

UMCES Compliance in Brief

Human Subjects in Research (IRB)

Federal and USM policies for the protection of human subjects require that UMCES and its employees protect the rights and welfare of human participants in research. To comply with these regulations, all faculty, staff and students who plan to use human participants in research must have prior approval from our Institutional Review Board (IRB).

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 all fall under these regulations.

UMCES' Federal Wide Assurance (FWA) with DHHS Office for Human Research Protections (OHRP) approval number is FWA00017005. The FWA includes an Institutional Review Board Authorization Agreement in place with the University of Maryland, College Park to submit applications for review to their IRB. This IRB 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.

UMCES has a designated Human Protections Administrator on the FWA which means all IRB applications must come through ORAA and be signed off by UMCES before the College Park IRB will review the application.

NOTE: Effective February 15, 2012, all human subjects protocols/applications must be submitted through the web-based site, IRBNet.org. Instructions and tutorials are available on the UMCP/IRB website. When registering in IRBNet you must associate yourself with the University of Maryland College Park because the application is being submitted to the UMCP IRB. Also, when preparing your package, you must share your package with Ginger Steelman, Assistant Director of ORAA, for review and signature before submitting to the UMCP IRB. Contact Ginger Steelman if you have questions.

NOTE: As of February 1, 2010, PIs, Co-PIs and research team members must complete IRB Training before the Initial Application or Renewal Application can be fully approved, or they must be temporarily removed from the research team until the training has been completed.

UMCP IRB website with access to all regulations and forms, including the required training: <http://www.umresearch.umd.edu/RCO/New/index.html>

UMCES Policy on Human Subjects in Research: <http://www.umces.edu/about/policy-IV-2.10>

Q&A: Do I need IRB Approval?

The following scenarios involve human subject work. Test your IRB knowledge!

Scenario 1:

We are the lead on a proposal. We have a subaward to a PI at another institution so the funding agency will fund us directly and we will then disperse the funds through a subaward. Human Subject Research is a component of the research, but the human subject component will be the responsibility of the subaward and completed entirely at their institution. They will submit an IRB through their institutional process.

Scenario 2:

We are a subaward on a proposal. We are a subaward to a PI at another institution so the funding agency will fund them directly and will then disperse the funds to us through a subaward. Human Subject Research is a component of the research, but the human subject component will be the responsibility of the lead and completed entirely at their institution. They will submit an IRB through their institutional process.

Scenario 3:

We are the lead on a proposal. We are submitting collaboratively, that is, the funding agency will fund each collaborative PI/institution directly. Human Subject Research is a component of the research, but the human subject component will be the responsibility of the non-lead collaborator and completed entirely at their institution. They will submit an IRB through their institutional process.

Scenario 4:

We are the non-lead on a proposal. We are submitting collaboratively, that is, the funding agency will fund each collaborative PI/institution directly. Human Subject Research is a component of the research, but the human subject component will be the responsibility of the LEAD collaborator and completed entirely at their institution. They will submit an IRB through their institutional process.

Question: Are we also required to submit an IRB protocol for these types of projects where we are not conducting the human subject research on UMCES' campus, or is the IRB submitted by the institution completing the research all that is required?

Answers:

Scenario 1: If this is federally funded and UMCES as the prime is not conducting human subject research (HSR), we are still considered engaged in HSR. If another institution will provide IRB review, we can enter into an Authorization Agreement with them. If it is not federally funded, obtain a copy of the IRB Approval from the other institution.

Scenario 2: UMCES is not engaged in HSR. No UMCES IRB approval is required.

Scenario 3: If this is federally funded and UMCES as prime is not conducting human subject research (HSR), we are still considered engaged in HSR. If another institution will provide IRB

review, we can enter into an Authorization Agreement with them. If it is not Federally funded, obtain a copy of the IRB Approval from the other institution.

Scenario 4: UMCES is not engaged in human subject research (HSR), therefore, IRB Approval would not be required here. Please obtain a copy of the IRB Approval for your records from the institution that is engaged in HSR.

These scenarios and their answers were vetted with the IRB office at UMD College Park.