General Research Updates: Conducting Human Research During the Pandemic

August 25, 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

Updates from UTHSA

Updates from VA

Updates from UHS
Telemedicine
Telemedicine Research Visits

• If the research visit is defined as 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, and additional informed consent may be required.

• The request may require MSDRP Committee approval depending on the School/Department. If required, it will occur independent from the regulatory review and approval.

• Individuals who plan to use telemedicine for research visits must assure review of the Telemedicine/Telehealth Medical Service State Regulatory Requirements Guidance Document.

• UTHSA Zoom is the only approved platform for telemedicine interactions.

• Template Consent wording is available in the Research FAQs.
## COVID Testing at UTHSA

<table>
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<tr>
<th>Required by institution/clinic</th>
<th>Required by the research protocol</th>
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| **UTHSA IRB Review**            | May be implemented without IRB approval | Requires IRB approval before implementation unless it is being done to eliminate an immediate hazard  

  May undergo review using Expedited review procedures |
| **Consent form**                | Does not require language in the consent form. | Requires information regarding the testing in the procedures section and risk section |
| **Protocol**                    | Does not require description in the protocol | COVID testing and methods used for testing: screening questionnaire and temperature check; nasal swab; nasopharyngeal swab must be included in the protocol |
Study Turnaround Times

Prioritization of Trials:
- COVID-19 Trials are prioritized by all UT Health Research Offices
- All other studies are first come first serve

Turnaround Times:
- Are consistently reviewed and monitored
- During COVID-19 and work from home timelines have not been impacted.
Remote Monitoring

New Draft Policy Developed, pending approval

- Allows access for monitors to access study patient data in EPIC.
  - Process will apply to on-site or offsite visits
- Access will be temporary (each visit will require a new request)
- Limited to patients on the study being monitored
Velos eResearch

Upgraded to Version 11.1.0

Upgrade included significant backend technology update:
  • Application web server
  • Oracle Database
  • Enhanced encryption and communication protocols

No current timeline for next version update.

Velos eResearch is now owned by WCG (WIRB-Copernicus Group, Inc.)
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

SOP: Conducting Research Home Visits During the COVID-19 Pandemic

Forum Slides: Conducting Human Research During the Pandemic
Questions?
Updates: VA
Updates from FAVHR

COVID Updates:

• Face to Face research activities have resumed in line with VA and BRU restrictions.

• Clinical Coordinators are encouraged to continue working from home as feasible for study requirements; however VA office space is accessible for coordinator use provided standard personal distancing and mask use is in place. While at the VA, masks must be worn unless employees is alone in a room with the door closed and locked.

• New study negotiations are in process for COVID and Non-COVID studies

• VA HR office has agreed to 3 weeks turnaround on WOC appointments to support COVID studies at the VA.
Updates from the VA

Can Central IRBs be used at the VA?

VA is now able to utilize the following IRBs for VA research

- VA Central IRB
- UTHSCSA IRB
- Advarra
- Western IRB (WIRB)
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

The Bartter Research Unit

• Approved Phase 1 transition plan was put on hold due to COVID surge (late June).
• Restarting at 50% capacity to accommodate funded research from this week.
• Space will be continued to be used for F2F interaction with subjects - and not for office work or telework.
• Research activities converted to telework will continue as such.
• The PIs will train their research team and 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 (electronic chart).
• The list of aerosol generating procedures were provided as a guideline to determine the need for prescreening COVID PCR testing for the patients 2 days prior to the study.
• Everyone entering the BRU need to use the sign in sheet and will be screened for symptoms and temperature.
Questions?
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. 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
UHS EPIC

UHS EPIC is now available!
Please associate your enrolled patients to their respective protocols
Please associate orders and encounters as well.
Remote desktop access to UHS is not available but you can use any UHS computer.
EPIC In Person Training Classes will be offered weekly for the next month.
Any study related issues, please e-mail research@uhs-sa.com
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

We’re meeting online! Our Concierge service has been changed to virtual meetings.

To reserve your appointment, complete the REDCap survey.

You can also copy and paste the link in the URL address bar.

https://redcap.uthscsa.edu/REDCap/surveys/?s=FDYWD3JFJD

To meet with multiple offices, you will need to complete the survey for each office.

Concierge Dates for Fiscal Year 2020-2021

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<tr>
<th>Date</th>
<th>Time</th>
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<tbody>
<tr>
<td>September 1, 2020</td>
<td>1pm - 4pm</td>
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