projects will be evaluated based on the following criteria:

- Management/Leadership
- Scientific/Technical Feasibility
- Clinical Impact
- Collaboration Synergies
- Economic Impact (Return on Investment) and Sponsored Research Multipliers
- Job Creation in Virginia
- Regulatory and reimbursement strategies
- Metrics for demonstrating substantive collaborations
- Barriers to Entry (IP, proprietary know-how, etc.)
- Follow on Funding Potential
- Time to Market

### **Award Administration**

Successful applicants will receive notification of their award status in the form of an award letter with a grant agreement template attached. Recipients will be identified as the prime university, partner university, and industry partner. The primary university will be responsible for completing the grant agreement, including the proposed milestones, budget, and anticipated timeline. Once the grant agreement is finalized, Virginia Catalyst will sign and circulate the partially executed agreement to all parties for signatures. Usually two weeks are allowed to return the signed agreement.

At this time, the industry partner must submit documentation in support of matching funds. Once all parties have signed the grant agreement, Virginia Catalyst will send out the fully executed master agreement to all parties.

The prime university is responsible for setting up subawards with both the partner university and the industry partner per the guidelines set forth in the master agreement.

Once all requirements have been met, Virginia Catalyst will make the initial disbursement to the prime university. The prime university will then make subsequent disbursements to the partner university and industry partner. Upon milestone completion, the prime university is responsible for notifying Virginia Catalyst and invoicing for the next milestone, at which point another disbursement will be made.

# **Invoicing Procedures**

Invoices should only be sent after Virginia Catalyst has received notification of milestone completion from an investigator and that notification has been approved by the CEO. Invoices should be submitted electronically to Mike Grisham at <a href="mailto:mgrisham@vbhrc.com">mgrisham@vbhrc.com</a>. Please also Cc Megan McMahon at <a href="mailto:mmcmahon@vbhrc.com">mmcmahon@vbhrc.com</a>.

# Reporting Requirements

The industry partner is responsible for submitting semi-annual progress reports during the project period. Once the project is completed, the industry partner will submit a final report, and annual reports for up to 5 years after the project end date. Virginia Catalyst will provide a template several weeks in advance of the report due date. These reports contain the following information:

- Progress on achieving the milestones by each recipient and/or its subcontractors;
- Summary of any intellectual property created;
- Commercialization of the project, if any;
- Economic impact including follow on funding from grants or capital raised, jobs created, etc., and
- Any other information requested by Virginia Catalyst that is reasonably necessary to comply with Virginia Catalyst's policies and/or any applicable laws, rules, regulations or legislation specific to Virginia Catalyst

In addition to the progress reports, Prime University shall also promptly notify Virginia Catalyst in writing upon the completion of any Milestone.

The template for semi-annual and annual progress reports is included in Appendix E.

Semi-annual report deadlines: February 15, August 15

Annual report deadline: February 15

# **Outcome Metrics**

- License agreements
- Publications and presentations

- Additional follow on funding from angel, venture capital or corporate ventures
- Acquisitions by industry
- FDA filings/approvals
- Additional funding from state and federal funding sources
- Improvement in health status of targeted populations
- Job creation in Virginia
- New collaborative ideas under development as a result of state-wide matching
- Media releases as a result of collaboration activity (this could be a press release, NPR story, university promotion of collaboration etc.)

**Call for Proposals** 





### FOR IMMEDIATE RELEASE

### **Media Contact:**

A.J. Guenther ConnellyWorks, Inc. (571) 323-2585 ext. 2130 aj@connellyworks.com

### Virginia Biosciences Health Research Corporation, "the catalyst", Announces Ten-to-One Return on Investment and New Grant Funding to Support Neuroscience Initiatives

Organization accepting applications for neuroscience initiatives involving Traumatic Brain Injury, Autism, ALS, Alzheimer's, Parkinson's, Mental Health, addiction and other brain disorders

RICHMOND, VA – April 6, 2017 – Virginia Biosciences Health Research Corporation (VBHRC/"the catalyst") today announced that it is accepting applications/letters of intent (LOIs) for Round 7 of grants to fund the development, validation and application of new approaches to diagnosing, preventing and treating neurological conditions, including brain injuries, brain developmental disorders, neurodegenerative disorders, neuropsychiatric and behavioral disorders, as well as addiction and substance abuse. The awards, which range from \$200,000 to \$800,000, will accelerate translational research in the Commonwealth of Virginia through collaborations between industry and Virginia research universities. The deadline for consideration is June 8, 2017. Applications/LOIs and grant criteria can be downloaded from the VBHRC website (www.vbhrc.com).

"VBHRC's seventh round of funding provides us an opportunity to continue our focus on neurological issues that will lead to a better understanding of how the brain works," said Mike Grisham, CEO, VBHRC/"the catalyst." "This enables us to research and address disorders of the brain including Traumatic Brain Injuries, Autism, ALS, Alzheimer's, Parkinson's, mental health, addiction and post-deployment issues of our military. Virginia's healthcare systems, universities and industry partners – in conjunction with the Department of Veterans Affairs – provide some of the most collaborative and innovative translational research programs in the country. This funding, provided by the Virginia General Assembly, will help accelerate this important research."

This round of funding is part of the Virginia Neuroscience Initiative, an effort intended to coordinate and advance the state's excellence in neuroscience research by expanding partnerships, infrastructure and resources. To date, VBHRC/"the catalyst" has awarded over \$10,400,000 for research around brain cancer therapeutics, diagnostics for Lyme disease, treatments for inflammatory bowel disease, tumor ablation for brain cancer and identifying novel biomarkers for glioblastoma, to name a few. Our program has resulted

in matching funds in excess of \$20 million and follow-on funding in excess of \$80 million. This is a ten-to-one return on investment, along with significant job creation.

VBHRC/"the catalyst" is a not-for-profit 501(c)(3) corporation funded by the Virginia General Assembly's general fund and six of Virginia's research universities including Eastern Virginia Medical School, George Mason University, University of Virginia, Virginia Commonwealth University, Virginia Polytechnic Institute and State University (Virginia Tech), Old Dominion University, and William and Mary.

### **About the Virginia Biosciences Health Research Corporation**

Virginia Biosciences Health Research Corporation (VBHRC), also known as "the catalyst," is a state created non-profit corporation. VBHRC's mission is to improve human health by accelerating translational research through collaborations between Virginia research universities and industry. The goal of "the catalyst" is to create an environment that builds relationships making Virginia a leader in collaborations, innovation, startups and job creation.

VBHRC evaluates grant applications on a semi-annual basis. Award recipients are those which accelerate translational research and commercialization. Letters of intent, applications and awards are accepted and evaluated on a rolling basis, and awards range from \$200,000 to \$800,000. For more information on criteria and to access a copy of the LOI template, visit <a href="www.vbhrc.com">www.vbhrc.com</a> or contact Megan McMahon at <a href="mmcmahon@vbhrc.com">mmcmahon@vbhrc.com</a>.

###

**LOI Guidelines** 





### Virginia Biosciences Health Research Corporation

# Funding Collaboration between Universities in Partnership with Industry REQUEST FOR PROPOSALS/LETTERS OF INTENT (LOI)

LOIs and Applications for Future Awards Accepted on an Ongoing Basis For Consideration in Round Seven: LOIs must be received by June 8, 2017

### Program:

This initiative is designed to improve human health by accelerating the commercialization of translational research through collaborations between Virginia research universities and industry. This round of grant funding is intended to address neuroscience initiatives involving Traumatic Brain Injury, Autism, ALS, Alzheimer's, Parkinson's, Mental Health, addiction and other brain disorders.

### Specific goals include:

- 1. Establishment of stronger working partnerships between Virginia academic research universities, the biotechnology industry, and health delivery systems that directly lead to an increase in collaboration efforts and movement of ideas & technology from academia to industry and health delivery systems.
- 2. Creation of an environment that fosters relationships that will make Virginia a national leader in university/industry collaboration, innovation, company formation and job creation.
- 3. Improvement of the health of Virginia's citizens and of Virginia's economy through investment, innovation, job creation, and improved patient care.

The CEO of VBHRC ("Virginia Catalyst") and the VBHRC Project Management and Oversight Panel will administer the Virginia Biosciences Health Research Corporation Initiative jointly. The Board of Directors of VBHRC must approve final awards.

### **Eligibility:**

- Proposals must come from *active and significant* collaboration between at least two Virginia research universities and one industry partner in the biosciences field.
- Proposals have a matching funding requirement, beginning at 1:1 and rising to up to a 6:1 for major projects.
- · Proposals must:
  - o clearly identify large unmet need(s) in the market
  - o demonstrate a positive impact on human health and/or patient care
  - o delineate a competitive advantage and/or clinical utility
  - o define commercialization pathways
  - o hold potential for high impact near-term success in generating other sponsored research, creating spin-off companies or otherwise creating new jobs
  - o be focused around the development, validation and application of new approaches to diagnosing, preventing and treating neurological conditions, including brain injuries, brain developmental disorders, neurodegenerative disorders, neuropsychiatric and behavioral disorders, addiction and substance abuse

### **Review Criteria:**

- Scientific and Clinical impact:
  - o Scientific/Clinical/Technical importance
  - o **Feasibility**
  - Alignment of research interests and capabilities of applicants and the industry partner
- Economic impact
- o Potential for job creation
- o Potential to create new intellectual property

- Potential to attract further investment funding (public or private)
- o Potential for advancing prospective products more quickly to the market
- Commercialization
- o Regulatory and reimbursement strategies
- o Barriers to entry/freedom to operate
- · Project management/leadership

### **Submission Guidelines:**

Letter of Intent Deadline: Round Seven – June 8, 2017

For Future Awards: Ongoing

A letter of intent (2-page maximum) prior to submission is required in advance of the application, and should include brief descriptions of the project and of the capabilities of the applicants to perform the research. These will be reviewed and appropriate submissions will be solicited for full applications. LOIs should be submitted by email to mgrisham@vbhrc.com.

Detailed guidelines for full applications will be provided in response to appropriate LOIs. Full applications should not exceed the 13 page PowerPoint Presentation Template (see downloads tab on website). The proposal should clearly address the scientific/technical importance and commercialization potential of the project and how the funding will be used. Also, specific milestones and timelines to achieve objectives should be clearly defined.

Inclusion of proprietary information in LOIs or full applications is discouraged unless absolutely necessary for evaluation. When proprietary information is provided, it should be clearly marked and submitted as an appendix to the proposal.

Grant awards will be made in the range of \$200-\$800K. Companies receiving awards will be required to prepare semi-annual progress reports and a final report for the VBHRC. Approvals for animal and/or human subjects (if needed) will be required "just in time" after awards are announced.

#### Selection:

Applications will be evaluated by the CEO of VBHRC and the Project Management and Oversight Panel. Feedback to the teams submitting proposals and on all funded team reports will be provided via the CEO of VBHRC.

### **Duration:**

Grants are awarded annually and can cover expenses over an 18-month time frame. Follow-on grants may be renewed on a competitive basis with new applications. Grants may be terminated and remaining funds recalled at mid-year if progress reports are not acceptable. Competitive renewal applications must have a comparison of milestones achieved versus those planned in the original submission.

### **Budgets:**

Eligible budget items include faculty and non-faculty salary support, clinical trial costs, operating supplies, minor equipment items, prototyping expenses, imaging/core equipment time, and travel directly associated with the research activity. VBHRC's indirect overhead rate for Universities is 30 percent. This overhead rate only applies to funds being utilized by the Universities; it does not apply to funds being used by an Industry Partner.

### **Contact Information**

Mike Grisham
President and CEO
Virginia Biosciences Health Research Corporation
"Virginia Catalyst"
901 East Cary Street, Suite 900
Richmond, VA 23219 mgrisham@vbhrc.com

# **Application Template**

### [Project Title]

Presentation to the Virginia Biosciences Health Research Corporation Project Management and Oversight Panel (Presentation Date)

# **ACATALYST**

### **Collaboration Partners**

Lead investigator name University

University
Department
Contact Information

Lead investigator name University

Department
Contact Information

Industry leader name

Company Title

Contact Information

Funding Requested:

Sourcing of matching funding:

ACATALYST

### Management

 Describe the background/experience of the management and scientific team members

### Commercialization

- What is the regulatory plan?
- What is the reimbursement plan?
- What are probable pathways for commercialization (i.e. manufacturing and distribution)?



# ACATALYST

### Economic Impact

- What follow-on funding will be required to commercialize this technology?
- What are the probable sources for that funding? (NIH, STTR/SBIR, Angel funding, venture capital, corporate partnerships, etc.)
- What is the plan to secure follow-on funding?
- Describe the potential for job creation as a result of project funding (first 2 years, 2-4 years, 5-7 years)



### Barriers to Entry

- o Describe the competitive advantage
- o Describe the current I.P. status
  - o Disclosures
  - o Patent applications
  - o Issued patents
  - Freedom to operate
- o Describe the patent strategy going forward
- Describe the status and plans for licensing, sponsored research, conflict of interest, etc.?



# Competitive Advantage

- Describe the competitive advantage
- o Describe the current I.P. status
  - Disclosures
  - Patent applications
  - o Issued patents
  - Freedom to operate
- Describe the patent strategy going forward
- Describe the status and plans for licensing, sponsored research, conflict of interest, etc.?



### Collaboration

- o Describe the collaborative synergies
- Describe the management structure, communication plan and accountabilities of each of the collaborators
- Describe how funds will be allocated among collaborators



### Milestones and Budget

- What are the milestones and timelines for commercialization?
- What is the estimated total cost to get to market?
- What are the milestones, timelines, and budgets for this project?
- What are the key business elements for success?
- What are the major risk factors?

# Clinical Need and Market Impact

- How will proposed solution improve patient outcomes and reduce costs?
- Existing approaches and strengths/limitations
- Clinical criteria for success
- Other competing technologies





# Clinical Need and Market Impact

- o Impact on human health/clinical utility
- Current standard of care
- Number of patients US and abroad
- Disease severity
- Cost of the disease
- Market size (dollars)

### Introduction

- Describe the unmet need/problem
- Describe the opportunity/solution
- Describe the product or service to be commercialized
- Describe the project

VBHRC VACATALYST



### Summary

• What are the key reasons this project should be funded?



# **Project Management and Oversight Panel Scorecard**

# **Objectives of the Process:**

Reviewer Comments on Market Need:

- 1) To fund innovative, collaborative, translational research projects that elevate the level of sponsored research and have the potential to significantly improve human health and create high value jobs in the Commonwealth.
- 2) To develop a process which is robust, objective, defendable as to design and execution and which yields powerful collaborations that produce world class technologies, products and services.

Grant Application	on Name
4= Exceeds Expectations 3= Meets Expectations some aspects 1= Does not meet expectations	2= Falls short of Expectations in NA= Not applicable for scoring
Scoring Criteria	
Market Need: This translational research project addresses a large significantly improving human health.	e unmet need and it can lead to
<ul> <li>Medical/Life science need (clinical)</li> <li>Innovative/Breakthrough Technology</li> <li>Competitive advantage over other approaches</li> </ul>	Score Score Score
<ul> <li>Size of market (patients/\$s)</li> </ul>	Score
Mark	et Need Average Score

91

# **Level of Collaboration:**

•	This project encompasses substantive real collaboration between a VBHRC	
	research universities and industry	Score
•	There is a defined process to manage the collaboration including c	lear
	accountabilities,	Score
	an internal communication plan and a methodology to declare and	solve
	breakdowns	Score
•	The collaboration has true synergies that will ensure creative deba	te, innovation,
	and the achievement of critical mass	Score
		-
	Level of Collaboration Average S	Score
Re	eviewer Comments on Level of Collaboration:	
		*
_		
Sc	<u>cientific Merit</u>	
•	Scientific and technical feasibility	Score
•	Stage of technical development	Score
•	Scientific and technical expertise/credibility	Score
•	The project technology is superior to competing approaches	Score
•	Scientific and product development milestones and timelines are c	
_	Colonial and product development inholoned and timelines are o	Score
•	There is adequate evidence that resources (financial and human) a	
•	achieve the timelines	Score
	Scientific Marit Avarage	Sooro

Reviewer Comments on Scientific Merit:

# Commercialization

<ul> <li>There is a clear understanding of who is the targeted custome</li> </ul>	er, what the unmet
need is, the size of the market (patients/\$s) and what the path	
commercialization is	Score
<ul> <li>The commercialization value proposition is clear, robust and c</li> </ul>	
	Score
<ul> <li>The technical solution is significantly scalable to achieve the cobjectives</li> </ul>	commercialization Score
<ul> <li>There is a clear collaborative pathway to transfer know-how as inventors to the commercialization or industry partner</li> </ul>	
inventors to the commercialization of industry parties	00016
Commercialization Average	Score
Reviewer Comments on Commercialization:	
ntellectual Property:	
<ul> <li>The intellectual property portfolio and patent strategy are adec</li> </ul>	quate to provide
barriers to entry and to obtain freedom to operate	Score
The applicable technology transfer offices of the universities a	re aligned with the
goals of the project and the proposed licensing terms will not be	oe a barrier to
commercialization	Score
•	
Intellectual Property Average	Score

93

Reviewer Comments on Intellectual Property:

Management and Leadership:	
<ul> <li>The management and scientific team have the necessary time to achieve the goals</li> </ul>	ne expertise and will allocate the Score
<ul> <li>If there is a gap in the management or scien recruit the talent needed</li> </ul>	tific team, there is a milestone plan to Score
Management and Lea	dership Average Score
Reviewer Comments on Management and Lead	ership:
<ul> <li>Follow On Funding:</li> <li>The project is well positioned to attract follow development and ultimately funding for common terms.</li> </ul>	
Fo	llow on Funding Score

Reviewer Comments on Follow On Funding:

mments:	W-1
Level of Collabora Scientific I Commercializa Intellectual Prop Management an	Need Average Score ation Average Score Merit Average Score ation Average Score perty Average Score ad Leadership Score
1 0110	w on Funding Score
Overall Application Sc	
	Level of Collabora Scientific I Commercializa Intellectual Prop Management an



# Award Letter Grant Agreement Template





November 3, 2015

RE: VBHRC Award Letter Agreement

Michael Laskofski. Associate Vice President of Research Operations Office of Research George Mason University 4400 University Drive, MSN 6D5 Fairfax, VA 22030

John C. Rudd Assistant Vice President Office of Sponsored Programs Virginia Polytechnic Institute and State University 300 Turner Street NW Suite 4200 (MC 0170) Blacksburg, Virginia 24061

Ross Dunlap President & CEO Ceres Nanosciences, Inc. 9385 Discovery Blvd Manassas VA 20109

On behalf of the Board of Directors of the Virginia Biosciences Health Research Corporation ("VBHRC"), I am pleased to inform you that the application (the "Application") of Ross Dunlap ("Project Manager, Ceres") entitled "Nanotrap® Tick-Panel Test Development" (the "Project") has been selected for funding through VBHRC. An award (the "Award") has been approved in the amount of \$500,000 over the project period November 15, 2015 through May 15, 2017. The Award will be dispersed to George Mason University ("Prime University") and utilized by Prime University in performing the Project pursuant to the terms of this Letter Agreement. Except as otherwise provided in this Letter Agreement, Project Manager shall be responsible for generally supervising and directing the performance of the Project, provided that Prime University shall have primary responsibility for all reporting and other administrative functions associated with the Project. Prime University, ("Partner University") and Project Manager may individually and collectively be referred to as "you" or "Recipient" throughout this Letter Agreement.

Each Recipient's ability to perform the research and commercialization as set forth in the Application are critically important in the granting of this Award. Prime University, Partner University, and Project Manager shall enter into one or more subcontract



agreements that govern the administration of the Project and shall promptly provide an executed copy of such subcontract agreement(s) to VBHRC.

In order to proceed, please provide by November 16, 2015 the executed signature page below and the name, email address, and phone number for the Prime University official, the Partner University official, and the Project Manager official that VBHRC may alert once disbursement is approved

Please provide all award acceptance materials to Mike Grisham by email at mgrisham@vbhrc.com Contingent upon successful completion of this process; Recipient is authorized to begin charging for Project work as of the Start Date.

The Award shall be disbursed pursuant to the schedule set forth on Schedule I attached hereto, provided that all funding is contingent on: (a) each Recipient's successful completion of the relevant milestones applicable to such Recipient (as defined on Schedule I) (each, a "Milestone"); (b) fulfillment of matching funds as identified on Schedule I; and (c) compliance with all reporting requirements of VBHRC, as further detailed in Exhibit A.

If you have any questions, please contact Mike Grisham at mgrisham@vbhrc.com or 804-545-5799.

Congratulations on your successful application. VBHRC looks forward to exciting contributions in technology and economic development that will arise from the Project.

By signing below, each Recipient agrees to be bound by the terms of this Letter Agreement and the attachments hereto, including without limitation, the terms and conditions set forth in Exhibit A, which are hereby incorporated by reference. In the event of a conflict between the terms of this Letter Agreement and the terms of the Application, the terms of this Letter Agreement shall control. This Letter Agreement may be executed in two or more counterparts (although it shall not be necessary that any single counterpart be signed by or on behalf of each of the parties hereto, and all such counterparts shall be deemed to constitute but one and the same agreement), may be transmitted by telecopy or email, and may be executed by facsimile signatures, and facsimile signatures shall have the effect of original signatures relative to this Letter Agreement.

Sincerely,

Michael Grisham, CEO

Virginia Biosciences Health Research Corporation

cc: Ross Dunlap (Ceres), Michael Laskofski (Mason), John Rudd (VTech)

Enclosures

# [Counterpart Recipient Signature Page to VBHRC Award Letter Agreement]

### ACKNOWLEDGED AND AGREED BY PRIME UNIVERSITY:

Ross Dunlap, President & CEO Ceres Nanosciences, Inc. 9385 Discovery Blvd Manassas VA 20109

Phone: 800-615-0418 x 202 Email: rdunlap@ceresnano.com



### Schedule I

### Disbursements and Milestones

#### Award Disbursements by VBHRC A.

				PR	IME -	MA	SON		SL	SUB - VTECH			SUB - CERES				
Milestones to be Achieved by Recipients with Disbursement Prior to Funding Next Disbursement	Date	VBHRC to Prime	Dire	ct	Indi (<=	rect 30%)	To	tal	Direct		lirect = 30%)	То	tal	Direc	t,	Tot	al
Criteria 1. Execution of contract	11/15/15	\$ 113,859	\$	30,000	\$	9,000	\$	39,000	\$ 20,000	\$	6,000	\$	26,000	\$	48,859	\$	48,859
Criteria 2. Optimized Nanotrap particles and workflows to achieve >90% antigen capture and elution efficiency in 20 mL human urine using automated sample preparation protocol.	3/30/16	\$ 62,963	\$	15,000	\$	4,500	\$	19,500	\$ -	\$		\$		\$	43,463	\$	43,463
Criteria 3. Clinical sample collection	7/30/16	\$ 52,887	\$		\$	-	\$		\$ 20,000	\$	6,000	\$	26,000	\$	26,887	\$	26,887
Criteria 4. Optimized assay and summary of performance data in the Pre-IDE meeting format for detection of OspA Lyme by EUSA.	10/31/16	\$ 57,297	S	15,000	\$	4,500	\$	19,500	\$ -	\$	,	\$		\$	37,797	\$	37,797
Criteria 5. Optimized Assay and summary of assay performance data and development documents for detection of 3-tick-borne diseases from a single urine sample processed with Nanotrap particles	1/31/16	\$ 83,081	\$	23,000	s	6,900	s	29,900	\$ -	\$		\$		\$	53,181	\$	53,181
Criteria 6. Confirm and outline FDA submission approach and data requirements	3/30/17	\$ 73,489	\$	28,684	\$	8,605	s	37,289	\$ 9,746	\$	2,924	Ť	12,669	\$	23,531	Ś	23,531
Criteria 7. Complete CAP documents for Lyme and tickborne multiplex TBD assay	5/15/17	\$ 56,423										-		\$	56,423	\$	56,423
TOTAL		\$ 499,999	\$	111,684	\$	33,505	\$	145,189	\$ 49,746	\$	14,924	\$	64,669	\$	290,141	\$	290,141

See Exhibit B for detailed Work Breakdown Structure associated with each Criteria



- B. Subject to achievement of the above-described Milestones and receipt of the corresponding Award disbursement from VBHRC, Prime University shall disperse a portion of the Award:
- (ii) to Partner University as follows:

		SUB - VTECH											
Milestones to be Achieved by Recipients with Disbursement Prior to Funding Next Disbursement	Date	Dir	ect		rect 30%)	To	tal						
Criteria 1. Execution of contract		\$	20,000	\$	6,000								
	11/15/15	-				\$	26,000						
Criteria 2. Optimized Nanotrap particles and workflows to achieve >90% antigen capture and elution efficiency in 20 mL human urine using automated sample preparation protocol.		\$	-	\$	-								
	3/30/16					\$							
Criteria 3. Clinical sample collection		\$	20,000	\$	6,000								
	7/30/16					\$	26,000						
Criteria 4. Optimized assay and summary of performance data in the Pre-IDE meeting format for detection of OspA Lyme by ELISA.		\$		\$	-								
	10/31/16					\$	-						
Criteria 5. Optimized Assay and summary of assay performance data and development documents for detection of 3-tick-borne diseases from a single urine sample processed with Nanotrap particles	1/31/16	\$	-	\$	-	s	_						
Criteria 6. Confirm and outline FDA submission approach and data requirements		\$	9,746	\$	2,924								
	3/30/17					ŝ	12,669						
Criteria 7. Complete CAP documents for Lyme and tickborne multiplex TBD assay	-,,						32,000						
	5/15/17												
TOTAL		\$	49,746	\$	14,924	\$	64,669						

### (iii) to Industry Partner as follows:

Milestones to be Achieved by Recipients with	Date	Direc	t	Tot	al
Disbursement Prior to Funding Next					
Disbursement					
Criteria 1. Execution of contract		\$	48,859		
	11/15/15			\$	48,859
Criteria 2. Optimized Nanotrap particles and workflows to		\$	43,463		
achieve >90% antigen capture and elution efficiency in 20 mL					
human urine using automated sample preparation protocol.	-				
	3/30/16			\$	43,463
Criteria 3. Clinical sample collection	,	\$	26,887		
	7/30/16			\$	26,887
Criteria 4. Optimized assay and summary of performance		\$	37,797		
data in the Pre-IDE meeting format for detection of OspA					
Lyme by ELISA.					
	10/31/16			\$	37,797
Criteria 5. Optimized Assay and summary of assay		\$	53,181		
performance data and development documents for					
detection of 3-tick-borne diseases from a single urine sample processed with Nanotrap particles					
processed with Nanotrap particles	1/31/16			\$	53,181
Criteria 6. Confirm and outline FDA submission approach		\$	23,531		
and data requirements					
	3/30/17			\$	23,531
Criteria 7. Complete CAP documents for Lyme and tickborne		\$	56,423		
multiplex TBD assay					
	5/15/17			\$	56,423
TOTAL		\$	290,141	\$	290,141

Expected disbursements to the Prime University from VBHRC:

### At Signing

\$\_113,859\_ to \_George Mason University from which \$26,000 to be distributed to Virginia Tech (Partner University) and \$48,859 to be distributed to Ceres Nanosciences (Industry Partner)

Targeted Payment Schedule

(This is only a non-binding guide. Payments are triggered by milestone achievement.)

Milestones to be Achieved by Recipients with Disbursement Prior to Funding Next Disbursement	Date		HRC to ime	Total Disbursements by VBHRC (to date)		
Criteria 1. Execution of contract						
	11/15/15	\$	113,859	\$	113,859	
Criteria 2. Optimized Nanotrap particles and workflows to achieve >90% antigen capture and elution efficiency in 20 mL human urine using automated sample preparation protocol.						
Criteria 3. Clinical sample collection	3/30/16	\$	62,963	\$	176,822	
Criteria 4. Optimized assay and summary of performance	7/30/16	\$	52,887	\$	287,006	
data in the Pre-IDE meeting format for detection of OspA Lyme by ELISA.	10/31/16	\$	57,297	\$	234,119	
Criteria 5. Optimized Assay and summary of assay performance data and development documents for detection of 3-tick-borne diseases from a single urine sample processed with Nanotrap particles	1/31/16	\$	83,081	\$	370,087	
Criteria 6. Confirm and outline FDA submission approach and data requirements	3/30/17	\$	73,489	\$	443,576	
Criteria 7. Complete CAP documents for Lyme and tickborne multiplex TBD assay	5/15/17	\$	56,423	\$	499,999	
TOTAL		\$	499,999		-	

#### C. Matching Funds:

\$500,000 from Gates funding program for urine based TB test development

Unless otherwise agreed by VBHRC in writing, matching funds in support of the Project must be received by the applicable Recipient and available at some period between the Start Date and End Date in order to qualify under this Letter Agreement. If federal funds are being used to satisfy the matching requirement, advance approval from the applicable federal agency must be provided prior to execution of this Letter Agreement

#### D. Acceptable Subcontractors (in addition to Project Manager):

- i. Principal Investigator: Dr. Lance Liotta
- ii. Co-PIs: Dr. James Palmieri, Dr. Tom Inzana

# EXHIBIT A Terms and Conditions

- a. Unless otherwise identified in the Application or on Schedule I, each Recipient and acceptable subcontractor (as identified on Schedule I) must be located in and perform the Project in Virginia.
- b. Prime University, Partner University and Project Manager shall (i) retain title to any invention first conceived or actually reduced to practice in the performance of the work funded by this Letter Agreement solely by its own faculty member(s) and/or employee(s) and/or student(s) ("Prime University IP" or "Partner University IP", as the case may be), and (ii) each shall be joint owners of any invention first conceived or actually reduced to practice in the performance of the work funded by this Agreement jointly by faculty member(s) and/or employee(s) and/or student(s) of each entity ("Joint IP"). For any jointly owned inventions, all parties shall have the opportunity to preview and comment on all documents of record used in filing, prosecuting, and maintaining of any patent application. For avoidance of doubt, ownership and other rights in and to pre-existing intellectual property of the parties shall not be affected by this Letter Agreement or its performance; except that Prime University and Partner University shall have a limited right to utilize Project Manager's pre-existing intellectual property as may be reasonably necessary for performing the Project.

Prime University and Partner University hereby grant to Project Manager a first option to negotiate with Prime University and or Partner University for an exclusive or nonexclusive license to any Prime University IP and or Partner University IP, as the case may be, and/or for an exclusive license to either university's share of any Joint IP. The university parties agree to disclose in confidence to Project Manager, in detailed writing, each and every invention developed and or conceived in the performance of the work funded by this Letter Agreement which may be patentable or otherwise protectable under the United States patent laws in Title 35, United States Code (the "Disclosure"). Project Manager may exercise the option by sending written notice to Prime University and or Partner University, as the case may be, within ninety (90) days following Disclosure. Upon exercise of the option, the parties shall negotiate in good faith an acceptable license agreement to include some or all of the following basic terms: (i) a mutually agreeable royalty rate; (ii) mutually agreeable minimum royalties; and (iii) the right to sublicense. The license shall also provide that either Prime University or Partner University, as the case may be, shall, at no additional cost to Project Manager except for relevant travel costs, provide Project Manager with sufficient technical assistance to ensure transfer of the technology from the applicable university to Project Manager. If Project Manager fails to exercise its option within the 90-day option period, or if, after Project Manager exercises its option, the parties fail to execute a license agreement with respect to the technology covered by the Disclosure within six (6) months from the date the option is exercised, the option shall expire and the applicable university shall be free to negotiate with third parties without any obligation to Project Manager

Non

- c. For purposes of determining whether property was developed "wholly or predominantly" through the use of state funds for the purposes of Section 23-4.4 of the Code of Virginia, awards made from VBHRC shall not be considered state or general funds.
- d. Any equipment that is purchased by a Recipient (and/or any subcontractors of a Recipient) with proceeds of the Award shall be owned by the Recipient unless otherwise agreed in writing by the Project Manager and the Recipient.
- e. In the event that VBHRC provides advanced funding in support of the project, award monies not earned by Prime University on or before the End Date (unless VBHRC provides its written consent to extend the timeline for the Project) must be returned to VBHRC promptly.
- f. Each Recipient acknowledges and agrees that the Award amount identified in this Letter Agreement is final. No Recipient shall be entitled to any additional funds from VBHRC, regardless of whether such Recipient exceeds the budgeted amount for the Project.
- g. Prime University shall deliver to VBHRC quarterly progress reports and a final report, each such report to contain the following information: (i) progress on achieving the Milestones by each Recipient and/or its subcontractors; (ii) summary of any intellectual property created; (iii) commercialization of the Project, if any; (iv) Economic impact including follow on funding from grants or capital raised, jobs created, etc. and (v) any other information requested by VBHRC that is reasonably necessary to comply with VBHRC's policies and/or any applicable laws, rules, regulations or legislation specific to VBHRC. In addition to the aforementioned quarterly reports, Prime University shall also promptly notify VBHRC in writing upon the completion of any Milestone. Upon VBHRC's request, Prime University shall also report on commercialization and/or other outcomes of the Project for up to five (5) years after the period of performance of the Project. Additional report guidelines and due dates will be provided by VBHRC. Prime University shall (a) obtain all information from the Partner University, the Project Manager, and any other subcontractors necessary to provide the reports to VBHRC; and (b) as a condition to the appointment of any subcontractor hereunder, require that such subcontractor provide all such information to Prime University in a timely manner. Each of Project Manager and Partner University expressly agrees to provide Prime University with all information necessary to deliver the reports required hereunder to VBHRC. Notwithstanding the foregoing, Recipient shall notify VBHRC immediately if its ability to perform pursuant to the terms and conditions of this Letter Agreement, including those conditions set forth herein, is compromised for any reason or may be reasonably expected to become so compromised. Upon completion of a project milestone and receipt of a complete progress report described herein, VBHRC will review and process the payment due to the Prime University within 20 days. The Prime University will process the payment due to each Recipient within 30 days of receiving payment from VBHRC and receipt of an invoice from Recipient.
- h. VBHRC may, upon reasonable notice to any Recipient and/or any other subcontractor appointed hereunder, audit financial and/or other records associated with the Project.

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- i. Each Recipient shall (i) perform the Project pursuant to the specifications set forth in the Application; and (ii) use reasonable efforts to achieve the Milestones..
- j. With respect to its relation to VBHRC under this Letter Agreement, each Recipient is an independent contractor and shall be free to exercise its discretion and independent judgment as to the method and means of performing the Project. No Recipient, nor any of their respective employees or students shall, by virtue of this agreement, be employees of VBHRC and, accordingly, shall not be entitled to any benefits or privileges provided by VBHRC to its employees. Notwithstanding the foregoing, Prime University shall (a) appoint each of the Partner University and the Project Manager as subcontractors pursuant to one or more written subcontract agreements (a copy of which shall be provided to VBHRC); and (b) not, unless otherwise identified on Schedule I, appoint any other subcontractors to perform the Project, without the prior written consent of VBHRC.
- k. Recipient agrees to immediately notify VBHRC of any instance of non-compliance by the Recipient with any term or condition of this Letter Agreement. VBHRC may terminate this Letter Agreement, the Award and all of its obligations hereunder in the event of a failure of a Recipient to cure an instance of non-compliance by any Recipient with the terms and conditions of this Letter Agreement within thirty (30) days of written notice by VBHRC of such non-compliance.
- I. This Letter Agreement, the Application and the Award shall be governed in all respects by the laws of the Commonwealth of Virginia.
- m. Neither this Letter Agreement nor any right, remedy, obligation or liability arising hereunder or by reason hereof shall be assigned by either party without the prior written consent of the other. Notwithstanding the foregoing, Prime University may subcontract its duties hereunder in a written contract with the Partner University, the Project Manager, and/or any other subcontractor identified on Schedule I or approved by VBHRC in writing, provided that Prime University shall remain responsible for its obligations hereunder, including without limitation, performance of the Project pursuant to the terms of this Letter Agreement and the Application, and provided further that Prime University shall not subcontract its duties hereunder to any entity organized as a 501(c)(3) without the prior written consent of VBHRC. Prime University is responsible for paying all amounts owed to all subcontractors appointed under the Project. VBHRC has no liability or obligation to pay any amount to the Partner University, the Project Manager, and/or any other subcontractor appointed hereunder. All subcontracts will relieve VBHRC of all liability for payment to the Partner University, the Project Manager, and/or the applicable subcontractor. Prime University shall ensure that all necessary disclosures are made to the employers of Project Manager, any subcontractor and/or the Principal Investigator hereunder, shall obtain any necessary waivers of conflicts of interest as required by applicable law, and shall provide satisfactory written evidence of the foregoing upon the request of VBHRC.



- n. Any notice required to be given under this Letter Agreement, and any invoice, payment, or communication associated with the performance of this Letter Agreement shall be deemed made if given by registered or certified mail, postage prepaid, and addressed to the address set forth on the first page of this Letter Agreement.
- o. No term or conditions of this Letter Agreement may be amended or waived without the prior written approval of VBHRC.
- p. THE RESEARCH TO BE PERFORMED IN CONNECTION WITH THE PROJECT IS EXPERIMENTAL IN NATURE. EXCEPT AS EXPRESSLY SET FORTH IN THIS LETTER AGREEMENT, RECIPIENTS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH REGARD TO THE RESEARCH. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT ANY PARTY'S USE OF THE RESEARCH DELIVERABLES OR INTELLECTUAL PROPERTY ARISING OUT OF THE PROJECT WILL NOT INFRINGE ANY THIRD PARTY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD PARTY RIGHTS. RECIPIENTS MAKE NO REPRESENTATION AS TO THE USEFULNESS OF RESEARCH DELIVERABLES OR INTELLECTUAL PROPERTY. IF ANY PARTY CHOOSES TO EXPLOIT RESEARCH DELIVERABLES OR INTELLECTUAL PROPERTY IN ANY MANNER WHATSOEVER, IT DOES SO AT ITS OWN RISK.
- q. For the duration of this Letter Agreement, Prime University shall maintain (under its insurance through the Commonwealth of Virginia Insurance Program) insurance coverage for protection from claims under workers compensation, automobile liability, general liability, and professional liability. Upon request of VBHRC, Prime University shall provide a copy of its Certificate of Insurance.
- r. The parties shall use reasonable efforts to amicably resolve disputes arising out of this Letter Agreement, prior to commencing any formal legal proceedings. Pending resolution of any such dispute by settlement or by final judgment, the parties shall proceed diligently with performance.
- s. Neither party shall be responsible to the other for failure to perform any of the obligations imposed by this Letter Agreement, provided such failure shall be occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, failure or destruction, in whole or in part, of machinery or equipment or failure of supply of materials, discontinuity in the supply of power, governmental interference, civil commotion, riot, war, strikes, labor disturbance, transportation difficulties, labor shortage or any other conditions of whatsoever nature or description beyond their reasonable control.
- t. It is understood that all parties are subject to U.S. laws and regulations controlling the export of certain items, commodities, defense articles, confidential information, proprietary technical data or source code, collectively hereafter referred to as "Items." All parties are obligated to comply with applicable U.S. export laws and regulations (including

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the Arms Export Control Act, as amended, and the Export Administration Act of 1979). Prior to providing any Items which are subject to U.S. export laws and regulations, and prior to furnishing any Items where oral instruction or inspection may disclose technical data subject to such export controls, the disclosing party shall notify receiving party's designated representative responsible for contract issues in writing of the Items and applicable export controls. Receiving party shall have the right to decline or limit the receipt of such Items, and any task requiring receipt of such Items. The transfer of Items may require a license from the cognizant agency of the U.S. government. The parties agree to cooperate in securing any license which the cognizant agency deems necessary in connection with this Letter Agreement.

- u. All provisions of this Letter Agreement shall be applicable only to the extent that they do not violate any applicable law, and are intended to be limited to the extent necessary so that they will not render this Letter Agreement invalid, illegal or unenforceable under any applicable law. If any provision of this Letter Agreement shall be held invalid, illegal or unenforceable, the validity, legality or enforceability of other provisions of this Letter Agreement shall not be affected thereby.
- v. No waiver of any right or remedy hereunder by either of the parties shall be deemed to be a waiver of any other right or remedy of any subsequent right or remedy of the same kind.
- w. No party will use the name of any other in any advertising or make any form of representation or statement in relation to the Letter Agreement, which would constitute an express or implied endorsement of any commercial product or service without first having obtained written permission of the other Party.

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# Exhibit B: Work Breakdown Structure

					Tim	eline		
Aim 1. Est	ablish Nanotrap enrichment and detection reagents and workflows for at least 3 tick-borne disease s.	Team Member	Q1	Q2	Q3	Q4	Q5	Q6
.1	Selection and confirmation of detection antibody performance and validation including epitope mapping and confirmation of a conserved region	GMU/Ceres						
.1.1	Identification and validation of antigens, lysate and monoclonal antibodies and sources for screening and assay development.	GMU						
.1.2	Production and validation of monoclonal antibodies if an alternative source is not identified.	GMU						
.1.3	Perform epitope mapping and cross-reactivity database search	GMU						
.2	Nanotrap screen, enrichment, elution, and detection of captured antigens for Lyme, Babesiosis, Ehrlichiosis and/or Bartonella spiked into human urine	Ceres/GMU						
.2.1	Production and characterization of particles for screening experiments	Ceres	-					
2.2	Optimization of Nanotrap sample processing and workflow development	Ceres		9.00		1		T
2.3	Support for optimization of Nanotrap sample processing and workflow development effort	GMU				1		1
.3	Develop magnetic Nanotrap-based urine processing workflow and optimization	Ceres				1		1
.3.1	Work with Beckman to install and adapt BioMek solution for Nanotrap processing	Ceres				1		+
.3.2	Verify automated sample processing results with standard Nanotrap processing results	Ceres				1		+
	Verify automated Jumple processing results with standard Harlottap processing results	CCICS			-	1		1
.3.3	Collect assay performance data using automated Nanotrap workflow	Ceres	<u> </u>					
	Criteria 1. Execution of contract		<b>P</b>	1		-		+
	Criteria 2. Optimized Nanotrap particles and workflows to achieve >90% antigen capture and elution efficiency in 20 mL human urine using automated sample preparation protocol.				•			
Aim 2. Co	llect clinical data to confirm assay performance (precision, sensitivity, specificity)	Team Member						
2.1	Evaluation and selection of downstream multiplex immunoassay	Ceres/GMU						
2.1.1	Identify best immunoassay format for FDA approval AND multiplex analysis (ELISA, Bead, Lateral flow)	Ceres/GMU						
2.1.2	Assess current OspA ELISA performance	Ceres/GMU						
2.1.3	Determine multiplex approach and secondary label options	Ceres/GMU						
2.2	Immunoassay development. Determination of assay performance with front-end Nanotrap sample enrichment	Ceres/GMU						
2.2.1	Optimize Lyme 'single-plex assay performance and confirm sample processing compatibility	Ceres/GMU						1
2.2.2	Collect Lyme 'single-plex' performance data for Pre-IDE meeting summary	Ceres/GMU					1	1
2.2.3	Develop 'single-plex' assays and sample processing workflows for the other 2 TBDs.	Ceres/GMU	<b> </b>			1	1	1
2.2.4	Collect assay performance data for 'single-plex' versions of TBD assays	Ceres/GMU		1				
2.2.5	Develop 3-plex TBD assay	Ceres/GMU		1			1	
2.2.6	Collect assay performance data for Pre-IDE Summary document and CAP test development documents	Ceres/GMU		1				1
LILIO	Criteria 4. Optimized assay and summary of performance data in the Pre-IDE meeting format for detection		<b></b>	1				1
	of OspA Lyme by ELISA.	Ceres/GMU				-	•	
	Criteria 5. Optimized Assay and summary of assay performance data and development documents for detection of 3-tick-borne diseases from a single urine sample processed with Nanotrap particles	Ceres/GMU						•
Aim 3. De	evelop CAP/CLIA assay documentation	Team Member						
3.1	Clinical sample collection for at least 25 Lyme positive, 25 Bartonella positive, 25 Babesiosis (Ehrliciosis) positive and 25 negative controls.	VT/GMU/Ceres						
3.1.1	Develop IRB protocol and establish clinical sample collection sites. Collect samples and clinical history data including completed test history.	Ceres/VT						
3.2	Complete CAP/CLIA test development, data collection and document all procedures procedures for test deployment	Ceres/GMU						
3.3	Launch Test in GMU CAP/CLIA Lab	Ceres/GMU/VT			-			1
3.4	Identify Hospital network laboratories and other CAP accredited sites for potential test clone	Ceres						
	Criteria 3. Clinical sample collection	Ceres/GMU/VT				•		
	Criteria 7. Complete CAP documents for Lyme and tickborne multiplex TBD assay	Ceres/GMU			1			
Aim 4. F	A Pre-IDE Submission	Team Member						
4.1	Contract FDA regulatory consultants to review collected data for Pre-IDE submission and meeting	Ceres/GMU						
	Complete data analysis and summary for Pre-IDE meeting with the FDA (Begin with a Lyme single-plex	Ceres/GMU/VT						
4.2	assay)							
4.2	assay)  Coordinate clinical study sites for assay performance data collection and verification for FDA 510k submission	Ceres/GMU						





## Quarterly Report for VBHRC Project Submitted by Prime University In Partnership with Partner University and Industry Partner

Project "PROJECT TITLE" was aw period PROJECT START DATE th	arded a total of \$ AWAR rough PROJECT END D	LD AMOUNT by VBHROATE.	C on <u>DATE OF GRAN</u> T	AWARD for the
As of CURRENT DATE, disbursen	nents in the amount of \$_	have been re	eceived from VBHRC fo	or the project.
Summary of Achievements:				
Milestones Achieved:				
	Milestone	*	Date Achiev	<b>red</b>
Milestone 1:				
Milestone 2:				
Milestone 3:				
Milestone 4:				
Have there been any changes to Mil	estone scope or timetable	es?If yes,	please explain.	
				Total Contributions
	Contributions by	Contributions by	Contributions by	by Project
	Prime University	Partner University	Industry Partner	Team
Publications, Presentations				
resulting from project Intellectual Property created				
Intellectual Property created	-			
Follow-On Funding Raised				
since the initial grant was				
awarded				
(including additional grants, contracts, equity funding, etc.)				
Number of Jobs created to date				
Projected number of Jobs to be				
created in the next three years				
Respectfully submitted by: Name:				
Prime University:				
Date:				





**Virginia Neuroscience Initiative** 

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strength through collaboration

# **Major Accomplishments in 2017**

**Memo of Understanding on the VNI** was signed off by all the Vice Presidents for Research (VPRs) and CEOs of member universities and medical centers by December 2016.

**VNI Website** was established in January 2017 and 150 e-mails sent to companies doing drug development and testing (i.e. Contract Research Organizations (CROs) and Pharma) announcing the VNI.

**Presentations on the VNI** began in January 2017. So far, we have met with representatives from Pharma and CROs at two national conferences as well have held several one-on-one meetings and teleconferences with CROs. In Virginia, presentations were made to the Prince William County Life Sciences Leadership Group, small biotech firms, and the faculties and staffs of the participating universities and medical centers.

**Agreements** between Virginia Catalyst and all ten member institutions were executed in March 2017 for their participation in the VNI. Funds are being provided to support staff and efforts to increase collaborations in neuroscience research among the faculty and staff of our universities and medical centers.

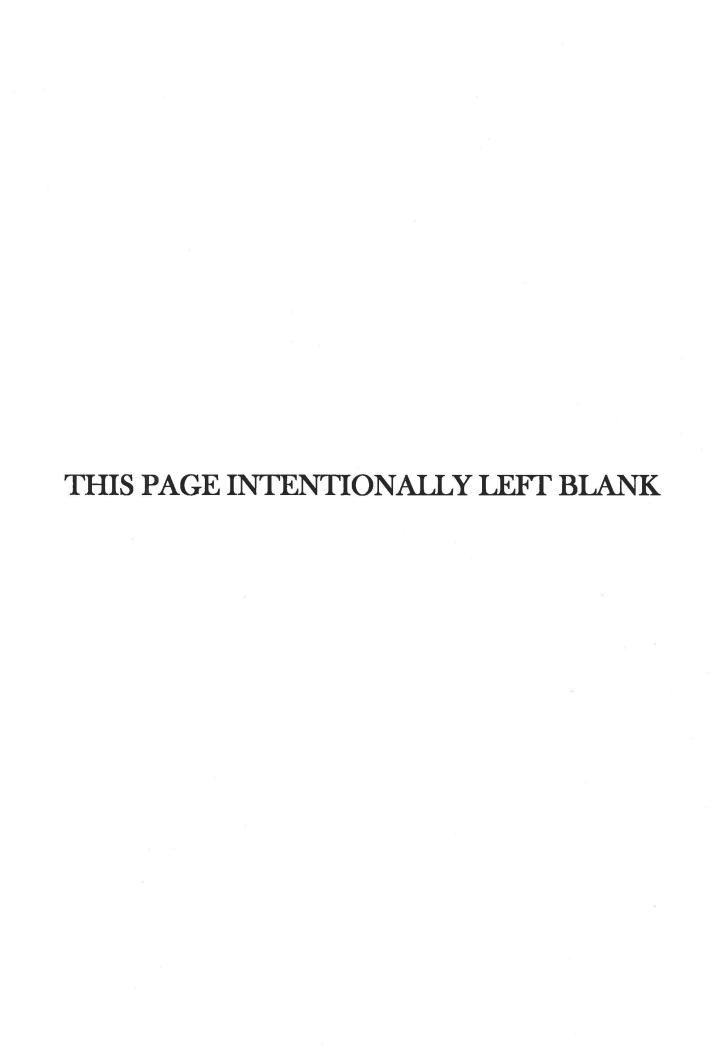
VNI Neuroscience Directory now has more than 1200 researchers and scientists as members.

Patient Registry is in place at our five member medical centers in the Commonwealth allowing us to rapidly identify and calculate the numbers of patients we have with a particular neurological disorder.

Clinical Trials Network is active, allowing our five medical centers to act as one when performing a clinical trial of a new treatment for a neurological disorder. All five medical centers have agreed to use a centralized office for human research protection for all clinical trials.

A Core Facilities Memo of Understanding regarding the sharing of core research facilities at the seven universities of the VNI was fully executed in July 2017.

Master Confidentiality and Clinical Trial Agreements are currently being negotiated between Virginia Catalyst and the ten member institutions of the VNI. These will significantly speed up contract negotiations for new bench research and clinical trials between the private sector and our universities and medical centers.



# Virginia Biosciences Health Research Corporation Research Agreement for Virginia Neuroscience Initiative (VNI)

This Agreement is made and entered into as of the date signed by both parties below (i.e. the "Effective Date") and is between Virginia Biosciences Health Research Corporation, a Virginia corporation ("Sponsor") and the Rector and Visitors of the University of Virginia ("Institution"), a public research university located in the Commonwealth of Virginia, for work to be conducted by its faculty member and employee James R. Stone, M.D., Ph.D. ("Investigator"). In consideration of the covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which each party acknowledges, Sponsor and Institution agree as follows.

- 1. Grant. Sponsor hereby awards a grant to Institution to serve as the lead independent entity for Sponsor's project entitled, "Establishment and Maintenance of the Infrastructure for the Virginia Neuroscience Initiative (VNI)". Institution agrees to provide the services set forth in the Statement of Work attached as Exhibit A hereto or to any Statement of Work subsequently entered into between Sponsor and Institution pursuant to this Agreement (collectively, the "Services"). Institution accepts such grant and agrees to render the Services to Sponsor in accordance with the terms of this Agreement and the terms of the Statement of Work. Neither party shall be obligated by the terms of a Statement of Work until same has been executed by duly authorized representatives of both parties. Any duly executed Statement of Work shall be deemed part of this Agreement and is hereby incorporated by reference. To the extent that a term or provision of a Statement of Work conflicts with a term or provision of this Agreement, the term in the Statement of Work shall control for activities under that Statement of Work.
- 2. Duties of Institution and Investigator. Institution, through its Investigator, shall perform the Services in accordance with the standards of skill and care in Institution's business and profession, satisfy all requirements of the Statement of Work, and at all times strictly adhere to all of Sponsor's reasonable standards and policies as shall be communicated in writing to Institution from time to time and agreed by the parties.

As described in the Statement of Work, the Institution shall manage and oversee the conduct of the Services and agrees to be responsible for all activities undertaken by Institution pursuant to this Agreement and shall supervise the work of all persons who assist in performing the Services. During the Services, the Institution agrees to promptly notify Sponsor in writing at such time as it becomes aware that the Investigator shall be unable or unwilling to complete the Services. Approval of a substitute will not be unreasonably withheld by either Institution or Sponsor. If Institution and Sponsor are unable to agree on an acceptable substitute Investigator within a period of thirty (30) days following such notice, this Agreement may be terminated by Sponsor pursuant to Section 6 hereof.

- 3. Compensation. Sponsor shall reimburse Institution for Services in accordance with the Budget attached to each Statement of Work. Each Budget shall clearly indicate the payment amounts and payment mechanisms.
  - 4. Ownership of Intellectual Property.
- (a) Representations and Certifications. Institution represents and certifies as follows:
- i. all creative work of any type developed in connection with this Agreement or any Statement of Work, unless required by or anticipated by that particular Statement of Work, shall be Institution's own original work and not derived from any third-party source or material without express authorization therefor and without prior written disclosure to Sponsor;

- ii. except as may be allowed pursuant to subsection "iii" below, all creative work of any type developed in connection with this Agreement shall be created by Institution or Institution's employees acting within the scope of their employment;
- iii. Institution shall not retain any Sub-Institution, consultant, or other nonemployee (a "Sub-Institution") to perform services under this Agreement without obtaining Sponsor's prior, express written approval and a signed agreement acceptable to Sponsor that binds the Sub-Institution to the confidentiality and ownership of intellectual property terms of this Agreement; and
- iv. The execution of this Agreement and performance of services for Sponsor will not violate any obligations of Institution to any third party;
- (b) Acknowledgment. The Services may require Institution to work with processes, know how, copyrighted materials, and other intellectual property owned solely and exclusively by Sponsor (collectively, the "Sponsor Background Intellectual Property").
- (c) License of Sponsor Background Intellectual Property. During the term of this Agreement, Sponsor grants to Institution a limited, nonexclusive license to use the Sponsor Background Intellectual Property and the Confidential Information (as defined below) solely for the purpose of rendering Services pursuant to this Agreement or any Statement(s) of Work, and only as necessary to render such Services.
- (d) License of New Intellectual Property. All right, title and interest in any patents and patent applications (including those in foreign countries), inventions, creations, all new or useful art, discoveries, experimental works, ideas, improvements, developments, designs, original works of authorship, copyrights, copyright applications, applications, systems, formulae, reports and memoranda, processes, manufacturing techniques, artwork, software, computer programs, any other copyrightable or patentable works, and all related know-how devised, planned, applied, created, discovered or invented by Institution, in performing the Services (hereinafter referred to as "Inventions") shall vest in and shall be the sole and absolute property of Institution. For Inventions arising jointly from multiple contributing members of the VNI in collaboration, the intention is for the parties to negotiate ownership of such Inventions in good faith. Promptly after Institution obtains knowledge of any Invention, Institution will disclose it to Sponsor. Institution agrees to provide a non-exclusive, worldwide, royalty free license to Sponsor to use the Inventions for noncommercial internal research purposes.
- (e) Institution Retained Rights. Nothing in this Agreement obligates Institution to assign to Sponsor whatever rights Institution may have in pre-existing copyrighted material, general know how, or material not created pursuant to this Agreement (Institution Background Intellectual Property). Notwithstanding the foregoing, to whatever extent any Institution Background Intellectual Property is included as a deliverable within the Services rendered by Institution or any work product provided to Sponsor, Institution: (i) shall disclose the existence of such Institution Background Intellectual Property to Sponsor; and (ii) hereby grants to Sponsor a paid-up, royalty-free, nonexclusive, irrevocable, perpetual, worldwide license to reproduce, distribute, display, use, modify, create derivative works of, license and sublicense applicable Institution Background Intellectual Property only to the extent necessary for Sponsor to exploit the deliverables.
- (f) Written Records, Institution agrees to keep and maintain adequate and current written records of all work product made by Institution in connection with performing the Services. The records will be in the form of notes, sketches, drawings, and any other format that may be specified in the Statement of Work.

- Confidential Information. Confidential Information is defined as information of a confidential or proprietary nature provided by either party (a "Disclosing Party") to the other (a "Receiving Party") in connection with the Services that is marked in writing as "Confidential", or if transmitted orally, that is reduced to writing and confirmed as Confidential within 30 business days. Confidential Information does not include information that is or becomes generally known other than as a result of a breach of this Agreement, breach of confidentiality, or other wrongful act; was independently developed by Institution prior to disclosure by Sponsor; is disclosed by a third party holding same lawfully and not under a duty of confidentiality to the Disclosing Party; or is required to be publicly disclosed by law or regulation. The Receiving Party is authorized to use Confidential Information of the Disclosing Party only as is necessary to render Services under a related Statement of Work. The Receiving Party shall take all steps practicable to preserve Confidential Information in confidence. The Receiving Party shall not use any Confidential Information for his, her or any third party's benefit and shall not disclose Confidential Information or permit it to be disclosed to any third party without Disclosing Party's express written consent. Upon the completion of the Services, or at any time upon the request of the Disclosing Party, the Receiving Party shall return to Disclosing Party all Confidential Information. The confidentiality obligations shall survive the termination or expiration of this Agreement or the applicable Statement of Work for a period of three years following the termination date of the Services.
- 6. Term and Termination. This Agreement shall commence upon the Effective Date and continue for 24 months or until terminated in accordance with this Section. Either Sponsor or Institution may terminate this Agreement at any time without cause upon 90 days' written notice to the other party. In addition, Sponsor may terminate this Agreement upon thirty (30) days' prior written notice of termination for material breach by Institution, if said breach is not cured within the 30-day period if: (i) Institution/Investigator breaches any agreement relating to Confidential Information, Sponsor Background Intellectual Property, or Inventions; (ii) Institution/Investigator abandons its efforts to render the Services; (iii) Institution/Investigator violated any applicable law or regulation; or (iv) Institution/Investigator becomes the subject of a bankruptcy proceeding, or makes a general assignment for the benefit of creditors. Likewise, this Agreement may be terminated by Institution upon thirty (30) days' prior written notice of termination for material breach by Sponsor, if said breach is not cured within the 30-day period. Upon termination or expiration of this Agreement, all licenses granted between Sponsor and Institution shall lapse and expire completely and automatically. The parties agree that, upon termination or expiration, neither party shall make any further use of the other party's Background Intellectual Property or Confidential Information.
- 7. Independent Institution Relationship. Institution shall be an independent Institution and not an agent, employee or servant of Sponsor. Institution shall have no authority to bind Sponsor, by contract or otherwise. Sponsor will not be responsible for withholding or paying any income, payroll, Social Security or other federal, state or local taxes, making any insurance contributions, including unemployment or disability, or obtaining worker's compensation insurance on Institution's behalf.
- **8. Liability.** To the extent permitted by the Virginia Tort Claims Act, Code of Virginia §8.01-195 et seq. and all other applicable Virginia law, both parties agree to be responsible for the negligent acts or omissions of its officers, employees, or agents arising out of its obligations under this Agreement. Nothing contained herein shall constitute a waiver of the sovereign immunity of the Institution or the Commonwealth of Virginia.
- 9. Miscellaneous. This Agreement is specific to Institution, and Institution may not assign (by operation of law or otherwise), subcontract, delegate, or transfer in any way any of his or her rights and obligations under this Agreement. The provisions of this Agreement are severable, and if any one provision is determined to be void, unenforceable, or contrary to law or public policy, the remainder of this Agreement will remain valid and enforceable. The provisions of Sections 4, 5, 8, and 9 of this Agreement shall survive the expiration or termination of this Agreement. Waiver by one party of any breach of any provision of this

Agreement shall not operate or be construed as a waiver by that party of any subsequent breach. This Agreement supersedes any prior agreements or understandings, and constitutes the entire agreement between the parties, relating to the subject matters hereof. This Agreement can be modified only in writing signed by both Institution and Sponsor. This Agreement may be executed in two or more counterparts, and each counterpart, when so executed and delivered, shall constitute a complete and original agreement. Notwithstanding principles of conflicts of law of any jurisdiction to the contrary, the parties agree that all terms and provisions of this Agreement are to be construed and governed exclusively by the laws of the Commonwealth of Virginia. Any action on or other legal proceeding arising out of or relating to this Agreement shall be brought in the state courts of the Commonwealth of Virginia, and Institution and Sponsor hereby each agree and submit to the personal jurisdiction and venue of any court therein.

IN WITNESS WHEREOF, the parties have executed this Independent Institution Agreement intending to be bound hereby as of the Effective Date.

The Rector and Visitors of the	Virginia Biosciences Health Research Corporation:
University of Virginia:	1.10.1
Lyno Koplin	Michael Grisham, CEO
Assistant Director of Contracts	Wiender Grisham, Cao
Date: 1 April, 2017	Date: 3/2//7

# **Exhibit A: Statement of Work (SOW)**

Company	The Virginia Biosciences Health Research Corporation (VBHRC)
President & CEO	Michael Grisham
Principal Investigator	James R. Stone, MD, PhD
Institution	University of Virginia
SOW Title Establishment and Maintenance of the Infrastructure for the	
	Neuroscience Initiative (VNI) at University of Virginia
Date	02/27/2017

### I. INTRODUCTION/BACKGROUND

The Virginia Biosciences Health Research Corporation (VBHRC) has instituted the Virginia Neuroscience Initiative (VNI), an innovative, statewide collaborative approach that will bring neuroscientists, medical providers and industry participants who share a common mission to accelerate research on treatments for various neurological and psychiatric disorders. At the core of the VNI, are seven participating academic institutions; Virginia Commonwealth University (VCU), College of William & Mary, George Mason University, University of Virginia (UVA), Eastern Virginia Medical School, Old Dominion University, and Virginia Tech, and five major medical centers; UVA Health System, VCU Health, Sentara Healthcare Norfolk, Inova Hospital Fairfax, and Carilion Clinic Roanoke. The VNI will be both an incubator and accelerator for clinical and translational research in neurological and psychiatric disorders, as well as provide economic opportunities and benefits for the Commonwealth through expanded federal government funding (NIH, DoD, NSF, etc.), private equity funding, philanthropy funding, new company formation and corporate sponsored research.

Through the VNI, the VBHRC will provide financial support and technical assistance to investigators to foster new collaborations and facilitate neuroscience research initiatives at the state's seven major universities and five major medical centers. The VNI's primary directives will be 1) to create a neuroscience registry of scientists and medical professionals in Virginia who perform basic, translational and/or clinical research on the normal nervous system or on neurological and/or psychiatric disorders; 2) facilitate the internal use of the electronic medical records (EMRs) of the participating medical centers to establish *de facto* registries of patients without (control group) or with various neurological and/or psychiatric disorders who may wish to participate in research; and 3) to create a clinical trials network that will be capable of enrolling patients with a neurological and/or psychiatric disorder or condition into sponsored observational studies and clinical trials. Taken together, the registries and network will help foster new collaborations between neuroscientists, clinicians and industry partners.

### The Neuroscience Registry

This registry, which will exist on the VNI website, will contain the names of neuroscientists from academia and industry in the Commonwealth who are involved in basic or translational research on the nervous system, scientists in related fields, and medical professionals who treat patients with neurological disorders and/or carry out research with such patients and are interested in participating in the VNI. The registry will be a searchable database containing basic biographical information for each scientist/clinician, descriptions of their research interests and any



biorepositories or core laboratories they might direct and be willing to make available to the other VNI members, links to their webpage, and how they can be contacted.

### The Neurological Disorders Registry

The registry is derived from the active EMRs of the five participating medical centers and thus, contains the current protected health information (PHI) of more than six million Virginians. While the EMRs will remain under the complete control of each respective medical center, the internal utilization of these records for a common purpose will create a *de facto* registry. The EMRs of each medical center contain this PHI in standardized formats and include common data elements and neuroimaging. PHI of those patients with a specific neurological or psychiatric disorder will be accessed only after approval of the research study by the local Office of Human Subjects Protection or Internal Review Board (IRB), and only to the extent permitted by the IRB.

#### The Clinical Trials Network

Physicians from our five clinical sites and researchers from their affiliated universities bring exceptional expertise to all aspects of human subject research, clinical research and clinical trials and are capable of rapidly implementing screening and enrolling of human subjects and patients from the registry (i.e. the EMRs). When appropriate, investigators at the five medical centers and affiliated universities will participate in network clinical trials, other forms of human subject (including patient)-based research and observational studies. The study staff will also monitor enrollment, treatment (if applicable), and follow patients/subjects recruited into research studies. Each new clinical investigation coordinated by the VNI will have a "Principal Investigator" (PI) who is a physician from one of the five medical sites. Human subjects' research including those with patients that are not clinical studies or trials may have an appropriately qualified scientist or clinician PI from the clinical sites' affiliated university. In the case of clinical studies/trials, the PI will be intimately familiar with the full continuum of care for that neurological or psychiatric disorder under study. The VNI and PI will form a "PI Working Group" that will include interested Sub-Investigators from the other four medical centers and affiliated universities who are also well-versed with the disorder research and/or clinical condition under study. The PI Working Group will review the scientific merit and objectives of the study, what is being tested, which data need to be collected, how the study intervention is administered (if applicable), how the patients should be managed, and what special training of personnel might be required. Once a study is approved by the PI Working Group, additional working groups will be formed to deal with matters related to 1) Human Subjects Protection, 2) Feasibility & Logistics, 3) Clinical Coordination, 4) Grants & Contracts, 5) Intellectual Property, and 6) Telecommunications. It is understood and agreed the decisions of such working groups will not conflict with the internal policies of each participating institution or with applicable law.

### II. MEMO OF UNDERSTANDING

The success of the VNI is dependent upon the cooperation of all the participating institutions. A non-binding Memorandum of Understanding has been executed between Dr. Phillip Parrish, Interim Vice President for Research at the University of Virginia, and Mr. Michael Grisham, CEO of the VBHRC, which communicates to both parties the direction and intent of the VNI and indicates UVA's support of those goals for the benefit of UVA and the good of the Commonwealth.

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### III. PROJECT MANAGER

Randall E. Merchant, Ph.D. is serving as the VBHRC's "Project Manager" for the VNI. The Project Manager will meet regularly with UVA's Principal Investigator (defined below) at each of the academic institutions and hospitals to lay the groundwork and help build collaborations needed to move the VNI forward and make it a functioning entity. He also will provide advice and feedback on regulatory issues and methodologies as well as provide technical assistance (as requested) for activities that relate to establishing studies at each hospital and affiliated university and enrolling subjects in trials. The Project Manager will also enter into discussions with university units/individuals/companies with expertise in information technology so that he can provide counsel to the CEO of the VBHRC on the design of the informatics and big data platforms as needed for clinical trials to make them both secure and user-friendly.

### IV. PRINCIPAL INVESTIGATOR

The Project Manager will monitor activities associated with the VNI conducted at UVA in order to confirm that these are accomplished as intended, on time, and within budget. To achieve these goals, clearly-defined responsibilities and specific deliverables will be assigned to Dr. James Stone, UVA's "Principal Investigator". Principal Investigator will oversee the establishment and maintenance of the infrastructure for the VNI and in doing so facilitate the formation of new collaborations among scientists, clinicians and administrators at other academic institutions and medical centers in the Commonwealth.

The Principal Investigator must be flexible in terms of working with scholars from various diverse backgrounds and personal experiences. The overall duties of the Principal Investigator will support the mission of the VNI by 1) aiding the recruitment of scientists and clinicians into The Neuroscience Registry on the VNI website; 2) facilitating formation of new collaborative research studies between scientists and clinicians from UVA with their counterparts from other institutions; 3) helping lay the groundwork to organize and conduct any VNI-organized clinical trials and other research projects at UVA; and 4) assisting investigators, when asked, in the production of reports to the VBHRC.

The Principal Investigator will serve as chief liaison between the VNI Project Manager and the physicians, scientists, and staff at UVA. The Principal Investigator will be expected to communicate regularly with the Project Manager and respond promptly to any telephone or email messages from the Project Manager. The Project Manager will review operations with Principal Investigator at least once a month and, as circumstances warrant, help Principal Investigator coordinate resource allocation, evaluate personnel, plan and approve expenditures, respond to queries, and with regards to clinical studies, monitor progress on data collection and management. The Principal Investigator will provide the Project Manager with quarterly and annual reports on his activities as they relate to the Deliverables (below).

### V. DELIVERABLES

UVA's Deliverables will be the submission of quarterly and annual reports (per Subsection VII.5 below) detailing progress toward the following goals and associated activities:

 Encourage UVA faculty and medical center staff to join the Neuroscience Registry on the VNI website.

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- 2. Encourage the faculty, medical center staff, and administrators to participate in VNI-relevant working groups.
- 3. Facilitate efforts to improve access to UVA core facilities by scientists from other VNI member institutions.
- 4. Encourage UVA faculty, post-doctoral fellows, and graduate students to visit and/or host visits from VNI member institution laboratories to encourage the sharing of knowledge, techniques, and expertise as well as foster collaborations between universities.
- 5. Assist with searches of the University of Virginia Medical Center EMR and clinical data repository (CDR) to determine the number of patients with a specific neurological disorder.
- 6. Be prepared to provide a part-time clinical coordinator who will identify and contact patients to participate in any IRB-approved clinical research projects of the VNI. Support for these and any relevant clinical research activities will be provided through a separate agreement and budget specific to a given clinical trial.
- 7. Provide a member from UVA to the Clinical Coordinators Working Group which will compose standard operating procedures for enhancing the recruitment of patients and the collection of study data.
- 8. Identify someone at UVA suitable to serve as member to the Grants & Contracts Working Group which will write and/or review agreements for VNI clinical trials network studies. Salary support and travel for work this point of contact would perform to support the VNI that would go above and beyond their UVA job duties will be provided separately.
- 9. Identify someone at UVA suitable to serve as member of the Human Subjects Working Group which will work towards streamlining the application, review, and approval process for VNI clinical trials network projects as well as review protocols with regards to regulations governing human research and human subjects' protection. Salary support and travel for work this point of contact would perform to support the VNI will be provided separately.
- 10. Identify someone at UVA suitable to join the Telecommunications Working Group whose members will explore ways of using new telecommunication methods to break down the distance barriers between our participating universities and medical centers. Salary support and travel for work this point of contact would perform to support the VNI that would go above and beyond their UVA job duties will be provided separately.
- 11. Identify someone at UVA suitable for the Intellectual Property (IP) Working Group which will be formed in anticipation of the issues of IP that might arise as a consequence of new discoveries from a collaborative effort. Salary support and travel for work this point of contact would perform to support the VNI that would go above and beyond their UVA job duties will be provided separately.

### VI. PERIOD OF PERFORMANCE

This Statement of Work will begin on or about 01 January 2017 and will be completed by 31 December 2018. This contract may be amended and renewed bi-annually, contingent upon available funds.

### VII. MONITORING PROGRESS

UVA and the VBHRC agree that satisfactory progress on the Statement of Work will be monitored by the Project Manager during the life of the agreement as follows:

- Communication and progress updates between the Project Manager and Principal Investigator will occur at least monthly in person or via telephone.
- 2. Activities to encourage enrollment in The Neuroscience Registry at UVA will be ongoing and monitored by Project Manager through written reports from the Principal Investigator.

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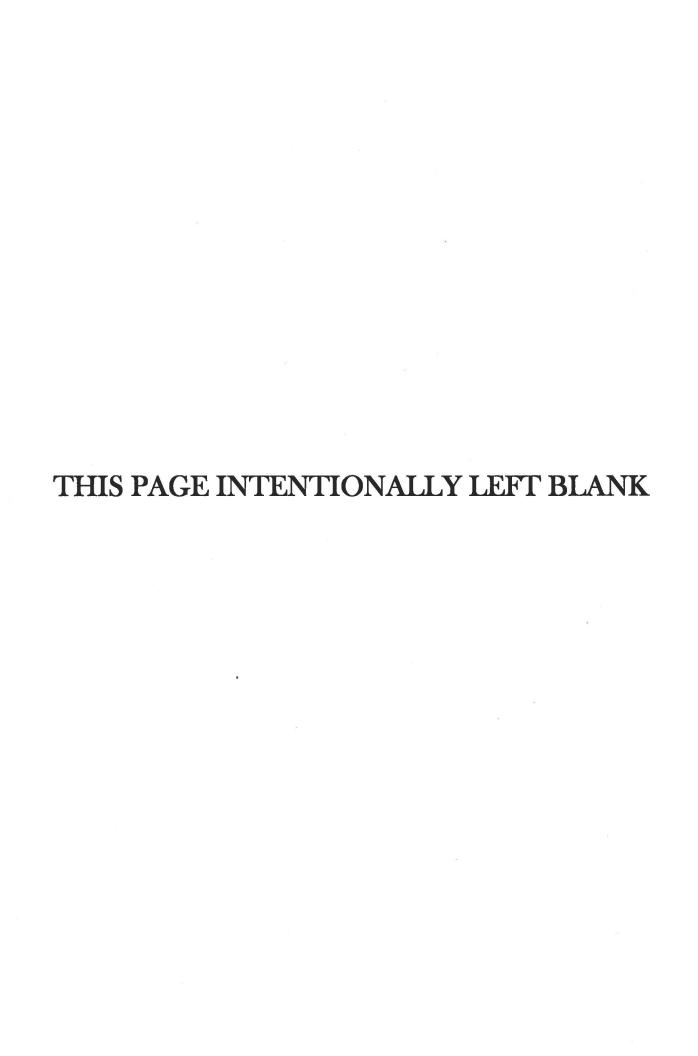
- 3. Meetings between the Principal Investigator and Project Manager will be scheduled to monitor progress, discuss information in interim reports, and agree to any changes to the statement of work and/or schedule of payments; such changes will be agreed in a signed modification to this agreement.
- 4. UVA will provide quarterly and annual progress reports to the Project Manager. These progress reports will coincide with the calendar quarter for quarterly reports (3/31, 6/30, 9/30, 12/31) and 12/31 for annual reports.
- 5. Financial reporting periods will also coincide with the quarterly dates. UVA will provide invoices that reflect the budget approved for funding the award, i.e., salaries, fringe benefits, equipment, supplies, travel, other directs and indirect costs. Principal Investigator will request Project Manager's approval for any significant variance from the approved budget. The Project Manager will review invoices for concordance with the statement of work and contract.

### VIII. ACCEPTANCE CRITERIA

The quarterly or annual progress reports will be deemed acceptable when the Project Manager (VNI) and the VBHRC have reviewed and approved. Quarterly reports will be reviewed for progress of each stage of the project, and will either be deemed acceptable or returned to the Principal Investigator with a request for additional clarification or information.

#### IX. BUDGET AND PAYMENT SCHEDULE

- 1. This is a cost-reimbursement contract. VBHRC will reimburse UVA for all direct and indirect costs incurred in performance of the Research with maximum funding of \$98,085 in Year 1 and maximum funding of \$98,085 for Year 2. The annual total constitutes \$75,450 direct costs and \$22,635 overhead (30%). The parties estimate that this amount is sufficient to satisfactorily perform the basic activities; provided, however, that if the funds are exhausted in performance of the Statement of Work, UVA will provide an estimate of further funds required to continue or complete the Statement of Work and will continue if such funds are available.
- 2. Invoices will be sent via electronic mail to Project Manager at remerchant@vbhrc.com. Checks will be made payable to the Rector and Visitors of the University of Virginia and mailed to: Office of Sponsored Programs, P.O. Box 400195, Charlottesville, Virginia 22904-4195. Each payment will reference the Statement of Work and UVA Principal Investigator for purposes of identification.
- 3. Should a payment become sixty (60) days past due, University reserves the right to suspend performance of this Agreement until such payment is received.



# Core Laboratory Resource Sharing Agreement between Virginia Research Institutions

Seven academic research institutions in Virginia have signed a memorandum of understanding (MoU) to share core facilities and resources in an effort to advance the research enterprise in the Commonwealth. The Vice Presidents for Research from the University of Virginia, Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Old Dominion University, Virginia Tech and William & Mary, working together with Virginia Catalyst, have achieved a breakthrough in collaborations that will greatly increase Virginia's competitiveness nationally and globally It will do so by increasing the accessibility for investigators affiliated with one institution to major resources at the partner institution. The main means by which this will be accomplished is by reciprocal offer of internal rates at certain institutional core laboratories.

The affected resources are as follows:

# Virginia Commonwealth University

Cancer Mouse Models Core Center for Molecular Imaging **Chemical and Proteomic Mass** Spectrometry Core Laboratory **Lipodomics and Metabolomics Mass Spectrometry Core Laboratory** Flow Cytometry Core Laboratory Microscopy Core Laboratory Nanomaterials Characterization Core Laboratory Genomics/Next Generation Sequencing Core Laboratory Structural biology Core Laboratory Tissue and Data Acquisition and Analysis Core (TDAAC)\*\* Transgenic / Knock-out Mouse Core Laboratory Mid-Atlantic Twin Registry

### Contact

Bryan Rowland VCU Manager of Research Infrastructure Telephone: (804) 828-9862 Email: blrowlan@vcu.edu

# **University of Virginia**

Advanced Microscopy Facility Antibody Engineering and Technology Core **Bioinformatics Core** Biomolecular Analysis Facility Biomolecular Magnetic Resonance Facility Biorepository and Tissue Research Facility\*\* **Exercise Physiology Core DNA Sciences Core** Flow Cytometry Core Genetically Engineered Murine Model Core Molecular Electron Microscopy Core Molecular Imaging and Radiochemistry Research Histology Core Stem Cell Core **Tissue Culture Facility** 

### Contact

Jay W. Fox, Ph.D.
Professor of Microbiology, Immunology, and Cancer Biology
Director of Shared Resources

# Virginia Polytechnic Institute and State University

VTCRI Fluorescence Assisted Cell Sorting Core Facility VTCRI Super Resolution Core Microscopy Facility VTCRI Animal behavioral core VTCRI Optical imaging core VTCRI Core Human Neuroimaging Lab VTCRI Cryo-electron microscopy facility

# **Eastern Virginia Medical School**

EVMS Biorepository and Histology
Core\*\*
Flow Cytometry Core
Microscopy and Imaging Core
Proteomics Core
Molecular Core Facility
Bioinformatics and Bioanalytic Core

### Contact

Dr. William J. Wasilenko Tel: (757) 466-8480

# George Mason University

Animal Care and Use Facilities Research Computing Microscopy Magnetic Resonance Imaging Center for Applied Proteomics and Molecular Medicine **Molecular Characterization Laboratory** Tissue Processing and Imaging Laboratory Mass Spectrometry Laboratory Nanofabrication Laboratory **CAP/CLIA Clinical Proteomics** Laboratory **Metabolomics Laboratory** Microbiome Analysis Center Small Molecule, Peptide, and Protein **Engineering Spectroscopy Laboratory NMR** Laboratory Spectroscopy Laboratory

### Contact

Micheal Laskofski Associate Vice President of Research Operations George Mason University Office of Sponsored Programs (703) 993-4573

# **Old Dominion University**

Viper Dynanmomenter Instrument Lab Applied Research Center (ARC) equipment Flow Cytometry Facility Center for Isotope and Trace element analysis **Electron Microscopy Laboratory DNA Sequencing Laboratory Biology Vehicle** CBP WQL-CC C/N Autoanalyzer CBP WQL-CC C/C Analyszer CBP WQL-CC C/C Spectrophotometer CBP WQL-CC C/C Standard Analyses CBP WQL-CC C/C Analyszer CBP WQL-CC C/C R/V Bayrunner CBP WQL-CC C/C Field Equipment Major Instrumentation Cluster Center - IRMS R/V Fav Slover Research Vessels - small boats Electronic Support Electron Probe Microanalyzer Virtual Environments Lab **CCPO Profiler ICP-MS** facility **Animal Care Facility Computing Resources** 

#### Contact

Karen Eck, PhD
Assistant Vice President for Research
Office of Research
Old Dominion University
(757) 683-3707
Email: keck@odu.edu

# **College of William and Mary**

**Bioengineering Core Lab** Cellular and Cytometry Cellular Analytical Core Imaging laboratories hard matter - nonionizing methods Biomaterial imaging Core Imaging Laboratories soft matter ionizing methods Live-cell, in vitro, and in vivo multiphoton neuroscience neuroimaging lab Laser-scanning confocal (fixed tissue) imaging core lab Surface characterization core lab Magnetic studies Core - 17.6T solid state NMR, Squid magnetometry, liquid **NMR** Living Human subjects neurophysiology Marine Biology Seawater Lab 1 Marine seawater lab 2 Marine cytometry center core Marine research vessel core operations

### **Contacts**

Director: Christopher A. Del Negro, Ph.D Professor of Applied Science, Coordinator Core Resources (757) 221-7808

Deputy Director: Eric L. Bradley, Ph.D Professor of Biology, Science Precinct Coordinator and EMT Liaison (757) 221-2220



# **Neuroscience Directory**

	CARILION	EVMS	GMU	INOVA	ODU	SENTARA	UVA	VCU	VT	W&M	OTHERS	TOTAL
	(100)	(50)	(60)	(150)	(60)	(100)	(250)	(250)	(100)	(50)	(150)	(1320)
03/05/17	2	11	10	0	10	3	0	43	1	1	9	90
03/07/17	3	13	11	1	11	3	0	49	1	1	9	102
03/13/17	14	17	12	1	11	6	2	52	1	8	11	135
03/20/17	14	20	18	2	11	19	2	57	8	17	14	182
03/27/17	15	24	29	2	16	22	1	68	11	20	16	224
03/29/17	15	28	30	2	17	27	1	70	20	21	17	248
04/03/17	15	29	30	2	23	27	1	70	23	22	17	259
04/17/17	15	40	31	2	26	29	1	71	23	26	20	285
04/24/17	20	40	32	2	26	29	1	71	23	30	22	296
05/01/17	22	40	33	2	26	29	1	74	34	31	22	314
05/08/17	22	44	33	4	26	29	1	77	34	31	31	332
05/15/17	25	44	33	4	26	29	1	78	35	31	32	338
05/22/17	25	46	33	4	26	30	4	92	35	31	34	360
05/29/17	26	50	36	4	26	30	4	92	36	31	39	374
06/05/17	26	58	38	4	26	30	5	92	36	31	42	388
06/12/17	26	60	38	9	27	30	7	94	36	31	43	401
06/19/17	27	62	43	10	27	30	7	94	36	31	43	410
06/26/17	36	63	46	11	27	30	<b>33</b>	94	36	36	42	454
07/03/17	37	63	46	11	27	30	42	263	36	38	43	636
07/10/17	38	63	48	11	<b>27</b>	32	47	270	39	39	43	657
07/17/17	39	63	51	11	27	32	51	463	40	39	45	861
07/24/17	40	63	51	11	51	32	<b>53</b>	566	40	39	46	992
07/31/17	40	63	51	12	51	32	<b>53</b>	<b>572</b>	40	39	47	1000
08/07/17	46	63	51	12	51	32	<b>55</b>	<b>573</b>	65	39	48	1035
08/14/17	47	63	51	12	71	32	<b>55</b>	571	100	39	47	1088
08/21/17	47	63	. 51	13	71	32	67	576	142	57	47	1166
08/28/17	47	64	51	33	71	32	67	580	157	57	<b>52</b>	1211
09/04/17	47	65	51	33	71	32	67	580	173	<b>57</b>	52	1228
09/11/17	47	66	51	33	71	32	68	581	189	57	52	1247
09/19/17	47	66	64	33	71	32	69	581	204	57	40	1275



# **Patient Registry**

The **Patient Registry** is data system with access to nearly a half-million Virginians diagnosed with a neurological condition, such as Alzheimer's, Parkinson's, ALS, or a mental health condition. The Registry enables approved draws from active electronic medical records (EMRs) of the five participating medical centers (Inova, Sentara, UVA Health System, VCU Health and Carilion), comprising six million individuals. Our collaborative research team can access this searchable database on an anonymous basis to rapidly quantify the number of patients meeting specific eligibility for proposed clinical trials of new treatments and, if the trial proceeds, to recruit patients in the trial. **This allows our researchers to be more competitive in acquiring grants and brings in funding for clinical trials.** 

Scenario An investigator at VCU is seeking patients for a new study on women with multiple sclerosis. The investigator runs a search for patients at VCU Health and comes up with a total of 403 eligible patients based on study inclusion vs. exclusion criteria.

ELIGIBILITY SEARCH	TOTAL NUMBER OF PATIENTS
Total Unique EMRs	1,515,922
Living Patients	1,459,606
Women	446,695
18-60 years old	248,059
Multiple Sclerosis Diagnosis	894
Seen since January 1, 2011	805
Exclude Obesity	698
Exclude Cardiovascular Disease	507
Exclude Renal Disease	502
Exclude Diabetes	492
Exclude Cancer	480
Never Treated with a NSAID	403

**Scenario** The investigator is a member of the Virginia Neuroscience Initiative, and is able to utilize the statewide Patient Registry, comprising almost **6 million individuals** diagnosed with a neurological condition.

MEDICAL CENTER	<b>TOTAL MS PATIENTS</b>	<b>TOTAL ELIGIBLE</b>
Carilion Clinic Roanoke	1453	296
Inova Hospital Fairfax	1023	433
Sentara Healthcare Norfolk	905	194
UVA Health System	1260	650
VCU Health System	894	403

By using the research tools provided by the Virginia Neuroscience Initiative, the investigator now has access to nearly 2,000 potential study subjects.





# **About Covance**

Covance Inc., a global clinical research organization (CRO), is the world's most comprehensive drug development company.

A **clinical research organization (CRO)** is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

We're dedicated to advancing healthcare and delivering Solutions Made Real® by providing high-quality nonclinical, preclinical, clinical and commercialization services to pharmaceutical and biotechnology companies to help reduce the time and costs associated with drug development. Because of our broad experience and deep knowledge, we're in a unique position to provide insights to our client partners that go above and beyond testing.

We also offer laboratory testing services to the chemical, agrochemical and food industries and are a market leader in toxicology services, central laboratory services, discovery services and a top global provider of Phase III clinical trial management services.

# About LabCorp®

In 2015, LabCorp® (NYSE: LH) acquired Covance Inc., creating the world's leading healthcare diagnostics company, providing comprehensive clinical laboratory services and end-to-end solutions for drug and diagnostics development and commercialization. Laboratory Corporation of America® Holdings (NYSE: LH), an S&P 500 company, is a world leading life sciences company, providing comprehensive clinical laboratory and end-to-end drug development services. With net revenue in excess of \$8.5 billion in 2015, LabCorp's 50,000 employees serve clients in 60 countries.

### Our Mission

Our mission is to bring new and innovative medicine to patients sooner.

### Our Vision

Our vision is to be recognized by clients as:

- The undisputed leader in providing drug development services
- A trusted partner whose hallmarks are
- Great people
- High-quality data
- A proven track record of integrating and streamlining the development process

### **Our Values**

Our values are to strive for operational and service excellence through a relentless focus on People, Process and Clients.



# PRAHEALTHSCIENCES



# We are dedicated to the future of clinical development and to every life it saves.

# Our Story

The story of PRA Health Sciences would naturally talk about how we've become one of the world's largest CROs. It would talk about our innovation and growth and would speak to our operational efficiencies and transparency. It would highlight our expertise and customization. And it would touch on the incredible differences we've made, over our more than 30 years, in helping to bring to market everything from niche treatments and therapies to blockbuster drugs.

More than anything else, our story would be about people. Not only our over 13,000 employees operating in more than 80 countries, though they'd certainly be a big part of it, but also the people that inspire them. The heroes of any PRA Health Sciences story are the clients we serve and the people whose lives we help improve, all over the world. And our story has only just begun.

# **Executive Team**

Since our inception in 1976, PRA has amassed a level of expertise that has enabled us to conduct complex global clinical trials across all therapeutic areas and provide outsourced clinical services across all phases of pharmaceutical and biotech drug development.

Our teams of experts are the core of the company promoting our forward-thinking culture with innovation, continuous attention to detail, constant quality improvement and a high priority approach to safety and timelines. Our pioneering mindset and specialist knowledge can make an enormous difference to your study.

# Expertise

At PRA Health Sciences, providing innovative solutions for our clients is what we do. Side by side with our clients, we strive to move drug discovery forward, helping them to develop life-saving and life-improving drugs. With our unique blend of expertise, we provide comprehensive clinical development services across all phases. From full service clinical development to the pioneering Embedded Solutions<sup>TM</sup> model, PRA provides a broad spectrum of solutions that meet the demands of a diverse marketplace.

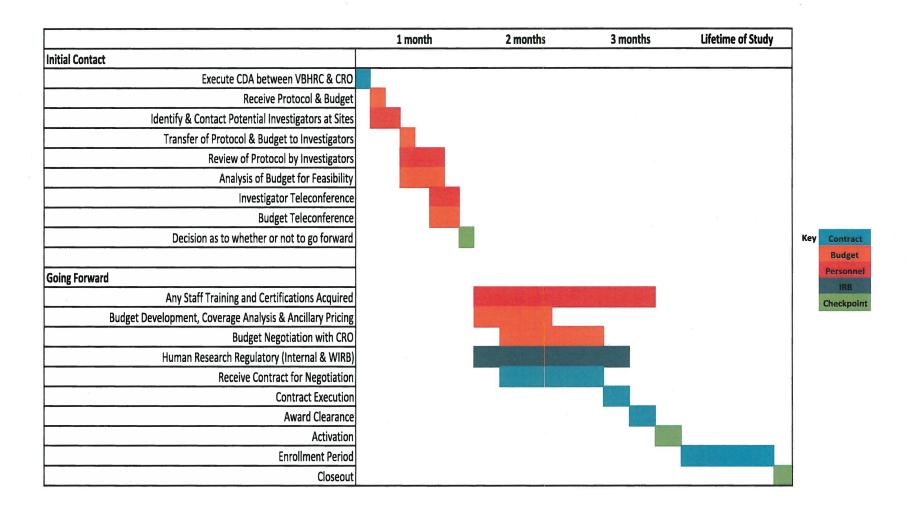
As a top five CRO, we have worked on 100+ marketed drugs across several therapeutic areas and conducted the pivotal or supportive trials that led to FDA and/or international regulatory approval of 70+ such drugs.

# Awards and Recognition

PRA and our employees have won numerous awards and accolades in the CRO industry. In 2015, we were named PharmaTimes' Clinical Company of the Year—The Americas for the third time and International Clinical Company of the Year for the second year in a row. In addition, many of our employees have won gold, silver, and bronze medals in various categories honoring clinical research and project management. We were also named BioPharma Asia's Best CRO in Asia for the second time and awarded Life Science Leader's CRO Leadership awards in Biotech for Productivity, Regulatory, and for the second year in a row, Quality.

PRA Health Sciences
4130 ParkLake Avenue, Suite 400, Raleigh, NC 27612
+1 (919) 786-8200

#### **Clinical Trials and Research Network Workflow**





**Accelerated Clinical Trial Agreement** 



# Virginia Biosciences Health Research Corporation OPERATING BUDGET

January through December 2015

	FISCAL YEAR 2018							TOTAL
	Jan	Feb	Mar	Apr	May	Jun	FY 2018	18 MONTHS
5200 - Virginia Neuroscience Initiative								
Direct University & Medl Ctr Payments	157,650			157,650			630,600	630,600
Project Manager	18,725	18,725	18,725	18,725	18,725	18,725	224,700	262,150
Administrative support	2,085	2,085	2,085	2,085	2,085	2,065	25,000	30,000
Web Site and Marketing	1,600	800	800	1,600	800	800	12,800	15,200
Travel	415	415	415	415	415	435	5,000	5,830
Project management	-		-	•	-	-	× •	132,056
Total 5220 - Commowealth Patient Registry	180,475	22,025	22,025	180,475	22,025	22,025	898,100	1,075,836





## **Background**



#### FY 17-18 Budget Language

payments. The payments are based on negotiated grants awarded to select projects that invest in Virginia and meet specified job creation and capital investment targets.

- Aerospace Engine Facility Incentive Payments. Includes reductions of \$8.5 million GF the first year and \$3.7 million GF the second year. The reduction recognizes that the company will not reach certain performance milestones to qualify for the full amount of previously planned grant payments. \$12.7 million NGF is appropriated in FY 2018 to fund anticipated grant payments based on expected job creation and investment totals, having been previously appropriated from the general fund.
- Transfer Balances to General Fund. Item 3-1.01 transfers to the general fund excess cash balances of \$2.5 million in the Aerospace Engine Manufacturing Supplier Cluster Grant Fund.
- Virginia Economic Development Incentive Grant (VEDIG) Program. Reduces funding by \$2.8 million GF in FY 2018 based on a revised payment schedule. Grants are awarded to companies that have met investment and job creation criteria required by VEDIG performance agreements. Language authorizes the Governor to award additional grants up to \$4.0 million in aggregate beginning on July 1, 2017, but before June 30, 2018, to eligible companies.
- Pulp, Paper, and Fertilizer Advanced Manufacturing Performance Grant Program Fund. Includes a reduction of \$3.0 million GF the second year. The previously planned FY 2017 grant payment is also delayed to FY 2018 in expectation that the qualified company will meet performance targets a year later than originally planned.



- Virginia Biosciences Health Research Corporation. Reduces FY 2018 funding by \$1.25 million GF, leaving \$2.5 million GF the first year and \$3.75 million GF the second year. Funding is used for grants to eligible projects and to develop a statewide clinical trials network focusing on brain science.
- Eliminate Tourism Growth Fund. Removes funding of \$500,000 GF the second year
  for the Virginia Tourism Growth Fund, a grant program administered by the
  Virginia Tourism Corporation designed to support medium-sized tourism
  development projects.
- Advanced Shipbuilding Production Facility Grant. Includes \$6.0 million GF in FY 2018 to fund an economic development incentive grant program pursuant to Chapter 723 of the 2016 Acts of Assembly. The grant program incentivizes the construction and operation of a new facility related to the production of a class of nuclear warships for the United States Navy.



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FY2017 FY2018

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FY2017 FY2018

- D. Out of the appropriation for this Item, \$6,000,000 the first year and \$3,000,000 the second year from the general fund and an amount estimated at \$150,000 the first year and \$150,000 the second year from nongeneral funds shall be deposited to the Governor's Motion Picture Opportunity Fund, as established in § 2.2-2320, Code of Virginia. These nongeneral fund revenues shall be deposited to the fund from revenues generated by the digital media fee established pursuant to § 58.1-1731, et seq., Code of Virginia. Such funds shall be used at the discretion of the Governor to attract film industry production activity to the Commonwealth.
- E. Out of the appropriation for this Item, \$8,878,000 the first year and \$3,729,000 the second year from the general fund shall be used in support of the location of an aerospace engine facility in Prince George County. The funds may be used for grants in accordance with §§ 59.1-284.20, 59.1-284.21, and 59.1-284.22, Code of Virginia. The Director, Department of Planning and Budget shall transfer these funds to the impacted state agencies upon request to the Director, Department of Planning and Budget by the respective state agency.
- F.1. Out of the appropriation for this Item, \$4,200,000 the first year and \$4,400,000 the second year from the general fund shall be deposited to the Virginia Economic Development Incentive Grant subfund of the Virginia Investment Partnership Grant Fund to be used to pay investment performance grants in accordance with § 2.2-5102.1, Code of Virginia. In the second year, \$800,000 from the Virginia Economic Development Incentive Grant subfund of the Virginia Investment Partnership Grant Fund is hereby appropriated and shall be used to pay investment performance grants in accordance with § 2.2-5102.1, Code of Virginia.
- 2. Consideration should be given to economic development projects that 1) are in areas of high unemployment; 2) link commercial development along existing transportation/transit corridors within regions; and 3) are located near existing public infrastructure.
- G. Out of the appropriation for this Item, \$7,155,840 the first year from the general fund shall be deposited to the Advanced Shipbuilding Training Facility Fund to be used to pay grants in accordance with § 59.1-284.23, F., Code of Virginia.
- H. Out of the appropriation for this Item, \$2,000,000 the first year and \$3,000,000 the second year from the general fund shall be deposited to the Pulp, Paper, and Fertilizer Advanced Manufacturing Performance Grant Program Fund to be used for performance grants in accordance with § 59.1-284.28, Code of Virginia.
- I.1. Out of the appropriation for this Item, \$2,500,000 the first year and \$5,000,000 the second year from the general fund shall be provided for the Virginia Biosciences Health Research Corporation (VBHRC), a non-stock corporation research consortium initially comprised of the University of Virginia, Virginia Commonwealth University, Virginia Polytechnic Institute and State University, George Mason University and the Eastern Virginia Medical School. The consortium will contract with private entities, foundations and other governmental sources to capture and perform research in the biosciences, as well as promote the development of bioscience infrastructure tools which can be used to facilitate additional research activities. The Director, Department of Planning and Budget, is authorized to provide these funds to the non-stock corporation research consortium referenced in this paragraph upon request filed with the Director, Department of Planning and Budget by VBHRC.
- 2. Of the amounts provided in J.1. for the research consortium, up to \$2,500,000 the first year and \$5,000,000 the second year may be used to develop or maintain investments in research infrastructure tools to facilitate bioscience research.
- 3. The remaining funding shall be used to capture and perform research in the biosciences and must be matched at least dollar-for-dollar by funding provided by such private entities, foundations and other governmental sources. No research will be funded by the consortium unless at least two of the participating institutions, including the five founding institutions and any other institutions choosing to join, are actively and significantly involved in collaborating on the research. No research will be funded by the consortium unless the research topic has been vetted by a scientific advisory board and holds potential for high impact near-term success in generating other sponsored research, creating spin-

ITEM 106.

Item Details(\$)
First Year Second Year
FY2017 FY2018

Appropriations(\$)
First Year Second Year
FY2017 FY2018

off companies or otherwise creating new jobs. The consortium will set guidelines to disburse research funds based on advisory board findings. The consortium will have near-term sustainability as a goal, along with corporate-sponsored research gains, new Virginia company start-ups, and job creation milestones.

- 4. Other publicly-supported institutions of higher education in the Commonwealth may choose to join the consortium as participating institutions. Participation in the consortium by the five founding institutions and by other participating institutions choosing to join will require a cash contribution from each institution in each year of participation of at least \$50,000.
- 5. Of these funds, up to \$500,000 the first year and \$500,000 the second year may be used to pay the administrative, promotional and legal costs of establishing and administering the consortium, including the creation of intellectual property protocols, and the publication of research results.
- 6. The Virginia Economic Development Partnership, in consultation with the publicly-supported institutions of higher education in the Commonwealth participating in the consortium, shall provide to the Governor, and the Chairmen of the Senate Finance and House Appropriations committees, by November 1 of each year a written report summarizing the activities of the consortium, including, but not limited to, a summary of how any funds disbursed to the consortium during the previous fiscal year were spent, and the consortium's progress during the fiscal year in expanding upon existing research opportunities and stimulating new research opportunities in the Commonwealth.
- 7. The accounts and records of the consortium shall be made available for review and audit by the Auditor of Public Accounts upon request.
- 8. Up to \$2,500,000 of the funds managed by the Commonwealth Health Research Board (CHRB), created pursuant to § 23-278, Code of Virginia, shall be directed toward collaborative research projects, approved by the boards of the VBHRC and CHRB, to support Virginia's core bioscience strengths, improve human health, and demonstrate commercial viability and a high likelihood of creating new companies and jobs in Virginia.
- J.1. Out of this appropriation, \$209,859 the first year and \$209,868 the second year from the general fund shall be provided to the Virginia-Israel Advisory Board.
- 2. The Virginia-Israel Advisory Board shall seek prior approval of all travel and related expenditures from the Secretary of Commerce and Trade.
- 3. The Virginia-Israel Advisory Board shall report by January 15 of each year to the Chairmen of the Senate Finance and House Appropriations Committees on the board's activities and expenditure of state funds.
- K. Out of this appropriation, \$5,669,833 the first year and \$5,669,833 the second year from the general fund shall be available for eligible businesses under the Virginia Jobs Investment Program. Pursuant to § 2.2-1611, Code of Virginia, the appropriation provided for the Virginia Jobs Investment Program for eligible businesses shall be deposited to the Virginia Jobs Investment Program Fund.
- L. Out of this appropriation \$500,000 the first year and \$500,000 the second year from the general fund is provided for the purpose of attracting new tourism and hospitality projects and expanding existing tourism and hospitality projects in the Commonwealth. Funds shall be disbursed through the Virginia Tourism Authority as grants or loans to political subdivisions or business entities authorized to transact business in the Commonwealth based on criteria as approved by the Governor. The Governor shall transmit his specific criteria for awarding and distributing these funds to the Chairmen of the House Committee on Appropriations and the Senate Finance Committee prior to any expenditure of this appropriation.
- M. Out of this appropriation, \$500,000 the first year and \$500,000 the second year from the general fund may be provided to the Virginia Economic Development Partnership to facilitate additional domestic and international marketing and trade missions approved by the Governor. The Director, Department of Planning and Budget, is authorized to provide these funds to the Virginia Economic Development Partnership upon written approval of the Governor.

## ARTICLES OF AMENDMENT OF VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

The undersigned, on behalf of the nonstock corporation set forth below, pursuant to Title 13.1, Chapter 10, Article 10 of the Code of Virginia, states as follows:

- I. The name of the corporation is Virginia Biosciences Health Research Corporation (the "Corporation").
- 2. The Amended and Restated Articles of Incorporation of the Corporation are hereby amended by deleting Article VI in its entirety and replacing it with the following:
  - "1. The corporation shall be managed by a board of directors consisting of a maximum of fifteen directors, nine of whom shall be ex-officio directors. The nine exofficio directors shall be: the Secretary of Commerce and Trade of Virginia; the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority, the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; the president of Eastern Virginia Medical School, the president of Old Dominion University; and the president of the College of William & Mary. Each of the nine ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his or her agency or institution to act in his or her stead or terminate or replace an earlier designation. The Chair and Vice-Chair of the Board of Directors need not be ex-officio directors, but any ex-officio director may, by written notice to the Chair, require a meeting of the Board of Directors, and may require any matter or motion to be placed upon the agenda and voted upon.
  - 2. The remaining six directors shall be elected by the board of directors then serving in the manner more specifically provided in the bylaws. All other matters concerning the six elected directors shall be set forth in the bylaws of the corporation."
- 3. The foregoing amendment was duly adopted and approved by the Board of Directors of the Corporation effective as of October 31, 2016 by a vote of at least two-thirds of the directors in office. Member approval of the amendment was not required because the Corporation has no members.
  - 4. These Articles of Amendment will be effective upon filing.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the undersigned declares that the facts herein stated are true as of May 13, 2017.

VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION,

a Virginia corporation

By:

Mike Grisham

President and Chief Executive Officer

## ARTICLES OF AMENDMENT OF VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

The undersigned, on behalf of the nonstock corporation set forth below, pursuant to Title 13.1, Chapter 10, Article 10 of the Code of Virginia, states as follows:

- 1. The name of the corporation is Virginia Biosciences Health Research Corporation (the "Corporation").
- 2. The Amended and Restated Articles of Incorporation of the Corporation are hereby amended by deleting Article VI in its entirety and replacing it with the following:
  - "1. The corporation shall be managed by a board of directors consisting of a maximum of fourteen directors, eight of whom shall be ex-officio directors. The eight ex-officio directors shall be: the Secretary of Commerce and Trade of Virginia; the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; the president of Eastern Virginia Medical School; and the president of Old Dominion University. Each of the eight ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his agency or institution to act in his stead or terminate or replace an earlier designation. The Chair and Vice-Chair of the Board of Directors need not be ex-officio directors, but any ex-officio director may, by written notice to the Chair, require a meeting of the Board of Directors, and may require any matter or motion to be placed upon the agenda and voted upon.
  - 2. The remaining six directors shall be elected by the board of directors then serving in the manner more specifically provided in the bylaws. All other matters concerning the six elected directors shall be set forth in the bylaws of the corporation."
- 3. The foregoing amendment was duly adopted and approved by the Board of Directors of the Corporation effective as of January 6, 2016 by a vote of at least two-thirds of the directors in office. Member approval of the amendment was not required because the Corporation has no members.
  - 4. These Articles of Amendment will be effective upon filing.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the undersigned declares that the facts herein stated are true as of January \_\_\_\_\_\_ 2016.

VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION,

a Virginia corporation,

By:

Mike Grisham

President and Chief Executive Officer

## ARTICLES OF AMENDMENT OF VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

The undersigned, on behalf of the nonstock corporation set forth below, pursuant to Title 13.1, Chapter 10, Article 10 of the Code of Virginia, states as follows:

- 1. The name of the corporation is Virginia Biosciences Health Research Corporation (the "Corporation").
- 2. The Amended and Restated Articles of Incorporation of the Corporation are hereby amended by deleting Article VI in its entirety and replacing it with the following:
  - "1. The corporation shall be managed by a board of directors consisting of a maximum of thirteen directors, eight of whom shall be ex-officio directors. The eight exofficio directors shall be: the Secretary of Commerce and Trade of Virginia; the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; the president of Eastern Virginia Medical School; and the president of Old Dominion University. Each of the eight ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his agency or institution to act in his stead or terminate or replace an earlier designation. The Chair and Vice-Chair of the Board of Directors need not be ex-officio directors, but any ex-officio director may, by written notice to the Chair, require a meeting of the Board of Directors, and may require any matter or motion to be placed upon the agenda and voted upon.
  - 2. The remaining five directors shall be elected by the board of directors then serving in the manner more specifically provided in the bylaws. All other matters concerning the five elected directors shall be set forth in the bylaws of the corporation."
- 3. The foregoing amendment was duly adopted and approved by the Board of Directors of the Corporation effective as of February 25, 2014 by unanimous vote. Member approval of the amendment was not required because the Corporation has no members.
  - 4. These Articles of Amendment will be effective upon filing.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the undersigned declares that the facts herein stated are true as of March  $\underline{/0}$ , 2014.

VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION,

a Virginia corporation

By:

Mike Grisham
President and Chief Executive Officer

#### AMENDED AND RESTATED ARTICLES OF INCORPORATION

**OF** 

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

Effective July 25, 2013

I.

The name of the corporation is "Virginia Biosciences Health Research Corporation".

II.

- 1. The corporation is organized and shall be operated for educational and research purposes within the meaning of §501(c)(3) of the Internal Revenue Code of 1986, as amended ("Code"), including without limitation, fostering life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities located within the Commonwealth of Virginia, stimulating industrial partnerships and increased corporate sponsored research at universities located within the Commonwealth of Virginia, and encouraging clinical cooperation with universities located within the Commonwealth of Virginia for patient oriented studies.
- 2. The corporation shall have all powers and authority now or hereafter conferred upon nonstock, not-for-profit corporations organized under the laws of the Commonwealth of Virginia; provided, however, that (a) no part of the net earnings of the corporation shall inure to the benefit of, or be distributable to its officers, directors, or other private persons, except that the corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purposes set forth above, (b) no substantial part of the activities of the corporation shall be the carrying on of propaganda or otherwise attempting to influence legislation (except as provided in §501(h) of the Code), and the corporation shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office, and (c) notwithstanding any other provision of these articles, the corporation shall not carry on any other activities not permitted to be carried on (i) by a corporation operated exclusively for charitable and educational purposes within the meaning of, and exempt from federal income tax under, \$501(c)(3) of the Code (or corresponding Section of any future federal tax code), or (ii) by a corporation, contributions to which are deductible under §170(c)(2) of the Code (or corresponding Section of any future federal tax code).
- 3. With respect to funds appropriated to the corporation by the Commonwealth of Virginia, and notwithstanding any other provision of these Articles of Incorporation, the corporation shall not make any payment or distribution of such funds appropriated by the Commonwealth of Virginia to a charitable institution unless (a) the institution is owned or controlled by the Commonwealth of Virginia, or (b) the payment is reasonable compensation for

services or other value provided to the corporation by the entity. This Section 3 of Article II shall be interpreted *in pari materia* with Article IV, § 16 of the Constitution of Virginia. The board of directors shall implement the accounting procedures necessary to ensure the corporation's compliance with the provisions of this Article II, Section 3.

Ш.

In compliance with §13.1-814 of the Code of Virginia, the corporation shall not have the authority to issue shares of stock. No dividend shall be paid out and no part of the income of the corporation shall be distributed to its directors or officers, except that the corporation may pay compensation in a reasonable amount to its directors or officers for services rendered.

IV.

The corporation shall have no members.

٧.

The initial registered office of the corporation shall be located at 1715 Pratt Drive, Suite 2700, Blacksburg, Virginia, in the county of Montgomery, Virginia and the initial registered agent shall be Michael P. Drzal who is a resident of Virginia and a member of the Virginia State Bar and whose business address is the same as the address of the initial registered office.

VI.

- 1. The corporation shall be managed by a board of directors consisting of a maximum of thirteen directors, seven of whom shall be ex-officio directors. The seven ex-officio directors shall be: the Secretary of Commerce and Trade of Virginia: the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; and the president of Eastern Virginia Medical School. Each of the seven ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his agency or institution to act in his stead or terminate or replace an earlier designation. The Chair and Vice-Chair of the Board of Directors need not be ex-officio directors, but any ex-officio director may, by written notice to the Chair, require a meeting of the Board of Directors, and may require any matter or motion to be placed upon the agenda and voted upon.
- 2. The remaining six directors shall be elected by the board of directors then serving in the manner more specifically provided in the bylaws. All other matters concerning the six elected directors shall be set forth in the bylaws of the corporation.

- 1. To the full extent that the Virginia Nonstock Corporation Act, as it exists on the date hereof or may hereafter be amended, permits the limitation (which limitation shall be (i) \$1 or the minimum amount allowed to be stated by such Act if a specific dollar amount is required to be stated or (ii) the full extent of the limitation set forth in such Act if no specific dollar amount is required to be stated) or elimination of the liability of directors or officers, a director or officer of the corporation shall not be liable to the corporation for monetary damages. Any amendment to or repeal of this Article shall not adversely affect any right of protection of a director or officer of the corporation for or with respect to any acts or omissions of such director or officer occurring prior to such amendment or repeal.
- 2. To the full extent permitted and in the manner prescribed by the Virginia Nonstock Corporation Act and any other applicable law, the corporation shall indemnify a director or officer of the corporation who is or was a party to any such proceeding by reason of the fact that he is or was such a director or officer or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. The board of directors is hereby empowered, by majority vote of a quorum of disinterested directors, to contract in advance to indemnify any director or officer.
- 3. The board of directors is hereby empowered, by majority vote of a quorum of disinterested directors, to cause the corporation to indemnify or contract in advance to indemnify any person not specified in Section 2 of this Article VII who was or is a party to any proceeding, by reason of the fact that he is or was an employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, to the same extent as if such person were specified as one to whom indemnification is granted in Section 2.
- 4. The corporation may purchase and maintain insurance to indemnify it against the whole or any portion of the liability assumed by it in accordance with this Article VII and may also procure insurance, in such amounts as the board of directors may determine, on behalf of any person who is or was a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against any liability asserted against or incurred by any such person in any such capacity or arising from his status as such, whether or not the corporation would have power to indemnify him against such liability under the provisions of this Article VII.
- 5. In the event there has been a change in the composition of a majority of the board of directors after the date of the alleged act or omission with respect to which indemnification is claimed, any determination as to indemnification and advancement of expenses with respect to any claim for indemnification made pursuant to Section 2 of this Article VII shall be made by special legal counsel agreed upon by the board of directors and the proposed indemnitee. If the board of directors and the proposed indemnitee are unable to agree upon such special legal

counsel, the board of directors and the proposed indemnitee each shall select a nominee, and the nominees shall select such special legal counsel.

- 6. The provisions of this Article VII shall be applicable to all actions, claims, suits or proceedings commenced after the adoption hereof, whether arising from any action taken or failure to act before or after such adoption. No amendment, modification or repeal of this Article VII shall diminish the rights provided hereby or diminish the right to indemnification with respect to any claim, issue or matter in any then pending or subsequent proceedings that is based in any material respect on any alleged action or failure to act prior to such amendment, modification or repeal.
- 7. Reference herein to directors, officers, employees or agents shall include former directors, officers, employees and agents and their respective estates, heirs, executors and administrators.

#### VIII.

For any period during which the corporation is a "private foundation" as defined by Section 509 of the Code, and only during such period(s), the corporation shall be subject to the following restrictions and prohibitions:

- (a) the corporation shall distribute its income for each taxable year at such time and in such manner as not to become subject to the tax on undistributed income imposed by §4942 of the Code;
- (b) the corporation shall not engage in any act of self-dealing as defined in §4941(d) of the Code;
- (c) the corporation shall not retain any excess business holdings as defined in §4943(c) of the Code;
- (d) the corporation shall not make any investments in such manner as to subject it to tax under §4944 of the Code; and
- (e) the corporation shall not make any taxable expenditures as defined in §4945(d) of the Code.

#### IX.

Upon the dissolution of the corporation, the board of directors shall, after making provision for the payment of all of the liabilities of the corporation, dispose of all of the assets of the corporation (a) for one or more of the exempt purposes of the corporation within the meaning of \$501(c)(3) of the Code, provided that all such assets are distributed to an organization or organizations that are owned or controlled by the Commonwealth of Virginia; (b) to a fund, foundation or corporation, or more than one organization organized and operated exclusively for

charitable, scientific, or educational purposes as shall at the time qualify as an exempt organization or organizations under §501(c)(3) of the Code, provided that such organization or organizations are owned or controlled by the Commonwealth of Virginia; or (c) to the Commonwealth of Virginia.

X.

These Articles may be amended only by two thirds vote of all directors in office, including a majority of all ex-officio directors listed in Section 1 of Article VI, or their designees. No amendment of these Articles and no provision of the Bylaws may alter the majority control exercised by the Commonwealth of Virginia as provided in Article VI, nor authorize payments or disposition of assets prohibited in Section 3 of Article II.

#### **ARTICLES OF INCORPORATION**

OF

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

The undersigned hereby forms a nonstock, not-for-profit corporation under the provisions of the Virginia Nonstock Corporation Act, Chapter 10, Title 13.1 of the Code of Virginia, and adopts articles of incorporation of said corporation as follows:

I.

The name of the corporation is "Virginia Biosciences Health Research Corporation".

II.

The corporation is organized and shall be operated for educational and research purposes within the meaning of §501(c)(3) of the Internal Revenue Code of 1986, as amended ("Code"), including without limitation, fostering life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities located within the Commonwealth of Virginia, stimulating industrial partnerships and increased corporate sponsored research at universities located within the Commonwealth of Virginia, and encouraging clinical cooperation with universities located within the Commonwealth of Virginia for patient oriented studies.

The corporation shall have all powers and authority now or hereafter conferred upon nonstock, not-for-profit corporations organized under the laws of the Commonwealth of Virginia; provided, however, that (a) no part of the net earnings of the corporation shall inure to the benefit of, or be distributable to its officers, directors, or other private persons, except that the corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purposes set forth above, (b) no substantial part of the activities of the corporation shall be the carrying on of propaganda or otherwise attempting to influence legislation (except as provided in §501(h) of the Code), and the corporation shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office, and (c) notwithstanding any other provision of these articles, the corporation shall not carry on any other activities not permitted to be carried on (i) by a corporation operated exclusively for charitable and educational purposes within the meaning of, and exempt from federal income tax under, §501(c)(3) of the Code (or corresponding Section of any future federal tax code), or (ii) by a corporation, contributions to which are deductible under §107(c)(2) of the Code (or corresponding Section of any future federal tax code).

In compliance with §13.1-814 of the Code of Virginia, the corporation shall not have the authority to issue shares of stock. No dividend shall be paid out and no part of the income of the corporation shall be distributed to its directors or officers, except that the corporation may pay compensation in a reasonable amount to its directors or officers for services rendered.

IV.

The corporation shall have no members.

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The initial registered office of the corporation shall be located at 1715 Pratt Drive, Suite 2700, Blacksburg, Virginia, in the county of Montgomery, Virginia and the initial registered agent shall be Michael P. Drzal who is a resident of Virginia and a member of the Virginia State Bar and whose business address is the same as the address of the initial registered office.

VI.

The corporation shall be managed by a board of directors. Directors shall be elected by the board of directors then serving in the manner more specifically provided in the bylaws. The number of directors and all other matters concerning the directors shall be set forth in the bylaws of the corporation.

#### VII.

- 1. To the full extent that the Virginia Nonstock Corporation Act, as it exists on the date hereof or may hereafter be amended, permits the limitation (which limitation shall be (i) \$1 or the minimum amount allowed to be stated by such Act if a specific dollar amount is required to be stated or (ii) the full extent of the limitation set forth in such Act if no specific dollar amount is required to be stated) or elimination of the liability of directors or officers, a director or officer of the corporation shall not be liable to the corporation for monetary damages. Any amendment to or repeal of this Article shall not adversely affect any right of protection of a director or officer of the corporation for or with respect to any acts or omissions of such director or officer occurring prior to such amendment or repeal.
- 2. To the full extent permitted and in the manner prescribed by the Virginia Nonstock Corporation Act and any other applicable law, the corporation shall indemnify a director or officer of the corporation who is or was a party to any such proceeding by reason of the fact that he is or was such a director or officer or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. The board of directors is hereby empowered, by majority vote of a quorum of disinterested directors, to contract in advance to indemnify any director or officer.

- 3. The board of directors is hereby empowered, by majority vote of a quorum of disinterested directors, to cause the corporation to indemnify or contract in advance to indemnify any person not specified in Section 2 of this Article VII who was or is a party to any proceeding, by reason of the fact that he is or was an employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, to the same extent as if such person were specified as one to whom indemnification is granted in Section 2.
- 4. The corporation may purchase and maintain insurance to indemnify it against the whole or any portion of the liability assumed by it in accordance with this Article VII and may also procure insurance, in such amounts as the board of directors may determine, on behalf of any person who is or was a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against any liability asserted against or incurred by any such person in any such capacity or arising from his status as such, whether or not the corporation would have power to indemnify him against such liability under the provisions of this Article VII.
- 5. In the event there has been a change in the composition of a majority of the board of directors after the date of the alleged act or omission with respect to which indemnification is claimed, any determination as to indemnification and advancement of expenses with respect to any claim for indemnification made pursuant to Section 2 of this Article VII shall be made by special legal counsel agreed upon by the board of directors and the proposed indemnitee. If the board of directors and the proposed indemnitee are unable to agree upon such special legal counsel, the board of directors and the proposed indemnitee each shall select a nominee, and the nominees shall select such special legal counsel.
- 6. The provisions of this Article VII shall be applicable to all actions, claims, suits or proceedings commenced after the adoption hereof, whether arising from any action taken or failure to act before or after such adoption. No amendment, modification or repeal of this Article VII shall diminish the rights provided hereby or diminish the right to indemnification with respect to any claim, issue or matter in any then pending or subsequent proceedings that is based in any material respect on any alleged action or failure to act prior to such amendment, modification or repeal.
- 7. Reference herein to directors, officers, employees or agents shall include former directors, officers, employees and agents and their respective estates, heirs, executors and administrators.

#### VIII.

For any period during which the corporation is a "private foundation" as defined by Section 509 of the Code, and only during such period(s), the corporation shall be subject to the following restrictions and prohibitions:

- (a) the corporation shall distribute its income for each taxable year at such time and in such manner as not to become subject to the tax on undistributed income imposed by §4942 of the Code;
- (b) the corporation shall not engage in any act of self-dealing as defined in §4941(d) of the Code;
- (c) the corporation shall not retain any excess business holdings as defined in §4943(c) of the Code;
- (d) the corporation shall not make any investments in such manner as to subject it to tax under §4944 of the Code; and
- (e) the corporation shall not make any taxable expenditures as defined in §4945(d) of the Code.

IX.

Upon the dissolution of the corporation, the board of directors shall, after making provision for the payment of all of the liabilities of the corporation, dispose of all of the assets of the corporation (a) for one or more of the exempt purposes of the corporation within the meaning of §501(c)(3) of the Code or (b) to a fund, foundation or corporation, or more than one organization organized and operated exclusively for charitable, scientific, religious or educational purposes as shall at the time qualify as an exempt organization or organizations under §501(c)(3) of the Code.

Dated: November 8, 2012

Michael P. Drzal, Incorporator

#### AMENDMENT TO SECOND AMENDED AND RESTATED BYLAWS

OF

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

- 1. Article VI, Section 1 of the Second Amended and Restated Bylaws (the "Bylaws") of Virginia Biosciences Health Research Corporation, a Virginia nonstock corporation (the "Corporation"), is hereby amended and superseded in its entirety by the following:
  - "1. Number and Qualification. All corporate powers shall be exercised by or under the authority of, and the business and affairs of the Corporation shall be managed under the direction of, the Board of Directors. The Board of Directors shall consist of fifteen (15) persons who have demonstrated an interest in and concern for, as well as an ability to decide and address issues impacting upon, the Corporation's purposes, objectives and activities. The directors shall have the sole voting power. No person shall be denied membership on the Board of Directors by virtue of national origin, sex, religious affiliation, race, creed, color, or profession."
- 2. Article VI, Section 2 of the Bylaws of the Corporation is hereby amended and superseded in its entirety by the following:
  - Elections. At all times, nine (9) of the directors shall consist of ex-officio directors designated by entities controlled by the Commonwealth of Virginia. This is intended to satisfy Article IV, §16 of the Constitution of Virginia. The nine ex-officio directors shall be: the Secretary of Commerce and Trade of Virginia; the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; the president of Eastern Virginia Medical School; the president of Old Dominion University; and the president of the College of William & Mary. Each of the nine ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his or her agency or institution to act in his or her stead or terminate or replace an earlier designation. With respect to the additional six (6) directors: (a) one (1) director shall be a representative of the United States Department of Veterans Affairs ("VA Representative"); (b) two (2) directors shall be representatives of statewide health care system providers in Virginia ("Health Care System Representatives"); and (c) the Board of Directors shall designate an additional three (3) directors, such three (3) directors to be designated as follows: (x) one (1) director shall be a representative of a life sciences company; (y) one (1) director shall be a representative of a venture capital firm that regularly invests in life sciences companies; and (z) one (1) director shall be a statewide representative of the biosciences industry in Virginia."
- 3. Article VI, Section 17 of the Bylaws of the Corporation is hereby amended and superseded in its entirety by the following:
  - "17. <u>Committees and Panels</u>. The Board of Directors may create one or more committees and/or panels and appoint members of the Board of Directors to chair them.

Members of the committees and/or panels other than the chairperson need not be directors. Each committee and/or panel may have two or more members, who shall serve at the pleasure of the Board of Directors. The provisions of this Article that govern meetings, action without meetings, and quorum and voting requirements of the Board of Directors, shall apply to committees and panels and their members as well. Each committee and panel may exercise the authority of the Board of Directors as delegated by the Board of Directors, subject to Section 13.1-869(D) of the Code. Without limiting the generality of the foregoing, the Board of Directors shall establish a Project Management and Oversight Panel with eleven (11) members. Each of the University Representatives shall nominate three (3) candidates for the Project Management and Oversight Panel, and the Board of Directors shall select eleven (11) of such twenty-one (21) candidates to constitute the members of the Project Management and Oversight Panel. The eleven (11) members of the Project Management and Oversight Panel shall include: (i) six (6) scientists from disciplines related to the scientific fields in which the Corporation will likely pursue proposals, and one of such six (6) scientist members will be a medical doctor or a clinical practitioner; (ii) three (3) individuals that represent life sciences companies; and (iii) two (2) individuals that represent venture capital firms that actively invest in life sciences companies. The Project Management and Oversight Panel will work with the CEO and Board of Directors to develop criteria that shall govern the (a) Corporation's project solicitation from universities and companies; (b) review of projects in which the Corporation engages, and related decisions regarding the management and/or continuation of such projects; and (c) award of funds to companies and/or universities by the Corporation."

4. Except as expressly amended and superseded hereby, the Bylaws of the Corporation shall remain in full force and effect.

Effective Date: March 7, 2017

#### AMENDMENT TO SECOND AMENDED AND RESTATED BYLAWS

**OF** 

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

- 1. Article VI, Section 1 of the Second Amended and Restated Bylaws (the "Bylaws") of Virginia Biosciences Health Research Corporation, a Virginia nonstock corporation (the "Corporation"), is hereby amended and superseded in its entirety by the following:
  - "1. Number and Qualification. All corporate powers shall be exercised by or under the authority of, and the business and affairs of the Corporation shall be managed under the direction of, the Board of Directors. The Board of Directors shall consist of fourteen (14) persons who have demonstrated an interest in and concern for, as well as an ability to decide and address issues impacting upon, the Corporation's purposes, objectives and activities. The directors shall have the sole voting power. No person shall be denied membership on the Board of Directors by virtue of national origin, sex, religious affiliation, race, creed, color, or profession."
- 2. Article VI, Section 2 of the Bylaws of the Corporation is hereby amended and superseded in its entirety by the following:
  - Elections. At all times, eight (8) of the directors shall consist of ex-officio directors designated by entities controlled by the Commonwealth of Virginia. This is intended to satisfy Article IV, §16 of the Constitution of Virginia. The eight ex-officio directors shall be: the Secretary of Commerce and Trade of Virginia; the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; the president of Eastern Virginia Medical School; and the president of Old Dominion University. Each of the eight ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his agency or institution to act in his stead or terminate or replace an earlier designation. With respect to the additional six (6) directors: (a) one (1) director shall be a representative of the United States Department of Veterans Affairs ("VA Representative"); (b) two (2) directors shall be representatives of statewide health care system providers in Virginia ("Health Care System Representatives"); and (c) the Board of Directors shall designate an additional three (3) directors, such three (3) directors to be designated as follows: (x) one (1) director shall be a representative of a life sciences company; (y) one (1) director shall be a representative of a venture capital firm that regularly invests in life sciences companies; and (z) one (1) director shall be a statewide representative of the biosciences industry in Virginia."
- 3. Except as expressly amended and superseded hereby, the Bylaws of the Corporation shall remain in full force and effect.

Effective Date: January 6, 2016

#### AMENDMENT TO SECOND AMENDED AND RESTATED BYLAWS

**OF** 

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

- 1. Article VI, Section 2 of the Second Amended and Restated Bylaws (the "Bylaws") of Virginia Biosciences Health Research Corporation, a Virginia nonstock corporation (the "Corporation"), is hereby amended and superseded in its entirety by the following:
  - "2. <u>Elections</u>. At all times, eight (8) of the directors shall consist of ex-officio directors designated by entities controlled by the Commonwealth of Virginia. This is intended to satisfy Article IV, §16 of the Constitution of Virginia. The eight ex-officio directors shall be: the Secretary of Commerce and Trade of Virginia; the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University; the president of George Mason University; the president of Virginia Commonwealth University; the president of Eastern Virginia Medical School; and the president of Old Dominion University. Each of the eight ex-officio directors may, in a writing signed by the ex-officio director, designate an employee of his agency or institution to act in his stead or terminate or replace an earlier designation. With respect to the additional five (5) directors: (a) one (1) director shall be a representative of the United States Department of Veterans Affairs ("VA Representative"); (b) two (2) directors shall be representatives of statewide health care system providers in Virginia ("Health Care System Representatives"); and (c) the Board of Directors shall designate an additional two (2) directors, such two (2) directors to be designated as follows: (x) one (1) director shall be a representative of a life sciences company; and (y) one (1) director shall be a representative of a venture capital firm that regularly invests in life sciences companies."
- 2. Article VI, Section 17 of the Bylaws of the Corporation is hereby amended and superseded in its entirety by the following:
  - "17. Committees and Panels. The Board of Directors may create one or more committees and/or panels and appoint members of the Board of Directors to chair them. Members of the committees and/or panels other than the chairperson need not be directors. Each committee and/or panel may have two or more members, who shall serve at the pleasure of the Board of Directors. The provisions of this Article that govern meetings, action without meetings, and quorum and voting requirements of the Board of Directors, shall apply to committees and panels and their members as well. Each committee and panel may exercise the authority of the Board of Directors as delegated by the Board of Directors, subject to Section 13.1-869(D) of the Code. Without limiting the generality of the foregoing, the Board of Directors shall establish a Project Management and Oversight Panel with eleven (11) members. Each of the University Representatives shall nominate three (3) candidates for the Project Management and Oversight Panel, and

the Board of Directors shall select eleven (11) of such eighteen (18) candidates to constitute the members of the Project Management and Oversight Panel. The eleven (11) members of the Project Management and Oversight Panel shall include: (i) six (6) scientists from disciplines related to the scientific fields in which the Corporation will likely pursue proposals, and one of such six (6) scientist members will be a medical doctor or a clinical practitioner; (ii) three (3) individuals that represent life sciences companies; and (iii) two (2) individuals that represent venture capital firms that actively invest in life sciences companies. The Project Management and Oversight Panel will work with the CEO and Board of Directors to develop criteria that shall govern the (a) Corporation's project solicitation from universities and companies; (b) review of projects in which the Corporation engages, and related decisions regarding the management and/or continuation of such projects; and (c) award of funds to companies and/or universities by the Corporation."

3. Except as expressly amended and superseded hereby, the Bylaws of the Corporation shall remain in full force and effect.

Effective Date: February 25, 2014

#### SECOND AMENDED AND RESTATED BYLAWS

OF

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION ("Corporation"), a nonstock corporation duly formed under the provisions of the Virginia Nonstock Corporation Act. Chapter 10, Title 13.1 of the Code of Virginia ("Code"), hereby adopts the following Second Amended and Restated Bylaws of the Corporation which shall govern the management and operation of the Corporation's business and the regulation of its affairs, to the extent consistent with the Corporation's Articles of Incorporation ("Articles") and applicable law, and in accordance with Section 13.1-823 of the Code.

### ARTICLE I PURPOSE

The corporation is organized and shall be operated for educational and research purposes within the meaning of §501(c)(3) of the Internal Revenue Code of 1986, as amended, including without limitation, fostering life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities located within the Commonwealth of Virginia, stimulating industrial partnerships and increased corporate sponsored research at universities located within the Commonwealth of Virginia, and encouraging clinical cooperation with universities located within the Commonwealth of Virginia for patient-oriented studies.

### ARTICLE II DEFINITION OF TERMS

Unless otherwise stated in these Bylaws, all of the terms used in these Bylaws that are defined in Section 13.1-803 of the Code shall be deemed to have the meaning set forth in such Section of the Code. All pronouns and variations thereof shall be deemed to refer to the masculine or feminine, singular or plural, as the identity of the person or persons, may require.

## ARTICLE III ADOPTION

In accordance with Section 13.1-822 of the Code, these Bylaws shall become effective upon ratification, approval and formal adoption by the Board of Directors of the Corporation at its organizational meeting or any subsequent meeting.

### ARTICLE IV CORPORATE POWERS

Unless the Corporation's Articles of Incorporation provide otherwise, the Corporation shall have the same powers as an individual to do all things necessary or convenient to carry out its business and affairs, including, without limitation, those powers enumerated in Section 13.1-826 of the Code. In the event of an emergency as described in Article XIII, the Board of Directors shall have those emergency powers enumerated in Section 13.1-827 of the Code.

#### ARTICLE V NONSTOCK CORPORATION

In accordance with Section 13.1-814 of the Code, the Corporation shall not issue shares of stock. No dividend shall be paid and no part of the income of the Corporation shall be distributed to its directors or officers.

#### ARTICLE VI BOARD OF DIRECTORS

- 1. Number and Qualification. All corporate powers shall be exercised by or under the authority of, and the business and affairs of the Corporation shall be managed under the direction of, the Board of Directors. The Board of Directors shall consist of thirteen (13) persons who have demonstrated an interest in and concern for, as well as an ability to decide and address issues impacting upon, the Corporation's purposes, objectives and activities. The directors shall have the sole voting power. No person shall be denied membership on the Board of Directors by virtue of national origin, sex, religious affiliation, race, creed, color, or profession.
- 2. Elections. At all times, seven (7) of the directors shall consist of ex-officio directors designated by entities controlled by the Commonwealth of Virginia. This is intended to satisfy Article IV, §16 of the Constitution of Virginia. The seven ex-officio directors shall be: the Secretary of Commerce and Trade of Virginia: the President and Chief Executive Officer of the Virginia Economic Development Partnership Authority; the president of the University of Virginia; the president of the Virginia Polytechnic Institute and State University: the president of George Mason University: the president of Virginia Commonwealth University; and the president of Eastern Virginia Medical School. Each of the seven ex-officio directors may, in a writing signed by the exofficio director, designate an employee of his agency or institution to act in his stead or terminate or replace an earlier designation. With respect to the additional six (6) directors: (a) one (1) director shall be a representative of the United States Department of Veterans Affairs ("VA Representative"); (b) two (2) directors shall be representatives of statewide health care system providers in Virginia ("Health Care System Representatives"); and (c) the Board of Directors shall designate an additional three (3) directors, such three (3) directors to be designated as follows: (x) one (1) director shall be a representative of a large life sciences company; (y) one (1) director shall be a representative of a venture capital firm that regularly invests in life sciences

companies; and (z) one (1) director shall be a representative of a small and/or medium sized life sciences company with operations located within the Commonwealth of Virginia.

- 3. Term. The term of each director shall expire on the date that is three (3) years from the date on which he or she is elected (if he or she is elected at the annual meeting of the Board of Directors), or on the date that the third annual meeting of the Board of Directors is held after the date on which he or she is elected (if he or she is elected between annual meetings of the Board of Directors) or, if earlier, (i) such earlier time as is specified at the initial election of such director or (ii) when his or her successor shall have been duly elected and qualified. Notwithstanding the foregoing, the appropriate designator identified in Section 2 above may choose to extend the term of any elected director for one additional three (3) year term. Despite the expiration of a director's term, such director shall continue to serve until his or her successor is elected and qualifies or until there is a decrease in the number of directors. Any director named to replace a director shall serve for the unexpired term of the director whom he or she is replacing.
- 4. <u>Resignation and Removal</u>. A director may resign at any time by delivering written notice to the Board of Directors or the Chair. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. The Board of Directors may remove one or more directors with or without cause. A director may be removed if the number of votes cast to remove him constitutes a majority of the votes entitled to be cast at an election of directors.
- 5. <u>Vacancy</u>. If a vacancy occurs on the Board of Directors, including a vacancy resulting from an increase in the number of directors, the vacancy may be filled by the appropriate designator identified in Section 2 above.
- 6. Annual Meeting. The Board of Directors shall meet at least annually during the month of January for the purposes of general organization, the election of officers and directors, the designation of committees/panels and consideration of any other business that may properly be brought before the meeting. The failure to hold the annual meeting at the time stated herein shall not affect the validity of any corporate action.
- 7. Regular or Special Meetings in Addition to the Annual Meeting. Regular or special meetings of the Board of Directors may be held upon notice by word-of-mouth, letter, telegram, cable, phone or electronic mail delivered not later than forty-eight (48) hours preceding the time for the meeting, upon call of the Chair or at least two (2) directors. The Chair shall call a meeting of the Board of Directors upon his or her receipt of written notice requiring a meeting by any ex-officio director.
- 8. <u>Place of Meetings</u>. Meetings of the Board of Directors, annual, regular or special, may be held either within or without the Commonwealth of Virginia.
- 9. <u>Ouorum and Voting</u>. Action may be taken on a matter by the Board of Directors only at a meeting at which a quorum is present. A quorum of the Board of Directors shall consist

of not less than a majority of the number of voting directors on the Board of Directors. If a quorum is present when a vote is taken, the affirmative vote of a majority of voting directors present is the act of the Board of Directors.

- 10. Conduct of Meetings. The Chair shall preside over all meetings of the directors. If the Chair is not present, the Vice Chair or, if there be none, the Secretary shall preside. If none of the aforementioned persons are present, a chair shall be elected by the meeting. The Secretary shall act as secretary of the meetings if present. If the Secretary is not present, the person presiding over the meeting shall appoint a secretary of the meeting. The Board of Directors may permit any or all directors to participate in a regular or special meeting by, or conduct a meeting through the use of, any means of communications by which all directors participating may simultaneously hear each other during the meeting.
- Board of Directors' meeting may be taken without a meeting if the action is taken by all voting members of the Board of Directors. The action shall be evidenced by one or more written consents stating the action taken, signed by each director either before or after the action taken, and included in the minutes or filed with the corporate records reflecting the action taken. Action taken under this Section is effective when the last director signs the consent unless the consent specifies a different date, in which event the action taken is effective as of the date specified therein provided the consent states the date of execution by each director. A consent signed under this Section shall have the same effect of a meeting vote and may be described as such in any document.
- 12. Appointment of Chair, Vice Chair, Secretary and Treasurer. The Chair, Vice Chair, Secretary and Treasurer (collectively, the "Board Officers") shall be elected by the Board of Directors at each annual meeting of the Board of Directors, or upon a vacancy, and shall serve at the pleasure of the Board of Directors. Any Board Officer may resign at any time by delivering written notice to the Board of Directors. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made at a later date and the Corporation accepts the future effective date, it may fill the pending vacancy before the effective date if his successor does not take office until the effective date. The Board of Directors may remove any Board Officer at any time with or without cause. Whenever any vacancy occurs in any Board Officer position, the vacancy shall be filled by the Board of Directors.
- 13. <u>Duties of Chair</u>. The Chair shall preside over all meetings of the Board of Directors, and shall perform all duties incident to such office and such other duties as may from time to time be assigned to him or her by the Board of Directors.
- 14. <u>Duties of Vice Chair</u>. In the Chair's absence, the Vice Chair shall preside over meetings of the Board of Directors and discharge such other duties pertaining to the office of the Chair that may arise during the Chair's absence. The Vice Chair also shall perform such other duties as may from time to time be assigned by the Board of Directors.

- Duties of Secretary. The Secretary shall attend all meetings of the Board of Directors, and shall have the responsibility for preparing and maintaining custody of minutes of the directors meetings and for authenticating records of the Corporation. The Secretary shall keep or cause to be kept in a book provided for the purpose a true and complete record of the proceedings of all meetings. The Secretary shall be custodian of the records and the seal of the Corporation and shall see that the seal is affixed to all documents, the execution of which on behalf of the Corporation under its seal have been duly authorized. The Secretary shall attend to the giving of all notices and shall perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 16. <u>Duties of Treasurer</u>. The Treasurer shall furnish at meetings of the Board of Directors, or whenever requested, a statement of the financial condition of the Corporation, and shall perform such other duties as these Bylaws or the Board of Directors may prescribe.
- Committees and Panels. The Board of Directors may create one or more committees and/or panels and appoint members of the Board of Directors to chair them. Members of the committees and/or panels other than the chairperson need not be directors. Each committee and/or panel may have two or more members, who shall serve at the pleasure of the Board of Directors. The provisions of this Article that govern meetings, action without meetings, and quorum and voting requirements of the Board of Directors, shall apply to committees and panels and their members as well. Each committee and panel may exercise the authority of the Board of Directors as delegated by the Board of Directors, subject to Section 13.1-869(D) of the Code. Without limiting the generality of the foregoing, the Board of Directors shall establish a Project Management and Oversight Panel with eleven (11) members. Each of the University Representatives shall nominate three (3) candidates for the Project Management and Oversight Panel, and the Board of Directors shall select eleven (11) of such fifteen (15) candidates to constitute the members of the Project Management and Oversight Panel. The eleven (11) members of the Project Management and Oversight Panel shall include: (i) six (6) scientists from disciplines related to the scientific fields in which the Corporation will likely pursue proposals, and one of such six (6) scientist members will be a medical doctor or a clinical practitioner; (ii) three (3) individuals that represent life sciences companies; and (iii) two (2) individuals that represent venture capital firms that actively invest in life sciences companies. The Project Management and Oversight Panel will work with the CEO and Board of Directors to develop criteria that shall govern the (a) Corporation's project solicitation from universities and companies; (b) review of projects in which the Corporation engages, and related decisions regarding the management and/or continuation of such projects; and (c) award of funds to companies and/or universities by the Corporation.

### ARTICLE VII OFFICERS

1. General. The officers of the Corporation shall consist of a President, and such other officers and assistant officers and agents as may be deemed necessary by the Board of

Directors from time to time. All officers shall be elected by the Board of Directors and shall serve at the pleasure of the Board of Directors for such compensation as may be fixed by the Board of Directors. Any two or more offices may be held by the same person. A duly appointed officer may appoint one or more officers or assistant officers if authorized by the Board of Directors.

- 2. Resignation and Removal. An officer may resign at any time by delivering written notice to the Board of Directors. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made at a later date and the Corporation accepts the future effective date, it may fill the pending vacancy before the effective date if his successor does not take office until the effective date. The Board of Directors may remove any officer at any time with or without cause and any officer or assistant officer, if appointed by another officer, may likewise be removed by such officer.
- 3. <u>Vacancies</u>. Whenever any vacancies shall occur in any office, the vacancy shall be filled by the Board of Directors.
- 4. <u>The President.</u> The President shall be the chief executive officer and shall have active executive management of the operations of the Corporation, subject to the control of the Board of Directors. The President shall see that all policies, orders and resolutions of the Board of Directors are carried out and perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 5. <u>Transfer of Authority.</u> In case of the absence of any officer of the Corporation or for any other reason that the Board of Directors may deem sufficient, the Board of Directors may transfer the powers or duties of that office to any other officer or to any other director or employee of the Corporation.

# ARTICLE VIII SPECIAL CORPORATE ACTS NEGOTIABLE INSTRUMENTS, DEEDS AND CONTRACTS

All checks, drafts, notes, bonds, bills of exchange, and orders for the payment of money of the Corporation (collectively, the "Orders For Payment"); all deeds, mortgages, and other written contracts and agreements to which the Corporation shall be a party; and all assignments or endorsements of registered bonds or other securities owned by the Corporation, shall be signed by such officers and/or directors as the Board of Directors may from time to time direct, provided that all Orders For Payment shall be signed by an officer and countersigned by the Treasurer. Subject to the foregoing, the Board of Directors may authorize any one of its officers to sign any of such instruments, for and in behalf of the Corporation, without necessity of countersignature; may designate officers or employees of the Corporation, other than those named above, who may, in the name of the Corporation, sign such instruments; and may authorize the use of facsimile signatures of any of such persons.

### ARTICLE IX TRANSACTIONS WITH DIRECTORS

Any contract or other transaction between the Corporation and one or more of its directors, or between the Corporation and any firm of which one or more of its directors are members or employees, or in which they are interested, or between the Corporation and any corporation or association of which one or more of its directors are shareholders, members, directors, officers or employees, or in which they are not interested, shall be valid for all purposes, notwithstanding the presence of the director or directors at the meeting of the Board of Directors of the Corporation that acts upon, or in reference to, such contract or transaction, and notwithstanding his or their participation in the action, only if the fact of such interest be disclosed or known to the Board of Directors and the Board of Directors shall, nevertheless, authorize or ratify such contract or transaction, the interested director or directors to be counted in determining whether a quorum is present and to be entitled to vote on such authorization or ratification. This section shall be construed to invalidate any such interested contract or transaction that would otherwise be valid under the common and statutory law applicable to it.

### ARTICLE X CORPORATE SEAL

The corporate seal shall be in such form as shall be approved by the Board of Directors.

### ARTICLE XI FISCAL YEAR

The fiscal year of the Corporation shall be determined by the Board of Directors in its discretion, subject to applicable law.

### ARTICLE XII AMENDMENTS

Any action taken or authorized by the Board of Directors which would be inconsistent with the Bylaws then in effect, but is taken or authorized by the affirmative vote of not less than the number of directors that would be required to amend these Bylaws so that the Bylaws would be consistent with such action, shall be given the same effect as if these Bylaws had been temporarily amended or suspended to the extent necessary to permit the specific action so taken or authorized.

These Bylaws may be amended or repealed by the majority vote of the voting directors at a meeting at which a majority of the voting directors then in office is present, provided that written notice shall be given of such meeting and shall include (i) notice that an amendment to these Bylaws will be considered at such meeting and (ii) a fair summary of such amendment to be acted upon.

### ARTICLE XIII EMERGENCY BYLAWS

In the event that a quorum of the Corporation's Board of Directors cannot readily be assembled because of some catastrophic event, the Board of Directors of the Corporation may, consistent with Section 13.1-824 of the Code, adopt other bylaws to be effective only in such an emergency, which bylaws shall be subject to amendment or repeal by the Board of Directors, and shall provide procedures for calling a meeting, and designation of additional or substitute directors, as well as other provisions necessary for managing the Corporation during such emergency. All provisions of these Bylaws consistent with such emergency bylaws shall remain effective during such emergency. Such emergency bylaws shall not be effective after such emergency ends. Corporate action taken in good faith in accordance with such emergency bylaws shall bind the Corporation and may not be used to impose liability on a director, officer, employee or agent of the Corporation.

Effective: July 25, 2013

#### AMENDED AND RESTATED BYLAWS

**OF** 

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION ("Corporation"), a nonstock corporation duly formed under the provisions of the Virginia Nonstock Corporation Act, Chapter 10, Title 13.1 of the Code of Virginia ("Code"), hereby adopts the following Amended and Restated Bylaws of the Corporation which shall govern the management and operation of the Corporation's business and the regulation of its affairs, to the extent consistent with the Corporation's Articles of Incorporation ("Articles") and applicable law, and in accordance with Section 13.1-823 of the Code.

### ARTICLE I PURPOSE

The corporation is organized and shall be operated for educational and research purposes within the meaning of §501(c)(3) of the Internal Revenue Code of 1986, as amended, including without limitation, fostering life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities located within the Commonwealth of Virginia, stimulating industrial partnerships and increased corporate sponsored research at universities located within the Commonwealth of Virginia, and encouraging clinical cooperation with universities located within the Commonwealth of Virginia for patient-oriented studies.

### ARTICLE II DEFINITION OF TERMS

Unless otherwise stated in these Bylaws, all of the terms used in these Bylaws that are defined in Section 13.1-803 of the Code shall be deemed to have the meaning set forth in such Section of the Code. All pronouns and variations thereof shall be deemed to refer to the masculine or feminine, singular or plural, as the identity of the person or persons, may require.

### ARTICLE III ADOPTION

In accordance with Section 13.1-822 of the Code, these Bylaws shall become effective upon ratification, approval and formal adoption by the Board of Directors of the Corporation at its organizational meeting or any subsequent meeting.

### ARTICLE IV CORPORATE POWERS

Unless the Corporation's Articles of Incorporation provide otherwise, the Corporation shall have the same powers as an individual to do all things necessary or convenient to carry out its business and affairs, including, without limitation, those powers enumerated in Section 13.1-826 of the Code. In the event of an emergency as described in Article XIII, the Board of Directors shall have those emergency powers enumerated in Section 13.1-827 of the Code.

## ARTICLE V NONSTOCK CORPORATION

In accordance with Section 13.1-814 of the Code, the Corporation shall not issue shares of stock. No dividend shall be paid and no part of the income of the Corporation shall be distributed to its directors or officers.

### ARTICLE VI BOARD OF DIRECTORS

- 1. Number and Qualification. All corporate powers shall be exercised by or under the authority of, and the business and affairs of the Corporation shall be managed under the direction of, the Board of Directors. The Board of Directors shall consist of not less than nine (9) nor more than fifteen (15) persons who have demonstrated an interest in and concern for, as well as an ability to decide and address issues impacting upon, the Corporation's purposes, objectives and activities. The initial Board of Directors shall consist of thirteen (13) persons. The directors shall have the sole voting power. No person shall be denied membership on the Board of Directors by virtue of national origin, sex, religious affiliation, race, creed, color, or profession.
- 2. <u>Elections.</u> At all times, a majority of the Board of Directors shall consist of persons designated by entities controlled by the Commonwealth of Virginia. This is intended to satisfy Article IV, §16 of the Constitution of Virginia. One (1) director shall be designated by each of the following universities (collectively, the "University Representatives"): University of Virginia, Virginia Polytechnic Institute and State University, George Mason University, Virginia Commonwealth University and Eastern Virginia Medical School. Five (5) additional directors shall be designated by the Secretary of Commerce and Trade of Virginia, such five (5) directors to be designated as follows: (a) one (1) director shall be a representative of the Secretary of Commerce and Trade of Virginia; (b) two (2) directors shall be representatives of statewide health care system providers in Virginia ("Health Care System Representatives"); (c) one (1) director shall be a representative of the United States Department of Veterans Affairs ("VA Representative"); and (d) one (1) director shall be a representative of the Virginia Economic Development Partnership. The Board of Directors shall designate an additional three (3) directors, such three (3) directors to be designated as follows: (x) one (1) director shall be a

representative of a large life sciences company; (y) one (1) director shall be a representative of a venture capital firm that regularly invests in life sciences companies; and (z) one (1) director shall be a representative of a small and/or medium sized life sciences company with operations located within the Commonwealth of Virginia.

- 3. Term. The term of each director shall expire on the date that is three (3) years from the date on which he or she is elected (if he or she is elected at the annual meeting of the Board of Directors), or on the date that the third annual meeting of the Board of Directors is held after the date on which he or she is elected (if he or she is elected between annual meetings of the Board of Directors) or, if earlier, (i) such earlier time as is specified at the initial election of such director or (ii) when his or her successor shall have been duly elected and qualified. Notwithstanding the foregoing, the appropriate designator identified in Section 2 above may choose to extend the term of any elected director for one additional three (3) year term. Despite the expiration of a director's term, such director shall continue to serve until his or her successor is elected and qualifies or until there is a decrease in the number of directors. Any director named to replace a director shall serve for the unexpired term of the director whom he or she is replacing.
- 4. <u>Resignation and Removal</u>. A director may resign at any time by delivering written notice to the Board of Directors or the Chair. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. The Board of Directors may remove one or more directors with or without cause. A director may be removed if the number of votes cast to remove him constitutes a majority of the votes entitled to be cast at an election of directors.
- 5. <u>Vacancy</u>. If a vacancy occurs on the Board of Directors, including a vacancy resulting from an increase in the number of directors, the vacancy may be filled by the appropriate designator identified in Section 2 above.
- 6. Annual Meeting. The Board of Directors shall meet at least annually during the month of January for the purposes of general organization, the election of officers and directors, the designation of committees/panels and consideration of any other business that may properly be brought before the meeting. The failure to hold the annual meeting at the time stated herein shall not affect the validity of any corporate action.
- 7. Regular or Special Meetings in Addition to the Annual Meeting. Regular or special meetings of the Board of Directors may be held upon notice by word-of-mouth, letter, telegram, cable, phone or electronic mail delivered not later than forty-eight (48) hours preceding the time for the meeting, upon call of the Chair or at least two (2) directors.
- 8. <u>Place of Meetings</u>. Meetings of the Board of Directors, annual, regular or special, may be held either within or without the Commonwealth of Virginia.
- 9. Quorum and Voting. Action may be taken on a matter by the Board of Directors only at a meeting at which a quorum is present. A quorum of the Board of Directors shall consist

of not less than a majority of the number of voting directors on the Board of Directors. If a quorum is present when a vote is taken, the affirmative vote of a majority of voting directors present is the act of the Board of Directors.

- 10. Conduct of Meetings. The Chair shall preside over all meetings of the directors. If the Chair is not present, the Vice Chair or, if there be none, the Secretary shall preside. If none of the aforementioned persons are present, a chair shall be elected by the meeting. The Secretary shall act as secretary of the meetings if present. If the Secretary is not present, the person presiding over the meeting shall appoint a secretary of the meeting. The Board of Directors may permit any or all directors to participate in a regular or special meeting by, or conduct a meeting through the use of, any means of communications by which all directors participating may simultaneously hear each other during the meeting.
- 11. Action Without a Meeting. Any action required or permitted to be taken at a Board of Directors' meeting may be taken without a meeting if the action is taken by all voting members of the Board of Directors. The action shall be evidenced by one or more written consents stating the action taken, signed by each director either before or after the action taken, and included in the minutes or filed with the corporate records reflecting the action taken. Action taken under this Section is effective when the last director signs the consent unless the consent specifies a different date, in which event the action taken is effective as of the date specified therein provided the consent states the date of execution by each director. A consent signed under this Section shall have the same effect of a meeting vote and may be described as such in any document.
- 12. Appointment of Chair, Vice Chair, Secretary and Treasurer. The Chair, Vice Chair, Secretary and Treasurer (collectively, the "Board Officers") shall be elected by the Board of Directors at each annual meeting of the Board of Directors, or upon a vacancy, and shall serve at the pleasure of the Board of Directors. Any Board Officer may resign at any time by delivering written notice to the Board of Directors. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made at a later date and the Corporation accepts the future effective date, it may fill the pending vacancy before the effective date if his successor does not take office until the effective date. The Board of Directors may remove any Board Officer at any time with or without cause. Whenever any vacancy occurs in any Board Officer position, the vacancy shall be filled by the Board of Directors.
- 13. <u>Duties of Chair</u>. The Chair shall preside over all meetings of the Board of Directors, and shall perform all duties incident to such office and such other duties as may from time to time be assigned to him or her by the Board of Directors.
- 14. <u>Duties of Vice Chair</u>. In the Chair's absence, the Vice Chair shall preside over meetings of the Board of Directors and discharge such other duties pertaining to the office of the Chair that may arise during the Chair's absence. The Vice Chair also shall perform such other duties as may from time to time be assigned by the Board of Directors.

- Directors, and shall have the responsibility for preparing and maintaining custody of minutes of the directors meetings and for authenticating records of the Corporation. The Secretary shall keep or cause to be kept in a book provided for the purpose a true and complete record of the proceedings of all meetings. The Secretary shall be custodian of the records and the seal of the Corporation and shall see that the seal is affixed to all documents, the execution of which on behalf of the Corporation under its seal have been duly authorized. The Secretary shall attend to the giving of all notices and shall perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 16. <u>Duties of Treasurer</u>. The Treasurer shall furnish at meetings of the Board of Directors, or whenever requested, a statement of the financial condition of the Corporation, and shall perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 17. Committees and Panels. The Board of Directors may create one or more committees and/or panels and appoint members of the Board of Directors to chair them. Members of the committees and/or panels other than the chairperson need not be directors. Each committee and/or panel may have two or more members, who shall serve at the pleasure of the Board of Directors. The provisions of this Article that govern meetings, action without meetings, and quorum and voting requirements of the Board of Directors, shall apply to committees and panels and their members as well. Each committee and panel may exercise the authority of the Board of Directors as delegated by the Board of Directors, subject to Section 13.1-869(D) of the Code. Without limiting the generality of the foregoing, the Board of Directors shall establish a Project Management and Oversight Panel with eleven (11) members. Each of the University Representatives shall nominate three (3) candidates for the Project Management and Oversight Panel, and the Board of Directors shall select eleven (11) of such fifteen (15) candidates to constitute the members of the Project Management and Oversight Panel. The eleven (11) members of the Project Management and Oversight Panel shall include: (i) six (6) scientists from disciplines related to the scientific fields in which the Corporation will likely pursue proposals, and one of such six (6) scientist members will be a medical doctor or a clinical practitioner; (ii) three (3) individuals that represent life sciences companies; and (iii) two (2) individuals that represent venture capital firms that actively invest in life sciences companies. The Project Management and Oversight Panel will work with the CEO and Board of Directors to develop criteria that shall govern the (a) Corporation's project solicitation from universities and companies; (b) review of projects in which the Corporation engages, and related decisions regarding the management and/or continuation of such projects; and (c) award of funds to companies and/or universities by the Corporation.

## ARTICLE VII OFFICERS

1. General. The officers of the Corporation shall consist of a President, and such other officers and assistant officers and agents as may be deemed necessary by the Board of

Directors from time to time. All officers shall be elected by the Board of Directors and shall serve at the pleasure of the Board of Directors for such compensation as may be fixed by the Board of Directors. Any two or more offices may be held by the same person. A duly appointed officer may appoint one or more officers or assistant officers if authorized by the Board of Directors.

- 2. <u>Resignation and Removal.</u> An officer may resign at any time by delivering written notice to the Board of Directors. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made at a later date and the Corporation accepts the future effective date, it may fill the pending vacancy before the effective date if his successor does not take office until the effective date. The Board of Directors may remove any officer at any time with or without cause and any officer or assistant officer, if appointed by another officer, may likewise be removed by such officer.
- 3. <u>Vacancies</u>. Whenever any vacancies shall occur in any office, the vacancy shall be filled by the Board of Directors.
- 4. <u>The President</u>. The President shall be the chief executive officer and shall have active executive management of the operations of the Corporation, subject to the control of the Board of Directors. The President shall see that all policies, orders and resolutions of the Board of Directors are carried out and perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 5. <u>Transfer of Authority</u>. In case of the absence of any officer of the Corporation or for any other reason that the Board of Directors may deem sufficient, the Board of Directors may transfer the powers or duties of that office to any other officer or to any other director or employee of the Corporation.

# ARTICLE VIII <u>SPECIAL CORPORATE ACTS</u> NEGOTIABLE INSTRUMENTS, DEEDS AND CONTRACTS

All checks, drafts, notes, bonds, bills of exchange, and orders for the payment of money of the Corporation (collectively, the "Orders For Payment"); all deeds, mortgages, and other written contracts and agreements to which the Corporation shall be a party; and all assignments or endorsements of registered bonds or other securities owned by the Corporation, shall be signed by such officers and/or directors as the Board of Directors may from time to time direct, provided that all Orders For Payment shall be signed by an officer and countersigned by the Treasurer. Subject to the foregoing, the Board of Directors may authorize any one of its officers to sign any of such instruments, for and in behalf of the Corporation, without necessity of countersignature; may designate officers or employees of the Corporation, other than those named above, who may, in the name of the Corporation, sign such instruments; and may authorize the use of facsimile signatures of any of such persons.

### ARTICLE IX TRANSACTIONS WITH DIRECTORS

Any contract or other transaction between the Corporation and one or more of its directors, or between the Corporation and any firm of which one or more of its directors are members or employees, or in which they are interested, or between the Corporation and any corporation or association of which one or more of its directors are shareholders, members, directors, officers or employees, or in which they are not interested, shall be valid for all purposes, notwithstanding the presence of the director or directors at the meeting of the Board of Directors of the Corporation that acts upon, or in reference to, such contract or transaction, and notwithstanding his or their participation in the action, only if the fact of such interest be disclosed or known to the Board of Directors and the Board of Directors shall, nevertheless, authorize or ratify such contract or transaction, the interested director or directors to be counted in determining whether a quorum is present and to be entitled to vote on such authorization or ratification. This section shall be construed to invalidate any such interested contract or transaction that would otherwise be valid under the common and statutory law applicable to it.

### ARTICLE X CORPORATE SEAL

The corporate seal shall be in such form as shall be approved by the Board of Directors.

### ARTICLE XI FISCAL YEAR

The fiscal year of the Corporation shall be determined by the Board of Directors in its discretion, subject to applicable law.

### ARTICLE XII AMENDMENTS

Any action taken or authorized by the Board of Directors which would be inconsistent with the Bylaws then in effect, but is taken or authorized by the affirmative vote of not less than the number of directors that would be required to amend these Bylaws so that the Bylaws would be consistent with such action, shall be given the same effect as if these Bylaws had been temporarily amended or suspended to the extent necessary to permit the specific action so taken or authorized.

These Bylaws may be amended or repealed by the majority vote of the voting directors at a meeting at which a majority of the voting directors then in office is present, provided that written notice shall be given of such meeting and shall include (i) notice that an amendment to these Bylaws will be considered at such meeting and (ii) a fair summary of such amendment to be acted upon.

### ARTICLE XIII EMERGENCY BYLAWS

In the event that a quorum of the Corporation's Board of Directors cannot readily be assembled because of some catastrophic event, the Board of Directors of the Corporation may, consistent with Section 13.1-824 of the Code, adopt other bylaws to be effective only in such an emergency, which bylaws shall be subject to amendment or repeal by the Board of Directors, and shall provide procedures for calling a meeting, and designation of additional or substitute directors, as well as other provisions necessary for managing the Corporation during such emergency. All provisions of these Bylaws consistent with such emergency bylaws shall remain effective during such emergency. Such emergency bylaws shall not be effective after such emergency ends. Corporate action taken in good faith in accordance with such emergency bylaws shall bind the Corporation and may not be used to impose liability on a director, officer, employee or agent of the Corporation.

Effective: June 14, 2013

#### **BYLAWS**

OF

#### VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION

VIRGINIA BIOSCIENCES HEALTH RESEARCH CORPORATION ("Corporation"), a nonstock corporation duly formed under the provisions of the Virginia Nonstock Corporation Act, Chapter 10, Title 13.1 of the Code of Virginia ("Code"), hereby adopts the following Bylaws of the Corporation which shall govern the management and operation of the Corporation's business and the regulation of its affairs, to the extent consistent with the Corporation's Articles of Incorporation ("Articles") and applicable law, and in accordance with Section 13.1-823 of the Code.

### ARTICLE I PURPOSE

The corporation is organized and shall be operated for educational and research purposes within the meaning of \$501(c)(3) of the Internal Revenue Code of 1986, as amended, including without limitation, fostering life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities located within the Commonwealth of Virginia, stimulating industrial partnerships and increased corporate sponsored research at universities located within the Commonwealth of Virginia, and encouraging clinical cooperation with universities located within the Commonwealth of Virginia for patient-oriented studies.

### ARTICLE II DEFINITION OF TERMS

Unless otherwise stated in these Bylaws, all of the terms used in these Bylaws that are defined in Section 13.1-803 of the Code shall be deemed to have the meaning set forth in such Section of the Code. All pronouns and variations thereof shall be deemed to refer to the masculine or feminine, singular or plural, as the identity of the person or persons, may require.

### ARTICLE III ADOPTION

In accordance with Section 13.1-822 of the Code, these Bylaws shall become effective upon ratification, approval and formal adoption by the Board of Directors of the Corporation at its organizational meeting or any subsequent meeting.

### ARTICLE IV CORPORATE POWERS

Unless the Corporation's Articles of Incorporation provide otherwise, the Corporation shall have the same powers as an individual to do all things necessary or convenient to carry out its business and affairs, including, without limitation, those powers enumerated in Section 13.1-826 of the Code. In the event of an emergency as described in Article XIII, the Board of Directors shall have those emergency powers enumerated in Section 13.1-827 of the Code.

### ARTICLE V NONSTOCK CORPORATION

In accordance with Section 13.1-814 of the Code, the Corporation shall not issue shares of stock. No dividend shall be paid and no part of the income of the Corporation shall be distributed to its directors or officers.

### ARTICLE VI BOARD OF DIRECTORS

- 1. Number and Qualification. All corporate powers shall be exercised by or under the authority of, and the business and affairs of the Corporation shall be managed under the direction of, the Board of Directors. The Board of Directors shall consist of not less than nine (9) nor more than fifteen (15) persons who have demonstrated an interest in and concern for, as well as an ability to decide and address issues impacting upon, the Corporation's purposes, objectives and activities. The initial Board of Directors shall consist of thirteen (13) persons. The directors shall have the sole voting power. No person shall be denied membership on the Board of Directors by virtue of national origin, sex, religious affiliation, race, creed, color, or profession.
- 2. <u>Elections.</u> One (1) director shall be designated by each of the following universities (collectively, the "University Representatives"): University of Virginia, Virginia Polytechnic Institute and State University, George Mason University, Virginia Commonwealth University and Eastern Virginia Medical School. Five (5) additional directors shall be designated by the Secretary of Commerce and Trade of Virginia, such five (5) directors to be designated as follows: (a) one (1) director shall be a representative of the Secretary of Commerce and Trade of Virginia; (b) two (2) directors shall be representatives of statewide health care system providers in Virginia ("Health Care System Representatives"); (c) one (1) director shall be a representative of the United States Department of Veterans Affairs ("VA Representative"); and (d) one (1) director shall be a representative of the Virginia Economic Development Partnership. The Board of Directors shall designate an additional three (3) directors, such three (3) directors to be designated as follows: (x) one (1) director shall be a representative of a large life sciences company; (y) one (1) director shall be a representative of a venture capital firm that regularly invests in life sciences companies; and (z) one (1) director shall be a representative of a small

and/or medium sized life sciences company with operations located within the Commonwealth of Virginia.

- 3. Term. The term of each director shall expire on the date that is three (3) years from the date on which he or she is elected (if he or she is elected at the annual meeting of the Board of Directors), or on the date that the third annual meeting of the Board of Directors is held after the date on which he or she is elected (if he or she is elected between annual meetings of the Board of Directors) or, if earlier, (i) such earlier time as is specified at the initial election of such director or (ii) when his or her successor shall have been duly elected and qualified. Notwithstanding the foregoing, the appropriate designator identified in Section 2 above may choose to extend the term of any elected director for one additional three (3) year term. Despite the expiration of a director's term, such director shall continue to serve until his or her successor is elected and qualifies or until there is a decrease in the number of directors. Any director named to replace a director shall serve for the unexpired term of the director whom he or she is replacing.
- 4. <u>Resignation and Removal</u>. A director may resign at any time by delivering written notice to the Board of Directors or the Chair. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. The Board of Directors may remove one or more directors with or without cause. A director may be removed if the number of votes cast to remove him constitutes a majority of the votes entitled to be cast at an election of directors.
- 5. <u>Vacancy</u>. If a vacancy occurs on the Board of Directors, including a vacancy resulting from an increase in the number of directors, the vacancy may be filled by the appropriate designator identified in Section 2 above.
- 6. Annual Meeting. The Board of Directors shall meet at least annually during the month of January for the purposes of general organization, the election of officers and directors, the designation of committees/panels and consideration of any other business that may properly be brought before the meeting. The failure to hold the annual meeting at the time stated herein shall not affect the validity of any corporate action.
- 7. Regular or Special Meetings in Addition to the Annual Meeting. Regular or special meetings of the Board of Directors may be held upon notice by word-of-mouth, letter, telegram, cable, phone or electronic mail delivered not later than forty-eight (48) hours preceding the time for the meeting, upon call of the Chair or at least two (2) directors.
- 8. <u>Place of Meetings</u>. Meetings of the Board of Directors, annual, regular or special, may be held either within or without the Commonwealth of Virginia.
- 9. Quorum and Voting. Action may be taken on a matter by the Board of Directors only at a meeting at which a quorum is present. A quorum of the Board of Directors shall consist of not less than a majority of the number of voting directors on the Board of Directors. If a

quorum is present when a vote is taken, the affirmative vote of a majority of voting directors present is the act of the Board of Directors.

- 10. <u>Conduct of Meetings</u>. The Chair shall preside over all meetings of the directors. If the Chair is not present, the Vice Chair or, if there be none, the Secretary shall preside. If none of the aforementioned persons are present, a chair shall be elected by the meeting. The Secretary shall act as secretary of the meetings if present. If the Secretary is not present, the person presiding over the meeting shall appoint a secretary of the meeting. The Board of Directors may permit any or all directors to participate in a regular or special meeting by, or conduct a meeting through the use of, any means of communications by which all directors participating may simultaneously hear each other during the meeting.
- 11. Action Without a Meeting. Any action required or permitted to be taken at a Board of Directors' meeting may be taken without a meeting if the action is taken by all voting members of the Board of Directors. The action shall be evidenced by one or more written consents stating the action taken, signed by each director either before or after the action taken, and included in the minutes or filed with the corporate records reflecting the action taken. Action taken under this Section is effective when the last director signs the consent unless the consent specifies a different date, in which event the action taken is effective as of the date specified therein provided the consent states the date of execution by each director. A consent signed under this Section shall have the same effect of a meeting vote and may be described as such in any document.
- 12. Appointment of Chair, Vice Chair, Secretary and Treasurer. The Chair, Vice Chair, Secretary and Treasurer (collectively, the "Board Officers") shall be elected by the Board of Directors at each annual meeting of the Board of Directors, or upon a vacancy, and shall serve at the pleasure of the Board of Directors. Any Board Officer may resign at any time by delivering written notice to the Board of Directors. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made at a later date and the Corporation accepts the future effective date, it may fill the pending vacancy before the effective date if his successor does not take office until the effective date. The Board of Directors may remove any Board Officer at any time with or without cause. Whenever any vacancy occurs in any Board Officer position, the vacancy shall be filled by the Board of Directors.
- 13. <u>Duties of Chair</u>. The Chair shall preside over all meetings of the Board of Directors, and shall perform all duties incident to such office and such other duties as may from time to time be assigned to him or her by the Board of Directors.
- 14. <u>Duties of Vice Chair</u>. In the Chair's absence, the Vice Chair shall preside over meetings of the Board of Directors and discharge such other duties pertaining to the office of the Chair that may arise during the Chair's absence. The Vice Chair also shall perform such other duties as may from time to time be assigned by the Board of Directors.

- Directors, and shall have the responsibility for preparing and maintaining custody of minutes of the directors meetings and for authenticating records of the Corporation. The Secretary shall keep or cause to be kept in a book provided for the purpose a true and complete record of the proceedings of all meetings. The Secretary shall be custodian of the records and the seal of the Corporation and shall see that the seal is affixed to all documents, the execution of which on behalf of the Corporation under its seal have been duly authorized. The Secretary shall attend to the giving of all notices and shall perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 16. <u>Duties of Treasurer</u>. The Treasurer shall furnish at meetings of the Board of Directors, or whenever requested, a statement of the financial condition of the Corporation, and shall perform such other duties as these Bylaws or the Board of Directors may prescribe.
- Committees and Panels. The Board of Directors may create one or more 17. committees and/or panels and appoint members of the Board of Directors to chair them. Members of the committees and/or panels other than the chairperson need not be directors. Each committee and/or panel may have two or more members, who shall serve at the pleasure of the Board of Directors. The provisions of this Article that govern meetings, action without meetings, and quorum and voting requirements of the Board of Directors, shall apply to committees and panels and their members as well. Each committee and panel may exercise the authority of the Board of Directors as delegated by the Board of Directors, subject to Section 13.1-869(D) of the Code. Without limiting the generality of the foregoing, the Board of Directors shall establish a Project Management and Oversight Panel with eleven (11) members. Each of the University Representatives shall nominate three (3) candidates for the Project Management and Oversight Panel, and the Board of Directors shall select eleven (11) of such fifteen (15) candidates to constitute the members of the Project Management and Oversight Panel. The eleven (11) members of the Project Management and Oversight Panel shall include: (i) six (6) scientists from disciplines related to the scientific fields in which the Corporation will likely pursue proposals, and one of such six (6) scientist members will be a medical doctor or a clinical practitioner; (ii) three (3) individuals that represent life sciences companies; and (iii) two (2) individuals that represent venture capital firms that actively invest in life sciences companies. The Project Management and Oversight Panel will work with the CEO and Board of Directors to develop criteria that shall govern the (a) Corporation's project solicitation from universities and companies; (b) review of projects in which the Corporation engages, and related decisions regarding the management and/or continuation of such projects; and (c) award of funds to companies and/or universities by the Corporation.

## ARTICLE VII OFFICERS

1. <u>General</u>. The officers of the Corporation shall consist of a President, and such other officers and assistant officers and agents as may be deemed necessary by the Board of Directors from time to time. All officers shall be elected by the Board of Directors and shall

serve at the pleasure of the Board of Directors for such compensation as may be fixed by the Board of Directors. Any two or more offices may be held by the same person. A duly appointed officer may appoint one or more officers or assistant officers if authorized by the Board of Directors.

- 2. Resignation and Removal. An officer may resign at any time by delivering written notice to the Board of Directors. A resignation shall be effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made at a later date and the Corporation accepts the future effective date, it may fill the pending vacancy before the effective date if his successor does not take office until the effective date. The Board of Directors may remove any officer at any time with or without cause and any officer or assistant officer, if appointed by another officer, may likewise be removed by such officer.
- 3. <u>Vacancies</u>. Whenever any vacancies shall occur in any office, the vacancy shall be filled by the Board of Directors.
- 4. <u>The President</u>. The President shall be the chief executive officer and shall have active executive management of the operations of the Corporation, subject to the control of the Board of Directors. The President shall see that all policies, orders and resolutions of the Board of Directors are carried out and perform such other duties as these Bylaws or the Board of Directors may prescribe.
- 5. <u>Transfer of Authority</u>. In case of the absence of any officer of the Corporation or for any other reason that the Board of Directors may deem sufficient, the Board of Directors may transfer the powers or duties of that office to any other officer or to any other director or employee of the Corporation.

# ARTICLE VIII <u>SPECIAL CORPORATE ACTS</u> <u>NEGOTIABLE INSTRUMENTS, DEEDS AND CONTRACTS</u>

All checks, drafts, notes, bonds, bills of exchange, and orders for the payment of money of the Corporation (collectively, the "Orders For Payment"); all deeds, mortgages, and other written contracts and agreements to which the Corporation shall be a party; and all assignments or endorsements of registered bonds or other securities owned by the Corporation, shall be signed by such officers and/or directors as the Board of Directors may from time to time direct, provided that all Orders For Payment shall be signed by an officer and countersigned by the Treasurer. Subject to the foregoing, the Board of Directors may authorize any one of its officers to sign any of such instruments, for and in behalf of the Corporation, without necessity of countersignature; may designate officers or employees of the Corporation, other than those named above, who may, in the name of the Corporation, sign such instruments; and may authorize the use of facsimile signatures of any of such persons.

#### **ARTICLE IX**

### TRANSACTIONS WITH DIRECTORS

Any contract or other transaction between the Corporation and one or more of its directors, or between the Corporation and any firm of which one or more of its directors are members or employees, or in which they are interested, or between the Corporation and any corporation or association of which one or more of its directors are shareholders, members, directors, officers or employees, or in which they are not interested, shall be valid for all purposes, notwithstanding the presence of the director or directors at the meeting of the Board of Directors of the Corporation that acts upon, or in reference to, such contract or transaction, and notwithstanding his or their participation in the action, only if the fact of such interest be disclosed or known to the Board of Directors and the Board of Directors shall, nevertheless, authorize or ratify such contract or transaction, the interested director or directors to be counted in determining whether a quorum is present and to be entitled to vote on such authorization or ratification. This section shall be construed to invalidate any such interested contract or transaction that would otherwise be valid under the common and statutory law applicable to it.

### ARTICLE X CORPORATE SEAL

The corporate seal shall be in such form as shall be approved by the Board of Directors.

## ARTICLE XI FISCAL YEAR

The fiscal year of the Corporation shall be determined by the Board of Directors in its discretion, subject to applicable law.

### ARTICLE XII AMENDMENTS

Any action taken or authorized by the Board of Directors which would be inconsistent with the Bylaws then in effect, but is taken or authorized by the affirmative vote of not less than the number of directors that would be required to amend these Bylaws so that the Bylaws would be consistent with such action, shall be given the same effect as if these Bylaws had been temporarily amended or suspended to the extent necessary to permit the specific action so taken or authorized.

These Bylaws may be amended or repealed by the majority vote of the voting directors at a meeting at which a majority of the voting directors then in office is present, provided that written notice shall be given of such meeting and shall include (i) notice that an amendment to these Bylaws will be considered at such meeting and (ii) a fair summary of such amendment to be acted upon.

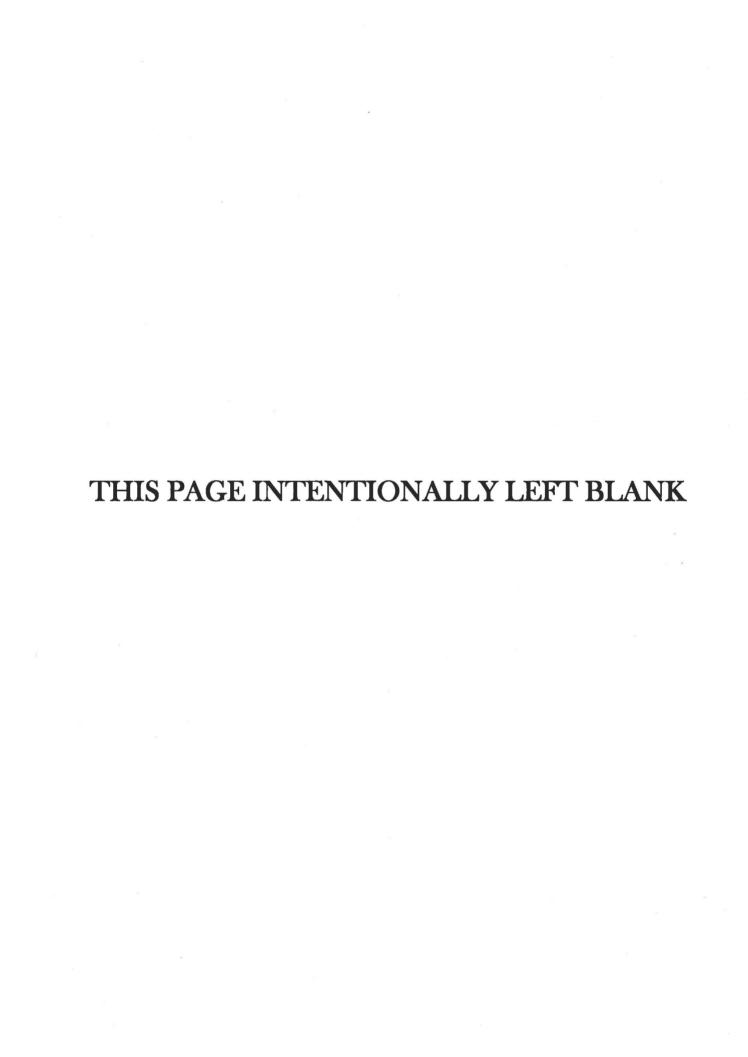
### ARTICLE XIII EMERGENCY BYLAWS

In the event that a quorum of the Corporation's Board of Directors cannot readily be assembled because of some catastrophic event, the Board of Directors of the Corporation may, consistent with Section 13.1-824 of the Code, adopt other bylaws to be effective only in such an emergency, which bylaws shall be subject to amendment or repeal by the Board of Directors, and shall provide procedures for calling a meeting, and designation of additional or substitute directors, as well as other provisions necessary for managing the Corporation during such emergency. All provisions of these Bylaws consistent with such emergency bylaws shall remain effective during such emergency. Such emergency bylaws shall not be effective after such emergency ends. Corporate action taken in good faith in accordance with such emergency bylaws shall bind the Corporation and may not be used to impose liability on a director, officer, employee or agent of the Corporation.

Effective: November 8, 2012

### **Designated Board Seats – July 31, 2017**

Designated Board Seat	Current Board Member
Secretary of Commerce and Trade	Todd Haymore
of Virginia or his/her designee	Secretary of Commerce and Trade
<ol> <li>President and Chief Executive         Officer of the Virginia Economic         Development Partnership Authority         or his/her designee     </li> </ol>	Matt McLaren Business Investment Manager, Technology Virginia Economic Development Partnership
<ol><li>President of the University of Virginia or his/her designee</li></ol>	Melur (Ram) K. Ramasubramanian, Ph.D. Vice President for Research
President of the Virginia Polytechnic Institute and State University or his/her designee	Michael Friedlander, Ph.D. Founding Executive Director, Virginia Tech Carilion Research Institute, and Associate Provost for Health Sciences
<ol><li>President of George Mason University or his/her designee</li></ol>	Deb Crawford, Ph.D. Vice President for Research
6. President of Virginia Commonwealth University or his/her designee	Francis L. Macrina, Ph.D. Vice President for Research
<ol><li>President of Eastern Virginia Medical School or his/her designee</li></ol>	Jerry L. Nadler, M.D. Vice Dean for Research
8. President of Old Dominion University or his/her designee	Morris Foster, Ph.D. Vice President for Research
<ol><li>President of College of William and Mary or his/her designee</li></ol>	Dennis Manos, Ph.D. Vice Provost for Research and Graduate/Professional Studies
10. Representative of the United States Department of Veteran Affairs	David X. Cifu, M.D. National Director for PM&R Services
11. Representative of statewide health care system provider in Virginia	Howard P. Kern President and CEO Sentara Healthcare
<ol><li>Representative of statewide health care system provider in Virginia</li></ol>	Vacant
13. Representative of a life sciences company	Jason Walsh Former Vice President Mediatech Inc., a Division of Corning
14. Representative of a venture capital firm that regularly invests in life sciences companies	Thomas D. Roberts, III General Partner Harbert Management Corporation
15. Statewide representative of the biosciences industry in Virginia	Jeffrey M. Gallagher CEO Virginia Bio



### **Board of Directors - July 31, 2017**

### **University Directors**

### Deborah Crawford, Ph.D.

Vice President for Research
Office of the Provost
George Mason University
(703) 993-2685 dcrawfo7@gmu.edu

#### Michael J. Friedlander, Ph. D.

Chair, Dept of Biomedical Science
Associate Provost for Health Sciences
Founding Executive Director, Carilion Research
Institute
Virginia Tech
(540) 526-2013 friedlan@vtc.vt.edu

#### **Morris Foster (Treasurer)**

Vice President for Research Old Dominion University (757) 683-3466 mfoster@odu.edu

#### Francis L. Macrina. Ph.D.

Vice President for Research Virginia Commonwealth University (804) 827-2262 macrina@vcu.edu

#### Jerry L. Nadler, M.D.

Professor and Chair
Department of Internal Medicine
Eastern Virginia Medical School
(757) 446-8910 NadlerJL@EVMS.EDU

#### Melur (Ram) K. Ramasubramanian

Vice President for Research University of Virginia 434.243.1100 rammk@virginia.edu

#### Dennis Manos, Ph.D.

Vice Provost for Research and Graduate/Professional Studies Director, Applied Research Center Director, William and Mary Research Institute William and Mary 757-871-9581 dmanos@wm.edu

### U.S. Department of Veterans Affairs David X. Cifu, M.D. (Chairman)

Chairman and Herman J. Flax, M.D. Professor Department of PM&R Virginia Commonwealth University National Director for PM&R Services U.S. Department of Veterans Affairs (804) 675-5597 David.Cifu@va.gov

### **Health Care System Providers**

#### Mr. Howard Kern

President and Chief Executive Officer Sentara Healthcare 6015 Poplar Hall Drive (757) 455-7110 HPKERN@sentara.com

### **Commonwealth of Virginia**

#### Matt McLaren

Business Investment Manager, Technology Virginia Economic Development Partnership 901 East Cary Street PO Box 798 Richmond, VA 23218 (804) 545-5736 mmclaren@yesvirginia.org

#### **Todd Haymore**

Secretary of Commerce and Trade Commonwealth of Virginia (804) 225-4372 todd.haymore@governor.virginia.gov

### Private Equity/Venture Capital Director

#### Thomas D. Roberts, III (Secretary)

Partner
Harbert Venture Partners
1210 East Cary Street, Suite 400
Richmond, VA 23219 troberts@harbert.net

### <u>Large and Medium Size Life Science</u> Company Directors

### Jason Walsh (Vice Chairman)

Former Vice President
Mediatech Inc A Division of Corning
Manassas, Virginia
(703) 471-5955 walshit@corning.com

### Virginia Biosciences Industry Jeff Gallagher

CEO Virginia Biotechnology Association 800 E. Leigh Street (804) 643-6360 jgallagher@vabio.org

#### **CEO**

(not on the Board of Directors)
Mike Grisham, CEO
901 East Cary Street, Suite 900
Richmond, VA 23219
(804) 545-5799 mgrisham@vbhrc.com



# Project Management and Oversight Panel July 31, 2017

### **Science and Clinical**

### Ali Andalibi, Ph.D.

Associate Dean of Research George Mason University

### James P. Bennett, Jr. M.D., Ph.D.

Professor and Chair Department of Neurology School of Medicine Virginia Commonwealth University

### O. John Semmes, PhD

Director Leroy T. Canoles, Jr. Cancer Research Center Eastern Virginia Medical School

### Jerry Strauss, Ph.D.

Professor of Obstetrics and Gynecology Virginia Commonwealth University

### George S. Bloom, Ph.D.

Professor of Biology, Cell Biology and Neuroscience Director, Neuroscience Undergraduate Program University of Virginia

### **Venture Capital Firms**

#### **Scott Meza**

Shareholder and Attorney at Law Angel Investor Greenberg Trauig

#### **Bob Creeden**

Managing Director
UVA Seed Fund and New Ventures

### **Life Science Companies**

### **Rony Thomas**

President and CEO LifeNet Health, Inc.

#### James C. Powers

Chairman and CEO Hemoshear, LLC

### **Jeff Conroy**

Founder and CEO Embody, LLC

#### **Gerard Eldering**

President Innovate Tech Ventures



Mitchell Wiggins Statement of Financial Position 2017



### Virginia Biosciences Health Research Corporation

Mitchell, Wiggins & Company LLP 1802 Bayberry Court, Suite 300 Richmond, Virginia 23226

This representation letter is provided in connection with your audit of the financial statements of Virginia Biosciences Health Research Corporation (the Corporation), which comprise the statement of financial position as of December 31, 2016, the related statements of activities, functional expenses and cash flows for the year then ended, and the related notes to the financial statements, for the purpose of expressing an opinion on whether the financial statements are presented fairly, in all material respects, in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

We confirm, to the best of our knowledge and belief, that as of the date of the auditor's report:

#### **Financial Statements**

- 1. We have fulfilled our responsibilities, as set out in the terms of the audit arrangement letter dated December 7, 2016, for the preparation and fair presentation of the financial statements referred to above in accordance with U.S. GAAP.
- 2. We acknowledge our responsibility for the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.
- 3. We acknowledge our responsibility for the design, implementation and maintenance of internal control to prevent and detect fraud.
- 4. Significant assumptions used by us in making accounting estimates, including those measured at fair value, are reasonable and reflect our judgment based on our knowledge and experience about past and current events, and our assumptions about conditions we expect to exist and courses of action we expect to take.
- 5. Related-party relationships and transactions have been appropriately accounted for and disclosed in accordance with the requirements of U.S. GAAP.
- 6. All events subsequent to the date of the financial statements, and for which U.S. GAAP requires adjustment or disclosure, have been adjusted or disclosed.
- 7. The effects of all known actual or possible litigation and claims have been accounted for and disclosed in accordance with U.S. GAAP.

#### Mitchell, Wiggins & Company LLP

- 8. The following have been properly recorded and/or disclosed in the financial statements:
  - a. Recordable contributions, by appropriate net asset class;
  - b. Reclassifications between net asset classes:
  - c. Allocations of functional expenses based on a reasonable basis;
  - d. Concentrations of credit risk; and
  - e. Receipt of a determination from the Internal Revenue Service that the Corporation is exempt from federal income taxes as a Section 501(c)(3) not-for-profit corporation, and that the Corporation has complied with the IRS regulations regarding this exemption.
- 9. We have no knowledge of any uncorrected misstatements in the financial statements.

#### Information Provided

- 10. We have provided you with:
  - a. Access to all information, of which we are aware, that is relevant to the preparation and fair presentation of the financial statements such as records, documentation and other matters;
  - b. Additional information that you have requested from us for the purpose of the audit;
  - c. Unrestricted access to persons within the entity from whom you determined it necessary to obtain audit evidence; and
  - d. Minutes of the meetings of the governing board and committees, or summaries of actions of recent meetings for which minutes have not yet been prepared.
- 11. All transactions have been recorded in the accounting records and are reflected in the financial statements.
- 12. We have disclosed to you the results of our assessment of risk that the financial statements may be materially misstated as a result of fraud.
- 13. We have no knowledge of allegations of fraud or suspected fraud affecting the entity's financial statements involving:
  - a. Management;
  - b. Employees who have significant roles in the internal control; or
  - c. Others where the fraud could have a material effect on the financial statements.
- 14. We have no knowledge of any allegations of fraud or suspected fraud affecting the Corporation's financial statements received in communications from employees, former employees, regulators or others.

### Mitchell, Wiggins & Company LLP

- 15. We have no knowledge of noncompliance or suspected noncompliance with laws and regulations whose effects should be considered when preparing financial statements. Additionally, we specifically represent that we are responsible for determining that we are not subject to the requirements of the Single Audit Act because we have not received, expended or otherwise been the beneficiary of the required amount of federal awards during the period of this audit.
- 16. We are not aware of any pending or threatened litigation and claims whose effects were considered when preparing the financial statements, and we have not consulted legal counsel concerning litigation or claims.
- 17. We have disclosed to you the identity of the entity's related parties and all related-party relationships and transactions of which we are aware.
- 18. We are aware of no significant deficiencies, including material weaknesses, in the design or operation of internal controls that could adversely affect the Corporation's ability to record, process, summarize and report financial data.
- 19. There have been no communications from regulatory agencies concerning noncompliance with, or deficiencies in, financial reporting practices.
- 20. During the course of your audit, you may have accumulated records containing data that should be reflected in our books and records. All such data have been so reflected. Accordingly, copies of such records in your possession are no longer needed by us.

Michael Grisham President and CEO

David Cifu, Chairman of the Board

5/31/2017

Date

/lj



### **Financial Statements**

FY 2017



# Virginia Biosciences Health Research Corporation

Financial Statements

December 31, 2016

### Virginia Biosciences Health Research Corporation

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### Independent Auditor's Report

Board of Directors Virginia Biosciences Health Research Corporation Richmond, Virginia

### Report on the Financial Statements

We have audited the accompanying financial statements of Virginia Biosciences Health Research Corporation, which comprise the statement of financial position as of December 31, 2016, the related statements of activities, functional expenses, and cash flows for the year then ended, and the related notes to the financial statements.

### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Virginia Biosciences Health Research Corporation as of December 31, 2016, and the changes in its net assets and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

We have previously audited Virginia Biosciences Health Research Corporation's 2015 financial statements, and we expressed an unmodified audit opinion on those audited financial statements in our report dated June 29, 2016. In our opinion, the summarized comparative information presented herein as of and for the year ended December 31, 2015, is consistent, in all material respects, with the audited financial statements from which it has been derived.

Mitchell, Wiggins & Company LLP

Richmond, Virginia May 31, 2017

# Statement of Financial Position December 31, 2016, with Comparative Totals as of December 31, 2015

Assets	2016	2015
Cash	\$ 3,854,792	\$ 4,069,481
Total assets	\$ 3,854,792	\$ 4,069,481
Liabilities and Net Assets		
Current Liabilities		
Accounts payable	\$ 8,003	\$ 329,376
Net Assets		
Unrestricted	3,846,789	3,740,105
	3,846,789	3,740,105
Total liabilities and net assets	\$ 3,854,792	\$ 4,069,481

Statement of Activities Year Ended December 31, 2016, with Comparative Totals for the Year Ended December 31, 2015

	Unres	Unrestricted		
	2016	2015		
Revenue	4			
Contributions, Virginia General Assembly				
Program support	\$ 2,000,000	\$ 2,250,000		
General and administrative support	500,000	250,000		
Contributions, Member Universities				
College of William & Mary	50,000	-		
Eastern Virginia Medical School	50,000	50,000		
George Mason University	50,000	50,000		
Old Dominion University	50,000	50,000		
University of Virginia	50,000	50,000		
Virginia Commonwealth University	50,000	50,000		
Virginia Polytechnic Institute and State University	50,000	50,000		
Interest income	1,865	-		
Total revenue	2,851,865	2,800,000		
Expenses				
Program services	2,678,948	1,962,852		
Management and general	66,233	88,423		
Total expenses	2,745,181	2,051,275		
Change in net assets	106,684	748,725		
Net assets, beginning	3,740,105	2,991,380		
Net assets, ending	\$ 3,846,789	\$ 3,740,105		

Statement of Functional Expenses Year Ended December 31, 2016, with Comparative Totals for the Year Ended December 31, 2015

			To	tal
	Program	Management		
	Services	and General	2016	2015
Accounting services	\$ -	\$ 22,660	\$ 22,660	\$ 21,915
Conferences	11,129	-	11,129	-
Consulting	60,304	-	60,304	56,920
Dues and subscriptions	-	348	348	-
Grant expenses	2,396,634	•	2,396,634	1,706,245
Legal expenses	-	19,006	19,006	43,043
Marketing and promotion	1,700	-	1,700	4,500
Meals and entertainment	175	-	175	2,265
Memberships and sponsorships	12,400	-	12,400	500
Miscellaneous	-	543	543	526
Office expenses	-	138	138	153
Other program expenses	-		<u>-</u>	199
Parking	-	1,720	1,720	1,375
Payroll taxes	9,273	1,030	10,303	10,276
Salaries and wages	180,000	20,000	200,000	196,667
Telephone		788	788	716
Travel and lodging	7,333	-	7,333	5,975
	\$ 2,678,948	\$ 66,233	\$ 2,745,181	\$ 2,051,275

Statement of Cash Flows Year Ended December 31, 2016

Cash Flows from Operating Activities	
Change in net assets	\$ 106,684
Adjustments to reconcile change in net assets to net cash provided by (used in) operating activities	
Changes in operating liabilities	
Accounts payable	(321,373)
Net cash (used in) operating activities	 (214,689)
Cash and cash equivalents, beginning	4,069,481
Cash and cash equivalents, ending	\$ 3,854,792

**Notes to Financial Statements** 

December 31, 2016

#### Note 1. Nature of Organization and Summary of Significant Accounting Policies

#### *Nature of organization*

Virginia Biosciences Health Research Corporation (the Corporation) was organized as a not-for-profit corporation in 2013 and is operated for educational and research purposes. The mission of the Corporation is to foster life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities. The five founding institutions are Eastern Virginia Medical School, George Mason University, University of Virginia, Virginia Commonwealth University, and Virginia Polytechnic Institute and State University. Old Dominion University was admitted in December 2013 and College of William & Mary was admitted in October 2016. Research is to be centered in three focus areas: bioinformatics and medical informatics, point of care diagnostics, and drug discovery and delivery.

A summary of the Corporation's significant accounting policies follows:

#### Basis of accounting

The financial statements are presented on the accrual basis of accounting.

#### Financial statement presentation

Under current accounting standards, the Corporation is required to report information regarding its financial position and activities according to three classes of assets: unrestricted net assets, temporarily restricted net assets, and permanently restricted net assets. The net asset classes are summarized as follows:

Unrestricted net assets include board designated and other unrestricted funds. The unrestricted funds include revenue and expenses used currently for the general operations of the Corporation. Contributions that are restricted by the donor are reported as increases in unrestricted net assets if the donor restrictions expire in the fiscal year in which the contributions are recognized.

Temporarily restricted net assets include contributions restricted by donor designation or time restrictions and are reported as increases in temporarily restricted net assets. When a restriction expires either with the passage of time or by actions of the Corporation, temporarily restricted net assets are released and reclassified to unrestricted net assets. Temporarily restricted net assets consist of pledged contributions due in future years. The Corporation did not have any temporarily restricted net assets at December 31, 2016.

Permanently restricted net assets include contributions restricted by donor designation that they be maintained permanently by the Corporation. The Corporation currently does not have any permanently restricted net assets.

Notes to Financial Statements

December 31, 2016

## Note 1. Nature of Organization and Summary of Significant Accounting Policies (continued)

#### Cash and cash equivalents

The Corporation considers all highly liquid investments with an initial maturity of three months or less to be cash equivalents.

#### Pledges receivable

Pledges are recognized when the donor makes a promise to give to the Corporation that is, in substance, unconditional. Contributions that are restricted by the donor are reported as increases in temporarily restricted net assets. When a restriction expires, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statements of activities as net assets released from restrictions.

#### Revenue recognition

The Corporation recognizes revenue in the year it is earned.

#### **Use of estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

#### **Income taxes**

The Corporation is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code and is not classified as a Private Foundation.

The Financial Accounting Standards Board issued guidance on accounting for uncertainty in income taxes. Management evaluated the Corporation's tax positions and concluded that the Corporation had taken no uncertain tax positions that require adjustment to the financial statements to comply with the provisions of this guidance. Currently, the Corporation's 2013 through the 2015 tax years are open and subject to income tax examinations by the taxing authorities.

The Corporation includes penalties and interest assessed by income taxing authorities in management and general expenses. The Corporation did not have penalties and interest relating to income taxes for the year ended December 31, 2016.

Notes to Financial Statements

December 31, 2016

#### Note 2. Prior-Year Summarized Comparative Information

The financial statements include certain prior-year summarized comparative information in total but not by asset class. Such information does not include sufficient detail to constitute a presentation in conformity with generally accepted accounting principles. Accordingly, such information should be read in conjunction with the Corporation's financial statements for the year ended December 31, 2015, from which the summarized information was derived.

#### Note 3. Concentration of Credit Risk

The Corporation maintains its cash balances in one financial institution. The balances are insured by the Federal Deposit Insurance Corporation up to \$250,000. At December 31, 2016, the Corporation's uninsured cash balances total approximately \$3,600,000.

#### Note 4. Pledged Contributions Receivable

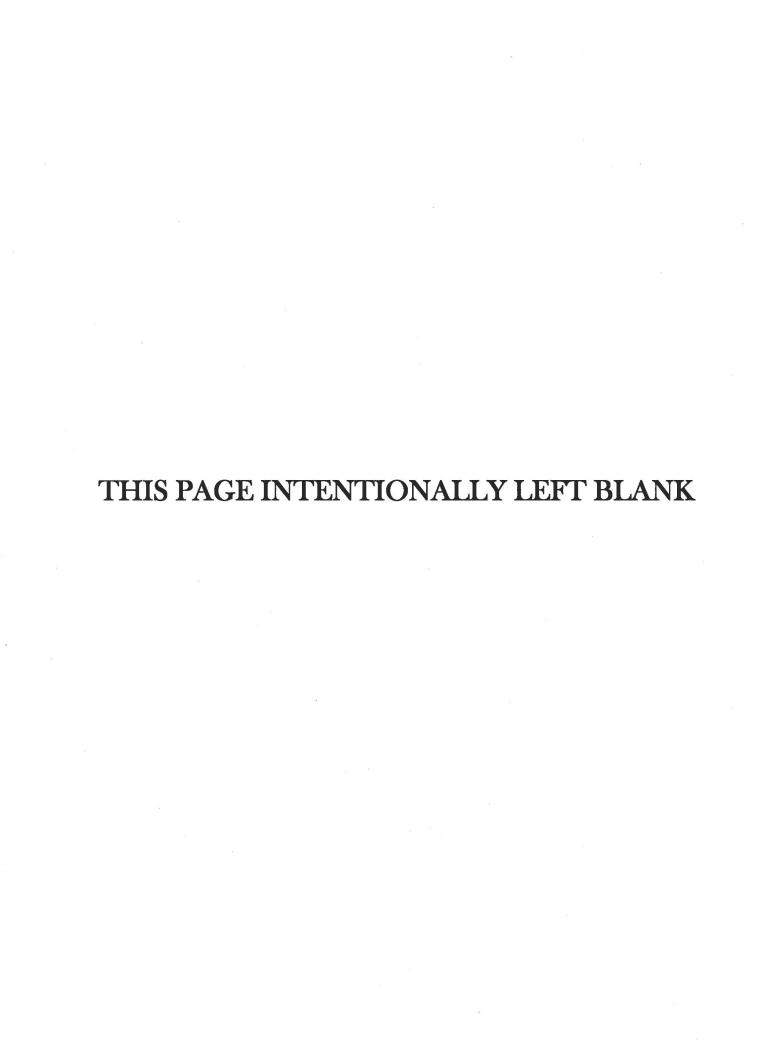
The Corporation's policy is to record only written pledged contributions receivable. The Corporation had no pledged contributions receivable at December 31, 2016.

#### Note 5. Subsequent Events

Management has evaluated subsequent events through May 31, 2017, the date which the financial statements were available for issue.

Subsequent to year, the Corporation was appropriated by the Commonwealth of Virginia additional funds totaling \$3,750,000 to further promote research in the biosciences, as well as to promote the development of bioscience infrastructure tools to facilitate additional research activities in the Commonwealth.

**Annual Report** 





VIRGINIA ECONOMIC DEVELOPMENT PARTNERSHIP PO. Box 798 . 901 East Cary Street Richmond, Virginia 23218-0798 804-545-5600 . www.YesVirginia.org

November 1, 2016

The Honorable Terence R. McAuliffe Governor of the Commonwealth of Virginia Patrick Henry Building, 3rd Floor 1111 East Broad Street Richmond, Virginia 23219

The Honorable Thomas K. Norment Co-Chair, Senate Committee on Finance Post Office Box 396 Richmond, Virginia 23218

The Honorable S. Chris Jones Chair, House Committee on Appropriations Post Office Box 406 Richmond, Virginia 23218 The Honorable Emmett W. Hanger, Jr. Co-Chair, Senate Committee on Finance Post Office Box 396 Richmond, Virginia 23218

Re: Virginia Biosciences Health Research Corporation

Dear Governor McAuliffe, Senator Norment, Senator Hanger, and Delegate Jones:

Chapter 780, Item 106:I of the 2016 Acts of Assembly includes funding for the Virginia Biosciences Health Research Corporation (VBHRC), a 501(c)(3) non-stock corporation, to serve as a catalyst to accelerate and focus life science research momentum at Virginia's universities.

Chapter 780, Item 106:I.6 requires that you be provided by, November 1 of each year, a written report summarizing the activities of the consortium, including, but not limited to, a summary of how any funds disbursed to the consortium during the previous fiscal year were spent, and the consortium's progress during the fiscal year in expanding upon existing research opportunities and stimulating new research opportunities in the Commonwealth.

The detail hereafter provides an update on the specific progress of this initiative to date.

#### **Background**

Efforts of VBHRC focus on stimulating collaborations and partnerships with our research universities and industry. These efforts are meant to have a positive economic impact to the Commonwealth by increasing corporate-sponsored research resulting in commercializing new technologies, starting new companies and expanding the evolvement of bio and pharmaceutical companies in Virginia. The founding members are Virginia's premiere research institutions: Virginia Commonwealth University, Eastern Virginia Medical School, George Mason University, Virginia Polytechnic Institute and State University and the University of Virginia. Old Dominion University became the sixth member of the consortium effective January 2014.

At its October 31, 2016 meeting, the Board approved William & Mary becoming the seventh member of the consortium.

The Commonwealth committed funding for Fiscal Years 2013 and 2014 to establish the core objectives of the consortium and, in addition, the President of each member university agreed to commit a cash contribution to participate. The Commonwealth's commitment over these two years totaled \$5 million, supplemented by a \$100,000 contribution from each member university distributed as \$50,000 each year.

In Fiscal Year 2015, VBHRC did not receive any funding from the Commonwealth or its member universities. For Fiscal Year 2016, VBHRC received \$2,500,000 in funding from the Commonwealth and a total of \$300,000 (\$50,000 each) from its member universities.

Pending the admission of William & Mary as a member of the consortium, VBHRC is governed by a 14-member Board of Directors. The primary duties of the Board include recruitment and selection of a Chief Executive Officer, development of the policies and goals of VBHRC, and the review and approval of research partnerships as recommended by a Project Management and Oversight Panel. The Board is comprised of the following:

- Representatives of the six (6) university members, with one (1) member appointed by the President of each member university:
  - 1. Eastern Virginia Medical School: William J. Wasilenko, Ph.D. (elected Board Secretary 07/25/13)
  - 2. George Mason University: Deborah Crawford, Ph.D.
  - 3. University of Virginia: Erik Hewlett, M.D.
  - 4. Virginia Commonwealth University: Francis L. Macrina, Ph.D.
  - 5. Virginia Polytechnic Institute and State University: Michael Friedlander, Ph.D.
  - 6. Old Dominion University: Morris Foster, Ph.D. (elected Board Treasurer 1/6/2016)
- Secretary of Commerce and Trade: Todd P. Haymore
- The President and CEO of the Virginia Economic Development Partnership or his or her designee: Dan Gundersen, Interim President & CEO, VEDP
- A representative of the United States Department of Veterans Affairs: David X. Cifu, M.D. (elected Board Chair 10/22/15).
- Two (2) representatives of statewide health care system providers in Virginia:
  - 1. Sentara Healthcare: Howard Kern
  - 2. Open position

- Two (2) directors, one of whom is to be a representative of a venture capital firm that regularly invests in life science companies and the other, of whom, is to be a representative of a life sciences company.
  - 1. Tom Roberts, General Partner, Harbert Venture Partners
  - 2. Jason Walsh, Director, Strategic Growth, Corning Life Sciences (elected Board Vice-Chair 1/6/2016)
- A statewide representative of the biosciences industry in Virginia: Jeffrey M. Gallagher, CEO, Virginia Bio

The VBHRC Project Management and Oversight Panel is comprised of the following ten (10) members:

- Science and clinical appointments:
  - 1. Stanley A. Hefta, Ph.D., Professor, Director, Strategic Planning and Business Development, Virginia Bioinformatics Institute of Virginia Tech
  - 2. Ali Andalibi, Ph.D., Associate Dean of Research, George Mason University
  - 3. Jerry L. Nadler, M.D., Professor and Chair, Department of Internal Medicine, Eastern Virginia Medical School
  - 4. Gerard Eldering, President, Innovate Tech Ventures
  - 5. James P. Bennett, Jr., M.D., Ph.D., Emeritus Professor and Former Chair, Department of Neurology, School of Medicine, Virginia Commonwealth University
  - 6. Scott Meza, Shareholder and Attorney at Law, Greenberg Traurig
- Venture Capital firm appointments:
  - 7. Cody Nystrom, Managing Director, SJF Ventures (appointed 10/31/16)
- Life Science company appointments:
  - 8. Rony Thomas, President & CEO, LifeNet Health, Inc.
  - 9. James C. Powers, Chairman and CEO, Hemoshear, LLC
  - 10. Jeff Conroy, Founder, Embody, LLC

Non-government related positions on the Board, as well as the Project Management and Oversight Panel, are filled on a pro bono basis by qualified individuals who hold important bioscience-related expertise, value the public service nature of this position and possess a sincere interest in helping to advance Virginia's bioscience community.

The Project Management and Oversight Panel, the CEO, and the Board developed criteria in the first year to govern project solicitation from universities and companies, funding awards, project

review and continuation, and related project management issues and decisions. VBHRC's two strategic initiatives center on the neurosciences and cardiovascular metabolics fields. From these two initiatives, VBHRC has developed three main focus areas that include bio-informatics and medical informatics, point of care diagnostics, and drug discovery and delivery.

#### **Progress on Core Objectives**

The following detail breaks down milestones and accomplishments in Fiscal Year 2016, with information on VBHRC's structure, governance, research, and project activity.

#### August 2015

• The VBHRC Board met on August 31, 2015, and approved Round Four of grant disbursements for five projects, totaling \$2,233,500 in funding. The Board also received an overview of strategic initiatives and priorities, including an update on the status of the Neuroscience Initiative (the "Brain State" initiative) and the Cardiac Metabolic Initiative, and approved the initiation of Round Five of funding in the amount of \$864,118. Round Five is to be focused on neuroscience projects, with one element of project scoring being the ability to demonstrate interest by "big pharma" or "big biotech."

#### October 2015

 October 22: VBHRC Board of Directors meeting held and all agenda items executed, including approving the election of David Cifu as Chair and the adoption of new banking resolutions.

#### January 2016

• January 6: VBHRC Board of Directors meeting held and all agenda items executed, including approving the election or re-election, as applicable, of David Cifu, Howard Kern, Tom Roberts, and Jeff Gallagher as directors and the election of Board officers, and approving two (2) Round 5 projects in an aggregate amount of \$687,057.

#### June 2016

June 29: VBHRC Board of Directors meeting held and all agenda items executed, including approving the Independent Auditors' Report of Mitchell Wiggins & Company on the financial statements of VBHRC as of and for the year ended December 31, 2015, including the unqualified opinion of the auditors contained therein, approving the 2016 budget, and discussing anticipated collaborations with the Virginia Research Investment Committee and the Commonwealth Health Research Board.

#### **Ongoing Activity:**

Although this report is focused on FY 2016, it has been our practice to also include details of ongoing efforts into the current fiscal year. On October 31, 2016, the VBHRC Board of

Directors meeting was held and all agenda items were executed, including approving the admission of William & Mary as a participating university, modifying VBHRC's fiscal year and cash management practices, and appointing Cody Nystrom to the Project Management and Oversight Panel. Additionally, the Board approved a resolution to recommend to the Commonwealth Health Research Board (CHRB) that VBHRC and CHRB "co-fund" seven (7) projects totaling \$3,525,000 with VBHRC contributing \$2,125,000 and CHRB to contribute \$1,400,000. This is consistent with CHRB's statutory mandate to support Virginia's core bioscience strengths, improve human health and demonstrate commercial viability and a high likelihood of creating new companies and jobs in Virginia.

Through Round 4, VBHRC has funded 16 projects involving six (6) Virginia research universities and 14 industry partners in the amount of \$6.7 million with \$19.6 million in matching funds. Subsequently, there has been \$48.8 million in follow on investment in commercializing these projects.

VBHRC is developing research tools to build infrastructure, which will accelerate funding from the federal government (NIH, NSF, DARPA), industry and philanthropy. These tools include state-wide patient registry, state-wide clinical trial network, linking our bio-repositories, and providing shared data connectivity. This effort is being led by Dr. Randall Merchant in coordination with our research universities and our health care systems including Sentara, Inova, UVA Health Systems, VCU Health Systems and Carillion.

On behalf of VBHRC and its Board of Directors, thank you for your continued support of these important and innovative efforts to transform Virginia's economy. As always, please do not hesitate to contact Mike Grisham or me if we can be of any assistance.

Sincerely,

Alexander R. Thorup

Manager, Legislation & Policy

cc: Ms. Betsey Daley, Staff Director, Senate Committee on Finance

Mr. Robert P. Vaughn, Staff Director, House Committee on Appropriations

The Honorable Todd P. Haymore, Secretary of Commerce & Trade

Mr. Mike Grisham, Chief Executive Office, Virginia Biosciences Health Research Corporation



From: Bradley Bryan Miller < bmiller@lilly.com>

Date: Fri, 22 Jan 2016 04:00:19 +0000

To: mgrisham@vbhrc.com>mgrisham@vbhrc.com>
Cc: Ryan Westphal<a href="mailto:westphal">westphal</a> ryan@lilly.com>; Christer

Nordstedt < nordstedt christer@lilly.com >

Subject: Letter of Support from Eli Lilly - Tailored Therapeutics Neuroscience

#### Dear Michael,

We believe that if Virginia invested in a state-wide patient registry and a state-wide clinical trial network, this would be attractive to us. This, combined with your university collaboration model and matching funds program, would give Virginia a competitive edge in working with big pharma on research collaboration projects.

In particular, the availability of a biofluids biobank linked to EMRs from well-characterized patients in Virginia with neurologic disorders would be of the highest value to divisions such as ours in pharma (personalized medicine), as we seek to discover markers of drug response and disease subcategorization in collaboration with Virginia clinical research institutions.

Please do not hesitate to contact me if there is any additional indication of support I can provide.

#### Sincerely,

#### Brad

Bradley Bryan Miller MD, PhD
Senior Director
Tailored Therapeutics Neuroscience
Eli Lilly and Company
Lilly Corporate Center, Indianapolis IN 46285 U.S.A.
317.433.2589 (office) | 317.432.1997 (mobile)
bmiller@lilly.com | www.lilly.com



From: "Alexander, Robert" < Robert.C.Alexander@pfizer.com>

Date: Fri, 22 Jan 2016 14:57:39 +0000

To: mgrisham@vbhrc.com<mgrisham@vbhrc.com>
Cc: Frank Yocca<fdyoccaconsulting@yahoo.com>

Subject: VA Registry

Dear Michael

We believe that if Virginia invested in a state wide patient registry and a state wide clinical trail network, this would be attractive to us. This combined with your university collaboration model and matching funds program would give Virginia a competitive edge in working with big pharma on research collaboration projects.

Sincerely,

Robert C. Alexander M.D.

robert.alexander@pfizer.com

Vice President, Chief Medical Officer BioTherapeutics R&D Clinical Head, Neuroscience & Pain Research Unit Pfizer, Inc.
610 Main Street, 5th floor
Cambridge, MA 02139
Office: 617.674.7201
Cell: 267.495.9149

From: John Dunlop < john.dunlop@azneuro.com>
Date: Thursday, January 21, 2016 4:34 PM
To: Mike Grisham < mgrisham@vbhrc.com>

Subject: Neurological Disorders Registry and Biorepository

Dear Mike

Thank you for sharing with me the idea around the Virginia wide Neurological Disorders Registry and Biorepository. It is clear that if Virginia invested in a state wide patient registry and a state wide clinical trail network, this would be attractive to pharma. This combined with your university collaboration model and matching funds program would give Virginia a strong platform for working with companies on research collaboration projects.

Sincerely John

#### **John Dunlop PhD**

Head, Neuroscience Innovative Medicines

AstraZeneca Neuroscience

Research & Development | Innovative Medicines & Early Development 141 Portland Street, Cambridge, MA 02139
Mobile: (609) 213-9854 F: (617) 679 1682

www.azneuro.com

#### Certified Public Accountants

October 30, 2017

Board of Directors and Management Virginia Biosciences Health Research Corporation c/o Virginia Economic Development Partnership 901 E. Cary Street, Suite 900 Richmond, Virginia 23219

We have audited the financial statements of Virginia Biosciences Health Research Corporation (the Corporation) for the six months ended June 30, 2017, and have issued our report thereon dated October 27, 2017.

Current audit standards require the auditor to communicate certain matters to keep those charged with governance adequately informed about matters related to the financial statement audit that are, in our professional judgment, significant and relevant to the responsibilities of those charged with governance in overseeing the financial reporting process.

The following summarizes those communications:

#### The Auditor's Responsibility Under Generally Accepted Auditing Standards

As stated in our engagement letter dated October 3, 2017, which was signed on your behalf by Mr. Michael Grisham, President and CEO, our responsibility, as described by professional standards, is to express an opinion about whether the financial statements prepared by management with your oversight are fairly presented, in all material respects, in conformity with accounting principles generally accepted in the United States of America. Our audit of the financial statements does not relieve you or management of your responsibilities.

#### Planned Scope and Timing of the Audit

We performed the audit according to the planned scope and timing previously communicated to you through the engagement letter and other communications about planning matters.

#### **Significant Audit Findings**

#### • Qualitative Aspects of Accounting Practices

Management has the ultimate responsibility for the appropriateness of the accounting policies used by the Corporation. The significant accounting policies used by the Corporation are described in Note 1 to the financial statements. The Corporation did not adopt any significant new accounting policies nor have there been any changes in existing significant accounting policies during the current period. We did not identify any significant or unusual transactions or significant accounting policies in controversial or emerging areas for which there is a lack of authoritative guidance or consensus. We did not discuss with management any alternative treatments within generally accepted accounting principles for accounting policies and practices related to material items during the current audit period. There are no significant transactions that have been recognized in the financial statements in a different period than when the transaction occurred.

Accounting estimates are an integral part of the financial statements prepared by management and are based upon management's current judgment. The process used by management encompasses their knowledge and experience about past and current events and certain assumptions about future events. Certain accounting estimates are particularly sensitive because of their significance to the financial statements and because of the possibility that future events affecting them may differ significantly from those expected. The most sensitive estimates are summarized below. We evaluated the key factors and assumptions used to develop the estimates in determining that they are reasonable in relation to the financial statements taken as a whole.

#### Allocation of Functional Expenses

Current accounting standards require organizations to report expenses by their functional classification, such as by their programs and supporting activities. The Corporation has estimated the President and CEO's salary to consist of 90% for program services and 10% for management and general activities.

The disclosures in the financial statements are neutral, consistent, and clear. Certain financial statement disclosures are particularly sensitive because of their significance to financial statement users.

• Difficulties Encountered in Performing the Audit
We encountered no significant difficulties in dealing with management in performing and completing our audit.

#### Corrected and Uncorrected Misstatements

Professional standards require us to accumulate all known and likely misstatements identified during the audit, other than those that are trivial, and communicate them to the appropriate level of management. Audit adjustments proposed by us were made by the Corporation and are summarized in the accompanying schedule.

We also accumulate uncorrected misstatements, which are determined to be immaterial to the financial statements taken as a whole. We did not identify any uncorrected misstatements.

#### • Disagreements with Management

For purposes of this letter, professional standards define a disagreement with management as a financial accounting, reporting, or auditing matter, whether or not resolved to our satisfaction, that could be significant to the financial statements or the auditor's report. We encountered no disagreements with management during the course of our audit.

#### • Management Representations

We have requested certain representations from management that are included in the management representation letter dated October 27, 2017.

#### • Management Consultations with Other Independent Accountants

In some cases, management may decide to consult with other accountants about auditing and accounting matters, similar to obtaining a "second opinion" on certain situations. If a consultation involves application of an accounting principle to the Corporation's financial statements or a determination of the type of auditor's opinion that may be expressed on those statements, our professional standards require the consulting accountant to check with us to determine that the consultant has all of the relevant facts. To our knowledge, there were no such consultations with other accountants.

#### • Other Audit Findings or Issues

We generally discuss a variety of matters, including the application of accounting principles and auditing standards, with management each year prior to retention as the Corporation's auditor. However, these discussions occurred in the normal course of our professional relationship, and our responses were not a condition to our retention.

• Recently Issued Accounting Standards Updates (ASU):

#### ASU No. 2016-02, Leases

This new accounting standard will affect entities that lease assets, such as real estate and equipment, and will require lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases and will also require additional disclosures. At this time, we believe the new standard will be effective for the fiscal year ending June 30, 2021. Early adoption/application is permitted.

#### ASU No. 2016-14, Presentation of Financial Statements of Not-for-Profit Entities

This new accounting standard will change the way all nonprofits classify net assets and prepare financial statements. Additional disclosures will also be required regarding liquidity and availability of cash as well as transparency in the reporting of financial performance measures. At this time, we believe the new standard will be effective for the fiscal year ending June 30, 2019. Early adoption/application is permitted.

Board of Directors and Management

October 30, 2017

This report is intended solely for the information and use of the Board of Directors and management of the Corporation, and is not intended to be and should not be used by anyone other than these specified parties.

Mitchell Wiggins

#### Virginia Biosciences Health Research Corporation Adjusting Journal Entries June 30, 2017

Account	Debit	Credit
5290 - VNI Project Management	23,436.62	
5210.vc - Virginia Commonwealth Univ	1,539.07	
5210.ev - EVMS	2,127.59	
2000 - Accounts Payable		27,103.28
	27,103.28	27,103.28

To record additional accounts payable located during testing of subsequent disbursments.

4010 - General and Administrative Support 4005 - Program Support 300,000.00

300,000.00

To reclass program support revenue per State's appropriation



Financial Statements

June 30, 2017

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Certified Public Accountants

#### Independent Auditor's Report

Board of Directors Virginia Biosciences Health Research Corporation Richmond, Virginia

#### Report on the Financial Statements

We have audited the accompanying financial statements of Virginia Biosciences Health Research Corporation, which comprise the statement of financial position as of June 30, 2017, the related statements of activities, functional expenses, and cash flows for the six months then ended, and the related notes to the financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Virginia Biosciences Health Research Corporation as of June 30, 2017, and the changes in its net assets and its cash flows for the six months then ended in accordance with accounting principles generally accepted in the United States of America.

Mitchell Wiggins

Richmond, Virginia October 27, 2017

# Statement of Financial Position June 30, 2017

Assets	
Current Assets	
Cash and cash equivalents	\$ 3,139,772
Pledges receivable	
Commonwealth of Virginia	2,950,000
Member universities	350,000
Total current assets	\$ 6,439,772
Liabilities and Net Assets Current Liabilities	
Accounts payable	\$ 31,559
Total current liabilities	 31,559
Net Assets	
Unrestricted	3,108,213
Temporarily restricted	3,300,000
Total net assets	 6,408,213
Total liabilities and equity	\$ 6,439,772

Statement of Activities Six Months Ended June 30, 2017

	Unrestricted	Temporarily Restricted	Totals
Revenue			
Contributions, Virginia General Assembly			
Program support	\$ 300,000	\$ 2,950,000	\$ 3,250,000
General and administrative support	500,000	-	500,000
Contributions, Member Universities			
College of William & Mary	-	50,000	50,000
Eastern Virginia Medical School	-	50,000	50,000
George Mason University	-	50,000	50,000
Old Dominion University	-	50,000	50,000
University of Virginia	-	50,000	50,000
Virginia Commonwealth University	-	50,000	50,000
Virginia Polytechnic Institute and State University	-	50,000	50,000
Interest income	5,250	-	5,250
Total revenue	805,250	3,300,000	4,105,250
Expenses			
Program services	1,495,151	-	1,495,151
Management and general	48,675	-	48,675
Total expenses	1,543,826		1,543,826
Change in net assets	(738,576)	3,300,000	2,561,424
Net assets, beginning	3,846,789		3,846,789
Net assets, ending	\$ 3,108,213	\$ 3,300,000	\$ 6,408,213

# Statement of Functional Expenses Six Months Ended June 30, 2017

	Program Services	nagement I General	Total
Accounting services	\$ -	\$ 15,480	\$ 15,480
Conferences	803	-	803
Consulting	4,950	-	4,950
Grant expenses	1,368,206	-	1,368,206
Legal expenses	-	20,699	20,699
Marketing and promotion	7,728	-	7,728
Meals and entertainment	1,292		1,292
Memberships and sponsorships	10,500	-	10,500
Miscellaneous	-	406	406
Office expenses	-	202	202
Parking	-	810	810
Payroll taxes	6,932	770	7,702
Salaries and wages	90,000	10,000	100,000
Telephone	-	308	308
Travel and lodging	4,740	-	4,740
	\$ 1,495,151	\$ 48,675	\$ 1,543,826

Statement of Cash Flows Six Months Ended June 30, 2017

Cash Flows from Operating Activities	
Change in net assets	\$ 2,561,424
Adjustments to reconcile change in net assets to net cash provide	ed
by (used in) operating activities	
Changes in operating assets	
Pledges receivables	(3,300,000)
Changes in operating liabilities	
Accounts payable	23,556
Net cash (used in) operating activities	(715,020)
Cash and cash equivalents, beginning	3,854,792
Cash and cash equivalents, ending	\$ 3,139,772

**Notes to Financial Statements** 

June 30, 2017

#### Note 1. Nature of Organization and Summary of Significant Accounting Policies

#### Nature of organization

Virginia Biosciences Health Research Corporation (the Corporation) was organized as a not-for-profit corporation in 2013 and is operated for educational and research purposes. The mission of the Corporation is to foster life sciences research at universities located within the Commonwealth of Virginia by providing resources for partnering between public and private institutions and non-profit universities. The five founding institutions are Eastern Virginia Medical School, George Mason University, University of Virginia, Virginia Commonwealth University, and Virginia Polytechnic Institute and State University. Old Dominion University was admitted in December 2013 and College of William & Mary was admitted in October 2016. Research is to be centered in three focus areas: bioinformatics and medical informatics, point of care diagnostics, and drug discovery and delivery. During 2017, the Corporation changed its fiscal year-end to June 30.

A summary of the Corporation's significant accounting policies follows:

#### Basis of accounting

The financial statements are presented on the accrual basis of accounting.

#### Financial statement presentation

Under current accounting standards, the Corporation is required to report information regarding its financial position and activities according to three classes of assets: unrestricted net assets, temporarily restricted net assets, and permanently restricted net assets. The net asset classes are summarized as follows:

Unrestricted net assets include board designated and other unrestricted funds. The unrestricted funds include revenue and expenses used currently for the general operations of the Corporation. Contributions that are restricted by the donor are reported as increases in unrestricted net assets if the donor restrictions expire in the fiscal year in which the contributions are recognized.

Temporarily restricted net assets include contributions restricted by donor designation or time restrictions and are reported as increases in temporarily restricted net assets. When a restriction expires either with the passage of time or by actions of the Corporation, temporarily restricted net assets are released and reclassified to unrestricted net assets. Temporarily restricted net assets consist of pledged contributions due in future years.

Permanently restricted net assets include contributions restricted by donor designation that they be maintained permanently by the Corporation. The Corporation currently does not have any permanently restricted net assets.

Notes to Financial Statements

June 30, 2017

## Note 1. Nature of Organization and Summary of Significant Accounting Policies (continued)

#### Cash and cash equivalents

The Corporation considers all highly liquid investments with an initial maturity of three months or less to be cash equivalents.

#### Pledges receivable

Pledges are recognized when the donor makes a promise to give to the Corporation that is, in substance, unconditional. Contributions that are restricted by the donor are reported as increases in temporarily restricted net assets. When a restriction expires, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statements of activities as net assets released from restrictions.

#### Revenue recognition

The Corporation recognizes revenue in the year it is earned.

#### **Use of estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

#### **Income taxes**

The Corporation is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code and is not classified as a Private Foundation.

The Financial Accounting Standards Board issued guidance on accounting for uncertainty in income taxes. Management evaluated the Corporation's tax positions and concluded that the Corporation had taken no uncertain tax positions that require adjustment to the financial statements to comply with the provisions of this guidance. Currently, the Corporation's 2014 through the 2016 tax years are open and subject to income tax examinations by the taxing authorities.

The Corporation includes penalties and interest assessed by income taxing authorities in management and general expenses. The Corporation did not have penalties and interest relating to income taxes for the six months ended June 30, 2017.

**Notes to Financial Statements** 

June 30, 2017

#### Note 2. Concentration of Credit Risk

The Corporation maintains its cash balances in one financial institution. The balances are insured by the Federal Deposit Insurance Corporation up to \$250,000. At June 30, 2017, the Corporation's uninsured cash balances total approximately \$2,912,000.

#### Note 3. Pledged Contributions Receivable

The Corporation's policy is to record only written pledged contributions receivable. Management estimates that no allowance for doubtful accounts is required. All pledged contributions receivable at June 30, 2017, are current pledges receivable. Since the pledges are due in less than one year, no discount is necessary to determine the present value of the unconditional promises to give.

The pledged contributions receivable as of June 30, 2017, are as follows:

Commonwealth of Virginia	\$2,950,000
College of William & Mary	50,000
Eastern Virginia Medical School	50,000
George Mason University	50,000
Old Dominion University	50,000
University of Virginia	50,000
Virginia Commonwealth University	50,000
Virginia Polytechnic Insitute and State University	50,000
	\$3,300,000

#### Note 4. Subsequent Events

Management has evaluated subsequent events through October 27, 2017, the date which the financial statements were available for issue.