

Annual Report on Human Subjects Research State Fiscal Year 2021

To the Governor and the General Assembly of Virginia

July 31, 2021

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, Employment Services Organizations and Area Agencies on Aging 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 were two (2) new applications reviewed during the State Fiscal Year 2021. The HRRC conducted five (5) reviews to previously approved studies, and there was one study closure.

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 2021. 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 2021.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of July 1, 2021, the HRRC had seven members and one alternate.

This document is the HRRC's twenty-first 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

Kathy a Hayfield

During State Fiscal Year (SFY) 2021, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed eight (8) applications.

SFY 2021 Research Applications	·
Studies that Received Initial Approval	2
Studies that were Amended / Continued	5
Studies that were Closed	1
Studies that were Cancelled or Withdrawn	0
TOTAL	8

Studies Receiving Initial Approval during SFY2021

Study Title	Principal Investigator	Review Type	Control Number
Collaborative and Culturally Responsive Practices of Transition Professionals to Support Black Students with High Incidence Disabilities	Dr. LaRon Scott Amber Ruiz Brown VCU	Exempt	SFY21-002
The Good Life CAFÉ: Community Access and Financial Empowerment	Dr. Rebecca S. Salon National Disability Institute	Exempt	SFY21-001

Studies Continued/Amended

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 / Continuing Review	SFYI3-003	October 15, 2021
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 (U of R Review)	SFY09-002	September 10, 2021

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
Effects of a 9-month Internship Intervention for Military Dependents with ASD	Paul Wehman, Ph.D. I Carol M. Schall, Ph.D. VCU	Expedited	SFY17-005	July 26, 2022

Studies Closed During State Fiscal Year 2021

	Ms. Gina Livermore Mathematica	Expedited	SFY17-004	October 1, 2020
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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 SFY09-00I and SFY09-002 and the research protocols of Dr. Robert Schmidt .

² The DARS HRRC has in place a Memorandum of Understanding with the University of Richmond Institutional Review Board ()RB) to act as the IRB of record for SFY09-00I and SFY09-002 and the research protocols of Dr. Robert Schmidt.