

State Fiscal Year 2006
Annual Report of the Human Research Review Committee,
Department of Rehabilitative Services



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Commissioner

August 8, 2006

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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 and the Woodrow Wilson Rehabilitation Center (WWRC). This document is the HRRC's sixth annual report on the research studies reviewed and approved by the Committee.

Composition of the Committee is governed by 22 VAC 30-40-60. As of June 30, 2006, the HRRC had six members, one non-voting coordinator, and two alternates.

The *Code* also requires that Centers for Independent Living (CILs) and Employment Services Organizations (ESOs) designate a human research review committee. CILs and ESOs have three options for satisfying this requirement. They can affiliate with the DRS HRRC, establish their own committee or partner with other CILs and/or ESOs, covered by the regulations, to establish a committee.

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

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Executive Summary

The Human Research Review Committee (HRRC) must review applications for all human research activities involving DRS clients and/or employees not covered by policies and regulations for the protection of human participants promulgated by any federal government agency.¹ The purpose of the review is to ensure compliance with state-mandated research guidelines. Annually, DRS must submit to the Governor, the General Assembly, and the 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, Expedited Review and Full Committee Review. Four new applications were reviewed during the state fiscal year and three were approved by Expedited Review. The fourth application was later withdrawn by the investigator before a review decision could be made. The HRRC also reviewed seven studies that continued beyond the initial approval period. The HRRC has no evidence suggesting that there have been any significant deviations from study procedures as approved for either new studies or studies that continued beyond the initial one-year approval.

During State Fiscal Year 2006, the Office for Human Research Protections (OHRP), United States Department of Health and Human Services (HHS) approved the DRS application to conduct federally-funded or sponsored research in accordance with the Code of Federal Regulations (CFR) 45 CFR 46. If not renewed, this Federalwide Assurance will expire on August 11, 2008.

Also during State Fiscal Year 2006, DRS requested that Centers for Independent Living (CILs) and Employment Services Organizations (ESOs) provide updated information about which of the three options they elected to satisfy the requirement for designation of a human research review committee. Specifically, CILs and ESOs were asked to do one of the following: 1) establish their own human research review committee, 2) collaborate with one or more other CIL and/or ESO covered by the regulations (22 VAC 30-40-10 *et seq.*) to establish a human research review committee, or 3) affiliate with the DRS Human Research Review Committee.

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 or the WWRC. Additionally, Employment Services Organizations (ESOs) that have vendor agreements with DRS and Centers for Independent Living (CILs) have three options for satisfying the requirements of this State law. These options are: 1) establish their own human research review committee, 2) collaborate with one or more other CIL and/or ESO covered by the regulations (22 VAC 30-40-10 et seq.) to establish a human research review committee, or 3) affiliate with the DRS Human Research Review Committee. This document is the HRRC's sixth 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.* 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, 3) investigator periodic progress reports, and 4) 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 proposal 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, and equitable selection criteria for research 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 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 the Coordinator.

The next type of review is termed Expedited Review (22 VAC 30-40-90). The HRRC Chair or Coordinator 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 is termed Full Committee Review. This type of review is carried out at a convened meeting composed of a quorum. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

SFY 2006 Research Applications Reviewed

Four new applications were reviewed during the state fiscal year and three of these studies were approved by expedited review. The fourth application was withdrawn by the investigator before a review decision could be made. SFY 2006 initial review applications are listed in Table 1.

Initial approvals for research studies under the three types of review are granted for up to one year from the date of HRRC approval. Projects lasting longer than one year must be reviewed by the Committee at least annually. During SFY 2006, there were seven studies classified as continuing reviews. These studies are summarized in Table 2.

All research involving human participants that was conducted or authorized by DRS or the WWRC during SFY 2006 was reviewed by the HRRC. The HRRC has no evidence suggesting that there have been any significant deviations from study procedures as approved for either studies that received initial review during SFY 2006 or studies that continued beyond the initial one year approval.

CIL and ESO Compliance 22 VAC 30-40-40 (B)

During SFY 2006, CILs and ESOs were asked to update DRS records about the option they elect to comply with the requirement to designate a human research review committee. CILs and ESOs have three options that can be used to satisfy this requirement: 1) establish their own human research review committee, 2) collaborate with one or more other CIL and/or ESO covered by the regulations to establish a human research review committee, or 3) affiliate with the DRS Human Research Review Committee. The 16 CILs and 76 ESOs² have responded to this request. The option chosen by each CIL and each ESO is listed in Table 3.

² The actual number of ESOs that have Federal Identification Numbers (FINs) is greater than the number specified here because several ESOs have administrative authority for all branches within the organization. As an example, Frontier Health is included in the count but not its branch ESOs. In addition, one agency provides services as both an ESO and a CIL and is included in the total count of both CILs and ESOs.

Table 1: Studies that received initial review during State Fiscal Year 2006

Study Title	Type of Review	Date Approved	Periodic Review	Control Number
Aphasia treatment via speech-generating barcode reader: Does technology make a difference?	Expedited Review	July 19, 2005	Annual	SFY06-001
Job Coaching Assistance with Personal Digital Assistants (PDAs)	Expedited Review	October 6, 2005	June 2006	SFY06-002
An outcomes-based assessment of potential Medicaid buy-in participants who are applicants to the Virginia Department of Rehabilitative Services	Withdrawn by Investigator	N/A	N/A	SFY06-003
Barcode-generated language and naming facilitation in aphasia	Expedited Review	June 29, 2006	Annual	SFY06-004

Table 2: Studies that received continuing review during State Fiscal Year 2006

Study Title	Type of Continuing Review	Date of Initial Approval	Control Number	Current Status
Rehabilitation Counselor Satisfaction with Psychological and Neuropsychological Evaluation Reports for Adults with Learning Disabilities	Exempt Review	January 22, 2003	SFY03-0003	Study Discontinued
Virginia Department of Rehabilitative Services (DRS) Survey of Working Personal Assistance Services (PAS) Consumers	Full Committee Review	January 2, 2004	SFY04-0001	Data collection completed; study pending data analysis
Substance Abuse and Neurotrauma Survey	Exempt Review	April 20, 2005	SFY05-0004	Completed
Substance Abuse and Neurotrauma Comorbidity: A Needs Assessment of Treatment Providers	Exempt Review	April 20, 2005	SFY05-0005	Completed
Substance Abuse, Neurotrauma and Rehabilitative Services Survey	Expedited Review	April 20, 2005	SFY05-0006	Completed
Assessing the Need for Substance Abuse Treatment Services Among Persons with SCI and TBI in Virginia	Exempt Review	June 21, 2005	SFY05-0007	Completed
Job Coaching Assistance with Personal Digital Assistants (PDAs)	Expedited Review	October 6, 2005	SFY06-002	Pending continuing review

Table 3: Covered entities (ESOs and CILs) and their human research review committee affiliation

Agency/Organization	Type Agency/ Organization ¹	HRRC Designated to Review Proposed Research ²
Access Independence, Inc.	CIL	DRS
Appalachian Independence Center	CIL	DRS
Blue Ridge Independent Living Center & New River Valley Satellite Office	CIL	DRS
Clinch Independent Living Services	CIL	DRS
disAbility Resource Center	CIL	DRS
Eastern Shore Ctr. for Independent Living	CIL	DRS
Endeppence Center, Inc.	CIL	DRS
Endeppence Center of Northern Virginia	CIL	DRS
Indeppence Empowerment Center	CIL	DRS
Indeppence Resource Center	CIL	DRS
Junction Center for Independent Living	CIL	DRS
Lynchburg Area Center for Independent Living	CIL	DRS
Peninsula Center for Independent Living	CIL	DRS
Piedmont Independent Living Center	CIL	DRS
Resources for Independent Living, Inc. & Crater District CIL Satellite	CIL	DRS
Alexandria CSB	CSB/ESO	Establish own HRRC
Arlington CSB - The Job Avenue and Woodmont Programs	CSB/ESO	DRS
Chesterfield Employment Services	CSB/ESO	DRS
Colonial CSB & Colonial Workshop, Inc.	CSB/ESO	DRS
Crossroads Community Services Board	CSB/ESO	DRS
Goochland-Powhatan CSB	CSB/ESO	DRS
Hampton/Newport News CSB	CSB/ESO	DRS
Hanover County CSB	CSB/ESO	DRS
Henrico MR/MH	CSB/ESO	Establish own HRRC
Highlands Community Services ³	CSB/ESO	Does not participate in human research
Loudoun County CSB	CSB/ESO	DRS
Mt. Rogers Industrial Developmental Ctr.	CSB/ESO	Local Human Rights Committee

Table 3: Covered entities (ESOs and CILs) and their human research review committee affiliation

Agency/Organization	Type Agency/ Organization ¹	HRRC Designated to Review Proposed Research ²
Prince William County MH Services, Supported Employment Program	CSB/ESO	DRS
Region 10 CSB, Blue Ridge House	CSB/ESO	DRS
Rockbridge Area CSB	CSB/ESO	DRS
Valley CSB	CSB/ESO	DRS
Virginia Beach DHS	CSB/ESO	DMHMRSAS ⁴
Career Support Systems	ESO	DRS
Chesapeake Services Systems, Inc.	ESO	DRS
Commonwealth Support Systems	ESO	DRS
Commonwealth Supportive Services	ESO	DRS
		Establish own
Community Alternatives, Inc.	ESO	HRRC
Danville ARC Hatcher Center	ESO	DRS
Didlake, Inc.	ESO	DRS
Eggleston Services	ESO	DRS
Emmett Jones & Associates	ESO	DRS
		Does not
Every Citizen Has Opportunities (ECHO) ³	ESO	participate in human research
Friendship Industries, Inc.	ESO	DRS
Frontier Health (comprising Frontier Bristol, Frontier Kingsport, Developmental Services, Independence Unlimited)	ESO	DRS
GENEX-Northern	ESO	DRS
Genex-Tidewater	ESO	DRS
Goodwill Industries of Central Virginia	ESO	DRS
Goodwill Industries of Danville	ESO	DRS
Goodwill Industries of Hampton Roads	ESO	DRS
Goodwill Industries of TENNVA	ESO	DRS
Goodwill Industries of the Valleys & affiliates	ESO	DRS
Hired Hands, Inc.	ESO	DRS
Horizon Goodwill Industries	ESO	DRS
ICON Community Services, Inc.	ESO	DRS
Jackson River Enterprises, Inc.	ESO	DRS
Job Discovery, Inc.	ESO	DRS
Lifespan Services	ESO	DRS
Longwood Industries, Inc.	ESO	DRS

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Agency/Organization	Type Agency/ Organization ¹	HRRC Designated to Review Proposed Research ²
Lynchburg Sheltered Industries	ESO	DRS
MARC Workshop	ESO	DRS
Mercer Co. Opportunity Industries	ESO	DRS
Mount Vernon Lee Enterprises	ESO	DRS
NW Works, Inc. (Northwestern Workshop Inc.)	ESO	DRS
Open Doors, Inc.	ESO	Establish own HRRC
PARC Services	ESO	DRS
Pleasant View	ESO	Local Human Rights Committee
PORTCO, Inc.	ESO	DRS
PRS, Inc. (formerly Psychiatric Rehabilitation Services, Inc.)	ESO	DRS
Rappahannock Goodwill Industries	ESO	DRS
Rockbridge Area Occupational Center, Inc.	ESO	DRS
RSVP, Inc. (Rehabilitative Services & Vocational Placement, Inc.)	ESO	DRS
ServiceSource	ESO	DRS
Sheltered Workshop of Altavista	ESO	DRS
Shen-Paco Industries	ESO	DRS
SOC Enterprises	ESO	DRS
St. John's Community Services	ESO	DRS
STEPS, Inc. (Southside Training Employment Placement Services, Inc.)	ESO	DRS
Sugar Plum, Inc.	ESO	DRS
Supported Employment of Virginia	ESO	DRS
Sussex-Greenville-Emporia Adult Activity Services, Inc.	ESO	DRS
The ARC of the Virginia Peninsula, Inc. & Lewis B. Puller Center	ESO	DRS
The Choice Group	ESO	DRS
The Greater Richmond ARC - Civitan Workshop	ESO	DRS
The Mill House	ESO	DRS
VCUHS/Physical Medicine & Rehabilitation	ESO	VCU ⁵
Vector Industries, Inc.	ESO	DRS
WAC Industries/W.C. Ham Center	ESO	DRS

Table 3: Covered entities (ESOs and CILs) and their human research review committee affiliation

Agency/Organization	Type Agency/ Organization ¹	HRRC Designated to Review Proposed Research ²
Warren County Workshop, Inc.	ESO	Establish own HRRC
WorkSource Enterprises, Inc.	ESO	DRS
Wright Choices, Inc.	ESO	DRS
Valley Associates for Independent Living (VAIL)	Provides services as both ESO & CIL	DRS

Notes:

1. DRS has partnerships with community-based employment and supported employment services from Employment Services Organization (ESOs) and from ESOs that are part of Community Services Boards (CSBs). The actual number of ESOs that have Federal Identification Numbers (FINs) is greater than the number of ESOs in this table because several ESOs in the above table have administrative authority for all branches within the organization. As an example, Frontier Health is listed in the above table but not its branch ESOs.
2. 22 VAC 30-40-40 gives DRS agencies/organizations the option to 1) establish their own human research review committee, 2) collaborate with one or more other CIL and/or ESO covered by the regulations to establish a human research review committee, or 3) affiliate with the DRS Human Research Review Committee.
3. Some agencies/organizations indicated that their policies prohibit the conduct of research involving their clients. Therefore, these agencies/organizations have decided that they do not need the services of a human research review committee.
4. The Virginia Department of Mental Health Mental Retardation and Substance Abuse Services (DMHMRSAS) is charged with reviewing all research protocols involving humans for Virginia's Community Services Boards.
5. The Virginia Commonwealth University (VCU) Institutional Review Board (IRB) is charged with reviewing all research protocols involving humans for affiliates of the VCU Health System (HS).

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.)