



COMMONWEALTH OF VIRGINIA

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August 24, 2005

MEMORANDUM

TO: The Honorable Mark R. Warner
Governor of the Commonwealth of Virginia

Members of the Virginia General Assembly

THROUGH: The Honorable Jane H. Woods
Secretary of Health and Human Resources

FROM: James A. Rothrock

SUBJECT: State Fiscal Year 2005 Annual Report of the Human Research Review Committee

I am pleased to provide you with the 2005 Annual Report of the Department of Rehabilitative Services' Human Research Review Committee. Section 51.5-14.01 of the *Code of Virginia* requires this report as a means of keeping the Governor and General Assembly informed of the Committee's work. Within the report, you will find an explanation of the Committee's role and summaries of human research projects reviewed by the Committee during State fiscal year 2005.

I would be glad to respond to any questions that you may have about the report or the Human Research Review Committee.

Attachment: *State Fiscal Year 2005 Annual Report of the Human Research Review Committee, Department of Rehabilitative Services*

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State Fiscal Year 2005
Annual Report of the Human Research Review Committee,
Department of Rehabilitative Services



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

August 2005

Members of the Human Research Review Committee

Chair

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

Vice-Chair

Myra Owens, M.S.
Lead Analyst Research and Evaluation, DRS

Members

Frederick Capps, Ed.D.
Director of Psychological Services, WWRC

Michael Nakatsuka
Citizen, Commonwealth of Virginia

Asha Rodwell, M.S.
Lead Counselor, DRS

Sandra Wagener
Executive Director, Resources for Independent Living

Steven L. West, Ph.D.
Assistant Professor, Dept. of Rehabilitation Counseling, VCU

Alternate Committee Members

Barbara J. Burkett, Ph.D.
Lead Research Analyst, WWRC

Pamela Duff, M.D.
Medical Consultant, DRS

HIPAA Consultant

Divette M. Brisco, M.S.
HIPAA Coordinator/Risk Manager, 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 or any of its partner organizations covered by the *Code*.

The DRS Commissioner established the HRRC in August 2000 to review and approve all research to be conducted or authorized by DRS, the Woodrow Wilson Rehabilitation Center (WWRC), any of the 16 Centers for Independent Living (CILs), or any of the 83 Virginia Employment Services Organizations (ESOs) that partner with DRS in the delivery of services to persons with disabilities. This document is the HRRC's fifth annual report on the research studies reviewed and approved by the Committee.

Composition of the Committee is governed by 22 VAC 30-40-60. During State Fiscal Year (SFY) 2005, two alternate members were added to the Committee structure to ensure that a quorum can be achieved when regular members are not able to attend convened meetings. As of June 30, 2005, the HRRC had seven regular members and two alternates.

I wish to express my appreciation to the members of the HRRC for their commitment to this important endeavor.

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

August 24, 2005

Table of Contents

Executive Summary	v
Introduction.....	1
HRRC Responsibilities and Process	1
Types of HRRC Review	2
SFY 2005 Research Applications Reviewed	3
Appendix A: <i>Code of Virginia</i> Section 51.5-14.01.....	A-1

Executive Summary

The Human Research Review Committee (HRRC) must review applications for all non-federally funded¹ research that involves DRS clients and/or employees before the research is begun. The purpose of the review is to ensure compliance with state-mandated research guidelines.

There are three types of reviews: Exempt Review, Expedited Review and Full Committee Review. Seven new applications were reviewed during the state fiscal year and four of those studies were approved, one by Expedited Review and three by Exempt Review. In the case of three other applications, HRRC approval was not required. The HRRC also reviewed two studies that continued beyond the initial one-year approval.

The HRRC has no evidence suggesting that there have been any significant deviations from study procedures as approved for either new studies or the two studies that continued for at least one year beyond the initial approval.

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 also 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 also 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), 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, the WWRC; any of the 16 CILs, or any of the 83 ESOs that partner with DRS in the delivery of services to persons with disabilities that involve DRS consumers or staff. This document is the HRRC's fifth annual report on the research studies reviewed and approved by the Committee.

HRRC Responsibilities and Process

HRRC review and approval of applications for all proposed non-federally funded² research involving human participants is governed by 22 VAC 30-40-10 *et seq.* 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) investigator application, 2) voluntary informed consent, and 3) investigator periodic progress reports.

² The regulatory guidance for federally-funded or sponsored human research is provided in 45 CFR 46.

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 proposal is submitted to the chair for review and approval. Elements of review include consideration of potential benefits and risks and the methodology of the research, the degree of risk associated with nontherapeutic research, the protection of the rights and welfare of participants, voluntary informed consent, competency of the research investigators, equitable selection criteria for research participants, and whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants. All research applications are reviewed within 45 days of submission of a complete 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 and approval is termed Exempt Review (22 VAC 30-40-80). 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 chair or by one or more HRRC members designated by the chair.

The next type of review and approval is termed Expedited Review (22 VAC 30-40-90). The HRRC chair or designee 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 study has already been approved by another human research review committee.

The third type of review and approval is termed Full Committee Review (Section V, Subsection C, *DRS Procedures for Review of Research with Human Participants*). This type of review is carried out at a convened meeting at which a majority of the membership of the HRRC is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

SFY 2005 Research Applications Reviewed

Seven new applications were reviewed during the state fiscal year and four of these studies were approved by the Committee. One research application was approved by “Expedited Review” and three applications were approved by “Exempt Review”. In the case of two other applications, HRRC approval was not required. It was determined that the activities to be performed by DRS staff in support of each of the two proposed research studies was limited to the role of consultant. Additionally, each of these two studies had been reviewed and approved by another institution’s human research review committee prior to being submitted for HRRC review. Another application was incomplete and returned to the investigator and as of June 30, 2005 the investigator had not resubmitted the application.

Initial approvals for research studies under the three types of review are granted for up to one year from the date of HRRC review. Projects lasting longer than one year require submission of a form documenting the status of the research study and must be approved by the HRRC before it can continue. During SFY 2005, the HRRC reviewed two studies that were continuing beyond the initial one-year approval.

The HRRC has no evidence suggesting that there have been any significant deviations from study procedures as approved. Research applications reviewed by the Committee are listed in Table 1.

Table 1: Studies that received initial review during State Fiscal Year 2005

Study Title	Type of Review	Date approved	Periodic Review	Control Number
Evaluation of a Training Program to Advance Career Goals for Persons with Spinal Cord Injury	WWRC served as a consultant to this study and no research activities were performed at/or by WWRC staff		N/A	SFY05-0001
Education Needs of Adults with Spinal Injury/Disease and their Caregivers in Pressure Ulcer Prevention and Management	WWRC served as a consultant to this study and no research activities were performed at/or by WWRC staff		N/A	SFY05-0002
Comparison of Driving Abilities of Older Drivers following a Driver's Assessment with the General Population of Older Drivers	Incomplete application was returned to research investigators. As of June 30, 2005, the HRRC had not received a complete application.		N/A	SFY05-0003
Substance Abuse and Neurotrauma Survey	Exempt Review	4/20/2005	Annual	SFY05-0004
Substance Abuse and Neurotrauma Comorbidity: A Needs Assessment of Treatment Providers	Exempt Review	4/20/2005	Annual	SFY05-0005
Substance Abuse, Neurotrauma and Rehabilitative Services Survey	Expedited Review	4/20/2005	Annual	SFY05-0006
Assessing the Need for Substance Abuse Treatment Services Among Persons with SCI and TBI in Virginia	Exempt Review	6/21/05	Annual	SFY05-0007

Table 2: Studies that received an annual review during State Fiscal Year 2005

Study Title	Type of Continuing Review	Date of Initial approval	Control Number
Rehabilitation counselor satisfaction with psychological and neuropsychological evaluation reports for adults with learning disabilities	Exempt Review	1/22/2003	SFY03-0003
Virginia Department of Rehabilitative Services (DRS) Survey of Working Personal Assistance Services (PAS) Consumers	Full Committee Review	1/2/2004	SFY04-0001

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.)