Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Department of Rehabilitative Services
Virginia Administrative Code (VAC) citation	__22__ VAC_30__-_40___
Regulation title	Protection of Human Research Participants
Action title	Amendments to conform to human subjects research federal regulations and to ensure consistency with *Code of Virginia* requirements.
Date this document prepared	April 11, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

These regulations will provide a basis for the Department of Rehabilitative Services to oversee human subjects research involving the Department of Rehabilitative Services, the Woodrow Wilson Rehabilitation Center, sheltered workshops, and independent living centers. The regulations provide guidelines for initiating and conducting research in a manner that will protect human subjects from harm. They also provide for a human research review committee to review and approve human research activities based on these established guidelines. The regulations also delimit the responsibilities of the human research review committee and delimit its reporting requirements.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Section 51.5-14.01 of the *Code of Virginia* requires the Commissioner of the Department of Rehabilitative Services to promulgate regulations pursuant to the Administrative Process Act to effectuate the provisions

of §32.1-162.16 for human research conducted or authorized by the department, any sheltered workshop, or independent living center, or Woodrow Wilson Rehabilitation Center.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The Department has determined the proposed regulatory amendments are needed to bring the Department's regulations governing the participation of human subjects in research in compliance with the federal regulations of the same nature and to delimit the responsibilities and reporting requirements of the Human Research Review Committee.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Modifications to these regulations include:

1) adding 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) changing 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) changing 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 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 are changed to ensure consistency with 45 CFR 46.109 & 45 CFR 46.111.
8) The compositions of the human research review committee is changed to ensure consistency with 45 CFR 46.107
9) Regulation governing inclusion of minors as research volunteers is added. The language for this regulation comes from 45 CFR §46.401 et seq. and 34 CFR 97.101 et seq.
10) The kinds of research that may receive expedited review and expedited review procedures are changed to mirror 45 CFR § 45.110.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The Department has conducted a review of the federal law. Two alternatives were identified. Alternative 1 was to have no change to the Department's existing regulations for the protection of human research subjects. However, the existing regulations are not reflective of the changes that have been made in the federal regulations, nor do the existing regulations address using minors as subjects in human research.

The second alternative, therefore, was to amend the regulations so that they would be consistent with the current federal regulations and address the use of minors in human research. This alternative was selected as the best course of action.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to

Vanessa Rakestraw, 8004 Franklin Farms Drive, Richmond, VA 23229
Email: Vanessa.Rakestraw@drs.virginia.gov
Fax: (804) 662-7696

Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The Office of the Attorney General has provided guidance and technical support to the Department in the development of the amended regulations. The Department's Human Research Review Committee Has provided suggestions, and the Department will be inviting public comment during the development of these regulations.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These proposed amendments will ensure that the rights and welfare of the department's clients and staff who volunteer to participate in research studies are protected. The protections are ensured in several ways. First, these amendments specify procedures for obtaining the informed written consent of prospective research volunteers and require that the human research review committee approve the research activities and oversee the informed consent process. Second, the regulations respect the authority and rights of parents by requiring that parental permission be obtained prior to the involvement of children in any research activities. Additionally, these regulations require the assent of children prior to participation in research. Third, these regulations ensure that participation in research is voluntary and entered into with adequate knowledge about: 1) the research procedures; 2) risks and/or benefits; 3) the extent to which confidentiality of records identifying the individual will be maintained; 4) appropriate alternative procedures or courses of treatment; 5) whom to contact for answers to pertinent questions about the research and research volunteer's rights; 6) refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled; and 7) discontinuing participation at any time without penalty or loss of benefits to which the individual is otherwise entitled.

These regulations have no negative impact on an individual's efforts to achieve economic self-sufficiency, no negative impact on family income, and do not erode the martial commitment.