May 2, 2002

The Honorable Parris N. Glendening
Governor of Maryland
State House
Annapolis, Maryland 21401-1991

Dear Governor Glendening:

We have reviewed and hereby approve for constitutionality and legal sufficiency House Bill 917, "Human Subject Research – Institutional Review Boards." In so doing, we have identified two matters of statutory construction that warrant brief discussion.

The first point concerns the relationship between House Bill 917 and the federal regulations on the protection of human subjects. For the reasons that follow, we conclude that, on the one hand, House Bill 917 requires all human subject research in Maryland to be considered as covered by these regulations, despite limitations in the regulations themselves that limit their applicability. On the other hand, House Bill 917 preserves for Maryland researchers the provision of the federal regulations that exempts certain categories of research from the remainder of the regulations.

One objective of the bill, in the words of the title, is to "requir[e] a person conducting human subject research to comply with federal regulations on the protection of human subjects." This objective is accomplished by means of a prohibition on the conduct of human subject research unless the research complies with the federal regulations. § 13-1602(a) of the Health-General Article (page 3, lines 1-3). The bill goes on to provide that the prohibition applies "notwithstanding any provision in the federal regulations on the protection of human subjects that limits the applicability of the federal regulations to certain research ...." § 13-1602(b) (page 3, lines 4-7).

What provision in the federal regulations is referred to by this "notwithstanding" clause? In our view, this clause refers specifically to 45 C.F.R. § 46.101(a), which describes the scope of the core federal regulations on the protection of human subjects. Section 46.101(a) generally limits the applicability of the protective regulations, 45 C.F.R. Part 46, Subpart A, to human subject research that is "conducted, supported, or otherwise subject to [federal] regulation." Conversely, if research is *not* conducted, supported, or otherwise regulated by the federal government, the limited scope of § 46.101(a) means that the regulations are inapplicable to that research. As the National Bioethics Advisory Commission stated last year, "An unknown amount of nonfederally funded research is completely unregulated under the federal system." 1 *Ethical and Policy Issues in Research Involving Human Participants* 12 (2001). It is this regulatory gap that House Bill 917 fills, by imposing the federal regulations on research to which the regulations would otherwise be inapplicable by reason of funding source.[1]

The "notwithstanding" clause in House Bill 917, however, does not negate for Maryland researchers another provision in the federal regulations, 45 C.F.R. § 46.101(b), which identifies certain categories of research that may be deemed exempt from the substantive requirements of the regulations. Unlike § 46.101(a), this provision does not limit the applicability of the federal regulations to certain research; rather, for certain research to which the federal regulations *are* applicable, the provision excuses compliance with requirements elsewhere in the regulations. Therefore, under the applicable federal regulations, a person may conduct research in an exempt category without, for example, obtaining review by an institutional review board. A Maryland researcher likewise may do so under House Bill 917, because such a person is conducting the research "in accordance with the federal regulations on the protection of human subjects" and, consequently, does not violate the prohibition in § 13-1602(a) of the Health-General Article.

Implicit in the federal regulations, and therefore in House Bill 917's mandate for compliance with these regulations, is the requirement that a person have in place a

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[1]The same is true of the federal regulations governing research involving prisoners and children, which under House Bill 917 apply to all such research, regardless of funding source, notwithstanding language in 45 C.F.R. §§ 46.301(a) and 46.401(a), which limits the applicability of 45 C.F.R. Part 46, Subparts C and D, to research that is conducted or supported by the federal Department of Health and Human Services.

reasonable process for determining whether research falls within one of the exempt categories. The principal federal research oversight agency has advised as follows:



> Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. [I]nvestigators should not have the authority to make an independent determination that research involving human subjects is exempt ....[2]

A second point concerns § 13-1603, which provides for disclosure of institutional review board minutes. The basic command of this provision is that minutes be made available for inspection upon request, after redaction of any portions that contain confidential or privileged information. § 13-1603(a) and (b) (page 5, lines 2-7). The provision also states that these minutes "are not public records" under the Maryland Public Information Act. § 13-1603(c) (page 5, lines 8-10). The effect of the latter language is that, when an institutional review board at a governmental unit receives a request for minutes, it is to provide the minutes in accordance with House Bill 917; the exemptions and the various procedural requirements in the Public Information Act are inapplicable.

Very truly yours,

J. Joseph Curran, Jr.
Attorney General

JJCjr/JS/ads
cc: Joseph C. Bryce
Secretary of State
Karl Aro
Hon. James W. Hubbard

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[2]OPRR Report 95-02 (May 5, 1995), available at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc95-02.htm.