Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	State Board of Health (Virginia Department of Health)
Virginia Administrative Code (VAC) citation	12VAC5-20
Regulation title	Regulations for the Conduct of Human Research
Action title	Amend regulations for clarity, efficiency and effectiveness following periodic review.
Date this document prepared	November 18, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The final amendments update and clarify the current regulations regarding the conduct of human research to more closely reflect current practice and to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on human subjects and researchers. The current regulations were originally promulgated and effective July 1, 1993 under statutory authority granted by the 1992 session of the Virginia General Assembly. The regulations were last amended in 2010. Based on findings from the most recent periodic review, the final regulations will: amend the definitions of 'human research", "informed consent", and "legally authorized representative" to be consistent with Code of Virginia § 32.1-162.16 et seq. and federal regulations 45 CFR Part 46; provide additional clarity on committee review procedures; add the requirement that the committee ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) and federal and state regulations regarding disclosure of Personal Health Information (PHI); provide additional clarification of the informed consent requirements; and revise the required reporting dates for the human subject research committee to report yearly activities and for the commissioner to report the listing of institutions that are subject to federal regulations regarding human subject research and are exempt from 12VAC5-20.

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 or board taking the action, and (3) the title of the regulation.

The Virginia State Board of Health approved the text of the final amendments for the "Regulations for the Conduct of Human Research," 12VAC5-20 on December 4, 2014.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Section 32.1-12.1 of the *Code of Virginia* charges the State Board of Health with promulgating regulations pursuant to the Administrative Process Act (§ 2.2-4000 *et seq*.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 *et seq*.) of this title for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by the Department. The imperative form of the verb "shall" is used in § 32.1-12.1 making the Board's authority to regulate the provisions of Chapter 5.1 (§ 32.1-162.16 *et seq*.) for human research mandatory rather than discretionary.

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.

Several aspects of the regulations regarding the Conduct of Human Research need updating and clarifying. As a result of the Periodic Review, it was noted that the 2010 regulation amendments did not include a revised definition of "human research". The changes add a definition for this term and a definition for "protected health information." The changes amend the definitions for "informed consent" and "legally authorized representative" to provide greater clarity to the regulations. In addition, the regulations amend the requirements of the composition of the human research review committee. The current state regulations require that each committee have at least seven members, however, the federal regulations require that each committee have at least five members (45 CFR 46.107 (a)). Reducing the number of members will reduce the burden on the state while continuing to provide the protection of human research subjects. The amendments provide additional details regarding the elements of the committee review process to ensure consistency with § 32.1-162.19 of the *Code of Virginia*. The amendments provide greater clarity to the informed consent process, and eliminate repealed Code sections in the categories of human research exempt from regulation. The amendments are updates that will assist in ensuring the public health, safety and welfare of the citizens of the Commonwealth.

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 final amendments to the regulations include:

1) Updating the definition of "Human Research."
2) Adding a definition of "Minor Increase over Minimal Risk."
3) Adding a definition of "Subject" or "Human Subject."
4) Replacing the term "participants" with "subjects" in various sections.
5) Eliminating the detail elements of informed consent in the definition section (12VAC5-20-10). This information is duplicated in Section 100.
6) Amending the definition of "Legally Authorized Representative" to be consistent with § 32.1-162.16.
7) Add a definition of "Protected Health Information (PHI)".
8) In Section 30, replace the term "human participants" with "human subjects" to be consistent with language used in § 32.1-162.16.
9) Add subsection F in Section 40 to clarify that no official or employee of the institution or agency conducting or authorizing the research is qualified to act as a legally authorized representative of a subject in human research.
10) In Section 50, the committee reporting requirement is changed from January 31 to March 31st each year.
11) In Sections 50 and 60 the term "chairman" is amended to "chair."
12) Section 70 is amended to require that the committee have at least 5 members instead of at least 7 members.
13) Section 70 is amended to indicate that consideration will be given to the inclusion of members experienced in working with categories of vulnerable subjects that are regularly reviewed by the committee.
14) In Section 80, a new subsection A is added to clarify that no human research shall be conducted unless a research committee has reviewed and approved the project. The section is also amended to provide details as to the elements of the project that are to be considered in the review.
15) Section 80(D) is amended to delete the requirement that the committee approve a written procedure for when a subject has a complaint regarding the research. The requirement that the committee develop a procedure is retained.
16) In Section 80, a new subsection G requires that the committee chair provide a written report to the head of the institution regarding any violation that led to either a suspension or termination of the research.
17) In Section 80, a new subsection I requires that the committee ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) and federal and state regulations regarding disclosure of Personal Health Information (PHI).
18) In Section 80, a new section J provides that cooperating institutions conducting research may enter into a joint review, rely on another qualified committee or come to an agreement that avoids duplication of review effort.
19) Section 90(A) is amended and new subsections B and C are added to provide additional clarification on when and how an expedited review can be completed and clarifies the authority to suspend or terminate approval for a project.
20) Section 100 is amended and new subsections B, C, D, E and G are added to further clarify the informed consent requirements and when the committee may waive the informed consent requirement.

21) In Section 110 the reference to the Alzheimer's Disease and Related Disorders Registry is eliminated along with the reference to § 32.1-116.1:2.
22) In Section 130 the reporting date is changed from January 31 to March 31 annually.

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.

1) There are no disadvantages to the public.
2) There are no disadvantages to the agency or the Commonwealth. An advantage is that the amended regulations will provide greater clarity on the committee review process.
3) There are no other pertinent matters of interest related to this action.

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
10: Definitions	N/A	Added a definition of "minor increase over minimal risk"	Provides greater clarity to the term as used in 12VAC5-20-100.
70 : Composition of Research Review Committee	If the committee regularly reviews research that has an impact on vulnerable subjects, the committee shall have in its membership one or more individuals primarily concerned with the welfare of these subjects.	If the committee regularly reviews research that has an impact on vulnerable subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.	Provides greater consistency with federal regulations
80: Elements of Committee Review Process	Refers to "undue influence"	"Influence" is deleted and replaced with "inducement"	Provides consistency with the term used in the definition of Informed Consent in Section 10.
100: Informed Consent	N/A	Delete number 8."A statement that there may be other risks not yet identified."	This is redundant with number 3 in the final amendments.

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.

No comments were received during the public comment period following the publication of the proposed stage.

Commenter	Comment	Agency response
N/A	N/A	N/A

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Section 10: Definitions	N/A	Definition of "Human Research"	The definition is amended to be consistent with the definition in § 32.1-162.16.
Section 10: Definitions	N/A	Definition of "Informed Consent"	The definition is amended to eliminate the detailed elements of informed consent that are duplicated in 12VAC5-20-100.
Section 10: Definitions	N/A	Definition of "Legally authorized representative"	This definition is amended to be consistent with § 32.1-162.16.
Section 10: Definitions	N/A		Add definition of "minor increase over minimal risk"
Section 10: Definitions	N/A		Add definition of "Protected health information (PHI)".
Section 10: Definitions	NA		Add definition of "Subject or Human Subject"
Section 10: Definitions	N/A	Current regulations use the term "participants".	The term "participants" is amended to "subjects" to be consistent with language used in § 32.1-162.16 et seq.
Section 30: Applicability	N/A	Current regulations use the term "human participants".	The term "participants" is amended to "subjects" to be consistent with language used in § 32.1-162.16 et seq.
Section 40: Policy	NA	Current regulations use the term "may".	The term "may" is amended to "shall" to require that no human research be conducted without informing the subject of risks.
Section 40: Policy	N/A	Current regulations reference 12VAC5-20-100 F and H of this chapter.	Remove reference to "F and H of this chapter".
Section 40: Policy	N/A		New subsection F clarifies that no official or employee of the institution or agency conducting or authorizing the research is

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			qualified to act as a legally authorized representative of a subject in human research.
Section 40: Policy	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 40: Policy	N/A	Current regulations use the term "research."	The term "research" is amended to "human research" for consistency.
Section 50: Review Process for Department	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 50: Review Process for Department	N/A	Current regulations require the committee to report yearly activities by January of each year.	The reporting requirement is amended to March 31 of each year.
Section 50: Review Process for Department	N/A	Current regulations reference "chairman".	The term "chairman" is amended to "chair".
Section 60: Review for Institutions or Agencies Funded or Licensed by the Department	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 60: Review Process for Institutions or Agencies Funded or Licensed by the Department	N/A	Current regulations reference "chairman".	The term "chairman" is amended to "chair".
Section 70: Composition of Research Review Committee	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 70: Composition of Research Review Committee	N/A	Current regulations state If the committee regularly reviews research that has an impact on vulnerable subjects, the committee shall have in its membership one or more	To provide greater consistency with federal regulations, this is amended to state that consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these vulnerable subjects.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		individuals primarily concerned with the welfare of these subjects.	
Section 70: Composition of Research Review Committee	N/A	Current regulation requires that the committee have at least seven members.	The requirement that the committee have at least seven members is amended to be at least 5 members in order to be consistent with the federal regulations (45 CFR § 46.107(a)) and provide greater efficiency.
Section 80: Elements of Committee Review Process	N/A		New subsection A clarifies that no human research shall be conducted unless a research review committee has reviewed and approved the project and provides details as to the elements of the project that are to be considered in the review.
Section 80: Elements of Committee Review Process	N/A	Current regulation requires that the committee approve or develop a written procedure for when a subject has a complaint regarding the research.	Deletes the requirement in subsection D that the committee approve a written procedure and retains the requirement that the committee develop a procedure to be followed when a research subject has a complaint.
Section 80: Elements of Committee Review Process	N/A		New subsection F provides that the committee shall have the authority to suspend or terminate approval of research that is not conducted according to committee requirements or that is associated with unexpected serious harm to subjects.
Section 80: Elements of Committee Review Process	N/A		New subsection G requires that the committee chair provide a written report to the head of the institution of any violation that led to either a suspension or termination of human research.
Section 80: Elements of Committee Review Process	N/A		New subsection I requires that the committee ensure compliance with HIPAA and federal and state regulations regarding disclosure of PHI.
Section 80: Elements of Committee Review Process	N/A		New subsection J provides that cooperating institutions conducting research may enter into joint review, rely upon the review of another qualified committee or come to an agreement that will avoid duplication of effort. The section provides details on the content of any such agreements and the approval process.
Section 90: Expedited Review of Human	N/A	Current regulations authorize the committee to conduct an expedited review of a human research	Amends section to add that the research shall involve procedures that are in one or more categories established by the U.S. Secretary of Health and Human Services

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Research Projects		project which involves no more than minimal risk to the subjects.	and published in the Federal Register.
Section 90: Expedited Review of Human Research Projects	N/A		New subsection B clarifies when the expedited review procedure may be used.
Section 90: Expedited Review of Human Research Projects	N/A		New subsection C clarifies that the expedited review may be carried out by the chair or by one or more reviewers designated by the chair. The reviewers may exercise all the authority of the IRB except that they may not disapprove the research. A research project can only be disapproved after review in accordance with 12VAC5-20-80.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for informed consent to participate as a research subject.	Subsection A(1) is amended to add the requirement that information be provided on how the results of the human research will be disseminated, and how the identity of the individual will be protected.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for informed consent to participate as a research subject.	Subsection A(2) is amended to add the requirement that information on side effects, risks and benefits of any appropriate alternative procedures or therapies be disclosed.
Section 100: Informed Consent	N/A		New subsection A(3) requires a description of any adverse consequences and risks to be expected and an indication whether there may be other significant risks not yet identified as an element of informed consent.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for informed consent to participate as a research subject	Subsection A(4) is amended to include that a person may withdraw consent or discontinue participation from the research without fear of reprisal.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for informed consent to participate as a research subject	Subsection A(5) is amended to include in the elements of informed consent information on any medical care that may be available if an injury occurs.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for informed consent to participate as a research subject	Subsection A(6) is amended to include in the elements of informed consent an offer to answer any inquiries (if applicable) from the legally authorized representative and a description of the ways that any concerns may be raised or questions asked.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Section 100: Informed Consent	N/A		A new subsection B clarifies that no human research shall be conducted in the absence of informed consent and clarifies the conditions under which informed consent must be obtained.
Section 100: Informed Consent	N/A		New subsection C clarifies that informed consent shall not include any language through which the individual waives legal rights including any release of any person, institution or agency from liability for negligence. Also, no individual shall be forced to participate in human research if the investigator knows that participation is protested by the individual.
Section 100: Informed Consent	N/A		New subsection D clarifies that a legally authorized representative may not consent to human research unless it will present no more than a minor increase over minimal risk and that no aspect of the research is contrary to the religious beliefs or basic values of the individual.
Section 100: Informed Consent	N/A		New subsection E and subsections E(1)-(4) clarify when the research review committee may approve a consent procedure that does not include or that alters some of the elements of informed consent. These include when the risk is no more than minimal; the alteration will not adversely affect the rights and welfare of the individual; the research cannot be practicably carried out without the omission, wavier or alteration; and the individuals are provided with additional pertinent information after their participation.
Section 100: Informed Consent	N/A		New subsection G provides additional clarification of when the research review committee may waive the requirement for informed consent. This includes if the only record linking the individual and the research would be the consent document and the risk would be potential harm from a breach of confidentiality. In this case, each individual will be asked whether they want documentation linking them with the research and their wishes govern. The committee may require the investigator to provide individuals with a written statement explaining the research.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Section 110: Categories of Human Research Exempt from Regulation	N/A	Current regulations exempt research designed to study large scale anonymous vital records and registry data including the Statewide Alzheimer's Disease and Related Disorders Registry (32.1-71.1) and references section 32.116.1:2 relating to the Emergency Medical Services Patient Care Information System.	Amend subsection 2 to delete "The Alzheimer's Disease and Related Disorders Registry" as Section 32.1-71.1 of the Code of Virginia was repealed in 1994. Section 32.116.1:2 relating to the Emergency Medical Services Patient Care Information System has expired.
Section 120: Committee Records	N/A	Current regulations require that an overview of approved human research projects and the results be made public on the department's website.	Amend subsection C to specify that each research review committee of a state institution or agency shall provide an overview of approved projects and results on their website.
Section 130: Applicability of Federal Policies	N/A	Current regulations require institutions whose human research is subject to federal regulations to notify the commissioner annually that they are exempt from this chapter and they are in compliance with the federal regulations. The commissioner is required to report this information in an annual report to the Governor and the General Assembly by January 31.	Amend Section 130 to change the reporting date from January 31 to March 31 annually.