1. PURPOSE

1.1. This SOP describes how the Institution may use an external IRB for human research.

2. SOP Statement

2.1. The Institution may rely on an external IRB to serve as the IRB of Record for certain TAMU research protocols.

2.1.1. TAMU may rely upon the IRB of another organization when investigators at TAMU receive a NIH grant or sub-award (or other federal funds) that mandate the use of an external IRB or single IRB.

2.1.2. TAMU may rely on an External IRB when site is subcontracted and IRB approval has already been processed by a non-affiliated appropriately qualified IRB.

2.1.3. The TAMU HRPP reserves the right to determine on an individual study basis whether or not to accept an External IRB review. The HRPP will evaluate for the institution the external IRB and the circumstances of the request.

2.1.4. TAMU investigators may not initiate or engage in any human research activities until the TAMU HRPP has evaluated and acknowledged a new study application in the electronic system regardless of any External IRB approval.

2.1.5. When relying on an External IRB, whether it is for a single research project or a portion the institution's research portfolio, the External IRB will meet Federal Agency regulations for the conduct of human subjects research and IRB review; the IRB is registered with OHRP and has a Federalwide Assurance (non commercial IRBs) and if not part of an AAHRPP organization will be able provide appropriate human protections, given the risk of the research.

2.1.6. When TAMU relies on an External IRB to serve as the IRB of record, the External IRB is evaluated by the TAMU HRPP to determine if it meets specific criteria for the protection of human research subjects and, if so, written agreements are executed.

2.1.7. There will be a formal written agreement between TAMU and the External IRB delineating the roles and specific responsibilities of each party.

2.2. Authorization Agreement:

2.2.1. An authorization agreement, initiated by either the External IRB or TAMU, is used to document the agreement of both parties.

2.2.2. The written authorization agreement must outline the responsibilities of the external IRB and TAMU and the researcher/s.

2.2.3. The authorization agreement is kept in the HRPP administrative files and will be made available upon official request.

3. RESPONSIBILITY

3.1. The Institution' investigators in conjunction with the HRPP is responsible for carrying out the policy.

4. PROCEDURE:

4.1. TAMU HRPP Responsibilities:

4.1.1. The investigator seeks approval from the HRPP Director or designee to use an external IRB to serve as the IRB of Record and provides justification for reliance on the external IRB.

4.1.2. The HRPP Director or designee assesses whether an external IRB is qualified to serve as the IRB of Record for TAMU human subject research project by verifying the following:

4.1.2.1. The organization's Human Research Protection Program is accredited by AAHRPP or will be able provide appropriate human protections, given the risk of the research.

4.1.2.2. Has an active Federalwide Assurance (FWA) on file with the Federal Office for Human Research Protection (non-commercial IRBs)

4.1.2.3. The IRB is registered with OHRP.

4.1.2.4. The Board Membership satisfy the requirements of 45 CFR 46.107 and 21 CFR 56.107.

4.1.2.5. The external IRB has an adequate process in place to notify the TAMU IRB and researcher(s) of its approvals, determinations, reportable events, suspensions, and terminations/

4.1.2.6. In the opinion of TAMU HRPP Director or designee the external IRB can fulfill its responsibilities as outlined in the written authorization agreement.

4.1.3. If it is determined that the external IRB is qualified to serve as the IRB of Record, a written authorization agreement is initiated, by either the external IRB or TAMU, which documents the agreement of both parties.

4.1.4. The following information from the external organization is provided to the TAMU HRPP Director or designee:

4.1.4.1. The IRB's Federalwide Assurance (FWA) number

4.1.4.2. IRB's Institution/organization (IORG) number

4.1.4.3. The contact information for the external IRB's Institutional Official (name, address, telephone number, e-mail address)

4.1.4.4. The contact information for the external IRB's Administrator and/or designated point of contact (name, address, telephone number, e-mail address)

4.2. TAMU Investigator Responsibilities:

4.2.1. Comply with the external IRB's requirements, directives per the Authorization Agreement and local institutional requirements.

4.2.2. Must not enroll individuals in any research protocol prior to the following:

4.2.2.1. Review and approval by the external IRB, and

4.2.2.2. Verification of local review requirements and written confirmation of the external IRB approval from the TAMU HRPP.

4.2.3. Ensure the safe and appropriate performance of the research. This includes, but is not limited to ensuring the qualifications of research staff; monitoring protocol compliance; maintaining compliance with state, local or organizational requirements related to the protection of human subjects; providing a mechanism to receive and address concerns from local study subjects and others about the conduct of the research; and investigating, managing, and providing notification to the external IRB and the TAMU HRPP of any study-specific incidence, experience, or outcome that rises to the level of an unanticipated problem and/or serious or continuing non-compliance.

4.2.4. Provide the external IRB with any local context issues relevant to the research protocol.

4.2.5. Disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.

4.2.6. Promptly report to the external IRB any proposed changes in the research. The investigator must not initiate changes in the research (including changes in the consent document) without prior IRB review and approval or TAMU HRPP confirmation, except

where necessary to eliminate apparent immediate hazards to the subjects.

4.2.7. When responsible for enrolling subjects, will obtain, document, and maintain records of consent for each subject or subject's legally authorized representative as stipulated by the IRB. The investigator will utilize the TAMU consent, assent, and/or HIPAA templates, as appropriate.

4.2.8. Will provide to the external IRB any data and safety monitoring reports they receive, either at continuing review, upon request by the reviewing IRB, or on an emergent basis, if appropriate.

4.2.9. Provide updates to the external IRB and TAMU HRPP whenever a principal investigator is no longer the responsible party for a research project under the purview of the external IRB.

4.2.10. Provide the contact person and contact information for the TAMU HRPP Director or Designee to the external IRB.

4.2.11. Documenting request for reliance on the External IRB through the IRB electronic system (iRIS).

4.2.11.1. Document the initial request for reliance by submitting an application in iRIS.

4.2.11.1.1. The investigator agrees not to proceed with any study related activities until the TAMU HRPP has evaluated and given written confirmation of the reliance on the External IRB review.

4.2.11.2. Document any updates, continuing reviews and modifications to the research approved by the external IRB including the following reportable new information:

4.2.11.2.1.1. new risks and unanticipated problems

4.2.11.2.1.2. harm experienced by a subject

4.2.11.2.1.3. non-compliance, audits by external agencies

4.2.11.2.1.4. monitoring reports, protocol deviations

4.2.11.2.1.5. breach of confidentiality

4.2.11.2.1.6. un-reviewed changes taken to eliminate apparent immediate harm to a subject

4.2.11.2.1.7. incarceration of a subject

4.2.11.2.1.8. unresolved subject complaint

4.3. External IRB Responsibilities include, but are not limited to:

4.3.1. Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research.

4.3.2. Conduct review of potential unanticipated problems, adverse events, and/or serious or continuing non-compliance.

4.3.3. Provide notification to researcher staff and relying institution in writing of its determinations and decisions.

4.3.4. Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the relying institution upon request.

4.3.5. When appropriate, and as indicated in the written authorization agreement, conduct on-site or remote post-approval monitoring or audits.

4.3.6. Maintain an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21 CFR 56.107 and which provides special expertise as needed to adequately assess all aspects of each study.

4.3.7. Promptly notify the TAMU Institutional Official or designee if there is a suspension or termination of the external IRB's authorization to review a study.

4.3.8. Provide the TAMU HRPP Director or designee, the contact person and contact information for the reviewing IRB.
4.3.9. Maintain appropriate documentation per record retention policies, including an OHRP-approved Federalwide Assurance (non-commercial IRBs) for human subjects research.
4.3.10. Notify the TAMU HRPP Director or designee of any changes to external IRB's FWA.

4.4. Documenting the Reliance on an External IRB of Record
4.4.1. The Investigator is responsible for documenting the reliance when an External IRB Is allowed to serve as the IRB of Record for any TAMU research by completing the following:
4.4.1.1. Create a new study in the IRB electronic system (iRIS) and complete the sections applicable to external IRB review..
4.4.1.2. Attach copies of protocol specific materials, supporting documents and correspondence in the IRB electronic system. Use Worksheet: External IRB Review of Onsite Research (HRP-335) as guide.
4.4.1.3. Submit External IRB study to the HRPP/IRB Administrative Staff for Institutional Confirmation of External IRB Research.

4.5. Institutional Confirmation of Research and verification of local review requirements when TAMU relies on an external IRB to serve as the IRB of record.
4.5.1. The HRPP staff carries out these activities:
4.5.1.1. Use Worksheet: External IRB Review of Onsite Research (HRP-335) to verify that the External IRB Research submitted by the investigator is complete.
4.5.1.2. If submission is not complete or requires clarifications contact the investigator and request pre-review clarifications or stipulations. Offer the investigator the opportunity to make to provide additional information.
4.5.1.3. Continue processing once the investigator responds to the request for additional information.
4.5.1.4. Obtain other institutional approvals as needed and document in the electronic system.
4.5.1.5. Verify that the research is appropriate for the institution.
4.5.1.6. External IRB approval correspondence has been received
4.5.1.7. Consult with the Associate Vice President for Research or others as needed.
4.5.2. If the research is appropriate for this institution, generate correspondence notifying the investigator that the external IRB review has been confirmed and the research may proceed.
4.5.3. If the research is not appropriate for the institution generate correspondence notifying the investigator that the research may not be carried out at TAMU and the reasons for the decision.

4.6. MATERIALS: Use Worksheet: External IRB Review of Onsite Research (HRP-335).

4.7. REFERENCES:
4.7.1. AAHRPP 1.2