University of Maryland Institutional Review Board (IRB) and Maryland Cooperative Extension Program Evaluation Guidelines for Maryland Cooperative Extension Faculty and Staff

When do I need to submit a proposal to the IRB?

All proposed research that involves (1) intervention or interaction with human subjects, (2) the collection of identifiable private data on living individuals and/or (3) data analysis of identifiable private information on living individuals requires review and approval by the IRB ***prior to the initiation*** of the research.

Maryland Cooperative Extension (MCE) has an IRB liaison who is available to explain the overall process and conduct preliminary reviews of IRB applications if there is confusion. The liaison can help with guidance through the IRB approval process and their signature is required to submit an initial application for IRB approval. Your program leader can provide you the name of the current IRB liaison for MCE.

What is considered Research?

Research is defined by the federal regulations as "*a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.*" There is a category of research called "exempt" which means that the research may be reviewed and approved by the Campus IRB manager or assistant IRB manager if the research involves no more than minimal risk to the subjects and the only involvement of human subjects will be in one or more of the exemption categories described at http://www.umresearch.umd.edu/IRB/irb_Exemption%20Categories.htm . Please note that exempt research must not begin until approval is obtained from the campus IRB office.

What is a Human Subject?

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Does Program Evaluation need IRB review?

It depends. See the situations below.

YES - If the evaluation meets either of the following requirements, IRB review is needed:

- The findings are to be published in scholarly publications such peer-reviewed journals with the intent to contribute to generalizable knowledge and the evaluation involved systematic investigation. Not all projects published in peer-reviewed journals or publications meet the Federal definition of research.
- The intent of the evaluation is to develop theory or generate generalizable knowledge and the evaluation involves a systematic investigation.

Generalizable knowledge –Includes one or more of the following concepts:

- The knowledge generated contributes to a theoretical framework of an established body of knowledge.
- Publications, presentations or other distribution of the results is intended to inform the field of study.
- The results are expected to be generalized to a larger population beyond the site of data collection.
- The results are intended to be replicated in other settings.

The term "generalizable knowledge" is used to distinguish the results of research from the results of non-research activities such as "practice" activities. "For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual client or program participant. By contrast, the term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge, as defined previously.

NO- If the evaluation meets the following requirements, IRB review is not needed:

- The primary purpose of the evaluation is to assess the program and not to develop or contribute to generalizable knowledge. In this instance, evaluation is a management tool for monitoring and improving the program. Program evaluation that does not require IRB review must still comply with professional and ethical standards of the University of Maryland Cooperative Extension.
- The information gathered is intended for internal use.
- The information gathered will not be published in places that develop or contribute to generalizable knowledge. Many popular publications that are designed to share program evaluation information with stakeholders, funders, legislators, participants and the general public in venues such as partner reports, annual reports, newspapers, newsletters, fact sheets, brochures, trade publications, popular press, conferences, trainings, and Web sites, may be included in this category.

If at a later date you decide to publish in a scholarly venue because the findings are important and the data you have obtained warrant publication, the campus IRB will not grant retroactive approval for researchers to publish data which was not collected from an IRB approved project.

Grants and IRB Approval?

Many granting agencies now require IRB approval to implement a grant that is funded. The usual process is to submit the grant application through ORAA as usual, and when you receive notification that the grant is funded, you can then submit an initial application for IRB review.

Steps for Submitting an Initial Application for IRB Review?

1) Download the most recent application from the following website: http://www.umresearch.umd.edu/IRB/irb_application%20and%20consent%20form.htm

2) Fill out the face page with your signature (the principal and co-investigator), funding agency, ORAA proposal number (if applicable), and exempt category (if applicable).
3) Attach to the face page text that addresses the 10 sections including issues such as subject selection, procedures, risks and benefits, confidentiality, information and consent forms, conflicts of interest and HIPAA compliance. These are brief and easily done using project information. Finally, you must include all supporting materials such as the survey, consent forms, etc.
    a. For many projects using surveys, it is common to ask for a waiver from the use of consent forms which would negatively impact the success of a survey.
4) Since MCE faculty are located across the state the IRB office has allowed the Initial Application and supporting materials to be submitted electronically. After you complete the materials, send them by Email to the MCE Liaison and that person will check over the packet and help you determine if there are any problems that should be addressed before it is submitted to the Campus IRB office.
5) When the application is ready to be submitted insert your electronic signature on the face page and send it to the MCE Liaison who will then submit their electronic signature and send it to the Campus IRB office and send a copy to the Regional Director, if requested. Any follow-up correspondence from the IRB office is to be handled directly by the principal investigator, not the MCE Liaison.

What is the Turnaround Time for IRB Review?

There are three types of IRB review with different turnaround times:

1) Exempt review – about 3 weeks
    a. This applies to research in one of the six exemption categories and involve no greater than minimal risk. Exempt review means that the application is exempt from further review and approval beyond the IRB manager. This applies to most MCE projects which are different types of surveys sent to clientele, which is **exemption category 2. Exemption category 3** is similar but applies to public officials. The exemption category is noted on the face page. A full explanation of the six exemption categories can be found at: http://www.umresearch.umd.edu/IRB/irb_Exemption%20Categories.htm . The IRB manager will reply to the PI and may ask for some changes.
2) Expedited review – about 4 weeks
    a. This typically applies to research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus groups, etc (Category 7). These projects present no greater than minimal risk and are typically reviewed by an IRB Board member and have reasonably quick turnaround.
3) Full Board review – at least one month
    a. Few MCE projects fall in area that include research involving greater than minimal risk (e.g. clinical trials). The Board is comprised of 15 members with expertise in varying disciplines that review these applications.

What About Projects Involving Youth?

If the project involves “practice” activities commonly used in MCE (that is not research as defined above), then IRB approval is probably not required. However, any “research” that includes surveys

or interviews with children must be submitted to the Campus IRB office and it will not qualify for exemption. Therefore, it will have to go through an expedited or full board review, depending on the activity.

What If I Am Unsure the Project Requires IRB Approval?

The first step would be to contact the MCE Liaison. If a faculty, staff or student is still unsure if a project requires IRB approval and wants an official letter stating whether a project requires IRB approval, they should submit a *'Request for Determination of Non-Human Subject or Non-Research Form'* to the campus IRB manager, Joe Smith at: Office of Research Enhancement and Compliance University of Maryland, College Park Lee Building, Room 2100 Zip 5125 College Park, Maryland 20742-5121
301-405-0678 (voice); 301-314-1475 (fax); Email: jsmith@umresearch.umd.edu
The form may be accessed from the following website address:
http://www.umresearch.umd.edu/IRB/irb_application%20and%20consent%20form.htm
For further clarification, please contact your program leader for the name of the current MCE IRB Liaison.

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