State Fiscal Year 2003

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

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Commissioner

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Authority and Duties of the Committee

Section 51.5-5.1 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 2003 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 the department 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 third 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 were several resignations from the Committee during SFY 2003 and efforts are ongoing to find suitable replacements. As of June 30, 2003, the Committee had eight active members.

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 members of the network. As an example, Frontier Health is composed of several branches (Developmental Services,

To carry out its oversight responsibilities, the Committee reviews and approves research applications for proposed research. The Committee follows procedures as specified by 22 VAC 30-40-10 *et seq*. and applicable Federal regulations concerning human subject research. The primary Federal regulatory body 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 Committee 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 completed 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 five of these studies were approved by the HRRC during State Fiscal Year 2003. Four research applications were approved by "exempt review", one research application was approved by "expedited review", one investigator withdrew the research application, and three research applications were incomplete and were returned to the

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Independence Unlimited, Opportunities Unlimited-Bristol, and Opportunities Unlimited-Kingsport) and the same administrative authority covers all branches of Frontier Health.

investigators for corrective actions. As of June 30, 2003, the three applications that were returned to the investigators were still pending the Committee's receipt of the requested information. The Committee has no evidence suggesting that there have been any significant deviations from any approved research applications. A list of research applications reviewed by the Committee is at Appendix B. 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]). On April 7, 2003, the Committee Chair, Vice Chair and one other committee member conducted a site visit related to this continuing review application. No significant deviations from the application, as approved, were noted during the site visit. During the timeframe in which this study was conducted, two study volunteers died. All evidence indicates that the deaths were unrelated to this minimal risk study. There were no continuing reviews for applications that were initially approved during SFY 2000, SFY 2002 or SFY 2003. On August 5, 2002, the HRRC unanimously voted to suspend study #00008. On October 1, 2002, the Committee received written notification from the investigator that he terminated the study. No study volunteers were harmed as a result of termination of this study.

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 and array of community based programs and the Department, 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 Department 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, 2003

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

Michael Nakatsuka
DRS Consumer

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

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

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

Terry Vaughn
Citizen, Commonwealth of Virginia

Sandra Wagener
Executive Director
Central Virginia Independent Living Center

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

[2] Chair, HRRC

[3] Vice Chair, HRRC

Appendix B: Studies Reviewed During State Fiscal Year 2003

Study Title	Type of Review	Date approved	Periodic Review	DRS Control Number
Fairfax Area Disability Services Board 2002 Needs Assessment Survey	Exempt	10/3/2002	Annual	SFY03-0001
Piedmont Regional Disability Services Board 2003 Needs Assessment survey	Exempt	12/6/2002	Annual	SFY03-0002
Rehabilitation counselor satisfaction with psychological and neuropsychological evaluation reports for adults with learning disabilities	Exempt	1/22/2003	Annual	SFY03-0003
Model System for Spinal Cord Injuries Project	NA	Investigator withdrew the application		SFY03-0004
Self-Employment Study of People with Disabilities		Approval pending receipt of additional information from investigator		SFY03-0005
Short Term Rehabilitation Unit Woodrow Wilson Residential Aphasia Program Pilot	Expedited	6/12/2003	Annual	SFY03-0006
Use of Weight-bearing Transfer Brace by an Individual with Tetraplegia and Limited Wrist Extension Range of Motion for Performing Level Transfers		Approval pending receipt of additional information from investigator		SFY03-0007
A Needs Assessment of Virginians with Spinal Cord Injury		Approval pending receipt of additional information from investigator		SFY03-0008
Urinary Incontinence and Moderate to Severe Traumatic Brain Injury: Epidemiology and Treatment	Exempt	6/9/2003	Annual	SFY03-0009

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 2003

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.	On April 7, 2003, the Committee Chair, Vice Chair and one other committee member conducted a site visit. No significant deviations from the application, as approved, were noted during the site visit. During the timeframe of this study, two study volunteers died. All evidence indicates that the deaths were unrelated to this minimal risk study.	5/22/2001	00007