

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

COUHES

**COUHES Protocol #**

# Local Context Form for Relying Site

*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 to serve as the IRB of record.*

*Upload a copy of this form with your reliance request.*

## I. GENERAL INFORMATION

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| 1. Title of Study*Title must match the COUHES protocol. Include the COUHES Protocol number at the top of this form.*  |
|       |
| 2. MIT Principal Investigator |
| Name:       | Email:       |
| Title:       |
| 3. MIT Point of Contact |
| Name:       | Email:       |
| Title:       |
| **4. Relying Site**  |
| Relying Site Institution:       |
| **5. Relying Site PI**  |
| Name:       | Email:       |
| Title:       |

## II. SITE INFORMATION

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| **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.****A site IRB representative must complete the information below.*** |
| **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.**As the IRB of Record, MIT policies and procedures will be followed in the conduct of this study (https://couhes.mit.edu/policies-procedures). If the Relying Site IRB requires the use of any institution policies, procedures, or guidance include please indicate 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:      |
| F. Are there other considerations that are not readily apparent from the research protocol or from other documents submitted to the IRB that are specific to this site (not this may include funding requirements)?[ ]  Yes [ ]  No If yes, please explain:      |
| **2. Human Subject Training** |
| A. Do all individuals at the institution who are involved in this protocol have the appropriate credentials and/or qualifications, including human subject training, and meet the institution’s standards for eligibility to conduct research? [ ]  Yes [ ]  No If available, please share your human subject training policy:        |
| **3. 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 |
| **4.**  **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:       |
| **5. SMARTIRB Indemnification**  |
| 1. MIT requires an indemnification agreement for research deemed to be greater than minimal risk. Please select one of the following:

[ ]  Relying Institution has signed the SMARTIRB Identification Addendum.[ ]  Relying institution requires application of the SMARTIRB Indemnification Addendum for this study[ ]  Relying institutions does NOT require application of the SMARTIRB Indemnification Addendum for this study[ ]  Relying institution has NOT signed the SMARITRB Indemnification Addendum.   |

## To be completed 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:       |