OM 6.5.0 Research Involving Human Subjects

1. Definitions

Research is defined as the planned and organized generation of data, whether or not there is a plan for publication or dissemination. Human subjects are involved whenever data about individuals or groups are generated by planned or organized activities, or results from post hoc examination of records that contain information about individuals or groups.

The term "human subject" shall apply to any living individual about whom an investigator (whether professional or student) conducting research obtains certain information: (1) data acquired through intervention or interaction with one or more human subjects, (2) data acquired through studies involving human tissue or biological specimens (e.g., blood), or (3) identifiable private information about one or more human subjects, regardless of the subjects' affiliation (or lack of affiliation) with Clarkson University.

2. Ethical Policy

Since Clarkson is a recipient of federal funds for human subjects research, Clarkson’s IRB is regulated by the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (DHHS) and the University is required to maintain a Federalwide Assurance (FWA) of Compliance with the DHHS. The DOR is responsible for maintaining Clarkson University’s FWA. According to the terms of Clarkson’s Federalwide Assurance (FWA), “All of the Institution’s human subjects research activities, regardless of whether the research is subject to Federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the "Common Rule."

3. Roles and Responsibilities

Per Federal requirements, the Principal Investigator (PI) is responsible for maintaining compliance with University policies and procedures and Federal rules and regulations pertaining to human subjects research, whether it is conducted by faculty, staff, assistants, students, or any other research collaborator.

The Division of Research is responsible for supporting the PIs and IRB by:

a. Maintaining the University’s Federal-Wide Assurance (FWA),
b. Maintaining compliance of University activities with the FWA,
c. Providing oversight of the Institutional Review Board (IRB),
d. Providing training for PIs and IRB members regarding University policies and procedures, and Federal rules and regulations with respect to human subjects research,
e. Maintaining a web page regarding IRB procedures and University and Federal policies and procedures on human subjects research, and
f. Apprising all researchers involved in Human Subjects Research of any changes with administrative or regulatory requirements.

The Institutional Review Board (IRB) is responsible for reviewing all proposed human subjects research prior to its initiation as mandated by Federal regulations and University procedures.

4. Institutional Review Board (IRB)
The University maintains an IRB with the mandate of protecting the rights and welfare of humans who participate in research. IRB membership is comprised of a minimum of five voting members (See Section 2.10.2.III.D for more information).


All human subjects research activities initially must be reviewed and approved or exempted by the IRB as indicated in this Section 6.5.3.

5. Review Criteria & Procedures

Researchers conducting research involving human subjects must consult the DOR website for current procedures concerning such research. It is the responsibility of the Principal Investigator (PI) to ensure compliance with University policies and procedures pertaining to research involving human subjects, whether it is conducted by faculty, staff, assistants, students, or any other research collaborator.

All research involving human subjects initially must be reviewed and approved by the IRB. The requirement for a full IRB review may be waived but only when certain exemptions permitted by Federal rules and regulations apply. The IRB must be consulted when determining whether an exemption is appropriate for a given circumstance. IRB applications for review of research proposals and for possible exemption from a full IRB review may be obtained in electronic form by download from the DOR website or by contacting the DOR directly.

Additional information about IRB procedures is available on the IRB web page. See Section 2.10.2.III.D and Section 6.4.3.III.A of this Operations Manual for further information.

History

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