

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

COUHES

**COUHES Protocol #**

**CONTINUing review questionnaire**

*All protocols must be renewed prior to the expiration date. To ensure continued approval, complete and return this form by the deadline for the COUHES meeting prior to your expiration date (see dates and deadlines:* [*https://couhes.mit.edu/about-couhes/dates-and-deadlines*](https://couhes.mit.edu/about-couhes/dates-and-deadlines)*).*

*If this form is not received by the required date, the study will be administratively closed and related research grants will be suspended. If administratively closed, no research with human subjects can be conducted under this protocol.*

*Answer all questions. Incomplete applications will be rejected and returned for completion. Indicate N/A where the question does not pertain to your application.* ***Do not use this form to request changes****, attach an Application for Changes to an Approved Protocol form. If you are not requesting renewal of this protocol, submit the Final Report Closure Form. See forms and templates:* [*https://couhes.mit.edu/forms-templates*](https://couhes.mit.edu/forms-templates)

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| **I. BASICINFORMATION** |
| 1. Title of Study |
|       |
| 2. Principal Investigator |
| Name:       | Building and Room #:       |
| Title:       | Email:       |
| Department:        | Phone:       |
| **3. Indicate Current Study Status***If the research activities are complete, please submit a* [*Final Report Closure Form*](https://couhes.mit.edu/forms-templates) *and do not complete the Continuing Review Questionnaire.*  |
| [ ]  Open to Enrollment [ ]  Data Analysis Only  |
| **4. Funding***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       |
| B. Institutional Funding: |
|  [ ]  Gift [ ]  Departmental Resources [ ]  Other (explain)       |
| C. [ ]  No Funding |
| D. Has there been a change in funding during the past approval period? [ ]  Yes [ ]  No *If yes, please explain:*      |
| **10. Statement of Financial Interest** |
| Has there been a change in financial interest for any investigator? [ ]  Yes [ ]  No *If yes, please explain:*     *If yes, and unless already submitted, please attach**a* ***Supplement for Disclosure of Financial Interest*** *for each change.*  |
| **II. STUDY PROGRESS** |
| 1. Has there been a change in any of the following:*If the changes below have not been approved, submit an Application for Changes to an Approved Protocol form.* |
| A. Study personnel? [ ]  Yes [ ]  No *If yes, please explain:*      *Attach the current* [*Personnel List*](https://couhes.mit.edu/forms-templates)*.* |
| B. Recruitment of subjects? [ ]  Yes [ ]  No *If yes, please explain:*      |
| C. Experimental procedure? [ ]  Yes [ ]  No *If yes, please explain:*      |
| D. Experimental drugs? [ ]  Yes [ ]  No [ ]  N/A  *If yes, please explain:*      |
| E. Amount of blood drawn? [ ]  Yes [ ]  No [ ]  N/A  *If yes, please explain:*      |
| F. Amount of radiation exposure? [ ]  Yes [ ]  No [ ]  N/A  *If yes, please explain:*      |
| G. Other aspects of the study that affect the rights of the subject? [ ]  Yes [ ]  No *If yes, please explain:*      |
| H. Has an amendment been submitted for the changes checked above? [ ]  Yes [ ]  No [ ]  N/A *If no, please explain:*      |
| **2. Study Protocol***Provide an outline of the approved current research protocol including summary of progress. You should provide sufficient information for effective review by non-scientist members of COUHES. Define all abbreviations and use simple words. Unless justification is provided, this part of the continuing review application must not exceed 2 pages.* |
| A. Outline of the approved current research protocol:     B. Summary of progress during the past approval period:      |
| **3. Subject Enrollment***Subjects consented over the last approval period includes all subjects consented since the original approval or last renewal. This excludes amendment approval or adverse event notices. Approval periods vary and are included on all COUHES approved documents.* |
| A. Consented over last approval period:  Adults:       Minors:       | 1. Total subjects consented:

 Adults:       Minors:       |
| C. Number of subjects approved to be consented for this study:  Adults:       Minors:       |
| D. Number of subjects withdrawn from the study (include subjects consented but not studied):       i. State reason for withdrawal and state if an Adverse Event Report form was submitted:       |
| E. Are all subject signed consent forms on file?*(Do* ***not*** *submit signed copies to COUHES)* [ ]  Yes [ ]  No *If no, please explain:*      |
| F. Are you recruiting subjects from the Principal Investigator's lab or their class? [ ]  Yes [ ]  No *If yes, COUHES recently updated their policy involving MIT Students and Lab Members as subjects. See:* [*http://couhes.mit.edu/guidelines/mit-students-and-lab-members-subjects*](http://couhes.mit.edu/guidelines/mit-students-and-lab-members-subjects)*. All changes to an approved protocol require the submission of an Application for Changes to an Approved Protocol form.* |
| 4. Drugs or Devices |
| Does this study involve an investigational device or drug?[ ]  Yes [ ]  No  |
| **5. Adverse Effects/Unanticipated Problems** *All adverse effects and/or unanticipated problems must be reported to COUHES. If you have not reported an adverse event and/or an unanticipated problem, please attach an adverse event/unanticipated problem reporting form.* |
| Have subjects experienced any adverse effects and/or unanticipated problems since last approval?  [ ]  Yes [ ]  No  |
| **6. Subject Complaints**  |
| A. Have there been any subject complaints?  [ ]  Yes [ ]  No  *If yes, please explain:*      |
| B. If yes, have they been reported to COUHES?  [ ]  Yes [ ]  No [ ]  N/A  *If yes, please explain:*      |
| 7. Additional Reports |
| A. Does your study require approval of any other committee(s) (at or outside MIT)? [ ]  Yes [ ]  No *If yes, attach current approval letters.* |
| B. Is your study funded by the NIH? [ ]  Yes [ ]  No *If yes, attach* *a copy of the NIH Progress Report.* |
| C. Does your study require a Data Safety Monitoring Board (DSMB)? [ ]  Yes [ ]  No *If yes, attach* *a copy of the DSMB Progress Report.* |
| 8. Study Results  |
| Have any results of the study been published? [ ]  Yes [ ]  No  *If yes, provide bibliographic information.*       |
| 9. Informed Consent |
| Please attach a copy of the informed consent document(s) currently in use. This should be the version most recently approved by COUHES.*Indicate if the requirement for informed consent has been waived by COUHES:* [ ]  |

**Signature of Principal Investigator Date**

**Print Full Name and Title**

**Signature of Department Head Date**

**Print Full Name and Title**

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