

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

COUHES

**COUHES Protocol #**

**Reliance Request Form (Reviewing IRB)**

*Complete this form when MIT is serving as the reviewing IRB. The reviewing institution will serve as the IRB of record for the study. This form is required for EACH institution requesting MIT serve as the IRB of record.*

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| I. GENERAL INFORMATION |
| 1. Title of Study*Title must match the COUHES protocol.*  |
|       |
| 2. MIT Principal Investigator |
| Name:       | Email:       |
| Title:       |
| 3. MIT Point of Contact |
| Name:       | Email:       |
| Title:       |

**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.  |

**III. 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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#### IV. OUTSIDE SITE INFORMATION

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| 1. Site Lead Investigator*All site-specific investigators must be listed on the COUHES Comprehensive Review Application under the Non-MIT Affiliates section of Personnel List. See:* [*http://couhes.mit.edu/forms-templates*](http://couhes.mit.edu/forms-templates) |
| Name:       | Email:       |
| Title:       |
| 2. 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 MIT 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. Site Study Description**Provide a brief summary of this site’s role in the proposed study.  |
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| **2. Research activities at outside site** |
| [ ]  Medical Records Review [ ]  Obtaining Informed Consent [ ]  Subject Interactions [ ]  Recruitment [ ]  No activities at this site.  |
| **3. Indicate types of data that will be received or analyzed by outside site** |
| [ ]  Identifiable [ ]  Anonymized (data was collected without identifiers) [ ]  Coded/De-identified but this relying site does not have access to the key linking subjects to the data [ ]  Coded/De-identified but this relying site does have access to the key linking subjects to the data [ ]  Data are not being received or analyzed by this relying site [ ]  Other:       |
| **4. Data/Specimen use at outside site***Indicate use of data or specimens by outside investigators.* |
| [ ]  Analysis [ ]  Collection [ ]  Creation of Repository [ ]  Banking [ ]  Other:       |

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| **Section B****Site IRB Specific Information***This section is required for all Reliance Requests. The site-specific IRB must complete and sign off before submission to COUHES.* |
| **VI. SITE SPECIFIC INFORMATION** |
| **1. Site Context***Please indicate below if there are any site-specific requirements per the site IRB, institution policy, state or otherwise required by this site.**A site IRB representative must complete the information below.* |
| A. Are there any state laws that the Reviewing IRB will need to consider when reviewing this study?[ ]  Yes [ ]  No If yes, describe the specific requirements:      B. Are there any community or cultural differences for the local population of subjects that require consideration?[ ]  Yes [ ]  No If yes, please describe:       |
| C. Does the site have a posted policy or institution policies that apply to this research (such as age of assent policy, consent process for those with impaired decision-making capacity, use of short forms for non-English speaking individuals, or translation of consent forms for non-English speaking individuals)?[ ]  Yes [ ]  No If yes, please describe the site-specific policy and provide a link to the policy:       |
| D. Please describe any institutionally-required consent form language for: Compensation in the event of research related injury:      Pregnancy testing in minors:      Genetic testing:      Site policy or state law:        |
| E. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site?[ ]  Yes [ ]  No If yes, please explain:      |
| **VI. Ancillary Reviews** |
| A. Have all the Ancillary Reviews (i.e. Scientific, Institutional Biosafety Committee, Radiation, Chemical and environmental, EHS, etc.) required by the outside site been reviewed and approved? [ ]  Yes [ ]  No [ ]  N/AIf no, please explain:      If data involves the collection of PHI as defined by HIPAA, please acknowledge COUHES will not serve as the Privacy Board for the external site and the site investigator will ensure HIPAA requirements are met prior to conducting the research. [ ]  I acknowledge. [ ]  N/A |
| **1.**  **Outside Conflicts of Interests (COI)** |
| A. Has a Conflict of Interest been identified for any investigators at this local site? [ ]  Yes [ ]  No If yes, describe the Conflict of Interest and include a copy of the COI management plan:       |

**To be complete by site IRB only**

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| **Site IRB Only***IRB representative completing section B of this form must review and sign before submission to COUHES.* |
| IRB Representative completing this form:      | Email:       |
| Signature:  | Date:       |

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