



Annual Report on Human Subjects Research

***State Fiscal Year 2023:
July 1, 2022 – June 30, 2023***

To the Governor and the General Assembly of Virginia

July 19, 2023

Virginia Department for Aging and Rehabilitative Services
Human Research Review Committee
2023 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) that have a vendor relationship with DARS, and Area Agencies on Aging (AAA).

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 January 25, 2026. 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 new application reviewed during the state fiscal year (SFY) 2023. Four studies were amended or continued, and three 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 2023. 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 2023. Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of July 1, 2023, the HRRC had five members and one alternate. This document is the HRRC's twenty-third 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

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Commissioner

During SFY 2023 the DARS HRRC reviewed 8 applications.

SFY 2023 Research Applications	
Initial Approval	1
Amended or Continued	4
Closed	3
Cancelled or Withdrawn	0
Total	8

Initial Approval:

Study Title	Principal Investigator	Review Type	Control Number
Pathways to Careers Using Partnerships, Apprenticeships and Equity ¹	Susan Foley, University of Massachusetts Boston	Cooperative	SFY23-001

¹University of Massachusetts Boston (UMB) is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and UMB on 7/6/22.

Amended or Continued:

Study Title	Principal Investigator	Review Type	Control Number
The Good Life CAFÉ: Community Access and Financial Empowerment	Dr. Rebecca Salon, National Disability Institute	Exempt	SFY21-001
Effects of a Customized Employment Intervention on the Employment Outcomes of Youth with Intellectual Disabilities and/or Autism Spectrum Disorder	Dr. Katherine Inge, Virginia Commonwealth University	Expedited	SFY17-007
Effects of Knowledge Translation Methods on VR Counselors Providing Pre- ETS to Youth with Significant Disabilities	Susan McKelvey, Virginia Commonwealth University	Expedited	SFY20-001

14-16 Years of Age: A Pilot RCT			
Effects of a 9-month Internship Intervention for Military Dependents with ASD	Drs. Paul Wehman and Carol Schall	Expedited	SFY17-005

Closed:

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

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

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

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