

**Massachusetts Institute of Technology**
Committee on the Use of
Humans as Experimental Subjects

COUHES

**Reliance**

**Request #**

*(internal use only)*

**Reliance Request Form (Relying IRB)**

*Complete this form when MIT is serving as the relying IRB. The relying institution will cede IRB review to an outside organization only when the institution has a Federal Wide Assurance (FWA) and COUHES has conducted a review of the outside IRB approved documents.*

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| I. GENERAL INFORMATION |
| 1. Title of Study*Title must match any existing reliance requests.*  |
|       |
| 2. Overall Principal Investigator*Overall Principal Investigator for the reliance request. MIT investigator should not be the overall* *Principal Investigator when MIT is the relying institution.*  |
| Name:       | Email:       |
| 3. Proposed Reviewing IRB*Indicate below who will serve as the IRB of record for the reliance agreement.* |
| 1. Reviewing IRB:

 IRB Point of Contact (if available):       Email:       |
| B. Indicate if the Reviewing IRB has approved the protocol:[ ]  Yes (include a copy of the approval letter, protocol and approved consent form(s)).  If yes, what risk level did the IRB assign to the protocol:      [ ]  Pending review, expected approval date:       |

**II. FUNDING**

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| **1. Indicate if study is Federally Funded and if MIT is the lead institution.** For Federally Funded research, the IRB of record should be identified in the proposal or by the funding agency. |
| [ ]  Study is Federally funded and MIT is the lead institution on the grant/award. [ ]  Study is Federally funded and MIT is NOT lead institution on the grant/award. [ ]  Study is not Federally funded.  |
| **2.** **Funding Source***Do not leave this section blank. If your project is not funded, check No Funding.* |
| A. Sponsored Project Funding: |
| [ ]  Current Proposal Grant/Proposal #       Sponsor       Title       [ ]  Current Award Grant/Account #       Sponsor      Title        |
| [ ]  Gift [ ]  Departmental Resources  [ ]  Other (explain)      [ ]  No Funding |
| **3. MIT Statement of Financial Interest** |
| A. Does the investigator, study personnel, or their Family have a financial interest in a company or other organization involved in this study?[ ]  Yes [ ]  NoB. Could the work contemplated in this project reasonably appear to affect a company or other organization in which the investigator, study personnel, or their Family have a financial interest? [ ]  Yes [ ]  No C. Does this study contemplate:i. Receiving or using any data (e.g., proprietary data sets, data sets, confidential information) from a company or other entity organization in which the investigator, study personnel, or their Family have a financial interest [ ]  Yes [ ]  Noii. Receiving or using any materials (e.g., drugs, devices, biological agents, investigational medical devices) from a company or other entity organization in which the investigator, study personnel, or their Family have a financial interest [ ]  Yes [ ]  Noiii. Granting subawards to a company or other entity organization in which the investigator, study personnel, or their Family have a financial interest [ ]  Yes [ ]  Noiv. Making purchases from a company or other entity organization in which the investigator, study personnel, or their Family have a financial interest [ ]  Yes [ ]  NoIf ‘yes’ was checked for any of the questions above, then attach a Supplement for Disclosure of Financial Interest for each individual with an interest. This supplement and detailed guidance are available on the COUHES website under Policies & Procedures in the [Financial Conflicts of Interest](https://couhes.mit.edu/policies-procedures/financial-conflicts-interest) section. |

**II. STUDY INFORMATION**

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| **1. Study Description** *Provide a brief summary study activities and reason for the proposed study. Use non-technical language that can be understood by non-scientists.*  |
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#### III. MIT SITE INFORMATION

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| 1. MIT Principal Investigator*MIT Principal Investigator must have PI Status as determine by MIT Policy:* [*http://couhes.mit.edu/definitions#Principal%20investigator*](http://couhes.mit.edu/definitions#Principal%20investigator) |
| Name:       | Email:       |
| Title:       |
| 2. MIT Point of Contact |
| Name:       | Email:       |
| Title:       |
| 3. Indicate the status of your reliance request:  |
| **Reliance Type** |  **Complete appropriate section based off the selected Reliance Type** |
| [ ]  Smart IRB: #       |  | [ ]  **SECTION B** |
| [ ]  Institutional Review Board (IRB) Authorization Agreement (IAA). If available, include a copy with your submission.\* | [ ]  **SECTION A** | [ ]  **SECTION B** |
| [ ]  Not yet submitted.\*  | [ ]  **SECTION A** | [ ]  **SECTION B** |
| *\* COUHES will follow-up with the Point of Contact on the request.* |

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| **SECTION A****Site Specific Information***This section is not required for reliance submissions through SMARTIRB.* |
| **1. MIT Study Description***Provide a brief summary of MIT role’s in the proposed study.*  |
|       |
| **2. Type of Research Interaction with Participants at MIT**  |
| [ ]  Medical Records Review [ ]  Obtaining Informed Consent [ ]  Direct Subject Interactions [ ]  Recruitment [ ]  No activities at this site.  |
| **3. Indicate types of data that will be received or analyzed by MIT** |
| [ ]  Identifiable [ ]  Anonymized (data was collected without identifiers) [ ]  Coded/De-identified but MIT does not have access to the key linking subjects to the data [ ]  Coded/De-identified but MIT does have access to the key linking subjects to the data [ ]  Data are not being received or analyzed by MIT [ ]  Other:       |
| **4. Data/Specimen use at MIT** *Indicate use of data or specimens by MIT investigators.*  |
| [ ]  Analysis [ ]  Collection [ ]  Creation of Repository [ ]  Banking [ ]  Other:       |
| **5. Ancillary Reviews at MIT***Please describe any Ancillary Reviews required at MIT, including: EHS, Radiation Protection Program, Biosafety or International Coordinating Committee (High Risk Committee).* |
| A. Have all the MIT Ancillary Reviews been reviewed and approved? [ ]  Yes [ ]  No [ ]  N/AIf no, please explain:       |
| **6. Required Documentation** |
| A. In addition to this form, please include the following documents with your Reliance Request Form: [ ]  Reviewing IRB Approval Letter [ ]  Approved Consent Form [ ]  Any additional documentation that may assist during the review process.  |

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| **SECTION B***Required for ALL reliance requests.*  |
| **1. Injury Statement** |
| A. If participant interactions occur on MIT campus, consent form must include the **EMERGENCY CARE AND COMPENSATION FOR INJURY** in the COUHES consent forms. [ ]  No interactions at MIT [ ]  Participant interactions occur on campus and consent language has been updated.  |
| **2. Certification** |
| **I certify the information provided in this application is complete and correct.****I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by COUHES****I agree to comply with all MIT policies, as well all federal, state and local laws on the protection of human subjects in research, including:*** **ensuring all study personnel satisfactorily complete human subjects training;**
* **performing the study according to the approved protocol;**
* **implementing no changes in the approved study without COUHES approval;**
* **obtaining informed consent from subjects using only the currently approved consent form;**
* **protecting identifiable health information, to the extent required by law, in accordance with HIPAA requirements; and**
* **promptly reporting significant or untoward adverse effects.**
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**Signature of MIT Principal Investigator Date**

**Print Full Name and Title**

**Signature of Department Head Date**

**Print Full Name and Title**

**By signing this form, you confirm a scientific review of the proposed research has been conducted and that the proposed research is of scientific and scholarly validity.**

**Please submit this form and additional documentation by email to COUHES at** **COUHES@mit.edu****.**

**PERSONNEL LIST**

*Personnel is defined as anyone that plays a role in research involving human subjects, including direct contact, indirect involvement, analysis of data, blood or tissue samples. This extends to principal investigators, associate investigators, student investigators, study coordinators, visiting scientists, consultants, laboratory technicians and assistants.*

*All study personnel* ***must be listed*** *below. This listing must include contact information, a brief statement of qualifications and their study role.*

*Important note: all study personnel are required to complete* [*Human Subject Training*](https://couhes.mit.edu/education-and-training/training-research-involving-human-subjects) *before work begins on the project.*

**I. MIT AFFILIATES**

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| *Personnel name and e-mail address* | *Briefly describe qualifications*  | *Study role(s)* | *Obtaining consent* |
| Name:      Email:       |       |       | [ ]  |
| Name:      Email:       |       |       | [ ]  |
| Name:      Email:       |       |       | [ ]  |
| Name:      Email:       |       |       | [ ]  |
| Name:      Email:       |       |       | [ ]  |
| Name:      Email:       |       |       | [ ]  |
| Name:      Email:       |       |       | [ ]  |