

Annual Report on Human Subjects Research

State Fiscal Year 2024: July 1, 2023 – June 30, 2024

To the Governor and the General Assembly of Virginia

July 15, 2024

Virginia Department for Aging and Rehabilitative Services Human Research Review Committee 2024 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 four types of reviews: Exempt Review (regulatory oversight not required), Expedited Review (application reviewed and approved by one or more HRRC members), Full Committee Review (a quorum of members in attendance), and Cooperative Research Review (Authorization Agreement executed between two Institutional Review Boards). There were three new applications reviewed during the state fiscal year (SFY) 2024. Four studies were amended or continued, and one was 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 2024. 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 2024. Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of July 1, 2024, the HRRC has six members and one alternate. This document is the HRRC's twenty-fourth 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 2024 the DARS HRRC reviewed 8 applications.

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Cancelled or Withdrawn	0		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

Initial Approval:

Study Title	Principal Investigator	Review Type	Control Number
Evaluation of: Real	Michelle Yin,	Cooperative	SFY24-002
Pay for Real Jobs	Northwestern		
(RPRJ) Education and	University		
Outreach,			
Partnership			
Development,			
provisions of			
Individualized			
Services and Capacity			
Building (EPIC) in			
Virginia ¹			
HealthWise:	Marissa Galicia	Exempt	SFY24-001
Computer Coaching	Castillo, Eastern		
for Social	Virginia Medical		
Connectivity of Older	School		
Adults			
Rehabilitation	Ayesha De Mond,	Cooperative	SFY24-003
Services	Mathematica		
Administration (RSA)			
Disability Innovation			
Fund (DIF) Program			
Evaluation ²			

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 Knowledge	Susan McKelvey,	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			
Pathways to Careers	Susan Foley,	Cooperative	SFY23-001
Using Partnerships,	University of		
Apprenticeships and	Massachusetts		
Equity ³	Boston		

Closed:

Study Title	Principal Investigator	Review Type	Control Number
Effects of a	Katherine Inge,	Expedited	SF17-007
Customized	Virginia		
Employment	Commonwealth		
Intervention on the	University		
Employment			
Outcomes of Youth			
with Intellectual			
Disabilities and/or			
Autism Spectrum			
Disorder			

¹The American Institutes for Research (AIR) is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and AIR on 12/13/23.

²Health Media Lab (HML) is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and HML on 6/6/24.

³University of Massachusetts Boston (UMB) is serving as the IRB of Record. IRB Authorization Agreement successfully executed between DARS and UMB on 7/6/22.