



COUHES Guidance on Restart of Direct Person-to-person Human Subject Research

Updated on June 30, 2021

COVID-19 Updates and Restart Policies

This page provides important information regarding human subjects research during COVID-19 disruptions. We will continue to update this page as new information becomes available. Ongoing protocols with approved Restart Requests are NOT required to resubmit if there are no changes to the study location or person-to-person interactions

The following procedures to restart direct person-to-person human subject research apply to ALL MIT research, whether conducted on campus at MIT or off campus, and whether the research was exempt from COUHES review or formally reviewed and approved by COUHES. Investigators must complete a self-certification procedure in COUHES Connect prior to restarting their study for each protocol. If an investigator meets ALL certification requirements then no further action is required. If an investigator however, is unable to meet ALL the certification requirements, then they must submit an “Application to Re-start Human Subjects Research” and receive an approval from COUHES before re-opening their studies (See instructions: <https://couhes.mit.edu/covid-19-updates>). As part of this application, investigators can describe any unique circumstance relating to their protocol.

This policy does not apply to COUHES approved research that does NOT involve any in-person contact.

When planning to re-open your study, in-person contact should be limited to activities that cannot be done in other ways and the duration of contact must be as short as possible. Activities that can be conducted remotely (such as prescreening questionnaires, follow-up surveys, etc.) must continue to be conducted remotely if feasible.

For on-campus research, the restart is limited to studies recruiting subjects that are at least 12 years old. For off-campus research, the restart continues to be limited to studies recruiting healthy adult subjects. Studies of additional categories of subjects will be permitted as soon as circumstances warrant.

Please note COUHES approval is necessary but not sufficient for the resumption of human subjects research.

Additional MIT policies may apply. These include:

Local COVID-related regulations and restrictions where the research is being conducted. See MIT Now for latest information:

<https://now.mit.edu/>

MIT policies regarding visitors.

<https://now.mit.edu/policies/campus-visitor-policy/>

MIT travel policies.

<https://covid.mit.edu/travelers-visitors>

<https://icc.mit.edu/travel-abroad/safety-and-security/international-travel-risk-policy-country-warning-levels>

Please review the relevant information below pertaining to your person-to-person human subject research interactions:

All Research.....Page 3

On-Campus Research.....Page 6

Off-Campus Research.....Page 7

All Research

The information below pertains to all person-to-person human subject research, regardless of study location.

Q1. What do I need to do to ensure subjects are within the allowed categories of study?

All subjects must complete a COVID-19 consent form addendum. See forms:

<https://couhes.mit.edu/covid-19-updates>) appropriate to the study's location (on-campus or off-campus) and study population (on-campus consent addendum vs. on-campus parental consent addendum). This form must be completed and reviewed by the research study staff within 24 hours prior to the subject's arrival at the study site.

For investigators who are unable to follow the procedures, you will need to provide a detailed explanation in your "Application to Re-start Human Subjects Research."

Q2. Can the COVID-19 consent form addendum be completed electronically?

Yes. Please see COUHES guidance on electronic consent at <http://couhes.mit.edu/guidelines/electronic-consent>.

Q3. If a subject is schedule for multiple visits, will they need to complete the consent addendum prior to each visit?

Yes, subjects must complete the consent addendum within 24 hours prior to their arrival for each visit.

Q4. Are there additional COVID-19 investigator specific requirements?

Additional MIT policies may apply – See section above.

Q5. Will I have an opportunity to describe any special circumstances relating to my research that prevent me from certifying to the COUHES requirements for restarting direct person-to-person research?

Yes. You can provide a detailed explanation of your circumstances within the "Application to Restart Human Subject Research."

Q6. What if I change my approved protocol to conduct the research in a COVID environment?

If you are changing any aspect of the study for which you do not already have approval (including study population, subject recruitment, experimental procedures, consent mechanisms or study personnel), you will need to submit a Change Form: <http://couhes.mit.edu/forms-templates>.

For Exempt Research no change form is required, but if the changes alter their previous Exempt Evaluation, then investigators must submit a new Exempt Evaluation.

Q7. Is there a limit on how many subjects can be studied at the same time?

No, but investigators should only include subjects and guests required for the completion of the research.

Q8. Do I need to submit an application to restart with COUHES if my research is reviewed and approved by an outside IRB?

Yes. If direct person-to-person human subject research is conducted on the MIT campus, investigators

must submit the “Application to Restart Human Subjects Research” to COUHES@mit.edu.

If NO direct person-to-person human subject interactions occur on the MIT campus, then investigators must consult with the reviewing IRB.

Q9. What is the turnaround time for COUHES to review my “Application to Restart Human Subjects Research”?

Applications are processed in order that they are received and we make every effort to review them as soon as possible. You are welcome to contact COUHES to check on the status of your application.

Q10. How do I contact COUHES for additional questions?

COUHES staff are working remotely. Please email COUHES@mit.edu with questions or concerns. If you wish to discuss by phone, please share your contact information, and a member of the COUHES staff will follow up. You may also leave a voicemail at 617-253-6787.

Q11. Do I still need to submit hard copies?

No. Hard copies are not required until further notice. The “Application to Re-start Human Subjects Research” is submitted through COUHES Connect. New comprehensive review applications can also be submitted through COUHES Connect.

Q12. Does COUHES have any recommendation on conducting research remotely?

The following are some options for you to consider:

- Recruiting subjects via phone call, email or Amazon MTurk.
- Internet-based consent or oral consent, depending on the subject population and risk of study.
- Conducting surveys via MIT Qualtrics if appropriate for your data classification risk level.
- Conducting interviews via Skype, Zoom, or over the telephone. (If recording, make sure to include this activity in the informed consent.)
- Using postal or courier services to send subjects and receive back from them study equipment such as wearable devices.

Q13. If I need to analyze data on my personal computer from home in order to keep working on my project, how do I address data-security requirements?

If your remote research operation maintains compliance with your approved protocol data security controls and (if applicable) with your data-use agreement no further action is required, except if you plan to analyze high-risk data on your personal computer. Investigators are highly encouraged to follow COUHES Data Protection guideline on how best to secure their data according to their data classification risk level. Link to data protection guideline: <http://couhes.mit.edu/guidelines/data-protection>

If feasible, we ask you only analyze coded or de-identified data without any personal identifiers on your personal computer. Any personally identifiable information, such as the key linking codes to personal identifiers, should be stored on password-protected and encrypted MIT computers, servers, or other secure storage options such as MIT Dropbox.

Data from your home computer should be transferred to secure MIT computers and deleted from your home computer as soon as possible.

High-risk data: **If you plan to analyze high-risk data (e.g., national security, illegal activity, identifiable health records, HIPAA data, identifiable genetic data, identifiable student records, identifiable financial records, identifiable employment records, identifiable sexual preference, SSN, etc.) on your personal computer, please submit a change form to COUHES.** You are encouraged to contact IS&T to ensure your remote operation continues to protect high-risk data. PIs will be required to certify that IS&T's guideline for Securing High Risk Information will be implemented before analyzing data on personal computers. Please see COUHES Data Protection guideline for more information on how best to secure your data. <http://couhes.mit.edu/guidelines/data-protection>

Q14: Do I need to file a Restart Request for all of the protocols that appear in my restart list in COUHES Connect?

No. You only need to submit a Restart Request for protocols involving direct person-to-person interaction. For example, if you are doing data analysis and your protocol does not involve any new in-person interactions even if the protocol had in-person interactions prior to March 15, 2020, you do NOT need to file a restart request. Similarly, if your research is limited to remote activities, such as online surveys, virtual interviews, and analysis of data already collected, you do NOT need to file a restart request.

Q15: I have an exempt protocol that was approved prior to Jan 2019 under the pre-2018 rule (old rule), how do I submit a request to re-start my research involving direct person-to-person interactions?

Exempt studies (approved prior to Jan. 21, 2019) will not appear on the Restart Research list. Please submit an Exempt Evaluation via COUHES Connect. Once you receive an exempt status via this process, you will be able to apply to re-start your research involving direct person-to-person interaction. Most exempt research approved prior to January 21, 2019 should continue to receive exempt status after completing the Exempt Evaluation in COUHES Connect. Please see COUHES Connect guidance for more information: <http://couhes.mit.edu/couhes-connect-resources/couhes-connect-guidance>

Q16: Who should have access to consent addendum and registry of subjects? How long should researchers keep them?

Both the consent addendum and registry of subjects are considered study documents and should be retained by the research team for 3 years after completion of the study. This information should be maintained by the research team and may be shared with others at MIT who have legitimate need to know this information to maintain the health and safety of the MIT community and possibly other local health authorities.

Q17: What if my study involves on-and-off campus research activities?

For investigators conducting direct person-to-person research on-and-off campus, please submit a restart request appropriate for each activity. The restart request via COUHES Connect will allow investigators to submit for both on-and-off campus sites.

Q18: Are participants required to report their vaccine status?

No, participants are not required to report their vaccine status as part of their participation unless the approved study protocol specifically state vaccination as an inclusion criteria.

On-campus

The information below pertains to direct person-to-person research conduct on-campus. In addition to the policies describe below and in the restart process, investigator should also review any DLC or other application MIT policies related to in-person interactions.

Q1. Are there additional COVID-19 subject specific requirements?

Yes. For research at MIT, you must provide the subject with information about the logistics of the visit. This should include information about the point of entry, that they will be escorted to and from the study site, along with any additional MIT or DLC policies. You must keep a registry of subjects and guests for future tracking purposes that records their time and point of entry and exit.

Q2. Can subjects bring guests with them to MIT campus?

Yes, guests are permitted on-campus if required by the research study. Guests accompanying adult human subject participants are required to complete the COVID Consent Form Addendum (on-campus) and agree to the terms described in the form (contact tracing, COVID symptoms, withdrawal, etc.). Guests (such as parents/guardians) accompanying their minor child are required to complete the COVID Parental consent addendum. See Q3 below for more details.

Q3. For minor subjects between 12 and 18 years old, is a parent/guardian required to complete a parental consent addendum for the child and for him/herself?

Yes, a parent/guardian is required to complete a Parental Consent Addendum on behalf of his/her child and him/herself within 24 hours prior to arrival at MIT. Only children 12 and older are permitted on campus.

Q5: What if my research involves MIT students and lab members as subjects?

Research involving MIT students or lab members will still require the submission of a Restart Request. If the research involves students or lab members from the Principal Investigator's lab or their class, investigators must include a third party to consent those subjects. See: <http://couhes.mit.edu/guidelines/mit-students-and-lab-members-subjects>. Any changes to the approved protocol require an amendment.

Q6. What if I learn that a subject that participated in my study tested positive for COVID-19?

You have a responsibility to activate contact tracing. For on campus research, you should log into the COVID Pass system and indicate that you and others may have been exposed to an individual who tested positive. You may also contact MIT Medical directly at 617-253-4865 or send an email to covid19reports@mit.edu and await further instructions.

Q7: Do Human Subjects coming to MIT campus need to apply for COVID Pass?

No, all subjects and guests must complete a COVID-19 consent form addendum (See forms: <https://couhes.mit.edu/covid-19-updates>) certifying their health status. This form must be completed and reviewed by the research study staff within 24 hours prior to the subject's arrival at the study site.

Q8: Should subjects' contract tracing be stored with the research data?

No, research data should be stored separately. Consent addendum and contact information is captured only for contract tracing purposes.

Q9. My approved protocol includes subjects both under and over 12 years old, do I need to submit an Application for Changes to an Approved Protocol if I only plan to enroll subjects 12 or older?

No, if your approved protocol already includes subjects 12 years and older in the study population, no further action is required.

Q10: Can human subjects and their guests be granted Tim Ticket access?

No. COUHES requires researchers to maintain a registry of subjects and their guests for future tracking purposes that records their time and point of entry and exit for contact tracing purposes. This requirement cannot be accurately fulfilled if human subjects have unescorted access to MIT buildings. Human subjects should be escorted by a COVID pass compliant MIT individual from the research team.

Off-campus

The information below pertains to direct person-to-person research conduct off-campus. In addition to the policies describe below and in the restart process, investigator should also review any other applicable local policies and site specific requirements related to in-person interactions.

Q1. Are there additional COVID-19 subject specific requirements?

No but investigator must abide by applicable site-specific requirements and local policies.

Q2. What if I learn that a subject that participated in my study tested positive for COVID-19?

Please contact the appropriate local health authorities.

Q3. Do I need to apply to re-start if my research is off-campus, international, and/or conducted by a third party on behalf of MIT?

Yes. All MIT direct person-to-person human subject research conducted off campus whether exempt from COUHES review or formally reviewed and approved by COUHES, must complete the self-certification procedure and if required, the "Application to Restart Human Subjects Research" form (See forms: <https://couhes.mit.edu/covid-19-updates>).

If the off-campus research is ceded to an outside IRB, then please consult with your reviewing IRB. You do not need to apply to re-start with COUHES.

When conducting research outside of MIT, you are required to comply with local health authority requirements and other applicable local requirements at the site regarding COVID-19 safety standards on social distancing, hygiene and equipment and space disinfecting, including MIT policies on travel to off-campus sites. COUHES might impose additional requirements as necessary to protect the safety of the subjects.

Q4. My approved protocol includes both healthy subjects and high-risk for COVID-19 or vulnerable populations, but I will only study healthy subjects for the immediate future. Do I need to submit an Application for Changes to an Approved Protocol if I only plan to enroll healthy subjects?

No, if your approved protocol already healthy subjects and research activities are limited to healthy subjects, then no further action is required.