INSTITUTIONAL GUIDANCE

1. Is the Office of Sponsored Programs (OSP) reviewing/approving Confidentiality/Nondisclosure and Clinical Trial Agreements at this time?
Yes, COVID-19 related projects are receiving priority.

2. Is the Clinical Trials Office reviewing clinical trials at this time?
Yes, COVID-19 related clinical trials are receiving priority. Study teams should evaluate how illness and absences, drug shortages, facility closures and/or restrictions, or lack of required personal protective equipment may impact treatment delivery or monitoring before submitting new studies.

3. Are there specific restrictions on human subjects research at this time?
No, however human research is subject to applicable institutional and clinical guidelines. The PI and study team must consider whether current conditions or policies represent a risk to the successful completion of a subject’s participation including:
- Research team illness and absences
- Study drug or supply shortages
- PPE shortages
- Study site closures and/or restrictions on non-patient visitation
- Availability of clinical services needed to conduct study procedures (e.g., pharmacy, lab or imaging)

The PI is responsible for assessing the study-specific situation and making decisions whether it is safe to start or continue an approved study.

4. Are onsite sponsor monitoring visits allowed at UTHSA?
Yes. UTHealth San Antonio has lifted the previous restriction on on-site sponsor monitoring. Monitors must adherence to the institution’s visitor policy. See additional information and updated guidance here: https://wp.uthscsa.edu/coronavirus/university-measures/research/
Check with the research offices at affiliate hospitals as applicable for additional institution specific policies.

5. Will the UTHSA’s policy on remote monitoring/access to EMR be revised in light of travel restrictions and limited onsite visits to campus?
Currently, remote access to our electronic medical record (EMR) by sponsor’s monitors to verify data accuracy is not possible. The VPR Office understands the importance of having this option and is working with appropriate stakeholders to release a remote monitoring policy. Additional information about this policy will be provided as soon as it becomes available.

6. How should I obtain informed consent in the setting of isolation to prevent transmission of communicable diseases?
For minimal risk studies in which verbal consent with waiver of documentation has been approved by the IRB, the following can be implemented:

The method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study should be documented in the research record. An information sheet can be provided to the subject via electronic means for future reference by the subject.

If a participant is on a ventilator or cannot otherwise consent for themselves, then use of a Legally Authorized Representative (LAR) is required. Verbal consent with the LAR can be obtained and documented as above in the research record.

If the subject is in the outpatient or home setting, the subject may be consented via telephone or remote technology (having received the information sheet in the mail or otherwise).
**For greater than minimal risk studies** in which verbal consent with appropriate documentation has been approved by the IRB, the following can be implemented:

If the subject is able to understand and comprehend the information provided as part of informed consent but is unable to write on a consent document, the method used for communication with the prospective subject (verbal communication) and the specific means by which the prospective subject communicated agreement to participate in the study should be documented in the research record. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document.

If a participant is on a ventilator and is unable to provide consent on their own behalf, then use of a Legally Authorized Representative (LAR) is required. Verbal consent with a witness can be obtained with appropriate documentation as described above.

If the subject is in the outpatient or home setting, the subject may be consented via telephone or remote technology (having received the consent in the mail or otherwise). Documentation of the signature can be obtained by: Electronic signature Scanned and emailed or faxed back to the study team Photograph of signature/signature page sent back to the study team

If it is not possible to obtain a digital image of the signed page, the study team should:
- Document that the participant signed and dated the ICF;
- Document that an imaging device was not available; and
- Have a witness to the consent process.

The entire consent process must be documented in the study records.

7. **What is the institution’s policy on use of phone, video, or web conferencing for research participant interactions and are there specific requirements for telemedicine/telehealth visits?**

The University has institutional licenses with Microsoft Teams, WebEx and Zoom to use for virtual meetings and web-based video conferencing with internal users and external guests. Zoom is the **only platform approved** for participant interactions. To request a Zoom license, contact the IMS Service Desk at 210-567-7777 or ims-servicedesk@uthscsa.edu. Recording confidential data and PHI is prohibited on Zoom unless the IRB has approved the remote participant interaction and recording. Additional information for virtual interactions can be found here [https://uthealthsa.sharepoint.com/IMS/Pages/InfoSec/virtual-meetings.aspx](https://uthealthsa.sharepoint.com/IMS/Pages/InfoSec/virtual-meetings.aspx).

**IMPORTANT NOTE:** If your research related participant interaction is defined as telehealth/telemedicine (i.e. you are utilizing your professional license as part of the visit **and/or are required to document the visit within Epic**), the clinical requirements of the institution and your School / Department must be followed. Additional informed consent may be required **and final review and approval by the MSRDP Telehealth Committee is required.** Policy and process development for the MSRDP Telehealth Committee is currently underway. Additional information will be provided as it becomes available.

For the two additional forms required for a Telehealth/Telemedicine service, see the Institutional Compliance and Privacy Office link: [https://uthealthsa.sharepoint.com/RAC/Pages/HIPAA.aspx](https://uthealthsa.sharepoint.com/RAC/Pages/HIPAA.aspx) (under section titled: Patient Rights Under HIPAA). The two forms are titled: “Telemedicine Informed Consent and Patient Complaint Procedure” and “Telemedicine Notice of Privacy Practices”. Definitions of what constitutes telemedicine and telehealth visits can be found at: [https://statutes.capitol.texas.gov/Docs/OC/htm/OC.111.htm](https://statutes.capitol.texas.gov/Docs/OC/htm/OC.111.htm) (section 111.001 (3) and (4)).

8. **What language is required to be included in the protocol and consent form if phone, video, or web conferencing is necessary AND you will be audio and/or video recording?**

The protocol and consent form should include details of phone, video, or web-conferencing where there are plans to record the audio or video session. Researchers should be mindful of the population and sensitivity of the data being collected (it is recommended that questions about criminal activity, civil liability, and/or any questions that could be damaging to their financial standing, employability, insurability, and reputation not be audio and/or video recorded or collected through electronic conferencing systems).

**Template language to be included in the protocol:**
This study involves remote and/or virtual research interactions with participants by the research staff. Research activities will be audio and/or video recorded by [include appropriate selection below]:
- the conferencing platform being utilized for the remote visit (i.e. Zoom); or
- an independent device (separate from the conferencing platform, i.e. Zoom)

Therefore, privacy and confidentiality are not guaranteed due to the nature of the electronic conferencing platforms that will be used.

Template language to be included in the consent form under “Procedures”
- Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. You will be audio and/or video recorded by [include appropriate selection below]:
  - the conferencing platform being utilized for the remote visit (i.e. Zoom); or
  - an independent device (separate from the conferencing platform, i.e. Zoom)
- Therefore, privacy and confidentiality are not guaranteed due to the nature of the research environment.

Template language to be included in the consent form under “Risks”
- Due to the use of online conferencing systems, your privacy and confidentiality is not guaranteed.

Template language to be included in the consent form under “Signatures”

Please indicate whether you give your permission to be videotaped.

☐ Yes

______________________________
Initials of participant or individual authorized to consent on behalf of the participant

Date

☐ No

______________________________
Initials of participant or individual authorized to consent on behalf of the participant

Date

9. Does UTHSA have additional safeguards in place for patient participation in research studies in light of the Coronavirus pandemic?
   Yes- All research activities must adhere to sanitation and screening guidelines posted at all facilities where research is taking place. See VPR updates posted on our website for additional guidance: https://wp.uthscsa.edu/coronavirus/university-measures/research/

   **NOTE:** Currently, research participants considered to have active COVID-19 disease are not allowed on campus for research purposes. University leadership is working on plans for conducting research on campus for studies involving participants with active disease. Additional information about this policy will be provided as soon as it becomes available.

**UTHSA IRB GUIDANCE**

10. What if a participant is unable to make it for a research study visit?
    If a participant at a site is unable to complete a required study related activity per the IRB approved protocol, this is a protocol departure. Protocol departures that are minor in nature (subjects rights, safety, or welfare are not adversely affected or possibly adversely affected) and are outside of the control of the investigator are considered deviations and do not require prompt reporting to the IRB. Document the deviation in a tracking log and summarize and report the deviation at the time of the study’s continuing review.

11. How will protocol violations be handled at this time?
    Protocol violations are departures that are under the control of the investigator and adversely affect the subjects rights, safety, or welfare. Violations require prompt reporting in accordance with the UTHSA IRB’s Noncompliance Policy.
The Decision Tree - Evaluating Departures may help in determining whether protocol departures require prompt reporting.

12. Can study procedures be modified to address the impacts of COVID-19?
Yes - addressing the impact of COVID-19 may result in some departures being required to eliminate an immediate risk to subjects or others. More information on what changes can be made and when to notify the UTHSA IRB may be found here: http://research.uthscsa.edu/irb/COVID.pdf

13. What is the IRB’s contingency plan for IRB review and approval for continuing renewals?
The UTHSA IRB is conducting all business activities through remote means, including conducting the continuing review and approval of ongoing human subjects research, where applicable.

14. Am I required to obtain IRB approval of a notification document informing subjects about changes to hospital policies on COVID-19 screening?
No - The IRB recommends notifying subjects of the halting of study procedures, changes to study visits, etc. by appropriate means of communication for the patient populations. Document when the notification was made and the method used to notify subjects in the subject’s research record.

15. Does a Sponsor memo describing a halt in enrollment procedures or an investigators voluntary halt of study related activities need to be reviewed/approved by the IRB through the amendment process?
No - These changes can be communicated to the IRB by sending an email to IRBMail@uthscsa.edu and including: the protocol number, PI Name, and date voluntary halt was initiated.

16. What language is required to be included in the consent form if phone, video, or web conferencing is necessary AND you will be audio and/or video recording?
See response to Institutional Guidance #8.

17. Is an IRB amendment required to request a waiver to obtain a witness signature as an institutional requirement during the COVID-19 pandemic?
No – If there are difficulties obtaining a witness signature due to the limited number of individuals present for the consenting process due to the pandemic, you may document the deviation as a protocol departure in a tracking log, and summarize and report the deviation at the time of the study’s continuing review.

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**EXTERNAL IRB GUIDANCE**

1. Should I follow local UTHSA IRB guidance for external IRB studies?
No – Follow guidance provided by the IRB of record for that particular study and any posted institutional guidance located on our website: https://wp.uthscsa.edu/coronavirus/university-measures/research/.

- Advarra IRB COVID-19 Guidance
- Brany IRB COVID-19 Guidance
- Sterling IRB COVID-19 Guidance
- WIRB COVID-19 Guidance