Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Department of Rehabilitative Services
Virginia Administrative Code (VAC) citation	22 VAC 30 -40
Regulation title	Protection of Participants in Human Research
Action title	2007 Amend regulations to conform to federal regulations pertaining to human subjects research
Date this document prepared	12/18/2007

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.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

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. In addition, minor changes in language have been made to ensure consistency with 45 CFR 46.101 et seq. The definition of sheltered workshop has been changed so that only those vocational rehabilitation service programs that have a vendor relationship with the department and are not operated by a community services board are to be covered by this regulation. Independent living centers and sheltered workshops no longer have the option to establish their own human research review committee or to affiliate with other centers or workshops to establish a central human research committee. Independent living centers and sheltered workshops covered by this regulation must affiliate with the DRS human research review committee. Procedures for obtaining the informed written consent of prospective research subjects have been changed to ensure consistency with the requirements of federal regulations. The composition of the human research review committee that reviews research proposals to determine if they meet the requirements of this regulation has been changed to ensure consistency with federal requirements. A new section has been added that governs the inclusion of minors as research subjects. Procedures for expedited review and the description of research that may receive expedited review have been changed to reflect existing federal regulations.

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., the 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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

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.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

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.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

This regulatory action serves to protect the welfare of human participants in research. The regulation poses no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

The proposed regulations bring the existing regulations in conformation with the existing federal requirements and are not more restrictive than federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is particularly affected

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency is 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

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

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	None
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	This regulation affects researchers who want to conduct research involving consumers of the Department of Rehabilitative Services, Woodrow Wilson Rehabilitation Center, Centers for Independent Living and Sheltered Workshops. The regulation also provides enhanced protections for the rights of consumers who volunteer to participate in research activity.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	On average, the Department of Rehabilitative Services Human Research Review Committee receives about 4-5 research proposals per year.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	The only projected costs to affected entities is the cost involved in completing the application requirements to submit proposed research for review to the Human Research Review Committee. However, this cost already exists with the current regulations.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

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.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternate regulatory methods for small businesses that can be used that will be less stringent yet ensure the protection of human participants in research.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
No comments received		

Family impact

Please assess the 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.

The only potential impact that this regulation is expected to have on the family is that it will help to maintain and protect the welfare of family members. Although a child must agree to be a participant in research, a parent or guardian must also provide consent for the child to participate.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section	Current requirement	Proposed change and rationale

	number, if applicable		
22VAC30-40-10. Definitions		Definitions currently exist in the regulation.	Additions, deletions and changes in the definitions are proposed to ensure that the definitions comply with federal requirements and are more comprehensive and explanatory. Definitions for the following terms are added: agent, assent, covered entity, guardian, Human Research Review Committee or HRRC, HRRC approval, human research subject, identifiable private information, informed consent, minor, parent, and permission. Legally authorized representative has been redefined. Sheltered workshop has been redefined to not include facilities operated by a Community Services Board which are covered under separate regulations promulgated by DMHMRSAS. The definition of voluntary informed consent is deleted because other definitions are provided that are more explanatory.
22VAC30-40-30 Applicability		Currently, the regulation states that it is applicable to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants.	This statement is being deleted as unnecessary because there is no facility operated, funded or licensed by the department, other than the Woodrow Wilson Rehabilitation Center, sheltered workshops and independent living centers which are specifically included.
22VAC30-40-40 Policy		The current regulation allows an institution to establish its own research review committee, work with other institutions to establish a single committee or use the Department of Rehabilitative Services' established committee.	The ability of an institution to establish its own research review committee or work with other institutions to establish a single committee is being deleted. Institutions must utilize the Department of Rehabilitative Services' committee. Adds a provision regarding cooperative research projects. Adds a provision that any research that is undertaken without the intention of involving human subjects, but later proposes to involve human subjects, must be reviewed and approved by the HRRC before research using human participants is undertaken. Adds a provision that the commissioner may impose additional conditions necessary to protect human subjects if these conditions are necessary. This statement allows a remedy to protect human participants in the event an

			unforeseen or unknown danger may exist in a proposed research project.
22VAC30-40-50 Certification process		Institutions seeking to conduct or sponsor human research are required to submit statements to the research review committee assuring that all human research activities will be reviewed and approved by a research review committee. Institutions shall report annually on their committee structure and include committee minutes.	This requirement is changed to provide that no later than 45 days after the end of each state fiscal year, Woodrow Wilson Rehabilitation Center, sheltered workshops and independent living centers shall send a written report to the commissioner assuring that all human subjects research conducted during the fiscal year was reviewed and approved by the department's HRRC prior to implementation of that research or that no human subjects research was conducted during that state fiscal year. A provision is added that the HRRC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the HRRC's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the HRRC's action and shall be reported promptly to the research investigator, the commissioner and the head of other appropriate covered entity. Adds that research covered by 22 VAC 30-40-10 et seq. that has been approved by the HRRC may be subject to further appropriate review and approval or disapproval by officials of the covered entities. However, those officials may not approve the research if it has not been approved by the HRRC.
22VAC30-40-60. Composition of the human research review committee		This current section applies to any research committee established and contains provisions regarding the composition of research committees.	The section is changed to apply only to the Department of Rehabilitative Services' human research committee consistent with the change in 22 VAC 30-40-40. Adds new requirements for the department's human research committee composition. Additional membership requirements are imposed on the HRRC by 34 CFR 350.4(c) and 356.3(c) for research sponsored by the National Institute on Disability and Rehabilitation Research. When minors with disabilities or persons with mental disabilities are purposefully included as research subjects, the HRRC's membership must include at least one person who is primarily concerned with the welfare of these research subjects.

			Except when exempt or expedited review procedures are used, proposed research shall be reviewed at convened meetings at which a majority of members is present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
22VAC30-40-70. HRRC review of research and criteria for approval.		This section currently applies to any research committee.	This section is changed to apply to the Department of Rehabilitative Services' human research committee consistent with 22 VAC 30-40-40. Provides that the HRRC shall require that information given to prospective subjects as part of informed consent process is in accordance with 22 VAC 30-40-100. The HRRC may require that information, in addition to that specifically mentioned in 22 VAC 30-40-100, be given to prospective subjects when in the HRRC's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. The HRRC shall require documentation of informed consent or may waive documentation in accordance with 22 VAC 30-40-100 D and 22 VAC 30-40-100 E. If the HRRC decides to disapprove a research project, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. HRRC shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. Delineates the requirements to approve research covered by these regulations.
22VAC30-40-80. Kinds of research exempt from committee review.		Currently delineates the kinds of research exempt from committee review.	Changes the wording in this section to comport with federal human research requirements and language. Specifically, adds additional statements regarding research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior. Also, research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens; and

			research and demonstration projects.
22VAC30-40-90. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.		The committee may conduct an expedited review of a human research project which involves no more than minimal risk to the participants if (i) another institution's or agency's human research review committee has reviewed and approved the project	Deletes this provision. Review by another institution's review committee does not allow for an expedited review from the HRRC. This requires the department to review research proposals that it is approving instead of accepting another institution's approval. Adds that the commissioner may restrict, suspend, terminate, or choose not to authorize the HRRC's use of the expedited review procedure.
22VAC30-40-100. Informed consent.		Currently contains provisions regarding informed consent.	These provisions are being changed to comport with federal requirements and language. The proposed regulation provides an outline of the specific basic elements which must be provided to prospective human subjects before legally effective informed consent is obtained. Provides that the HRRC can require additional elements to be added to informed consent to protect the prospective subject and that the HHRC may alter some of the stated elements under certain circumstances. Adds a statement that the requirements in this chapter are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective. Provides that this chapter does not limit the authority of a physician to provide emergency medical care if permitted to do so under applicable laws. No person shall be forced to participate in human research, and each subject shall be given a copy of the signed consent form except in circumstances provided in this regulation. No legally authorized representative may consent to nontherapeutic research unless the human research committee determines such research will present no more than a minor increase over minimal risk to the prospective subject, and no nontherapeutic research shall be performed without the consent of the human subject. The documentation required for legally effective informed consent is specified and the human research review committee

			waiver requirements for signed consent are specified.
22VAC30-40-110. Committee records.		Currently applies to any committee records.	Now applies only to HRRC consistent with 22 VAC30-40-40. Adds statement that the documentation of committee shall identify members by name, earned degrees, representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to HRRC deliberations; and any employment or other relationship between each member and the covered entity; for example: full-time employee, part-time employee, member of governing panel or board, or paid or unpaid consultant. A list of written procedures for the committee to follow is provided. Delineates the information that must be included in the committees written procedures. Includes state requirement to post an overview of approved human research projects and the results of such projects on the department's website.
22VAC30-40-120 Mandatory Reporting		Currently applies to any research review committee.	Changed to apply only to HRRC consistent with 22VAC30-40-40.
22VAC30-40-130 Role of the department and the commissioner		Currently applies to any research review committee.	Changed to apply only to HRRC consistent with 22VAC30-40-40.
22VAC30-40-150 Applicability of federal policies		Currently applies to human research at institutions.	Changed to apply to HRRC, which must notify the commissioner at least annually of its compliance with federal policies and regulations for the protection of human research subjects when the HRRC reviews or approves federally funded or sponsored human research proposals.
	22VAC30-40-160. Additional Protection for Minors Involved as Subjects in Research.		This new section discusses the specific requirements that a research proposal must include when proposing to conduct research with minors. The federal regulations for protecting minors who are human research participants are more stringent. Therefore, this section has been added to parallel the federal regulations. A covered entity may conduct or fund research using minors if the HRRC determines that the assent of the prospective minor subject and the permission of the minor's parent or

			guardian are obtained. Additional conditions for protecting minors may also be required, depending upon the level of risk and the therapeutic outcome to the prospective subject.
	22VAC30-40-170. Research involving minors.		This new section specifies which exceptions covered in 22VAC30-40-80 may be applied when conducting research involving minors.

Enter any other statement here