

Annual Report on Human Subjects Research

State Fiscal Year 2017

To the Governor and the General Assembly of Virginia

July 2017

Virginia Department for Aging and Rehabilitative Services Human Research Review Committee 2017 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 to be conducted or authorized by DARS, the Wilson Workforce and Rehabilitation Center (WWRC), and Centers for Independent Living and Employment Services Organizations that have a vendor relationship with DARS.

The HRRC also 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 June 23, 2020.

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). Five new applications were reviewed during the State Fiscal Year 2017, and 4 were approved by Expedited Review, 1 by Exempt review. The HRRC also conducted six continuing/amended reviews to previously approved studies, and received two study closures.

To the best of the Committee's knowledge, all research involving human volunteers conducted or authorized by DARS or the WWRC during SFY 2017 was reviewed by the HRRC. The HRRC has no evidence suggesting that there were any significant deviations from study procedures as approved by the HRRC for the studies that were reviewed and approved by the DARS HRRC during SFY 2017.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2017, the HRRC had seven members and one alternate.

This document is the HRRC's sixteenth Annual Report. I wish to express my appreciation to the members of the HRRC for their commitment to supporting this important endeavor.

James A. Rothrock Commissioner During State Fiscal Year (SFY) 2017, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed 12 applications.

SFY 2017 Research Application Requests		
Studies that Received Initial Approval	5	
Studies that were Amended / Continued	6	
Studies that were Closed	2	
Studies that were Cancelled or Withdrawn	1	
TOTAL	14	

Studies Receiving Initial Approval during SFY2017

Studies Receiving Initial Approval	9			
	Principal	Type of		
	Investigator	Review	Control	Expiration
Study Title			Number	Date
The Effect of Occupational	Ms. Courtney	Exempted	SFY17-001	N/A
Therapy Intervention Group on	Halsey – Mary			
Travelers with Disabilities	Baldwin			
	University			
Perceptions of Law Enforcement by	Eric S. Snow –	Expedited	SFY17-002	PI Withdrew
Families of Individuals with	Radford	-		Application
Disabilities.	University			(9/15/2016)
Vacant (Proposal not HSR)	Vacant	Vacant	SFY17-003	N/A
Pathways to Careers Initiative	Ms. Gina	Expedited	SFY17-004	November
	Livermore -			22, 2017
	Mathematica			
Effects of a 9-month Internship	Paul Wehman,	Expedited	SFY17-005	December,
Intervention for Military	Ph.D. / Carol M.	-		21, 2017
Dependents with ASD	Schall, Ph.D.			
-	VCU			
Effects of a Customized	Dr. Katherine	Expedited	SFY17-006	February 18,
Employment Intervention on the	Inge -VCU	_		2018
Employment Outcomes of Youth	-			
with Intellectual Disabilities and/or				
Autism Spectrum Disorders				

Studies Continued/Amended

Study Title	Principal	Type of	Control	Expiration
	Investigator	Review	Number	Date
Vocational Rehabilitation Counselors' Experiences with Clients who have Autism Spectrum Disorders	Dr. Kim Murza, University of Northern Colorado	Exempted	SFY15-001	N/A

Commonwealth of Virginia State Agency and Provider Survey of Neurobehavioral Services and Support	Dr. Cynthia O 'Donoghue - , James Madison University	Expedited / CR	SFY15-002	September 30, 2017
Effectiveness of Knowledge Translation Strategies to Promote Supported Employment Knowledge and Outcomes	Katherine J. Inge, PhD VCU	Expedited /CR	SFY14-002	September 30, 2017
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 /CR	SFY13-003	October 15, 2017
Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR) ¹	Robert Schmidt, Ph.D. UofR	Continuing/ Amended (U of R Review)	SFY09-001	September 10, 2017
Assessing Longitudinal Employment Impacts of DRS Service Provision ²	Robert Schmidt, Ph.D. UofR	Continuing/ Amended (U of R Review)	SFY09-002	September 10, 2017

Studies Closed During State Fiscal Year 2017

	Principal Investigator	Control	Closure Date
Study Title		Number	
The Impacts of Wraparound Supports on the Rehabilitation of Individuals with Disabilities	Kristen Chesser - WWRC	SFY16- 001	June 16, 2016
The Effects of Occupational Therapy Intervention Group on Travelers with Disabilities	Ms. Courtney C. Halsey – Mary Baldwin University	SFY17- 001	April 14, 2017

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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 SFY09-001 and SFY09-002 and the research protocols of Dr. Robert Schmidt.
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