Virginia Regulatory Town Hall

Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Department 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:	September 28, 2001

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

This regulation provides 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.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

There are two Virginia Code sections that authorize the promulgation of this regulation. Virginia Code § 37.1-10 details the powers and duties of the State Mental Health, Mental Retardation and Substance Abuse Services Board (The Board). It states that the Board shall have the power and duty "to make, adopt and promulgate such rules and regulations as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by the Commissioner or the Department."

Additionally, Virginia Code § 37.1-24.01 states that, "The Board shall promulgate regulations…for human research…to be conducted or authorized by the Department, any community service boards, or any facilities operated, funded, or licensed by the Department."

According to the Office of the Attorney General, the Board is not only authorized to promulgate the human research regulations, it is "required to do so."

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

The Department contacted more than 400 interested persons and organizations, including all programs licensed by DMHMRSAS, to request comments as part of the periodic review of this regulation. Two responses were received as a result of this effort.

1. Southwestern Virginia Mental Health Institute: The respondent requested that the definition of "human research" stated in the regulations be broadened to include research that "does not necessarily depart from the application of accepted therapeutic methods."

Agency Response: Per the Office of the Attorney General, the Board may change the definition of "human research" only to make it consistent with the definition that appears in the Code of Virginia. Any broadening of the definition of "human research" would necessitate a change to the Code of Virginia. The Department is currently reviewing the need for this change. The process for changing the Code of Virginia is outside the scope of this periodic review.

2. Henrico Area Mental Health & Retardation Services: This respondent stated that in most cases, "external" researchers such as university students and faculty conduct human research at

community service boards rather than community service boards initiating human research projects. The respondent further stated that for the most part, these "external" researchers are required to follow university-based protocols regarding human research that are "often more rigorous" than those required by the Department.

The respondent would like the regulation to address the issue of the authority of other research review committees outside of the Department and "honor the authority of research committees governed by other state departments, provided that the committees meet or exceed the requirements of protection of participants in human research, as set forth in 12 VAC 35-180-10 et seq."

Agency Response: Protecting the rights and health of participants in human research conducted in the mental health, mental retardation, and substance abuse services system is of utmost concern to the Department. For this reason it is important that providers seek approval from a research review committee, even when a university institutional review board has reviewed and approved a study. This requirement is an important means for assuring that the specific concerns of consumers of the mental health, mental retardation, and substance abuse services system are addressed. The Department does not recommend changes based on this comment.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The regulation has three identifiable goals:

- To protect the rights and health of the participants in human research conducted in the mental health, mental retardation and substance abuse system.
- To ensure that participation in human research is voluntary and entered into with adequate knowledge of the research procedures, risks, and benefits.
- To minimize the costs and intrusiveness of the administrative procedures to research organizations and the citizens of Virginia.

There was a general consensus among the participants in this review that the current regulations comply with these basic goals. However, it was determined that certain definitions in the regulations specifically the definitions of "human research," "informed consent," and "authorized representative" are not consistent with the Code of Virginia and should be revised. Additionally, revisions are necessary to meet the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and possibly other federal regulations.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The Department has conducted an analysis of the applicable state law and public comment. Several alternatives for resolving the issues identified by this Periodic Review are listed below.

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 as well as 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 minor revisions should be made to the regulatory provisions to comply with current Virginia Code and federal requirements.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The Department and State Board recommends that the human research regulations be amended. The current regulations generally fulfill the statutory mandate. However, relatively minor modifications should be made to ensure consistency with current Virginia Code. Additionally, revisions will be made to meet the requirements of applicable federal regulations such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Substance

Please detail any changes that would be implemented.

The Board is proposing to update the current definitions of "human research," "informed consent" and "authorized representative" in order to be consistent with the current Virginia Code. Other specific revisions will be made to comply with the requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other applicable federal regulations, as necessary.

Family Impact Statement

Please provide a preliminary 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 does not erode the marital commitment.