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May 17, 2002

Greg Koski, Ph.D., M.D.
Director
Office for Human Research Protections
The Tower Building
1101 Wootten Parkway, Suite 200
Rockville, Maryland 20852

Dear Dr. Koski:

I am writing to inform OHRP of the enactment of legislation in Maryland that may be of interest to you. Effective October 1, 2002, House Bill 917 (copy attached) will:

- apply the requirements of 45 C.F.R. Part 46 (or counterpart FDA regulations) to all research conducted in Maryland, regardless of funding source;

- require institutional review boards to make their minutes (after redaction of any confidential or privileged information) available to any person upon request; and

- empower the Attorney General of Maryland to seek injunctive or other judicial relief "to prevent the conduct of human subject research in violation of the federal regulations on the protection of human subjects or this subtitle" (i.e., the new Maryland law).

This last provision is drafted, however, with the intent that those who are subject to federal oversight of their research will not face redundant investigations or possibly inconsistent findings. Consequently, should the Attorney General's Office receive a

complaint about an alleged violation of federal regulations, we will promptly inform OHRP and, if OHRP asserts jurisdiction, defer to OHRP's judgment whether an investigation is warranted.

I hope that you find this information useful. We in the Attorney General's Office regard this legislation as an important step in protecting research participants and promoting public confidence in the integrity of the research enterprise, and we look forward to cooperating with OHRP in furthering these objectives.

Very truly yours,

Jack Schwartz
Assistant Attorney General
Director, Health Policy Development