

Annual Report on Human Subjects Research

State Fiscal Year 2022

To the Governor and the General Assembly of Virginia

July 22, 2022

Virginia Department for Aging and Rehabilitative Services Human Research Review Committee 2022 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 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 (CIL), Employment Service Organizations (ESO), and Area Agencies on Aging (AAA) that have a vendor relationship with DARS.

The HRRC complies with federal requirements for the Protection of Human Subjects (45 CFR 46). The US 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 three new applications reviewed during the state fiscal year (SFY) 2022. Four studies were amended or continued and four studies were closed.

To the best of the Committee's knowledge, the HRRC reviewed all research involving human volunteers conducted or authorized by DARS, WWRC, CIL, ESO or AAA during SFY 2022. The HRRC has no evidence suggesting that there were any significant deviations from study procedures, as approved by the HRRC, for the studies approved, amended or continued during SFY 2022. Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of July 1, 2022, the HRRC had five members and one alternate. This document is the HRRC's twenty-second 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 SFY 2022 the DARS HRRC reviewed 11 applications.

SFY 2022 Research Applications			
Initial Approval	3		
Amended or Continued	4		
Closed	4		
Cancelled or Withdrawn	0		
Total	11		

Initial Approval:

Study Title	Principal Investigator	Review Type	Control Number
The Effects of	Loveleen Kaler	Cooperative	SFY22-001
Sensory-Based	(Doctoral Candidate);		
Intervention in	Dr. Sarah McCadden,		
Individuals with	Mary Baldwin		
Sensory Processing	University		
Concerns in the			
Workplace: A Pre and			
Post Test Mixed			
Method Analysis ¹			
Let's Get Organized	Carrie Clawson	Cooperative	SFY22-002
(LGO) ²	(Doctoral Candidate);		
	Dr. Sheri		
	Montgomery, Mary		
	Baldwin University		
Sleep Intervention	Patti Drescher	Cooperative	SFY22-003
Program for VR	(Doctoral Candidate);		
Clients ³	Dr. Sheri		
	Montgomery, Mary		
	Baldwin University		

¹Mary Baldwin University (MBU) is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and MBU on 12/22/21.

²MBU is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and MBU on 2/14/22.

³MBU is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and MBU on 3/16/22.

Amended or Continued:

Study Title	Principal Investigator	Review Type	Control Number
The Good Life CAFÉ:	Dr. Rebecca Salon,	Exempt	SFY21-001
Community Access	National Disability		
and Financial	Institute		
Empowerment			
Effects of a	Dr. Katherine Inge,	Expedited	SFY17-007
Customized	Virginia		
Employment	Commonwealth		
Intervention on the	University		
Employment			
Outcomes of Youth			
with Intellectual			
Disabilities and/or			
Autism Spectrum			
Disorder			
Effects of Knowledge	Elizabeth Getzel,	Expedited	SFY20-001
Translation Methods	Virginia		
on VR Counselors	Commonwealth		
Providing Pre- ETS to	University		
Youth with			
Significant Disabilities			
14-16 Years of Age: A			
Pilot RCT			
Effects of a 9-month	Drs. Paul Wehman	Expedited	SFY17-005
Internship	and Carol Schall		
Intervention for			
Military Dependents			
with ASD			

Closed:

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 Brown Ruiz (Doctoral Candidate), Virginia Commonwealth University	Exempt	SFY21-002
Facilitating Employment for Youth with Autism: A	Drs. Paul Wehman and Carol Schall, Virginia	Expedited	SFY13-003

Replication Study of an Internship Model to Identify Evidence Based Research Practices	Commonwealth University		
Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR)	Dr. Robert Schmidt, University of Richmond	Cooperative	SFY09-001
Assessing Longitudinal Employment Impacts of DRS Service Provision	Dr. Robert Schmidt, University of Richmond	Cooperative	SFY09-002