**COVID-19 Updated Guidance: Human Research****
August 18, 2021

Due to recent concerns related to the surge in COVID cases, the Office of the Vice President for Research is providing updated information related to conducting human subjects research.

## Updated Guidance

1. Previous guidance regarding face-to-face interactions with research participants was based on the category of research (e.g., COVID-related, therapeutic and nontherapeutic research). This approach has been phased out and the same directives apply to all clinical research involving face-to-face interactions.
2. Additional approval to conduct nontherapeutic research by the Principal Investigator's Chair has also been discontinued.

3. Campus visits by Research Sponsor Monitors/Staff
Whenever feasible, we recommend postponing in-person monitoring and site initiation visits on the UTHSA campus or using an approved remote option.

On-campus visits by sponsor personnel should only be scheduled for activities that are essential to participant safety or study integrity. Essential sponsor visits are a critical business function and authorized. Monitors should be masked and follow social distancing and other applicable guidelines.

If essential on-campus visits are necessary, notify Dr. Joseph Schmelz, Assistant Vice President for Research (schmelz@uthscsa.edu) prior to the monitor's arrival date.

Remote monitoring options (UTHSA)

Sponsor monitors can now remotely access the university's electronic health record using EpicCare Link. Submit the "Research Monitoring Visit Request" Form to request access (please allow two weeks to process). For assistance with sponsor access to Epic:

Cancer Research - Mays-CC-Monitoring@uthscsa.edu;
Non-Cancer Research - VPRCTO@uthscsa.edu

## Guidance that has not changed

- All research activities must adhere to sanitation and screening guidelines in effect at all performance sites. University COVID updates are posted at https://wp.uthscsa.edu/coronavirus/. If you have questions, you may contact COVID-19@uthscsa.edu.
- The Principal Investigator (PI) remains responsible for implementing and monitoring changes to COVID-19 control strategies and assuring that the research team has appropriate staffing, resources, and training to support in-person interactions with research participants.
- Whenever feasible, conduct research procedures remotely or on the phone (e.g., conduct informed consent and interviews virtually).
- 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

- Telemedicine/Telehealth Medical Service State Regulatory Requirements Guidelines must be followed when the research video conferencing involves a telemedicine/telehealth medical service delivered by a health professional licensed, certified, or entitled to practice in Texas and acting within their scope under Texas rules. Zoom is the only platform approved for these video conferencing participant interactions. Telemedicine/Telehealth Medical Service State Regulatory Requirements Guidance Document
- Sponsor Monitoring at University Health - Complete the UH online request form to schedule onsite monitoring

IRB Guidance

- Obtaining informed consent or 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).
- Obtaining informed consent 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

- Required language 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*]: 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 is 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 is 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 with initials of participant or individual authorized to consent on behalf of the participant
          __No with initials of participant or individual authorized to consent on behalf of the participant
- 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.
- 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.
- Guidance provided by the IRB of record for a particular study should be followed for any studies approved by an external IRB. This is in addition to any posted institutional guidance at UT Health San Antonio.

***Note: this guidance is informed by communications from the Office of the President (August 5 & 23, 2021).*