Tampa General Hospital
POLICY & PROCEDURE

__ Organizational __ Hospital __ Ambulatory Services _X_ Departmental

Title: New Information

Original Issue Date: 7/15/2019 Review Date: Revision Date:	**Number:** **OCR-224**	**Page:** 1 of 5

Originating Department: Office of Research Compliance **Approved by:** Sally Houston, MD

1 PURPOSE

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

1.2 The process begins when the study team or the Office of Clinical Research (OCR) identifies an information item.

1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the reviewing IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The organization will promptly 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.

3.1.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

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

4 RESPONSIBILITIES

4.1 The study team with the assistance of the OCR, as needed, carry out this procedure.

5 PROCEDURE

5.1 For research overseen by the USF IRB, review each item of information and answer the following questions and complete the Submit RNI Pre-Review Activity, when appropriate: *(See attached flowchart for a diagram of the flow of this procedure.)*

5.2 For research overseen by other external reviewing IRBs, review each item of information and answer the following questions and follow the reporting process of the reviewing IRB, when appropriate: *(See attached flowchart for a diagram of the flow of this procedure.)*

5.2.1 Is this an Allegation of Non-Compliance?

5.2.2 Is this a Finding of Non-Compliance?

5.2.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.2.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.3 If you the study team is unable to answer a question, consult the OCR or Research Compliance Officer (RCO).

5.4 If the OCR and RCO are unable to answer a question, the RCO will follow “SOP: Investigations (OCR-025)” to make a determination.

5.5 If the answer is "yes" to one or more questions, then follow the corresponding sections below.

5.5.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.5.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.5.1.2 If no, determine if any other corresponding sections apply.

5.5.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.5.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.5.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.5.3 Non-Serious/Non-Continuing Non-Compliance

5.5.3.1 Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

5.5.3.2 If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, the RCO will consider the Non-Compliance to be Continuing Non-Compliance and will follow the procedures for Serious or Continuing Non-Compliance.

5.5.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

5.5.4.1 Confirm your decision with the OCR or RCO.

5.5.4.2 Submit the information to the reviewing IRB 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 in your opinion the rights and welfare of subjects might be adversely affected before the reviewing IRB can review the information, contact the RCO to consider a Suspension of IRB Approval following the "SOP: Suspension or Termination Issued Outside of Convened IRB (OCR-026)."

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 submit this information to the reviewing IRB to 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. Contact the OCR for assistance with this.

5.7.2.2 If the subject's involvement in the research can be stopped, 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 promptly report all decisions to the Department of Defense (DOD).

5.7.4 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.

5.8 If the information involves any of the following, notify the RCO who will complete and send a "TEMPLATE LETTER: - AAHRPP Notice of Information Item (OCR-529)" 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:

5.8.1 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.

5.8.2 Litigation, arbitration, or settlements initiated related to human research protections.

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

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

6 MATERIALS

6.1 SOP: Investigations (OCR-025)

6.2 SOP: Suspension or Termination Issued Outside of Convened IRB (OCR-026)

6.3 TEMPLATE LETTER: AAHRPP Notice of Information Item (OCR-529)

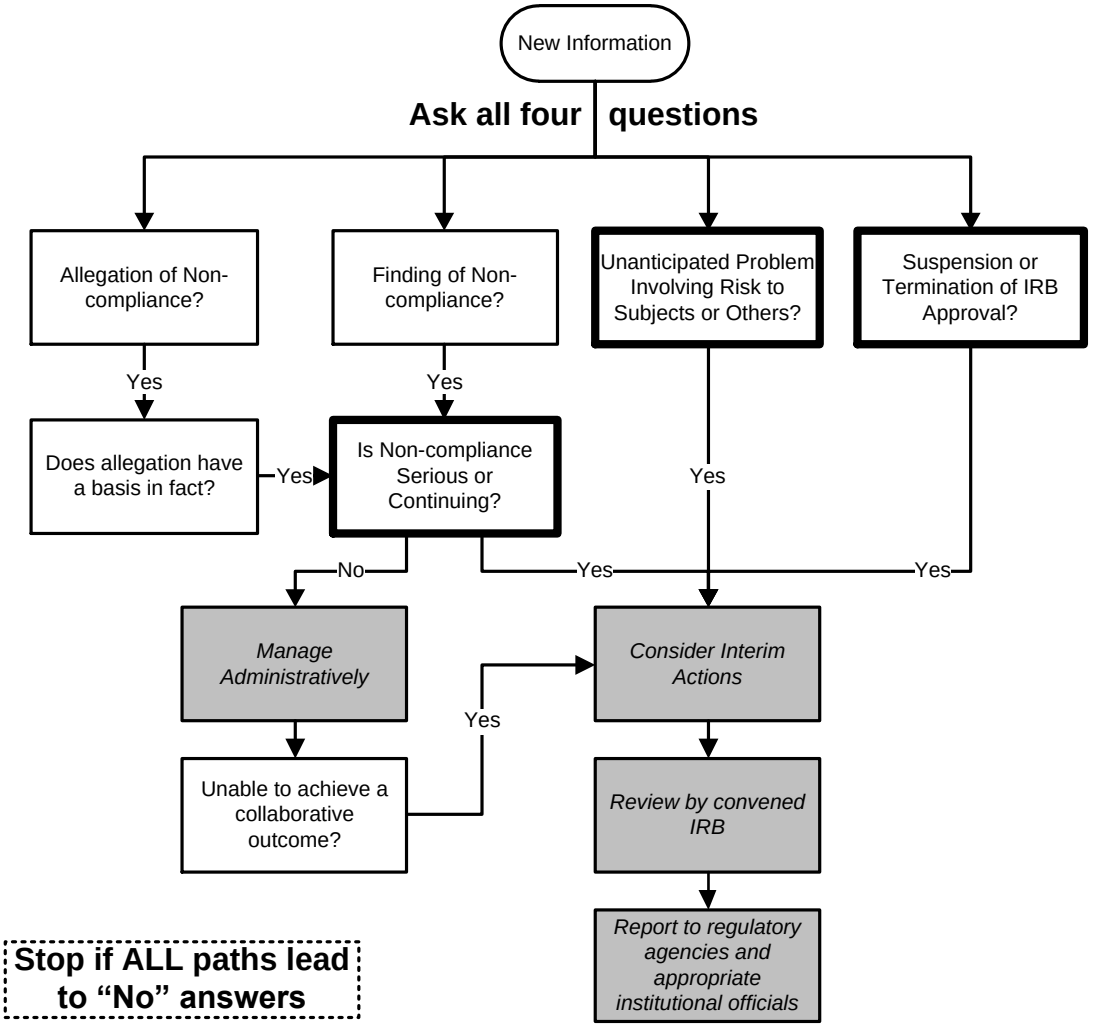
7 REFERENCES

7.1 21 CFR §56.108(b)

7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)

7.3 Flowchart (Attached)

7.4 List of Reportable Information Items (Attached)


New Information
Ask all four questions
Allegation of Non-compliance?
Finding of Non-compliance?
Unanticipated Problem Involving Risk to Subjects or Others?
Suspension or Termination of IRB Approval?
Yes
Yes
Does allegation have a basis in fact?
Yes
Is Non-compliance Serious or Continuing?
Yes
Yes
No
Yes
Manage Administratively
Consider Interim Actions
Yes
Unable to achieve a collaborative outcome?
Review by convened IRB
Report to regulatory agencies and appropriate institutional officials
Stop if ALL paths lead to "No" answers

Report the information items that fall into one or more of the following categories to the reviewing IRB within five business days using the applicable IRB form:

Information that does not fall under any of the categories below does not require reporting to the IRB. Please contact the Office of Clinical Research or the Research Compliance Officer if you have questions.

1) Information that indicates a new or increased risk, or a new safety issue. For example:
   a) New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   b) An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
   c) Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
   d) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
   e) Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
   f) Any changes significantly affecting the conduct of the research
2) Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
   a) A harm is "**unexpected**" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
   b) A harm is "**probably related**" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
3) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
4) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
5) Written reports of study monitors that includes a finding of another issue on this list.
6) Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7) Breach of confidentiality.
8) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
9) Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10) Complaint of a subject that cannot be resolved by the research team.
11) Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
12) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)