

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

COUHES

Application for Department of defense sponsored or supported

exempt research

*Investigators conducting exempt research sponsored or supported by the Department of Defense must complete this form. The form must be completed in its entirety and included with your Exempt Evaluation submission in COUHES Connect.*

*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. Exempt Evaluation Number:**  |
|       |       |
| **3. Principal Investigator**  | **4. Faculty Sponsor (If required)** |
| Name:       | Name:      |
| Email:       | Email:       |
| **5. Point of Contact (PoC)**  |
| Name:       | Email:       |
| **6.** **Funding** *Funding must be included in the Exemept Evaluation and included in your application.* |
| A. Sponsored Project Funding: |
| [ ]  Current Proposal Grant/Proposal #       Sponsor       Title       [ ]  Current Award Grant/Account #       Sponsor      Title        |
| B. Institutional Funding: |
| [ ]  Gift Departmental Resources  [ ]  Other (explain)        |
| **7. 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. |
| **8. 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.*   |
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| **9. 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.* |
|       |
| **10. 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.* |
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| **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.* |
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**III. 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? Indicate if the study will include active duty members.      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.).* |
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| **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.* |
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**STUDY PERSONNEL**

**MIT Personnel must be listed in the Exempt Evaluation under the Personnel Tab. All MIT personnel must have active human subject training to participate in the research.**

**IV. STUDY PERSONNEL**

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| *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.* *MIT Affiliated Personnel MUST be listed in the Exempt Evaluation. 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.*  |
| **A. 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:       |       |       |  |