

FAQs: Impact of COVID-19 on Human Subjects Research

Last updated April 14, 2021.

Click [here](#) for a pdf version of these FAQs. For information on the process to restart in-person human subjects research at BMC and BU Medical Campus, please see FAQ #30 below.

Please also see:

- Information from the CTSI: <http://www.bu.edu/ctsi/covid-action/>
- Information from BU: <https://www.bu.edu/covid-19-information/>
- Information from BMC: <https://www.bmc.org/covid-19/covid-19-research-related-information>
- Information on COVID-19-Related Research Workflow and Review Processes from BMC Research Operations: [COVID Research Workflow and Review Processes \(As of 5-14-20\) – Compiled PDF](#)
- Information from FDA: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-trials>
- Information from OHRP: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>
- Information from NIH: https://grants.nih.gov/grants/natural_disasters/corona-virus.htm
- The Zoho Discussion Group for Clinical Research Professionals: <http://www.bumc.bu.edu/crro/research-professional-network/resources-programs/q-a-forum/>

Or contact medirb@bu.edu with any additional questions.

Resource for COVID-19 Biospecimen Research: The COVID-19 Biorepository is an institutional resource for obtaining biospecimens for COVID-19 research. The Biorepository is active and is accepting biospecimen requests. For information, please see the COVID-19 Biorepository website: <https://www.bmc.org/research/covid-biorepository>

1. What types of disruptions to research are occurring now?

On Thursday, March 12, 2020, the Institutional Officials at Boston University Medical Campus and Boston Medical Center determined that most research activities involving in-person interactions with subjects **MUST STOP** until further notice. The only exceptions are if canceling or postponing the activities would either (A) increase the risk to the subject's safety or wellbeing or (B) deprive the subject of a potential direct benefit. This is being done to protect research subjects.

2. What does this pause mean for interactions with enrolled subjects in the Boston area? (EDITED 4/14/21)

Most research activities that involve face-to-face interaction with subjects at BMC or the BU Medical Campus must stop until approval for in-person interaction has been obtained.

The exceptions are:

- 1) The research holds the potential for direct benefit to the subject (e.g., investigational drug, devices or surgical procedure) and the interaction is required to deliver that potential direct benefit
- 2) Collection of safety data (based on clinical judgment of the importance of the visit to detect potential adverse events)

Research on the Charles River Campus should follow the BU guidelines: [BU CRC IRB Statement on Research Concerns of COVID-19 \(Coronavirus\)](#)

3. What does this pause mean for interactions with enrolled subjects outside the Boston area? (EDITED 3/24/20)

The decision to pause most face-to-face activities was based on the situation in Boston and the need to free up resources at BMC and protect research subjects and staff. The Principal Investigators of studies in other locations should use their judgment (and the judgment of colleagues) to determine the most prudent approach for studies outside of Boston. IRB permission is not needed to either continue or pause study activities.

4. What does this pause mean for research activities that involve no face-to-face interactions?

Research activities that involve no face-to-face interactions with subjects may continue.

5. Should enrollment be halted right now? (UPDATED 4/14/21)

Yes, until you receive approval for in-person research activities (see FAQ #30 below). The only exceptions would be studies where there is no in-person subject contact (e.g., on-line only) and studies with the potential for direct benefit, that is, benefits that are not available through standard of care. Existing studies that would like to convert to a remote consent process should submit an amendment to use a modified signature page (see #23 below). See also #16 below for how to this halt in enrollment affects recruitment activities.

6. What is the effect of the pause on pending studies?

The IRB will continue to review and approve submissions. For studies that are approvable, but involve in-person interactions with study subjects and do not have the potential for direct benefit, the IRB will approve the study but explicitly note that enrollment cannot start until institutional approval for in-person interaction is obtained.

7. What types of additional disruptions to research may occur in the future? (EDITED 3/24/20)

The Principal Investigator of studies that are not paused should develop a plan to continue study activities that are essential to subject safety and wellbeing in the face of

significant staffing shortages, being unable to obtain study drugs or protective equipment, or further limits on the availability of BMC clinical services and space.

8. What is the most important consideration in responding to research disruptions?

It is the responsibility of the Principal Investigator to identify any research procedures that would be essential to continue for the safety and well-being of the subjects, and to develop a plan to continue to deliver these procedures and monitor for safety even in the face of disruptions.

9. What else is important to plan for?

Principal Investigators must identify procedures that are not essential to subject safety but that are important to the integrity of the study data, and determine whether there are alternative methods to mitigate the loss of data, such as remote contact by phone or secure email.

10. What steps will assist in minimizing the impact of potential future disruptions?

(EDITED 3/24/20)

Principal Investigators should ensure study files are shared to a secure cloud-based storage (for BMC [Box.com](#), for BU, various [cloud services](#)) and ensure that research staff have secure remote access. Principal Investigators should also have a plan for communicating among study staff, including handing off responsibilities from staff who are ill.

11. Do research subjects need to be screened for COVID-19?

Please consult the [latest guidance](#) for screening patients at BMC.

12. How do subjects need to be notified of visit cancellations and changes?

When a study visit needs to be cancelled or changed to a phone call or on-line encounter, the subject should be told the reason and that they will be contacted again when the visit can be rescheduled. These messages to subjects do not require IRB approval. BMC Research Operations and the IRB have created the following Subject Communication template that you may use and modify as needed:

<http://www.bumc.bu.edu/irb/files/2020/03/COVID-19-subject-letter-template.docx>

13. How does the IRB need to be notified of visit changes?

Visit changes must be made in a way that protects the safety and well-being of subjects, and therefore such changes would be considered [minor deviations](#), which must be summarized at the time of continuing review or status check-in. The IRB considers that changes made in response to COVID-19 disruptions are NOT [major deviations](#), even though there could potentially be significant damage to the overall completeness, accuracy and/or reliability of the data collected for the study. Some examples of visit changes that would be considered minor deviations are omitting visit procedures that cannot be done remotely, canceling visits if doing so would not deprive benefit or impact safety, and adding the use of new remote/virtual methods for subject interaction, provided these methods comply with institutional policy for privacy and confidentiality protections.

The IRB has posted a customizable template for recording minor deviations resulting from the pause in research due to COVID-19. To download the template, click here: <http://www.bumc.bu.edu/irb/files/2020/03/COVID-19-Minor-Deviation-Log-Template.docx>

If a circumstance does arise with the potential to harm a subject (for example, a crucial in-person treatment or safety visit is impossible), the study team's focus should be on ways to mitigate the potential harm. After this occurs, the IRB should be notified by a Reportable Events and New Information (RENI) submission.

Please note that sponsors may have additional requirements for documenting any missed or altered visits. See the recent [FDA Guidance](#).

14. How does the IRB need to be notified of other protocol changes? (UPDATED 4/14/21)

Other modifications to the approved protocol, such as adding new remote consent processes (see #23 below) and/or requesting changes to HIPAA determinations, must be submitted using a Change Request and Amendment form and must receive IRB approval prior to implementation, unless the modification is done to prevent apparent immediate harm to the subject, in which case the IRB should be notified by a Reportable Events and New Information (RENI) submission.

Please note that modifications to research given an exempt determination by the IRB do not need to be reported to the IRB unless they change the exempt determination.

15. Who else needs to be notified of the pause?

Studies with another IRB of record (ceded studies) should contact that IRB to let them know about the pause and determine any additional reporting requirements.

Funded studies should contact the Clinical Trial Office (CTO@bmc.org), BMC Research Operations (Research.Finance@bmc.org), or BU Sponsored Programs (ospera@bu.edu) to coordinate any necessary communication to sponsors.

BMC Research Operations has provided the following template which can be used for BMC-managed studies to notify sponsors, funding sources, and/or external IRBs of the pause in research activities:

<http://www.bumc.bu.edu/irb/files/2020/03/COVID-19-sponsor-funding-source-letter-template.docx>

16. Can recruitment activities continue? (EDITED 4/14/21)

Potential subjects may be contacted by mail, email, or phone to determine interest and eligibility. Most recruitment activities involving face-to-face interactions with potential subjects are NOT allowed without institutional approval. The only exception is recruitment for studies with the potential for direct benefit, that is, benefits that are not available through standard of care. For studies that do not have the potential for direct benefit, the potential subjects should be told during the recruitment process that their

enrollment could be delayed. This additional messaging does NOT need prior IRB approval.

17. What other restrictions have BU and BMC placed on research? (UPDATED 4/14/21)

Principal Investigators must prepare for the potential cessation of in-person on-campus research while managing essential equipment (e.g., refrigerators and freezers). Plans are due on Wednesday, March 25, 2020.

Please use the following links for the most up-to-date information:

BU: <https://www.bu.edu/covid-19-information/>, including this link to the March 21 message concerning the potential cessation of research activities: <https://www.bu.edu/researchsupport/2020/03/21/memo-preparation-for-potential-cessation-of-in-person-on-campus-research/>

BMC: <https://www.bmc.org/covid-19/covid-19-research-related-information>, including links at the bottom of the page under “Research Related.”

18. How will study participants receive investigational drugs?

The Investigational Pharmacy Service (IPS) is fully staffed and continues to provide services. If the decision and accommodations have been made to bring a subject in for an in-person visit, IPS will provide the study medication and coordinate with the Study Coordinator to have medication picked up or delivered to the treatment area. If an in-person visit is not possible, the PI or Study Coordinator should contact the sponsor to determine if alternate options may be available. This will need to be evaluated on a case by case basis. Some sponsors/protocols/IRBs will allow for medications to be administered in alternate treatment centers or in the subject’s home by the subject/caregiver or a nursing service.

Depending on the medication itself (controlled substance, drugs requiring temperature monitoring, drugs requiring immediate use once mixed, etc.), IPS may be able to coordinate delivery of the medication to the subject’s home (i.e. courier, FedEx, UPS, USPS, etc.). The sponsor/CRO would be the best source to provide guidelines regarding how to handle the medication, if not already listed in the protocol or pharmacy manual. The sponsor/CRO would need to indicate how they may want in-transit temperature monitoring data to be collected, chain of custody, and/or acknowledgement of receipt documented. This will need to all be spelled out as a single event Note To File or an amendment to the Pharmacy Manual for the duration of the study. The sponsor/CRO should instruct the PI/SC what the plan is regarding what the subject should do with unused study drug. If additional packaging supplies are required, i.e. temperature monitoring devices or packaging materials, the sponsor/CRO is expected to supply them or specify what they are authorizing the site to purchase. Sponsor/CRO should indicate what type of delivery services are authorized and how they are to be billed.

IPS pharmacists will be available to the PI/SC to ensure that all the investigational dispensing issues have been asked and answered. IPS phone 617-638-6774 p 2809.

19. How can privacy be protected in communications? (UPDATED 3/30/20)

The best methods for communication are phone, BMC Zoom, BU Zoom Meetings for HIPAA, and BU Teams. Please also consider using Epic's patient portal, My Chart, for communication if the subject uses it. For BMC email, type "secure" in the subject line, which creates a secure messaging system. For BU research, you should use the [BU SecureMail email service](#) (free to use) unless the patient or research subject has agreed – ideally in writing – to use non-secure communications via email or text.

Study staff who are using their personal phones may wish to block their number from appearing as the incoming number on the subject's phone by pressing *67 prior to dialing, or by using [Doximity Dialer](#).

20. Can staff take physical/paper records home? (NEW 3/24/20)

No. The best way to access study subject information while working remotely is scanning or copying electronic research data to a securely protected platform (for BMC, [Box.com](#); for BU, various [cloud services](#)) or a shared file area behind the BMC/BU firewall, such as a Department "G: Drive." Password protection, encrypted equipment, and automatic logoff when accessing research data are required. Please contact Michelle Irick, Senior Research Compliance Manager, at Michelle.Irick@bmc.org for concerns or additional information.

21. How can study materials be shipped to subjects? (NEW 3/24/20)

Study staff should set-up a FedEx account to deliver study-related IRB approved materials that cannot be emailed (see #19 above). BU Research Administration or BMC Research Operations at RIS@bmc.org can assist with setting up these accounts.

22. Who can answer questions about budget issues?(NEW 3/24/20)

Please contact your [BU Research Administrator](#) or [BMC Research Operations](#) for help with questions about amending the study budget for unforeseen COVID-19 related costs such as FedEx charges or study cell phones, staff salaries, etc.

23. Are there special considerations for COVID-19 research? (UPDATED 4/14/21)

The review of work relating to COVID-19 will be done in parallel by the multiple responsible offices (IRB, grants, Clinical Trial Office, IBC, etc.). A committee has been set up specifically to review research involving interaction with inpatient COVID-19 subjects:

Scientific Review: BMC has established a COVID-19 research scientific review committee, chaired by Benjamin Linas, MD, MPH, to review and prioritize proposals for COVID-19 research at BMC. PIs of studies involving interaction with inpatients should send a synopsis of their study to Johanna.chesley@bmc.org and Minhao.yin@bmc.org, including a supporting bibliography, that is sufficiently detailed that the committee can judge the scientific merit of the idea in comparison with other proposal treatment trials. In return, they will send some forms for the PI to fill out to make the formal request of the scientific review committee.

For all COVID-19 studies, that both do and do not involve interaction with inpatients, please contact the IRB as soon as possible to discuss the timeline for the IRB submission at medirb@bu.edu.

24. Where can funding opportunities related to COVID-19 be found?

- NIH Guide for Grants and Contracts – search results for “COVID-19”
- NSF – Dear Colleague Letter: Provisioning Advanced Cyberinfrastructure to Further Research on the Coronavirus Disease 2019 (COVID-19) – posted 3/5/2020: <https://www.nsf.gov/pubs/2020/nsf20055/nsf20055.jsp>

25. What guidance is available for conducting COVID-19 research using an emerging pathogen, such as SARS CoV2?

Researchers interested in conducting research with emerging pathogens such as SARS CoV2, should contact the Institutional Biosafety

Committee: <https://www.bu.edu/researchsupport/compliance/ibc/#contacts-tab>

26. What considerations are involved in receiving and/or sending materials (i.e. plasma, virus, pathogens, etc.) relating to COVID-19 from or to another organization/collaborator?

For Boston Medical Center:

- Please contact MTARequest@bmc.org for assistance.
- All requests should include ‘COVID-19 for coronavirus’ in the subject line.
- When receiving material: The organization/collaborator providing material to BMC usually provides a Material Transfer Agreement (MTA). Please request a template from the provider organization/collaborator and forward it to MTARequest@bmc.org for legal review. In the event the provider prefers to use a MTA template from BMC, the research attorneys can generate the document.
- When sending material: The Grants & Contracts office via MTARequest@bmc.org will prepare and send a draft MTA to the organization /collaborator for review.
- For requests for specimens from the Department of Pathology and Laboratory Medicine, see link here: <http://www.bumc.bu.edu/busm-pathology/covid-19-faqs/>

For Boston University Medical Campus:

- Please submit an online Material Transfer Agreement (MTA) Request:
 - Incoming MTA’s: <https://www.bu.edu/researchsupport/forms-policies/material-transfer-agreement-mta-request-incoming-mtas/>
 - Outgoing MTA’s: <https://www.bu.edu/researchsupport/forms-policies/material-transfer-agreement-mta-request/>
- BU researchers seeking to receive or share a limited data set or a data set with PHI should complete and submit the online data use agreement request form

found here: <https://www.bu.edu/researchsupport/forms-policies/data-use-agreement-form/>

27. What updates are required to ClinicalTrials.gov records? (NEW 3/25/20)

Certain studies listed on ClinicalTrials.gov that have paused recruitment should have their recruitment status changed from Recruiting or Enrolling by Invitation to Suspended, within 30 days of the change. The ClinicalTrials.gov administrator, Karla Damus (damusk@bu.edu) is in the process of contacting study teams where this change may be required and will offer assistance, or will make the status change, as requested by the study team. In addition, it is likely that the Primary Completion Date and the Study Completion Date will have to be extended for paused studies. Again, Karla will be contacting and assisting study teams as their Primary Completion Date or Study Completion Date approaches. Please contact Karla with questions or for additional information.

28. What is the effect of the pause in research on Massachusetts Controlled Substances Registration (MCSR) Research Licenses? (NEW 3/25/20)

The requirement that PIs who are conducting any study that has an IND must obtain an individual MCSR research license prior to administering any drug *has not changed*. We recommend that PIs keep to the pre-pause schedule for applying for their MCSR research licenses, even if all of their studies are paused, to avoid any delays in restarting once the pause is lifted. Please contact the MCSR research license administrator, Karla Damus (damusk@bu.edu) with any questions about the research license schedule or requirements.

29. Can study monitors get remote access to EPIC? (NEW 4/9/20)

Monitors can get “over-the-shoulder” access to EPIC by participating in a secure remote meeting (see #19 above) with study staff in which a study staff member accesses EPIC and shares their screen with the monitor.

30. What is the time frame for restarting in-person research at BMC and BU Medical Campus? (UPDATE 4/14/2021)

The decision by the Institutional Officials at Boston University Medical Campus and Boston Medical Center to pause most in-person interactions with subjects in mid-March was based on the COVID-19 situation in Boston and the need to free up resources at BMC and protect research subjects and staff. The evolving circumstances of the COVID-19 pandemic will continue to drive decisions regarding when to restart in-person research activities.

BMC re-opened the ambulatory clinics at the hospital in early June 2020 at a reduced patient volume, in accordance with the state’s re-opening plan. Increases in ambulatory capacity will be gradual and will depend upon the success of preventing infection, both at the hospital and in the community. As patients begin to come back to the clinics, the institutions are aware that restarting on-campus research is an important and related topic. There are many complex factors that are being considered as part of this discussion, such as how to prioritize the still-reduced resources and space on-campus, how to efficiently

minimize the number of research staff engaged in face-to face participant interactions, and how to optimize the protections for participants and research staff.

The institutions have now released a new communication about in-person research. This communication applies to clinical research occurring at Boston Medical Center, including BU Principal Investigators performing research within BMC clinical space. *BU or BMC lab space or non-clinical research should still go through applicable departmental review and approval to host research staff safely.*

A. Now that the hospital has entered Phase A, we would like to re-confirm the importance of prioritizing research visit types in the following order.

1. Research visits are completed remotely, with no in-person interaction.
2. Research visits involve piggybacking on routine care visits within or outside of the PI's home department, depending on the location of the service. These visits continue to require approval from the clinic to use of the space for research purposes*.
3. If research visit types described in #1 and #2 above are not possible and a research-only in-person visit must occur, the visit can only be scheduled after the clinic has granted approval for use of the space*.

*Clinic approval may include a review from: section chiefs, clinical operations, or department administrators. Please, confirm your section or department's requirements to confirm clinical volume. The GCRU also requires review and approval, please contact the GCRU directly for further information.

We continue to ask study teams to implement this visit type prioritization even for patients who are 2-weeks post their 2nd vaccination (Pfizer or Moderna) or who have received a single dose of the J&J vaccine.

BMC Research Re-start is no longer required to submit for on-going or new clinical research as of 3/22/21. Instead, please follow the guidance above.

B. Research monitor, and auditor, visits should be treated with the same level of priority as above and also require departmental approval if a fully remote monitoring visit is not possible. If on-campus monitoring is the only option, the department is responsible for providing a visitor exemption for the study team and must confirm the following guidelines are met: <https://www.bmc.org/visiting-us/visitor-policies>. Please, consider all options before a monitor comes to campus, such as but not limited to, a hybrid monitoring experience involving some work completed remotely via ChartLink or scanned secure records, followed by an in-person review if unavoidable.

C. We welcome you to visit "[Remote Study Design Optimization](#)" documentation for additional guidance. Please, also review the "[Remote Monitoring Chartlink Access Workflow](#)" to provide monitors or auditors access to BMC's EHR.

Please email: ClinicalTrialOffice@bmc.org with any questions or comments.

BU investigators doing any in-person research, including field research, and BMC investigators doing in-person research in BU space (including in the GCRU), must first receive approval* from [BU Office of Research](#) to interact with subjects in-person for this specific study.

*Please note that the IRB does not need to review your approval confirmation.

31. If I am approved to see subjects in-person for research purposes, when and how should I talk with subjects about the risks of exposure to COVID-19 during a research visit? (NEW 8/24/2020)

For studies requiring an in-person visit *for research purposes only*, the communication with the subject when setting up the visit must include a statement such as:

“Do you have any concerns about this visit because of the COVID-19 pandemic?”

Study teams need to be prepared to discuss the risks of exposure to COVID-19 in the context of the particular disease or condition being studied (if any), as well as being able to describe the mitigation measures in place specific to the particular study visit. Subjects should be given the opportunity to decline the visit or withdraw from the study if they have concerns about the risks of COVID-19 exposure.

The opportunity to discuss this information should be presented to subjects before all types of in-person visits; this includes when the visit is to BMC or the BU Medical Campus, and/or for in-home visits conducted by study personnel.

The specific language of this conversation with subjects does not need to be approved by the IRB. Please also note that the risks of exposure to COVID-19 because of a study visit should not be added to consent forms or study protocols. Instead, this conversation prior to the visit is the appropriate place to address this risk and explain the mitigation practices in place.

32. What if I need to make substantive changes to the design of my study due to COVID-19? (NEW 9/30/2020)

The rapidly-changing research landscape facing study teams due to COVID-19 has made it difficult for researchers to quickly and effectively update their study protocols and applications in response. Certain requirements face all investigators seeking to conduct research in this environment, such as COVID-19 testing for subjects prior to their on-site interactive study visits. The IRB continues to ask that you omit those requirements from your study protocol and consent form since they are not specific to the research procedures, but rather are institutional requirements for COVID-19 exposure risk mitigation (see FAQ #31 above)

However, many projects require substantive changes specific to the design of the research. These changes may include new processes for remote consent, utilizing a hybrid plan of remote and in-person visits, sending subjects to outside labs closer to their homes, or even substituting important research scans or tests for others that require less in-person contact. Such items often require changes to study documents, including protocols, study applications, and consent forms.

Given the complexity of such changes, and the high likelihood that study designs will continue to change based on developments related to COVID-19, it becomes extremely difficult to maintain cohesive study documentation. **As such, the IRB is recommending a protocol addendum and/or consent addendum approach.** This approach allows study teams to efficiently respond to changes in institutional requirements and sponsor requirements. Such a process includes submission of the following (as applicable) for temporary study changes related to COVID-19:

- 1) A separate protocol addendum document describing the temporary changes to study design during COVID-19 restrictions. This should include any new scheduling, visit type (in-person, remote), new or substituted procedures, and new consent processes. In addition, this document should explain what sections of the currently approved protocol it is temporarily replacing.
- 2) A separate consent form addendum that describes the changes in procedures compared to the pre-COVID-19 approved consent form, and explains how the study will be conducted during COVID-19 restrictions.
- 3) If your study does not have a separate protocol, then the temporary design changes should be outlined in the applicable study application sections in a discrete COVID-19 Procedures paragraph that is clearly identified as separate from the originally approved application language (not interwoven throughout the existing pre-COVID procedures).

This approach allows researchers to be more responsive to rapidly evolving COVID-19-related changes, and the flexibility to return to the original study plan, by retiring addendums, without substantially overhauling existing study documentation.

PLEASE REMEMBER:

The IRB continues to ask that you omit purely COVID-19 related risk mitigation requirements (i.e., COVID-19 testing for subjects prior to their on-site interactive study visits, COVID-19 screenings, etc.) from the study protocol and consent form if they do not otherwise affect study-specific procedures and/or study visit schedules. These activities are not specific to the research, but rather are institutional requirements for COVID-19 exposure risk mitigation. Please see FAQ #31 for a more detailed discussion of how these activities should be communicated to subjects.

IRB submissions are highly variable. The most appropriate way to modify a protocol depends on such factors as study design, study population, and expected duration, to

name only a few. If you are unsure about how to modify your study, feel free to reach out to the IRB at medirb@bu.edu for further guidance.