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 in which MIT is involved is subject to audit by the COUHES office.

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Requirements

The policies outlined below are required for human subject research conducted by MIT investigators 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.

Exempt Evaluations that have not been approved (Not submitted, pending Princpal Investigator approval, pending Faculty Sponsor aapproval or pending COUHES approval) for more than a year are automatically deleted and considered un-approved research. All exmept research must be determined exempt prior to starting human subject involvement.

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 re-certification every three years.

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

The Principal Investigator and Faculty Sponsor must manage the status of all personnel involved in their exempt research in COUHES Connect, such as adding and removing personnel. Principal Investigator and Faculty Sponsor are responsible for ensuring that all study personnel are trained, and that any person whose training has lapsed no longer participates in the research and is removed as study personnel.

For studies with a sponsored award as a funding source, the Principal Investigator and Faculty Sponsor are responsible to review and approve all changes to the Research Team tab in COUHES Connect. Others managing the tab on behalf of the Principal Investigator and Faculty Sponsor are responsible for ensuring the PI and Faculty Sponsor has approved any changes made to this section.

Investigators involved in human subject research must maintain their training throughout their engagement in the research. Principal investigators and faculty sponsors have a responsibility to ensure that all study personnel maintain their training until the research is complete.

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 proposed 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 Reportable New Information (such as adverse events or subject compliants) to COUHES.
8. Providing ongoing supervision of the study.
9. Review and approve all changes to the Research Team tab. Others managing the tab on behalf of the Faculty Sponsor are responsible for ensuring the Faculty Sponsor has approved any changes made to this section.

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.

Investigator must review COUHES' Policy on Recruitment of Participants with Pre-Existing Relationships when the study population includes MIT students and individuals with pre-existing relationships with the investigator or PI.

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:

- **Overview** - Basic overview of the research and purpose. Include a statement that the project is conducted for MIT research.
- **Voluntary** - Statement that participation is voluntary and that subjects may decline to answer any or all questions and may decline further participation, at anytime, without adverse consequences.
- **Risk and Benefits** – Describe both the potential benefits of the research and any possible risks to participants, such as survey questions may make subjects feel uncomfortable.
- **Confidentiality and Privacy** – 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 de-identified data may be shared with other reserachers or for other research purposes, include statement explain the limits and use of data.
- **Contact Information** – Include contact information for the investigators and COUHES' so participants know who to reach out to with questions or concerns.

COUHES Contact Information: *You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a study participant you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.*

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.

Collecting personal data from participants residing in the EEA (European Union) requires additional research protections known as the GDPR (General Data Protection Regulation). Specific language included in the consent form templates is required. This language must specify what type of data is being collected, (e.g. racial or ethnic origin; political opinions; religious or philosophical beliefs; trade union membership; processing of genetic data; biometric data; health data; and/or sex life or sexual orientation information).

More information regarding GDPR (General Data Protection Regulation) is available on the COUHES website: https://couhes.mit.edu/guidelines/general-data-protection-regulation-gdpr-and-research-activities

Reporting - Adverse Events and Unanticipated Problems

Reportable New Information, such as 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 events must be reported 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 re-certification of exempt status and must be resubmit as a new Exempt Evaluation. 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/.

On November 1, 2021, China enacted a new data privacy law, the Personal Information Protection Law (PIPL). The new law affects how data can be collected from research subjects in China. If your research involves collecting information from subjects in China, contact COUHES as soon as possible regarding compliance with a new China Privacy Law.

End Date and Closure

Investigators must include an end date for the research specifying the date that the research will be completed. The end date must be maintained accurately in COUHES Connect throughout the study. Studies will automatically close after the end date and no human subject research can continue under this protocol. Before the study closes, investigators can extend the end date by following the guidance on our website: https://couhes.mit.edu/couhes-connect-resources/couhes-connect-guidance. Email reminders are sent to PI , faculty sponsor and the person who created the protocol prior to the closure date for those investigators to update the exempt evaluation.

Once the exempt research is complete, investigators are expected to close their study in COUHES Connect.

Investigators can contact COUHES directly if they need further assistance after a study is automatically closed after the end date: COUHES@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