

# Senate OKs bill to tighten rules on human research

## Governor expected to sign legislation

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Moving to restore trust in a system marred by a recent death, the General Assembly gave final approval yesterday to legislation tightening regulations and boosting disclosure for medical experiments involving human subjects.

The Senate passed a bill sponsored by Del. James W. Hubbard of Prince George's County, sending it to Gov. Parris N. Glendening for his expected signature.

"This legislation adds more public accountability, more public confidence and the ability to understand what is transpiring while research is going on," Hubbard said.

Representatives of universities and a technology group said yesterday they agree with the legislation, a scaled-back version of which was approved.

"We've always supported the intent of the bill, and we hope it will maintain and increase public confidence in the research community," said Joanne E. Pollak, vice president and general counsel of [Johns Hopkins Medicine](#).

In June, a volunteer died in a Hopkins asthma experiment, and the death focused fresh attention on the topic of human experimentation. In August, the Maryland Court of Appeals released a decision that criticized a [Kennedy Krieger Institute](#) lead paint study in which two families claimed their children were poisoned.

The new law would apply federal research standards to all human experiments in Maryland, even those conducted by private groups and companies. It also would open records of experiments to public inspection, and allow the attorney general to intervene in tests that don't comply with the law.

University representatives said they typically follow federal standards because they receive funding from the U.S. government.

"The federal requirements mandate that," said T. Sue Gladhill, vice president for legislative affairs for the University System of Maryland. "The bottom line is, you

have to do everything in your power to protect human subjects. And we do that. Patient safety is one of the most important values we possess."

Added Dyan L. Brasington, president of the High Technology Council of Maryland: "If what they are trying to do is close potential loopholes where human subjects would not be covered by federal rules and regulations, clearly we applaud that effort."

Most private companies also follow the federal regulations, Brasington said.

Under the bill, review boards that approve experiments would be required to open their meeting records to public scrutiny - something that universities do not do now.

The measure also would allow the state attorney general to seek court injunctions to block research at private companies that don't follow the federal regulations.

These requirements are particularly important in Maryland, Hubbard said, because the state boasts the nation's third-largest biotechnology industry, behind those in California and Massachusetts.

Sun staff writer Howard Libit contributed to this article.

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