Virginia Department for Aging and Rehabilitative Services Human Research Review Committee 2014 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 Woodrow Wilson 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 July 16, 2017.

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). Four new applications were reviewed during the State Fiscal Year 2014. Two were approved by Expedited Review, one approved by Exempt Review and one is pending The HRRC also conducted five 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 2014 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 2014.

Composition of the HRRC is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2014, the HRRC had seven members and one alternate.

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

Jom A. Botterall

James A. Rothrock Commissioner During State Fiscal Year (SFY) 2014, the Virginia Department for Aging and Rehabilitative Service, Human Research Review Committee reviewed 11 applications.

SFY 2014 Research Application Requests					
Studies that Received Initial Approval	4				
Studies that were Amended / Continued	5				
Studies that were Closed	2				
Studies that were Cancelled or Withdrawn	0				
TOTAL	11				

Studies Receiving Initial Approval during SFY2014

	Principal	Type of Review		
	Investigator		Control	Expiration Date
Study Title			Number	
Center on Effective Rehabilitation	Deepti		SFY14-	
Technology Services Case Studies	Samant		001	
	Raja, PhD	Expedited		August 1, 2014
	Syracuse			
	University			
Effectiveness of Knowledge	Katherine		SFY14-	
Translation Strategies to Promote	J. Inge,	Expedited	002	November 30,
Supported Employment Knowledge	PhD	Expedited		2014
and Outcomes	VCU			
Clinical Supervisors' Perception of	Dr.			
Counselor Characteristics that Lead	Margaret	Exempt	SFY14-	N/A
to Effective and Well-Balanced	Glenn	Exempt	003	1N/A
Practices	WVU			
Rural Contracted Services-	Catherine			
Practices in the Field	Ipsen,			
	Ph.D.	TBD	SFY14-	
	University		004	TBD
	of Montana		004	
	Rural			
	Institute			

Studies Continued/Amended

	Principal	Type of Review	·	
Study Title	Investigator		Control Number	Expiration Date
A Randomized Control Trial of the	Lynwood		11001	
Apple Ipod Touch as a Vocational Support Technology for Adults with Autism Spectrum Disorder.	(Tony) O. Gentry, Ph.D. OTR/L	Continuing/Amended Expedited	SFY10- 003	August 18, 2014
Longitudinal Administrative Rehabilitation on Occupational Data Repository (LARDOR) ¹	Robert Schmidt, Ph.D. UofR	Continuing/ Amended (U of R Review)	SFY09- 001	September 10, 2014
Assessing Longitudinal Employment Impacts of DRS Service Provision ²	Robert Schmidt, Ph.D. UofR	Continuing/ Amended (U of R Review)	SFY09- 002	September 10, 2014
Statewide Traumatic Brain Injury (TBI) - Needs and Resource Assessment in Virginia	Dr. Mary A. Moore VCU	Exempt	SFY13- 002	N/A
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	SFY13- 003	Pending Review

Studies Closed During State Fiscal Year 2014

	Principal		
	Investigator	Control	Closure Date
Study Title		Number	
A Collaborative Public/Private	Dr. Carol		
Employment Training and Placement	Schall	SFY09-	August 28, 2012
Model for Transition Age Youth With	VCU	008	August 28, 2013
Autism Spectrum Disorders			
Development and Feasibility of an	Kate Baxter		
Internet Intervention for Adults with	WWRC	SFY11-	Amril 4, 2014
Spinal Cord Injury to Prevent Pressure		003	April 4, 2014
Ulcers			

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 SFY09-001 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 (IRB) to act as the IRB of record for SFY09-001 and SFY09-002 and the research protocols of Dr. Robert Schmidt.