Update: Conducting Human Research During the Pandemic

June 11, 2020
During the Forum:

• Mute your mics to avoid echoing or background noise

• Do not activate your camera to preserve bandwidth

• Best to join via Microsoft App so you can be identified by your UTHSA domain name

• In lieu of voicing your questions, use the chat function, a moderator will respond to your question.
Overview

• General updates
• Updates from VA
• Updates from UHS
• Virtual Concierge
Updates to FAQs
Remote monitoring

In-person sponsor study monitoring can resume after the applicable performance site (e.g., Mays CC, UHS, VA) lifts any restrictions on non-patient visitation.

UT Health San Antonio has lifted the restriction for approved visitors which includes sponsor monitors for on-site visitors with adherence to the institution’s visitor policy.

Remote access to our electronic medical record (EMR) by sponsor’s monitors to verify data accuracy is not available.
Telehealth/Telemedicine Research Visits

• If the research visit is defined as telehealth/telemedicine (i.e. individuals utilizing professional license as part of the visit and/or are required to document the visit within EPIC) the clinical requirements of the institution and the School / Department must be followed, additional informed consent may be required, and final review by the MSRDP Telemedicine Committee is required.

• The policy and process is being defined by the MSRDP Telemedicine Committee.

• More information available here: https://uthealthsa.sharepoint.com/RAC/Pages/HIPAA.aspx
Telehealth/Telemedicine Research 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.
- Contact IT support to request a Zoom license.
- Recording confidential data and PHI is prohibited on Zoom unless the IRB has approved the remote participant interaction and recording.
- Stay up to date with information related to Telehealth visits here: [https://uthealthsa.sharepoint.com/IMS/Pages/InfoSec/virtual-meetings.aspx](https://uthealthsa.sharepoint.com/IMS/Pages/InfoSec/virtual-meetings.aspx)
Recording Research Visits

- The protocol and consent form should include details of phone, video, or web-conferencing.
- Researchers should be mindful of the population and sensitivity of the data being collected.
  - Special consideration should be made when the method of conducting the visit may involve information 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 system.
- Template consent form language for conducting research procedures using phone, video, or web conferencing, where audio and/or video recording is available on the UTHSA Research FAQs.
Safeguards for Research Participants

All research activities must adhere to sanitation and screening guidelines posted at all facilities where research activities will take place.

Research participants considered to have active COIVD-19 disease are not allowed on campus for research purposes.

The University leadership continue to work on plans for conducting research on campus for studies involving participants with active disease.
Witness Signature

- Per UTHSA policy, a witness signature is required as part of the documentation of informed consent.

- If a witness is not available at the time informed consent is obtained due to the pandemic, it is acceptable to document the event as a protocol deviation that may be reported at the time of continuing review.

- Not to be confused with the required witness signature for informed consent using a short form.
Questions?
Updates: VA
Are there specific guidelines for conducting human research at the STVHCS currently in place?

- A memorandum was received on June 2, 2020, outlining the steps that are required and recommended to be completed for the administrative hold on the VA-funded non-critical in-person research subject interactions to be lifted by the Chief Research and Development Officer.
- To resume VA-funded studies, each PI needs to complete a risk assessment plan which includes steps taken to mitigate risks for patients, research personnel and others in the facility eg. PPE, physical distancing, cleaning/sanitization after visits, limiting unnecessary exposure within the hospital.
Updates from the VA

Can non-essential research staff return to the workplace at the VA? If not yet, is there a timeline for return?

Non-essential research staff can return to the workplace at the VA although staff are encouraged to telework. Face masks are part of the dress code and social distancing has to be maintained. Everyone entering the VA is being screened.

Are Face-to-face interaction with subjects currently allowed?

Yes. Plan for phased reopening of the Bartter Research Unit was approved and it will be explained in more detail in the next slide. There is some research conducted in other clinics and they will follow the transition plan of the clinic where their study is being conducted. As mentioned earlier, recommendations have been provided by Office of Research and Development (ORD) which when completed, permission will be sought by VA leadership from ORD to lift the administrative hold for VA-funded studies.
Updates from the VA

The Bartter Research Unit Phased Opening Plan

- Phase 1 already started at 50% capacity for funded research activity. Based on assessment of PPE use and other safety measures, expansion to a full capacity is planned in 2-3 months (phase2)
- Space is used for F2F interaction with subjects, and not for office work or telework to reduce the number of staff in the unit at the same time.
- Research activities converted to telework will continue as such
- The PIs are asked to train their research team who will need to acknowledge understanding of the BRU transition plan regarding safety measures -social distancing, prescreening, and PPE compliance – before the use of BRU services.
- The research team are asked to prescreen all via phone using a VA recommended screening sheet at least 24 hours prior to appointment. These documents are scanned into the CPRS.
- The list of aerosol generating procedures were provided as a guideline to determine the need for prescreening COVID 19 PCR testing for the patients 3-5 days prior to the study.
- Everyone (nursing, physician, dietary, admin, etc) entering the BRU need to use the sign in sheet and will be screened for symptoms and temperature.
Questions?
Updates: UHS
University Health System

Conducting Human Research during the Pandemic
Deidre Winnier, PhD
Clinical Research, Director
Research

COVID-19 trials are being conducted.
Research procedures needed for patient safety purposes are being allowed.
Screening patients for research is allowed.
Elective surgeries are being scheduled.
For staff whose offices are located on UHS campus, they can return to work, provided they follow the appropriate guidelines in regard to PPE, social distancing and daily health screening.
Visits

Outpatient clinics are open and research can continue.
All in-person visits require Covid-19 screening and appropriate PPE.
Universal masking in all areas is encouraged as it demonstrates a commitment to protecting the health of our patients, staff and community.
Monitoring

At this time, onsite monitoring, SIVs and SQVs are not being allowed. Remote access to EMR is not permitted (same as before Pandemic) WebEx “over-the-shoulder” monitoring is allowed. Virtual SIVs and SQVs are permitted.

Please submit a request on the University Health System’s Clinical Research Department Internet Page: http://hr.universityhealthsystem.com/Research/Monitoring_Appt-Form.asp
EPIC Training

UHS EPIC Go Live is July 11, 2020

EPIC training is currently being conducted until June 28th.

All research coordinators are required to take 3 research coordinator classes: 1 is an e-learning module and 2 are in-person classes.

Please sign up for the live classes as soon as possible or you will not have EPIC access.
Latest Information

COVID-19 Updates from University Health System
https://www.universityhealthsystem.com/coronavirus-covid19

Contact the Clinical Research Office
research@uhs-sa.com or call 210-743-6450
Questions?
Virtual Concierge
Virtual Concierge

We have moved virtual!

OIRB Website: http://research.uthscsa.edu/irb/
Right hand side of webpage, link is also available on OCR website.

Receive dedicated assistance from the following offices:

- COI & COC
- CTO
- OIACP
- OIRB
- OCR
- VA Research
Virtual Concierge

During the Virtual Concierge session, individuals receive dedicated assistance from the comfort of their personal work area.

- Concierge Sessions are in 30-minute increments
- If you need to meet with multiple offices, you can request these at the same time, but separate meeting invites will be sent by each office.
- Virtual Concierge meetings will be held using Microsoft Teams App
  - Best to join via Microsoft App so you can be identified by your UTHSA domain name as document sharing may occur using the Teams virtual meeting platform
- Upcoming dates are consistent with the current Concierge schedule
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- Conflict of Commitment  
- Reporting outside activities/iDisclose  
- Protecting intellectual property  
- Export control | - External Sponsor Solicitations  
- Feasibility Assessments  
- Protocol Development  
- Coverage Analysis  
- Budget Development & Negotiation  
- Participant Payments  
- Industry Sponsor Billing  
- Velos eResearch (CTMS) | - Animal use Application  
- Prompt Reporting  
- Post Approval Monitoring (PAM) |
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Latest Updates for UT Health San Antonio

COVID-19 Updates Specific to Research at UT Health San Antonio

• [https://wp.uthscsa.edu/coronavirus/university-measures/research/](https://wp.uthscsa.edu/coronavirus/university-measures/research/)

• COVID-19 Hotline: **210-450-8000**

• COVID-19 Email: [COVID-19@uthscsa.edu](mailto:COVID-19@uthscsa.edu)
Latest Updates for UT Health San Antonio

Additional Guidance and Resources for Research:

OIRB Website: http://research.uthscsa.edu/irb/

Links are also available on OCR and CTO websites.

Includes Info Related to:

- Questions Related to Changes to Human Subject Research made in Response to COVID-19
- UT Health San Antonio COVID-19 Research FAQs
- COVID-19 Suggested Screening Questionnaire
- SOP Template: Conducting Research Home Visits During COVID-19
- Forum Presentations

Office of the Institutional Review Board

- Questions Related to Changes to Human Subjects Research Made in Response to COVID-19
- UT Health San Antonio COVID-19 Research FAQs
- COVID-19 Suggested Screening Questionnaire
- Forum Slides: Conducting Human Research During the COVID-19 Pandemic
Questions?