
Michigan State University Institutional Review Board (IRB) and Michigan State University Extension Program Evaluation Guidelines for Michigan State University Extension Faculty and Staff

Federal and university regulations require that an institutional review board (IRB) must review and approve all research projects involving human subjects and materials of human origin before research can begin.

Program evaluation is becoming increasingly important to Michigan State University Extension work. Our funders, collaborators and audiences expect us to be able to share data about our programs with them. At Extension Conference in fall 2004, in fact, MSU Extension educators were challenged to conduct at least one formal program evaluation a year by Margaret Bethel, who was then the director of MSU Extension.

Because we work with people, our program evaluation efforts fall under federal and MSU regulations governing research involving human subjects. As we work to gather data on our programs, we must comply with these regulations, which are designed to protect the rights and welfare of human subjects.

Federal and university regulations require that an institutional review board (IRB) must review and approve all research projects involving human subjects and materials of human origin before research can begin. Therefore all such research that is conducted by any representative of Michigan State University – whether student, faculty or staff member – in connection with the researcher’s institutional responsibilities must have prior approval from MSU’s IRB. This fact sheet presents IRB requirements for program evaluation in Extension and explains criteria as a guide to deciding when to seek IRB approval.

Who Can Apply for IRB Approval?

MSU Extension staff who are regular faculty or fixed-term employees with the rank of assistant professor or higher may apply directly to the IRB to be responsible investigators (serve as sole or co-project responsible investigators). MSU Extension staff who **are not** regular faculty or **are not** fixed-term employees with the rank of assistant professor or higher must have special IRB approval to apply to be a responsible investigator. This approval is valid for a three-year period. MSU Extension staff in the second category should have their dean and chair or director send a letter to Peter Vasilenko, (by e-mail to ucribs@msu.edu or by U.S. mail to IRB, Michigan State University, 202 Olds Hall, East Lansing, MI 48824) requesting special approval for the applicant to serve as a responsible investigator for research projects. A copy of the applicant’s current CV (curriculum vitae) must be included with the request. Such applications have been usually approved for MSU Extension program leaders and can be renewed annually. All investigators who seek IRB approval of their research must complete the IRB tutorial before submitting an application. For more information see: http://www.humanresearch.msu.edu/training/training_index.htm.

These guidelines were developed by Peter Vasilenko, Ph.D., Chair, Michigan State University Institutional Review Boards, and Diane Ruonavaara, Ph.D., Michigan State University Extension.

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Deciding Whether Program Evaluation Requires UCRIBS Approval

Program evaluation **does** need IRB approval if it meets either of the following requirements:

- The intent of the evaluation is to develop theory or generate generalizable knowledge.
- The findings are to be published in scholarly publications or scholarly presentations.

Program evaluation **does not** need IRB approval if it meets **all** of the following requirements:

- The primary purpose of the evaluation is to assess the program. In this instance, evaluation is a management

tool for monitoring and improving the program.

- The information gathered is intended for internal use.
- The information gathered will not be published or will be published only in popular publications or media for public relations purposes and there is no intent to publish in scholarly publications or scholarly presentations.
- Data is presented as de-identified and aggregated descriptive data.

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, you **must** seek IRB approval for use of “existing data” collected during the program evaluation. Program evalua-

tion that does not require IRB approval must still comply with professional and ethical standards of Michigan State University Extension.

To obtain IRB forms see

<http://www.humanresearch.msu.edu/>.

At times it may be difficult to determine whether IRB review is necessary or not. For further clarification, please contact:

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University Committee on Research

Involving Human Subjects
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Phone: 517-355-2180

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Supporting Definition of Terms

De-identified and Aggregate Descriptive Data – De-identified data is data that has no names or other information that can be used to identify the individual associated with the data that has been collected. Aggregate descriptive data is combined data about general characteristics of the population being evaluated (that is, demographics) and impact data. For example, 7% of participants live in rural areas and 80% of participants indicated that they intend to use the Food Guide Pyramid to plan more balanced meals.

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

- The knowledge generated contributes to a theoretical framework of an established body of knowledge
- The primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study
- Publications, presentations or other distribution of the results is intended to inform the field of study or are intended for professional purposes
- 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 setting
- Web-based publications for scholarly purposes

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 patient, 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. Generalizable knowledge is usually created to share with other people, such as through scholarly presentations and publications.

Human subject – A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through investigation or interaction with the individual or 2) identifiable private information. In some cases, if there is no identifiable human subject to be protected (de-identified data); there may be no need for IRB review.

Popular publications – Popular publications are those designed to share program evaluation information with stakeholders, funders, legislators, participants and the general public in popular venues such as partner reports, annual reports, newspapers, newsletters, brochures and Web sites.

Program evaluation – The systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program, improve program effectiveness or inform decisions about future programming (Patton 1975.)

Research – A systematic investigation that is designed to develop or contribute to generalizable knowledge. Research can include testing and evaluation.

Scholarly publications – Scholarly publications are those that are published in research reports or peer-reviewed journals (whether in printed form or on the Web) or presented at academic conferences.

Decision Tree for MSU Extension Staff Deciding Whether to Seek IRB Approval

