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

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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.

All direct person-to-person human subjects research may restart subject to certain restrictions. Initially the restart will be limited to studies recruiting healthy adult subjects. Studies of additional categories of subjects will be permitted as soon as circumstances warrant.

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.

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. Use and occupancy of MIT facilities. (See note below regarding human subjects counting against occupancy limits for a given space.)

https://covid19.mit.edu/campus-operations
https://covid19.mit.edu/returning-to-work-on-campus
https://research.mit.edu/research-resources/covid-19-related-information-mit-research-community

MIT policies regarding visitors. (See note below regarding meeting and escorting subjects.)

https://covid1.mit.edu/travelers-visitors

MIT travel policies.

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

MIT Human Resources policies regarding paid staff (including postdocs).

https://covid19.mit.edu/for-staff
https://hr.mit.edu/covid19

MIT regulations regarding student researchers.

https://covid19.mit.edu/undergraduate-students
https://covid19.mit.edu/graduate-students

Please read the following:

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://couches.mit.edu/covid-19-updates) certifying their health status. This form must be completed and reviewed by the research study staff 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?

Q3. 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, and that subjects must wear facial coverings, observe social distancing, and follow bathroom use and elevator density policies.
You should also keep a registry of subjects for future tracking purposes that records their time and point of entry and exit.
For off-campus research, you will need to abide by applicable site-specific requirements.
Q4. Are there additional COVID-19 investigator specific requirements?
Additional MIT policies may apply – See section above.

Q5. How does on-campus human subject research relate to space density requirements?
All subjects studied on campus must be factored into the space density planning (Planning Exercise A and B calculations). Note: human subjects count against the occupancy limits for a given space. It is the responsibility of the PI to coordinate with all applicable Departments, Labs, or Centers to ensure compliance with space density requirements. See detailed guidelines here: https://research.mit.edu/research-resources/covid-19-related-information-mit-research-community.
The assigned densities cannot be exceeded when studying human subjects. This does not apply to off campus research.

Q6. 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.”

Q7. 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 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.

Q8. Can subjects bring guests with them to MIT campus?
At present, only healthy adults will be allowed to be subjects and they cannot bring guests to campus. As additional categories of subjects are permitted, parents of minor children, legal guardians, caretakers, or others who needs to come as a study requirement will be allowed to accompany subjects to MIT campus. They also will need to complete a separate COVID-19 consent form addendum prior to arrival to MIT with a subject.

Q9. Is there a limit on how many subjects can be studied at the same time?
COUHES will consider this on a case-by-case basis taking into consideration the nature and the duration of the in-person contact. Note that the densities assigned under RR Planning Exercises A and B cannot be exceeded when studying human subjects.

Q10. 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.
For off campus research, contact the appropriate local health authorities.

Q11. 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).

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.

Q12. 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.

Q13. 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.

Q14. 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.

Q15. 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 must be sent to COUHES@mit.edu.

Q16. 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.
- 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

Q17. 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.

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.

Q18: 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.

Q19: 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
Q20: 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 maybe 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.

Q21: Do Human Subjects coming to MIT campus need to apply for COVID Pass?
No, all subjects 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 24 hours prior to the subject’s arrival at the study site.