

DASH-Research IRB Important Information

1. Any new study submission must include a protocol document, which will be uploaded as a separate attachment. We have created three templates for you to use, which can be accessed on our [website](#):
 - a. The Exempt 4 ONLY Protocol Template should be used for chart review studies and others that fall under exempt category 4
 - b. There is also a template for studies in other exempt categories, and one for expedited/full board studies

2. For all new study submissions, a **Study Personnel Appendix must be included**. The template can be found on our [website](#). This appendix should include every individual working on the study, whether they are from UTHSC COM-Knoxville, UT Medical, UTK, UTHSC, or any other institution. Please attach it at section 3 of the Local Study Team Members section of the Smart Form in DR IRB.
 - a. Local study team members should also be added to section 2 of the Local Study Team Members section of the Smart Form in DR IRB. This initiates the required DASH Conflict of Interests (COI) Disclosure. For study team members not in DASH, the investigator is responsible for determining and documenting if they have a COI.
 - b. For changes in study personnel for studies that were already approved in iMedRIS, this appendix only needs to include the personnel being added, unless the duties of an existing team member have changed.

3. If a study includes drugs, devices, HIPAA protected data, blood draws or bio-samples, or if you are requesting a waiver or alteration of consent, the corresponding appendix or appendices from our [website](#) should be attached to the DR IRB submission.

4. Any reportable new information, such as a Deviation from the IRB-approved protocol, adverse event, unanticipated problem, participant complaint, suspension or termination by the sponsor, investigator, or external institution, or an internal or external audit should be reported via DR IRB. This report should include the Reportable New Information Appendix from our [website](#).

5. Continuing Review submissions should also include the appropriate Appendix from our [website](#).
 - a. There is no longer a separate form to submit in DR IRB to close a study. This can be done by submitting a continuing review form and selecting the appropriate options in the Research Milestones section of the Smart Form in DR IRB.
 - b. If desired, a study modification (amendment) can be submitted on the same form with the Continuing Review
6. **When submitting in DR IRB the study PI must submit every submission. This has replaced the sign off. The PI may assign a PI Proxy to submit on their behalf.**
 - a. To assign a PI Proxy, log into DR IRB and open the study. The assign PI Proxy button is on the left side of the page, under Next Steps. The PI Proxy must be listed as study personnel before they can be assigned as proxy.

Next Steps

View Study

Printer Version

 Assign Coordinator

 Assign PI Proxy

7. The IRB office will assign new study submissions to Departmental Reviewers as appropriate using the Ancillary Reviews function in DR IRB. This will be done by IRB office staff after we receive your submission.
8. DR IRB has the capability **to initiate reliance agreements** within the system, but our campus has chosen not to use this feature because it presents an additional administrative burden. Instead, we will document our reliance agreements outside of DR IRB. This is why researchers are instructed to **select No to question 5 on the Smart Form, Basic Study Information section.**

9. If your study requires a reliance agreement and you want UTHSC COM-Knoxville to be the reviewing IRB, submit a new study and attach the appropriate study protocol template. In your protocol, also include the following information:
 - a. Who the external collaborators are and what study tasks they will complete. Be sure to include whether they will have access to identifiable data or not.
 - b. Include in the protocol, or email Jen Engle (jmengle@utmck.edu) to provide contact information for someone in the IRB office of the collaborating institution who can assist with the reliance agreement.

10. If your study requires a reliance agreement and you want the UTHSC COM-Knoxville IRB to rely on another IRB, submit a new study and attach the appropriate study protocol (completed through the section on Collaborative Research), and attach the External IRB Approval Form from our [website](#).

11. Step-by-step videos to help with navigation of DR IRB can be found in the Help menu (from your DR IRB dashboard, click on IRB, then Help Center, then Videos). Additional training and support materials can be found here: [Institutional Review Board \(IRB\)](#) (Note: you must use your UTHSC login information to access this site).