Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Mental Health, Mental Retardation, and Substance Abuse Services
VAC Chapter Number:	12 VAC 35-180-10 et seq.
Regulation Title:	Regulations to Assure the Protection of Participants in Human Research
Action Title:	Amend Regulation 12 VAC 35-180-10 et seq.
Date:	January 27, 2003

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

These regulations provide the regulatory basis for the Department of Mental Health, Mental Retardation and Substance Abuse Services (Department) to oversee research involving human subjects receiving services in the mental health, mental retardation, and substance abuse services system. The regulation details guidelines for the initiation of human research activities in institutions operated, funded, or licensed by the Department. Additionally, it provides for local review and approval of human research activities through the establishment of research review committees. This regulation also outlines the reporting requirements of research review committees to the Department.

The proposed amendments to these regulations include several changes, including (a) specifying an "order of priority" for obtaining consent from legally authorized representatives; (b) requiring that if two or more persons qualify as the legally authorized representatives and have equal priority, then both must agree to participation; (c) specifying conditions under which a legally authorized representative may not consent for the prospective subject; (d) specifying additional items that must be considered in the review of the proposed study (e.g., risks are minimized by not exposing subject to unnecessary risks, whether additional safeguards are in place for vulnerable populations such as children, and pregnant women); (e) requiring compliance with the research provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), specifically those regarding use and disclosure of "protected health information" (PHI) created for research; and (f) correcting inconsistencies with the Agency's *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services*, 12 VAC 35-115-10 et seq. (Human Rights Regulations) by requiring that subjects be notified of "how the results of the study will be disseminated" and by adding "treatment" to the list of examples used to define "minimal risk."

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed Rules and Regulations to Assure the Protection of Participants in Human Research (Human Research Regulations) under Va. Code §§ 37.1-10 and 37.1-24.01. The Office of the Attorney General further certifies that the proposed regulations are constitutional and do not conflict with other federal or state laws or regulations. Further, the Virginia Code requires the State Board for Mental Health, Mental Retardation and Substance Abuse Services (Board) to promulgate the regulations to effectuate these the provisions regarding human research.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

Amendments to these regulations are required to address changes to the Virginia Code regarding human research effective July 1, 2002; to reflect additional protections provided to subjects in human research required by HIPAA; and to reflect additional requirements included in the human rights regulations which were recently promulgated by the Board. Finally, other changes have been made to ensure consistency in terminology and definitions between the Virginia Code regarding human research and these regulations. These changes will provide consistency across several regulatory documents, thus preventing confusion in the conduct of research and the protection of human subjects.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The proposed amendment updates the current definitions of "human research," "informed consent," "minimal risk" and "authorized representative" in order to be consistent with the current Virginia Code and the Human Rights Regulations. Other specific revisions are proposed to comply with the requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other applicable federal regulations, as necessary. Another revision eliminates the requirement that the witness to the informed consent may not be involved in the conduct of the research. Finally, the elements to be considered in the review and approval of a human research study are modified.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

The proposed changes offer several advantages to the public. Most importantly, additional protections are provided to the subjects in human research, thus reducing their exposure to risk. Second, language is simplified and certain provisions are clarified, thus reducing ambiguity and the possibility of misinterpretation.

The proposed changes also offer several advantages to the Commonwealth and to the Department. First, they bring the Human Research Regulations into compliance with the Virginia Code on human research and the federal HIPAA regulations. Second, they provide for consistency between the Human Research Regulations and the Human Rights Regulations, thus preventing conflicting guidance in the conduct of human research. They provide for additional protections to the participants in human research and help to ensure the lawful conduct of research by the Commonwealth and Department.

The only disadvantage is that it adds requirements to the conduct of human research. However, these new requirements are minimal and are not likely to discourage the conduct of research.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The Department already has in place a process to monitor compliance with these regulations. The proposed changes will not require any new activities and, therefore, will not result in additional costs to the Department or Commonwealth. Similarly, given the nature of the changes, it is not anticipated that there will be any additional costs to localities; no additional requirements are made of localities other than those already required by the new federal HIPAA regulations.

Those affected by the regulations are the Department's Central Office and institutions and agencies operated, funded, or licensed by the Department, and those who seek to conduct human research within institutions and agencies operated, funded, or licensed by the Department, whether they are affiliated with those institutions/agencies or not (e.g., university-based researchers). While these regulations apply to a large number of institutions, over the past few years there have typically been fewer than 15 studies initiated within the services system, with the involvement of fewer than a dozen different institutions/agencies.

Given the nature of the proposed changes, it is not anticipated that they will result in any additional costs to the affected individuals and institutions.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

12VAC35-180-10. Definitions

- Terms are presented in alphabetical order for ease of reference.
- Definitions are added for "health information," "individually identifiable health information," private information," and "protected health information" to coincide with the inclusion of HIPAA requirements regarding research.

- The definition of "human research" is revised to be consistent with the Virginia Code definition.
- The definition of "informed consent" is revised to be consistent with the Virginia Code definition.
- The definition of "legally authorized representative" is revised to be consistent with changes to the Virginia Code effective July 1, 2002. In particular, these changes establish an "order of priority" for which authorized representative may give consent for the prospective subject.

12VAC35-180-4. Policy.

- Eliminates the requirement that the witness who signs the informed consent form cannot be involved in the conduct of the research. This change is consistent with the Virginia Code and eliminates a requirement that was burdensome to researchers while not providing a significant increase in protection to the prospective subject.
- Changes the threshold for subjects receiving care in a residential or hospital setting to participate in nontherapeutic research from not greater than minimal risk to no more that a minor increase over minimal risk. This change makes this section of the regulations consistent with the threshold required for consent given by legally authorized representatives in cases of nontherapeutic research.

12VAC35-180-60. Composition of research review committees.

- Strikes language requiring that a research review committee may not consist "entirely of men or entirely of women." This language was redundant given other language in this section requiring that committees have "diversity of its members, including consideration of race, gender…"

12VAC35-180-70. Elements of each committee's review process.

- Adds a requirement that in reviewing human research, the committee consider whether the risks to subjects are minimized by using procedures consistent with sound research design and by using procedures already performed on the subjects for diagnostic and treatment purposes. This change is required to reflect changes in the State Code.
- Adds a requirement that in reviewing human research, the committee consider whether additional safeguards have been included to protect the rights and welfare of vulnerable populations (e.g., children, pregnant women). This change is required to reflect changes in the State Code.
- Eliminates the requirement for the committee to consider "whether appropriate studies in nonhuman systems have been conducted…" This requirement is not in the State Code or Federal regulations on human research.
- Clarifies that when an institution or agency does not have a research review committee, the chief executive officer or his designee may enter into an agreement to have another institution's committee conduct the human research review. This is needed to cover situations in which an institution may want to participate in a human research project but does not have a standing research review committee.
- Adds a requirement that research review committees ensure compliance with the Health Insurance Portability and Accountability Act of 1996 regarding the use and disclosure of

protected health information created for research. This addition is required to comply with new Federal regulations.

12VAC35-180-80. Kinds of research exempt from committee review.

- Deletes "Research involving solely the use and analysis of the results of standardized psychological …tests" as one of the types of research exempt from review. This brings this section of the regulations into compliance with the Virginia Code.

12VAC35-180-100. Informed consent.

- Adds language such that if two or more persons who qualify as legally authorized representative have equal decision making priority, they must all consent to the research in order for the prospective subject to participate. This addition is required to comply with changes to the Virginia Code effective July 1, 2002.
- Adds language such that, notwithstanding consent provided by a legally authorized representative, no person can be forced to participate in any human research if the investigator knows that the prospective subject does not want to participate. It further clarifies that in cases where the prospective subject suffers from "organic brain disease causing progressive deterioration of cognition for which there is no known cure…" that experimental treatment authorized by the legally authorized representative does not constitute force. This addition is required to comply with changes to the Virginia Code effective July 1, 2002.
- Adds language such that a legally authorized representative may not consent to participation in human research for a prospective subject if the representative knows that the research in contrary to the religious beliefs or basic values of the prospective subject. Also specifies types of nontherapeutic research for which the legally authorized representative cannot provide consent. This addition is required to comply with changes to the Virginia Code effective July 1, 2002

Alternatives

Please describe the specific 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.

The Department has conducted an analysis of the applicable state law and public comment. Several alternatives were considered for meeting the purpose of these regulations:

Alternative 1- No regulation. This alternative was rejected. The Board is required to promulgate regulations for human research to comply with its statutory mandate. Moreover, repealing these regulations without replacing them would eliminate an important tool for protecting the health and safety of consumers who are involved in human research in the mental health, mental retardation, and substance abuse service system.

Alternative 2 - No change to the human research regulations. This alternative was rejected. The existing Human Research Regulations have not been revised since they were promulgated in

May of 1993, and revisions are necessary to update these regulations to be consistent with the current Virginia Code, Human Rights Regulations, and applicable federal regulations.

Alternative 3 – Amend the regulation. This alternative is recommended. It was determined that generally this regulation provides the regulatory guidance necessary for the oversight of human research, as required by § 37.1.24.01 of the Code of Virginia. However, certain revisions should be made to the regulatory provisions to comply with current Virginia Code, Human Rights Regulations, and federal requirements.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

One comment was received during the NOIRA period. The commenter suggested adding language at 12 VAC 35-180 of the existing regulations to indicate that the requirements for committee review apply only to human research and do not apply to other types of research that does not involve human subjects.

Response:
This section of the existing regulations was revised to reflect the language in the Virginia Code at § 32.1-162.19, which clearly states that the committee is established to review human research activities.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Members of the Department staff with expertise in the relevant process and the Office of the Attorney General reviewed the proposed regulation to ensure that it is written clearly and incorporates the applicable legal protections for individuals who elect to participate in human research projects. No public comments were received by the agency that reflected concerns about the clarity of the regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The Board will review the regulations to evaluate the need for amendments or revisions within three years of the effective date or in accordance with the periodic review schedule established by the relevant Executive Order. The review shall consider changes in Federal regulations, State Code and other Department regulations that have an impact on the human research regulatory process.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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 regulations, with proposed amendments, will better protect the rights and health of individuals receiving services and families involved in human research in the mental health, mental retardation, and substance abuse system. The regulations respect the authority and rights of parents in education, nurturing, and supervising their children. Additionally, this regulation encourages personal responsibility by ensuring that participation in human research is voluntary and entered into with adequate knowledge of the research procedures, risks, and benefits.

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 marital commitment.