



TOPIC: University System of Maryland Policy on Human Subjects Research (IV-2.10)

COMMITTEE: Education Policy and Student Life

DATE OF COMMITTEE MEETING: March 13, 2013

SUMMARY: The current USM Policy on Human Subjects Research requires that institutional review boards (IRBs) be institution-specific IRBs when an institution's faculty are involved in research or research is occurring on a campus. Additionally, when working with outside agencies (e.g., NIH), those agencies require that institutions use their central IRB processes. The proposed amendment will allow campus officials (ethical conduct experts) the opportunity to determine whether they can entrust a central IRB from an outside agency.

The Attorney General's office has approved of the wording of this amendment, and the Council of University System Presidents and the Academic Affairs Advisory Council support this amendment.

ALTERNATIVE(S): The Committee may choose to deny the proposed amendment or may recommend edits to the proposed changes.

FISCAL IMPACT: There is no fiscal impact associated with this amendment.

CHANCELLOR'S RECOMMENDATION: That the Committee on Education Policy and Student Life recommend that the Board of Regents approve the amendment to the University System of Maryland Policy on Human Subjects Research (IV-2.10) allowing designated campus-based ethical conduct experts to determine whether they can trust institutional review boards from outside agencies.

COMMITTEE RECOMMENDATION: Approval DATE: March 13, 2013

BOARD ACTION: DATE:

SUBMITTED BY: Joann A. Boughman 301-445-1992 jboughman@usmd.edu

IV-2.10- UNIVERSITY **SYSTEM** OF MARYLAND POLICY ON HUMAN
SUBJECTS OF RESEARCH Suggested draft changes 2/28/13

Zakiya Lee 2/28/13 10:39 AM

Deleted: SYSTEM

(Approved by the Board of Regents April 25, 1991; Amended by the Board on June 23, 2006; Amended by the Board on December 12, 2008)

The policy of the University System of Maryland is to respect and protect the rights and welfare of individuals. In the conduct of research, actions of the University System of Maryland and its constituent institutions will be guided, to the extent that they are applicable, by principles as set forth in such nationally accepted documents as the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (April 18, 1979). Actions of the University System of Maryland and its constituent institutions will also conform to applicable federal, state, and local laws and regulations.

In accordance with this policy, all University System of Maryland research activities which involve human subjects, regardless of the level of risk foreseen, require review and approval, prior to the initiation of the activity. An Institutional Review Board (IRB) shall have jurisdiction over all reviews and approvals in accord with procedures set forth in recognized documents, e.g. Federal Wide Assurance (**FWA**) and/or applicable regulations and policies including other policies adopted by the System or an institution.

OFFICIALS OF THE SYSTEM OR AN INSTITUTION MAY NOT APPROVE RESEARCH INVOLVING HUMAN SUBJECTS THAT HAS NOT BEEN APPROVED BY AN IRB. HOWEVER, OFFICIALS OF AN INSTITUTION MAY DISAPPROVE RESEARCH THAT HAS BEEN APPROVED BY AN IRB; IRB APPROVAL IS NOT THE ONLY APPROVAL REQUIRED FOR THE CONDUCT OF HUMAN SUBJECTS RESEARCH.

Those research activities in which human subjects may be exposed to more than minimal risk must be reviewed at a convened meeting of an IRB; other research activities may be reviewed in the manner

determined by the IRB under its procedures. An individual is considered to be at more than minimal risk if exposed to the possibility of harm -- physical, psychological, social, legal, or other -- as a consequence of participation as a human subject in any research activity which departs from the performance of routine physical or psychological examinations and tests, or which departs from established and accepted procedures necessary to meet the individual's needs, or which increases the probability or magnitude of risks ordinarily encountered in daily life.

This policy applies to all research activities and to all development, training, and improvement or other related activities containing a research and development component. Furthermore, it applies to any such activity performed on the premises of the University System of Maryland or its constituent institutions and to any such activity performed elsewhere by faculty, students, or employees under University System of Maryland auspices.

To carry out this policy the University System of Maryland institutions will maintain a sufficient number of IRBs with appropriate membership to provide for adequate reviews. The IRBs will have the authority to approve, to require modification as a condition of approval, and to disapprove proposed activities that are covered by this policy. Furthermore, the IRBs will have the authority to determine whether or not any activity is covered by the policy and whether it requires review by an IRB.

An institution may rely upon an external IRB for review and approval of research if (a) the institution's responsible official, identified in its FWA, approves use of the external IRB and (b) the external IRB meets federal standards, as determined by the responsible official.

NO OFFICIAL OF THE SYSTEM OR A CONSTITUENT INSTITUTION SHALL TAKE ANY ACTION INTENDED TO INFLUENCE OR COERCE AN IRB, OR ANY OF ITS MEMBERS, TO APPROVE SPECIFIC RESEARCH.

Replacement for: BOR VII-5.00