

**COVID-19 and/or remote work IRB FAQs**

**Can I continue to conduct research on my IRB approved protocol?**

Please follow the most recent OCR guidance as to what research protocols and specific research activities should and should not continue. See the OCR website at <http://bsdocr.bsd.uchicago.edu/fac-staff/covid19.html> for the most recent updates.

**If I want to change my existing, approved study to allow for remote research data collection, web conferencing, etc., how do I do that?**

If your currently approved study does not allow for remote research data collection, please submit an amendment to modify your data collection procedures. As applicable, please include a statement in the amendment to specify that these changes only apply during the time of UCMC-imposed restrictions on research during the COVID-19 pandemic.

After the amendment has been submitted in AURA IRB by the PI, send an email to [COVID19-IRB@bsd.uchicago.edu](https://mail.uchospitals.edu/owa/redir.aspx?C=Ad9UBZdTi5871kte3o0Iyw-CTTZ9eiW5w3jWntLS7xoEKXN8R8zXCA..&URL=mailto%3aCOVID19-IRB%40bsd.uchicago.edu) so that the IRB can batch similar amendments and process these types of amendments efficiently.

The clinical care landscape has significantly changed due to the COVID19 pandemic. If your study is collecting research data from clinical visits, and clinical care has changed during the COVID19 pandemic, an amendment to the IRB protocol may not be required. For example, if clinical care visits are being conducted via UCMC telehealth capabilities, and research data are collected from those clinical visits, an amendment to the IRB protocol is not required. This is because the change for research is in line with clinical operations rather than a change to research itself.

"Web conferencing" for a focus group study is a different activity than a "telehealth" visit in line with what is being done for clinical standard of care. Therefore, while a clinical trial may not require an amendment if a visit that is a research AND clinical visit is occurring via telehealth communication, a different type of study may require an amendment if the web conferencing or virtual visit is not in line with standard of care at the moment.

For FDA-regulated studies, researchers are required to track changes made to research operations as result of COVID19 for annual reporting.

All study teams should consider including an update on changes in practice in a report to the IRB at time of continuing review.

As per FDA regulations, if changes are "necessary to eliminate apparent immediate hazards to the human subjects," these may be implemented to protect the subjects prior to IRB approval of an amendment. The IRB should still be notified of the change as soon as possible.

As a reminder, if you have questions please contact COVID19-IRB@bsd.uchicago.edu

**My study would like to ship the study drug directly to our subjects. Would that be allowed?**

Each study may have different considerations based on the following information. Sponsor requirements may also differ between studies.

Drug will be shipped by IDS

An amendment to the IRB study may not be needed if:

* your sponsor does not require an amendment
* investigational drug shipment directly to subjects is the only change proposed AND
* drug is being shipped by UCMC Investigation Drug Service, not by an outside company.

Drug is not being shipped by IDS or other changes are also proposed

On the other hand, if drug-related monitoring required by the research, such as all required lab work or in person safety assessments, will not be done at present and subjects will still receive drug, an amendment will be needed. Similarly, if an outside company will be shipping drug or the sponsor has required an amendment, an amendment to the IRB protocol should be submitted in AURA-IRB.

Please consider the following questions when submitting the amendment and provide details, as applicable.

* How are the subjects being informed that drug will be shipped? Are you planning to phone them and discuss the process with them?
* Is PHI being disclosed outside UCMC without prior authorization? Is a waiver of authorization under HIPAA being requested? [Note that if a waiver of authorization is being requested, this must be documented in AURA. See next section]
* Is drug being shipped by our UCMC IDS or by an outside company? Which outside company?
* What is the specific drug and how is it administered (e.g. oral pill, injection, etc)? How will subjects know how to take the drug (e.g. are instructions being given or sent with the drug)?
* Is the investigational product a controlled substance that is prohibited from direct mailings and or does the product require temperature controls?
* What are the drug’s research monitoring requirements? How will safety considerations related to drug administration be handled, if monitoring assessment are not being performed?

Although this change to the protocol may require that subjects be informed of the change, it may not require a formal re-consent with signed documentation from the subject. Please be sure the amendment is clear about whether signed documentation of consent will be required from subjects related to this change or not.

For all studies, the research team should clearly document in the research record any and all information that is provided to the subject and how the subject was informed of changes to the research protocol.

As a reminder, per FDA regulations, if changes are "necessary to eliminate apparent immediate hazards to the human subjects," these may be implemented to protect the subjects prior to IRB approval of an amendment. The IRB should still be notified of the change as soon as possible.

**How do I obtain authorization to disclose PHI or obtain a waiver of authorization to disclose PHI to a drug company in order to ship drug to a clinical trial subject?**

If PHI is being given to an outside company in order to ship drug directly to a subject, then PHI is being disclosed. If possible, written authorization should be obtained from a research subject to disclose PHI outside UCMC as part of a research study. This authorization can be documented either within a revised version of the current consent/authorization form or in a separate authorization document. To obtain a signed form, authorizations can be sent via email, fax, or snail mail to a subject, signed, and then scanned, faxed, or mailed back to the research team.

Recognizing that under the current conditions, signed authorization is not always feasible, waiver of authorization can be requested. You will need to document the rationale for waiver (see following) and confirm that disclosure of PHI would be tracked in the medical record.

Waiver of authorization requires a researcher to document:

1) the minimal risk to privacy

2) that the PHI is necessary for the research

3) an adequate plan to protect the identifiers from improper use and disclosure

4) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research

5) assurance that the protected health information will not be reused or disclosed AND

6) that "the research could not practicably be conducted without the waiver or alteration."

**Can I make other changes with the amendment?**

If you are making COVID-19-related changes and are requesting prompt processing of the amendment, please remove all other changes from the amendment.

**When is an amendment not required?**

If your approved study does not specify that data collection will be in person, and you are otherwise following your approved protocol, an amendment is not needed.

**If I am voluntarily placing my study on hold, is an amendment required?**

No, an amendment is not required if you are placing your study on hold due to the current pandemic.

**Will deadlines for continuing reviews (CRs) be extended?**

Expirations are automated in the AURA system so there is no way to extend approval beyond an expiration date. Please continue to submit continuing review materials when they are due. Continuing reviews can be submitted through the AURA IRB system. The IRB staff are working remotely and will continue to process continuing reviews.

**Should any of these studies happen to have CRs due before the situation resolves, should we report the studies as “on hold” in the CR submission? If yes, would the IRB still be willing to stamp the consent forms for future use?**

Please report the current status of your study at time of CR, whether it is temporarily on hold or otherwise. If you report that your study is temporarily on hold due to the current restrictions associated with the COVID-19 pandemic, but would otherwise still be accruing, the IRB will stamp the consent form(s) approved to be used when restrictions are lifted.

**I would like to do research on COVID-19. Can this be fast-tracked?**

Yes. You will need to submit a protocol through the AURA IRB system in the usual manner. Please then email COVID-19-IRB@bsd.uchicago.edu to alert the IRB office that the study has been submitted.

**Is the IRB still reviewing non-COVID-19-related research?**

Yes. The IRB is prioritizing emerging research if possible, but the IRB continues to review amendments and continuing reviews for research not related to COVID-19, as well as new research protocols. If this changes, the IRB will notify its research community.