THE UNIVERSITY of TENNESSEE
GRADUATE SCHOOL OF MEDICINE

IRB NEWSLETTER

2020

Kim C. Mason, PharmD, IRB Chair

THIS ISSUE:

REMOTE ACCESS TO THE IRB OFFICE

Since mid-March, IRB staff has been working almost exclusively from home offices. To accommodate researchers with their research projects, we are offering a remote "open-door" invitation via Zoom or Teams. This allows us to work one-on-one with investigators, providing step-by-step instructions in iMedRIS (sharing screens) and answering questions as we work through your iMedRIS application with you. To begin the process, please contact Cindy Langley or Jacque Van Audenhove via email to schedule an appointment. Normal hours are M-F, 8am - 5pm, but we will also have the flexibility to schedule a session at other times more convenient for researchers. Things to consider prior to meeting with the IRB staff include:

- **Investigator selection and research team** – include personnel with research experience, subject specific knowledge and research training
- **Study Design** – secondary or primary research, observational, experimental etc.
- **Study Population** - inclusion/exclusion, vulnerable populations, barriers to accessing your targeted population
- **Data Collection** – how to securely access, collect, share and store data. Use of Excel, REDCap, or OneDrive
- **Consent Process** – who will obtain, verbal vs. written, alteration or waiver, how to demonstrate participant understanding
- **HIPAA authorization vs. waiver** – practicable to obtain authorization or justification for a waiver
- **Data Analysis** - appropriate use of statistics, consider including a biostatistician on study team

NEW SIGN-OFF (SIGNATURE ROUTING) PROCEDURE IN iMedRIS

To reduce delays in IRB submissions, the sign-off procedure in iMedRIS has been revised. The IRB no longer requires all key study personnel to sign-off on an **initial submission**. The Principal Investigator (PI) and Department Chair are still required to sign-off on initial submissions to the IRB. **If the PI is a student, resident or fellow, their Faculty Advisor must also sign-off.** Remember, the IRB does not receive submissions until all sign-offs are completed. It is the responsibility of the PI to ensure the sign-offs are routed to the appropriate personnel and completed.

ALTERNATIVE PROCEDURES DURING PUBLIC HEALTH EMERGENCY

The UTGSM IRB approved a new policy for alternative procedures during a public health emergency. SOP#037 can be found on the IRB website under the Current SOP section. The SOP includes information and guidance noted below:

GENERAL CONSIDERATIONS FOR ALL RESEARCH ACTIVITIES

- Risk Mitigation
- Non-essential versus essential research determination

CONSIDERATIONS FOR ONGOING RESEARCH

- Pausing research activities
- Temporarily closing patient enrollment
- Process for crisis-related amendments
- Alternative communication process with participants

CONSIDERATIONS FOR NEW STUDIES

- Prioritization of studies
- Alterations or delay of study procedures

ADDITIONAL CONSIDERATIONS

- Alternative methods of obtaining consent
- Study monitoring

REMINDER: CHECK EXPIRED EMAIL ADDRESSES

If you expect to be receiving emails from iMedRIS, but have not received them, check for expired email addresses. Expired hospital emails containing “mc” are no longer functional.

SCHEDULE A TRAINING SESSION

IRB staff will schedule a time to provide training, specific to your needs, including the IRB submission and review process and/or iMedRIS training. Currently, IRB staff is working remotely. Training sessions via Zoom or Teams can be scheduled for your convenience.

CONTACTS

For questions or information contact UTGSM's IRB office or visit our website at: http://gsm.utmck.edu/irb/main.cfm

Jacque Van Audenhove, MS, CIP, IRB Director, jvanaudenhove@utmck.edu

Cindy Langley, RN, CIP, IRB Regulatory Specialist, clangley@utmck.edu