1 PURPOSE

1.1 To identify the official at Texas A&M University charged with overall responsibility for the Human Research Protection Program (HRPP). To delineate the role and responsibility of the Institutional Official (IO).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 SOP Statement

3.1 In accordance with Texas A&M University Rule 15.99.01.M1 the Institutional Official is the individual authorized to act for the university and to assume on behalf of the university the obligations imposed by federal law and regulations. The Vice President for Research Is the university's Institutional Official.

3.2 The Institutional Official may delegate these authorities as appropriate to other experienced individuals of the HRPP including to members of the Division of Research Senior Administrative Leadership Team, but may not delegate institutional authority for the IO role.

3.3 The Institutional Official shall not approve research that has been disapproved or not yet approved by the IRB.

4 RESPONSIBILITIES

4.1 The Institutional Official is responsible for carrying out these procedures.

5 PROCEDURE

5.1 The general administrative obligations of the IO include:

5.1.1 Designating one or more Institutional Review Boards (IRBs) that will review research covered by the institution's FWA;

5.1.2 Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties;

5.1.3 Providing access to training and educational opportunities for the IRB and investigators;

5.1.4 Promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;

5.1.5 Establishing standard operating procedures (SOPs) for human subjects research and ensuring effective institution-wide communication and guidance on these SOPs.

5.1.6 Ensuring that investigators fulfill their responsibilities;

5.1.7 Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;

5.1.8 Ensuring that the IRB members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.

5.1.9 Suspending or terminating research approved by one of the Institution's IRBs, as needed for subject safety.

5.1.10 Disallowing research approved by one of the Institution's IRBs or an External IRB if the research does not meet the institution's requirements.

5.1.11 Serving as a knowledgeable point of contact for OHRP and other federal agencies, or delegating this responsibility to another appropriate individual;

5.2 The Institutional Official may delegate some or all of the following responsibilities as appropriate to one or more experienced individuals of the HRPP including to members of the Division of Research Senior Administrative Leadership Team:

5.2.1 Appointing IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations;

5.2.2 Appointing the IRB chair or co-chairs. Suspending or terminating the appointment of any chair or co-chair who is fulfilling his/her responsibilities and or obligations;

5.2.3 Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;

5.2.4 Managing and administering funds to help the IO ensure that adequate personnel, space and other resources are allocated to the HRPP;

5.2.5 Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);

5.2.6 Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal agencies;

5.2.7 Developing and implementing an educational plan for IRB members, staff and investigators;

5.2.8 Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards. all applicable regulations and institutional policies;

5.2.9 Performing periodic evaluation of the performance of the IRB members and administrative staff;

5.2.10 Recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRB;

5.2.11 Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP;

5.2.12 Overseeing daily operations of the IRB and HRPP in accordance with the SOPs.

5.3 Any delegation of duty by the Institutional Official should be in writing.

5.4 Duties that should not be delegated by Institutional Official include the following:

5.4.1 Signatory authority for the FWA;

5.4.2 Completing recommended Assurance training for the IO;

5.4.3 Ensuring that the IRB functions independently and that its chair or chairs and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB;

6 MATERIALS

6.1 Texas A&M University Rule 15.99.01.M1

7 REFERENCES

7.1 45 CFR 46.103(b)