TO: Speaker of House of Delegates
President of the Senate
Chair of House Appropriations
Chair of Senate Finance Committee

FROM: William Hazel, MD, George Mason University, on behalf of Named Institutions

DATE: October 31, 2019

RE: Virginia Commonwealth Clinical Research Network (VCCRN)- Budget Item 164#1c

In 2019, the Commonwealth of Virginia appropriated funds to George Mason University, in collaboration with Eastern Virginia Medical School, Old Dominion University, the University of Virginia, Virginia Commonwealth University, Virginia Polytechnic Institute and State University, INOVA, and Sentara Health System (together "Named Institutions"), to conceptualize a Virginia Commonwealth Clinical Research Network ("VCCRN") that will facilitate the conduct of clinical trials across institutions and enhance the economic and health impact of clinical trials to Virginians. This funding was used to engage Huron Consulting Group in the development of a strategy and business plan for VCCRN. Huron has extensive experience in clinical research, networks, Cancer Centers, and other research organizations. Huron worked closely with the Named Institutions and stakeholders across the Commonwealth. It assessed our strengths, challenges, and opportunities in clinical research and subsequently formulated a strategy to optimize Virginia clinical research, which has been universally endorsed by stakeholders at a September retreat.

In its assessment, Huron observed that Virginia has many of the assets of peer states; however, it has not reached a comparable level of clinical research activity. The current structure of institutions in Virginia drives institutional efforts and as result there is no individual or entity charged with encouraging and enabling collaborations across the state. Huron recognized that Virginia has two NIH grant-funded Clinical and Translational Science Institutes and two National Cancer Institute-Designated Cancer Centers; however, these mechanisms tend to benefit their home institutions and some affiliates; however, their impact statewide has been limited. In addition, a high percentage of Virginians receive their health care at non-academic health systems which do not tend to view clinical research as an institutional priority. The institutional research partnerships that are in place tend to be complicated by such factors as differences in culture, expertise, and priorities which limit their effectiveness. Commonwealth-sponsored initiatives have been successful in commercialization and start-ups but do not have focused expertise on overcoming barriers to enhancing economic, health and social impact of clinical research. As a result, the *collective power of Virginia clinical research* on health, disparities and inclusion, workforce, and the economy has not been fully realized, and Virginia continues to lose ground to states that have clinical research platforms to optimize collective capabilities.

Huron concluded that the General Assembly is uniquely positioned to transform clinical research in Virginia. With its backing, a VCCRN could have an unparalleled ability to engage and deliver. The VCCRN would use its state leadership role ("neutral party"), coupled with expertise in clinical research, to bring stakeholders 'to the table' in order to find common approaches to shared problems. By building on existing strengths, the result would be a new level of collaboration across research institutes and health systems to conduct clinical research that will advance the health of Virginians and reduce the social determinants of health inequities. This, in turn, would position Virginia to compete more effectively for grants and contracts, conduct meaningful clinical trials, attract top-flight researchers, and develop the workforce. Evidence that this is possible is the Huron engagement itself, during, one stakeholder stated, 'This is the *first* time we have all come together and are really ready to work on *common* solutions to shared problems."

To move forward, Huron recommends funding to formally establish the Virginia Commonwealth Clinical Research Network. This funding will support continuation of the Governance Committee, the hiring of a manager to oversee VCCRN and additional planning of the three initial VCCRN services proposed herein; an interim report will be submitted no later than November 1, 2020 on how these services will be developed with a request for funding. The VCCRN should be housed within the newly proposed organization for innovation and commercialization.

Virginia Commonwealth Clinical Research Network (VCCRN)

Assessment and Planning Report

Submitted to: Chairs of the House Appropriations and Senate Finance Committees,
President of the Senate and Speaker of House of Delegates
October 31, 2019

Table of Contents

I. Background and Overview

In 2019, the Commonwealth of Virginia designated funds from the Commonwealth's General Fund to George Mason University ("GMU"), in collaboration with Eastern Virginia Medical School ("EVMS"), Old Dominion University, the University of Virginia ("UVA"), Virginia Commonwealth University ("VCU"), Virginia Polytechnic Institute and State University (Virginia Tech), INOVA, and Sentara Health System (together, "Named Institutions'"), to create the Virginia Commonwealth Clinical Research Network ("VCCRN"). The stated intent for VCCRN was to facilitate the conduct of significant clinical trials across multiple institutions in the Commonwealth in areas that include oncology, mental health and substance abuse. As such, VCCRN would facilitate identifying and recruiting patients across the Commonwealth, foster opportunities for research funding, and enable in-state commercialization of breakthrough products and services.

The legislative mandate (Budget Item 164#1c) , which became effective July 1, 2019, to George Mason University, along with the Named Institutions, was to engage a consultant to develop a strategy and business plan for a VCCRN and submit its report to the Chair of the House Appropriations and Senate Finance Committees no later than November 1, 2019.

Together, the Named Institutions selected a nationally respected consulting firm with extensive experience that matched the specific needs of VCCRN. The chosen firm, Huron Consulting Group ("Huron"), has significant experience in clinical research, including networks, Cancer Centers, and Clinical and Translational Science Awards (CTSAs). Of note, Huron, which is a global management consulting company, had considerable direct experience with multiple Virginia-based organizations. Huron provides services to the Healthcare, Higher Education (academics, research), Life Sciences, and Commercial sectors and is known for partnering with clients to develop strategies and implement solutions that result in transformative change and long-term success. (See Appendix A for a Huron Consulting Group profile.) The Huron team was led by Beverly Ginsburg Cooper, who has extensive front-line and consulting experience in consortia, cancer centers, CTSAs, and research organizations. (See Appendix B for a Huron team profiles.)

a. Project Goals

Pursuant to approved legislation, the goals for VCCRN were initially defined as:

- Provide a statewide network that will increase local access to clinical trials, facilitate recruiting patients, and expand researcher access to a clinical base.
- Prioritize clinical trials important to Virginians in areas that may include oncology, mental health, and substance abuse.
- Create opportunities for research funding and commercialization of breakthrough products and services.

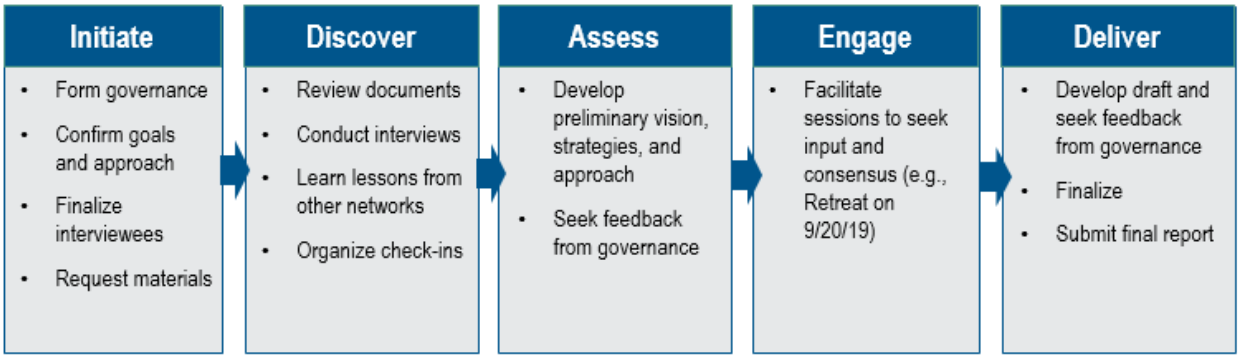
During its engagement, Huron used these goals as guideposts, along with the overall vision for VCCRN. It then used its findings to drive and shape the strategies presented in this report so that they would best meet the goals of the General Assembly and address the needs of stakeholders throughout the Commonwealth.

b. Huron Charge and Approach

Huron was charged with assessing the potential of a statewide clinical trials network to elevate clinical trials activity and economic impact (e.g., grants, contracts, recruitment and retention, workforce development) throughout the Commonwealth of Virginia. Additional goals were to assess the potential of the network relative to improving population health and addressing the social determinants of health inequities / disparities.

As seen in **Figure 1**, below, Huron's engagement included five distinct yet integrated phases.

Figure 1. Huron's Phased Approach.



Each phase is summarized below. See Appendix C for the draft Huron Engagement Timeline.

1. *Initiate*

All institutions named the Commonwealth's funding legislation were invited to appoint a representative to the Engagement Governance Committee. The charge of the Engagement Governance Committee was to provide information, feedback, and insights to Huron. Committee sessions were also used to facilitate visioning, test concepts, and prioritize options.

Each individual on the Engagement Governance Committee (see Appendix D for Engagement Governance Committee members) has a senior position within his/her institution and has a record of inter-institutional collaboration. William Hazel, MD, who previously served as the Virginia Health and Human Resources Secretary, was appointed by GMU as its representative and subsequently was asked to serve as the Chair of the Engagement Governance Committee. Dr. Hazel contributed his extensive knowledge of Virginia institutions as well as a lifelong passion to improve health, address inequities, and boost the economic power of research.

With Huron, the Engagement Governance Committee defined the core principles that would drive the planning process and subsequent development of VCCRN. These included:

- Engage and create collective vision.
- Be inclusive and encourage diversity of representation.
- Minimize overlap with existing institutional efforts and factor in Commonwealth initiatives.
- Broaden the focus of VCCRN from clinical trials to clinical research.

Of note, the Engagement Governance Committee's request to change VCCRN's focus from clinical trials to clinical research (see last bullet, above) proved to be transformative. By broadening VCCRN's focus, stakeholder organizations immediately became far more enthusiastic. They and other stakeholders recognized the potential of a clinical research-focused VCCRN to support a far *broader* range of researchers (including laboratory and population-based scientists) and to provide *substantive* benefit to research institutes, health systems, and interest groups alike. Beyond this, they realized the potential of a re-envisioned VCCRN to make Virginia competitive for larger grants and contracts; to conduct clinical trials based on Virginia discoveries within the Commonwealth; and to impact health outcomes and inequities in all regions. The definition of Clinical Research used in this report is presented in **Figure 2,** below.

Figure 2. Definition of Clinical Research.

Definition of Clinical Research

For purposes of this report, Huron adopted the National Cancer Institute's definition of ***Clinical Research****, in which people, or data or samples of tissue from people, are studied to understand health and disease. Clinical Research helps find new and better ways to detect, diagnose, treat, and prevent disease. Types of clinical research include clinical trials, which test new treatments for a disease, and natural history studies, which collect health information to understand how a disease develops and progresses over time. Examples of clinical research include:*

- ***Treatment Research****, which involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy.*
- ***Prevention Research****, which looks for better ways to prevent disorders from developing or recurring and may study medicines, vitamins, vaccines, minerals, or lifestyle changes.*
- ***Diagnostic Research****, which looks for better ways to identify a particular disorder or condition.*
- ***Screening Research****, which seeks better ways to detect disorders or health conditions.*
- ***Quality of Life Research****, which explores ways to improve comfort and the quality of life for individuals with an illness.*
- ***Genetic Research****, which seeks to better predict disorders by understanding how genes and illnesses are related.*
- ***Epidemiological Research****, which help identify patterns, causes, and control of disorders in groups of people.*

2. *Discover*

Huron visited all Named Institutions and conducted telephone interviews with representatives from other hospital systems, stakeholder organizations, and Commonwealth-sponsored research initiatives. Huron also met with government leaders to gain insights into perspective.

Figure 2, on the following page, provides a summary of the stakeholder organizations which were interviewed. In total, Huron traveled across the Commonwealth and interviewed more than 75 individuals. (See Appendix E for Named Institution Clinical Research Profiles.)

Figure 3. Stakeholder Interviews.

Named Institutions

- Eastern VA Medical School
- George Mason University
- INOVA
- William and Mary University
- Old Dominion University
- Sentara Health System
- University of Virginia
- Virginia Commonwealth University
- Virginia Polytechnic Institute and State University/Carilion Clinic

Hospitals Systems

- Valley Health
- Ballad Health

Multi-Institutional Research Organizations

- UVA iTHRIV
- VCU Wright Center

VA-Funded Research Initiatives

- Virginia Catalyst
- Virginia Neuroscience Initiative
- VaBio

Stakeholder Groups

- Medical Society
- Hospital Association

Government Offices

- Commerce and Trade
- Health and Human Resources
- Health Equity
- Higher Education

Given limited resources and time, it was agreed that Huron would not conduct any original research or data gathering. As a result, Huron relied on information provided by stakeholders or available sources.

3. *Assess*

Huron used several approaches to assess the current strengths, challenges, and opportunities of Virginia Clinical Research. This included gathering insights through interviews and available documents. Huron also relied on its extensive knowledge of clinical research activities across the country, and beyond.

Throughout its assessment phase, Huron remained sensitive to the underlying principles set forth by the Engagement Governance Committee as well as its charge from the General Assembly.

4. *Engage*

To foster inclusion, engagement, and collaboration, all interviewees, as well as additional stakeholders, were invited to a full-day retreat September 20, 2019. The purpose of this retreat, which was facilitated by Huron, was to share interim findings, gain feedback, and foster stakeholder discussion about VCCRN structure and priorities.

A total of 25 individuals attended the event, which was held at the Patrick Henry Building in Richmond, Virginia. The results of this retreat informed Huron's findings and shaped the recommendations presented in this report.

(See Appendix F for Stakeholder Planning Retreat Agenda and Attendees.)

Stakeholder Retreat Quote

At the closing session of the VCCRN Stakeholder Retreat, when each attendee was asked to provide comments, a member of the Engagement Governance Committee remarked:

> **"This is the *first* time we have all come together and are really ready to work on common solutions to shared problems."**

5. *Deliver*

Huron was charged with submitting its assessment of Virginia Clinical Research, along with recommended strategies, and an implementation plan to Dr. Hazel on behalf of GMU by mid-October. Once approved, the report was to be submitted to the Chair of the House Appropriations and Senate Finance Committees, President of the Senate and Speaker of House of Delegates, by Dr. Hazel on behalf of GMU, as grantee, no later than November 1, 2019.

II. Assessment

Huron assessed the current state of Virginia Clinical Research in light of the General Assembly's goals, existing capabilities across the Commonwealth, existing Commonwealth-funded investments, and peers around the country. Huron then reached conclusions about Virginia's strengths, challenges, threats, and opportunities.

Huron's assessment is presented below and is divided into five categories:

- Stakeholder Perspectives
- SWOT Analysis (Strengths, Weaknesses, Opportunities, and Threats)
- Peer Comparators
- Key Findings
- Conclusions

a. Stakeholder Perspectives

Presented below is a summary of what Huron heard from four stakeholder groups: Researchers, Physicians, Clinical Research Professionals, and Institutions. Each of these groups is vital to the future success of Virginia Clinical Research.

Researchers

- Relative to peers, Virginia universities and health systems provide limited resources for clinical research.
- Virginia researchers lack access to biomedical information (patient data from electronic health records), big data analytic tools, and biospecimens from patients. These resources are vital to attracting and retaining top-flight researchers, securing major grants and contracts. Such capabilities are also vital for Virginia to increase its reputation and overall competitiveness in life sciences.
- Researchers lack access to data associated with social determinants of health.

- Following graduation or early-stage faculty appointments, successful researchers are frequently recruited to other states where there are more resources and support.
- Virginia researchers have difficulty enrolling the needed number of patients from their home institution alone, and thus must seek partners to conduct novel trials with narrow eligibility criteria. Oftentimes, they seek partners in other states rather than colleagues within the Commonwealth.
- Commonwealth-sponsored initiatives have focused on commercializing existing discoveries and attracting industry-sponsored trials, not on creating the infrastructure and capabilities that foster growth in clinical research that are needed to build a clinical research pipeline that is more robust, innovative, and directly relevant to Virginians.

Physicians

- After graduating from Virginia-based academic programs, physicians often join non-academic Virginia health systems. Despite an interest in clinical research, they are oftentimes challenged by the limited resources, training, and incentives in non-academic settings.
- Physicians also have limited access to information and resources to conduct cost-effectiveness studies, which can help enhance quality, improve outcomes, and control health care costs.

Clinical Research Professionals

- There are limited resources to train clinical research staff and advance their skills over time.
- Once experienced, clinical research staff are frequently recruited to organizations outside the Commonwealth or to industry.

Institutions

- Institutions recognize that inter-institutional issues are preventing them from optimizing their collective potential in clinical research, e.g., different priorities, processes, expertise.
- Institutions agree that expert leadership will be needed to drive the development of common-ground solutions, e.g., common tools, resources, and services; unified contracting and budgeting.
- Institutions agree while several Commonwealth-led initiatives have been successful in such areas as commercialization and start-ups, they have not been as successful in clinical research.
- Institutions are concerned that a new Commonwealth entity might dilute or duplicate institutional efforts and might not effectively balance stakeholder interests.
- Institutions are also concerned that a new Commonwealth entity might divert funds away from institution-specific support.
- Several institutions face challenges in sustaining a capable clinical research workforce, e.g., the loss of even one individual can impact a small team.

b. SWOT Analysis

Huron assessed Virginia's Clinical Research strengths, weaknesses, opportunities, and threats relative to the General Assembly's goals, current capabilities, and best-practice peers. In general, Huron found that Virginia has top-flight faculty and physicians, universities, research organizations, and health care systems. However, Virginia lacks the clinical research leadership, organization, and infrastructure (e.g., technology, resources) that help best-practice states succeed.

Huron's SWOT analysis is summarized in **Figure 4**, presented below.

Figure 4. SWOT Analysis, Virginia Clinical Research Landscape.

Strengths

- Highly respected educational and research institutions
- High-quality health systems
- Commonwealth investment in life sciences
- 2 CTSAs, 2 NCI Cancer Centers
- Inter-institutional partnerships to conduct research
- Geographic location; proximity to federal agencies and premier research-focused organizations

Weaknesses

- Most patient care provided in non-academic institutions with varied interest in clinical research
- Clinical research infrastructure growing at some institutions, but remains limited overall
- Results from inter-institutional partnerships are mixed; some, however, are early in development
- Commonwealth-led initiatives focus on commercialization and start-ups; investment in clinical research has been small and impact has been limited
- Overall, clinical research is conducted in institutional silos—lack of shared infrastructure or compelling rationale to collaborate and be more impactful together
- Researchers lack access to data associated with social determinants of health
- Investigators go out of state to find partners to conduct trials built on Virginia discoveries
- Efforts to connect researchers with local providers and diverse populations have been limited; distrust reported as an ongoing concern of communities

Threats

- Accelerating growth in competition through regional and state clinical research programs that build on collective strengths
- Limited commitment of institutional leaders to clinical research
- Competition with other Commonwealth-funded initiatives
- Underfunding and unrealistic timeframe/expectations for VCCRN
- Limited institutional support and engagement in VCCRN
- Competition with other states

Opportunities

- Development of Commonwealth-led leadership, infrastructure and processes that will improve competitiveness, e.g., contracting, activation time, accruals, quality
- Development of neutral state-led leadership, processes, and technology to support multi-site activities
- Investment in training and workforce programs to build and retain clinical research talent
- Closure of gaps in capabilities needed to be top performing
- Increased public awareness and value of clinical research

c. Peer Comparators

Virginia is physically located in one of the 'top ten' life science clusters in the country. Its cluster spans Maryland, Virginia, and Washington, DC. A primary driver of regional success is the research grant funding and industrial activity associated with Johns Hopkins University and, to a lesser extent, the University of Maryland.

Virginia is the 12th most populated state with 8.5 million residents; however, it is ranked 19th in NIH funding ($415 million). In addition, at $12 billion, Virginia's biopharmaceutical economic output is ranked 22nd nationally. In 2017, Virginia conducted 759 clinical trials and had 17,685 enrollments, placing it in the top 20 overall. However, it had a total biopharmaceutical industry site-based trial investment of $267.2 million and total site-based economic impact of $695.7 million, both of which were below the national average of $292.9 million and $819 million, respectively.

Similar in population size to Virginia, the state of New Jersey is 11th in state population rankings with 8.9 million residents. New Jersey has a similarly sized clinical research portfolio with 792 active clinical trials and 16,649 enrollments. However, New Jersey has a higher total biopharmaceutical industry site-based trial investment of $320.4 million (+10%) and a total site-based economic impact of $879.7 million (+26%).

While far smaller in population size with 5 million residents and 23rd in state rankings, South Carolina has a similarly-sized clinical trials portfolio with 708 active clinical trials and 18,475 enrollments, However, South Carolina has a higher biopharmaceutical industry site-based trial investment of $331.7 million (+24%) and a total site-based economic impact of $829.4 million (+19%).

These figures reflect the viewpoint of stakeholders, based on interviews, as well as Huron's observation that Virginia has not maximized its collective capabilities in Clinical Research.

(See Appendix G for additional Life Sciences Metrics.)

d. Key Findings

Overall, Huron determined that the current structure of institutions in Virginia drives institutional efforts and as result there is no individual or entity charged with encouraging and enabling collaborations across the state.

In its assessment, Huron made the following critical-path observations about Virginia clinical research:

1. Virginia has many of the advantages of peer states; however, it has not reached a comparable level of clinical research activity. (See Appendix H for Statewide Models.)

2. Huron recognized that Virginia has two NIH grant-funded Clinical and Translational Science Institutes and two National Cancer Institute–Designated Cancer Centers; however, these mechanisms tend to benefit their home institutions and thus have limited impact statewide.

3. A high percentage of Virginians receive their health care at non-academic health systems, and these organizations tend to not view clinical research as an institutional priority

4. While inter-institutional research partnerships are in place, they tend to be complicated by such factors as differences in culture, expertise, and priorities, and thus the level of success anticipated has not been realized.

5. Commonwealth-sponsored initiatives been successful in commercialization and start-ups; however, they have not focused on overcoming barriers to clinical research.

Each of these findings is described below.

1. Virginia has many of the assets of peer states; however, it has not reached a comparable level of clinical research activity.

As seen in **Figure 5.1**, below, Virginia has many of the elements that drive research growth and economic success. Despite multiple strengths and advantages, Virginia has not been able to capitalize on opportunities in the way that other peer areas have. Signs and symptoms of missed opportunities are presented in **Figure 5.2.**

Figure 5. Virginia's Advantages, Gaps, and Opportunities in Clinical Research

5.1 Advantages in Clinical Research

- Pre-eminent universities and educational programs that train excellent researchers and physicians
- High-quality health systems
- Commonwealth investment
- Mid-Atlantic location, with proximity to biopharma companies and federal agencies
- 2 Clinical and Translational Science Institutes
- 2 NCI-Designated Cancer Centers

5.2 Signs and Symptoms of Missed Opportunities

- Not considered 'go to' place by pharma
- Investigator-initiated studies based on researcher discoveries are limited even in the top universities of the state
- Novel trials that require multiple sites to achieve recruitment targets are limited and typically involve out-of-state partners
- Research consortia are not the norm
- Institutional leaders vary in their valuation of clinical research to their organization
- Investigators and institutions lacked interest in industry clinical trial opportunities identified by Commonwealth-backed initiatives

2. Huron recognized that Virginia has two NIH grant-funded Clinical and Translational Science Institutes and two National Cancer Institute-Designated Cancer Centers; however, these mechanisms tend to benefit their home institutions and thus have limited impact statewide.

VCU and UVA have NIH-funded Clinical and Translational Science Institutes and NCI-Designated Cancer Centers. The federal grants that fund Clinical and Translational Science Institutes (CTSIs) programs are awarded to train and develop clinical and translational scientists and clinical research professionals; improve the quality and efficiency of clinical trials conduct; and enhance biomedical informatics and data use. Consistent with Huron's experience,

Virginia-based CTSIs tend to benefit investigators at the academic home (e.g., VCU, UVA) and have limited added-value partner organizations or other organizations around the region. (Note: UVA partners with INOVA, and Virginia Tech/Carilion; VCU partners with UVA, EVMA, Virginia Tech/Carilion Clinic, and INOVA)

VCU and UVA also have NCI-Designated Cancer Centers. Grant funding from NCI provides partial funding for cancer clinical research infrastructure and other resources to support to high-impact cancer research (e.g., biostatistics). No NCI funding for designated Cancer Centers may be used to support *non-cancer* research. Based on interviews, VCU and UVA Cancer Centers appear to have modest clinical trial programs; efforts are on-going to bolster accrual and infrastructure, particularly in light of the Cancer Centers' desire to reach the highest designation of Comprehensiveness.

3. A high percentage of Virginians receive their health care at non-academic health systems, and these organizations tend to not view clinical research as an institutional priority

Health system executives in Virginia are focused on quality, safety, and cost effectiveness. Unlike peers in other regions or states, which view clinical research as necessary to compete with academic medical centers and health systems in their service area, Virginia health system executives did not view clinical research as a competitive strategy. This may in part result from limited regional competition due to CON restrictions.

Health system leaders noted that they were most interested in clinical research when their physicians viewed it as a priority. When clinical research is provided, health system leaders commented on the challenge of recruiting and retaining talented staff and addressing short periods of high activity.

4. Partnerships between universities and large health systems are complicated and some have not realized anticipated results in clinical research.

Despite high promise, cross-institutional collaborations have proven to be challenging in execution. This was reported to be the result of a variety factors, including changes in institutional leadership; shifting organizational priorities; differences in research expertise and processes between organizations; and lack of common resources and infrastructure. In addition, institutions lack dedicated champions and infrastructure to maximize the success of these cross-institutional opportunities.

5. Commonwealth-sponsored initiatives been successful in commercialization and start-ups; however, they have not focused on overcoming barriers to clinical research.

The Commonwealth has made significant investments to stimulate research activity—and impact—in recent years. These investments have helped to bolster the economy, retain talent, and drive discoveries. Investments have been in the form of both awards to individual institutions (e.g., annual commitments) and support of cross-institutional partnerships (e.g., INOVA, UVA, and GMU partnership).

The Commonwealth has also supported state-wide organizations to bolster life sciences activity. These include: (1) Virginia Biotechnology Association (VaBio); (2) Virginia (VA) Catalyst; and (3) Virginia Neurosciences Initiative (VNI), whose funding has come via the VA Catalyst. By design, these entities have focused on attracting industry to Virginia, helping investigators form start-up companies, and facilitating partnerships that will help bring products to market faster. Each initiative is profiled below:

- The Virginia Biotechnology Association (VaBio) is a non-profit trade association for life sciences industry. VaBio advances life sciences industry interests in Virginia and grows its economic impact by advocating for effective public policies, supporting entrepreneurs and businesses, and educating biotech leaders.
- Virginia (VA) Catalyst is a biosciences commercialization accelerator. It advances economic development across the Commonwealth by advancing entrepreneurship, attracting investment capital, and catalyzing commercialization of innovations through start-ups.
- The Virginia Neurosciences Initiative (VNI) fosters growth in basic and translational neuroscience research through infrastructure and research tools. VNI working groups, retreats, and other collaborative mechanisms encourage interactions among investigators at five medical centers and seven universities.

While these initiatives have been successful in commercialization, start-ups, and life science sector growth, they have not been equally successful in clinical research, based on Huron's interviews. VNI recently launched efforts to foster growth in neuroscience clinical trials. As an example, VNI signed agreements with Clinical Research Organizations (CROs), which contracts with sites to conduct clinical trials that are sponsored by CRO pharma clients. VNI also identified some trials and brought them to stakeholder organizations, but only a few trial agreements were executed due to lack of investigator interest or organizational capability. During interviews with VNI's parent organization, VA Catalyst, leadership agreed strongly that Virginia needed enabling resources and leadership in clinical research; however, at the same time, VA Catalyst lacks internal expertise in clinical research and had resource limitations due to other priorities. Note: *During the writing of this report*, *Huron was notified of VA Catalyst's decision to terminate funding of VNI effective December 31, 2019, following approval by its Governance Committee.*

e. Conclusions

The collective potential of Virginia Clinical Research on health, disparities and inclusion, workforce, and the economy has not been fully realized. And, Virginia continues to fall behind peers with competitive strengths in this area.

The General Assembly is uniquely positioned to transform Virginia clinical research through VCCRN. With Commonwealth backing, VCCRN will have an unparalleled ability to engage and deliver. VCCRN will use its state leadership role ("neutral party"), coupled with expertise in clinical research, to bring stakeholders 'to the table' in order to find common approaches to shared problems. VCCRN will build upon (not duplicate) existing institutional capabilities and will provided the needed Commonwealth-support leadership and expertise to bring institutions together and find common ground solutions to shared challenges.

To realize the goals set forth for VCCRN, a dedicated infrastructure will be needed. VCCRN should be established as a new entity and housed within the newly proposed innovation and commercialization organization, assuming it is given the empowerment, resources, and expert clinical research leadership to realize the expanded scope.

The impact of VCCRN will be a new level of collaboration across research institutes and health systems that will advance the health of Virginians and reduce the social determinants of health inequities through high-impact, meaningful clinical research. As a result of VCCRN and growing collaborations, Virginia will be better positioned to compete for grants and contracts, conduct clinical research that is directly relevant to residents, attract and retain talented researchers, and develop a workforce pipeline.

Evidence of VCCRN Potential to Succeed

Evidence of VCCRN's potential was found throughout the Huron engagement. As one stakeholder stated during the Stakeholder Retreat,

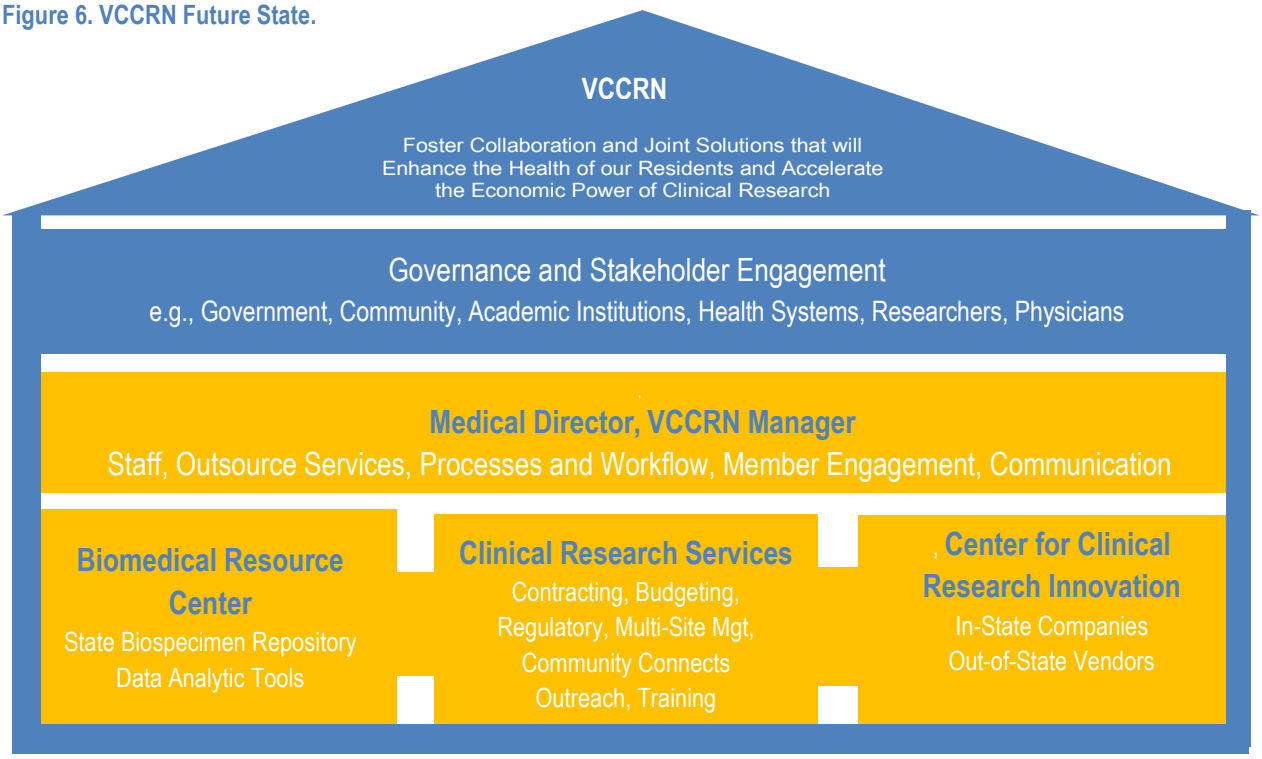
> **"This is the *first* time we have all come together and are really ready to work on *common* solutions to shared problems."**

Based on its assessment of Virginia Clinical Research during this engagement, Huron developed a draft mission, vision statement, and core strategies for VCCRN. It then tested these concepts with the Governance Committee and other stakeholders and received additional feedback during the stakeholder retreat.

Through this iterative process, Huron reaffirmed its conclusion that VCCRN was critical to achieving the goals and aspirations of the General Assembly and validated its recommended strategies, services, and resources ("solutions").

The Future-State VCCRN is visually portrayed in **Figure 6**, below.

Figure 6. VCCRN Future State.



Mission

The mission of VCCRN is to *foster collaboration and joint approaches* in order to *accelerate* the growth and impact of clinical research across Virginia.

Vision

VCCRN will foster *common* solutions that will enhance the *collective* power of Virginia Clinical Research on the economy and on population health, including inequities, across the Commonwealth.

Strategy

As the Commonwealth-endorsed and funded Clinical Research Accelerator, VCCRN will provide the leadership and expertise, collaborative mechanisms, shareable tools, and direct services needed to overcome institutional barriers and realize the collective potential of Virginia in clinical research.

Organizing Principles

- Engage stakeholders across the Commonwealth
- Reflect diversity of needs among residents and institutions
- Minimize overlap with existing (institutional and Commonwealth) efforts
- Focus on clinical research, not just clinical trials
- While remaining disease agnostic, disease-oriented pilots or services may evolve based on highest interest/demand

Core Values

Collaboration – Stewardship - Inclusion - Innovation, Mobilization, and Acceleration - Value Addedness

Benefit to General Assembly

Because VCCRN reports to the General Assembly, it will serve as a neutral party in its quest to find common ground.

Each dollar invested in VCCRN will have the multiplier effect of benefiting all universities, research institutes, and health systems in the Commonwealth engaged in clinical research.

Business Plan Components

This section summarizes the four business components required to successfully plan and launch the initial services and capabilities of VCCRN over the next 2 years:

1. Governance, Leadership, and Organizational Structure
2. Commonwealth-wide Biospecimen and Data Resource
3. Clinical Research Services Office
4. Center for Clinical Research Innovation

1. Governance, Leadership, and Organizational Structure

Rationale

Virtually no Virginia institution has the critical mass of capabilities and resources to consistently compete against leading life science clusters such as Boston. While clinical research in Virginia is high quality, systems are fragmented. For example, academic institutions conducting clinical research are not under the same organizational umbrella as

health care systems that deliver a majority of patient care. Thus, high-impact clinical research mandates partnering among organizations. However, to date, leaders across the Commonwealth acknowledge that research partnerships have proven to be challenging due to multiple factors and have had varying degrees of success.

Strategy

The first step in planning and establishing VCCRN as the Clinical Research Accelerator for the Commonwealth is the development of an effective governance, leadership, management, and organizational structure. Year 1 steps will include:

1. Establish a VCCRN Governance Committee, building upon the Engagement Governance Committee with potential modifications in membership.
2. Appoint Medical Director for VCCRN to chair 01/ Committee (1) and provide guidance to VCCRN manager (3) and external consultants (8).
3. Recruit an experienced manager and core staff to operationalize VCCRN.
4. Create stakeholder advisory groups to guide the development of the initial services that will be offered by VCCRN and described below.
5. with the advisory groups, develop detailed strategic, implementation, and financial plans for selected VCCRN services, using external experts as needed with plans to be submitted to General Assembly by the end of Year 1 (11/01/2020).
6. Hold stakeholder retreats to sustain engagement and transparency (one retreat every 6 months in Year 1 and at least one retreat in Year 2).
7. Develop communication tools and mechanisms to foster high awareness, encourage utilization of VCCRN services, and maintain active support and engagement among stakeholders.
8. Continue use of external consultants during planning and launch, until internal capabilities and resources are in place.

As noted above, VCCRN should live within the newly proposed collaboration and commercialization organization.

Impact

VCCRN will develop shareable solutions that benefit multiple researchers and institutions. VCCRN will foster collaborations in a way that would not be possible.

2. Commonwealth-wide Biospecimen and Data Resource

Rationale

Patient specimens (e.g., tissue, blood, urine), and related clinical information have become the 'gold' of scientific discovery, driving clinical research innovation and commercialization that is directly meaningful to local patients and communities. A high-quality virtual repository that provides easy access to large quantity of patient specimens and high-quality data helps attract and retain researchers, increase grant competitiveness, support patient care/quality studies, and foster industry relationships.

Currently, biospecimen and data analytic resources are institutionally focused and thus limited in size, scope, and access. In contrast, a number of states and regions have created collaborative biorepository and data analytics resources.

Strategy
VCCRN will capitalize on existing resources to create a virtual biorepository and data sharing service for Virginia. Through the VCCRN Biomedical Resource Center, investigators will be able to access de-identified patient material across all Virginia institutions through a single portal that is staffed by experienced service-oriented personnel.

Year 1 steps will include:

1. Formation of an advisory group to assist in assessment of current capabilities and gaps.
2. Development of multi-year plan and budget.
3. Appointment of Manager and core personnel, as needed, to launch initial services and coordinate development of full capabilities over time.

Impact
A Commonwealth-wide resource with a single portal that provides user-friendly access to high-quality specimens and data will immediately:

- Foster research directly relevant to Virginians, with an opportunity to address health disparities and improve patient outcomes.
- Increase NIH and foundation grant success.
- Attract researchers and collaborators, as well as industry and biopharma sponsors.
- Create opportunities with foundations, advocacy groups, and companies that have special health / disease interests.

3. Clinical Research Services Office

Rationale
Institutions are creating research alliances to increase their collective ability to secure industry contracts and conduct clinical research that requires a larger patient base. Alliances create legal entities to enable one-stop contracting and budgeting on behalf of participating institutions. Often, alliances also provide services fee-for-service. Alliances can have a significant impact on the community by increasing awareness of the value of clinical research, training physicians and staff, enhancing access trials, and reducing barriers to participation.

Strategy
VCCRN will develop a variety of high-quality clinical research services that will be available on a fee-for-service basis to Virginia institutions. These services will be attractive to institutions when there are staffing gaps, excessive workloads, unanticipated fluctuations in demand, and gaps in staff experience. Some services will reduce duplication of effort and attract sponsors that would otherwise not contract with sites that do not have strong accrual records.

The following services are initially envisioned for the Clinical Research Services Office on a fee-for-service basis:

1. Budgeting and Contracting.
2. Regulatory (Institutional Research Board [IRB], FDA) Functions
3. Clinical Research Coordinators

Initially, services may be delivered by outside contractors until demand makes it cost-effective to hire full-time staff.

In addition to the delivery of direct services, the Clinical Research Services Office will develop a *Community Connects Program* with expert advisory guidance provided by the Virginia Office of Health Equity. The goal of the Program will be to increase awareness, understanding, and engagement in clinical research, with a focus on underserved communities and health disparities. Services that may be developed (based on available resources and interest) under the umbrella of the Community Connects Program are:

1. Community education programs on the value of participation in clinical research.
2. Training program on diversity and cultural sensitivity for investigators and staff (institutions may make course compulsory or elective).
3. Training/workforce development program for community research ambassadors.
4. Training/workforce development program for research navigators.
5. Internships with placement at VCCRN and network institutions for underserved minorities in order to spark interest and advocacy for clinical research and develop pipeline for increased minority representation.

Year 1 steps will include:

1. Assessment of stakeholder needs in collaboration with advisory group
2. Identification of outsourcing opportunities; negotiation of agreements
3. Implementation of outsourcing pilot
4. Development of plan for service roll-out over time

Impact

The Clinical Research Services Office will accelerate the conduct of trials arising from Virginia-based discoveries. The streamlining in administrative burden will attract industry sponsors as well as collaborating institutions across the country.

The Community Connects Program will foster communication, engagement, and collaboration between residents and researchers through which they will together identify the needs of highest priority to Virginians, develop meaningful research agendas, conduct studies relevant to the Commonwealth, increase participation, and facilitate dissemination of research findings. This program will enhance the relevance of studies to residents and enhance the impact of research findings to Virginian health and outcomes. Beyond this, there will be workforce pipeline programs and opportunities so that clinical research professionals of the future will increasingly mirror the residents they serve and support.

4. Center for Clinical Research Innovation

Background

Virginia is home to companies with technology, tools, and services that foster clinical research and could benefit stakeholders across the Commonwealth. High innovation will be necessary to increase access, identify eligible subjects, and foster participation in a large state with high rurality while controlling the overall cost of clinical research.

Strategy
The Center for Clinical Research Innovation will identify, screen, and promote the availability of new tools, technologies, telehealth capabilities, and other innovations by VA-based companies as well as those across the country. The goal of the Center is to find novel solutions that will enhance the conduct of clinical research, promote efficiency and access, control costs, and maximize outreach and engagement.

Year 1 steps will include:

1. Use advisory group to help identify companies
2. Promote the center to generate potential companies
3. Use advisory group to screen companies
4. Create a one to two events in Year 1 to present selected companies to stakeholders (structure TBD based on advisory group feedback)

Impact
The Clinical Research Innovation Center will boost Virginia's economy by promoting the adoption of state-based innovations and foster collaboration between VA-based companies and VCCRN stakeholders that will lead to the development or enhancement of novel clinical research products and services.

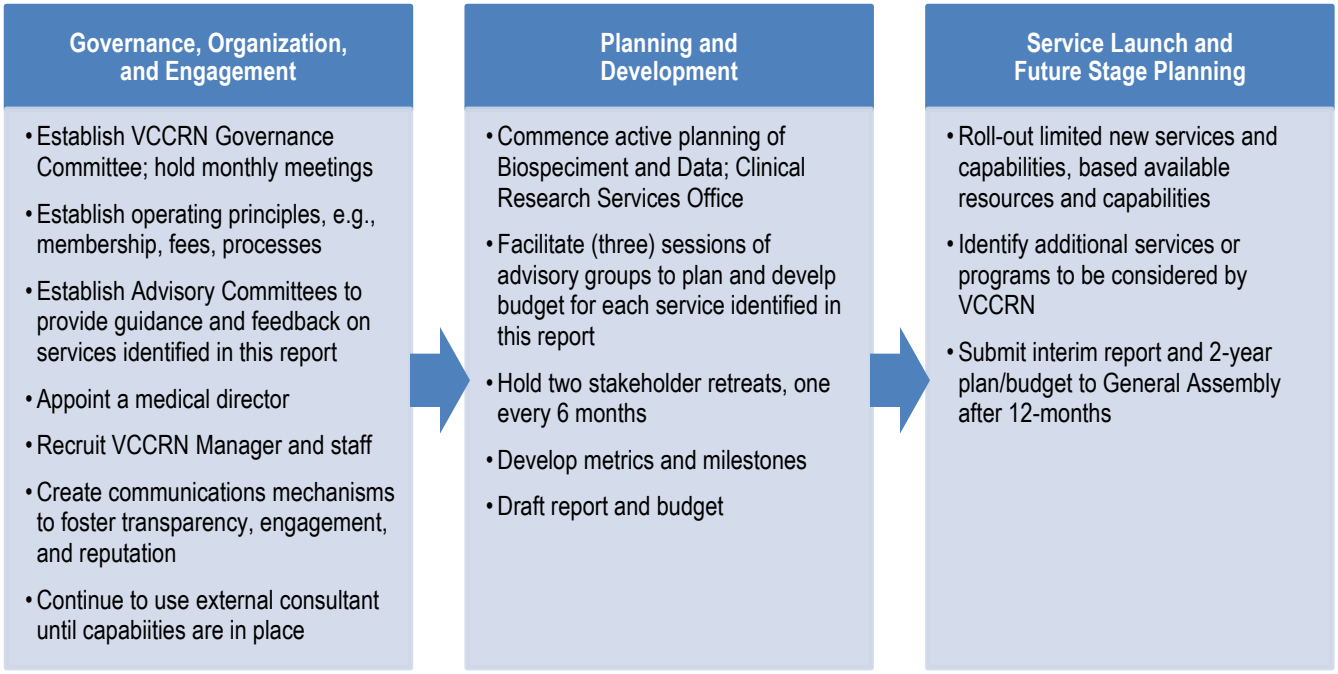
IV. Implementation Plan and Budget Request

Figure 6, on the following page, presents an Implementation Schema for Year I that includes the formation of a governance and organizational structure for VCCRN, the recruitment of a manager, and continued external consulting support until VCCRN capabilities are solidified. Also included is active planning for service development; interim roll-out based on availability of capabilities and resources; and submission of an interim report on how services will be developed with a request for funding for the following 2 years will be submitted by the end of Year 1.

Huron recommends Year 1 funding in the amount of $1.14M. This level of funding is needed to establish the VCCRN organization, continue planning of services, create a pilot launch, and prepare an interim report with two-year budget by November 1, 2010. (see Appendix I for Immediate Next Steps)

We have also prepared a high-level 3-year budget (see Appendix J), which will be refined through planning and budget development in Year I. *Note: this budget was prepared prior to being informed about the defunding of VNI.*

Figure 6. Year 1 Implementation Schema



VII. Summary

Huron has concluded that there is no individual or entity charged with encouraging and enabling collaborations in clinical research across the state. As such, the General Assembly is uniquely positioned to lead the transformation in Virginia Clinical Research by driving collaboration, coordination, and platform/resource development across stakeholders which will not be otherwise be fully realized. To effectively launch, VCCRN will require a 1-year continuation of the VCCRN governance leadership structure, recruitment of a VCCRN manager, and continued external consultant support and further planning of identified services which will culminate in a report to the Chairman of the House Appropriations and Senate Finance Committees 12-months after the 1-year continuation, which will describe how services will be developed with a request for funding.

VIII. Appendices

A: Huron Consulting Group Overview

B: Huron Team Profiles

C: Huron Engagement Timeline

D: Governance Committee Members

E: Named Institution Clinical Research Profiles

F: Stakeholder Planning Retreat

G: Life Science Metrics

H: Statewide Model Examples

I: Immediate Next Steps

J: High-level VCCRN Budget

Appendix A: Huron Consulting Group Overview

Huron Consulting Group is a leader in consulting services for many industries. Founded in 2002, Huron currently has a staff of nearly 3,000 who bring to their roles diverse backgrounds in industry, academia, healthcare, and other consulting environments. Huron's offices are strategically located around the country, including Chicago, Atlanta, Boston, Detroit, New York, Portland, and Washington, D.C.

The firm's number one priority is helping clients address complex challenges. This is achieved by building upon our depth and breadth of expertise in such areas as Cancer Centers, Strategy and Organization, Healthcare, Academia, Research, Higher Education, Life Sciences, and Business Advisory.

Huron's client base is diverse and includes major universities, academic medical centers, healthcare organizations, Fortune 500 companies, financial institutions, and government agencies firms. Importantly, Huron has worked with many of the NCI-designated and emerging cancer centers around the country, in addition to approximately 450 health systems, hospitals, and academic medical centers and 350 universities and research institutions.

The Huron Education Practice provides extensive knowledge and experience to solve the challenges facing today's public and private research universities, academic medical centers, and independent research foundations of all sizes in every core business function. Practice teams are led by Managing Directors who with at least 25 years of experience. Engagement teams work side-by-side with clients to develop strategies and implement actionable plans that achieve goals at the institutional, school, and department level.

Huron personnel maintain active in the higher education community by participating as members and subject matter experts in industry organizations including AACI, CCAF, ACE, NACUBO, EDUCAUSE, NCURA, SRA, HEUG, NAEP, SCTEM, NACCA and NECA. We regularly attend conferences and present to industry-focused groups. We remain up to date on issues and trends relevant to our clients while sharing our experiences with our client community.

The Huron Difference

Experience. The depth and breadth of Huron's experience gives us a full understanding of our client's culture, challenges, and expectations. We honor the values of each institution by listening and working collaboratively, And, we understand the necessity of fully engaging critical stakeholders to achieve success.

Collaboration. We value and foster a collaborative working environment as the path to success. We partner with institutions that thrive on team effort and bring a work culture that is respectful, inclusive, and open to all perspectives. Through partnership, we embrace joint ownership of challenges, solutions, and successes, recognizing that the best results are derived from team efforts.

Focus. We understand the complexities of cancer centers, universities, colleges, research institutions, and academic medical centers. As a result, we can focus on the challenges and solutions that are most critical, and which provide the highest return on investment. Our solutions deliver results quickly, without impacting our clients' ability to meet their responsibilities in other areas of their missions.

Results. We commit to measurable results, and we deliver those results on every engagement. We hold ourselves to the highest standards of professionalism in order to meet the high expectations that are set out for us.

Appendix B: Huron Team Profiles

Beverly Ginsburg Cooper, Managing Director

Beverly Ginsburg Cooper established the Cancer Center Service Line at Huron 5 years ago. Immediately prior to joining Huron, Ms. Ginsburg Cooper was the Senior Vice President for Research at Dana-Farber Cancer Institute (DFCI) and Associate Director for Administration at the Dana-Farber/Harvard Cancer Center (DF/HCC) consortium, which is comprised of five Harvard affiliated, independent hospitals and two schools. She has been on the external advisory boards of 13 Cancer Centers and a reviewer of multiple NCI-designated Cancer Center Support Grants.

Before this, Ms. Ginsburg Cooper was the Executive Director of the University of Pennsylvania's Abramson Cancer Center and served as its first cancer service line manager (COO, Cancer Services). In that role, she developed a 28-hospital network, a physician network, cancer marketing program, and interdisciplinary clinics. Ms. Ginsburg Cooper has also been Vice President of a major teaching hospital, COO of a community hospital within a multi-hospital system, president of a health care consulting group, and manager of multi-specialty practices.

Ellen McLaughlin, Director

Ms. McLaughlin has more than 20 years' experience in health care and research administration. Her expertise encompasses clinical trials and operations management, research services administration, clinical research, cancer center administration, strategic planning, and shared resource operations. Prior to joining Huron, Ellen served as the Director of Research Services Administration at Georgetown University's Lombardi Comprehensive Cancer Center. In that role, she was responsible for creating and sustaining an administrative infrastructure that served the Cancer Center's mission. In addition, she has served as the Associate Administrator for Research, Teaching and Academic Affairs at Georgetown and Senior Administrator for the Institute for Reproductive Health. Ellen, a registered nurse, and certified research administrator (CRA), has experience in inpatient and outpatient oncology clinical research care with expertise in clinical research operations and health care management positions. Ms. McLaughlin's post-doctoral work centers on the implications of big data and its ramifications on academic and clinical research care providers. Since joining Huron in 2014, she has engaged in numerous evaluations of aspirational cancer centers and their integral operational components and worked with centers to implement strategies for success. In addition, Ms. McLaughlin has worked closely with NCI-designated centers seeking to develop new consortium partnerships.

Jessie Pierre, Manager

Jessie Pierre has more than 20 years of experience in clinical research operations, research administration and project management. Ms. Pierre spent many years on the frontline of clinical research, managing various improvement projects for centralized offices and academic departments on behalf of a leading academic medical center. Today, Ms. Pierre's expertise includes clinical research management, strategic planning, clinical trials budget development, billing compliance, and process improvement strategies. She also has experience in managing various types of clinical research projects in leading academic medical centers for cancer centers, clinical departments and centralized offices. During her tenure at Huron, Ms. Pierre's engagements have included participating in the transformation of clinical research operations; serving as interim director of clinical trials support services for a

premier NCI-designated Comprehensive Cancer Center; serving as interim director for the clinical research office on behalf of two emerging Cancer Centers and assisting in their path to NCI designation; assisting a large health system in creating a regional research support infrastructure, and implementing operational performance improvements for a large medical center.

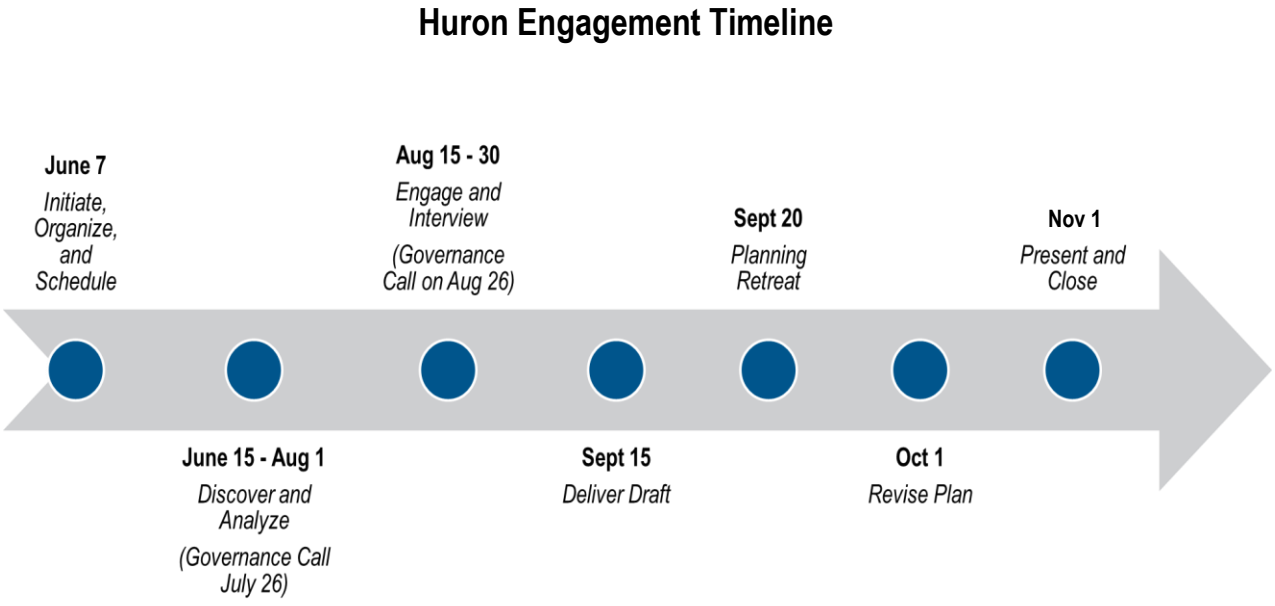
Tiffany Saavedra, Analyst

With more than 12 years of experience in healthcare and clinical research, Tiffany Saavedra specializes in the development, assessment, and implementation of clinical research solutions within academic medical centers, hospitals, and health systems. She has worked with more than 30 medical institutions and 10 pharmaceutical clients in areas related to strategic planning, clinical research operation improvement, protocol development, patient risk mitigation, global health, and research metrics analysis. Prior to joining Huron, Ms. Saavedra consulted for pharmaceutical clients in designing, implementing, and analyzing Phase I-IV interventional treatment protocols for high-risk pediatric and adult oncology patients. With many years on the frontline of academic clinical research and in clinical research management roles, Ms. Saavedra has worked across the research spectrum to build and strengthen clinical trial offices, reinvent patient recruitment strategies, assess compliance, create research staff training curriculum, and address the needs of underserved populations.

Appendix C: Huron Engagement Timeline

In Fall 2018, Huron Consulting Group was approached by the Cancer Center Administrator at UVA about the VCCRN opportunity. Beverly Ginsburg Cooper, Managing Director of the Huron Consulting Group Cancer Practice, contacted Dr. William Hazel who chose to lead the VCCRN effort and developed a sole source opportunity. During the intervening months, Huron supported Dr. Hazel as he drove effort to secure the engagement funding from the Virginia Legislature. In May 2019, Dr. Hazel informed Huron that the Legislation had passed, and it was time to begin contracting. Dr. Hazel spent the next several weeks seeking support among the named stakeholder institutions in order to ensure full support for Huron's engagement. The project contract was signed June 7, 2019, and planning commenced immediately.

Below is the 4-month timeline of Huron's approach to initiate, discover, assess, engage, and ultimately deliver the VCCRN strategy, business plan, and report to the Chairs of the House Appropriations and Senate Finance Committees no later than November1, 2019.



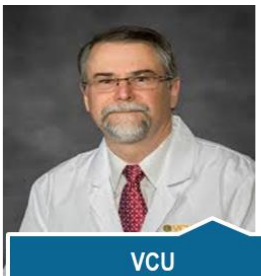
Appendix D: Engagement Governance Committee Members

The partner institutions identified in the Commonwealth legislation included universities that are state leaders in research and health systems that deliver the majority of health care services across the Commonwealth.

Each named stakeholder institution appointed a representative to the Governance Committee. All members hold senior positions at their institution and have a record of inter-institutional collaboration.

George Mason University
Bill Hazel, MD
Senior Advisor for Strategic Initiatives and Policy

INOVA Health System
Mickey Kim, MD, MBA
SVP, Research and Commercialization



VCU
Gerry Moeller, MD
Director Institute for Drug and Alcohol

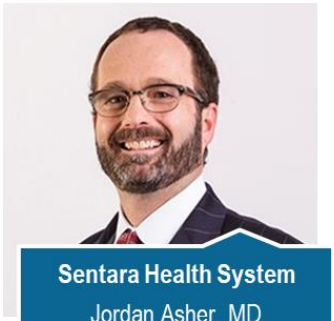
UVA
Sandra Burks, RN, BSN
Program Director, Translational Health Research Institute VA

VA Tech/Carilion
Paul Skolnik, MD,
Chair, Medicine

William & Mary College
Joshua Burk, PhD, Chair,
Department of Psychological Sciences

Eastern VA Med School
O. John Semmes, PhD
Director,
Cancer Research Center

Old Dominion University
Harold Riethman, PhD
Chair, Medical Diagnostic and Translational Sciences



Sentara Health System
Jordan Asher, MD
SVP,
Chief Physician Executive

VA Tech/Carilion
Michael Friedlander, MD,
Senior Dean for Research

Appendix E: Named Institution Clinical Research Profiles

EASTERN VIRGINIA MEDICAL SCHOOL (EVMS)

Eastern Virginia Medical School (EVMS) is a public medical school classified as a Special Focus Four-Year: Medical Schools & Centers in Norfolk, Virginia with no affiliation with an undergraduate institution. Training is coordinated through multiple medical centers in the Hampton Roads region, including the 555-bed Sentara Norfolk General Hospital, the region's only tertiary level 1 trauma medical care facility, and the 212-bed Children's Hospital of The King's Daughters, a regional pediatric referral care facility and only stand-alone children's hospital in the commonwealth.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

EVMS research teams generate $31M in annual funding through more than 237 ongoing projects. The campus includes the Jones Institute for Reproductive Medicine, which is the first institution in the US to have produced a viable fetus through in vitro fertilization. The Maternal-Fetal Medicine Program (MFM), offers several specialty programs to manage high risk pregnancy and the Strelitz Diabetes Center has made several important discoveries such as the role of INGAP gene in pancreatic insulin cell regeneration. Through the Sentara Center for Simulation and Immersive Learning, trainees receive simulation/standardized-patient education to create realistic training scenarios.

Known for its reproductive medicine as well as research in pediatrics, geriatrics, diabetes, and cancer; EVMS demonstrates leadership in community service and medical missions, as evidenced by faculty and alumni responsible for the founding of Operation Smile, Physicians for Peace, Global Brigades, and Contraception Research and Development (CONRAD).

FOCUS AREAS

- Biorepository
- Contraceptive Research and Development
- Cardiovascular Science
- Mental Health
- Prostate Cancer
- Diabetes
- Neurosciences
- Health Disparities

GEORGE MASON UNIVERSITY (GMU)

George Mason University (GMU) is a public research university in Fairfax, Virginia and designated as "R1: Doctoral University-Highest Research Activity" by the Carnegie Classification of Institutions of Higher Education, only one of four institutions in the Commonwealth to earn this distinction. Sponsored research activity in 2019 was $176M, with $29M focused in biohealth.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

GMU hosts more than $176M in sponsored research projects annually and is classified by the Carnegie Classification of Institutions of Higher Education among the US universities that receive the most research funding and award research/scholarship doctorates.

GMU examines chronic illnesses and disabilities with the Inova Health System. Some of its strengths include medical proteomics, biomedical research, and personalized medicine. In health, researchers focus on wellness, disease prevention, advanced diagnostics, and biomedical analytics.

GMU has an Institute for Advanced Biomedical Research (IABR), which was created in 2015 and focuses on bioengineering, chemistry, and proteomics.

Some of Mason's clinical partners include: Inova, Sentara, Virginia Commonwealth University, University of Colorado School of Medicine, Med Star National, National Institutes of Health, Lombardi Cancer Center, Walter Reed Army Institute of Research, University of Pittsburg, University of Colorado, University of California San Francisco (UCSF), UCLA.

FOCUS AREAS

- Proteomics
- Genomics
- Nanotechnology
- Diagnostics
- Metabolomics
- Functional Imaging
- Bioinformatics and Health Informatics
- Computing
- Psychology
- Social Work
- Rehabilitation/Human Performance
- Epidemiology

INOVA HEALTH SYSTEM (INOVA)

Inova Health System is a nonprofit health organization based in Falls Church, Virginia, near Washington, DC. The system is a network of hospitals, outpatient services, assisted living and long-term care facilities, and healthcare centers serving the needs of citizens in Northern Virginia, including the cities of Alexandria, Fairfax, and Falls Church and Alexandria, Arlington, Fairfax and Loudoun Counties.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

In 2017, Inova invested 22M in education/research and 25M in other community benefit. Inova's emphasis is on personalized medicine, research partnerships with biotech and pharmaceutical companies, and strategic collaborations with Virginia-based universities; largely through industry-funded studies. The Office of Research at Inova permit clinicians to participate in investigational studies by providing a variety of essential services to support their participation in inpatient and outpatient investigational studies, including administrative support, education, grant and budget/contract management, and technology transfer services. In recognition of the role of addiction to alcohol as well as prescription and illicit drugs in mental health disorders, Inova established the CATS (Comprehensive Addiction Treatment Services) program.

Relevant partnerships include University of Virginia and George Mason to develop Exxon site; University of Virginia CTSA, and Virginia Catalyst and Virginia Neuroscience Initiative.

FOCUS AREAS

- Neuroscience
- Genomics Research
- Personalized Medicine

OLD DOMINION UNIVERSITY (ODU)

Old Dominion University (ODU) is a public research university in Norfolk, Virginia and was established in 1930 as the Norfolk Division of the College of William & Mary. ODU is designated as "R1: Doctoral University-Highest Research Activity" by the Carnegie Classification of Institutions of Higher Education, only one of four institutions in the Commonwealth to earn this distinction and provides nearly $2B annually to the regional economy.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

Old Dominion University research teams generate $88M in annual funding through more than 400 ongoing projects.

Support for research is provided by the Office of Research and the Research Foundation. Although closely linked, the two are distinct and separate. The Office of Research, an administrative department of the university, assists faculty through a three-pronged approach: research development, research compliance, and licensing and technology. The ODU Research Foundation (a separate entity) provides sponsored research administration services, including pre-and post-award grant and contract administration.

FOCUS AREAS

- Mental Health
- Substance Abuse
- Ethnic and Racial Health Disparities in Adolescents
- Psychopathology in Families with Incarcerated Parents
- Moral Distress in Vets and Healthcare Providers
- Vets and Substance Abuse
- Suicide Prevention Link to Substance Abuse

SENTARA HEALTHCARE (SENTARA)

Based in Norfolk, Virginia, Sentara Healthcare is a not-for-profit healthcare organization serving Virginia and northeastern North Carolina. Sentara operates more than 300 sites, including 12 acute care hospitals with a total of 1,911 beds, nine outpatient care campuses, seven nursing centers, and three assisted living centers. Sentara operates four medical groups and a 3,800-provider medical staff, as well as a Clinically Integrated Network.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

Sentara provides health coverage plans, home health and hospice services, physical therapy and rehabilitation services, and specialized services, including Nightingale which became the region's first air ambulance. Its flagship hospital is the Norfolk General Hospital. A $93.5-M cancer center is scheduled to open in 2020 on the Sentara Leigh Hospital Campus.

Sentara provides a centralized clinical trials office with over 33 FTEs with sub-specialization, including pre- and post-award management. Research strengths include cardiology, oncology, neurology, and vascular; with relevant research networks in Alliance Cooperative Groups and the Virginia Neuroscience Institute. The Health Analytics Delivery Science Institute is a collaboration between EVMS and Sentara. The Institute's focus is to design, implement and evaluate clinical, patient-centered outcome effectiveness research projects.

As of July 2019, Sentara's clinical trial metrics include 161 active trials; >900 patients on a clinical trial; 1,029 patients on clinical trials including community partnerships; and 200 active clinical trials open including community partnerships.

As the largest integrated health system in Virginia, Sentara and Optima Health have access to vast amounts of data as early adopters in EMRs on the provider side and claims data of our 500,000+ member health plan.

FOCUS AREAS

- Vascular Disease
- Biorepository, in collaboration with EVMS
- Neurology
- Cardiovascular Disease
- Oncology

UNIVERSITY OF VIRGINIA (UVA)

As an NCI-designated Cancer Center headquartered in Charlottesville, Virginia, the University of Virginia (UVA) is designated as "R1: Doctoral University-Highest Research Activity" by the Carnegie Classification of Institutions of Higher Education, only one of four institutions in the Commonwealth to earn this distinction. UVA encompasses 11 academic schools interconnected with a Health System consisting of a 612-bed hospital providing care to 27,800 annual inpatient admissions and local and outreach clinics providing 887,490 outpatient visits.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

Sponsored research funding has increased for five consecutive years to 422M (FY2019). The Office for Research supports and promotes basic, clinical, and translational investigation in the School of Medicine (SOM). Top clinical research strengths include cardiovascular, endocrinology/diabetes, genomics, infectious disease, neuroscience, and oncology. The UVA Cancer Center has approximately 220 full and associate members divided into five research programs: Cancer Biology, Cancer Control & Population Health, Cancer Therapeutics, Molecular Genetics & Epigenetics, and Unaligned Research.

The institutional investment in research includes over 1.5M sf of dedicated research, laboratory, and workspace to support 988 current active sponsored awards, including 283 in the SOM. The integrated Translational Health Research Institute of Virginia (iTHRIV) serves as a research connection across all 11 schools and facilitates growth and team science across the institution.

FOCUS AREAS

- Neuroscience and Neurology
- Cardiovascular
- Diabetes
- Oncology
- Infectious Disease
- Genomics
- Endocrinology/ Diabetes
- Biorepository and Tissue Research
- Telehealth/Telemedicine

VIRGINIA COMMONWEALTH UNIVERSITY (VCU)

Virginia Commonwealth University (VCU), is a public research university in Richmond, Virginia, and is designated as "R1: Doctoral University-Highest Research Activity" by the Carnegie Classification of Institutions of Higher Education, only one of four institutions in the Commonwealth to earn this distinction.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

As one of the nation's top research universities, VCU attracted a record $310 million in sponsored research funding in fiscal year 2019. VCU supports a number of Core Laboratories that facilitate a wide variety of research in the biomedical, life, physical, and social sciences; and has entered into a reciprocal resource sharing agreement with University of Virginia, Eastern Virginia Medical School, George Mason University, Hunter McGuire VA Medical Center, Old Dominion University, Virginia Tech, and William and Mary.

Areas of clinical and translational research include the Center for Clinical and Translational Research (CCTR) and Institute for Women's Health. Additional supported resources include, Clinical Research Administration, Office of Assessment and Evaluation Studies, Women's Health Information Center, Office of Research, and VCU Across the Spectrum.

VCU Health serves patients with a high incidence of obesity-related diseases including diabetes, heart disease, and fatty liver disease, in addition to substance use disorders.

FOCUS AREAS

- Obesity
- Diabetes
- Cardiovascular Disease
- Oncology
- Substance Abuse
- Addiction
- Liver Disease
- Traumatic Brain Injury

VIRGINIA TECH (VT)

Located in Blacksburg, Virginia, Virginia Tech (VT) is the largest public university in Virginia and a designated "R1: Doctoral University-Highest Research Activity" by the Carnegie Classification of Institutions of Higher Education, only one of four institutions in the Commonwealth to earn this distinction. VT holds the highest amount of research expenditures in the Commonwealth of Virginia with $525M in annual research expenditures.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

VT is part of a recently awarded NIH CTSA grant in consortium with University of Virginia and INOVA Health, as well as their clinical partner, Carilion Clinic. VT does not provide healthcare as this is done through their private clinical partner, Carilion Clinic. Carilion coordinates the clinical research enterprise.

Clinical research strengths include addiction and substance abuse, traumatic brain injury, childhood developmental disabilities, cardiovascular disease, wound healing and scare reduction, and malignant brain cancer.

VA-relevant research networks include National NIH consortium, Virginia VNI, and iTHRIVE.

FOCUS AREAS

- Substance Abuse
- Addiction
- Behavioral Health
- Traumatic Brain Injury
- Cardiovascular Disease
- Childhood Developmental Disabilities
- Cancer, Including Structural Oncology
- Cognitive and Computational Neuroscience
- Regenerative Medicine
- Neurorehabilitation
- Developmental and Translational Neurobiology

VIRGINIA TECH/CARILION CLINIC (VT/CARILION)

Carilion Clinic, is a Roanoke, Virginia–based, tax-exempt, integrated health care organization that provides care for nearly 1M Virginians and West Virginians. Carilion owns and operates seven hospitals in the western part of Virginia as well as Jefferson College of Health Sciences and a joint venture medical school and research institute with VT.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

Carilion Clinic is home to the region's only Level 1 Trauma Center at Carilion Roanoke Memorial Hospital. Carilion Clinic Basic Science Research Laboratory is a secured, BSL2-certified facility that is equipped for a variety of research activities including molecular biology, microbiology, proteomics, and tissue culture.

Providing a centralized research office, the Department of Research and Development comprises 29 FTEs with clinical expertise in cancer, cardiology, heart surgery and vascular care, gastroenterology, neurology, neurosurgery, orthopedics, primary and preventive care, pediatrics, trauma, and women's health.

Relevant collaborations include Carilion partners with Virginia Tech for the Virginia Tech Carilion School of Medicine and Research Institute and iTHRIV (including UVA, INOVA, VT, Carilion clinic partners).

FOCUS AREAS

- Obesity/Metabolism
- Cancer Biology
- Cardiovascular Science
- Infectious Diseases/Immunology
- Neuroscience, Including Addiction, Computational Psychiatry, Neurobiology, Cognitive Neuroscience, and Decision-making Science
- Regenerative Medicine Research

WILLIAM AND MARY COLLEGE (W&M)

William & Mary (W&M) is a public research university in Williamsburg, Virginia, and is the second-oldest institution of higher education in the US, after Harvard University.

CLINICAL RESEARCH PROFILE (ORGANIZATION, RESOURCES, CAPABILITIES, STRENGTHS)

W&M has more than 30 undergraduate programs and more than 10 graduate and professional degree programs. Its highly ranked graduate schools include the Marshall-Wythe School of Law, the first law school in the U.S.; the School of Education; and the Mason School of Business.

Collaboration is key to the success of the W&M research community, supporting more than 20 research centers and institutions in the humanities and social sciences, professional schools, and the natural and computational sciences that represent the strongest of its interdisciplinary focus areas.

FOCUS AREAS

- Addiction
- Psychiatry
- Computational Neuroscience
- Behavioral and Cognitive Neuroscience
- Basic Science Research

Appendix F: Stakeholder Planning Retreat

Summary

On September 20th, 2019, representatives from the nine named stakeholder institutions and state government offices met in Richmond, Virginia to participate in the VCCRN Stakeholder Planning Retreat. The goal of this retreat was to bring together the stakeholder organizations that were interviewed during the assessment phase of Huron's engagement to 1) learn about Huron's observations and findings regarding the current state of Virginia clinical research vs. national peers; 2) realize opportunities to strengthen the competitiveness and economic power of Virginia in clinical research; and 3) provide feedback on a strawman proposal for VCCRN, focusing on vision, strategies, and services prior to Huron's report preparation for the General Assembly.

Location, Date, and Time

The Patrick Henry Building
1111 E Broad St,
Richmond, Virginia 23219
The West Reading Room
September 20, 2019
9:00AM – 4:00PM

The agenda and attendees at the VCCRN retreat are presented on the following pages.

Stakeholder Planning Retreat Agenda

9:00 – 9:30am	**BREAKFAST**
9:30 – 10:45am	Welcome, Introductions, and Objectives
	Background and Overview
	Huron Charge
	Huron Findings
10:45 – 11:00am	**BREAK**
11:00 – 12:00 pm	**Recommendations and Discussion**
11:00 – 11:30am	*VCCRN Business Office*
11:30 – 12:00pm	*VCCRN Research Office*
12:00 – 12:30pm	**LUNCH**
12:30 – 2:00pm	**Recommendations and Discussion**
12:45 – 1:15pm	*Multi-center Trial Program*
1:15 – 1:45pm	*Biomedical Informatics, Specimens and Analytics Core*
1:45 – 2:15pm	*Training Academy*
2:00 – 2:15pm	**BREAK**
2:15 – 3:45pm	**Recommendations and Discussion**
2:15 – 2:45pm	*Innovation Center*
2:45 – 3:15pm	*Community Connect Program*
3:15 – 3:45pm	*Management of Disease Specific Networks*
3:45 – 4:00pm	**DISCUSSION**
4:00pm	**Depart**

Stakeholder Planning Retreat Attendees

Attendees	Institution
Paul Skolnik, MD	Carilion Clinic
O. John Semmes, PhD	Eastern Virginia Medical School
William Hazel, MD	George Mason University
Skip Maupai	House Appropriations Committee - Health and Human Resources
Mary Beth McIntire	Medical Society of Virginia
Michelle Kelley, PhD	Old Dominium University - Dept of Psychology
Harold Riethman, PhD	Old Dominium University
Carolyn Rutledge, PhD	Old Dominium University - School of Nursing
Lauren Powell, PhD	Office of Health for the Commonwealth
Sarah Herzog	Senate Finance Committee
Carolyn Carpenter	Sentara
Anna James	Sentara
Alan Edwards	State Council of Higher Education for Virginia
Sandra Burks	University of Virginia
Robert Dreicer, MD	University of Virginia
Nicolas Restrepo, MD	Valley Health
Randall Merchant, PhD	Virginia Catalyst; Virginia Commonwealth University
David Cifu, MD	Virginia Commonwealth University
F. Gerard Moeller, MD	Virginia Commonwealth University
Sean Connaughton, JD	Virginia Hospital and Healthcare Association
Michael Friedlander, PhD	VTC/Fralin Biomedical Research Institute
Alexandra Hanlon, PhD	VTC/Fralin Biomedical Research Institute
Leslie LaConte, PhD	VTC/Fralin Biomedical Research Institute
Joshua Burk, PhD	William and Mary
Christine McCormick	Lobbyist

Appendix G: Life Science Metrics

Economic Impact of Biopharmaceutical Sector

The overall economic impact of the biopharmaceutical industry on the U.S. economy is substantial. The biopharmaceutical industry accounted for more than $1.3 trillion in economic output, representing 4.0% of total U.S. output and with a national average of $25.4 billion in 2015. This total economic impact includes $558 billion in revenues from biopharmaceutical businesses and $659 billion from suppliers and worker spending. Virginia's biopharmaceutical industry economic output was ranked 22nd nationally and below the national average at $12 billion. As such, Virginia ranks near such peers as Tennessee ($12.5 billion), Colorado ($13.7 billion), and Wisconsin ($14.1 billion). In 2015, the biopharmaceutical industry accounted for 4.8 million jobs across the U.S.; local employment impact within the Commonwealth was below the national average of 92,307, with 47,495 total jobs for Virginia.[1]

Economic Impact in Virginia

Biopharmaceutical Sector[1]

$12B
Total Output Supported by Biopharmaceutical Sector

$508,684
Output Per Employee in Direct Biopharmaceutical Sector Jobs

47,495
Total Jobs

10,137
Direct Jobs

Industry-Sponsored Clinical Trials[2]

759
Clinical Trials

17,685
Clinical Trial Participants

$267.2 Million
Investments at Clinical Trial Sites

$695.7 Million
Total Economic Impact of Clinical Trial Sites

Economic Impact of Industry-Sponsored Clinical Trials

The biopharmaceutical industry brings profound value to patients through new treatments and cures for society's most devastating and costly diseases and conditions, providing millions of patients with treatment options they would not otherwise have. Since 2000, PhRMA member companies have invested over $800 billion in the research and development of new treatments and cures, including an estimated $71.4 billion in 2017 alone.
Developing innovative new medicines is a complex process taking an average 10-15 years. Less than 12% of candidate medicines that make it into clinical trials will be approved by the U.S. Food and Drug Administration. Clinical trials are the most time- and resource-intensive part of the research and development process for a new medicine, and biopharmaceutical manufacturers support and conduct the majority of this important work. Yet,

[1] TEConomy Partners; Source: *The Economic Impact of the U.S. Biopharmaceutical Industry: 2015 National and State Estimates*, October 2017

without clinical trials, new medicines could not be approved and–most importantly–made available to patients who need them.[2]

A recent report from TEConomy Partners, supported by PhRMA, provides estimates of industry-sponsored clinical trial activity in each of the 50 states, including the number of trials active, the number of trial participants, the annual direct investment by biopharmaceutical companies to operate the clinical trial sites, and the total economic impact resulting from that investment, including the indirect economic effects that ripple through local economies.

There are a number of interesting findings in the report, as follows:

- In 2017, the biopharmaceutical industry sponsored more than 4,500 clinical trials of medicines in the U.S., involving a total of close to one million participants. Trials occurred in all 50 states, the District of Columbia, and Puerto Rico.
- The biopharmaceutical industry spent more than $15 billion directly in clinical trial sites across the U.S. in 2017. These amounts are in addition to the significant resources invested in clinical trial-related activities occurring outside the individual trial sites.
- The overall economic impact of company investments in U.S. clinical trial sites – which includes the ripple effect of expenditures by clinical trial vendors and contractors and spending by industry and vendor employees – totals nearly $43 billion in economic activity in communities throughout the U.S.
- The five states with the largest number of active clinical trials were: California (2,152), Florida (1,735), Texas (1,989), New York (1,707), North Carolina (1,196).

In 2017, Virginia conducted 759 clinical trials a total of 17,685 enrollments, placing it in the top 20 for both categories. Virginia had a biopharmaceutical industry site-based investment of $267.2 million and economic impact of $695.7 million, both of which were below the national averages ($292.9 million and $819 million, respectively). States that were comparable to Virginia in the number of clinical trials and enrollments had on average approximately $50 million more in biopharmaceutical industry investment in the trial sites and $200 million more in site based economic impact. For example, with 708 active clinical trials and 18,475 enrollments in 2017, South Carolina had a total biopharmaceutical investment of $331.7 million at trial sites and a total site-based economic impact of $829.4 million. New Jersey also had 792 active clinical trials and 16,649 enrollments with a biopharmaceutical industry's site-based trial investment of $320.4 million and a total economic impact of $879.7 million. This analysis provides a new lens and shows that industry-sponsored clinical trials are not only vital to the development of new treatments and cures for patients, but also play an important role in sustaining economic growth in communities throughout the country.

[2]PhRMA.org/clinical-trials; Source*: TEConomy Partners, Biopharmaceutical Industry-Sponsored Clinical Trials: Growing State Economies,* April 2019.

Economic Impact of Federally Funded Health-Related Research

Federal research funds provided by agencies, such as the National Institute of Health (NIH) and National Science Foundation (NSF), are vital components of the United States investment in potentially lifesaving, health-related research. In FY2019, the federal budget for NIH health-related research and development (R&D) accounted for $39.1 billion, which were directed towards research on cancer, infectious diseases, and other health adversities. Additionally, $8.1 billion was allocated to R&D at NSF for research related to physical sciences, space, and engineering.[4]With increased federally sponsored research, local state economies are strengthened by not only the development of new products that save and improve lives, but also growth in productivity through new businesses, services, and jobs within the state.

Ranked as the twelfth most populated state in the U.S., Virginia accounts for 8.5 million people. Although Virginia has been associated with the high performing Maryland-Virginia-D.C. research cluster, the majority of the federal research funding is driven by Johns Hopkins University and University of Maryland. In FY2018, Virginia was ranked the 19th most NIH-funded state with $415 million and a top-15 state for receiving $164 million in NSF funding. Despite the rankings, Virginia was unable to obtain the economic activity and supported jobs as seen by states of similar population size, such as North Carolina, Washington, and Massachusetts. Table 1, below, shows that in states with similar population sizes to Virginia, elevated federally funded grants ultimately lead to increased focus on improving lives, advancing innovation, and fueling the local economy.

Economic Impact in Virginia

Federally Funded Health-Related Research[3]

$467 Million
NIH Funding in FY2019 (10% increase from FY2017)

1,009
NIH Peer-Reviewed Funded Grants in FY2019

Top-Funded Research Institutions in Virginia[4]

- University of Virginia
- Virginia Commonwealth University
- Virginia Polytechnic Institute and State University (Virginia Tech)
- American Type Culture Collection
- ICF Macro, Inc.

[3]Projectreporter.nih.gov/reporter.cfm
Source: *NIH: Project Reporter*, October 2019

[4]UnitedforMedicalResearch.org
Source: *United Medical Research*, February 2019

Table 1: Local Economic and Biopharmaceutical Impact Linked to Federal Health-Related Research Funding[4,5]

State	Population (Million)	NIH Funding (FY2018)	NSF Funding (FY2018)	Jobs Supported	Economic Activity Supported	Biopharmaceutical Industry Impact
North Carolina	10.4	$ 1.4 Billion	$ 212 Million	22,657	$ 3.464 Billion	75,582 Jobs; 3,843 Businesses
New Jersey	8.8	$ 261.3 Million	$ 192 Million	5,187	$ 974 Million	93,824 Jobs; 2,897 Businesses
Virginia	**8.5**	**$ 415 Million**	**$ 164 Million**	**6,283**	**$ 1.194 Billion**	**24,163 Jobs; 1,897 Businesses**
Washington	6.8	$ 1.0 Billion	$ 159 Million	14,846	$ 2.562 Billion	33,564 Jobs; 1,744 Businesses
Massachusetts	6.6	$ 2.9 Billion	$ 524 Million	34,907	$ 6.765 Billion	93,912 Jobs; 2,567 Businesses
Maryland	6.0	$ 1.5 Billion	$ 171 Million	19,941	$3.582 Billion	36,194 Jobs; 2,281 Businesses

[5]https://faseb.org/; Source: Federation of American Societies for Experimental Biology, FY2018

Appendix H: Statewide Model Examples

Statewide Disease-Focused Research Alliance

Goals	Organization and Structure	Status
• Increase the number of oncologists statewide who participate in clinical trials. • Manage review and selection of protocols. • Manage the staff who support the conduct of clinical trials. • Provide a single point of entry for industry, i.e., contracting and budgeting. • Increase local access to national studies. • Increase community awareness of clinical trials. • Increase provider education	• 501c3 • Governance comprised of representative organizations. • Single point of contact for industry and partners to present multi-institutional studies. • Centralized research office, e.g., finance, SOPs, CRCs and education, auditing and monitoring. • Outreach program to raise awareness.	• Successful in increasing awareness, local access, and provider engagement. • Recent operational challenges have led to internal reorganization and refinement in organizational structure in order to address issues and position for long-term success.

Research Institution-Health System Partnership

Goals	Organization and Structure	Status
• Establish a preclinical research network to facilitate easy access to an urban region's robust research and development pipeline. • Enable transformative scientific progress. • Catalyze productive, long-term collaborations between the academic research community and for-profit research and development partners, specifically targeting life sciences start-ups.	• Universal, sponsored research agreement (SRA) with all potential industry partners interested in exploring preclinical discovery research with participating institutions. • Thirteen stakeholder institutions. • Potential local, national and international startup and biotech partners specializing in life sciences. • Single point of contact for industry and partners.	• Companies and universities can freely form partnerships according to best fit of needs, capabilities and research interests with the standardized SRA. • Overall value and impact of this consortium is still being evaluated due to its recent creation.

Multi-State Alliance

Goals	Organization and Structure	Status
• Improve the health and wealth of the region by creating an internationally recognized life. science and healthcare system • Provide single access point to resources and expertise in eight major cities. • Seek interested companies and funding bodies. • Bring together research, health science innovation and commercialization to benefit researchers, universities, hospitals, patients as well as commercial partners.	• Links eight universities and organizations that serve a MM population.	• Significant increase in contracts. • Collaborative voice for the health science economy. Partnerships with companies and successful collaborations to attract health science investment. • Stakeholders have "tremendous reach and engagement opportunities to advance health system innovation, and broker global health sector collaboration that facilitate knowledge exchange to improve performance, safety and health outcomes.

Appendix I. Immediate Next Steps

Presented below are the initial next steps required to executive the strategy and business plan presented in this report. This plan will be refined based on stakeholder feedback and available resources.

1. Create the Governance, Leadership and Organizational Structure for VCCRN

- Finalize the future state VCCRN organizational plan, include governance, leadership, infrastructure, core capabilities and services, financial plan and roll-out for initial set of services and resources.
- Re-appoint the VCCRN Governance Committee to provide continued guidance, oversight, and voice on stakeholder needs and actions; adjust membership as needed.
- Create Governance task forces or subcommittees to provide guidance on specific services or capabilities to be provided by VCCRN and or standing responsibilities of the Governance Committee (e.g., membership, financial matters, new initiative planning).
- Continue stakeholder retreats (e.g., annual) to foster joint strategic visioning, development of solutions, and identification of new ways for intuitions from capitalizing on their individual and collective strengths.
- Re-appoint a VCCRN Chair to lead efforts and provide strategic advice during planning and implementation; provide stipend for time and expenses.
- Hire an expert external firm with extensive experience in clinical research networks, strategy and organization to help operationalize the strategic direction set by the Governance Committee.
- By the end of Month 6, recruit and experienced clinical research manager to serve as VCCRN Manager and assistant to manage day to day activities and actively plan implementation.

2. Create a statewide Biospecimen and Data Resource

- Create an oversight subcommittee (reporting to the Governance Committee) to guide development and implementation. Appoint qualified chair and knowledgeable representatives from key organizations.
- Establish statewide virtual biospecimen network.
  - Assess other biorepository networks across the country (e.g., Louisiana, Dana-Farber/Harvard) for lessons learned.
  - Develop governing principles and best practices.
  - Integrate existing biorepository programs (i.e., Casis, EVMS biorepository) to create a single robust high-quality program.
- Establish a data sharing coordinating center or clearinghouse.
  - Develop data sharing plan, policies, and technology platform.
  - Develop tool (or partner with companies, e.g., TriNetiX) to aggregate, de-identify, and share data to answer complex research questions relevant to the Commonwealth.
- Identify services, tools, and opportunities to optimize statewide data for population health management and outcomes research.

3. Create a Clinical Research Services Office for Fee-For-Service Delivery

General

- Assess initial need and level of interest: survey/interview sites on needs and range of needs.
- Develop menu of services and fees.
- Hire full-time manager and core positions based on initial roll-out plan.
- Consider outsourcing some functions during ramp-up.
- Develop financial performance and utilization metrics.

Budgeting and Contracting

- Determine legal model to enable single signature contracts (LLC or 501c3).
- Create unified business terms that will resolve unfavorable contracting terms of the Commonwealth and participating institutions.
- Create a standard fee schedule / model for studies based on sponsor type.
- Develop a robust research charge master including start-up, recurrent and administrative fees.
- Develop policies and procedures to direct negotiations, sponsor push-back, and escalation processes.
- Develop master service agreements with pharmaceutical companies and CROs that will allow for speedier negotiation of work orders under each MSA.
- Hire contracting and budgeting staff (can outsource initially).

Regulatory Service

- Appoint regulatory staff to manage centralized regulatory process.
- Implement technology solution (e-reg data storage system) for document management, track progress, and handle service requests.

Clinical Research Staffing

- Define responsibilities for each role.
- Use of contractors followed by full time employees as demand warrants

4. Launch a Center for Clinical Research Innovation to Bring Novel Ideas to VCCRN Stakeholders

- Focus Innovation Center on finding novel opportunities to reduce clinical research access barriers, while improving efficiency and effectiveness on behalf of VCCRN institutions.
- Encourage review of tools and approaches by VA-based start-ups and R&D companies; promote awareness among VCCRN institutions.
    - Negotiate favorable terms with companies on behalf of VCCRN
- Increase Virginia company awareness and access to talented Virginia-based scientists and researchers; foster clinical trials partnerships.
    - Create favorable agreements with start-up companies to protect intellectual property but allow for equal profit sharing.

Appendix J: High-level Draft VCCRN Budget*

Line item	Comment	Year 1	Year 2	Year 3
PERSONNEL				
Medical Director*	Stipend	$25,000	$30,000	$30,000
VCCRN Administrator • Staff (1 FTE) (6 months)		$50,000	$125,000	$130,000
Administrative Assistant • Staff (1 FTE) (6 months)		$25,000	$55,000	$57,000
Communications Staff (1 FTE)	Manager/supplies	$50,000	$85,000	$85,000
Biomedical Repository • Director (1 FTE) • Analyst (1 FTE)		$50,000 (Q4)	$150,000	$155,000
Clinical Research Office (Y2) • Manager (1 FTE) • Navigators (2 FTE)		Planning, outsource	$200,000	$225,000
OPERATIONS				
VCCRN Program Development • Governance Meetings • Advisory Group Meetings • Travel for VCCRN Stakeholders • Office Expenses, including laptops • Communications		$150,000	$200,000	$200,000
Community Connects Program • Staff (1 FTE) • Travel • Program Development	Program development; stipends, travel, program development/staff	$100,000	$250,000	$350,000
Clinical Research Services • Communications, travel, program development	Outsource first, then staff or combination; direct staff time to be billed at cost; management is covered by VCCRN	$50,000	$100,000	$100,000
Biospecimen and Data Resource Program • Equipment, software, program service development	People, tool development	$50,000	$100,000	$150,000
Office of Clinical Research Innovation	Events, effort	$50,000	$100,000	$100,000
OTHER EXPENSES				
Consulting fees to support Governance and VCCRN launch		$240,000	$120,000	$120,000
Program Development		$300,000	$200,000	$100,000
TOTAL:		**$1,140,000**	**$1,715,000**	**$1,802,000**

Note: This budget was prepared prior to being informed about the defunding of VNI

TO: Speaker of House of Delegates
President of the Senate
Chair of House Appropriations
Chair of Senate Finance Committee

FROM: William Hazel, MD, George Mason University, on behalf of Named Institutions

DATE: January 21, 2020

RE: Response to the Huron Consulting Report done in conjunction with Virginia Commonwealth Clinical Research Network (VCCRN)- Budget Item 164#1c

On October 31, 2019, a report from Huron Consulting was submitted in response to Budget Item 164#1c that funded conceptualization of a "Virginia Commonwealth Clinical Research Network" that would facilitate conduct of clinical trials across institutions and enhance the economic and health impact of clinical trials for Virginians. Since submission of the report, representatives of a majority of the named institutions (University of Virginia, Virginia Commonwealth University, Virginia Polytechnic and State University, Old Dominion, University, William and Mary University, George Mason University, and Eastern Virginia Medical School as well as the Carilion Clinic) have taken the opportunity to discuss the report and offer comments and an alternative recommendation in the attached response.

These institutions are fully committed to the goal of increasing collaboration and coordination in support of the goals outlined by the consultants. We believe that the report understates progress to date which includes two NIH funded Clinical Translational Science Award Centers (CTSA's) and two National Cancer Institute Designated Cancer Centers, the Virginia Tech Carilion Research Institute, and the Virginia Catalyst. We recommend that in lieu of creating a new organization, the funds build upon existing CTSA capacities.

The stakeholder group recommends funding of $1.14M in FY 2021 and $1.715m in FY 2022 to leverage the expertise and administrative capacity in an existing NIH funded Clinical and Translational Science Award Center. The implementation would enable expansion of the clinical research networks, the development of innovative tools related to data and bio-specimens that would improve competitiveness for further grant funding from NIH and other agencies and organizations including industry, and provide support for institutions that wish to engage in clinical research but currently lack the expertise. The group also recommends funding for competitive grants that would promote multi-institutional research.

Report to Virginia General Assembly from Virginia Commonwealth Clinical Research Network Assessment and Planning group (George Mason University, Eastern Virginia Medical School, Old Dominion University, the University of Virginia (UVA), Virginia Commonwealth University (VCU), Virginia Polytechnic Institute and State University (VT), Inova Health System (Inova), Carilion Clinic, the College of William and Mary, and Sentara Health System).

On October 31, 2019, Report RD490 was submitted to the General Assembly by Huron Consulting Group. The university and academic health system stakeholders did not review or amend this report prior to its being submitted to the General Assembly. While the university and academic health systems cited in the report agree with the premise that Virginia is uniquely positioned to transform clinical research in the Commonwealth with the ensuing benefits to population health, innovation, our universities, and the economy through incentives and support for cross-institutional collaboration, the stakeholders believe that the existing infrastructure provides a sound base to build upon and therefor propose an alternative recommendation.

In lieu of establishing a new organization, the stakeholder group recommends funding of $1.14M in FY 2021 and $1.715m in FY 2022 to leverage the expertise and administrative capacity in an existing NIH funded Clinical and Translational Science Award Center. The implementation would enable expansion of the clinical research networks, the development of innovative tools related to data and bio-specimens that would improve competitiveness for large grants, and provide support for institutions and health systems that wish to engage in clinical research but currently lack the expertise or require additional support. The group also recommends funding for competitive grants that would promote multi-institutional research.

In support of our recommendations, The Virginia Commonwealth Clinical Research Network Assessment and Planning group would like to make the following points regarding clinical research in Virginia:

A strong foundation for cross-institution collaboration in clinical research already exists within the Commonwealth:

As stated in the report, the Commonwealth has many of the clinical research assets of peer states. These assets include two NIH funded Clinical and Translational Science Award (CTSA) funded research centers and institutes, and two National Cancer Institute designated Cancer Centers supported by Cancer Center Support Grants, as well as several Health Systems actively collaborating with academic institutions in large cross-state programs. Counter to what was stated in RD490, there are multiple significant collaborations within these institutions and between these institutions and other entities within the Commonwealth. Scientific journal publications between CTSA partnered institutions between 2014-2019 reflect robust statewide collaborations (See **Figure 1 next page**).

The integrated Translational Health Research Institute of Virginia (iTHRIV) is an NIH-funded CTSA representing a statewide partnership among public and private health systems, universities, and non-profit agencies. UVA is the NIH prime institution for iTHRIV, and current partners are Carilion Clinic, Inova Health System, and Virginia Tech. iTHRIV affiliate partners are the Licensing & Ventures Group and the Center for Open Science in Charlottesville, Virginia. iTHRIV was funded by the NIH in 2019 and focuses on the integration of data science and team science to accelerate clinical and translational research. Early initiatives for iTHRIV include the development of a shared architecture for a data Commons, a digital research platform to share documentation and data across a team of collaborative institutions. iTHRIV partner institutions have agreed to a structured research data mapping from our electronic health records and are working to implement across all iTHRIV clinical sites, to support our collaborations for clinical research. iTHRIV works closely with the Virginia Cooperative Extension network in support of community engaged health programming and research implementation. iTHRIV provides multiple pilot funding opportunities (~$280K/year) annually in support of

collaborative research across partner institutions through the NIH CTSA. In addition, iTHRIV shared governance structure promotes team science and ensures that iTHRIV programs remain aligned with individual institutional priorities as well. iTHRIV collaborates with multiple other CTSA institutions across the country and supports collaborations with multiple health systems and academic institutions in the region as well.

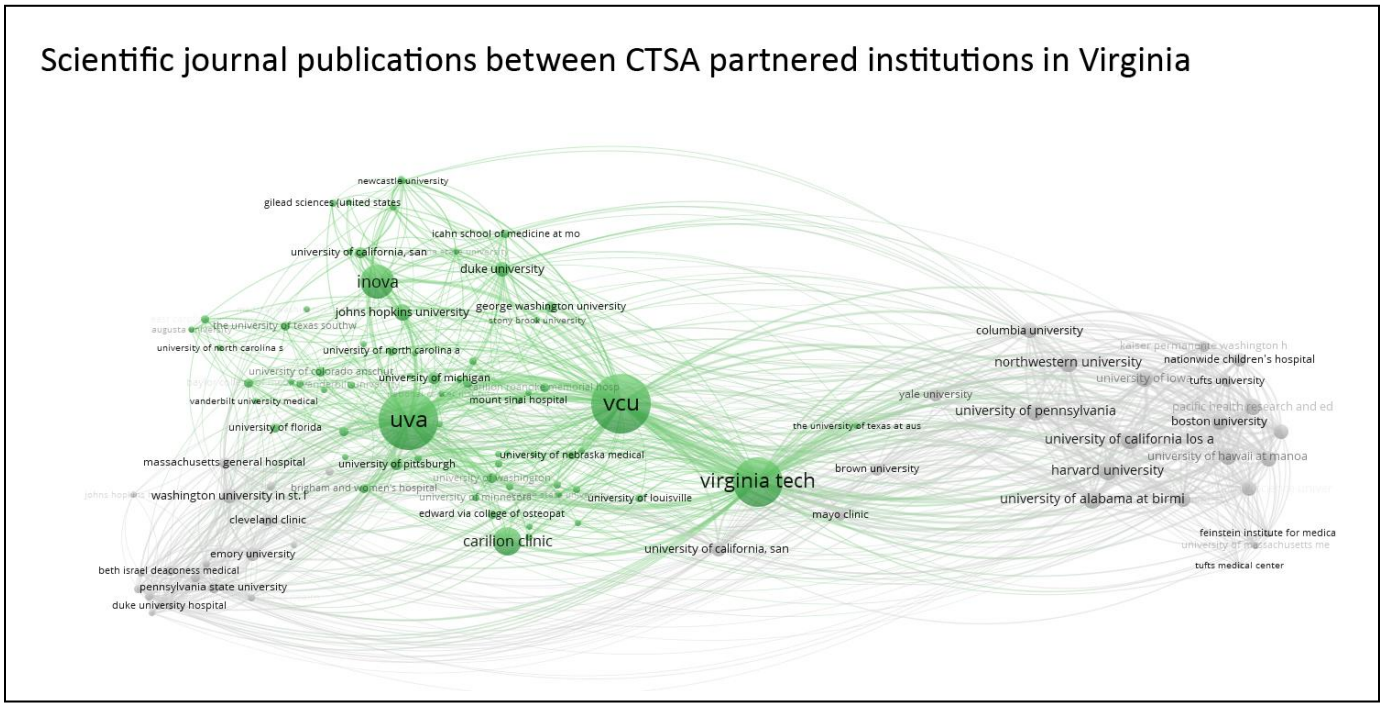


FIGURE 1: Health/biomedical scientific publications where a faculty member from a CTSA institution (UVA, VT, VCU, Carilion Clinic, or Inova) published an article with a faculty member from at least one other Virginia CTSA institution between 2014 and 2019. Source: Dimensions, November 2019

The VCU Clinical and Translational Science Award funded research center, the Wright Center for Clinical and Translational Research, has cross-Commonwealth collaborations with Virginia Tech, Carilion, EVMS, Sentara, and Inova, as well as healthcare providers from far southwest Virginia to the Northern Neck related to ongoing research activities to overcome the opioid epidemic. VCU Wright Center also has cross-Commonwealth research collaborations on a project funded by the Department of Defense (the Long-term Impact of Military-relevant Brain Injury Consortium or LIMBIC). These collaborations extend to the Hunter Holmes McGuire VA Medical Center and UVA. EVMS and VCU developed an MOU for collaboration to improve population health of the combined regions. Researchers within EVMS and the VCU CTSA and Massey Cancer Center have planned ongoing collaborative research projects. Leadership for the VCU CTSA in collaboration with the leadership within the EVMS Health Analytics and Discovery Science Institute are developing EVMS/Sentara faculty as candidates for the CTSA Translational Science Program.

Cross-institution collaborations related to biomedical Informatics are underway to share de-identified data to advance clinical trials. The Wright Center and iTHRIV have been collaborating with other academic health systems including UVA, EVMS/Sentara, and Virginia Tech/Carilion to implement TriNetX across all health systems that will increase industry clinical trial referrals across Virginia. Inova has plans to implement TriNetX in 2020. TriNetX accesses de-identified data on patient populations within the health systems that Industry can use to determine what sites are appropriate for clinical trials.

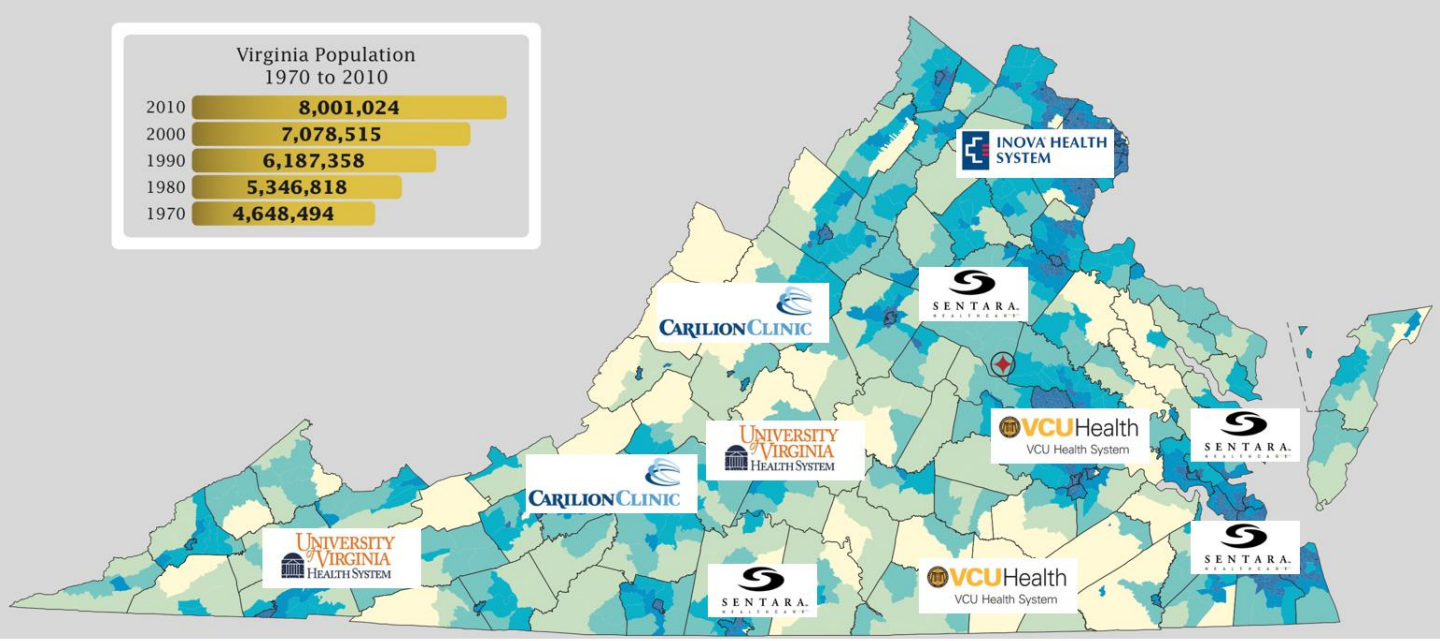
The UVA and VCU Cancer Centers have Commonwealth-wide collaborations to expand access to clinical trials in cancer. Massey's Clinical Research Affiliate Network extends its clinical trials statewide to provide more

patients easier access to the latest, cutting-edge cancer therapies and prevention methods. The Network enables multiple health systems and oncology medical practices across Virginia in Fredericksburg, Lynchburg, Petersburg, Richmond, South Hill, Winchester and Riverside Health System in Hampton Roads to access Massey's clinical research and offer more treatment options to their patients. The Network is supported in part by a highly competitive Minority/Underserved National Cancer Institute Community Oncology Research Program grant (NCORP-MU) received by Massey in 2014 and renewed in August 2019.

The UVA Cancer Center has a long history of research collaboration as well with universities and health systems statewide. Researchers from UVA and George Mason University have a long standing collaboration on brain tumor research which has resulted in multiple funded NIH RO1 awards as well as a Virginia VBHRC award, and includes multiple joint peer reviewed publications. A large gynecological oncology tumor biospecimen collection program is ongoing between UVA and Inova research teams. There are additional collaborative research projects underway between UVA and Inova, Virginia Tech and VCU as well. UVA and VCU are also actively engaged in community outreach activities, such as the 2019 Virginia Tobacco Free Higher Education Summit, and the upcoming Eliminate Tobacco Use Mid-Atlantic Summit which will also include Virginia Tech, Hampton University, the University of Richmond, and Norfolk State University. UVA has also partnered with VCU through a supplement from the National Cancer Institute to conduct a needs assessment that will represent the Commonwealth of Virginia. The two universities will collaborate to analyze the data and provide outcomes related to cancer needs in the Commonwealth.

In addition, over a decade ago, Virginia Tech and Carilion Clinic developed an academic health center in Roanoke that includes a nationally recognized research intensive medical school (VTCSOM), the Fralin Biomedical Research Institute with over $100M in active NIH awards and Carilion's clinics and hospital with translational research programs in cardiovascular health, addiction, cancer and brain and behavioral health and disease and pediatric neurorehabilitation. Virginia Tech Carilion (VTC) serves as the hub for the worldwide human functional brain imaging research network, the leader of the nation's only NIH supported pediatric stroke rehabilitation trials and the international addiction quit and recovery registry and program. The academic health center also includes a new research partnership on pediatric brain cancer with the Children's National Medical Center in Washington DC. Virginia Tech and Carilion Clinic also have multiple inter-institutional health science collaborations throughout the state and region including with VCU, UVA, ODU. VT coordinates The Center for Public Health Practice and Research that fosters interdisciplinary, collaborative public health practice and research activities among external public health agencies, organizations, practitioners and researchers throughout the state emphasizing community-based projects and as the state's land grant institution, co-manages (with Virginia State University) the statewide cooperative extension program that provides a decentralized network of interconnected centers across the commonwealth where Virginia Tech's interdisciplinary researchers and Virginia Cooperative Extension specialists can partner with industries to develop and deploy innovative technologies.

A large number of Virginians receive healthcare at institutions with active academic collaborations: Unlike what was suggested in the Executive Summary of RD490, health systems with active academic collaborations including Inova, Carilion Clinic, Sentara, Hunter Holmes McGuire VA Medical Center, Hampton VA Medical Center, VCU Health, and UVA Health serve a large number of Virginians extending across the entirety of the Commonwealth. As can be seen in the figure below, health systems with active academic collaborations with Virginia universities care for Virginians in all of the high-population density regions of the Commonwealth.



Duplicating existing clinical research infrastructure within the Commonwealth is inefficient and potentially harmful: While RD490 states that the proposed Virginia Commonwealth Research Network (VCCRN) should "build upon (not duplicate) existing institutional capabilities", it further proposes creation of "a new entity and housed within the newly proposed innovation and commercialization organization" which will have a new medical director, staff, and funding to oversee a state wide biorepository, clinical research services including contracting, budgeting, regulatory, community outreach and training, and a center for clinical research innovation. The report does not suggest how these new efforts would be integrated or build upon existing strengths in all of these areas within the Academic and Health System collaborators in the Commonwealth. By creating a new clinical research office and biorepository infrastructure instead of building upon existing strengths in these areas, competition and disagreements will likely take place. Likewise, a "fee for service" model which does not include sites where the vast majority of clinical research is taking place across the Commonwealth is highly unlikely to be successful.

The Virginia Research Resource Consortium is for institutions across the Commonwealth to present their research resources and areas of need to promote collaboration and resource sharing. State institutions, including EVMS, ODU, UVA, VCU, VT, and W&M are already sharing resources through the Core lab facilities. This agreement allows personnel across the Commonwealth to access specialized instruments and expertise to make research more efficient and cost effective.

Instead of creating a new entity, providing support for expanded collaboration across existing entities is needed: While Clinical and Translational Science Award funded research centers and institutes and National Cancer Institute designated Cancer Centers are actively pursuing Commonwealth-wide clinical research collaborations, funding to expand the scope of this work at outside institutions would enhance development of collaborations. **Support for additional collaborations in clinical research, community engagement, informatics, consultative support, and training would not only build upon existing strengths but improve the likelihood that the federal funding for these institutes and centers will be renewed in the future, as well create new funding for the present institutions, including the health systems, that are focused on applied research in order to serve their communities.** This funding would actively encourage expansion of clinical research at institutions and health systems which seek to expand industry clinical trials and NIH funded grants. In addition, federal CTSA supplemental funding opportunities, such as NIH PAR-19-337, may provide resources to support this expansion of scope.

Prior initiatives including the Virginia Neuroscience Initiative (VNI), supported by Virginia Catalyst developed master clinical trial agreements and mutual non-disclosure agreements focused on neuroscience. Additionally, the NIH-funded CTSA network has developed standardized templates for confidential non-disclosure, clinical trial agreements, and data transfer and use agreements which are available for use by all institutions to accelerate research collaborations. There has also been agreement across the universities for charging intra-institution rates for clinical services for research. This infrastructure could be built upon to develop clinical research beyond neuroscience related diseases.

Investment through existing CTSA structures help ensure the long term success of our CTSA programs in the commonwealth. NIH funding provided through the CTSA structure is limited, and significant institutional investments are required to maximize their success. Additional resources to expand the scope of these collaborations would benefit the commonwealth communities and extend the reach of these successful programs. Additional state resources would support:

- **Development of common goals and tools for stakeholders in the VCCRN**
    - Building on the needs assessment from the Huron consulting group and the existing resources across the commonwealth
    - Regular governance meetings to plan for expansion of existing or implementation of newly developed tools and resources which would include all participating institutions and health systems.
- **Increased collaboration through grant brewing and cross-commonwealth research projects**
    - Proposed collaborative research grants which would awarded based on merit with decisions made by the VCCRN governing body (which includes representation from all participating institutions and health systems)
    - Shared decision making for these competitive grant awards also promotes collaboration and development of programs with early infrastructure
- **Building new infrastructure to support clinical research**
    - Supplemental funding would be available to support the start-up salary costs for new Clinical Research Coordinators at sites with early clinical research infrastructure to allow time for development at these new sites. Decisions for allocation of funds based on competitive application process as needs are expected to vary across institutions and health systems.
    - Training, consultative services, and mentoring for new coordinators available through the existing CTSA and Cancer Center programs would be expanded

Summary Expected Outcomes:

The proposed VCCRN collaboration is expected to:

- **Increase funding for clinical research** in the Commonwealth from industry, private funding sources, federal and other foundation agencies
- **Increased number of sites** participating in clinical research
- **Increased number of clinical research studies** with **improved access** for communities across the Commonwealth
- **Increased clinical research collaboration** across the state, including academic and healthcare organizations that would like to participate in clinical research but are currently unable to do so or are underutilized
- Investing through our CTSAs helps ensure the **long-term success** of these programs.

High Level VCCRN Budget Proposal:

Line Item	Comment	Year 1	Year 2	Year 3
Program Administration	Personnel costs for hiring of a Director and partial administrative support role	$100,000	$140,000	$147,000
Clinical Research Coordinators	Competitive supplemental funding for VCCRN sites with early start-up clinical research infrastructure	$250,000	$250,000	$100,000
Clinical research grant funding	Up to $100,000 /each competitive awards	$450,000	$850,000	$1,050,000
Program Development	Governance meetings, communications, training, supplies and expenses (includes laptops for program administrator and newly hired CRCs)	$225,000	$250,000	$250,000
Totals		$1,025,000	$1,490,000	$1,547,000

Virginia Commonwealth University will serve as the administrative organization for handling, distributing and tracking these funds. All participating institutions and health systems will serve on the governing body for the VCCRN and will make funding decisions for the allocation of funds for the program.