

Department of Legislative Services
 Maryland General Assembly
 1999 Session

FISCAL NOTE

Senate Bill 307 (Senator Frosh)

Judicial Proceedings

The Decisionally Incapacitated Research Subject Protection Act

This bill specifies requirements for research involving “decisionally incapacitated individuals” (DII) or potentially decisionally incapacitated individuals. It provides for a process of informed consent and for the execution of a research advance directive that describes research in which an individual is willing to participate if the individual is or becomes unable to give informed consent. The bill authorizes a “research agent,” “health care agent,” “surrogate,” “proxy decision maker,” or “legally authorized representative” to provide consent for a DII to participate in certain research. It specifies standards for investigators and institutional review boards (IRB) regarding recruitment of DII. The bill requires a review board that approves research involving a DII to submit an annual report to the Department of Health and Mental Hygiene and the Attorney General describing the approved research protocols and level of risk.

Fiscal Summary

State Effect: FY 2000 general fund expenditures increase by \$41,800. Future year expenditures reflect annualization and inflation. Revenues would not be affected.

(in dollars)	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
GF Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditures	41,800	49,900	50,900	51,800	52,800
Net Effect	(\$41,800)	(\$49,900)	(\$50,900)	(\$51,800)	(\$52,800)

Note: () = decrease; GF = general funds; FF = federal funds; SF = special funds; - =indeterminate effect

Local Effect: The criminal penalty provisions of this bill are not expected to significantly affect local finances or operations.

Small Business Effect: None.

Fiscal Analysis

Bill Summary: The bill specifies that research should not be conducted on a DII if it could be done with a subject who provides informed consent. An investigator should seek to use a DII as a research subject only if the research is expected to yield knowledge important to understanding the subject's disorder. An investigator is required to obtain the informed consent of a legally authorized representative, a court, or a guardian before involving a DII in research.

An investigator is prohibited from involving a DII in research unless the research protocol has been approved by an IRB and the investigator conducts the research in conformity with the conditions imposed by the IRB. A researcher planning to involve a DII as a research subject must explain to an IRB (1) why the proposed research cannot be conducted without a DII; (2) the procedure to be followed in monitoring the health and safety of the research subject; and (3) whether consent will be sought from a legally authorized representative of the DII. An IRB is authorized to designate a proxy decision maker, monitor, or medically responsible clinician for research conducted by an institution served by an IRB.

The Office of the Attorney General must prepare a model form of a research advance directive. A research advance directive may be applied only to research that has a reasonable prospect of direct medical benefit to the individual or presents no more than a minimal risk to the individual, as determined by an IRB.

The bill provides for certain immunities, liabilities, disciplinary action, and penalties. The Department of Health and Mental Hygiene (DHMH) is authorized to order the termination of any research involving a DII that endangers the health or safety of a DII. An investigator who knowingly conducts research that has been terminated by an IRB or DHMH is guilty of a misdemeanor and on conviction is subject to a fine of up to \$10,000, imprisonment of up to 12 months, or both. DHMH must periodically study the effect of this bill on the protection of DII.

State Revenues: The criminal penalty provisions of this bill are not expected to significantly affect State revenues.

State Expenditures: DHMH advises that general fund expenditures could increase by an estimated \$35,840 in fiscal 2000, which accounts for the bill's October 1, 1999 effective date. This estimate reflects the cost of hiring one administrative officer to maintain a database of research in Maryland that involves a DII (as reported by IRBs), investigate complaints from the public, investigate whether any research should be terminated, supervise any required termination of research, and periodically prepare a report.

The Department of Legislative Services (DLS) advises, however, that the new administrator position should be contractual until more is known about the extent of research in Maryland that involves DII. Thus, general fund expenditures could increase by an estimated \$31,586 in fiscal 2000, which accounts for the bill's October 1, 1999 effective date. The estimate includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Salaries and Fringe Benefits	\$24,491
Other Operating Expenses	<u>7,095</u>
Total FY 2000 DHMH Expenditures	\$31,586

Future year expenditures reflect (1) full salaries with 2% annual increases; and (2) 1% annual increases in ongoing operating expenses.

The University System of Maryland advises that general fund expenditures could increase by an estimated \$45,980 in fiscal 2000, which accounts for the bill's October 1, 1999 effective date. This estimate reflects the cost of hiring two office clerks to handle the increased documentation, record keeping, and IRB reporting requirements of the bill. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

The Department of Legislative Services (DLS) advises, however, that 0.5 contractual positions should be sufficient until more is known about the extent of the bill's effect on IRB workload. Although the bill provides additional criteria for IRBs to consider, it should not increase the number of research projects that IRBs must review. Thus, general fund expenditures could increase by an estimated \$10,177 in fiscal 2000, which accounts for the bill's effective date. The estimate includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. Future year expenditures reflect (1) full salaries with 2% annual increases; and (2) 1% annual increases in ongoing operating expenses.

The criminal penalty provisions of this bill are not expected to significantly affect State expenditures.

Local Expenditures: The criminal penalty provisions of this bill are not expected to significantly affect local expenditures.

Information Source(s): Department of Health and Mental Hygiene (Community and Public Health Administration, Mental Hygiene Administration), University System of Maryland, Office of the Attorney General, Department of Legislative Services

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