State Fiscal Year 2004

Annual Report of the Department of Rehabilitative Services Human Research Review Committee

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Commissioner

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Table of Contents

Authority and Duties of the Committee

Section 51.5-14.01 of the Code of Virginia requires 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 Committee; including any significant deviations from the research applications as approved by the Committee. This report presents State Fiscal Year 2004 activities of the DRS HRRC.

The HRRC has internal oversight responsibilities for ensuring protection of the rights and welfare of DRS consumers 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 Committee in August 2000 to review and approve all research to be conducted or authorized by DRS or the Woodrow Wilson Rehabilitation Center (WWRC), as well as the Centers for Independent Living (CILs) and Virginia Employment Services Organizations (ESOs) that partner with DRS in the delivery of services to persons with disabilities. Elizabeth E. Smith, DRS Policy and Planning Director, is the Committee's Chair and this is the Committee's fourth annual report. The composition of the Committee is governed by 22 VAC 30-40-60 and a list of Committee members is provided at Appendix A. There was one resignation from the Committee during SFY 2004 and one continuing ESO vacancy. Efforts are ongoing to find a suitable ESO representative and a community-at-large member. As of June 30, 2004, the Committee had seven members and one alternate medical consultant.

The regulation gives DRS partner organizations the options to: 1) establish their own research review committee; 2) work with other institutions to establish a single committee; or 3) use the DRS established committee. As of this report, there are 103 organizations under the DRS umbrella (WWRC, one university based rehabilitation research and training center, 16 CILs, and 85 ESOs[1]).

[1] The actual number of ESOs that have Federal Identification Numbers (FINs) is greater than the number of ESOs reported here because several ESOs have administrative authority for a network of other ESOs and speaks for all

To carry out its oversight responsibilities, the Committee follows procedures as specified by 22 VAC 30-40-10 *et seq.* for the review and approval of applications for all proposed research involving human participants when such research is not federally funded or sponsored. The regulatory body for federally funded or sponsored human research is the Department of Health and Human Services. To supplement regulatory requirements, the Committee has a procedures manual which standardizes Committee 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.

The Committee meets monthly, or as needed, to fulfill its responsibilities and must meet at least once annually. A quorum of the Committee consists of a majority of its members including at least one member whose primary concerns are in nonscientific areas. The Committee's responsibilities begin when a research proposal is submitted to the Chair for review and approval. Elements of the Committee's review include consideration of potential benefits and risks and the methodology of the research, the degree of risk for 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 Committee's decision to approve or disapprove the proposed research activity, or of modifications required to secure approval.

Overview of Reviewed and Approved Research

Nine studies were reviewed and four of these studies were approved by the HRRC during State Fiscal Year 2004. One research application was approved by "full-review" and three applications were approved by "expedited review". One application was incomplete and returned to the

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members of the network. As an example, Frontier Health is composed of several branches (Developmental Services, Independence Unlimited, Opportunities Unlimited-Bristol, and Opportunities Unlimited-Kingsport) and the same administrative authority covers all branches of Frontier Health.

investigator and as of June 30, 2004 the investigator had not resubmitted the application. One of the nine applications was a federally funded study. The HRRC declined to review the federally funded study because DRS does not have the required assurance of compliance with the U.S. Department of Health and Human Services regulations (45 CFR 46.103) for the protection of human subjects. The remaining three of the nine applications did not require HRRC review because they had been reviewed and approved by another institution's human research review committee prior to being submitted to DRS and DRS' only involvement was the distribution of materials advertising these research studies. Therefore, DRS was not "engaged" in research. The Committee has no evidence suggesting that there have been any significant deviations from any approved research studies. A list of research applications reviewed by the Committee is at Appendix B and Appendix C provides and explanation of the three types of review.

The Committee received one continuing review application for research initially approved during SFY 2001 (DRS HRRC Control #00007 [see list at Appendix D]). This application will be reviewed by the full committee during its August 2, 2004 meeting. Another study (DRS HRRC control # SFY03-0003) involving survey research was pending expedited continuing review as of the end of SFY 2004.

Overview of DRS

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 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 and the DRS performs disability determinations for disability claims for benefits under the Social Security Disability Insurance, Supplemental Security Income Disability Programs and Medicaid Disability.

In addition to its agency programs, the 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 ESOs. DRS also works closely with 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 and training for people with disabilities.

Appendix A: Department of Rehabilitative Services Human Research Review Committee Members as of June 30, 2004

Frederick Capps, Ed.D.
Director of Psychological Services
Woodrow Wilson Rehabilitation Center

[2] Elizabeth Smith, J.D., M.S.
Director Policy and Planning, DRS

Michael Nakatsuka
DRS Consumer

Sandra Wagener
Executive Director
Resources for Independent Living

[3]Myra Owens, M.S.
Lead Analyst Research & Evaluation
Policy and Planning Division, DRS

Steven L. West, Ph.D.
Department of Rehabilitation Counseling
Virginia Commonwealth University

Asha Rodwell, M.S., CRC
Vocational Rehabilitation Counselor, DRS

Alternate Committee Member

[4]Pamela Duff, M.D.
Medical Consultant
DRS

[2] Chair, HRRC
[3] Vice Chair, HRRC
[4] Dr. Duff provides medical consultation to the HRRC.

Appendix B: Studies Reviewed During State Fiscal Year 2004

Study Title	Type of Review	Date approved	Periodic Review	DRS Control Number
Virginia Department of Rehabilitative Services (DRS) Survey of Working Personal Assistance Services (PAS) Consumers	Full Committee	September 8, 2003	Annual	SFY04-0001
Evaluation of a Training Program to Advance Career Goals for Persons with Spinal Cord Injury	Expedited Review	January 28, 2004	Annual	SFY04-0002
A Qualitative Needs Assessment of Virginians with Spinal Cord Injury	Expedited Review	January 27, 2004	Annual	SFY04-0003
Quantitative Assessment of Virginians with Spinal Cord Injury	Expedited Review	January 27, 2004	Annual	SFY04-0004
Differences in Family Functioning: Working Collaboratively with Families of Children who have Disabilities	Incomplete Application returned to Investigator	N/A	N/A	SFY04-0005
Mobile Telerehabilitation Evaluation II	This federally funded study was not reviewed because DRS does not have the required HHS Federal assurance (45 CFR 46.103)			SFY04-0006
Quality of Life and Communication Disability in Aphasia	WWRC is not engaged in research and will only release identifiable private information to the investigator once prior written permission from prospective study volunteers is obtained.			SFY04-0007
Evaluation of an Intervention Model for Family Crisis and Support	DRS is not engaged in research and will only distribute VCU approved recruitment materials to Consumers with TBI			SFY04-0008
Study of Emotional Adjustment after Brain Injury	DRS is not engaged in research and will only distribute VCU approved recruitment materials to Consumers with TBI			SFY04-0009

Appendix C: Types of Review

The Committee, through its Chair, determines whether the proposal merits exempt review, expedited review, or undergoes full review.

Research Exempt from Full Review

Unless they are covered by some other provision, the following kinds of research are exempt from full review by the Human Research Review Committee:

1. Research conducted in established or commonly accepted education settings, involving commonly used educational practices, such as:

    a) Research on regular and special education instructional strategies; or

    b) Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods.

2. Research involving solely the use and analysis of the results of standardized psychological, educational, diagnostic, aptitude, or achievement tests, if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

3. Research involving survey or interview procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants; and either:

    a) The participant's responses, if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or

    b) The research deals with sensitive aspects of the participants' own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.

4. Research involving solely the observation (including observation by participants) of public behavior, unless observations are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:

    a) The observations recorded about the individual, if they become known outside the research, could reasonably place the human participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability or reputation; or

    b) The research deals with sensitive aspects of the participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if the sources are publicly available, or if the information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: Based on the Federal definition of "existing data", research conducted on biological or pathological specimens obtained prospectively and/or taken strictly for research purposes or from future discarded clinical samples DOES NOT qualifies for exempt review.

Expedited Review

The Committee may conduct an expedited review of a human research project which involves no more than minimal risk to the participants if

1. another agency or organization human research review committee has reviewed and approved the project;

2. the review involves only minor changes in previously approved research and the changes occur during the approved project period; or

3. research activities involve no more than minimal risk and in which the only involvement of human participants will be one or more of the categories referred to in 34 CFR 97.110 as follows:

    a) Clinical studies of drugs or medical devices for which an investigational new drug application or investigational devise exemption application is not required.

    b) Collection of blood samples that meet NIH guidelines; Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

    c) Collection of biological specimens for research purposes by noninvasive means.

    d) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant

amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e) Research involving materials that have been collected solely for nonresearch purposes.

f) Collection of data from voice, video, digital, or image recording made for research purposes;

g) Research on individual or group characteristics that is not exempt;

h) Continuing review of research previously approved;

i) Continuing review of research that does not meet the preceding requirements but which had been reviewed by and research Committee that deems that no greater than minimal risk is involved and no additional risks have been identified.

For the expedited review, the Committee chair and one or more experienced reviewers designated by the chair from among members of the Committee may carry out the review. The reviewers may exercise all of the authorities of the Committee except that the reviewers may not disapprove the research. A research application may be disapproved only after review in accordance with the non-expedited procedure set forth in 22VAC 30-40-70.

All Committee members will receive printed notification of the actions of an expedited review.

Full Review

A full review shall include consideration of the following criteria for approval:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;

2. The degree of the risk, and if the research is nontherapeutic, whether it presents greater than minimal risk;

3. Whether the rights and welfare of the participants are adequately protected;

4. Whether the risks to the participants are outweighed by the potential benefits to them;

5. Whether the voluntary informed consent is to be obtained by methods that adequately and appropriately fulfill the requirements of these regulations and whether the written consent

form is adequate and appropriate in both content and language for the particular research and for the particular participants of the research;

6. Whether the research investigators proposing to supervise or conduct the particular human research are appropriately competent and qualified;

7. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness;

8. Whether appropriate studies in nonhuman systems if applicable have been conducted prior to the involvement of human participants; and

Appendix D: Continuing Review Research Applications SFY 2004

Study Title	Periodic Review Results	Date of Initial approval	DRS Human Research Control Number
Improving Community-Based Follow-up Services to Address Long-term Health Maintenance Needs for Persons with Spinal Cord Injury Residing in Southwest Virginia.	Full Committee Review is scheduled August 2, 2004.	5/22/2001	00007