

UMCES Policies

IV-2.10-UMCES Policy on Human Subjects in Research

I. Purpose and Applicability

This Policy establishes the framework and process by which the University of Maryland Center for Environmental Science respects and protects the rights and welfare of individuals involved as human subjects in UMCES activities. This policy establishes that in the conduct of research, actions of UMCES 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).

This policy applies to all UMCES research activities which involve human subjects, regardless of the level of risk foreseen, and requires review and approval, prior to the initiation of the activity.

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 UMCES and to any such activity performed elsewhere by UMCES faculty, students, or employees.

Data gathered involving human subjects covered by these regulations that have not been approved may not be used in reports of research results.

II. Research covered by these regulations

Research is defined by the U.S. Department of Health and Human Services as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." (45 CFR 46)

UMCES interpretation of research regarding "classroom activities," such as surveys, interviews, and observations, for example, which involve human subjects and which are designed for students to "learn how to" conduct research and NOT for the purpose of "developing or contributing to generalizable knowledge" (i.e., not used for any future outside-of-class publications or presentations), do not meet the definition of research and, therefore, do not fall under the oversight of the Institutional Review Board (IRB). This interpretation of "classroom activities" does NOT apply to data being collected for undergraduate or graduate theses, dissertations, or other formal research projects. However, if the principal investigator believes that there is even the slightest chance that the collected data will be used in a future research project or presentation, then IRB review should be conducted prior to beginning any aspect of the project. Moreover, this interpretation may not apply if unprotected populations (e.g., children or prisoners) serve as subjects/participants.

Research involving human subjects includes any form and method of information gathering. Project participant evaluations and surveys – in person, via the mail or email or telephone interviews are all covered.

III. Institutional Review Board

An Institutional Review Board (IRB) is a Committee designated by an institution to review, approve the initiation of, and conduct periodic review of research involving human subjects. Research involving human subjects also includes research that is limited to the collection of private information on individuals, i.e. surveys. The primary purpose of an IRB review is to

help assure the protection of the rights and welfare of human subjects. Investigators also share the responsibility for protecting human subjects.

UMCES has an Institutional Review Board Authorization Agreement in place with the University of Maryland, College Park to submit applications for review to their IRB.

The IRB that serves UMCES shall have jurisdiction over all reviews and approvals in accord with procedures set forth in recognized documents, Federal Wide Assurance document, and/or applicable regulations and policies including other policies adopted by the System or the University of Maryland, College Park. 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.

The IRB has 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 IRB has the authority to determine whether or not any activity is covered by the policy and whether it requires review by an IRB.

IV. Exempt Research, Expedited, and Full IRB Review

All non-biomedical scientists are subject to the same regulations as their biomedical colleagues, but the Federal Common Rule gives discretion to institutions and IRBs to match the severity of the review to the potential risk of harm to subjects. IRBs have two forms of reviewing proposals: Full (the entire IRB reviews the proposal) and Expedited (the IRB chair or a designee reviews the proposal for the committee). In addition the Common Rule specifies broad classes of research involving human subjects as Exempt from the policy's oversight. However, all research proposals involving human subjects must be inspected by the IRB, which decides whether the research is Exempt or qualifies for expedited or full-board review. Researchers do not have the authority to make this designation themselves.

V. Procedures

A. Pursuant to this policy, UMCES research involving human subjects requires prior (after the fact or retroactive approvals are not granted) review of applications by an Institutional Review Board (IRB).

B. Unless the sponsor require otherwise, UMCES research proposals involving human subjects may be submitted to the sponsor without IRB approval.

C. Federal funds may not be expended for research involving human subjects until and unless the requirements of the Federal Common Rule (45 CFR 46 - the federal human research subject protection policy, as mandated by the Executive Branch) have been satisfied.

D. Submission steps

1. All UMCES IRB applications must be submitted to the IRB through the UMCES designated Human Subjects Administrator.

2. The Office of Research Administration & Advancement (ORAA) is to act as a facilitator in this process and is to receive and coordinate all UMCES applications with the College Park IRB.

3. IRB application and full copy of research proposal are submitted through their Laboratory or Sea Grant Director's Office to UMCES/ORAA.

4. The approved IRB will come back through ORAA who will distribute to PIs and the appropriate Lab/Unit Business Office.

Approval Date: 2/19/07