COVID-19 and Human Subjects Research

Effective March 18, 2020 (**Updated 04.01.2020**)

This guidance will continue to be updated as new information becomes available and additional guidance is developed.

Restricted Activities

What activities are restricted? (Updated 03.18.2020)

On March 18, 2020, The HRPP/IRB announced that to protect research participants and help mitigate the spread of COVID-19, **all in-person interaction with research participants is to be placed on hold until further notice**. In-person interaction with research participants is allowed **only if** the research is critical to the treatment of a participant's significant and life-threatening condition. UT has very few, if any, active studies meeting this condition.

Are there exceptions to these restrictions? (**New 04.01.2020**)

Essential research interactions (as defined below) that cannot occur remotely may only be performed in-person if the IRB has made that determination.

Are these guidelines or true restrictions? (**New 04.01.2020**)

These restrictions are mandatory.

How long will these restrictions last? (**New 04.01.2020**)

The impacts and challenges of the COVID-19 pandemic are unprecedented. Our office continues to monitor the release of information from the University of Tennessee, federal agencies, state and local authorities. We are also communicating with our colleagues at other institutions to identify best practices and creative solutions to the challenges impacting our researchers as well as our ongoing operations. We will continue to update the UT research community as events unfold.

UT Knoxville HRPP/IRB Operations

Is the office operating normally? (Updated 03.18.2020)

Following the Chancellor's recommendations and the local Safer at Home order, HRPP personnel are working remotely. Although Blount Hall is closed, our office remains fully operational. IRB reviews and meetings are being conducted remotely until further notice.

Who can I contact with questions? (Updated 03.18.2020)

For general questions, researchers can contact the staff by email (utkirb@utk.edu) or phone message (865-974-7697). For questions about a specific study, contact your college/departmental liaison. All phone messages and emails are monitored and will be answered as soon as possible.

How will I know if the guidance or restrictions change? (**New 04.01.2020**)

New and updated information will be added to this guidance as it becomes available. In addition, our office will email any alerts on updates directly through the UTK iMedRIS listserve (i.e., those with active accounts in iMedRIS). To ensure you receive these updates, confirm that utk-imedris@listserv.uthsc.edu is included in your safe senders list.

Is the IRB prioritizing reviews of submissions? (**New 04.01.2020**)

Yes. We are prioritizing all new applications and amendment requests as follows:

Initial Reviews

- COVID-19 studies
- Application with funding approval needs

Amendment Requests:

- COVID-19 related changes
- Safety-related changes
- Funding changes

Ongoing Studies

Can I still interact with my research participants? (**New 04.01.2020)**

All researchers (faculty, staff and students) must abide by the following:

- In-person research interactions are on hold until further notice unless the interaction is **essential** to participants' health and well-being or their safety.
- Research interactions (both essential and non-essential) performed remotely with participants may continue.
- In-person research interactions that are non-essential are on hold until further notice.

Can I enroll new participants to my IRB approved study? (**New 04.01.2020)**

It depends on your research procedures.

- Studies involving no in-person interaction with research participants may continue enrollment.
- Studies involving in-person interactions with research participants **must place** enrollment on hold until further notice.

What research interactions are considered essential? (**New 04.01.2020)**

Research interactions should be considered as essential or non-essential in the context of the participant's health and/or well-being.

> **Essential** interactions are those conducted in ongoing therapeutic studies that hold the prospect of direct benefit to the participant. Studies that involve essential interactions are those that are critical to

the treatment of the participant's significant and life-threatening condition or critical to the participant's safety. Examples include drug, device or other therapeutic intervention studies.

Non-essential interactions are all other interactions with participants. Examples include:

- Behavioral or social science research interactions that are not critical to participant health or well-being.
- Observational study interactions.
- Non-therapeutic interventional study visits intended to improve health, but not for the treatment of a specific disease or condition.
- Therapeutic study visits for conditions that are not life-threatening in the near-term.

Who decides if a research interaction is essential? (**New 04.01.2020)**

The IRB makes this decision. If researchers believe their study meets the criteria for essential interaction, and they have a compelling reason for continuing in-person interaction with participants, principal investigators (PIs) may submit an amendment request to the IRB requesting an exception to these restrictions. PIs should describe the compelling justification for the appeal. The restrictions on in-person interactions must be followed for those studies seeking an appeal until such time as an appeal is granted.

The IRB advises researchers to contact their college/departmental liaison before submitting an amendment request to appeal these restrictions. UT has very few, if any, studies meeting the criteria for essential interactions. It is the IRB's expectation that all in-person research procedures have ceased.

Is IRB approval needed for communications to research participants informing them of the postponed research activities? (**New 04.01.2020)**

No, communications to participants intended to inform them that research activities are postponed does not require IRB review or approval.

Can I modify my study procedures to occur remotely? (03.13.2020)

Yes. Some researchers will be able to replace in-person interaction procedures with "remote" interaction options such as phone calls, online surveys, audio-video conferencing, email, postal mail, etc. Depending on your study, remote procedures can be used for recruitment, eligibility screening, obtaining informed consent, data collection, some interventions, administering compensation, etc.

Do I need IRB approval to modify/add study procedures? (03.13.2020)

This depends on the type of review your study received **and** the specific changes being made.

For Full Board and Expedited Studies:

Yes. All changes to modify study procedures require submission of an amendment request in iMedRIS.

For Exempt Studies Only:

Some changes can be made to exempt research studies without submission of an amendment request. All changes **not explicitly listed** as not requiring an amendment request must be submitted for review and approval via an amendment request.

Changes to exempt research **NOT REQUIRING** an amendment request include:

1. Changing from in-person survey/questionnaire to an online survey using UT's QuestionPro, Qualtrics, or REDCap (through UTHSC) survey tools **AND** anonymous data collection (study uses the survey tool's anonymize setting)
2. Changing from in-person interviews or focus groups to conducting those activities via Zoom

3. Adoption of a screening procedure, should the hold on in-person interactions be lifted, to determine whether the study visit should take place, be rescheduled, or canceled

Changes to exempt research **REQUIRING** an amendment request include any change not explicitly listed above, such as:

1. Changing from in-person survey/questionnaire to an online survey **using a survey tool other than** UT's QuestionPro, Qualtrics, or REDCap (through UTHSC), whether data are collected anonymously or with identifiers
2. Changing from in-person survey/questionnaire to an online survey **collecting identifiers** (including IP address), **regardless of the survey tool used**
3. Changing from in-person interviews or focus groups to conducting those activities **using a video conferencing software/tool other than Zoom**
4. If in doubt about what does and does not require an amendment request for exempt research, contact the IRB Office at (865) 974-7697 or utkirb@utk.edu.

How do I obtain a participant's consent using remote procedures? (**New 04.01.2020)**

Informed consent is a process that is usually documented in writing and signed by the participant. Under some circumstances the IRB can waive the requirement to obtain the participant's signature (i.e., waiver of documentation of consent).

Consent Methods Not Requiring a Participant's Signature

For research approved by expedited or full board review, a waiver of signed consent may be an option. The waiver of signed consent requires that a consent process be conducted with participant, but does not require the participant to provide written documentation of that process. Although the regulations allow for a few different ways that research may qualify for this waiver, this FAQ discusses the option most applicable to the adoption of remote procedures. A study may qualify for this waiver if the research:

- presents no more than minimal risk of harm to participants, and
- involves no procedures for which written consent is normally required outside of the research context (i.e., research involving activities subject to other laws that require a person's signed consent, such as HIPAA or FERPA, is not eligible for this waiver).

When the IRB approves a waiver of signed consent studies eligible for this waiver frequently use either verbal consent or implied consent.

Verbal Consent

Verbal consent means that the individual obtaining consent reads/explains a verbal version of a consent form (i.e. an information sheet or consent statement), and participants give their verbal consent in place of written consent to participate. Participants should be provided with a copy of the information sheet and given the opportunity to ask questions. If it is not feasible to provide subjects with an information sheet — for example, the only contact is by phone – submit a consent script with your amendment request.

The IRB recommends that researchers document in the research records when the consent discussion took place and if there were any issues.

Implied Consent

Many studies, such as survey research, provide consent information to prospective participants. Those participants do not typically express their consent directly to the researchers, instead their consent is implied through their choice to return a completed survey to the researchers. Implied consent may occur in both electronic and face-to-face settings, or through regular mail. Online survey studies often include the consent information at the beginning of the survey and participants are asked to click "Agree" or "Continue" if they wish to participate, but consent is still implied because participants do not actually "agree" until they submit or return their completed survey.

Obtaining Signed Consent When In-Person Interaction is Not Possible

Alternative Methods for Obtaining Signed Consent

Signed consent can be obtained by sending the consent form to prospective participants through U.S. mail, email, fax, a file sharing application (e.g., UT's Vault), etc. If the participant chooses to enroll in the study, they need only sign and return the consent form to the researchers.

Obtaining an Electronic Signature

Electronic signatures are often a source of confusion. To satisfy human research regulatory requirements for written consent, the following criteria must be incorporated into the electronic form.

- a valid electronic signature must be obtained (see definition below);
- the participant must be able to print (or save) a copy of the consent form (with or without signature); and
- include instructions to print or save a copy of the page presented on the electronic device unless the form will be provided to the participant by an alternative means.

Definition of a Valid Electronic Signature Standards

A valid electronic signature for consent could be the participant's typed name or it could even be as simple as a check mark or an X or any other symbol in a box on a form. Any method is valid provided that the mark or symbol is "logically associated" with the individual making that mark. To associate the individual to the mark, the participant could type their name or even be assigned a unique ID number.

Researchers need to be aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted and communicate those requirements to the IRB. For example, research activities subject to FERPA, HIPAA, FDA, etc. may be subject to additional requirements.

Researchers proposing to obtain a participant's electronic signature (in lieu of a written signature) should provide the IRB with information about

- how the electronic signature is being created,
- if the signature can be shown to be legitimate, and
- if the consent or permission document can be produced in hard copy for review by the potential participant.

One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signature that provides an encrypted identifiable "signature." For example, DocuSign or other system that authenticates the user.

Issues to Consider

Consent Process

Researchers must describe how the consent process will be conducted. For some studies it is sufficient to request participants to contact the researcher with any questions. For other types of studies, it may be necessary for the researchers to include a process to discuss the study with participants and address their questions.

Copy of Consent Document

In all cases, some form of the consent document must be made available to participants in a format they can retain.

Privacy, Confidentiality and Data Security

Researchers should describe any related protections that will be used

What should I include in my amendment request? (**New 04.01.2020)**

To assist us in conducting efficient reviews of amendment requests submitted in response to COVID-19, the IRB asks researchers to consider the following issues and address those applicable to their study their amendment request submission.

1. Address if the changes are temporary or permanent.
    - Temporary means remote interactions will be used until in-person interactions can resume.
    - Permanent changes mean that remote procedures will replace in-person interactions until the study is completed and closed with the IRB.
2. Consider if changes include recruitment, participant screening, the informed consent process, interventions, data collection methods, follow-ups, etc.
3. When making temporary changes to your study:
    - Identify which study activities are being placed **on hold** and which study activities **will continue** (some studies may already be approved for some remote procedure that will continue, like online surveys, etc.).
    - Do not include specific dates. Instead, state that regular in-person study activities will resume once the UT HRPP/IRB announces that it safe to do so. This will avoid having to submit follow-up amendments or reports should currently predicted end dates be changed.
    - If the modifications will require additional materials (to accommodate remote procedures) but you will resume use of the currently approved materials once restrictions are lifted, add materials for the remote procedures, instead of revising previously approved versions, to avoid additional amendments in order to resume the original activities.
4. IRB Application – Revise all screens relating to your changes. Below are iMedRIS screens frequently requiring revisions when remote procedures are added, but your study may require changes to different screens. For additional guidance, see UTK's IRB Application Instructions on the iMedRIS Help menu.
    - (925) Study Synopsis – Possible changes to eligibility screening (if after the informed consent procedure for the study), methods for interventions and data collection.
    - (1600) Participant Recruitment – Possible changes to how participants are identified, contacted (i.e., informed about the research opportunity), or screened for eligibility (if prior to the informed consent procedure for the study).
    - (2000) Risks and Benefits – Possible changes to potential risks to the participants, particularly for projects that collect sensitive and identifiable information. Examples include the introduction of additional informational/confidentiality risks from video recording an interview, or privacy risks of interviewing a domestic abuse victim at their home rather than a neutral location.
    - (2800) Privacy and Confidentiality – Possible changes such as using an online survey tool, moving data storage from hard drive to cloud account, etc.
    - (3050) Describe Payment – Possible changes in types of compensation and how compensation is provided to participants.
    - (3329) Informed Consent – Possible changes include a request to waive the requirement to obtain the participant's signature (online data collection, interviews, etc.).
    - (3440) Consent Process – Possible changes include obtaining a participant's signed informed through secured electronic mechanism in place of in-person consent procedures.
5. Revised or added study materials such as recruitment material, screening scripts or forms, consent forms, intervention materials, data collection instruments, etc.

6. Amendment Request form – The iMedRIS screens that are listed below are those are commonly required when adding remote procedures to a study, but screen revision requirements may vary based on your proposed changes.
    - (800) UTK General Study/Project Information, Item 1.3
        - Check Other Application Changes to address changes in any procedures used.
        - If revising an existing consent form, select Revise Currently Approved (English/non-English) Consent Form as applicable to the study.
        - If revising existing recruitment material, data collection materials, etc., select Other.
    - (810) Revisions of the Study/Project Application, Item 2.1, Rationale for Revision column – List *Coronavirus*. This will help flag these submissions for review.
    - (400) Revisions to English Consent Form(s) – Select yes if applicable to your study.
    - (600) Revisions to Non-English Consent Form(s) – Select yes if applicable to your study.
    - (900) Other Changes

What if an External IRB is the IRB of record for my study? (**New 04.01.2020)**

These restrictions on in-person interaction applies to all research conducted by UT employees, staff or students, even if the study is under review by an External IRB. The research team should notify the External IRB and follow all External IRB requirements for any modifications or reporting that occurs from these restrictions.

Do these requirements apply for international research? (**New 04.01.2020)**

Yes, even if the research is conducted abroad, procedures involving in-person interaction must be placed on hold indefinitely.

What is the difference between recruitment, enrollment and data collection? (**New 04.01.2020)**

The distinctions between these three processes are slightly different and need to be treated as such. The terms are defined as follows:

Recruitment

A range of activities involving identifying populations eligible for research participation and providing them with information about the research study through fliers, newspaper advertisements, social media posts, etc.

Enrollment

The act or process of verifying an individual's eligibility to participate in a research study and obtaining their informed consent.

Data collection

The process of gathering and measuring information on variables of interest that enables one to answer stated research questions, test hypotheses, and evaluate outcomes.

Do I need to notify the IRB if I plan postpone recruitment, enrollment or other study procedures? (**New 04.01.2020)**

When researchers must postpone activities or place entire studies on hold, study records should reflect the mandated restrictions. A report to the IRB is required only if one or more of the following apply to your study.

- Studies required to obtain continuing review should identify which activities were postponed/placed on hold in the continuing review request and explain the reason (i.e., COVID-19 related restrictions).

- Studies suspended at the request of an external funding agency or the study's Data Safety Monitoring Board, if there is one, should submit a Reportable New Information form.

What should I do if my research has funding? (**New 04.01.2020)**

If a funded (government, industry, or non-profit) study is placed on hold or modified to replace in-person procedures with remote or virtual procedures, follow sponsor guidance and if required, notify the sponsor as soon as is feasible. Alternately, researchers should contact the Office of Sponsored Programs, their program officer or consult the Council On Government Relations (COGR) FAQ Regarding COVID-19's Impact on Federal Awards.

Are there any study changes that do not require prior IRB review and approval? (**New 04.01.2020)**

If your study was approved under exempt review and the changes meet the criteria identified above, then submission for review and approval is not required.

Changes can be made to eliminate apparent immediate hazards to participants without prior IRB review and approval. However, the change must be reported to the IRB by submitting Reportable New Information form (Form 4) in iMedRIS within five (5) business days of the change.

What is meant by making a change to eliminate apparent immediate hazards to participants? (03.13.2020)

Eliminating an immediate hazard may include an action that reduces potential exposure to COVID-19. For example, 80 percent of the research participants are scheduled to come to campus on Tuesday through Friday to complete their second study visit. The study includes a total of four study visits total. The study visits are for the purposes of data collection (as opposed to administering a treatment). Late Monday afternoon the university announces that due to new recommendations from the Knox County Health Department, it will be closed the remainder of the week. Because it is unclear if and when those study visits can be rescheduled, the principal investigator decides to eliminate the second study visit and change the study visit total from four to three, and contacts participants to inform them of the change.

In this example, the PI is unable to submit an amendment request and obtain approval within the short time period in which a decision had to be made to protect the safety and welfare of research participants.

If I change my study to utilize remove procedures and my study is registered with ClinicalTrials.gov, do I need to update my ClinicalTrials.gov registration? (**New 04.01.2020)**

Maybe. The current ClinicalTrials.gov guidance on updating a registered study tell us that any research-related changes that are communicated to the subjects (past, ongoing, future) must be added to the study's ClinicalTrials.gov registration with 30 days after IRB approval of the modification. Additionally, some studies are modifying their research procedures to include COVID-19 related activities. The ClinicalTrials.gov information for the study should be updated to include these new procedures if they are done for research purposes.

New Studies

Can I submit new studies during the COVID-19 pandemic? (**New 04.01.2020)**

Yes. New applications are still being accepted and reviewed. New studies are be screened and routed for IRB review in accordance with our current procedures and timelines. However, these studies are subject to the restrictions currently in effect:

- Newly approved studies with in-person interactions may **not** begin until further notice.

- Newly approved studies with no in-person participant interaction may begin after receiving IRB approval.

I plan to submit a new study investigating COVID-19/Effects of the COVID-19 Pandemic. Is there anything I should include?

Include COVID-19 in the study title. Remember, in-person interactions remain restricted.

I am applying for a rapid response grant. How can I get my IRB application reviewed quickly?

The IRB is currently prioritizing reviews for COVID-19 related studies and applications with funding approval needs.

Response Planning and Preparedness

What plans should I make for my research? (Updated 03.18.2020)

Researchers were instructed to complete and submit their contingency plans using this form (see the March 16 Update for Research Community). We also recommend taking the following steps as applicable to your research.

1. Communicate changes in the research to research participants and, if applicable, participant caregivers
2. Identify emergency personnel essential to carrying out your research and make sure each person knows their responsibilities
3. Review your communication plan, or create a plan if you do not have one
4. Identify priorities in case study team members cannot work
5. Ensure that study team members who work remotely have access to files, data servers, etc. and that the security safeguards are as approved in the IRB application
6. Check the University's website regularly for information related to human research protection practice changes that may be required.

Remote Activities

Does the IRB recommend any online tools or applications? (**New 04.01.2020)**

The IRB strongly recommends using UT-supported platforms when possible. The IRB is familiar with the data protections provided by these resources. Using these resources in lieu of new apps or software will avoid delays in the review process.

- QuestionPro – surveys/questionnaires
- Qualtrics – surveys/questionnaires
- REDCap – through UTHSC (HIPAA compliant)
- Zoom

When selecting electronic tools and applications, confirm it has the needed functionality and features and that those features are activated. Depending on the product, default settings may not automatically activate the features that you intend to use.

Can I bring my data home? (**New 04.01.2020)**

There are ways to work with university data at home so long as you adhere to the privacy, confidentiality and data security safeguards approved in your IRB application. Data security changes deviating from the approved IRB application or the researcher's data security plan must be approved prior to generating, relocating, accessing, or storing the data. Below are a number of UT resources available to researchers.

- Working and Teaching Remotely
- Virtual Private Network (VPN)
- File Sharing Options for Sensitive Information
- Vault – allows sharing with non-UT collaborators
- File Storage Options for Sensitive Information
- NICS Advanced Computing Facility - SIP (HIPAA compliant)
- REDCap – through UTHSC (HIPAA compliant)

How can I work with my research data securely from a remote location? (**New 04.01.2020)**

In moving research operations from campus to remote locations, researchers need to consider the following:

- Are the appropriate data security and confidentiality measures in place?
- Is an amendment request required to allow for research activities with study data to be conducted at home or other remote location (such as modifications to data security/storage, impacts on privacy, etc.)?
- Is the use of the research data covered by a data use agreement (DUA) or other contractual obligations (such as a sponsor agreement, etc.)? If so, changes may also require notification and/or amendments to data use agreements or other sponsor agreements.
- If the research data is subject to additional regulatory requirements (FERPA, HIPAA, etc.), does the remote access include all required security safeguards?

What information do I include in my amendment/new application when using online tools or applications? (**New 04.01.2020)**

- Identify the specific product to be used.
- Some online tools and applications have optional settings/features. When these are used for a study, researchers must state in their IRB application that those features will be activated (e.g., QuestionPro's anonymize setting).
- If using an audio-video conferencing application, state whether audio or video will be used. Describe if those activities will be recorded. Some applications, like Zoom, allow users to record sessions.
- If using non-UT supported tools and application, describe all security safeguards.