Guidelines for Research: Determining if Institutional Review Board (IRB) Approval is Necessary

Excerpt taken from *Introduction to Human Subjects Research Protection: A Guide for Student Investigators*. Full text version can be found at http://www.irb.umich.edu/studentguide.pdf

Chapter 3- How do I know if I am conducting human subjects research?

Research projects meeting the regulatory definition of research with human subjects require either review and approval by an IRB, or a determination that the research is exempt. Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB.

The first question that must be considered is whether a project fits the regulatory definition of *research*, and if so, whether it also involves *human subjects*.

Is it research?

The federal regulations define *research* as "a **systematic investigation**, including development, testing, and evaluation, designed to develop or **contribute to generalizable knowledge**" (45 CFR 46.102(d)).

- A **systematic investigation** is an activity designed to test a hypothesis and to permit conclusions to be drawn. The research is described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.

- **Generalizable knowledge** is information expressed in theories, principles, and statements of relationships that can be widely applied. A plan to publish findings or present at a professional meeting generally, but not always, indicates an intention to contribute to generalizable knowledge.

- **Research** generally does not include activities such as the practice of public health, medicine, counseling, or social work. Studies for internal management purposes such as program evaluation, quality assurance, or quality improvement are not research because the intent is not to draw conclusions beyond the activity or program being studied. See: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html for more information.

- **A note about class activities –** Class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight because the intent is to teach methods, not to contribute to generalizable knowledge. For more information on this topic, see the UM Policy on Class Activities at http://www.hrpp.umich.edu/classroomresearch.html.

Questions? Contact Dr. Thomas Powell, SSW Institutional Review Board Member, at tpowell@umich.edu

When class activities are designed to collect data to be used by students beyond the classroom, for example for scholarly publication or use for future research, it is the responsibility of faculty advisor to assist students in obtaining IRB approval or exemption prior to the initiation of a human subjects research project.

- **A note about student internships –**Students within many units of the university are involved in internships or practica. Some student practica/internships may include research activities that are designed to contribute to generalizable knowledge and, thus, involve research that requires IRB review. Contact the IRB for assistance with determining whether your internship activities require IRB oversight.

- See also: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html for more information.

Does my project involve human subjects?

The federal regulations define a *human subject* as "a **living** individual **about whom** an investigator conducting research obtains (1) **data through intervention or interaction** with the individual or (2) **identifiable private information**" (45 CFR 46.102(f)(1)(2)).

- **"Living individual"** refers to data (information or specimens) collected from living subjects. For example, research using data from the 1880 Census would not be human subjects research. **"About whom"** refers to the fact that the information collected must be personal information about an individual. For example, a survey that collects data about the activities of an organization is not human subjects research.

- **"Intervention"** includes physical procedures, manipulations of the subject or the subject's environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.

- **"Interaction" r**efers to communication between the investigator and the subject. This includes face-to face, mail, internet and phone interactions, as well as other modes of communication.

- **"Individually identifiable"** means the identity of the subject is or may be readily ascertained by the investigator or others. Research with a de-identified data set is not research with human subjects because the data are not individually identifiable.

- **"Private information"** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

What if I'm not sure if my project involves research with human subjects?

The IRB staff can help you determine if your project involves research with human subjects. UM has identified a number of project types that are "not regulated" and therefore, do not require review by the IRB as human subjects research:

secondary analysis of publicly available data sets or other de-identified data sets that have been stripped of all identifiable information; case studies; class activities/research methods classes; journalism/documentary activities; quality assurance/quality improvement/program evaluation activities; oral history; research on organizations; and standard public health surveillance or prevention activities

- More information on these project types can be found in the UM Human Research Protection Program Operations Manual, Part IV (http://research-compliance.umich.edu/operations-manual-part-4).

Do I need to submit an application if my project does not involve research with human subjects?

An IRB application is not required for most types of "not regulated" research. If you would like a formal "not regulated" determination from the IRB, or if you are not sure if your project requires review, you can submit a brief application via eResearch, the web-based IRB application system (see Chapter 4 for more about eResearch). For some categories of research, eResearch allows investigators to use this process to self-generate a determination letter. You may also send this application to the IRB staff for review and determination. The IRB staff will issue a "not regulated" determination or will advise the investigator that the project does involve human subjects research and will recommend the submission of an exempt or standard application type via eResearch.

For additional resources for the conduct of international human subjects research, visit http://www.hrpp.umich.edu/policies/international.html.

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