



Annual Report on Human Subjects Research

State Fiscal Year 2020

To the Governor and the
General Assembly of Virginia

July 13, 2020

Virginia Department for Aging and Rehabilitative Services
Human Research Review Committee
2020 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 proposed or authorized by DARS, the Wilson Workforce and Rehabilitation Center (WWRC), Centers for Independent Living and Employment Services Organizations that have a vendor relationship with DARS.

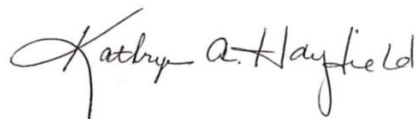
The HRRC complies with federal requirements for the *Protection of Human Subjects* (45 CFR 46). The U.S. Department of Health and Human Services approved the HRRC Federal wide Assurance (FWA#00008936) beginning August 15, 2005. The FWA is currently effective through March 23, 2023.

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 was one (1) new application reviewed during the State Fiscal Year 2020. The HRRC conducted five (5) reviews to previously approved studies, and there were two (2) study closures.

To the best of the Committee's knowledge, the HRRC reviewed all research involving human volunteers conducted or authorized by DARS or the WWRC during SFY 2020. The HRRC has no evidence suggesting that there were any significant deviations from study procedures as approved by the HRRC for the studies reviewed and approved by the DARS HRRC during SFY 2020.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of July 1, 2020, the HRRC had seven members and one alternate.

This document is the HRRC's twentieth 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) 2020, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed eight (8) applications.

SFY 2020 Research Applications	
Studies that Received Initial Approval	1
Studies that were Amended / Continued	5
Studies that were Closed	2
Studies that were Cancelled or Withdrawn	0
TOTAL	8

Studies Receiving Initial Approval during SFY2020

Study Title	Principal Investigator	Review Type	Control Number	Expiration
Effects of Knowledge Translation Methods on VR Counselors Providing Pre-ETS to Youth with Significant Disabilities 14-16 Years of Age: A Pilot RCT.	Elizabeth Getzel VCU	Expedited	SFY20-001	September 10, 2021

Studies Continued/Amended

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 / Continuing Review	SFYI3-003	October 15, 2020
Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR) ¹	Robert Schmidt, Ph.D. U of R	Continuing Review / Amended (Uof R Review)	SFY09-001	September 10, 2021
Assessing Longitudinal Employment Impacts of DRS Service Provision ²	Robert Schmidt, Ph.D. U of R	Continuing Review Amended (Uof R Review)	SFY09-002	September 10, 2021

Pathways to Careers Initiative	Ms. Gina Livermore Mathematica	Expedited	SFY17-004	September 30, 2020
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, 21,2020

¹The 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 SFY09-00I and SFY09-002 and the research protocols of Dr. Robert Schmidt.

²The 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 SFY09-00I and SFY09-002 and the research protocols of Dr. Robert Schmidt.

Studies Closed During State Fiscal Year 2020

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
The Effect of BST with In Situ Training on the Acquisition of Social Skills for Working Interning Youth and Young Adults with ASD"	Carol M. Schall, Ph.D./ Dr. Yaoying Xu VCU	Expedited	SFY19-002	June 29, 2020