State Fiscal Year 2009 Annual Report of the Human Research Review Committee, Department of Rehabilitative Services



James A. Rothrock, M.S., L.P.C. Commissioner

June 30, 2009

Members of the Human Research Review Committee

Chair Elizabeth E. Smith, J.D., M.S. Policy and Planning Director, DRS

Administrator/Coordinator

Divette M. Brisco, M.S. HIPAA Coordinator/Technology Risk Manager, DRS

> Members William E. Heinlein, Ed.D. Psychological Services, WWRC

Michael Nakatsuka Citizen, Commonwealth of Virginia

Lisa Lowe, M.S., L.P.C. Vocational Rehabilitation Counselor, DRS

Salvatore Lupica, J.D. Virginia Employment Commission

Sandra Wagener Executive Director, Resources for Independent Living

Alternate Committee Members Barbara J. Burkett, Ph.D. Vocational Rehabilitation Program Evaluator, DRS

> Pamela S. Duff, M.D. Medical Consultant, DRS

Preface

The *Code of Virginia* Section 51.5-14.01 directs the Department of Rehabilitative Services' (DRS) Human Research Review Committee (HRRC) to submit to the Governor, the General Assembly, and the DRS 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 DRS clients and employees who volunteer to participate in research conducted or authorized by DRS. The DRS Commissioner established the HRRC in August 2000 to review and approve research to be conducted or authorized by DRS, the Woodrow Wilson Rehabilitation Center (WWRC), Centers for Independent Living (CIL) and Employment Services Organizations (ESO) that have a vendor relationship with DRS.

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 September 25, 2011

Composition of the Committee is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2009, the HRRC had seven members and 2 two alternates.

This document is the HRRC's ninth 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, M.S., L.P.C. Commissioner

June 30, 2009

Summary

The Human Research Review Committee (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). Eight new applications were reviewed during the State Fiscal Year 2009. Two were approved by Full Committee Review, two were approved by Exempt Review, and three were approved by Expedited Review. The HRRC also received a study closure document for one study.

To the best of the Committee's knowledge, all research involving human volunteers conducted or authorized by DRS or the WWRC during SFY 2009 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 DRS HRRC during SFY 2009.

Studies that received initial approval during SFY 2009

Title: Longitudinal Administrative Rehabilitation/Occupational Data Repository (LARODR)

Principal Investigator: David Dean Ph.D

DRS Control # SFY09-001

Periodic Review: Annual

Approved by Full Committee Review - October 17, 2008

The purpose is to create a data repository to study long term impacts of the DRS Vocational Rehabilitation program and perform other types of analysis of interest to DRS.

Title: Assessing Longitudinal Employment impacts of DRS Service Provision

Principal Investigator: David Dean Ph.D

DRS Control # SFY09-002

Periodic Review: Annual

Approved by Full Committee Review – December 1,2008

The goal of this research project is to obtain scientifically defensible estimates of the earnings impacts resulting from the provision of job training services provided by the Virginia Department of Rehabilitative services (DRS) for persons with disabilities.

<u>Title</u>: Typology of Disability Orientations : A Study of Clients and Professionals at the Hiram G. Andrews Center

Principal Investigator: Melissa Murray, M.Ed, CRC

DRS Control # SFY09-003

Periodic Review: N/A

Approved by Exempt Review - January 15,2009

The purpose of the study is to determine disability orientations in association to client professional relationships, VR services and employment outcomes.

<u>Title</u>: <u>An Analysis of Pre-Admission and Resource Scheduling Processes at the Woodrow</u> <u>Wilson Rehabilitation Center (WWRC)</u>

Principal Investigator: Kyle A. Congleton

DRS Control # SFY09-005

Periodic Review: Annual

Approved by Exempted Review - April 3, 2009

This study will design a system for evaluating and updating capacity information for a rehabilitation center in an effort to streamline admittance and increase resource utilization.

<u>Title</u>: Pilot Study for the Autism Spectrum Disorder Assistive Technology for Cognition (ASDATC) – Validating the Efficacy of Hand Held Computers as Assistive Technology in Job Support for Adults with Autism Spectrum Disorders.

Principal Investigator: Lynwood (Tony) O. Gentry, PhD OTR/L

DRS Control # SFY09-006

Periodic Review: Annual

Approved by Expedited Review - May 26, 2009

This initial pilot study involves training five (5) individuals with ASD to use the supportive organizational functions of a PDA in an employment setting. Utilizing a repeated measures design, work performance will be assessed at pre-determined intervals. The outcomes to be measured include employment status, level of employment, support provided and satisfaction with intervention by participant, job support specialist and employer.

Title: An Auto-Adaptive Interface for Neuromuscular Disabilities - Phase II

Principal Investigator: Paula Martin, Occupational Therapist Sr.

DRS Control # SFY09-007

Periodic Review: Annual

Approved by Expedited Review - May 26, 2009

This study purpose is to develop an adaptable and cost effective assistive technology device that will accommodate and automatically adjust in order to improve access to computers for individuals with a wide variety of upper extremity neuromuscular disabilities. The device will

aid/enhance an individuals ability to access a computer and therefore improve their outlook for professional, personal and financial growth.

<u>Title</u>: A Collaborative Public/Private Employment Training and Placement Model for Transition Age Youth with Autism Spectrum Disorderrs (ASD)

Principal Investigator: Carol M. Schall, Ph.D

DRS Control # SFY09-008

Periodic Review: Annual

Approved by Expedited Review - June 26, 2009

The purpose of this research project is to conduct evidence based research on a nationally known vocational rehabilitation (VR) model (Project Search) for individuals with Autism Spectrum Disorders (ASD). This information may be useful to high schools and vocational rehabilitation agencies that endevour to use evidence based practices to serve individuals with ASD. This study will involve students with ASD from Henrico County Schools and the Faison School for Autism, as well as services of a Rehabilitation Counselor from the Virginia Department of Rehabilitative Services (DRS). The Faison School is a program operated by the VCU department of Psychiatry ans is therefore a VCU entity.

Studies Closed During State Fiscal Year 2009

	Type of	Date of		
	Continuing	Initial	Control	Closure Date
Study Title	Review	Approval	Number	
Factors Contributing to Success or				
Failure in Vocational Evaluation by	Full	March 3,	SFY08-	3/12/2009
Users of Augmentative and Alternative	Committee	2008	0002	5/12/2009
Communication Devices				