1. PURPOSE

1.1. This SOP establishes the process to manage new information to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2. The process begins when the IRB receives a new information item.
Information items requiring submission to the IRB are listed on HRP-029 - SOP- Reportable New Information Items.

1.3. The process ends when the IRB Chair, HRPP Director or designated reviewer has determined whether the information item: does not represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2. REVISIONS FROM PREVIOUS VERSION

2.1. Revised from previous version dated 5/30/2017.

3. SOP Statement

3.1. 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.

3.2. Allegations of suspected or actual noncompliance related to research reviewed by an external IRB are subject to this policy as applicable.

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

3.4. 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.

3.5. The IRB will initiate appropriate actions as needed to protect subjects participating in the research including suspension or termination of the research. See HRP-321 – WORKSHEET – Review of Information Items.

3.6. Reports of noncompliance may come in the form of a complaint or from the result of a 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).

3.6.1. These findings are handled internally then routed for IRB review, if appropriate.

3.6.2. Other university or agency departments may be included in the process, if appropriate.

3.7. 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.

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

3.9. 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.

3.10. Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Organizational Official or designee for further action.

3.11. The organization will promptly (no longer than 30 days) 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.

3.12. The organization will promptly (no longer than 30 days) notify the Federal department or agency funding the research of any Unanticipated Problem Involving Risks to Subjects or Others, Suspensions, Terminations, and Serious or Continuing Noncompliance as indicated in HRP-052 - SOP - Post Review.

3.13. For Department of Defense (DoD) research the report is sent to the DoD Human Research Protection Officer.

3.14. The organization will promptly notify the Department of Defense (DoD) if the IRB of record changes.

4. RESPONSIBILITIES

4.1. The IRB/HRPP staff carry out the pre-review procedures.
4.2. The IRB Chair, HRPP Director or Designated Reviewer carry out activities after the pre-review is complete.

5. PROCEDURE

5.1. Review each item of information and answer the following questions. *(See attached flowchart for a diagram of the flow of this procedure.)*
  5.1.1. Is this an Allegation of Non-Compliance?
  5.1.2. Is this a Finding of Non-Compliance?
  5.1.3. Is this an Unanticipated Problem Involving Risks to Subjects or Others?
  5.1.4. Is this a Suspension of IRB Approval or Termination of IRB Approval?
5.2. If you are unable to answer a question, consult the IRB chair or HRPP Director.
5.3. After completing the Pre-Review Activity assign the New Information item to the IRB chair, HRPP Director or designated reviewer.
5.4. If the IRB chair, HRPP Director or designated reviewer are unable to answer a question, initiate one of the following:
  5.4.1. HRP-025 - SOP - Investigations.
  5.4.2. HRP- 005 - SOP - Post Approval Monitoring (PAM) & Quality Assurance Plan
  5.4.3. Request a consultant
  5.4.4. Form an investigative subcommittee
    5.4.4.1. The investigative subcommittee may include outside expertise.
    5.4.4.2. The investigative subcommittee may provide recommendations to the IRB
  5.4.5. Prepare a written report describing the allegation and the outcome of any investigation, or post approval monitoring activity.
5.5. If the answer is “yes” to one or more questions, then the IRB Chair, HRPP Director or designated reviewer will follow the corresponding sections below.
  5.5.1. Consult with the Associate Vice President for Research or System Office General Counsel as needed.
  5.5.2. Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.
    5.5.2.1. If yes, follow the procedures under Findings of Non-Compliance.
    5.5.2.2. If no, follow the corresponding sections.
  5.5.3. Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.
    5.5.3.1. If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.
    5.5.3.2. If yes, follow the procedures under Serious or Continuing Non-Compliance.
  5.5.4. Non-Serious/Non-Continuing Non-Compliance
    5.5.4.1. Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan as needed or refer them to the PAM team or HRPP Director for help.
    5.5.4.2. If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.
  5.5.5. Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or

Others

5.5.5.1. Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

5.6. If the new information requires immediate action necessary in advance of the meeting, the IRB Chair, HRPP Director or other individual will consider a Suspension of IRB Approval following HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.

5.6.1. A new information item that requires immediate action to protect the rights and welfare of subjects may be placed on the next IRB agenda at any time prior to the meeting.

5.7. If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

5.7.1. Confirm that the subject is currently a Prisoner.

5.7.1.1. If the subject is currently not a Prisoner no other action is required.

5.7.2. Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.

5.7.2.1. If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.7.2.1.1. Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.7.2.1.2. Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.7.2.2. If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner,

5.7.3. For Department of Defense (DoD) research have the convened IRB promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.

5.7.3.1. Promptly report all decisions to the Department of Defense (DoD).

5.7.3.2. The Department of Defense (DoD) must concur with the IRB before the subject can continue to participate while a prisoner.

5.8. Take any additional actions required to resolve any concerns or complaints associated with the information.

5.9. If the information involves any of the following, complete and send HRP-529 - LETTER - AAHRPP Notice of Information Item to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

5.9.1. Negative actions by a government oversight office, including, but not limited to, OHRP Determination letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

5.9.2. Litigation, arbitration, or settlements initiated related to human subjects protections.

5.9.3. Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

5.10. Take any additional actions required to resolve any concerns or complaints associated with the information.

5.11. If the information does not involve Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, the IRB Chair, HRPP Director or designated reviewer will complete review and the IRB staff will prepare and send letter per HRP-052 - SOP -Post-Review.

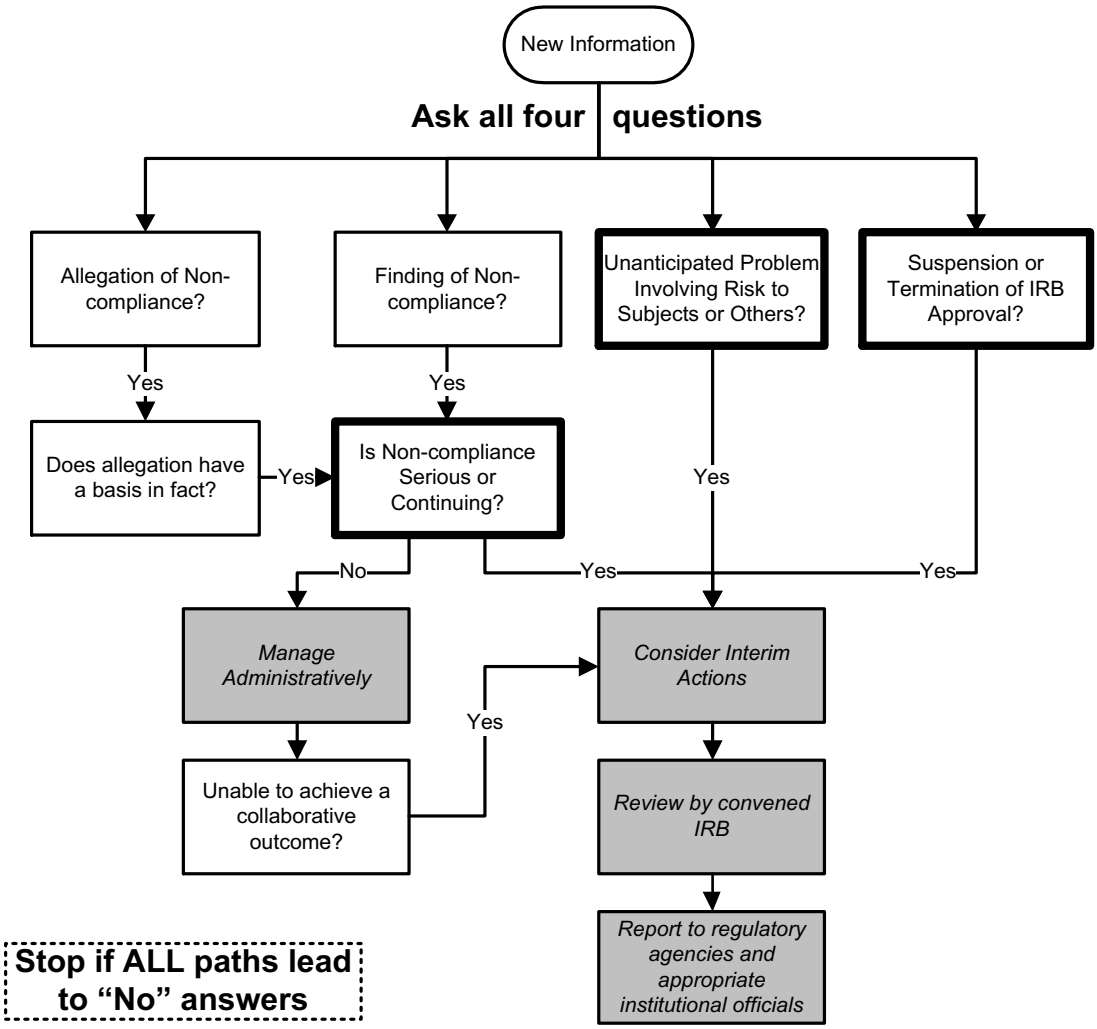
6. MATERIALS

6.1. HRP-005 - SOP - HRPP Post Approval Monitoring & Quality Assurance Plan
6.2. HRP- 018 - SOP - Managing Non-Compliance in Human Subject Research
6.3. HRP-025 - SOP - Investigations
6.4. HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
6.5. HRP-029 - SOP - Reportable New Information Items
6.6. HRP-052 - SOP - Post-Review
6.7. HRP-321 – WORKSHEET - Review of Information Items.
6.8. HRP-529 - LETTER - AAHRPP Notice of Information Item

7. REFERENCES

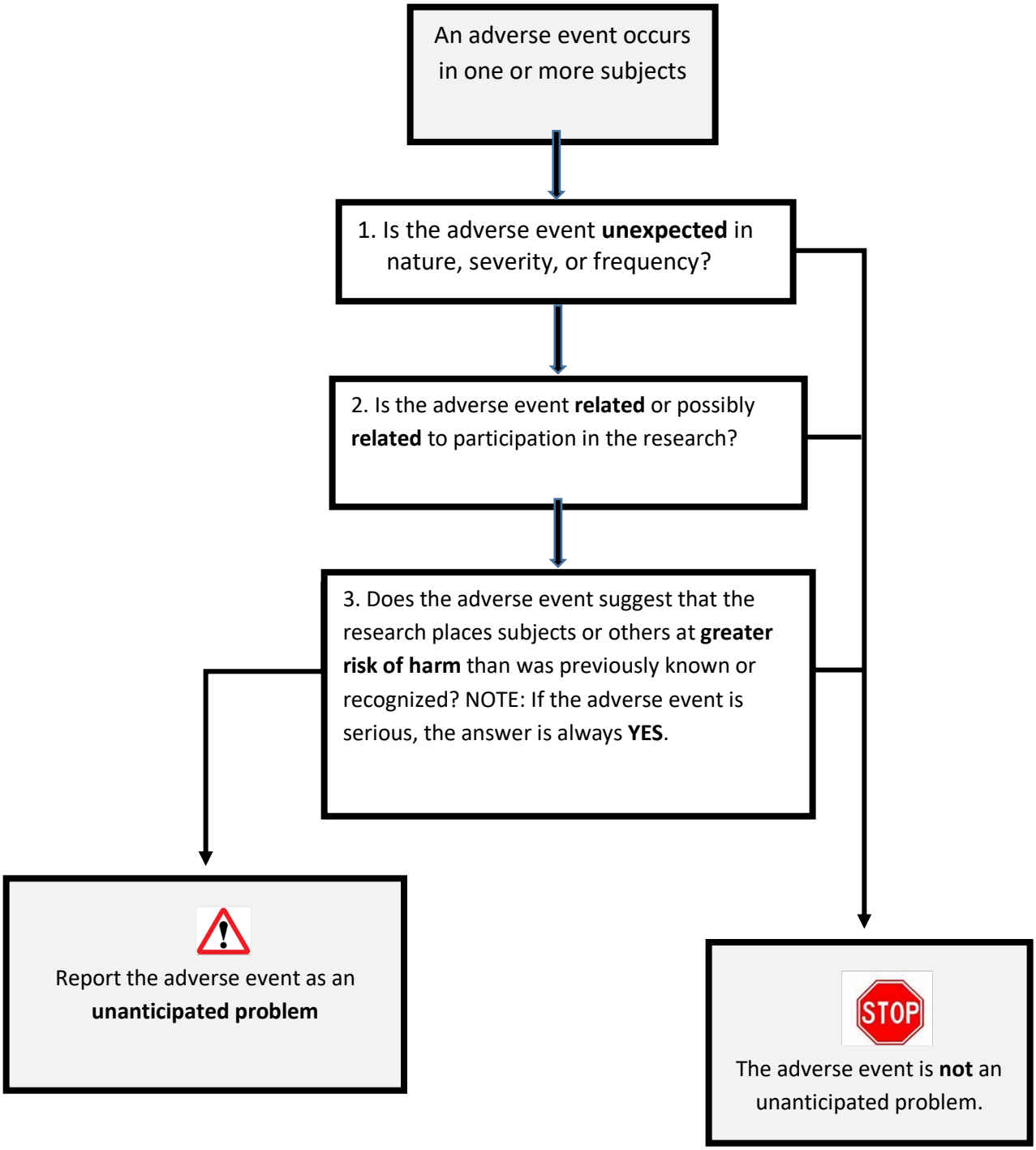
7.1. 21 CFR §56.108(b)
7.2. 45 CFR §46.108(a)
7.3. AAHRPP I.5.A, I.5.D, I-9, II.2.D, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, III.2.D
7.4. DoD Directive 3216.02

7.5. Flowchart



Unanticipated Problems Flow Chart

Ask all three questions



Unanticipated problems, in general, include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; (b) the characteristics of the subject population being studied; and

2. is related or possibly related to the research (this means that it is more likely than not, the incident, experience, or outcome was caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

There are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered adverse events. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased *risk* of harm, but no harm occurs.