Virginia Department of Planning and Budget

Economic Impact Analysis

22 VAC 40-890 Human Subject Research Regulations
Department of Social Services
Town Hall Action/Stage: 6126/9845
January 23, 2023

The Department of Planning and Budget (DPB) 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 19. The analysis presented below represents DPB's best estimate of these economic impacts.[1]

Summary of the Proposed Amendments to Regulation

As the result of a periodic review,[2] the Board of Social Services (Board) seeks to conform this regulation to the Code of Virginia (Code) and the Code of Federal Regulations (CFR), and to make clarifying changes.

Background

This regulation requires that the Department' of Social Services' (DSS) Institutional Review Board (IRB) review and approve any research sponsored by DSS, local departments of social services, DSS-licensed facilities, and DSS-authorized contractors.[3] According to the Code, human research is "any systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized

[1] Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.
[2] See https://townhall.virginia.gov/l/ViewPReview.cfm?PRid=1788.
[3] See https://www.dss.virginia.gov/about/irb.cgi.

knowledge."[4] The objective of this regulation is to "ensure the protection of the rights, welfare, and wellbeing of clients, staff or others who volunteer to participate in research."[5]

Federal regulations for the Protection of Human Subjects (Title 45 CFR Part 46; also known as the Common Rule) were significantly revised in 2018.[6] The Revised Common Rule expanded the types of research that qualify for either an exemption from IRB review or an expedited review, wherein only the IRB Chair or one appointed member reviews the application, on the basis that the research poses minimal risk to human subjects. The Revised Common Rule also eliminated the need for a continuing review for ongoing research initially approved under an expedited review process. Continuing review requirements were also waived for research that had progressed to the data analysis stage, where no further contact with human subjects would be necessary, or where any additional clinical follow-up data could be collected as part of patients' routine follow-up care. Other changes affect IRB reporting requirements and the required minimum number of IRB members."[7]

Besides clarifying changes, updating citations to the Code and the CFR, and reorganizing some provisions, the most substantive proposed changes are summarized as follows:

- Definitions (Section 10): Definitions that would be updated to be consistent with the Code include "facility," "human research," "informed consent," and "legally authorized representative."
- Research exempt from chapter (Section 30): This section would be aligned with federal regulation in 45 CFR 46.104(d) that was updated in 2018 to broaden the categories of research that would be eligible for exemption from IRB review "because they pose no more than minimal risk to subjects" and reduce the burden on the IRB as well as researchers.
- Informed consent (Section 50): An amendment would newly require that the voluntary informed consent must be witnessed. This change would align the regulation with 45CFR46.117. The agency reports that in practice, the IRB and researchers have already been complying with this federal regulation for some time.

[4] See https://law.lis.virginia.gov/vacode/32.1-162.16/
[5] See https://www.dss.virginia.gov/about/irb.cgi.
[6] See https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46.
[7] See page 1 of the Agency Background Document (ABD) here: https://townhall.virginia.gov/l/GetFile.cfm?File=73\6126\9845\AgencyStatement_DSS_9845_v2.pdf.

- Human research review committee (Section 60): The committee composition would be changed to "consist of at least five members" in order to align with 45CFR46.107. Currently, the regulation states the IRB must have at least 7 members.[8]
- Review and approval process (Section 70): A new provision would add to the regulation the circumstances in which continuing review of research is not required. This includes: 1) research eligible for expedited review in accordance with 22VAC40-890-80; or 2) research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: 1) data analysis, including analysis of identifiable private information or identifiable biospecimens, or 2) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
- Expedited review of human research participants (Section 80): New subsections that align with 45CFR46.110 have been added resulting in the addition of new subsections B, C, D and F. Subsections B and C refer to a list of Department of Health and Human Services-approved categories of research that qualify for expedited review.[9] Subsection D states who may conduct the expedited review and what their authority is to disapprove research. Research may only be disapproved under a non-expedited (full board) review. (The IRB has already implemented this provision in practice.) Subsection F states that research where identification of subjects and/or their responses would potentially place them at risk or be damaging to their financial standing, employability, reputation, etc. would only qualify for expedited review if reasonable and appropriate measures are taken to minimize risk of invasion of privacy and breach of confidentiality of data.
- Reporting (Section 90): More detail would be added about the content required to be in a report submitted by a local department, facility or contractor participating in a human subject research project reviewed by another research review committee to the department research review committee by December 1 of each year.

[8] See https://www.dss.virginia.gov/files/about/irb/about/SFY_2022-2024_VDSS_IRB_Members_Roster.pdf. The current IRB has 9 members.
[9] See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html.

Estimated Benefits and Costs

The proposed changes would primarily benefit DSS' IRB and researchers who conduct human subject research or program evaluations involving DSS' clients or client data. In particular, research activities that fall under the now-broadened criteria for exemption and for expedited review could be started sooner. Secondly, research subject to expedited review, along with research that has progressed to the data analysis or follow-up data collection stages, would not be subject to annual (or more frequent) continuing review requirements. These changes would also reduce the administrative burden for the DSS IRB Chairperson and IRB Coordinator. The change reducing the number of required IRB members from seven to five could lower IRB administrative costs but may not have any practical effect since the IRB already has nine members when only seven are required.[10]

Businesses and Other Entities Affected

The proposed changes would primarily affect researchers at public and private universities and research institutions in the Commonwealth who conduct human subject research or program evaluations involving DSS' clients or client data. DSS reports that there are roughly ten research organizations per year that conduct human subject research, authorized by DSS, local departments, or their contractors.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.[11] An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, the new requirements would reduce the requirements for some categories of low-risk research activities, and thus reduce the administrative burden for DSS IRB and researchers. Thus, an adverse impact is not indicated.

[10] DSS may want to maintain more members than are strictly necessary in order to ensure that the IRB adequately represents the needs and interests of DSS' clients.

[11] Pursuant to Code § 2.2-4007.04(D): 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. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

Small Businesses[12] Affected:[13]

Some private universities or research institutions affected by the proposed changes may be small businesses. However, DSS does not collect information on whether the research entities that apply for IRB approval are small businesses.[14] Nonetheless, the proposed amendments would not create new costs for any entities, including any small businesses, and could reduce their costs depending on the type of research they conduct.

Localities[15] Affected[16]

The proposed amendments would not impact localities or local governments.

Projected Impact on Employment

The proposed amendments would not affect total employment.

Effects on the Use and Value of Private Property

The proposed amendment would not affect the value of any private property or real estate development costs.

[12] 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."

[13] 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.

[14] See ABD, page 6.

[15] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[16] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.