



Periodic Review / Retain Regulation Agency Background Document

Agency name	Department of Behavioral and Developmental Services
Virginia Administrative Code (VAC) citation	12 VAC35-180
Regulation title	Human Research Regulations
Document preparation date	4/22/13

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 14 (2010) and 58 (1999).

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.

§37.2-203 outlines the duties and responsibilities of the State Board, which includes promulgation of regulations; §32.1-162 and 37.2-402 requires regulations governing human research; and 12VAC35-115-130 details individual human rights protections related to a provider's human research activities and 12VAC35-115-130 B.2 specifically requires providers to adhere to the provisions of 12VAC35-180.

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.

If the provision of 12VAC35-115-130 B.2. was modified to remove the reference to 12 VAC35-180, the Board could ask the Attorney General to identify additional agency policy and provisions in 12VAC35-115 that would be needed so that the requirements of §32.1-162 and §37.2-402 were addressed in 12VAC35-115 and DBHDS policy. The Board will be considering modifications to 12VAC35-115 at a meeting later in the year.

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.

There were no comments.

Effectiveness

Please 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.

12 VAC35-180 are necessary for the health, safety and welfare of the individuals served in state facilities, or by community providers.

Result

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

At an April 9th meeting, the State Board reviewed the OAG opinions, public comments, and other information resulting from the periodic review of 12 VAC35-180 and determined that the regulations should stay in effect without change.

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 agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

There is little to no impact on small business. These regulations were last modified in 2009 and the federal/state guidelines regarding human research have not changed in the past 4 years. There is a continuing requirement for the regulations.

Family impact

Please provide an analysis of the regulation's impact on the institution of the family and family stability.

12 VAC35-180 protects the rights of individuals receiving services, so there is no adverse impact on the family.