



## **Economic Impact Analysis Virginia Department of Planning and Budget**

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**12 VAC 5-20 – Regulations for the Conduct of Human Research**  
**Virginia Department of Health**  
September 16, 2013

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### **Summary of the Proposed Amendments to Regulation**

The State Board of Health (Board) proposes to reduce the number of required members on human research committees from seven to five, and make several other clarifying changes to these regulations. These regulations only apply to research either wholly or in part conducted by the Virginia Department of Health (Department), local health departments in the Commonwealth and to any facility operated, funded or licensed by the Department which conducts or which proposes to conduct or authorize research which uses human participants.

### **Result of Analysis**

The benefits likely exceed the costs for all proposed changes.

### **Estimated Economic Impact**

The regulations state that human research activity shall be reviewed and approved by a committee composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities. The current regulations require that the committee shall have at least seven members. The Board proposes to reduce the number of required members to five. Having five committee members is less burdensome and is consistent with federal regulation.<sup>1</sup>

The Board proposes several other changes to the language in these regulations. None of the other proposed amendments introduce any new requirements or changes to current

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<sup>1</sup> Relevant federal regulation: 45 CFR §46.107

requirements that are not either already in federal regulation or Virginia statute. Thus these other proposed changes will have no impact beyond improving clarity.

### **Businesses and Entities Affected**

The proposed amendments affect the Virginia Department of Health, local health departments in the Commonwealth and any facility operated, funded or licensed by the Department which conducts or which proposes to conduct or authorize research which uses human participants.

### **Localities Particularly Affected**

The proposed amendments do not disproportionately affect particular localities.

### **Projected Impact on Employment**

The proposed amendments will not likely affect employment.

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

The proposed amendments are unlikely to significantly affect the use and value of private property.

### **Small Businesses: Costs and Other Effects**

The proposed amendments are unlikely to significantly affect costs for small businesses.

### **Small Businesses: Alternative Method that Minimizes Adverse Impact**

The proposed amendments are unlikely to significantly affect costs for small businesses.

### **Real Estate Development Costs**

The proposed amendments do not affect real estate development costs.

### **Legal Mandate**

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of

persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, Section 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.