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| http://web.mit.edu/graphicidentity/images/seal_black_lg.gif | **Massachusetts Institute of Technology** Committee on the Use of Humans as Experimental Subjects  COUHES | **COUHES Protocol #** |
| **Submission Date** |

APPLICATION TO RESTART HUMAN SUBJECTS RESEARCH

*Request must be submitted through COUHES Connect. Visit couhes.mit.edu/covid-19-updates for more information.*

*Protocols requiring revisions to the approved procedures must submit an amendment to COUHES for review and approval. Submission can be in conjunction with this request.*

*Please note that you cannot re-start research until you have received all necessary approvals.*

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| I. BASIC INFORMATION | |
| 1. Title of Study | |
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| 2. Principal Investigator | |
| Name: | Building and Room #: |
| Title: | Email: |
| Department: | Phone: |
| II. Re-Start Summary | |
| 1. For detailed instructions and FAQs, visit couhes.mit.edu/covid-19-updates. | |
| A. Please describe the location(s) of the research: | |
| 2. Indicate below if your Restart Application applies to either of the following: | |
| A. Research involves **on-campus** direct person-to-person human interacts. | Complete section **III. On-Campus Research** |
| B. Research involves **off-campus** direct person-to-person human interacts. | Complete section **IV. Off-Campus Research** |
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| **III. On-Campus Research**  Complete this section if your research involves on-campus direct person-to-person research and did not qualify for immediate approval through the Restart Request questionnaire in Connect. | |
| 1. Is your study population limited to 12 years of age or above?  Yes  No  *If no, please explain the inclusion of children in the research and how COVID risk will be minimized:* | |
| 2. Study Personnel and Participant Requirements | |
| Please confirm you will comply with all applicable national, state and local health authority requirements, and MIT policies, regarding COVID-19 safety standards. See <https://now.mit.edu/>  Yes  No | |
| 3. COVD-19 Frequently Asked Questions | |
| Please confirm you have reviewed the COVID-19 Updates and Restart Policies: (<https://couhes.mit.edu/covid-19-updates>):  Yes  No | |
| 4. Study Participant Requirements | |
| A. Prior to arrival at the study site all adult subjects and guests must complete an approved COVID-19 consent form addendum (<http://couhes.mit.edu/forms-templates>). This form must be completed by the adult subject and/or guest and reviewed by the research study staff within 24 hours prior to the subject’s arrival at the study site. For minor subjects between 12 and 18 years old, a parent/guardian is required to complete a parental consent addendum for the child and for him/herself within 24 hours prior to arriving MIT.  Any subject or guest who indicates they have tested positive for COVID-19 within the past 2 weeks, had contact with a COVID-19 positive patient within the past 2 weeks, currently has symptoms suggestive of COVID-19, or is at high risk for severe complications from COVID-19, must be excluded from the study.  Will your research have procedures in-place to conduct the review as described above to exclude any subject or guest who meets the COVID-19 exclusion related criteria?  Yes  No  *If no, please explain in detail your COVID-19 consent addendum mechanism and exclusion procedures:* | |
| B. Please describe the type of the direct person-to-person contact study personnel will have with subjects. Include a detailed description of the proximity, the duration of contact, and precautions you plan to take (PPE, social distancing, sanitization, outdoors, etc.): | |
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| **III. Off-Campus Research**  Complete this section if your research involves off-campus person-to-person research and did not qualify for immediate approval through the Restart Request questionnaire in Connect. | |
| 1. Subject Population | |
| A. What categories of subjects will you be studying (check all that apply):   1. Adults under 65 2. Adults over 65 3. Children under 18 (specify the age range): 4. Pregnant women 5. Cognitively impaired individuals | |
| B. Does the inclusion criteria of your approved COUHES application include subjects who specifically have (check all that apply):   1. Diabetes 2. Cardiovascular disease 3. Chronic lung disease 4. Chronic kidney disease on renal dialysis 5. Chronic liver disease 6. Asthma 7. Severe Obesity (BMI>40) 8. Immunocompromising conditions or are on immunosuppressing medications 9. Any other major health problem. Specify: 10. Are residents of nursing homes or long-term care facilities | |
| 2. Study Personnel and Participant Requirements | |
| All study personnel and all subjects will comply with applicable national, state and local health authority requirements, and MIT policies, regarding COVID-19 safety standards. See <https://now.mit.edu/>  Please confirm you are able to ensure compliance with these requirements and policies:  Yes  No  *If no, please provide a detailed explanation of any special circumstances:* | |
| 3. COVD-19 Frequently Asked Questions | |
| Please confirm you have reviewed the COVID-19 Updates and Restart Policies: (<https://couhes.mit.edu/covid-19-updates>):  Yes  No | |
| 4. Study Participant Requirements | |
| A. Prior to arrival at the study site all subjects must complete an approved COVID-19 consent form addendum (<http://couhes.mit.edu/forms-templates>). This form must be completed by the subject and reviewed by the research study staff within 24 hours prior to the subject’s arrival at the study site.  Any subject who indicates they have tested positive for COVID-19 within the past 2 weeks, had contact with a COVID-19 positive patient within the past 2 weeks, currently has symptoms suggestive of COVID-19, or is at high risk for severe complications from COVID-19, must be excluded from the study.  Will your research have procedures in-place to conduct the review as described above to exclude any subject who meets the COVID-19 exclusion related criteria?  Yes  No  *If no, please explain in detail your COVID-19 consent addendum mechanism and exclusion procedures:* | |
| B. Please describe the type of the direct person-to-person contact study personnel will have with subjects. Include a detailed description of the proximity, the duration of contact, and precautions you plan to take (PPE, social distancing, sanitization, outdoors, etc.): | |
| IV. Required revisions | |
| A. Application for Changes to an Approved Protocol | |
| Will you be changing any aspect of the study for which you do not already have approval? This includes subject recruitment, experimental procedures, consent mechanisms or study personnel.  Yes  No  If yes, you will need to submit an application for changes to an approved protocol. (<http://couhes.mit.edu/forms-templates>)  For Exempt Research no change form is required, but if the changes alter your previous Exempt Evaluation then investigators must submit a new Exempt Evaluation. | |

Please note COUHES approval is necessary but not sufficient for the resumption of human subjects research. Additional MIT policies may apply, see: <https://couhes.mit.edu/covid-19-updates>.

**The Principal Investigator signature is captured during the submission process through COUHES Connect.**