State Fiscal Year 2007
Annual Report of the Human Research Review Committee, Department of Rehabilitative Services

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

July 31, 2007

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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. 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).

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 for a three year period that began August 15, 2005.

Composition of the Committee is governed by 22 VAC 30-40-60 and 45 CFR 46.107. As of June 30, 2007, the HRRC had six members, two alternates, a non-voting administrator/coordinator, and a non-voting Health Insurance Portability and Accountability Act (HIPAA) consultant.

The *Code of Virginia* 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. This document is the HRRC's seventh annual report.

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

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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, 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 (compliance with regulations not required), Expedited Review (application reviewed and approved by one or HRRC members) and Full Committee Review. Three new applications were reviewed during the State Fiscal Year 2007 and two were approved by Full Committee Review. By unanimous vote of the Full Committee, a third application was tabled because the Committee determined that the application materials were not adequate for the review process to take place. Subsequently, the investigator withdrew the application. 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 2007.

The HRRC also reviewed two studies that continued beyond the initial approval period; thus, required annual continuing review. However, one of these studies continued for almost five years beyond the one-year approval authority granted to the HRRC by 22 VAC 30-40-70(G) and 45 CFR 46.109(e). The lapse in continuing HRRC oversight of the research was, in part, associated with the fact that the HRRC was still establishing operating procedures at the time the study was initially approved on January 8, 2001. Also, at the time of initial approval, the research database had not been developed to track research studies and to facilitate ongoing HRRC follow-up with research investigators. By unanimous vote of the Full Committee, this study was closed to enrollment of new volunteers and to any further contact with volunteers ready enrolled in the study. In accordance with 45 CFR 46.103(b)(5), a report of continuing noncompliance was filed with the U.S. Department of Health and Human Services, Office for Human Research Protection.

On August 6, 2007, the DRS Notice of Intended Regulatory Action (NOIRA) will be published in the Virginia Register to allow for public comment on revisions to *Protection of Participants in Human Research* regulations (22 VAC 30-40-10 *et seq.)*. These regulations were revised to ensure that state regulations are in compliance with federal *Protections of Human Subjects* regulations at 45 CFR 46. Additionally, the revised regulations require that independent

[1] The regulatory guidance for federally-funded or sponsored human research is provided in 45 CFR 46. On August 15, 2005, 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 August 11, 2008.

living centers and sheltered workshops affiliate with the DRS Human Research Review Committee as intended in the Code of Virginia §51.5.14.01. The existing regulations gave these two organizations the options to establish their own human research review committee, to affiliate with other independent living centers and sheltered workshops to establish a central human research review committee, or to affiliate with the DRS Human Research Review Committee.

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) may affiliate with the DRS Human Research Review Committee. This document is the HRRC's seventh 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 two of these studies were approved by Full Committee Review. A third application was tabled because the Committee determined that the application materials were not adequate for the review process to take. Subsequently, the investigator withdrew the application. SFY 2007 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 approved continuance of the study. A study that is determined to be greater than minimal risk, must receive more frequent continuing reviews. During SFY 2007, two studies were classified as continuing reviews. 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 2007 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 two studies that received initial approval during SFY 2007. However, a minimal risk, nonexempt survey research study that was initially approved by the HRRC on January 8, 2001 (Table 3), continued for almost five years beyond the one-year approval authority granted to the HRRC by 22 VAC 30-40-70(G) and 45 CFR 46.109(e). The lapse in continuing committee review was, in part, associated with the fact that the HRRC was still establishing operating procedures at the time the study was initially approved. Also, the research database was not in place to track approved research studies and to facilitate ongoing HRRC follow-up with research investigators. The HRRC closed this study to new enrollment and to follow-up with volunteers already enrolled in the study. However, the investigator was permitted to submit a new application (SFY07-003) to obtain HRRC approval to proceed with data analysis and dissemination activities for data already collected. In accordance with 45 CFR 46.103(b)(5), a report of continuing noncompliance was filed with the U.S. Department of Health and Human Services, Office for Human Research Protection (Appendix B).

Notice of Intended Regulatory Action

On August 6, 2007, the DRS Notice of Intended Regulatory Action (NOIRA) will be published in the Virginia Register to allow for public comment on revisions to *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. Modifications to 22 VAC 30-40-10 *et seq.* include:

1) added definitions for the following terms: assent; agent; covered entities; guardian; human research review committee; human subject; human subject research; identifiable private information; informed consent; minor; parent; and permission;
2) changed the definitions of the following terms to mirror those contained in 45 CFR §46.102: interaction; intervention; institution; legally authorized representative; minimal risk; private information; and research;
3) changed the definition of sheltered workshop so that only those vocational rehabilitation services programs that have a vendor relationship with DRS and are not operated by a community services boards are included for the purposes of these regulations;
4) deleted the definition of "institution";

5) throughout the regulations, minor language changes were made to ensure consistency with 45 CFR 46.101 et seq.;
6) independent living centers and sheltered workshops no longer have the options to establish their own human research review committee or to affiliate with other independent living centers and sheltered workshops to establish a central human research review committee. Rather, independent living centers and sheltered workshops must affiliate with the DRS human research review committee as intended in the Code of Virginia §51.5.14.01;
7) procedures for obtaining the informed written consent of prospective research volunteers were changed to ensure consistency with 45 CFR 46.109 & 45 CFR 46.111;
8) the compositions of the human research review committee was changed to ensure consistency with 45 CFR 46.107;
9) regulation governing inclusion of minors as research volunteers was added. The language for this regulation comes from 45 CFR §46.401 et seq. and 34 CFR 97.101 et seq.; and
10) the kinds of research that may receive expedited review and expedited review procedures were changed to mirror 45 CFR § 45.110.

Table 1: Studies that received initial review during State Fiscal Year 2007

Study Title	Type of Review	Date Approved	Periodic Review	Control Number
An Auto-Adaptive Interface for Neuromuscular disabilities	Full Committee	Approved May 7, 2007 with recommended changes, final approval, June 28, 2007	Annual	SFY07-001
Use and Perceived Effectiveness of standing Frames and Knee Ankle Foot Orthoses	Full Committee	Tabled; subsequently, the investigator withdrew application	N/A	SFY07-002
The use of the Temperament and Character Inventory (TCI) in Vocational Rehabilitation	Full Committee	Approved May 7, 2007 with recommended changes, final approval, May 16, 2007	Annual	SFY07-003

Table 2: Studies that received continuing review during State Fiscal Year 2007

Study Title	Type of Continuing Review	Date of Initial Approval	Control Number	Current Status
Virginia Department of Rehabilitative Services (DRS) Survey of Working Personal Assistance Services (PAS) Consumers	Full Committee Review	January 2, 2004	SFY04-0001	Data collection and analysis completed; study pending closure
Job Coaching Assistance with Personal Digital Assistants (PDAs)	Expedited Review	October 6, 2005	SFY06-002	Data collection and analysis completed; study pending closure

Table 3: Lapsed Review

Study Title	Date of Initial Approval	Control Number	Current Status
The use of the TCI (Temperament and Character inventory) in Vocational Rehabilitation	January 8, 2001	None assigned	On March 26, 2007, the HRRC closed the study to enrollment of new subjects and to follow-up with subjects already enrolled. A report of continuing noncompliance was filed with OHRP, per requirement of 45 CFR 46.103(b)(5).

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: Lapsed Review Letter to OHRP

COMMONWEALTH of VIRGINIA

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

Department Of Rehabilitative Services
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April 12, 2007

Kristina Borror, Ph.D.
Division of Compliance Oversight
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Human Research Subjects Protections under Federalwide Assurance 00008936

Dear Dr. Borror:

The purpose of this letter is to inform you of an occurrence of continuing noncompliance regarding a research study previously approved by the Virginia Department of Rehabilitative Services' (DRS) Institutional Review Board (IRB). The facts are as follows:

1. On January 8, 2001, the DRS IRB approved a minimal risk, nonexempt survey research study entitled "*The use of the TCI (Temperament and Character Inventory) in Vocational Rehabilitation*". Stephen D. Jordan, M.S., CRC, is the investigator and an employee of this agency's Woodrow Wilson Rehabilitation Center (WWRC).
2. At the time of IRB approval, the purposes of the study were: 1) to examine the association of various disabilities with temperament and character personality dimensions as measured by the TCI; and 2) to determine the utility of the TCI in assessing vocational interest.
3. IRB approval automatically expired on January 7, 2002. However, the investigator continued to enroll new subjects for almost five additional years without seeking IRB continuing review. The last subject was enrolled in the study on November 13, 2006. Additionally, the investigator administered a follow-up questionnaire to many of the subjects approximately six months after each subject completed his/her vocational program at WWRC and had returned home. A total of 50 subjects were enrolled in the study between January 2001 and November 2006.
4. The TCI study was lost to IRB continuing oversight because it was not assigned a research project number and the IRB database was not in place at the time this study was approved. To the best of my knowledge, the study was not federally funded.

The lapsed review came to the attention of the IRB on February 13, 2007, and was discussed at the convened IRB on March 26, 2007. By unanimous vote, the IRB is requiring that any use of the data obtained from subjects enrolled in this study must include the following disclosure statement "Seventy-

two percent of the data collected during this research was obtained from subjects enrolled in the study beyond the expiration date of Institutional Review Board (IRB) approval." Additionally, the IRB decided that use of the data for publications, funding, presentations, or any other purpose must undergo prior review by the IRB Chair. These decisions were discussed with Dr. Andreason from your office and were deemed appropriate. Further, the study is closed to new enrollment and follow-up with subjects already enrolled. The PI is also required to submit an initial IRB application, existing data category, and receive approval prior to analysis of TCI research data. On March 29, 2007, the PI, the study sponsor, and the WWRC Director were informed of these decisions.

The DRS IRB was established August 8, 2000 in accordance with the Code of Virginia Section 51.5-14.01. The FWA was approved on August 15, 2005. The lapse in continuing review of the TCI research was, in part, associated with the fact that the IRB was still establishing operating procedures when this study was reviewed and approved. Annually, the IRB reviews less than 10 initial proposals.

Since March 2001, the IRB has had in place procedures for monitoring all proposals received. Specifically, each proposal is sequentially assigned a study number and is entered into a database. Also, each notice to an investigator of IRB approval identifies the specific study expiration date and informs the investigator of the requirement to seek continuing review no less than 60 days prior to the approval expiration date. In addition, the IRB and agency staff have received training on human subjects protection and, since May 2006, successful completion (a test score of 80 or better) of the Public Responsibility in Medicine and Research, Investigator 101 training has been required for all investigators prior to obtaining IRB review of proposed research. Finally, to ensure compliance with the requirement for IRB review of all nonexempt human subject research, I am strengthening training to the agency's leadership team, supervisors, and program managers.

If you have any questions regarding this matter, please contact Dr. Myra G. Owens, IRB Administrator, or Elizabeth E. Smith, IRB Chair, 804-662-7000.

With best regards, I am

Sincerely,

James A. Rothrock

Cc: Elizabeth E. Smith
Myra G. Owens