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Periodic Review and Small Business Impact Findings Where Result is "Retain the Regulation As Is"

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-20
Regulation title	Regulations for the Conduct of Human Research
Date	3/16/18

This information is required pursuant to Executive Order 17 (2014).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including: 1) the most relevant law and/or regulation; and 2) promulgating entity, i.e., agency, board, or person.

Section 32.1-12.1 of the Code of Virginia gives authority to the Virginia Department of Health (Board) to promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 *et seq.*) to carry out 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.

Alternatives

Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

No viable alternatives for achieving the purpose of the existing regulations could be determined. The regulations are administered in the least burdensome method.

Public comment

Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

One comment was received during the public comment period following publication of the periodic review. The commenter advised that the regulations be retained in current form.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

The regulations meet the criteria set out in Executive Order 17 (2014) as they are necessary for the protection of public health, safety and welfare of human research subjects. The regulations are clearly written and understandable.

Result

Please state that the reason why the agency is recommending that the regulation should stay in effect without change.

VDH is recommending the regulations remain in effect without change. The regulations, in their current form, provide for the ongoing conduct of human research.

Small business impact

In order to minimize the economic impact of regulations on small business, please include, pursuant to § 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 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. Also, include a discussion of the basis for the agency’s determination to retain the regulation as is, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

There is a continued need for the regulations, as the conduct of human research is still occurring in the Commonwealth. One public comment was received. The commenter recommended that the regulations be retained in current form. The regulations are clearly written and easily understandable. The regulations do not overlap, duplicate or conflict with any known federal or state law or regulation. Regulations are evaluated on an ongoing basis and these regulations were last amended in January

2016. Retaining the regulations in their current form does not appear to cause an adverse economic impact on small businesses in the Commonwealth of Virginia.