Investigator Responsibilities for Exempt Research

Investigator Responsibilities for Exempt Research assists MIT investigators in the conduct of human subject research. These guidelines ensure human subject research is conducted within MIT and COUHES policies and is required for all human subject research conducted under the auspices of MIT.

Review the following guidance carefully and affirm your research complies with all applicable policies. MIT investigators involved in the conduct of human subject research, including the Principal Investigator and Faculty Sponsor, must adhere to these standards throughout the course of the project. The Principal Investigator and Faculty Sponsor are responsible for oversite of all members of the research team review and compliance with these policies.

Research procedures must correspond with responses within the Exempt Evaluation. If the scope or procedures of the research undergo significant alterations, consider repeating the Exempt Evaluation to reaffirm exempt status.

Any deviation or violation of the Investigator Responsibilities for Exempt Research or alterations from the study as described in the Exempt Evaluation Questionnaire must be reported to the COUHES office for further review.

All human subject research conducted under the auspices of MIT is subject to audit by the COUHES office.

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Requirements

The policies outlined below are required for human subject research conducted under the auspices of MIT that has been granted exempt status as determined by the Exempt Evaluation. Any deviation from these policies constitutes a violation in the conduct of human subject research and may results in one or more of the following:

- Immediate suspension of the research and related grants.
- Suspension of all research related activities or grants.
- Further disciplinary actions.

Investigators can contact the COUHES office for guidance or clarification.

Human Subject Training

All personnel involved in human subject research must complete a human subject training course before embarking on research related activities. This requirement extends to all of the following: Principal Investigators, Faculty Sponsor, associate investigators, student investigators, visiting scientists, consultants, laboratory technicians and assistants.

Training is required for all those involved in any of the following activities:

- Direct contact (e.g. conducting interviews with subjects),
- Indirect involvement (e.g. analyzing survey results), and
- Analysis of data or biospecimens (e.g. analysis of previously collected skin samples).

In addition, investigators are required to undergo recertification every three years.

For more information, visit the https://couhes.mit.edu/training-research-involving-human-subjects.

Faculty Sponsor

Research led by students or investigators without PI Status requires oversite by a Faculty Sponsor.

Faculty Sponsor responsibilities include:

1. Oversite of all research related activities.
2. Knowledgeable of the rules and regulations governing human subject research.
3. Evaluating if the investigators have sufficient knowledge and experience to conduct the propose research.
4. Ensuring the research activities are conducted within the scope of the submitted Exempt Evaluation.
5. Monitoring the progress of the research.
6. Addressing any concerns or issues and conduct follow-up, as necessary.
7. Reporting any adverse events to COUHES.
8. Providing ongoing supervision of the study.

Belmont Principles

In 1979, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research released the Belmont Report, a document that provides the ethical framework for the federal regulations in the protection human research subjects. MIT investigators engaged in the conduct of Human Subject Research must adhere to the guidelines outlined in the Belmont Report and maintain those principles throughout the research.

The Belmont Principles are outlined in the CITI Training course for subject research and more information through the Office of Human Research Protection (OHRP), visit the https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

Informed Consent

Informed consent is required for research activities that involve an interaction between an investigator and a participant. The informed consent must contain the following elements:

- Basic overview of the research and purpose
- Statement that participation is voluntary;
- Subjects may decline to answer any or all questions and may decline further participation, at any time, without adverse consequences and
- Confidentiality and/or anonymity are assured or disclosure of the participant's responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

If your research involves a benign behavioral intervention and requires deception, participants must prospectively agree to the deception, and participants will be debriefed upon the completion of the research activities and allowed to withdraw their data.

Reporting - Adverse Events and Unanticipated Problems

Serious or unexpected adverse reactions or injuries and/or unanticipated problems experienced by subjects or others from their participation in a human subject research must be reported to COUHES within 48 hours. All other adverse events or protocol deviations to COUHES within 10 working days.

Changes or Revisions to the Research Study

Any change or revision to the research study that may affect or alter responses to the Exempt Evaluation or risk associated with the study require recertification of exempt status. This includes changes in experimental design, study procedures or addition of new subject populations.

Data Security

Human subject research data can oftentimes contain sensitive information. A breach of confidentiality possess a serious risk to individuals involved in your research. You are responsible to take the appropriate measures to ensure the safety and security of all research data. Visit MIT's IS&T website to for more information on better securing your data and hardware, https://ist.mit.edu/.

Guidance

For best human subject research practices, you are encouraged to review each point in this section and determine the best methods necessary to implement these points in your research. None of the aspects listed below are required for the conduct of exempt research, though encouraged, and are not subject to audit.

Elements of Informed Consent

Investigators should carefully review all aspects of participation in their study and create an appropriate outline to inform potential subjects of these aspects prior to their participation. The elements of consent, as outlined on http://couhes.mit.edu/informed-consent, are to help ensure participants are fully informed of the research activities prior to their participation.

Recruitment

Recruitment material should include some or all of the following:

- Participant is voluntary
- This is an MIT research project
- Purpose of the study
- Contact information
- Expected length of involvement

Recruitment should not be coercive or mislead subjects to the nature of the research.

Resources

For more information, visit the COUHES website: http://couhes.mit.edu/

Common Rule, 45 CFR 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (2018 Requirements)

Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html