

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

COUHES

**COUHES Protocol #**

Application for Comprehensive review

*Please complete all questions and provide sufficient detail. Indicate ‘N/A’ if a question does not pertain to your research. An incomplete application will be rejected and returned for completion.*

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| **I. BASIC INFORMATION** |
| **1. Title of Study** |
|       |
| **2. Principal Investigator** |
| Name:       | Building and Room #:      |
| Title:       | Email:       |
| Department:       | Phone:       |
| **3.** **Funding** *If the research is funded by an outside sponsor, please enclose one copy of the research proposal with your application. A draft of the research proposal is acceptable.* *Do not leave this section blank. If your project is not funded, check No Funding in section C.*  |
| A. Sponsored Project Funding: |
| [ ]  Current Proposal Grant/Proposal #       Sponsor       Title       [ ]  Current Award Grant/Account #       Sponsor      Title        |
| B. Institutional Funding: |
| [ ]  Gift [ ]  Departmental Resources  [ ]  Other (explain)        |
| C. No Funding |
| [ ]  This protocol will not be funded |
| **4. 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. |
| **5. Anticipated Dates of Research**  |
| Start Date:       | Completion Date:       |
| **6. Collaborating Institutions** *If you are collaborating with another institution(s), then you must obtain approval from that institution’s institutional review board (IRB) and forward the approval to COUHES.*   |
|       |
| **7. Location of Research** *If on the MIT campus, indicate where on campus. If you plan to use the facilities of the Clinical Research Center you will need to obtain approval of the MIT Clinical Research Center.* |
|       |
| **8. International** *Research conducted outside the United States may be subject to additional requirements.*  |
| A. Are you collecting or receiving identifiable data from subjects within the European Union (EU), European Economic Area (EEA), and/or United Kingdom (UK)?  [ ]  Yes [ ]  NoB. Is the project in, related to, or funded by a person or entity from China (including Hong Kong), Russia or Saudi Arabia? [ ]  Yes [ ]  No*If yes, additional review and approval is required. Please see Additional Review for additional**information.* |

**II. STUDY INFORMATION**

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| **1. Purpose of Study** *Provide a concise statement of the background, nature and reasons for the proposed study. Use non-technical language that can be understood by non-scientists.* |
|       |
| **2. Study Plan** *This section determines if the study plan meets the Federal definition of a clinical trial. COUHES will assist with any additional requirements based on the responses below. For more information available on COUHES website for Clinical Trials:* [*http://couhes.mit.edu/clinical-trials-mit*](http://couhes.mit.edu/clinical-trials-mit) |
| 1. Are the participants prospectively assigned to an intervention?

[ ]  Yes [ ]  No |
| 1. Is the study designed to evaluate the effect of the intervention on the participants?

[ ]  Yes [ ]  No |
| 1. Is the effect being evaluated a health-related biomedical or behavioral outcome?

[ ]  Yes [ ]  No |
| **3. Experimental Procedures***Provide an outline of your experimental procedures with a detailed description of your proposed study. When applicable, include copies of any questionnaires or standardized tests.* *Do not attach or copy sections of a grant application.**When applicable, include a detailed description of the experimental devices or procedures, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of any special diets.**Provide sufficient information for effective review by non-scientists. Define all abbreviations and use simple words. This section should not exceed 5 pages unless justification is provided for additional length.* |
|       |
| **4. Drugs and Devices** *If the research involves the administration of a novel drug not approved by the Food and Drug Administration (FDA) for the use outlined in the protocol, then the principal investigator (or sponsor) must obtain an Investigational New Drug (IND) approval from the FDA. If the study involves the use of an approved drug in an unapproved way, the investigator (or sponsor) must submit an application for an IND approval. If applicable, include a copy of the IND approval (new drug) or application (new use).**If the study involves the use of a novel medical device and the device poses significant risk to human subjects, the investigator (or sponsor) must obtain an Investigational Device Exemption (IDE) approval from the FDA.* *COUHES may determine an IDE or IND is appropriate during review.* |
| A. Will drugs or biological agents requiring an IND be used? [ ]  Yes [ ]  No*If yes, please provide details:*       |
| B. Will an investigational medical device be used?[ ]  Yes [ ]  No*If yes, please provide details:*       |
| **5. Radiation***Research involving the use of radiation or radioactive materials may require review from MIT’s Environment, Health, and Safety (EHS) Office. COUHES may determine EHS review is appropriate.* |
| A. Will radiation or radioactive materials be used? [ ]  Yes [ ]  No*If yes, please provide details:*       |
| B. Will any type of lasers be used? [ ]  Yes [ ]  No*If yes, please provide details:*       |
| **6. Diets** |
| A. Will special diets be used? [ ]  Yes [ ]  No*If yes, please provide details:*       |

**III. PERSONNEL**

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| **Fill out the personnel list at the end of this form.**  |

**IV. HUMAN SUBJECTS**

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| **1. Subjects** *The number of subjects must corresponded with the maximum number of subjects investigators will consent for the study.*  |

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| --- | --- |
| 1. Maximum number of subjects:

Adults:      Minors:       | 1. Specify age range(s):

Adults:      Minors:       |
| C. Inclusion and exclusion criteria: i. What are the criteria for inclusion or exclusion?      ii. Are any inclusion or exclusion criteria based on age, gender, or race/ethnic origin? (*Investigator must explain why and provide justification.)*     iii. Explain the inclusion of any vulnerable population(s) (e.g. children, cognitively impaired persons, educationally disadvantaged persons, non-English speakers, MIT students) and why.      |
| **2. Subject Recruitment** *Identification and recruitment of subjects must be ethically, legally acceptable, and free of coercion. Describe below what methods will be used to identify and recruit subjects. Include copies of recruitment documents (i.e. flyers, e-mails, advertisements, etc.).* |
|       |
| **3. Informed Consent** *Informed consent is required from all human subject research studies involving participants. Templates are available on the COUHES website under Forms & Templates* (<https://couhes.mit.edu/forms-templates>). *Under* ***very limited*** *circumstances, COUHES may waive the elements or requirement for informed consent. If you are requesting a* ***waiver or alteration of consent****, include the Waiver or Alteration of Informed Consent Request form.* |
| **Attach informed consent form(s) with this application.** |
| **4. Subject Compensation** *Payment must be reasonable in relation to the time and trouble associated with participating in the study. It cannot constitute an undue inducement to participate.* |
| A. Describe all plans to pay subjects in cash or other form of payment:      |
| B. Will subjects be reimbursed for travel and expenses?      |
| **5. Potential Risks** *A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g., appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.* |
| A. What are the risks/discomforts associated with each intervention or procedure in the study?      |
| B. What procedures will be in place to prevent/minimize potential risks or discomfort?      |
| **6. Potential Benefits** |
| A. What potential benefits may subjects receive from participating in the study?      |
| B. What potential benefits can society expect from the study?      |
| **7. Data Collection, Storage, and Confidentiality** |
| A. How will data be collected?      |
| B. Is there audio or videotaping? [ ]  Yes [ ]  No*Explain the procedures you plan to follow:*      |
| C. Will data be associated with personal identifiers or will it be coded?[ ]  Personal Identifiers [ ]  Coded *Explain the procedures you plan to follow.*      |
| D. Where will the data be stored and how will it be secured?      |
| E. What will happen to the data when the study is completed?      |
| F. Can data acquired in the study affect a subject’s relationship with other individuals (e.g. employee-supervisor, patient — physician, student-teacher, family relationships)? For research involving MIT students and lab members, see: <http://couhes.mit.edu/guidelines/mit-students-and-lab-members-subjects>.       |
| **8. Deception** *Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.* |
| 1. Will information about the research purpose and design be withheld from subjects?

[ ]  Yes [ ]  No*If yes, explain and justify:*       |
| **9. Adverse Effects** *Serious or unexpected adverse reactions or injuries, and/or unanticipated problems involving risks to subjects or others must be reported to COUHES within 48 hours. Other adverse events should be reported within 10 working days.* |
| A. What follow-up efforts will be made to detect any harm to subjects, and how will COUHES be kept informed?      |
| **10. Health Insurance Portability and Accountability Act (“HIPAA”)** *If your study involves individually identifiable health information and is sponsored by MIT Medical, an MIT Health Plan or another healthcare provider, then you must complete the questions below because HIPAA likely applies to your study. For more information regarding the applicability of HIPAA to human subjects research, please* [*click here.*](https://couhes.mit.edu/hipaa-guidance-document) |
| 1. Do you plan to obtain, use or disclose identifiable health information in connection with your research study?

[ ]  Yes [ ]  No*If YES, then all participants must complete an Authorization for Release of Protected Health Information Form. Please attach a copy of this draft form. You must use the* [*template*](https://couhes.mit.edu/forms-templates) *available on the COUHES website.**Alternatively, COUHES may grant a Waiver of Authorization in certain* ***very limited*** *circumstances when use of individually identifiable health information would pose only minimal risk to study participants (among other requirements). For additional information regarding whether your study might qualify for a waiver, please* [*click here.*](https://couhes.mit.edu/hipaa-guidance-document) |
| 1. Are you requesting a Waiver of Authorization?

[ ]  Yes [ ]  No [ ]  N/A*If yes, explain your rationale for concluding that:* 1. *use of participant health information poses no more than minimal risk;*
2. *the research could not be conducted without the waiver and*
3. *the research could not be conducted without the information.*

*In addition, please explain your plan for (i) ensuring the participant health information is not improperly used or disclosed either within MIT or to any outside third parties and (ii) destroying identifiers at the earliest possible opportunity*.      |
| C. Will the health information you will receive for use in this study be de-identified?[ ]  Yes [ ]  No [ ]  N/A*If yes, you do not need to obtain a signed Authorization for Release of Protected Health Information Form from study participants. Note, however, that if you receive identifiable participant health information that you plan to convert into de-identified information for use by other researchers, then you must obtain a signed Authorization for Release of Protected Health Information Form from each participant before receiving their identifiable health information for use in your study.*  |
| D. Will you be using or disclosing a limited data set?[ ]  Yes [ ]  No *If yes and you will only receive participant health information in limited data set form, then you do not need to obtain a signed Authorization for Release of Protected Health Information Form from study participants. You must complete a formal data use agreement with the party from whom you will receive the limited data set information in order for your application to be approved.**If yes and you will receive identifiable participant health information that you plan to convert into limited data set form for use by other researchers, then you must obtain a signed Authorization for Release of Protected Health Information Form from each participant before receiving their identifiable health information for use in your study. You must complete a formal data use agreement in order for your application to be approved.* |
| **11. Data Classification and Information Protection** *All new protocol submitted after* ***March 3, 2021*** *must complete this section. For more information, see the Information Protection section on the COUHES website:* [*http://couhes.mit.edu/guidelines/data-protection*](http://couhes.mit.edu/guidelines/data-protection)*. The assigned Data Classification level can be viewed in COUHES Connect:* [*https://couhes-connect.mit.edu/connect*](https://couhes-connect.mit.edu/connect)*This section is required with all submissions and applies to all data or information that will be used, collected, transmitted, analyzed, stored or otherwise handled in your research. This includes data obtained through intervention or interaction with an individual as well as data obtained without communication or interpersonal contact between investigator and subject. The questions apply to all forms of data including electronic data, physical data (i.e. paper), sensor data, video or audio recordings, etc.* |
| 1. Will you be collecting, transmitting, analyzing, storing or otherwise handling data or information that either: directly identifies individuals, or with respect to which there is a reasonable basis to believe that the information or data could be used to identify individuals? (Ex: data containing personal identifiers, coded data, audio, and/or videotaping)

[ ]  Yes [ ]  No1. If **yes**, identify the data collected that could be used to identify individuals: (Check all that apply) [ ]  personal identifiers [ ]  coded data [ ]  videotaping [ ]  audiotaping[ ]  other, please specify:       |
| 1. Will you be collecting, transmitting, analyzing, storing, or otherwise handling data or information that is protected by Federal, State or other laws or regulations? (Check all that apply)

[ ]  Student educational records - Family Educational Rights and Privacy Act (FERPA)[ ]  Health information and/or medical records - the Health Insurance Portability and Accountability Act (HIPPA)[ ]  Personally identifiable information (SSN, passport, etc.) about residents of the Commonwealth of Massachusetts - the Massachusetts Data Security Act[ ]  Other[ ]  No |
| C. Will you be collecting, transmitting, analyzing, storing or otherwise handling any of the following? (Check all that apply) |
| [ ]  National Security Information[ ]  Information regarding illegal activities[ ]  Financial records[ ]  Genetic information[ ]  Employment records | [ ]  Sexual preference[ ]  De-identified data from public websites[ ]  Anonymous specimens that are publicly available[ ]  Not collecting data with any sensitivity at all\*[ ]  Other |
| *\*Data is anonymous or de-identified without access to a linking code; AND, nothing in the data set could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability or reputation if the data is accidentally disclosed outside the research.* |
| D. Will you be receiving data under a Data Use Agreement from a third party? [ ]  Yes [ ]  NoIf yes, please attach a copy of this agreement to your application. |
| E. What will happen to the data when the study is completed?      |
|  |
| **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.**
 |

**Signature of 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.**

***Signed copies of the Comprehensive Review Application and supporting documents should be e-mailed to*** ***couhes@mit.edu******. In addition, two single sided hardcopies must be submitted to the COUHES office: Building E25-Room 143b.***



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

COUHES

**COUHES Protocol #**

**PERSONNEL LIST**

*This form must be attached with the Application for Comprehensive Review.* ***Any application submitted without a completed personnel list will be returned to you.***

*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**

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

***\*NOTE:*** *Please designate a person with whom COUHES should communicate regarding issues or questions about the protocol.*

**B. NON-MIT AFFILIATES**

*Proof of training must be attached for all non-MIT affiliates. Documentation from collaborating institutions may be submitted in lieu of training certificates.*

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