Economic Impact Analysis
Virginia Department of Planning and Budget

12 VAC 35-180 – Board of Mental Health, Mental Retardation, and Substance Abuse Services
Regulations to Assure the Protection of Participants in Human Research
February 5, 2003

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G 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. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

The proposed regulations will (i) establish an order of priority for obtaining consent from legally authorized representatives of human research subjects receiving services in the mental health, mental retardation, and substance abuse services system, (ii) require that if two or more persons qualify as the legally authorized representative and have equal priority, then all must provide consent, and (iii) specify the conditions under which the authorized representative may not consent for the prospective subject.

Estimated Economic Impact

These regulations contain rules for research involving human subjects who are receiving services in a facility operated, funded, or licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services (the department). Difficult issues arise when humans are used as subjects in a research. On one hand, research contributes to scientific advancement, which may improve the well being of the subjects or the society as a whole. On the other hand,

the subjects may be exposed to some additional risks in terms of dissemination of confidential information or potential health risks. Thus, protection is afforded to human research subjects through federal and state regulations. The class of research that may have direct health effects on human subjects (e.g. testing a new drug) is regulated by federal agencies such as Food and Drug Administration and is outside the scope of these regulations. According to the department, the types of research subject to these regulations do not pose significant direct health risks.

One of the principles of protecting human subjects is related to autonomy. It requires that subjects should be considered as autonomous agents and persons with limited autonomy are provided special protection. In practice, these goals are accomplished through informed consent process where the risks and benefits of the research are disclosed to the subject or the authorized representative. Another principle related to proposed changes is the beneficence. This principle requires that the benefits should be maximized for the subject while minimizing the possible harm and risks resulting from the research. The proposed changes appear to have the potential to reinforce these two principles.

Although the department proposes numerous changes, most of the proposed requirements are either clarifications of the current requirements, or minor changes. These are not expected have an effect on the current practice, but expected to improve the clarity of the regulations, which could produce some economic benefits in terms of preventing potential misinterpretations.

There are three changes proposed pursuant to changes in the Code of Virginia effective July 2002 that could be significant. One of these changes is the proposal to establish a priority order among the legally authorized representatives of the prospective research subjects. Generally, the proposed order is based on the relationship of the subject to the authorized persons and will give priority to the persons who are more closely related to potential subjects. The goal of the proposed order is to prevent a person with more distant family ties making a decision on research participation while a closer relative is available. The presumption is that a close relative would better protect the interests of the research subject, which may or may not be true in practice. This change will reduce the number of available authorized representatives from whom permission to participate may be obtained and may reduce the chance of obtaining a permission. A reduction in the number of available subjects, in turn, may slightly increase the costs

associated with the research. If close relatives better protect the interests of the subject, there may be some additional benefits depending on the nature of the research.

Furthermore, if there are two or more authorized representatives with the same priority, all of them must approve the participation in the research. Similar to the previous requirement, this may also reduce the number of available subjects, increase research costs slightly, and afford additional protection.

In addition, the proposed regulations will specify the circumstances under which the authorized representative may not give consent for participation in the research. A legally authorized representative will not be able to consent participation in research if the research is contrary to the beliefs of the prospective subject, or the research involves nontherapeutic sterilization, abortion, and psychosurgery. While this change is likely to benefit the prospective subjects by affording additional protection, it may too reduce the number of human subjects who could participate in the research.

In summary, the proposed changes have the potential to provide additional protection for human subjects involved in research, reduce potential risks to them, and may increase the research costs by reducing the number of available human subjects for research.

Businesses and Entities Affected

The proposed regulations apply to facilities operated, funded, or licensed by the department providing mental health, mental retardation, and substance abuse services and institutions/agencies that seek to conduct human research. According to the department, approximately 15 research projects involving human subjects are approved annually. The number of human subjects involved in these projects is not known.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment

The proposed regulations are unlikely to have any significant effect on employment.

Effects on the Use and Value of Private Property

The proposed regulations are not likely to have an effect on the use and value of private property.