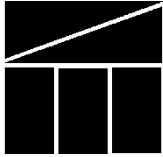


Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes  Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



## Virginia Department of Planning and Budget Economic Impact Analysis

---

**12 VAC 35-180 Regulations to Assure the Protection of Participants in Human Research**  
**Department of Behavioral Health and Developmental Services**  
**Town Hall Action/Stage: 5158 / 8430**  
December 12, 2018

---

### Summary of the Proposed Amendments to Regulation

Pursuant to a periodic review,<sup>1</sup> the State Board of Behavioral Health and Developmental Services (Board) proposes to allow a research subject to withdraw his participation without a loss of benefits to him and to require the research review committee to report termination or suspension of research to the principal investigator, appropriate institutional officers, head of the department or agency, and the commissioner.

### Result of Analysis

The benefits likely exceed the costs for all proposed changes.

### Estimated Economic Impact

The Board proposes to allow a research subject to withdraw his participation without a loss of benefits to him. According to the Department of Behavioral Health and Developmental Services (DBHDS), this is a federal rule and researchers are subject to this requirement if they are receiving federal funding.<sup>2</sup> The intent of this requirement is to make sure the participant is not coerced into being a part of research he no longer wishes to participate. This change may

---

<sup>1</sup> <http://townhall.virginia.gov/ViewPReview.cfm?PRid=1612>

<sup>2</sup> See 45 CFR 46.103(a).

elevate the chances of a researcher losing a subject in their study, but would ensure that participation is voluntary.

The Board also proposes to require the research review committee to report termination or suspension of research to the principal investigator, appropriate institutional officers, the department or agency head, and the commissioner with a statement of the reasons of the committee's action. According to DBHDS, the report would be rather short without creating any significant cost. The report would ensure transparency and help eliminate asymmetric information among the relevant parties.

The remaining proposed amendments are wording changes to improve the clarity of the regulation and are not expected to create any significant economic impact.

### **Businesses and Entities Affected**

The proposed change pertains to 13 DBHDS operated facilities and 1,300 licensed service providers. However, according to DBHDS, research involving human subjects is rare. There have been few applications in the recent past to conduct any such research.

### **Localities Particularly Affected**

The proposed amendment would not disproportionately affect particular localities.

### **Projected Impact on Employment**

The proposed amendment would not affect employment.

### **Effects on the Use and Value of Private Property**

The proposed amendment would not affect the use and value of private property.

### **Real Estate Development Costs**

The proposed amendment would not affect real estate development costs.

### **Small Businesses:**

#### **Definition**

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

### **Costs and Other Effects**

The proposed amendment would not have costs or other effects on small businesses.

### **Alternative Method that Minimizes Adverse Impact**

The proposed amendment would not impose adverse impacts on small businesses.

### **Adverse Impacts:**

#### **Businesses:**

The proposed amendment would not impose adverse impacts on businesses.

#### **Localities:**

The proposed amendment would not adversely affect localities.

#### **Other Entities:**

One of the proposed amendments may elevate the chances of a researcher losing a subject in their study to ensure that participation is voluntary.

### **Legal Mandates**

**General:** The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

**Adverse impacts:** Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.