

Michigan State University Human Research Protection Program	
<i>Subject:</i> Determination of Human Subject Research	
<i>Section:</i> 4-3	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by:</i> MSU Legal Counsel	<i>Approved by:</i> Vice President of Research and Graduate Studies, 4-21-2005
<i>Related Sections:</i> 4-1, 4-3-A, 4-3-B, 4-3-C, 4-3-D, 4-3-E, 6-9-A, 8-1	

Policy

The Institutional Review Board (IRB) staff and/or IRB chair determines whether an activity meets the definition of human subject research based on Federal regulatory definitions, 45 CFR 46.102(d), 21 CFR 50, or 21 CFR 56. The investigator does not make the determination.

Procedures

Investigators should contact the IRB chair or staff with any questions regarding whether an activity constitutes research and/or clinical investigation involving human subjects. The investigators will be asked by the IRB staff to send a description of the activity by email. The IRB staff, based on the definitions below, will determine whether the project is research or involves human subjects for cases in which the determination is obvious (e.g., student conducting interviews for a dissertation, etc.).

For cases in which the determination is difficult, the IRB staff will ask the investigator to email the IRB a description of the activity. The IRB chair may contact the investigator for additional information as needed. The IRB chair will make the determination based on the definitions below and send an email to the investigator with the determination. The determination will include an explanation of whether the activity requires submission to the IRB. The determination should be made within three to ten days of receipt of the question. Determination in cases where additional information is needed from the investigator may take additional time.

The determinations will be documented using the following method: any correspondence will be printed out or documented and will be kept in a file for a minimum of three years. At a minimum, the correspondence should include the description from the investigator and the IRB staff or the IRB chair's response.

See the following sections of the HRP Manual for policies and procedures on specific activities:

- 4-3-A Use of Commercially Available Human Cell Lines
- 4-3-B Use of Human Cadaver Tissues or Cells
- 4-3-C Use of Human Tissues from Commercial Sources or Tissue Banks
- 4-3-D Public Use Data Files

- 4-3-E Clinical Case Reports

Definitions and Evaluation Criteria: Department of Health and Human Services

When an activity meets the definition of “research” and uses “human subjects” as defined below, the DHHS regulations regarding the protection of human subjects apply.

1. The IRB chair or staff will first consider whether the activity involves research.

“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” 45 CFR 46.102(d)

Evaluation Criteria: The IRB chair or staff will evaluate whether the activity is a “systematic investigation” and whether it is “designed to develop or contribute to generalizable knowledge”.

To be considered a “systematic investigation”, the concept of a research project must:

- Attempt to answer research questions (in some research, this would be a hypothesis).
- Is methodologically driven, that is, it collects data or information in an organized and consistent way.
- The data or information is analyzed in some way, be it quantitative or qualitative data.
- Conclusions are drawn from the results.

Generalizable knowledge is knowledge that is “expressed in theories, principles, and statements of relationships” that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications. Masters’ theses and Ph.D. dissertations are considered to present generalizable knowledge.

“Generalizable knowledge” would include one or more of the following concepts:

- The knowledge 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.
- Publication, presentation 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.
- Web based publication for professional purposes.

2. If the activity is determined to be research, the IRB chair or staff will then determine if the research involves “human subjects”.

“**Human subject** is defined as a living individual(s) 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.” 45 CFR 46.102(f)

“**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.” 45 CFR 46.102(f)

“**Interaction** includes communication or interpersonal contact between investigator and subject.” 45 CFR 46.102(f)

“**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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.” 45 CFR 46.102(f)

Definitions: Food and Drug Administration

When an activity meets the definitions of clinical investigation and human subject provided below, the FDA’s regulations regarding the protection of human subjects also apply (e.g. 21 CFR 50, 21 CFR 56).

“**Clinical investigation** means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.” 21 CFR 56.102(c)

“**Test article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act” (42 U.S.C. 262 and 263b-263n). 21 CFR 50.3(j)

“**Human subject** means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.” 21 CFR 50.3(g)