1 PURPOSE

1.1 This document describes the management of multi-site research study information and/or communications by the lead Texas A&M University Principal Investigator (PI) and the TAMU Institutional Review Boards (IRB) when TAMU is serving as the coordinating institution.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 SOP Statement

3.1 When serving as the coordinating institution for the lead principal investigator, the Institution's IRBs are responsible for the review and tracking of information (including but not limited to reportable events, modifications to previously approved research, consent documents and continuing review reports) for approved multi-site research studies involving human subjects.

3.2 The TAMU lead Principal Investigator serves as an agent of TAMU and is responsible for the receipt and dissemination of all multi-site research study information to all sites considered engaged in the research.

4 RESPONSIBILITIES

4.1 The lead TAMU investigator or designee and the Institution's IRBs carry out these procedures.

5 PROCEDURE

5.1 Lead Principal Investigator Responsibilities:

5.1.1 The lead TAMU Principal Investigator is responsible for submitting an IRB electronic application in iRIS and providing the following information to the IRB:

5.1.1.1 A list of all sites/locations participating in the research study.

5.1.1.2 Confirmation of contact information (names, e-mails, addresses) for all sites/locations participating in the research study.

5.1.1.3 A plan for the review of each external site's IRB approval correspondence and approved consent documents.

5.1.1.3.1 The external sites IRB approval correspondence will include the type of review and information about any approval with conditions.

5.1.1.4 When the research study is federally funded or federally regulated, confirmation that each participating site has on file a Federalwide Assurance (FWA) with the Federal Office of Human Research Protections (OHRP).

5.1.1.5 Registration of study on ClinicalTrials.gov, when applicable.

5.1.1.6 A plan to assure that no participating site will begin the research (including recruitment activities) until IRB approval has been granted.

5.1.1.7 A method to assure that all sites participating in the research have the most current version of the protocol.

5.1.1.8 A method to assure that all sites participating in the research receive, when applicable, protocol amendments.

5.1.1.9 A method to assure that all sites participating in the research receive study related communications including reports of adverse outcomes, unanticipated problems, and interim results.

5.1.1.10 A plan for the collection and management of data from all sites/locations participating in the research.

5.1.1.11 A process for centralized reporting and evaluation of reportable events from all sites participating in the research.

5.1.1.12 If the external site plans to rely on the TAMU IRB the lead PI is responsible for consulting with the TAMU HRPP Director or designee who will oversee the completion of the TAMU IRB Authorization Agreement.

5.1.1.12.1 The Agreement will specify the roles and responsibilities of TAMU IRB and the relying organization.

5.1.1.12.2 The external site will be responsible for updating its FWA to reflect reliance upon the TAMU IRB if required per DHHS OHRP guidance.

5.1.1.12.3 The external site and the TAMU IRB will each maintain one fully executed original of the agreement for inspection by OHRP, as requested.

5.1.1 IRB submissions (e.g. modifications, continuing review report, reportable events, etc.):

5.1.1.1 If the TAMU PI's internal application is the mechanism for the initial and continuing IRB review for any external Relying Organization(s), the lead TAMU PI is responsible for receiving reports from all participating sites and submitting information to IRB in accordance with TAMU HRPP policies.

5.1.1.2 If an external site application is the mechanism for the initial and continuing TAMU IRB review for the external Relying Organization, the PI for the external site application is responsible for submitting information to the IRB in accordance with TAMU HRPP policies.

5.2 TAMU IRB Responsibilities:

5.2.1 When TAMU is serving as the coordinating institution for the lead principal investigator the TAMU IRB will perform initial review of each research application and all documentation relevant to the protection of human subjects. The TAMU IRB will conduct IRB review, including, but not limited to review of reportable events, modifications to previously approved research, and continuing review reports.

5.3 Department of Defense (DoD) Multi-site Research

5.3.1 For multi-site research involving the Department of Defense (DoD), the TAMU IRB and the lead TAMU Principal Investigator will adhere to additional responsibilities as set forth in the "Department of Defense (DoD) Addendum". The DoD Addendum is a formal agreement between the TAMU IRB and DoD organizations specifying requirements, roles, and responsibilities. For DoD requirements use WORKSHEET: Additional Federal Criteria (HRP-318) for DoD research.

6 MATERIALS

6.1 SOP: Reportable New Information Items (HRP-092)

6.2 WORKSHEET: Additional Federal Criteria (HRP-318)

7 REFERENCES

7.1 OHRP 45 CFR §46.103

7.2 AAHRPP 11.2.H