State Fiscal Year 2008
Annual Report of the Human Research Review Committee, Department of Rehabilitative Services

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

August 26, 2008

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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 Federalwide Assurance (FWA) for a three year period that began August 15, 2005. The FWA was renewed for another three year period effective April 25, 2008.

Composition of the Committee is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2008, the HRRC had seven members, two alternates, and a non-voting Health Insurance Portability and Accountability Act (HIPAA) consultant.

This document is the HRRC's eighth annual report. I wish to express my appreciation to the members of the HRRC for their commitment to supporting this important endeavor.

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Executive Summary

The Human Research Review Committee (HRRC) reviews applications for all human research activities involving DRS clients and/or employees.[1] The purpose of the review is to ensure compliance with state and federal requirements for the conduct of research that involves human volunteers. Annually, the HRRC must submit to the Governor, the General Assembly, and the DRS Commissioner a report on the human research projects reviewed and approved by the HRRC (*Code of Virginia* Section 51.5-14.01).

There are 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). Three new applications were reviewed during the State Fiscal Year 2008 and one was approved by Full Committee Review. One study was approved by Exempt Review. DRS entered into a Cooperative Agreement (45 CFR 46.114) with Virginia Commonwealth University for the third study. The HRRC has no evidence suggesting that there have been any significant deviations from study procedures as approved for applications initially approved during State Fiscal Year 2008. The HRRC also received study closure documents for four studies that continued beyond the initial approval period and had received continuing annual review. One other study was withdrawn by the investigators prior to HRRC approval.

During the fiscal year, DRS began the standard regulatory process (Code of Virginia, Sections 2.2-4007 to 4017) to revise the *Protection of Participants in Human Research* regulations (22 VAC 30-40-10 *et seq.)*. On August 6, 2007 the Notice of Intended Regulatory Action (NOIRA) was published in the Virginia Register to allow 30 days for public comment. There were no public comments during the first stage of the process. As of June 30, 2008 the "Proposed Stage" of the Human Research Regulations had passed review by the Department of Planning and Budget and the Secretary of Health and Human Resources. The regulations are currently pending review by the Governor's Office. Once approved by the Governor's Office, the proposed regulations will be published for public comment. Following the 60 days public comment period, the proposed regulations will proceed through the final stage.

[1] The regulatory guidance for federally-funded or sponsored human research is provided in 45 CFR 46.

Introduction

DRS provides and advocates for the highest quality services that empower individuals with disabilities to maximize their employment, independence and full inclusion into society. DRS operates the federal-state funded Vocational Rehabilitation (VR) program that provides eligible individuals with disabilities with a comprehensive array of services to enable them to obtain, retain, or advance in employment. DRS also operates the Woodrow Wilson Rehabilitation Center (WWRC), which provides comprehensive residential and outpatient services to individuals with multiple and complex disabilities. In addition, supports and services to enhance the independence of individuals with significant disabilities are provided through an array of community-based programs. DRS performs disability determinations on disability claims for benefits under the Social Security Disability Insurance, Supplemental Security Income Disability Programs and Medicaid Disability.

In addition to its agency programs, DRS has strong partnerships with many community-based rehabilitation providers across the Commonwealth. For example, DRS purchases facility-based employment and supported employment services from Employment Services Organizations (ESOs). DRS works closely with Centers for Independent Living (CILs), which provide independent living skills, training, advocacy, information and referral, and peer counseling for individuals with disabilities, as well as with community organizations and state agencies involved with education, training and/or employment for people with disabilities.

As mandated by the *Code of Virginia* Section 51.5-14.01 (Appendix A), the DRS Commissioner established the Human Research Review Committee (HRRC) in August 2000 to review and approve all research to be conducted or authorized by DRS or the WWRC. Additionally, Employment Services Organizations (ESOs) that have vendor agreements with DRS and Centers for Independent Living (CILs) are affiliated with the DRS Human Research Review Committee. This document is the HRRC's eight annual report on the research studies reviewed and approved by the Committee.

HRRC Responsibilities and Process

HRRC review and approval of applications for research involving human participants is governed by 22 VAC 30-40-10 *et seq.* and 45 CFR 46. To supplement regulatory requirements, the HRRC has a procedures manual which standardizes practices and activities, describes study participant complaint procedures, specifies the responsibilities of investigators, and provides templates for: 1) research applications, 2) voluntary informed consent, 3) conflict of interest disclosure, 4) investigator periodic progress reports, and 5) project closure.

The HRRC meets monthly, or as needed, to fulfill its responsibilities and must meet at least once annually. A quorum consists of a majority of its members, including at least one member whose primary concerns are in nonscientific areas. The HRRC's responsibilities begin when a research application is submitted to the Chair. Elements of review include consideration of potential benefits and risks, research methodology, informed consent process, competency of the research investigators, evaluation of potential conflict of interest, and equitable selection criteria for research participants. Each research application is reviewed within 45 days of submission of a complete HRRC application. Research investigators are notified in writing of the type of review, the decision to approve or disapprove the proposed research activity, or of modifications required to secure approval.

Types of HRRC Review

There are three types of review procedures that the HRRC can use to approve a research study. One type of review is termed Exempt Review (22 VAC 30-40-80 and 45 CFR 46.101(b)). Research studies must meet very specific requirements to qualify for this type of review. If the HRRC determines that the study is exempt, informed consent of prospective research participants is not required. Exempt studies are reviewed by the HRRC Chair or by the HRRC Administrator.

The next type of review is termed Expedited Review (22 VAC 30-40-90 and 45 CFR 46.110). The HRRC Chair or Administrator may determine that a research study is eligible for Expedited Review when the study presents no more than minimal risk to prospective participants and the research is on the list of categories approved for expedited review (45 CFR 46.110(a)) or research that only require minor changes in previously approved research during the period (of one year or less) for which approval is authorized (45 CFR 46.110(b)).

The third type of review is termed Full Committee Review. This type of review is carried out at a convened meeting composed of a quorum of committee members. For the research to be approved, it must receive the approval of a majority of those members present at the meeting. All applications that do not qualify for either Exempt Review or Expedited Review are reviewed by the full committee.

SFY 2007 Research Applications Reviewed

Three new applications were reviewed during the state fiscal year and one of these studies was approved by Full Committee Review. One study was approved by Exempt Review. DRS entered into a Cooperative Agreement (45 CFR 46.114) with Virginia Commonwealth University for the third study. SFY 2008 initial review applications are listed in Table 1.

Initial approval for a minimal risk research study is granted for a period not to exceed one year. Before research activities can carry on beyond the initial approval, the HRRC must conduct continuing review and approve continuance of the study. A study that is determined to be greater than minimal risk, must receive more frequent continuing reviews. The HRRC also received study closure documents for four studies that continued beyond the initial approval period and had received continuing annual review. One other study was withdrawn by the investigators prior to HRRC approval. These studies are summarized in Table 2.

To the best of the Committee's knowledge, all research involving human volunteers conducted or authorized by DRS or the WWRC during SFY 2008 were 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 one study that was approved by Full Committee Review during SFY 2008.

Standard Regulatory Process: Proposed Revisions to the Regulations

During the fiscal year, DRS began the standard regulatory process (*Code of Virginia* Sections 2.2-4007 to 4017) to revise the *Protection of Participants in Human Research* regulations (22 VAC 30-40-10 *et seq.)*. Ninety-nine percent of the changes to the regulations were made to ensure that state regulations are in compliance with federal regulations at 45 CFR 46. On August 6, 2007 the Notice of Intended Regulatory Action (NOIRA) was published in the Virginia Register to allow 30 days for public comment. There were no public comments during the first stage of the process.

As of this report the "Proposed Stage" of the Human Research Regulations had passed review by the Department of Planning and Budget and the Secretary of Health and Human Resources. The regulations are currently pending review by the Governor's Office. Once approved by the Governor's Office, the proposed regulations will be published for public comment. Following the 60 days public comment period, the proposed regulations will proceed through the final stage.

Table 1: Studies that received initial review during State Fiscal Year 2008

Study Title	Type of Review	Date Approved	Periodic Review	Control Number
Effect of a Web-Based Training Program on Practice Patterns for Professionals Recommending Manual Wheelchairs	Exempt	Approved November 5, 2007	None	SFY08-001
Factors Contributing to Success or Failure in Vocational Evaluation by Users of Augmentative and Alternative Communication Devices	Full Committee	Approved March 3, 2008	Annual	SFY08-002
Evaluation of Smart Home Technology in a Transitional Living Cottage for adults with acquired brain injury	Cooperative Agreement with VCU – DRS accepted VCU IRB Expedited Review, Category 4	VCU approval date: April 24, 2008	Annual	SFY08-003
See Appendix B for study synopsis				

Table 2: Studies Closed During State Fiscal Year 2008

Study Title	Type of Continuing Review	Date of Initial Approval	Control Number	Closure Date
Virginia Department of Rehabilitative Services (DRS) Survey of Working Personal Assistance Services (PAS) Consumers	Full Committee	January 2, 2004	SFY04-0001	7/19/2007
Job Coaching Assistance with Personal Digital Assistants (PDAs)	Expedited	October 6, 2005	SFY06-002	8/23/2007
An Auto-Adaptive Interface for Neuromuscular disabilities	Full Committee	May 7, 2007	SFY07-001	1/25/2008
The use of the Temperament and Character Inventory (TCI) in Vocational Rehabilitation	Full Committee	May 7, 2007	SFY07-003	8/1/2007
Use and Perceived Effectiveness of standing Frames and Knee Ankle Foot Orthoses	Full Committee	Tabled; then withdrawn by Investigator	SFY07-002	7/12/07

Appendix A: *Code of Virginia* Section 51.5-14.01

Commissioner to establish regulations regarding human research

The Commissioner shall promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department, any sheltered workshop, or independent living center, or Woodrow Wilson Rehabilitation Center. The regulations shall require the human research review committee, as provided in § 32.1-162.19, to submit to the Governor, the General Assembly, and the Commissioner or his designee, at least annually, a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved.

(2003, cc. 57, 73.)

Appendix B: Synopsis of studies that received initial approval during SFY 2008

Title: *Effect of a Web-Based Training Program on Practice Patterns for Professionals Recommending Manual Wheelchairs*

DRS Control # SFY08-001

Approved by Exempt Review

The purpose of this study is to make decisions about effective ways to train professional to use rehabilitation research in their clinical practice of recommending seating and wheeled mobility equipment. Researchers plan to study web-based training participants and traditional continuing education participants before, after, and six months following completion of the training program. In doing so, researchers hope to learn the influence of professional education programs on the daily practice of seating and mobility professionals.

Title: Factors Contributing to Success or Failure in Vocational Evaluation by Users of Augmentative and Alternative Communication Devices

DRS Control # SFY08-002

Approved by Full Committee Review

The investigators will screen existing information contained in medical records and client information data systems to generate hypotheses concerning the antecedents to the outcomes of the vocational evaluation process for augmentative-alternative communication (AAC) device users and to identify patterns of strengths and barriers to successful completions of the vocational evaluation process on the path towards employment. Evidence suggest that that few AAC users are successful in completing and obtaining vocational evaluation recommendations – a key entry point to the vocational rehabilitation process.

Title: *Evaluation of smart home technology in a transitional living cottage for adults with acquired Brain Injury*

DRS Control # SFY08-003

Cooperative Agreement with Virginia Commonwealth University

The investigator will team with staff at the Woodrow Wilson Rehabilitation Center (WWRC) to furnish and operate a “smart home” equipped transitional living cottage for individuals with acquired brain injury. The intervention will proceed as follows: (1) A cottage on the WWRC campus will be designated for this project; (2) members of the VCU project team will conduct and assessment of the cottage; (3) they will then purchase appropriate smart home equipment and outfit the cottage, collaborating, as needed, with physical plant staff from WWRC or outside

contractors hired by the VCU project team; (4) WWRC occupational therapists will be trained by the VCU project team to utilize the smart home technologies installed in the cabin; (5) WWRC clients with acquired rain injury who are deemed appropriate for a cottage-based transitional living experience will be asked to participate in the study and consented; (6) the OTs will teach participating clients how to utilize the smart home equipment in the cottage to promote safety and functional independence; and (7) participating clients will then live in the cottage for one to three weeks while transitioning to their communities. While living in the cottage, the client and treating OT will have access to the VCU project team for trouble-shooting and follow-along assistance, as needed.

When the participating client moves out of the cottage, both the treating OT and the client will be interviewed by the VCU project team to determine the effectiveness and usefulness of the smart home technologies. It is anticipated that at least five clients will participate in the project during its one year duration. Interview data will be analyzed and disseminated through appropriate publications and presentations. At the conclusion of the one-year trial, the smart home technology will remain in the cottage, available for use with subsequent WWRC clients, as deemed appropriate.