



Economic Impact Analysis Virginia Department of Planning and Budget

6 VAC 15-26 – Regulations for Human Subject Research
Department of Corrections
July 15, 2011

Summary of the Proposed Amendments to Regulation

The Board of Corrections proposes to 1) reduce the number of the Human Subject Research Review Committee (HSRRC) members from five to three and 2) require that all research proposals, research agreements, accompanying documentation and reports must be submitted to HSRRC electronically.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

These regulations establish rules for research projects involving the offenders housed by and the employees working for the Virginia Department of Corrections (DOC). These rules apply to any individual, group, or agency conducting research using human participants within the DOC, including any facility, program, or organization owned, operated, funded, or licensed by DOC.

One of the proposed changes will reduce the number of the HSRRC members from five to three. The members of HSRRC do not receive any compensation and perform their duties as a professional courtesy. DOC has had some difficulty finding enough volunteers to serve on this committee. Thus, the proposed changes will reduce the number of members that make up the committee from five to three. While this change is procedurally significant, no significant economic effect is expected.

Another proposed change will require that all research proposals, research agreements, accompanying documentation, and reports must be submitted to HSRRC electronically. DOC

notes that the current state of the communication technology makes it much easier to transfer information electronically compared to 1994 when these regulations were drafted. As a result the Board of Corrections proposes that all documents involving human subject research projects are communicated through electronic means. According to DOC, approximately 15 to 20 research proposals are received per year primarily from students or faculty associated with institutions of higher learning. The provision for electronic submission of research proposal documents is expected to reduce printing, handling, and postage costs that would have otherwise been incurred by the researchers in dealing with the paper copies.

According to DOC, all of the remaining changes merely clarify the practices already followed under these regulations. Since the remaining changes are not expected to affect the way these regulations are currently enforced, no significant economic effect is expected other than improving the clarity of the regulations.

Businesses and Entities Affected

DOC receives approximately 15 to 20 research proposals per year almost all of which are from students or faculty associated with institutions of higher learning.

Localities Particularly Affected

The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment

No significant impact on employment is expected.

Effects on the Use and Value of Private Property

No significant impact on the use and value of private property is expected.

Small Businesses: Costs and Other Effects

The proposed changes do not impose cost or other effects on small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact

The proposed changes do not impose adverse impact on small businesses.

Real Estate Development Costs

No significant impact on real estate development costs is expected.

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.H of the Administrative Process Act and Executive Order Number 107 (09). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, 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 adverse effect on small businesses, Section 2.2-4007.H 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.