Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) 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 regulation for clarity, efficiency and effectiveness following periodic review.
Date this document prepared	July 10, 2012

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.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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, the Virginia Department of Health plans to begin the regulatory process to amend these regulations. It is necessary to amend these regulations to make corrections to outdated citations and to enhance the clarity of the regulations in order to achieve improvements that will be reasonable, prudent and will not impose an unnecessary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 or the public.

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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The current regulations were originally promulgated and effective July 1, 1993 under statutory authority granted by the 1992 Session of the Virginia General Assembly. In 2010, the regulations were amended to make them consistent with changes in the applicable sections of the *Code of Virginia*. The amendments included defining a list of legally authorized representatives that could provide informed consent on behalf of the subject; limits on the legally authorized representatives consent powers, changes in the terminology of competent and not competent to capable and incapable of making an informed decision, and requiring that each human research review committee of a state institution or agency ensure that an overview of approved human research projects and the results of such projects are made public on the institution's or agency's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act. As a result of the Periodic Review, it was noted that the 2010 regulation amendments did not include a revised definition of "human research". Adding this definition and additional details regarding the elements of the committee review process and the informed consent process will provide greater clarity to the regulations and make them consistent with the applicable sections of the Code. 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 46.101 (a). Reducing the number of members will reduce the burden on the state while continuing to provide the protection of human research subjects.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

12VAC5-20-10. Definitions. Amend definition of "Human research" to make consistent with the definition used in §32.1-162.16 of the *Code of Virginia*. Amend definition of "Informed consent" and "Legally authorized representative" to provide increased clarity and add the definition of "Protected health information."

12VAC5-20-40. Policy. Amend this section to clarify who may act as a legally authorized representative.

12VAC5-20-70. Composition of human research review committee. Amend this section to require that each human research review committee have at least five members to make consistent with federal regulations (45 CFR 46.101 (a).

12VAC5-20-80 Elements of committee review process. Amend this section to provide greater detail and clarity on the elements that each review committee shall consider in conducting a review of a proposed human research project. The addition of the elements is consistent with the requirements of §32.1-162.19 of the *Code of Virginia*.

12VAC5-20-90. Expedited review of human research projects. Amend this section to provide clarity on the expedited review process including the committee's authority to suspend or terminate approval of research.

12VAC5-20-100. Informed consent. Amend this section to provide increased clarity in the informed consent process.

12VAC5-20-110. Categories of human research exempt from regulation. Amend this section to eliminate references to repealed Code sections and add a reference to the Virginia Immunization Information System.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The Board of Health, in conjunction with the Virginia Department of Health's Institutional Review Board, will consider alternative requirements and confirm that the proposed amendments to the existing regulations will clarify and simplify current regulations to be less burdensome, while also continuing to fulfill the Board's statutory mandate to protect the citizens of the Commonwealth.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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) the

probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to **Dev Nair, Ph.D., Virginia Department of Health, 109 Governor Street, 10th Floor, Richmond, VA, 23219, TEL: (804) 864-7662, FAX: (804) 864-7380, EMAIL: Dev.Nair@vdh.virginia.gov.** 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 day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action; however, pursuant to the agency's Public Participation Guidelines (12 VAC 5-11), a Regulatory Advisory Panel (RAP) will be appointed to assist in the development of the revised regulations. If you are interested in serving on the panel please contact Dev Nair, Ph.D., Virginia Department of Health, 109 Governor Street, 10th Floor, Richmond, VA, 23219, TEL: (804) 864-7662, FAX: (804) 864-7380, EMAIL: Dev.Nair@vdh.virginia.gov.

Family impact

Assess the potential 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.

Based upon its review and input received from users of the Virginia Department of Health Institutional Review Board and the public, the Board of Health will assess the impact any proposed amendments will have on the institution of the family and family stability. The goals of the Board include developing amendments that will not negatively impact (1) the authority and rights of parents in the education, nurturing, and supervision of their children, (2) the economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents, (3) the marital commitment, and (4) disposal family income.

Periodic review/small business impact review result

If this NOIRA is not the result of a periodic review/small business impact review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic

Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, please include, pursuant to Code of Virginia § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

No comments were received from the public during the recent periodic review.