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.

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 Investigator	Type of Review	Control	Expiration Date
Study Title	in, estigator		Number	zaprawon zave
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	2.15.010.0		2014
and Outcomes	VCU			
Clinical Supervisors' Perception of	Dr.			
Counselor Characteristics that Lead	Margaret	Exempt	SFY14-	N/A
to Effective and Well-Balanced	Glenn		003	
Practices	WVU			
Rural Contracted Services-	Catherine			
Practices in the Field	Ipsen,			
	Ph.D.		SFY14-	
	University	TBD	004	TBD
	of Montana			
	Rural			
	Institute			

Studies Continued/Amended

Principal	Type of Review		
Investigator		Control	Expiration Date
		Number	
•			
(Tony) O.	Continuing/Amended	SFY10-	August 18, 2014
Gentry,			
Ph.D.	Expedited	003	
OTR/L			
Robert	Continuing/		
Schmidt,	•	SFY09- 001	September 10, 2014
Ph.D.			
UofR	(U OI K Keview)		
Robert	Continuing/	SFY09- 002	September 10, 2014
Schmidt,	_		
Ph.D.			
UofR	(U OI K Keview)		
Dr. Mary		CEV12	
A. Moore	Exempt	-	N/A
VCU		002	
Paul			
Wehman,			
Ph.D. /		CEV12	
Carol M.	Expedited	-	Pending Review
Schall,		003	
Ph.D.			
VCU			
	Lynwood (Tony) O. Gentry, Ph.D. OTR/L Robert Schmidt, Ph.D. UofR Robert Schmidt, Ph.D. UofR A. Moore VCU Paul Wehman, Ph.D. / Carol M. Schall, Ph.D.	Lynwood (Tony) O. Gentry, Ph.D. OTR/L Robert Schmidt, Ph.D. UofR Robert Schmidt, Ph.D. UofR Robert Schmidt, Ph.D. UofR Robert Schmidt, Ph.D. UofR Dr. Mary A. Moore VCU Paul Wehman, Ph.D. / Carol M. Schall, Ph.D.	Investigator Lynwood (Tony) O. Gentry, Ph.D. OTR/L Robert Schmidt, Ph.D. UofR Robert Schmidt, Ph.D. UofR Robert Schmidt, Ph.D. UofR Dr. Mary A. Moore VCU Paul Wehman, Ph.D. / Carol M. Schall, Ph.D. Continuing/Amended Expedited Continuing/ Amended (U of R Review) SFY09- 001 SFY09- 002 SFY09- 002 SFY13- 002 SFY13- 003

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, 2013
Model for Transition Age Youth With	VCU	800	August 26, 2015
Autism Spectrum Disorders			
Development and Feasibility of an	Kate Baxter		
Internet Intervention for Adults with	WWRC	SFY11-	April 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.