TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER™ EL PASO
Office *of* Research

TTUHSC El PASO

Regulatory Lite ✓

A hint of research compliance tips for your everyday life

Remote Monitoring

COVID-19 has not made anything easy! Since the start of the pandemic we have had to make several changes in how we go about conducting research. Along with these changes, sponsors have started opting for remote monitoring instead of in-person monitoring visits. Because of this, our researcher community has had to face challenges on how monitoring visits are conducted on sponsored studies on campus.

In order to address this concern, the Office of Research reached out to our TTUHSCEP HIPAA Privacy Officer, Obumneme Eze, who is part of the Institutional Compliance Office. After some discussion, it was determined that remote monitoring with any and all research documentation that includes print-outs or downloads from TTUHSCEP EMR should only be shared through our TTUHSCEP's Box account. To do this, a file should be created on Box and access to that specific file should be shared with the CRA or study sponsor with a deadline. All documents must be de-identified prior to being scanned and uploaded, and documents must be deleted from Box after the deadline. In order to implement these procedures, Clinical Trial Agreements may need to be amended to state that CRAs and study sponsors may not print and may only view documents from the record on Box. Documents that can be scanned and uploaded include documents from TTUHSCEP EMR and any other study documentation that a CRA or sponsor is requesting to view. TTUHSCEP is not currently allowing TTUHSCEP EMR and regulatory research records to be viewed through WebEx.

This, of course, leads us to ask if the same can be implemented for records from UMC and EPCH. The answer to this question is "Maybe." According to UMC's Research Manager, Dani Joyner, UMC may allow remote review of patient records contained in their EMR system (CERNER) utilizing GoToMeeting or any other remote meeting application provided that TTUHSC EP has a BAA with that application vendor and that neither the recording feature nor the chat feature be utilized. TTUHSC EP research personnel may access UMC EP patient records for remote study monitoring review via the patient list established by the UMC EP Research Manager in CERNER. The UMC Research Manager can also assist in this process by working with the study monitor, and by screen sharing and navigating the CERNER patient list for the approved study. This may also apply to EPCH, but as of this moment, the agreement between EPCH/TTUHSC EP and the IRB has not been finalized.

*Please note that this does not refer to EDC systems and is specific to source documentation. If you have any additional questions, feel free to reach out to your Research Compliance Unit.