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## Periodic Review Report of Findings

<b>Agency name</b>	Department of Behavioral Health and Developmental Services
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC35-180
<b>Regulation title</b>	Regulations to Assure the Protection of Subjects in Human Research
<b>Date this document prepared</b>	October 9, 2018

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

## Acronyms and Definitions

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

"State Board" means the State Board of Behavioral Health and Developmental Services.

## Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.*

Section 37.2-203 of the Code of Virginia authorizes the State Board to adopt regulations that may be necessary to carry out the provisions of Title 37.2 and other laws of the Commonwealth administered by the commissioner and the department.

### Alternatives

*Please describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.*

There are no viable alternatives to this regulatory proposal. Revision of the existing regulation is the least burdensome alternative. Code of Virginia [§ 37.2-402](#) requires that the State Board adopt regulations regarding human research. The intent of these revisions is to make minor revisions to bring the regulatory language fully in line with current requirements in federal and state code and regulation.

### 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. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

Commenter	Comment	Agency response

1. No comments were received during the review.
2. 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.

### Effectiveness

*Pursuant to § 2.2-4017, please indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.*

As long as the Commonwealth allows human research, there is a continued need for the regulation. No comments were received during the review. The regulation provides a straightforward framework for the conduct of research. The regulation incorporates but does not fully overlap, duplicate, or conflict with federal or state law or regulation. The last period review was in 2009. Since that time, technology, economic conditions, or other factors have had no impact on Virginia’s need for the regulation.

### Decision

*Please explain the basis for the rulemaking entity’s decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).*

The periodic review found that the regulations were reasonable and consistent with the statutory requirements, with some minor revisions needed to better align with state and federal requirements.

This regulation needs to remain in place to ensure the health, safety, and welfare of the individuals involved in human research. Chapter 180 applies to the department and any person, entity, or organization offering services that are licensed, funded, or operated by the department; some of those service providers are small businesses. It also applies to any research review committee, as defined in the chapter, at one of these entities. Updated clarifications in the regulations will be helpful to those in the system using services, those providing services, and entities conducting human research.

### Small Business Impact

*As required by § 2.2-4007.1 E and F of the Code of Virginia, include 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, discuss why the agency's decision, consistent with the stated objectives of applicable law, will minimize the economic impact of regulations on small businesses.*

This regulation needs to remain in place to ensure the health, safety, and welfare of the individuals involved in human research. There is no reason to delay the adoption of these changes by using the standard process; there were no comments received during the public comment period of the periodic review. The structure set out in the regulation is in accordance with other applicable federal and state laws and regulations. It is not legally possible to minimize compliance and reporting requirements. This type of research is rare in the behavioral health and developmental services system, and the framework within which the research can be conducted is narrow. Thus, the impact to the provider is negligible and the edits represent only existing statute or regulation.