# THE UNIVERSITY of TENNESSEE

GRADUATE SCHOOL OF MEDICINE

# **IRB NEWSLETTER**

# **Summer 2019**

# THIS ISSUE:

Frequently Asked Questions

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# **FREQUENTLY ASKED QUESTIONS**

1. Why can't I log into iMedRIS?

Access to **<u>iMedRIS</u>** is through your **UT** NetID & Password which is not the same as your hospital login. **UT** NetIDs can be looked up here: <u>https://directory.utk.edu/index.jsp</u> . If you have forgotten your password, you will need to reset it at: <u>https://ds.utk.edu/passwords/reset.asp</u>. If you have attempted to reset your password and cannot get past the security questions, you will need to call the OIT helpdesk at 974-9900 and confirm your identity so they can unlock your account.

If you experience difficulties after logging into iMedRIS, switching to a different web browser may help and always turn off Pop-up blockers. If you continue to have problems, contact the IRB office.

#### 2. What is my NetID?

**UT** NetIDs can be looked up in the **UT** Directory at this link: <u>https://directory.utk.edu/index.jsp</u>. If your name is not in the **UT** Directory, IRB staff can look-up your **UT** NetID.

## 3. What is my password for iMedRIS?

IRB staff or members do not have access to any passwords except their own. If you have forgotten your password, you will need to reset it at: <u>https://ds.utk.edu/passwords/reset.asp.</u>

### 4. How do I submit a new research study in iMedRIS?

Once in iMedRIS, under PROJECT ASSISTANT, click on Create a New Project, then select the appropriate Project Application. For studies at the Graduate School of Medicine, select the UT Graduate School of Medicine/UHS Knoxville: IRB Study Application – GSM Knoxville Institutional Review Board (IRB). After selecting the correct application, follow the step by step instructions. Remember to hit the save button after each section.

5. How do I make changes and/or add personnel to my study?

Changes to an existing study must be approved by the IRB prior to implementation. In iMedRIS, open the study that you need to change and select a **Form 2** for protocol revisions or a **Form 5** for a change in personnel.

- 6. How do I log into CITI and what research training is required?
  - Go to <u>www.CITIProgram.org</u> and click "Register"
    Put Tennessee or Knoxville in the search box and select University of Tennessee Health Science
    Center <u>Knoxville SSO</u> and log in using your UT Net ID and password. Remember your UT Net ID & password are different from your hospital user ID and password.
  - Choose Group #3 Investigators and key Study Personnel for faculty & staff or Group #4 Fellows, Residents and Students. Note: The Conflict of Interest Module is only required if you are listed on grants going through the GSM Business Office otherwise, mark it "no" skip the animal question and click "Submit" at the bottom of the page.
  - On the home page, click "Start" next to the course name then click on the words "Integrity Assurance Statement" on the next page. Once you submit the "Integrity Assurance Statement" you will be taken to the list of modules.
  - Complete the required modules
  - Pick three additional modules from the Elective list within Group 3 or 4.
- 7. When will my study get reviewed?

Review times vary depending on the risk level of the study, the complexity of the study, whether prereview changes are required and the workload of IRB reviewers. For studies that qualify for Exempt Review, such as most record review studies, the turn-around time is typically less than a week. For studies that qualify for Expedited Review, such as most minimal risk studies without the use of drugs or a device, the turn-around time is typically within two weeks. For studies that are required to be reviewed by the convened, full board, the turnaround time varies. Application submission of studies requiring full-board review must be submitted according to scheduled submission/meeting dates. Please refer to IRB calendar for submission deadlines for full-board reviews. After the initial full-board review, the principal investigator will receive a letter outlining approval requirements.

8. Who needs to be on my study?

Anyone involved in the implementation or analysis of the study must be included. Additionally, if the Principal investigator is a student, fellow, or resident your faculty advisor must be included. For all studies, your Department Chair must be included.

- **9. Who needs to sign-off on my study?** For initial reviews, all key study personnel must sign-off including your faculty advisor and Department Chair.
- 10. How do I submit QI projects or a Case Report?

You may either call the IRB office or download specific forms (see UT GSM IRB website for forms) for QI projects and/or Case Reports. These forms must be submitted to the IRB office for review in order to travel for conference presentations. They do not need to be submitted in the iMedRIS system.

#### SCHEDULE A TRAINING SESSION

IRB staff will schedule a time to provide training specific to your needs to include the IRB submission and review process and/or iMedRIS training.

#### **iMedRIS ASSISTANCE**

Let us help you! Visit us in the IRB office on the 3<sup>rd</sup> floor of the GSM building. We will walk you through your submission. Use our computer or bring your own. We are happy to help!

#### **CONTACTS**

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

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