Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-20 et seq.
Regulation title	Regulations for the Conduct of Human Research
Action title	Amend the Virginia regulations for the Conduct of Human Research for clarity, efficiency and effectiveness
Date this document prepared	April 3, 2013

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

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The proposed 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 conducted pursuant to Executive Order 14, the proposed amendments will: revise 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 the commissioner to report the listing of institutions that are subject to federal regulations regarding human subject research and are exempt from 12 VAC 5-20 et seq.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

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 states that "the State Board of Health shall promulgate 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 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.

To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Virginia Department of Health conducted a periodic review of 12 VAC 5-20 et seq. "Regulations for the Conduct of Human Research" pursuant to Executive Order (EO) 14 (2010). As a result of this review, and in order to help protect the health, safety, and welfare of citizens, the Virginia Department of Health is providing proposed amendments to the regulations. It is necessary to amend these regulations to make corrections to outdated citations, provide consistency in language, and enhance the clarity of the regulations in order to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on users of the Virginia Department of Health's Institutional Review Board, human subject researchers or the public.

Substance

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

The proposed amendments to the regulations include:

1) Updating the definition of "Human Research."
2) Adding a definition of "Subject" or "human subject."
3) Replacing the term "participants" with "subjects" in various sections.

4) Eliminating the detail elements of informed consent in the definition section (12VAC 5-20-10). This information is duplicated in Section 100.
5) Amending the definition of "Legally Authorized Representative" to be consistent with § 32.1-162.16.
6) Add a definition of "Protected Health Information (PHI)".
7) In Section 30, replace the term "human participants" with "human subjects" to be consistent with language used in § 32.1-162.16.
8) 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.
9) In Section 50, the committee reporting requirement is changed from January 31 to March 31st each year.
10) In Sections 50 and 60 the term "chairman" is amended to "chair."
11) Section 70 is amended to require that the committee have at least 5 members instead of at least 7 members.
12) 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.
13) Section 80 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.
14) In Section 80, a new subsection F 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.
15) In Section 80, a new subsection H 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).
16) In Section 80, a new section I 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.
17) Section 90 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.
18) 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.
19) 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.
20) 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantages to the public, the agency and the Commonwealth is that the amended regulations will provide greater clarification on the requirements for human research and clarification on the protection of research subjects.
2) There are no disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters of interest related to this action.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

These regulations are no more restrictive than the federal regulations governing conduct of human research (45 CFR Part 46).

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.

There are no localities that bear any identified disproportionate material impact from these amended regulations.

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 board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board 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 via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Dev Nair, Virginia Department of Health, 109 Governor Street, 10th Floor, Richmond, VA 23219, TEL: (804) 864-7662, EMAIL: Dev.Nair@vdh.virginia.gov, FAX: (804) 864-7380. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	The Board does not anticipate any additional incurred cost to implement or enforce this proposed amended regulation
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	No additional impact on individuals, businesses or other entities.
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.	N/A
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	No additional costs will be incurred related to clarifying the Conduct of Human Research regulations
Beneficial impact the regulation is designed to produce.	Protection of the rights and welfare of participants in any research projects conducted or authorized by the department and any facility operated, funded, or licensed by the department.

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 two alternatives to the present action are to leave the current regulations intact or to make fewer changes to the regulations. However, in reviewing these regulations it has been decided to make all the changes included in this package to provide greater clarity and bring the regulations in line with current practice and the federal regulations.

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.

The regulatory change impacts the operation of the Virginia Department of Health Institutional Review Board, which does not meet the statutory definition of a small business. Therefore, the adverse impact on small businesses does not apply in the development of this regulatory action.

Public comment

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

Commenter	Comment	Agency response
Vinita Johnson	Personnel complaint against state agency (not VDH).	Comment reviewed and found not applicable to this specific regulation.

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 changes do not strengthen or erode the authority or rights of parents in the education, nurturing and supervision of their children; or 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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

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

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
Section 10: Definitions	N/A	Definition of "Human Research"	The definition is amended to be consistent with the §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 "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 qualified to act as a legally authorized representative.
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	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."

Funded or Licensed by the Department			
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 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) 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 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 the HIPAA and federal and state regulations regarding disclosure of PHI.
Section 80: Elements of	N/A		New subsection J provides that cooperating institutions conducting

Committee Review Process			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 Research Projects	N/A	Current regulations authorize the committee to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects.	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 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 an informed consent to participate as a research subject.	Subsection A. 1 is amended to add the requirement that information 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 an 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 that a description of any adverse consequences and risks to be expected and an indication whether there may be other significant risks not yet identified be disclosed as an element of informed consent.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for an 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 an 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 an 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 for the legally authorized representative and a description of the ways that any concerns may be raised or questions asked.
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 subsection E. 1-4 clarifies 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 which 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.
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 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 to change the reporting date from January 31 to March 31 annually.

Following the Board of Health's approval of the proposed revised regulations at their June 6th meeting, the Office of the Attorney General, based on their legal review, recommended the following additional revisions to the draft regulations:

- In Section 10 and Section 100 subsection B and C, change the term "individual" to "person."
- In Section 30, change the term "participants" to subjects".
- In Section 40, subsection D, change the term "will" to "shall".
- In Section 40, subsection E, change the term "individual" to "person, institution or agency".
- In Section 70, subsection E, change the term "may" to "shall".
- In Section 80, subsection A, insert "person" so that the section reads "authorized by a person, institution or agency".
- In Section 100, subsections B and C, change the term "individual" to "person".
- In Section 100, subsection D and E, change the term "individual" to "subject".