1 PURPOSE

1.1 This SOP establishes the process to manage any allegations of suspected or actual noncompliance reported to the Texas A&M University HRPP or IRB to ensure the protection of human subjects in research.

1.2 This process begins when any potential non-compliance is reported to the HRPP or IRB.

1.3 This process ends when the noncompliance is managed administratively, referred to the convened IRB or the allegation is determined to be unsubstantiated.

2 SOP Statement

2.1 This SOP applies to faculty, staff, students, residents and affiliated investigators or other affiliated individuals who are involved in human subjects research being conducted under the auspices of Texas A&M University regardless of the location of the research, regardless of the funding source or whether the research is funded or unfunded.

2.2 Suspected or actual non-compliance must be reported to the IRB. Use the form 'Reportable New Information' located in the electronic submission system.

2.3 IRB members and consultants do not participate in any review in which they have a conflict of interest, except to provide information requested by the IRB.

2.4 Allegations of noncompliance reported to the IRB will be reviewed in a timely manner to determine whether the allegation has a basis in fact or not.

2.5 Investigators are required to respond promptly to any inquiries, correspondence, or directives from either the HRPP or the IRB with respect to any allegations of or actual noncompliance.

2.6 The IRB will initiate appropriate actions as needed to protect subjects participating in the research including suspension or termination of the research.

2.6.1 Possible range of actions or restrictions considered by the IRB may include:

2.6.1.1 Investigator education.

2.6.1.2 Modification of the information disclosed during the consent process.

2.6.1.3 Notification of current participants when such information might relate to the participant willingness to continue to take part in the research.

2.6.1.4 Modification of the continuing review period.

2.6.1.5 Monitoring of the consent process or the research.

2.6.1.6 Referral to other administrative departments.

2.6.1.7 Modification of the research

2.6.1.8 Suspension of the research.

2.6.1.9 Termination of the research.

2.7 Reports of noncompliance may come in the form of a complaint or from the result of an review or a monitoring activity. If a complainant does not have access to the electronic system the report may be sent by other means available (email, fax, phone or in-person).

2.8 The institution will notify the federal department or agency funding the research of any for-cause investigation of that research by another federal department or agency or national organization.

2.9 For federal departments or agencies funding the research, non-compliance includes non-compliance with the requirements of that particular agency.

2.10 If a finding of serious or continuing non-compliance involves another TAMU System Member, the institution will notify the Institutional Official of the System Member.

3 REVISIONS FROM PREVIOUS VERSION

3.1 None

4 RESPONSIBILITIES

4.1 The IRB Chair or designee, HRPP Director and HRPP Post Approval Monitors carry out the responsibilities as indicated.

5 PROCEDURE

5.1 Investigators are required to report any instances of noncompliance that involves a potential risk to subjects or others, or involves failure to comply with federal regulations, state laws, Institutional policies, and/or requirements or determinations of the IRB or provisions of the approved protocol. See SOP: Reportable New Information Items HRP-029.

5.2 Noncompliance will be reviewed by the IRB Chair or designee to see:

5.2.1 If immediate action needs to be taken to ensure subject safety.

5.2.2 If the allegation has no basis in fact, generate correspondence with a determination of 'Allegation of Non-Compliance with no Basis in Fact'.

5.2.3 If the noncompliance is serious and/or continuing send to a meeting of the convened IRB and applicable parts of this SOP will apply.

5.2.4 If there is no serious or continuing noncompliance, generate correspondence with a determination of 'Noncompliance that is Neither Serious nor Continuing'.

5.3 The IRB Chair or designee may request as needed:

5.3.1 Additional information from the PI.

5.3.2 Consultation with General Counsel.

5.3.3 An investigative sub-committee that may include outside expertise.

5.3.4 The Post Approval Monitoring (PAM) team to conduct an inquiry/review into the allegation.

5.4 The investigator will be given the opportunity to respond to the allegations of suspected noncompliance.

5.5 Upon completion of the initial investigation into the allegation, the PAM staff will prepare a written report describing the allegation and the outcome of the review.

5.5.1 The PAM's report will be submitted to the IRB as Reportable New Information and a copy will be provided to the investigator.

5.5.2 If the allegation involves the IRB or any other component of the institution, the PAM team will forward the report to the HRPP Director, Associate VPR and Institutional Official as appropriate.

5.6 When required, a corrective action plan will accompany the report submitted to the IRB.

5.6.1 The corrective action plan will outline what steps the investigator has taken or will take to resolve the noncompliance and sufficient detail to ensure adequate measures or training is taken to prevent future violations and to prevent such noncompliance from occurring in any current or future research that may be conducted by the research team.

5.6.2 When appropriate, or upon request by an investigator, the PAM team may assist in the development of the corrective action plan to accompany the investigator's response.

5.6.3 The PAM team or the investigator may request additional input from the IRB Chair or HRPP Director.

5.7 If the noncompliance cannot be resolved as described above or an appropriate corrective action plan that is acceptable to the IRB cannot be developed, the IRB has the authority to impose corrective actions, take additional measures to protect human subjects or to refer the non-compliance to the Institutional Official (IO) with recommendations.

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6 MATERIALS

6.1 SOP: Reportable New Information Items (HRP-029)
6.2 SOP: New Information Process (HRP-024)

7 REFERENCES

7.1 45 CFR 46.103.b(5)
7.2 21 CFR 6.108 (b)(2)
7.3 AAHRPP 1.5.D