Creighton UNIVERSITY

Office of the Provost
Research Compliance

# COVID-19: FAQS RELATED TO HUMAN SUBJECTS RESEARCH AT CREIGHTON

## 1. Can I continue my human subjects research?

### High Prospect of Direct Benefit

*For example:*

- Research protocols involving treatments for acute, life threatening health conditions (e.g. treatment trials for cancers).
- Protocols where stopping the intervention (e.g. investigational drugs or vaccines or preventative drug regimens) could be harmful.

Studies with high prospect of direct benefit to subjects may continue (e.g. continued accrual, intervention, and assessment is based on the ability to implement precautions for the safety of participants and investigative staff) as long as those studies are conducted with adequate precautions to minimize risk of exposure to COVID-19 and there are research personnel available to complete those visits. Research teams must assess their studies on a case by case basis and modify studies to reduce the risk to participants and study personnel.

### Limited Direct Benefit

*For example:*

- Protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation (e.g. test results coming back that might have clinical implications for their care).

New subject accruals for research which involves face-to-face contact and where there is only limited direct benefit must be halted. Research interventions and assessments on already enrolled subjects may continue as long as those interventions can be performed with minimal risk to subjects and there are staff available to complete those visits.

**If the PI feels there is a compelling justification to continue enrollment in a limited direct benefit study, the study team must submit a written justification to IRB@creighton.edu. Please include the following information in the email communications:**

- What is the direct benefit to the subject that cannot be obtained outside the study?
- Please specify the reasons that enrollment cannot be postponed until restrictions are lifted?
- What specific measures will be taken to minimize in-person visits (e.g. visits may be done remotely or coincide with clinical visits)?
- Any other pertinent information that will help to make a decision to continue the research.

**Research for both 'High Prospect Direct Benefit' and 'Limited Direct Benefit' studies *must screen all research participants* for potential exposure to COVID-19. Screen all research participants for potential exposure to COVID-19 or symptoms of illness *before* they are scheduled for study or clinical care visits. Please refer to the guidelines released from the health system that you are operating within. For CHI Health sites, please contact Kayleen Joyce at Kayleen.Joyce@alegent.org to inquire about the CHI telephonic screening procedure.**

**Explore with your sponsor how to reduce risk to you and your participants by whether you can reduce number of visits, delay visits, or convert visits to online-only. Please see FAQ question #2 for more information.**

## No Direct Subject Benefit

All active research that uses direct face-to-face contact and has no direct subject benefit should be halted. No further accrual, research interventions, or assessments may take place, *unless* done remotely (Zoom, Skype, Telephone, Online Questionnaire, etc.).

**Research/scholarly activities that can be carried out remotely should continue during this time. Studies with no face-to-face participant interactions can continue as approved. If approved research can be modified to eliminate direct participant contact, see below.**

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# Protocol Changes and Modifications

2. If I want to make a change to a protocol to reduce risks to subjects (for example, to decrease number of study visits, or to give a "window" for a visit), is an IRB 'Request for Modification' required?

The CU IRB is required to follow policies and procedures for prospective review of Modifications with the exception of changes necessary to eliminate immediate hazards to the subject which may be made without prior approval of the IRB (per 45 CFR 46.108(a)(3)(iii), 21 CFR 56.108(a)(4) and CU IRB policy 121 'Modification of Approved Research'). However, the CU IRB requires these reports be submitted within 5 business days by submitting the 'Reportable New Information' form. The submission must outline a description of changes made and provide sufficient information in order for the CU IRB to conduct a risk assessment of the changes.

****Please contact the study sponsor to inform/obtain approval for your proposed changes. All proposed changes must be approved by the sponsor prior to submitting to the IRB.****

3. How can a PI modify study procedures to alter in-person visits to virtual/remote visits?

If the PI would like to modify their procedures to replace in-person study visits with virtual/remote or phone options for administering procedures such as questionnaires, surveys, check-ins, screening, and consenting, these changes must be approved in advance by the IRB as a Modification to the approved study.

The CU IRB will prioritize modifications related to COVID-19.

## Important notes for COVID-19 related amendments/modifications:

**When submitting a 'Request for Modification', please note in the submission to the IRB that the PI is adding the option to perform research remotely under the COVID-19 revised standards for human subjects research.** ***Include in the 'Request for Modification' form that once in-person research is allowed again, the study will return to previously approved procedures. Doing so will eliminate the need to submit another modification later when/if the PI wishes to resume normal study activities.***

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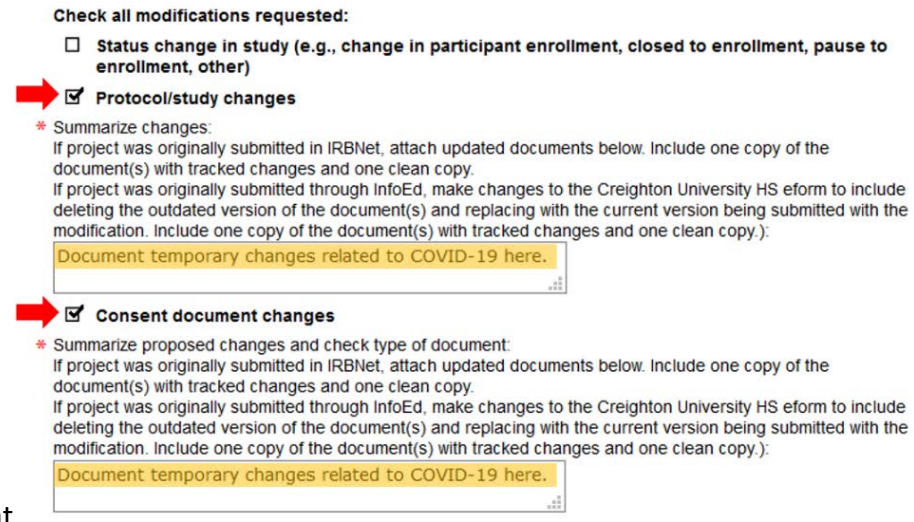
In the modification, please consider and address the following, where applicable:

- Potential impact on subject safety and protections
- Potential privacy and confidentiality concerns
- Data security requirements and obtaining IT security approval
- Explain how recordings are to be made remotely
    - Please note that at this time, Zoom is permissible for remote patient care. For more information, see the OCR and HHS 'Notification of Enforcement Discretion for Telehealth Remote Communications During COVID-19 Nationwide Public Health Emergency' published on March 23, 2020
- Potential impact on scientific integrity and/or benefits of the study
- Plan for how existing subjects will be notified (if their participation will be affected by the Amendment/Modification)

Note: Because these changes are only temporary, the 'Creighton University HS eForm' **does not** need to be updated, and edited versions of the study protocol and/or consent form(s) **do not** need to be uploaded, *unless* the changes affect subject risk/safety (e.g. shipping investigational products directly to research subjects or research subjects self-dispensing study drug). Simply document the COVID-19 related amendments/modifications in the 'Request for Modification' form. Where applicable, check the box(es) that will require temporary changes, and provide your explanation in the "Summarize changes" text box.




Information on how to submit a modification to an approved study can be found at here.

4. If I include/add a COVID-19 screening questionnaire before inviting them to campus for studies that are ongoing, do I need to inform the IRB?

No change in protocol is required unless you are using it as a change in eligibility criteria for the research. The following is from the CHI Institute for Research and Innovation:

*"All study teams should immediately implement procedures to incorporate mandatory telephone screening prior to scheduled study visits at your local facility. The screening algorithm for COVID-19 utilized by your local institution should be used. Such questions relate to recent travel, contacts, and current symptoms; however, the algorithm is rapidly evolving. To ensure the latest version of your local institution's approved screening questions is applied, please reference your facilities designated COVID-19 tools and resources in addition to the electronic medical record (document within the EMR accordingly) to decide if a research visit should proceed as scheduled.*

*In the event the telephonic screening participant meets criteria for isolation guidelines, they should be instructed to contact their primary care physician for further evaluation. The research visit should be postponed at least 14 days with a follow-up telephonic screening call to assess symptoms prior to the rescheduled visit. Study personnel should ensure documentation within the EMR for all such correspondence.*

*The incorporation of this mandatory telephonic screening procedure does NOT require IRB approval."*

5. If a protocol deviation/violation has occurred (for example, I made a change before getting IRB approval, or a subject didn't come to a scheduled visit), do I need to submit a Reportable New Information to the IRB?

It depends. Protocol deviations (e.g. out-of-window visits that do not constitute a safety risk to the subject) should be submitted on the continuing review application. However, protocol violations from study visit schedules that have or could have increased risks to participants should be promptly reported to CU IRB through a 'Reportable New Information' submission within 5 business days (per 45 CFR 46.108(a)(3)(iii), 21 CFR 56.108(a)(4)

and CU IRB policy 133 'Reportable New Information'). For examples of deviations and violations to an approved protocol, please consult the CU IRB Guidance Tools.

**Please call the IRB at 402-280-2126 or email us at IRB@creighton.edu with specific questions related to if a violation must be reported.**

## 6. What if a modification to the approved study cannot wait for IRB approval?

If it is in the best interest of the subject to eliminate an immediate apparent hazard to one or more participants and there is no time to obtain prior IRB approval, a researcher may do so. The PI must then submit this modification as reportable new information (RNI) within 5 business days to the IRB for review (per 45 CFR 46.108(a)(3)(iii), 21 CFR 56.108(a)(4) and CU IRB policy 133 'Reportable New Information').

## 7. I have paused enrollment of new subjects (or paused all research interventions). Must I still do a continuing review?

Yes. Federal regulations require re-review (continuing review) no less often than yearly. Therefore, CR must be submitted by the investigator and approved by 1 year after initial IRB approval, or the research approval will expire. InfoEd sends out reminders that CR is due starting 60 days, 30 days, and 7 days prior to deadline.

## 8. Does the consent form need to be modified when implementing remote study procedures?

No, consent forms do not need to be modified unless the modifications to the study protocol change the risks to participants.

## 9. How does the PI notify the IRB of an Initial Application or Modification related to SARS-CoV-2 or COVID-19?

To ensure timely processing of submissions related to COVID-19, we ask that the researcher identify an 'Initial Application' by including "COVID-19" in the title, and for 'Request for Modification' and 'Reportable New Information' forms, please include a statement notifying the IRB that the submission is related to SARS-CoV-2 or COVID-19.

****FAILURE TO IDENTIFY A SUBMISSION AS OUTLINED ABOVE MAY RESULT IN DELAYS IN REVIEW****

### 10. Can the PI decide to voluntarily pause, delay, or reschedule interactions with subjects until the COVID-19 outbreak has resolved?

Many industry-sponsored studies are choosing to suspend research activities for clinical trials. These decisions are in accordance with the 'FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic'. It is the PI's responsibility to consult with the study sponsor regarding decisions to voluntarily pause, delay, or reschedule interactions with subjects. If granted permission from the study sponsor, investigators are required to document the voluntary pause in the study records along with the justification and any actions taken in the event that this is needed during an audit.

For non-industry-sponsored studies, please contact the Creighton IRB at 402-280-2126 or IRB@creighton.edu.

## Research with Patients

### 11. What should a PI do in the case of a single patient emergency use scenario?

The procedures for a single patient emergency use of an investigational drug or device remains unchanged during this time. The policy for 'Emergency Use of Unapproved Drugs/Devices/Biologics' can be found on the Creighton IRB Website, policy 127. Read about the FDA Guideline.

### 12. What should be done about participant safety monitoring?

For clinical studies requiring in-person study visits in order to conduct safety monitoring of the participants, researchers should plan for alternatives to in-person monitoring visits, if possible. For example, interviews could be conducted by phone or email or perhaps the schedule of monitoring could be safely modified or delayed. Modifications to safety monitoring procedures should be approved in advance by the IRB, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval.

**If a PI does need to change an approved monitoring procedure to eliminate immediate possible danger, please report it to the CU IRB within 5 business days, following the Reportable New Information (RNI) procedures described in CU IRB policy 133 'Reportable New Information'.**

# Other

## 13. When does a PI need to update their Clinicaltrials.gov registration?

Studies registered at the federal site ClinicalTrials.gov that are modifying their research procedures to include testing for SARS-CoV-2 and/or assessment of COVID-19 symptoms should update the ClinicalTrials.gov information to include these new procedures, if they are done for research purposes. If new procedures are being added as public health surveillance activities in coordination with public health authorities, the registration information does not need to be modified. Any research-related changes that are communicated to the subjects (past, ongoing, future) must be added to the study's ClinicalTrials.gov registration within 30 days after IRB approval of the modification.

## 14. Can the process of consent be conducted via telephone, email or other remote technologies?

Yes. The authorized personnel may obtain consent by telephone, as approved by the IRB. In such instances, the authorized personnel shall provide informed consent to the human subject and his/her authorized representative, if applicable, over the telephone. The authorized personnel shall document in the research record the informed consent process. The CU IRB policy 117 (1.3) 'Informed Consent (Including Permission/Assent)' describes the requirements and process for obtaining informed consent by telephone.

## 15. What happens if I submit an IRB protocol for a study that is not deemed of a type that is eligible to start enrolling?

The IRB will continue to review all protocols. Protocols will be reviewed in order of urgency, so some studies, such as one deemed unable to start enrolling, may be delayed. But once reviewed, and even if it could be approved at another time, final approval will be delayed until it is felt safe to start the study. You will be informed of this decision so that if you have questions about its status or how it has been categorized, you can contact the IRB.