Coronavirus Update: Temporary IRB Protocol Revisions

Updated June 16, 2021

On June 4, 2021, the Office of Research announced a return of research labs to normal operations effective June 23, 2021. This includes all aspects of human subjects research. New IRB applications with in-person activities no longer require a COVID-19 safety plan.

If you currently have IRB approval for in-person research activities that included the use of either the Standard COVID-19 HSR Safety Plan or a Study-Specific Plan ONLY during pandemic restrictions, you can return to normal operations without requesting a study modification.

Modification requests are only required for:

- IRB studies not currently approved for in-person activities and in-person activities are now requested
- IRB studies approved for in-person activities that did not include flexibility by adding language indicating remote procedures would be used under pandemic conditions and in-person activities would be used under normal operations.

Researchers are also encouraged to inform study subjects that voluntary use of face-coverings is still acceptable.

As a reminder, any new research that involves human subjects, must get IRB approval before it can start. If you have questions email: irb@ucf.edu

IRB study scenarios for return to normal operations

1. Any study that is currently approved as remote only will have to stay remote unless a modification is submitted. If an investigator wants to switch it to in-person, they will have to submit a modification request to be in-person. Researchers will no longer have to follow a standard or study-specific safety plan for COVID-19 precautions.

2. Any study that was approved in-person pre-COVID-19 and went remote during COVID-19 restrictions with an IRB modification should be modified back to be in-person if the investigator considers that beneficial/needed. However, if the study was modified with the flexibility for remote during pandemic conditions and in-person during normal conditions, a modification would not be needed. Researchers will no longer have to follow a standard or study-specific safety plan for COVID-19 precautions in either case.

3. Any study that was approved as in-person during COVID-19 with COVID-19 precautions (either with the standard or a study-specific safety plan) can continue to be in-person without use of the safety plan as long as the study was written with the flexibility to only use the plan during pandemic conditions. A modification is required if the protocol was written to always include the safety plan.

4. Any study approved as in-person pre-COVID-19 but was stopped due to pandemic conditions can resume in-person without modifications as long as the study approval has not expired/lapsed. If study approval expired, a new application is required.

Updated June 23, 2020

1. If you can conduct your Human Subject Research remotely, continue to do so.

    - Protocol changes are necessary to accommodate remote research for Expedited and Full Board studies and *must* be reported via a study modification in Huron IRB

    - Although you may continue to conduct your Expedited or Full Board study remotely, the modification must be submitted to continue research remotely by 7/15/2020

    - Changes in Exempt studies *should* be reported via a study modification in Huron IRB

2. If you need to resume in-person research that does not require close personal contact or other high risk factors, follow the COVID-19 Human Subject Research (HSR) Standard Safety Plan (Link):

    - Submit an email using the template (link) to your Associate Dean for Research (ADR) requesting approval for restart based on your ability to meet all requirements.
    - For existing studies, once you receive permission to resume from your ADR, add a comment to your study in Huron IRB stating that you are able to follow the Covid-19 HSR Standard Safety Plan and then resume in-person research. You do not need to wait for IRB approval.

    - For new studies, during the IRB submission, add a comment to your study in Huron stating you are able to follow the Covid-19 HSR Standard Safety Plan. Once you receive approval from the IRB, you will be able to begin your in-person research.

3. If you need to resume in-person research that does require close personal contact or other high risk factors, develop a COVID-19 Human Subject Research (HSR) Study-Specific Safety Plan (link) to describe provisions you can put in place to minimize the risk of transmitting COVID-19 during the research process.

    - For existing studies, modify your study in Huron IRB and attach your Study-Specific Safety plan in the Local Site Documents, Other attachments section. Update your consent to include any changes to what your participant needs to do and update your protocol, section 6, first bullet point, to include those changes and to reference your Study-Specific Safety plan. Do not resume in-person research activities until the IRB has issued an approval letter for the modification.

    - For new studies, create a new study application in Huron IRB attach your Study-Specific Safety plan in the Local Site Documents, Other attachments section. Reference your Study-Specific Safety plan in your protocol, section 6, first bullet point. Wait for IRB approval before beginning human subjects research.

    - CITI has recently released COVID-19 information related to higher education that you may find useful in developing a study-specific safety plan. Logon to CITI from the IRB webpage and add COVID-19: Back to Campus (Fall 2020) to your course listing.

4. If you are on a study approved by an External IRB where the protocol or consent document has been modified, submit the modifications to your study in Huron IRB using the External Update function.

    - If you have in-person activities that can be conducted without close personal contact/or high risk factors, follow the instructions from 2 above.

    - If you have in-person activities that cannot be conducted without close personal contact/or high risk factors, follow the instructions from 3 above. In addition, discuss any proposed changes to the protocol or consent with the reviewing external IRB.

For Safety Plans, Participant Information Sheet, and Presentation – Resuming In-Person HSR see: https://corona.research.ucf.edu/human-subjects-research/

Updated April 10, 2020 – The IRB is making an update to guidance because of continued remote operations at UCF related to COVID-19.

Should I continue my protocol during the COVID-19 period?

All research involving face-to-face interaction must halt if it cannot be done via a different mechanism such as phone, Skype, Zoom, etc. If the researcher has reason to believe halting the research will add risk to the subject, the researcher should contact the IRB.

Updated March 13, 2020 -- Because of the unprecedented coronavirus -COVID-19 - situation, investigators may be required to alter their research protocols in some way to minimize the spread of this virus. We know this has IRB implications, so we are providing Temporary Protocol Revisions, procedures and guidance on when to notify the IRB.

What types of changes can I make to my protocol that do not require IRB approval?

In general, changes that:

*Are temporary in nature in order to limit subject exposure to the virus. This means that when this crisis is over, you will return to all pre-crisis procedures.

**Change on interaction methods, such as changes from face-to-face to over the phone or some other similar devices.
**Please remember that this change can only be implemented if it presents no greater risk to participants. For example, if your study was taking place in-person to avoid the risk by direct observations of the research subjects, a change to over the phone would not be permitted without a formal review by the IRB in the form of a modification.
** Do not add any additional risk to any subjects or study staff.
**You should make a note in your study records regarding the above mentioned minor temporary change(s) that were made along with the justification in case you are ever audited.

What type of changes "must" be approved by the IRB prior to implementing them?

In general, changes that:

* Are not being made as a direct result of the COVID-19 crisis, no matter how minor.

* Are greater-than-minimal risk changes that are a result of the COVID 19 crisis.
* Are on the protocol that is a greater-than-minimal risk study.

What if the greater-than-minimal risk revision can't wait for IRB approval?

If it is in the best interest of the subject, and will minimize or prevent transmission of COVID 19, then make the change, however:

* You should immediately notify the IRB by email at IRB@ucf.edu.
* You should make a note the change(s) in your study records with the justification.
* You must submit the revision of protocol with the change(s) to the IRB as soon as possible, noting that the revision was implemented because of an emergency, including the justification for that emergent change(s).

What if there is a desire or need to keep a temporary COVID-19-related change a permanent change?

*If the change is consistent with item #2 above, then initiate the change and submit the revision.
* When you submit the revision, please include in the description of the revision that the change was already implemented, and the reason it was implemented "emergently".

What if you decide to suspend your study until the COVID-19 crisis is over?

*There is no need to inform the IRB. However,

**If your study is a greater-than-minimal risk study that involves some type of patient care, you must ensure your suspension does not increase any risk to those study subjects.
**If possible, make sure you contact any study subject who will be affected by this suspension (i.e., a study visit will be cancelled, etc.)
**You should make a note in your study records of this temporary suspension along with the justification and any actions taken in case you are ever audited.

If you have any additional questions, contact the IRB at IRB@ucf.edu. Please be patient as we anticipate a large volume of requests at this time.