**Guidance for Completing the UT IRB Proposal Form for Sponsored Studies**

When completing the IRB Proposal Form, provide a brief summary of the requested information in each applicable section and include a reference to the corresponding section of the sponsor protocol where IRB staff can find additional pertinent information.

For example, the Procedures section in the IRB Proposal Form may state:

*Subjects will attend one 2-hour appointment per month for 6 consecutive months during which subjects will complete a physical exam, provide a 4ml blood sample, have an MRI scan and complete a battery of self-report questionnaires. Additionally, the researchers will record information from the subject’s EMR including dates of hospital admittance, diagnosis and lab results. Additional detailed information regarding study procedures can be found in the sponsor protocol, Sections 2.1-2.7.*

In some instances, the sponsor protocol may not include all information required for IRB approval. In these instances, the PI or study coordinator should provide additional detail beyond what is described in the sponsor’s protocol.

For example, a sponsor protocol may not provide sufficient detail regarding how the informed consent process will occur at UT. Thus, the PI or study coordinator should provide a summary of the consent process including who will consent subjects, when subjects will be consented, where the consent procedures take place and how the PI will ensure subjects have sufficient time to consider their participation. Additionally, a reference to the informed consent process outlined in the sponsor protocol should be included.

If the information provided in the IRB Proposal Form and the sponsor’s protocol is insufficient for the IRB to determine that the criteria for approval are met, the IRB will request that the researcher provide additional information or clarification in the IRB Proposal Form.

If you have any questions, please contact the IRB main line at 512-232-1543 or email irb@austin.utexas.edu for assistance.