1. Purpose

1.1. This SOP describes how the study team communicates with the IRB throughout the research process in order to ensure compliance with the regulations and to protect the safety and well-being of study subjects.

2. Scope and Responsibility

2.1. This SOP applies to all individuals participating in the conduct of clinical research at UTHealth. The investigator and all staff to whom an investigator assigns a study task are required to follow this SOP.

3. Policy

3.1. It is the policy of UTHSC-H that all research involving human participants must be reviewed and approved by the Committee for Protection of Human Subjects. No research activities may begin before IRB approval is obtained. Changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. Changes may be implemented only after written IRB approval is obtained.

4. Procedures

4.1. **Initial Application:** The research coordinator or regulatory specialist should use the iRIS application to submit initial application for IRB review and approval. No study procedures should be started until written IRB approval is obtained.

4.2. **Change Requests and Protocol Amendments:** The research coordinator or regulatory specialist should submit change requests for IRB review and approval via iRIS. Changes may be implemented only after written IRB approval is obtained. If the consent form has been revised,

4.3. **Personnel Changes:** All individuals involved in conducting clinical research must be approved by the IRB. Prior to adding any new collaborator or research staff on the study delegation log, a personnel change request must be submitted to the IRB via iRIS. When collaborators or study team members leave the study, remove them from the delegation log and submit a personnel change request to the IRB via iRIS to remove the study staff from the study in the iRIS record.

4.4. **Continuing Review:** The research coordinator or regulatory specialist must note the IRB approval expiration date and must make sure to submit a continuing review application at least 45 days before expiration date.

4.5. **Unanticipated problems involving risks to research subjects or others:** All unanticipated problems including adverse events, protocol deviations as described in the unanticipated problem SOP are reported to the IRB in a timely manner.

4.6. **Study Completion:** When a study is completed, the PI should submit study completion reports within 30 days after completion of the study. Completion reports should be submitted using the Study Closure Report via iRIS.

4.7. **Reliance:** ` if an external IRB has been chosen for IRB oversight:

4.7.1. Obtain permission to rely from UTHealth Houston IRB via iRIS submission.

4.7.2. Do not initiate any study procedures prior to written approval from reviewing IRB.

4.7.3. Submit personnel change request to UTHealth Houston IRB for any changes to personnel – whether adding new study team member or removing study team members.

4.7.4. Submit timely continuing review reports to the reviewing IRB.

4.7.5. Do not implement any protocol changes without approval from the reviewing IRB.

4.7.6. Notify UTHealth Houston IRB via iRIS of any unanticipated problems occurring at the UTHealth Houston site.

4.7.7.Notify UTHealth IRB via iRIS of study closure.

5. References

5.1. UTHealth IRB Policies and Procedures

5.2. UTHealth IRB Reliance Policies and Procedures

6. Appendices

6.1. None

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

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