



# Annual Report on Human Subjects Research

State Fiscal Year 2019

To the Governor and the General Assembly of  
Virginia

June 10, 2019

**Virginia Department for Aging and Rehabilitative Services  
Human Research Review Committee  
2019 Annual Report**

The *Code of Virginia* §51.5-132 directs the Department for Aging and Rehabilitative Services' (DARS) Human Research Review Committee (HRRC) to submit to the Governor, the General Assembly, and the DARS Commissioner, at least annually, a report on the human research projects reviewed and approved by the HRRC, including any significant deviations from the research applications as approved by the Committee. The HRRC has internal oversight responsibilities for ensuring protection of the rights and welfare of DARS clients and employees who volunteer to participate in research conducted or authorized by DARS. The DARS Commissioner established the HRRC in August 2000 to review and approve research to be conducted or authorized by DARS, the Wilson Workforce and Rehabilitation Center (WWRC), and Centers for Independent Living and Employment Services Organizations that have a vendor relationship with DARS.

The HRRC also complies with federal requirements for the *Protection of Human Subjects* (45 CFR 46). The U.S. Department of Health and Human Services approved the HRRC Federal wide Assurance (FWA#00008936) beginning August 15, 2005. The FWA is currently effective through March 23, 2023.

The HRRC conducts three types of reviews: Exempt Review (regulatory oversight not required), Expedited Review (application reviewed and approved by one or more HRRC members) and Full Committee Review (a quorum of members in attendance). Two new applications were submitted, reviewed and approved during the State Fiscal Year 2019. The HRRC conducted six reviews to previously approved studies, and there were no (0) study closures.

To the best of the Committee's knowledge, all research involving human volunteers conducted or authorized by DARS or the WWRC during SFY 2019 was reviewed by the HRRC. The HRRC has no evidence suggesting that there were any significant deviations from study procedures as approved by the HRRC for the studies that were reviewed and approved by the DARS HRRC during SFY 2019.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 10, 2019, the HRRC had seven members and one alternate.

This document is the HRRC's nineteenth Annual Report. I wish to express my appreciation to the members of the HRRC for their commitment to supporting this important endeavor.

  
Katheryn A. Hayfield  
Commissioner

During State Fiscal Year (SFY) 2019, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed 8 applications.

<b>SFY 2019 Research Applications</b>	
Studies that Received Initial Approval	2
Studies that were Amended / Continued	6
Studies that were Closed	0
Studies that were Cancelled or Withdrawn	0
<b>TOTAL</b>	<b>8</b>

**Studies Receiving Initial Approval During SFY2019**

There were two (2) initial applications submitted to the HRRC for review during SFY 2019.

Project Title	Principal Investigator	Type of Review	Control Number	Expiration Date
Employment According to African American Young Adults with Intellectual Disabilities	Dr. Khalilah R. Johnson VCU	Exempt	SFY19-001	None
The Effect of BST with In Situ Training on the Acquisition of Social Skills for Working or Interning Youth and Young Adults with ASD	Dr. Yaoying XU And Dr. Carol Schall VCU	Expedited	SFY19-002	January 10, 2020

**Studies Continued/Amended**

Study Title	Principal Investigator	Type of Review	Control Number	Expiration Date
Facilitating Employment for Youth with Autism: A Replication Study of an Internship Model to Identify Evidence Based Research Practices	Paul Wehman, Ph.D. / Carol M. Schall, Ph.D. VCU	Expedited /CR	SFY13-003	October 15, 2019
Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR) <sup>1</sup>	Robert Schmidt, Ph.D. U of R	Continuing / Amended (Uof R Review)	SFY09-001	September 10, 2019
Assessing Longitudinal Employment Impacts of DRS Service Provision 2	Robert Schmidt, Ph.D. U of R	Continuing / Amended (U of R Review)	SFY09-002	September 10, 2019
Pathways to Careers Initiative	Ms. Gina Livermore - Mathematica	Expedited	SFY17-004	November 22, 2019
Effects of a 9-month Internship Intervention for Military Dependents with ASD	Paul Wehman, Ph.D. / Carol M. Schall, Ph.D. VCU	Expedited	SFY17-005	December, 21, 2019
Effects of a Customized Employment Intervention on the Employment Outcomes of Youth with Intellectual Disabilities and/or Autism Spectrum Disorders	Dr. Katherine Inge – VCU	Expedited	SFY17-006	February 18, 2020

<sup>1</sup> The DARS HRRC has in place a Memorandum of Understanding with the University of Richmond Institutional Review Board (IRB) to act as the IRB of record for SFY09-001 and SFY09-002 and the research protocols of Dr. Robert Schmidt.

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**Studies Closed During State Fiscal Year 2019**

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None (0). There were no studies closed in SFY 2019.