



VIRGINIA DEPARTMENT FOR AGING
AND REHABILITATIVE SERVICES

Annual Report on Human Subjects Research

State Fiscal Year 2018

To the Governor and the General Assembly of Virginia

July 31, 2018

**Virginia Department for Aging and Rehabilitative Services
Human Research Review Committee
2018 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). There were no (0) new applications reviewed during the State Fiscal Year 2018. The HRRC conducted six continuing/amended reviews to previously approved studies, and received one study closure.

To the best of the Committee's knowledge, all research involving human volunteers conducted or authorized by DARS or the WWRC during SFY 2018 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 2018.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2018, the HRRC had seven members and one alternate.

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


Kathryn A. Hayfield
Commissioner

During State Fiscal Year (SFY) 2018, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed 6 applications.

SFY 2018 Research Application Requests	
Studies that Received Initial Approval	0
Studies that were Amended / Continued	6
Studies that were Closed	1
Studies that were Cancelled or Withdrawn	0
TOTAL	7

Studies Receiving Initial Approval during SFY2017

None

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, 2018
Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR) ¹	Robert Schmidt, Ph.D. UofR	Continuing / Amended (U of R Review)	SFY09-001	September 10, 2018
Assessing Longitudinal Employment Impacts of DRS Service Provision ²	Robert Schmidt, Ph.D. UofR	Continuing / Amended (U of R Review)	SFY09-002	September 10, 2018

¹ 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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Pathways to Careers Initiative	Ms. Gina Livermore - Mathematica	Expedited	SFY17-004	November 22, 2018
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, 2018
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, 2019

Studies Closed During State Fiscal Year 2018

Study Title	Principal Investigator	Control Number	Closure Date
The Effect of Occupational Therapy Intervention Group on Travelers with Disabilities	Ms. Courtney Halsey – Mary Baldwin University	SFY17-001	December 13, 2017