Title/Subject: **HUMAN SUBJECT RESEARCH**

Applies to: ☒ faculty ☒ staff ☒ students ☒ student employees ☐ visitors ☐ contractors

Effective Date of This Revision: April 9, 2024

Contact for More Information: Institutional Review Board, Office of Research Compliance

☐ Board Policy ☒ Administrative Policy ☐ Procedure ☒ Guideline

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BACKGROUND:

Central Michigan University (CMU) has provided a formal guarantee (Federal Wide Assurance, FWA 00000755) to the Department of Health and Human Services (DHHS) that it will follow mandated procedures to assure the protection of all human subjects involved in research projects.

CMU has opted to limit the application of the FWA to research funded by DHHS or federal agencies that have adopted the Common Rule (45 CFR 46, Part A). CMU reserves the right to apply "equivalent protections" to research that is not funded or otherwise subject to oversight by a Common Rule agency.

To comply with the DHHS regulations for the Protection of Human Subjects at 45 CFR 46 and the Federal Drug Administration (FDA) regulations for the Protection of Human Subjects at 21 CFR 50 and 56, CMU has established an Institutional Review Board (IRB) to review all research involving the use of human subjects and to implement institutional policy regarding such research. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human subjects. The IRB, composed of faculty and staff from a variety of disciplines plus non-university members, is directly responsible to the Vice President for Research and Innovation.

PURPOSE:

All research involving the use of human subjects conducted by CMU faculty, staff or students, or sponsored in part or in whole by CMU, must be reviewed and approved prior to the start of the project and then conducted in full compliance with the IRB/Human Research Protection Program (IRB/HRPP) policies and procedures.

DEFINITIONS:

Research shall mean a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. (DHHS, Code of Federal Regulations, 45, CFR 46.102(l)).

Human Subject shall mean a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or

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Authority: Robert O. Davies, President
History: 2011-07-01; 2019-07-01
Indexed as: Institutional Review Board; IRB; Research – Human Subject

analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (DHHS, Code of Federal Regulations, 45 CFR 46.102 (e)(1)).

POLICY:

The University is guided by the ethical principles regarding all research involving human subjects as set forth in the report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The Nuremberg Code, and the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

It is the responsibility of the individual investigator to ensure that appropriate ethical principles are adhered to in the conduct of research involving human subjects. The investigator is responsible for the ethical treatment, and prevention of negligent treatment, of research subjects by collaborators, assistants, students, or employees who are assisting in the research of the investigator, as well as his or her own behavior.

The primary ethical principles which must be considered in all research involving human subjects include:

1. *Maintaining subject autonomy*
2. *Maintaining the safety of the subject*
3. *Promoting benefit to the subjects and larger community*
4. *Conducting research in a fair and equitable manner*
5. *Honoring commitments made to subjects in a study*
6. *Maintaining and facilitating excellence in Human Subjects Research*

PROCEDURE:

CMU's Vice President for Research and Innovation will have overall responsibility under this Policy for CMU's IRB/Human Subjects Research Protection Program. Those duties are as follows:

1. Be responsible for compliance with all CMU policies and all applicable regulations for the protection of Human Subjects
2. Be the Signatory authority for the Federal Wide Assurance to the Office of Human Research Protections
3. Provide support to the Human Subjects Research Protection Program within the means of CMU

In the performance of these duties, the Vice President for Research and Innovation has the authority to delegate such activities as may be necessary in order to fulfill these duties.

To conduct its responsibility effectively, CMU maintains an Institutional Review Board (IRB) to review research protocols involving human subjects. The IRB is an autonomous body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under CMU auspices.

Each IRB Committee is composed of a minimum of 5 voting members nominated by the Vice President for Research and Innovation: 3 (or more) members of the university faculty and/or staff, at least one non-university member (who may not be part of the immediate family of a person who is affiliated with Central Michigan University), and at least one person with a non-scientific background.

The IRB has the following authority:

1. To approve, require modifications to secure approval, defer, or reject all research activities overseen and conducted by CMU, regardless of the location of these activities;
2. To suspend or terminate approval of research not being conducted in accordance with the IRB/HRPP policies and procedures or that has been associated with unexpected serious harm to participants;

3. To observe, or have a third party observe, the consent process; and
4. To observe, or have a third party observe, the conduct of the research.

Studies approved by the IRB at a convened meeting are subject to ongoing IRB full board review, at least yearly. The IRB may determine an expedited eligible study reviewed at a convened meeting can have future reviews done by a designated single IRB member. At the discretion of the IRB, some studies approved by expedited procedures may also be subject to annual review. If IRB approval lapses, all research activity must stop. The investigator may petition the IRB to continue an individual participant's research intervention/interaction during a period of lapsed IRB approval if the investigator believes that there is a safety concern or ethical issue such that it is in the best interest of the individual participant to do so.

The IRB has jurisdiction over all human subject research conducted under the auspices of CMU, regardless of funding source or performance site. Research conducted under the auspices of CMU includes research:

1. Conducted at CMU;
2. Conducted by or under the direction of any CMU employee or agent (including students) in connection with his or her institutional responsibilities;
3. Conducted by or under the direction of any CMU employee or agent (including students) using any property or facility of CMU; or
4. Involving the use of any CMU non-public information.

No research involving human subjects may commence until all institutional approvals (including from the IRB) are obtained.

CMU may review any research protocol and reserves the right to disallow that research to be conducted if, in the opinion of CMU, said research exposes the CMU enterprise to undue risk. CMU may not, however, override an IRB disapproval determination.

The Vice President for Research and Innovation and the IRB shall adopt a series of IRB/ HRPP policies and procedures to implement this Policy. These IRB/HRPP policies shall serve as the governing procedures for the conduct and review of all CMU's human subject research.