

FROM: Joshua M. Sharfstein, M.D.
Commissioner of Health
RE: Research involving Human Subjects
DATE : February 24, 2006

This memo outlines the new policy and procedures for the Health Department's participation in research involving human subjects.

The goal is to ensure that the Department only participates in ethical research that is line with our public health mission.

This new procedure requires two levels of review for each study.

Level 1: Ethical Review by an outside Institutional Review Board

As required by federal law and regulation, all research involving human subjects must be submitted to an Institutional Review Board (IRB). The IRB must then either approve the study or exempt it from review before the research may proceed.

We no longer have our own IRB at the Health Department. As a result, all research must be reviewed by an IRB at an outside institution that has signed an IRB affiliation agreement with the Health Department.

Institutions that have signed affiliation agreements include:

- Johns Hopkins Medical Institutions
- Johns Hopkins School of Public Health
- University of Maryland School of Medicine
- Maryland Department of Health and Mental Hygiene

Question: How do I get started with Level 1 review?

Answer: Once you have received a letter of approval from an outside IRB that has signed an affiliation agreement with the Health Department, you can proceed to the second level of review.

Level 2: Public Health Review in the Health Department

Public health review is not mandated by law or regulation. It has been developed to ensure that all research at the Health Department is consistent with our public health mission.

The public health review will be conducted by the appropriate Assistant Commissioner(s) and the Commissioner, as decided by the Commissioner or his/her designee. An ad hoc committee of experts, community members, and others may be convened to provide advice and guidance for this review.

In most cases, this review will be prompt. There is no requirement for an annual public health review. However, the Health Department may decide to re-review research projects at any time.

Question: **How do I get started with Level 2 review?**

Answer: It is the researcher's responsibility to obtain public health review prior to initiating any research.

Some affiliated outside IRBs will automatically refer a research protocol for a Level 2 review at the Health Department prior to finalizing their approval of the research.

Otherwise, researchers should send an email to Sarah.Norman@baltimorecity.gov with a copy of the protocol and approval letter from the outside IRB attached. You can explain in this email the relevance of the research to public health.

The public health review will then take place. When it is complete, you will receive an email and letter stating whether the project is approved or disapproved.

If the project is approved, the letter will ask that you keep the Health Department informed of any significant changes to the protocol, problems with the research, modifications of the IRB approval, extensions, and termination.

As always, the Health Department reserves the right to cease participation in any research project at any time.

Please do not hesitate to contact Sarah Norman (410-396-7356) or Sarah.Norman@baltimorecity.gov with any questions