Virginia Regulatory Town Hall

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Exempt Action Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-20
Regulation title	REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH
Action title	Regulations to be amended to make them consistent with changes made to applicable sections of the Code of Virginia.
Final agency action date	
Document preparation date	January 21, 2010

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 36 (06) and 58 (99).

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Senate Bill 542, effective July 1, 2002, amended Sections 32.1-162.16, 32.1-162.18 and 32.1-162.19 of the Code of Virginia concerning participation in human research. The definition of human research was changed to include research development, testing and evaluation and made the overall definition consistent with federal regulations.

Secondly, should a subject be deemed incapable of making an informed decision concerning participation in human research, the amendment to the Code broadens the list of legally authorized representatives that could provide informed consent on behalf of the subject. The list would include, in priority order, parent(s) of a minor, agents appointed under an advance directive that specifically authorizes research, legal guardians, spouses, children, parents of an adult subject, and adult siblings. However, if two or more persons who qualify as legally

authorized representatives and have equal decision–making priority disagree, the subject would not be enrolled in the study.

Thirdly, a legally authorized representative may not consent to participation on behalf of a prospective subject if he/she knows that it is contrary to the religious beliefs or basic values of the prospective subject. A legally authorized representative may not consent to research involving nontherapeutic sterilization, abortion, psychosurgery or admission to a facility or hospital for the mentally ill or mentally retarded.

Finally, the amendment to the Code changes the terminology of competent and not competent to capable and incapable of making an informed decision, and makes sections of the standards of the human research review committee consistent with other applicable sections of state law.

House Bill 2567, effective July 1, 2007, amended section 32.1-162.19 of the Code of Virginia, relating to human research review committees by 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.

Extant regulations for the conduct of human research are being amended to make them consistent with the above noted changes in the *Code*.

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.

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.

Amendments to the Regulations for the Conduct of Human Research are being made by the Virginia Department of Health to make them consistent with changes in these applicable sections of the Code of Virginia.

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

Although these changes would broaden the list of legally authorized representatives that could provide informed consent on behalf of the subject, they do not erode the authority and rights of parents or discourage the assumption of responsibility for one-self, one's spouse, and one's children and/or elderly parents. In fact, they may strengthen the assumption of responsibility for self because they provide a mechanism to allow for advanced directives.

Additionally, they may strengthen the assumption of responsibility for family members because they are more inclusive of the variety of familial relationships.

Periodic review

If this final regulation is not the result of a periodic review of the regulation, please delete this entire section. If this final regulation is the result of a periodic 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 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

Commenter	Comment	Agency response

No public comments were received.