

Department of Planning and Budget 2022 Fiscal Impact Statement

1. Bill Number: HB930

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|-----------------|-------------------------------------|--------------|--------------------------|------------|--------------------------|-----------|
| House of Origin | <input checked="" type="checkbox"/> | Introduced | <input type="checkbox"/> | Substitute | <input type="checkbox"/> | Engrossed |
| Second House | <input type="checkbox"/> | In Committee | <input type="checkbox"/> | Substitute | <input type="checkbox"/> | Enrolled |

2. Patron: Robinson

3. Committee: Health, Welfare, and Institutions

4. Title: Human research; research involving minors; requirements.

5. Summary: Establishes additional requirements for human research involving a minor as a human subject, defined in the bill, including requirements related to review of proposed and continuing research by institutional review boards and requirements related to parental consent to human research involving a minor.

6. Budget Amendment Necessary: Yes, general fund support under Items 154, 165, 173, 177, 181, 190, 197, 204, 208, and 225 of HB/SB 30.

7. Fiscal Impact Estimates: Preliminary, see Item 8.

8. Fiscal Implications: A number of Virginia's higher education institutions use Institutional Review Boards (IRB) affiliated with the institution to review all research involving human subjects, including minors. This bill would require human research involving minors to be reviewed by an IRB that is not affiliated with the institution or agency at which the research is proposed to be conducted. The requirement for external IRB review is expected to create an additional cost for a number of Virginia's higher education institutions, as explained below from institutions providing information related to this bill.

- **Virginia Commonwealth University (VCU):** VCU estimates an additional cost of \$979,000 per year for an external IRB to review all research involving minors. This estimate is based on a cost of \$2,400 per external IRB review and 408 studies involving minors that VCU is conducting at this time.
- **University of Virginia (UVA):** UVA estimates an additional cost of \$775,000 per year for an external IRB to review all research involving minors.
- **Virginia Polytechnic Institute and State University (VT):** VT estimates an additional cost of \$368,000 per year for an external IRB to review all research involving minors.

- **The College of William and Mary (W&M):** W&M estimates an additional cost of \$300,000 to \$500,000 per year for an external IRB to review all research involving minors.
- **Old Dominion University (ODU):** ODU estimates an additional cost of \$75,000 per year for an external IRB to review all research involving minors. This estimate assumes an external IRB review cost of \$2,000 per new protocol, \$1,000 per continuing review, and \$500 per amendment. ODU also notes that this estimated cost does not include projects from its college human subjects review committees that approved Category 1 exemptions (standard educational practices in standard educational settings) that involve minors. ODU anticipates an additional cost for such studies, which cannot be determined at this time.
- **Longwood University (LU):** LU indicates an indeterminate fiscal impact at this time.
- **George Mason University (GMU):** GMU estimates an additional cost of \$500,000 per year for an external IRB to review all research involving minors, which includes the cost of such reviews as well as staff support for additional continuous monitoring and expanded website posting requirements.
- **Norfolk State University (NSU):** NSU indicates an indeterminate fiscal impact at this time. To address the federal requirements regarding human research, including research involving minors, NSU has had to purchase and maintain systems at an annual cost to the school. NSU anticipates that that the additional requirements of this bill will result in increased costs, which cannot be determined at this time.
- **University of Mary Washington (UMW):** UMW indicates an indeterminate fiscal impact at this time.
- **University of Virginia's College at Wise (UVA Wise):** UVA Wise estimates an additional cost of \$10,000 per year for an external IRB to review all research involving minors.
- **Richard Bland College (RBC):** RBC does not currently conduct research and will not have an immediate fiscal impact. Any fiscal impact in future years is indeterminate at this time.

Additional institutions of higher education may experience similar fiscal impacts to those noted above.

The Department of Health does not anticipate a fiscal impact as a result of this bill.

9. **Specific Agency or Political Subdivisions Affected:** Department of Health, Virginia Commonwealth University, University of Virginia, Virginia Polytechnic Institute and State University, The College of William and Mary, Old Dominion University, Longwood University, George Mason University, Norfolk State University, University of Mary

Washington, University of Virginia's College at Wise, Richard Bland College, other public institutions of higher education

10. Technical Amendment Necessary: No

11. Other Comments: Several institutions note that this requirement may result in delays in conducting this research, which could increase costs and potentially reduce opportunities to apply for and receive external grant funding.

Also noted, it could be challenging and cost-prohibitive to implement the provisions of this legislation as institutions currently do not have arrangements with any other institutions or agencies for external IRBs. Because part of the IRB approval essentially is a seal of trust that researchers will conduct their research ethically, it is not standard for another institution to offer such a statement on behalf of those who are not their employees or students.

Finally, if the intent of the bill also is to require an independent IRB to review all research conducted by students training to be teachers in K-12 schools, there could be additional challenges as most proposals involving minors in education programs come from graduate students. The process of approving graduate student proposals involves one-on-one interaction and potentially multiple revisions, so that a final document adheres to appropriate guidelines. This interactive process occurs in a timeline consistent with conducting research within a particular course or two. Removing this ability for internal one-on-one interaction could be detrimental to both that timeline and the possibilities for guidance, as well as likely creating a prohibitive cost associated with using an external IRB.