Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Board of Mental Health, Mental Retardation and Substance Abuse Services
Virginia Administrative Code (VAC) citation	12 VAC 35-180
Regulation title	Regulations to Assure the Protection of [Subjects ~~Participants~~] in Human Research
Action title	Amendment
Document preparation date	November 7, 2003

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Do ***not*** *state each provision or amendment or restate the purpose and intent of the regulation.*

This regulation governs human research activities that involve individuals receiving services in institutions operated, funded, or licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services (Department). Additionally, it provides for local review and approval of human research activities through the establishment of research review committees. The regulation also outlines the reporting requirements of research review committees to the Department.

The proposed amendments (a) specify an "order of priority" for obtaining consent from legally authorized representatives; (b) require that if two or more persons qualify as the legally authorized representatives and have equal priority, all must agree to participation; (c) specify conditions under which a legally authorized representative may not consent for the prospective subject; (d) specify 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) require 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); and (f) correct 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."

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

At its meeting on October 29, 2003, the State Mental Health, Mental Retardation and Substance Abuse Services Board approved the amended Regulations to Assure the Protection of Subjects in Human Research for final promulgation.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, 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.

If the final text differs from the text at the proposed stage, please indicate whether the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

The Office of the Attorney General has confirmed that the Board has the authority under Virginia Code §§ 37.1-10 and 37.1-24.01 to promulgate the Regulations to Assure the Protection of Subjects in Human Research and is required to do so. The OAG further advised that the regulation is constitutional and does not conflict with any state or federal laws or regulations.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The amendments are needed to conform the existing regulation to changes to the Virginia Code regarding human research that became 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. It is also necessary to make other changes to ensure consistency in terminology and definitions in the Virginia Code. 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. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The proposed amendments update 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 HIPAA and applicable federal regulations. Another revision eliminates the requirement that the witness to the informed consent may not be involved in the conduct of the research. Finally, the amendment modifies the elements that are required to be considered in the review and approval of a human research study.

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 there are no disadvantages to the public or the Commonwealth, please indicate.

The proposed changes offer several advantages to the public. Most importantly, there are new protections for human research subjects, which will reduce 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 there are additional requirements for the conduct of human research. However, these new requirements are minimal and are not likely to discourage the conduct of research.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
Title of the Regulations	The title of the regulations was "Regulations to Assure the Protection of Participants in Human Research"	The word "participants" was replaced with "subjects."	The word was replaced to conform to the terminology used in the regulation text.
10	A definition of "private information" was provided. This term was used only one time in the definition of "human subject".	The definition or "private information" was eliminated. In the definition of "human subject," the term private information was replaced with "protected health information (PHI)."	It is not necessary to use the term "private information." PHI is an equivalent term that is used by HIPAA and is defined in this regulation. With this change, the term "PHI" is used consistently in the regulation.
10	The elements of informed consent did not track the language in the Virginia Code.	The elements of informed consent were re-ordered and revised for clarification and to more closely track the language in the Virginia Code (§ 32.1-162.16).	The Office of the Attorney General recommended the revised language.
10, 50 C., 60 A., 70 A., 90 A., 100 C. and D.	The term "research review committee" was used in the text of the regulation but was not defined.	A definition of "research review committee" was inserted in Section 10. This definition references Virginia Code § 32.1-162.19. In Sections 50 C., 60 A., 70 A, 90 A, and 100 C and D, the words "research review" were added to modify "committee" to be consistent with the defined term.	The definition was added to clarify the regulation.
30	Punctuation and language was not consistent in this paragraph.	Punctuation was added and the word "to" was deleted.	This is an editorial change for consistency.
40 C.*	The regulation did not specifically indicate that institutions or agencies	A provision was inserted stating that an institution or agency may participate in a human research	This change was requested by public comment and

	defined by the regulation may participate in research projects that are approved by a university institutional review board (IRB) even though this occurs in practice and is consistent with the Human Rights regulations.	activity when it has been approved by an university IRB.	recommended by Department staff.
50 A., 60 A.,	The term "institution" was used.	The term "or agency" was inserted after the word "institution."	This change is consistent with the defined term and was made for clarity.
70 A.6.	The provision uses the phase "…incapable of making a decision regarding consent…"	The phase was changed to "…incapable of providing informed consent…"	This change was recommended by the Office of the Attorney General and was made for clarity. (The regulation defines "informed consent.")
100 A.	The provision uses the phase "…capable of making an informed decision…"	The phase was changed to "providing informed consent…"	This change was recommended by the Office of the Attorney General and was made for clarity.
100 C.	The provision stated: "No non-therapeutic research shall be performed without the consent of the subject."	The words "or his legally authorized representative..." were added to the sentence.	The change was made for internal consistency and clarity.
130 C.	The provision stated: "…in response to § 37.1-84.1 of the Code of Virginia. "	The words "in response to" was changed to "pursuant to."	Editorial change recommended by the Office of the Attorney General.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Bob Lewis, Piedmont Geriatric Hospital	The commenter requested that a provision be inserted to allow other facilities to accept and rely on review of a university institutional review board (IRB) and to participate in research projects that	The function of a university IRB is the same as a research review committee and it is subject to the same legal requirements. The following provision was inserted at 12 VAC 35-180C: "Institutions or agencies, as defined by

	have been approved by a university IRB. The regulation was not clear as to whether the review of a human research proposal by a university IRB can be accepted by another facility without any further review by its research review committee.	this chapter, may participate in human research activity when such activity has been considered and approved by a university IRB that complies with the relevant requirements of § 32.1-162.19 of the Code of Virginia."

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10		Definitions are not in alphabetical order.	Terms are presented in alphabetical order for ease of reference.
10		The existing regulations are not entirely consistent with federal HIPAA requirements for research.	Definitions are added for "health information", "individually identifiable health information" and protected health information. These terms correspond with the inclusion of HIPAA requirements regarding research.
10		The definition of "human research" and "informed consent" are not consistent with the Virginia Code definitions.	These definitions have been changed to be consistent with the Virginia Code definitions.
10		The definition of "legally authorized representative" is not consistent with recent changes to the Virginia Code.	The definition has been changed to be consistent with current Code. In particular, these changes establish an "order of priority" for which an authorized representative may be consent for a prospective research participant.
10		A definition of "private information" was provided. This term is used in the definition of "human subject".	The definition has been eliminated because it is not needed. PHI is an equivalent term that is used by HIPAA and is defined in this regulation. "Private information" has been replaced with "PHI" and the and there is consistency in the use of terms within the regulation.
10		The term "research review committee" was used in the	A definition of "research review committee" was inserted in Section 10. This definition

		text of the regulation but was not defined.	references Virginia Code § 32.1-162.19. In Sections 50 C., 60 A., 70 A, 90 A, and 100 C and D, the words "research review" were added to modify "committee" for clarity to be consistent with the defined term
20		The section describes the legal authority for the regulation.	The section has been eliminated for stylistic reasons on the advice of the Registrar of Regulations.
40 A.		The section requires that the subject or his legally authorized representative be informed of the research in writing. It also requires that any witness to the consent may not be involved in the research.	The provision is clarified to require that no research may be conducted without obtaining "informed consent" from the subject or his legally authorized representative. It also eliminates the requirement that a witness who signs the informed consent may not be involved in the research. The change is consistent with Code requirements and eliminates a requirement that is burdensome to researchers while not providing a significant increase in the protection to the prospective subject.
40 C.		The regulation did not specifically state that institutions or agencies defined by the regulation may participate in research projects when they are approved by a university institutional review board (IRB).	A provision was inserted stating that an institution or agency may participate in a human research activity when it has been approved by a university IRB. This occurs in practice and is consistent with the Human Rights regulations.
40 C.	40 D.	The threshold for subjects in a residential setting to participate in research is "not greater than minimal risk."	The threshold was changed to "no more than 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 according to the Virginia Code.
60 B.		The provision requires that a research review committee may not consist "entirely of men or entirely of women."	This was eliminated. The language was redundant given that other language in this section (60 A) requires that committees have "diversity of its members, including consideration of race, gender…"
70 A. through H		This section, which describes the elements of each committee's review process, did not reflect the recent changes in the Virginia Code and federal HIPAA requirements.	(A 5.) 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 being performed on the subjects for diagnostic and treatment purposes. This change is required to reflect changes in the

			Virginia Code. (A 6.) 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 Virginia Code. (A 9.) Eliminates the requirement for the committee to consider "whether appropriate studies in nonhuman systems have been conducted…" This requirement is not included in the Virginia Code or Federal regulations on human research. (C.) 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. (H.) Adds a requirement that research review committees ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regarding the use and disclosure of protected health information created for research. This addition is required to comply with new Federal regulations.
80 2.		Exempts from review "…research involving solely the use and analysis of the results of standardized psychological …tests."	This exemption was eliminated to bring this section into compliance with the Virginia Code.
100 A., B. and C.		Details the requirements for informed consent that are necessary to participate in research activities.	Language was added such that if two or more persons who qualify as legally authorized representatives 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. Language was added 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. Language is added 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

The term "participant" was replaced with "subject" throughout the regulation to be consistent with terminology used in the Virginia Code.

Minor punctuation, editorial and language changes have been made in Sections 30, 50, 60, 70, 80, 90, and 100 for clarification and in response to recommendations from the Office of the Attorney General.

Impact on family

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

These regulations, with proposed amendments, will better protect the rights and health of individuals receiving services and their families who are involved in human research in the mental health, mental retardation, and substance abuse services system.