

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 9

Noncompliance Policy and Procedure

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I. Policy

- A. [Noncompliance](#) with the regulations or policies applicable to human research or noncompliance with the requirements or determinations of the IRB must be promptly reported to the IRB.
- B. Issues or events that are reported are considered *possible* noncompliance until a final determination is made by the convened IRB or designated IRB reviewer.
- C. Noncompliance that is determined to be serious or continuing must be promptly reported to the appropriate institutional officials, the Office for Human Research Protections (if applicable) and the Food and Drug Administration (if applicable).

II. Overview

- A. Noncompliance may be identified in a number of ways including for example:
 1. A report by an individual can be made directly to the IRB Office.
 2. The IRB may learn of noncompliance through its continuing review of ongoing research.
 3. Compliance reviews (audits) conducted by the Office of Regulatory Affairs and Compliance or one of the HSC affiliated institutional compliance offices.
 4. A report by an individual can be made directly to the Office of Regulatory Affairs and Compliance (Hotline) or one of the HSC affiliated institutional compliance offices.
 5. A report by another committee, department, institution, or official.
 6. A report from the study sponsor or sponsor's monitoring entity.

7. Collective evaluations of all departures (deviations and/or violations) contain instances of possible noncompliance and require prompt reporting to the IRB.
- B. For the purpose of this policy, all sources of possible noncompliance will be referred to as allegations until the issue is determined to be noncompliance by the IRB or designated IRB reviewer.
- C. This procedure starts upon discovery or identification of an event that meets the definition of [noncompliance](#) that is reportable to the IRB.
- D. This procedure ends when either:
1. The designated IRB review or convened IRB determines the event is neither serious or continuing noncompliance, or
 2. The convened IRB determines the event is serious or continuing noncompliance and prompt reporting to appropriate institutional officials and federal agencies (i.e., OHRP and FDA) is required (See [Reporting Policy and Procedure](#))
- E. Summary of responsibilities
1. Investigators and research staff are responsible for promptly reporting possible noncompliance to the IRB.
 - a) If the noncompliance also involves an [unanticipated problem involving risk to subjects or others](#), the investigators and research staff are responsible for taking appropriate action to protect the safety and welfare of the subject(s) and following the applicable [UPIRSO Policy and Procedure](#).
 - b) Protocol violations by definition adversely affect the science, rights, safety, or welfare of the subjects and also constitute noncompliance. Therefore, all violations must be reported promptly to the IRB according to the [Deviations and Violations Policy](#).
 - c) Protocol deviations do not affect or have the potential to affect the scientific soundness of the research or adversely affect or have the potential to adversely affect the rights, safety, or welfare of human subjects. Single protocol deviations are not generally considered noncompliance and prompt reporting to the IRB is not required according to the [Deviations and Violations Policy](#).
 - d) Results of any external audits that have identify issues with the potential to adversely affect the science, rights, safety, or welfare of the subjects must be promptly reported to the IRB.
 2. The OIRB staff is responsible for documenting the process to include communications, determinations and actions taken.

3. The Office of Regulatory Affairs & Compliance or an affiliated institution's compliance office is responsible for reporting to the IRB: 1) the results of IRB directed compliance reviews, 2) concerns from any other source, such as audits, that may indicate noncompliance, or 3) any complaint, concern, comment or question that may indicate noncompliance.

4. IRB Chair or designated IRB reviewer is responsible for initially reviewing reports or allegations of noncompliance and taking appropriate action (including no action). All reports of apparent serious or continuing noncompliance reported by the Research Compliance Officer (RCO) at the VA must be reviewed at the next convened IRB meeting.

III. Procedure

A. Submission and Screening of Allegations of Noncompliance

1. Reporting allegations to the Office of the IRB (OIRB)
 - a) Comments, concerns or complaints from research participants or family members of research participants, members of the research team, or individuals not otherwise affiliated with the institution that may also be [noncompliance](#) are accepted as verbal reports; however persons recording a complaint are encouraged to provide their concerns in writing.
 - b) Allegations of noncompliance from other members of the institution may be initially provided as verbal reports but must later be submitted in writing.
 - c) Principal Investigators are required to submit reports of noncompliance using the applicable Prompt Report Form.
 - d) Complaints that are not noncompliance are reviewed in accordance with the IRB [Complaints Policy and Procedure](#).
2. Prompt reporting timeframe for PI – the PI must report noncompliance to the IRB within 7 calendar days of discovery of the noncompliance issue. For research conducted at the VA, the prompt reporting timeframe for the PI is defined as 5 working days.
3. The IRB Director (IRBD) and IRB Associate Director (IRBAD) are designated IRB reviewers for this process. Given their positions in the IRB Office, these individuals are readily available to promptly review allegations of noncompliance. The reviewers are expected to communicate with the appropriate IRB Chair. The reviewers screen the allegation (or report) to determine whether the protocol has issues pertinent to other research review offices or committees, i.e., the Office of Clinical Research (OCR), the Institutional Biosafety Committee (IBC), South Texas Veterans Health Care System R&D, Radiation Safety Committee, Radioactive Drug Research Committee (RDRC), Office of Sponsored Programs (OSP), Conflict of Interest Committee (COIC), Office of Regulatory Affairs and Compliance (ORAC), and other affiliated groups. If it is determined that the allegations are pertinent to other research review entities, appropriate coordination will be planned (see [Coordination with Other Committees and Offices Policy and Procedure](#)).

B. Determination That an Allegation Is Justified or Unjustified

1. The IRB designated reviewer evaluates all allegations to determine whether they are substantiated (i.e., there are supporting documents or statements).
 2. If the issue possibly involves research misconduct defined as fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results, the IRB designated reviewer notifies the Assistant VP for Research Operations (AVPRO) or the Institutional Official, the VP for Research.
 3. If the IRB designated reviewer deems an allegation is unjustified (i.e., finds no supporting documents or statements)
 - a) the reviewer may dismiss the allegation as unjustified and;
 - (1) may decide to take no action, and
 - (2) may continue the review as a [complaint](#), or an [unanticipated problem](#) involving risks to subjects or others (following other IRB policies).
 - (3) may forward the event/information to OCR for review in accordance with [Institutional Review Policy and Procedure](#)
 - b) If the reviewer takes no action the decision will be communicated in writing to the complainant (if the identity of the person is known) and to the PI against whom the allegation was raised (respondent) or from whom the report was received.
 4. If the IRB designated reviewer determines that an allegation concerns **solely protocol deviations**, the reviewer
 - a) will process the concern according to the [Deviations and Violations Policy](#)
 - b) may process the concern as a [complaint](#), or an [unanticipated problem](#) involving risks to subjects or others, (following other IRB policies as applicable).
 - c) may manage the concern through communications with the PI. Management decisions and recommendations are based on the PI's stated plan to correct issues and prevent a future occurrence.
 5. If the IRB reviewer determines that an allegation may be **justified** and involves more than a protocol deviation, the reviewer:
 - a) may pursue further inquiry (data gathering, interview, etc) in order to determine whether the noncompliance is either [serious](#) or [continuing](#) (see III.C below); or
 - b) may forward the issue to a subcommittee or to the next convened meeting of the IRB .
- c. Subcommittee Review of an Allegation / Report of Noncompliance
1. If the allegation or report involves issues that are more serious than protocol deviations, the IRB reviewer may forward the allegation to a subcommittee of the IRB to evaluate the allegation or report. When the subcommittee of the IRB conducts the inquiry, the process includes the following:
 - a) If the allegation suggests that subjects are at immediate risk, the IRB Chair or IRB reviewer may immediately suspend IRB approval or take other actions as appropriate to protect the safety and welfare of subjects or protect the integrity of the research. If research is suspended (either partially or completely) the chair/reviewer will follow the applicable IRB policy on [Suspension and Termination of Research Policy and Procedure](#)

- b) If the issue possibly involves research misconduct, the inquiry may await the resolution of the assessment phase of the applicable institutional misconduct procedures such that they can occur in conjunction with each other if both procedures call for an inquiry and no immediate risk is present.
- c) The Chair may appoint one or more member(s) of the subcommittee (based on the seriousness and/or the frequency of violations and/or disregard for the federal regulations or the institutional policies and procedures applicable to human research) to gather information pertaining to the nature of the allegation, the procedures approved in the IRB protocol, and the procedures followed in conducting the study. The IRB reviewer, as a member of the IRB, may conduct the inquiry alone or with the assistance of other board members. With allegations involving less serious issues, the reviewer may gather the facts without the involvement of the additional members. In more serious cases, the IRB reviewer or subcommittee (collectively referred to as *inquiry members*) work together to gather the information for the IRB.
- d) The *inquiry members* may elect to interview the complainant(s) if applicable, or in cases where the complainant requests anonymity, the individual who received the original allegation may interview the complainant. The interviewer prepares a summary of the interview and gives the complainant the opportunity to comment on the written summary. In some cases, the complainant may have already submitted a written complaint, which the IRB inquiry member then verifies. An inquiry member may request additional information from the complainant.
- e) The inquiry member(s) may request a compliance review (audit) be conducted by the Office of Regulatory Affairs & Compliance or one of the HSC affiliated institutional compliance offices. The compliance office uses established review checklists to evaluate compliance with policies and provides the IRB with a written report;
- f) The IRB inquiry members may interview the subject of the allegation (respondent) or PI from whom the report was received and provide the opportunity to comment on the allegation and provide information. A summary of the interview is prepared, given to the respondent, who may comment on the summary. In some cases, the respondent may have submitted a written rebuttal to the complaint or report of noncompliance, which the reviewer verifies. The inquiry member may request additional information from the respondent.
- g) Depending on the nature of the allegation or report and the information collected during the interviews, the inquiry member(s) may: interview other individuals; examine research data; both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; the applicable approved IRB protocol; and any other pertinent information.

- h) The inquiry process is complete when the inquiry member(s) conclude that there is sufficient information related to the event to determine whether noncompliance occurred.
- (1) If the inquiry member(s) determine that the event was not noncompliance (dismissal of the allegation), the actions provided in the deviations section of this policy may be taken (see [II.B.4. above](#))
 - (2) If the inquiry member(s) determine that the event was noncompliance (finding of noncompliance), and the noncompliance is not serious or continuing, the actions provided in the deviations section of this policy may be taken (see [II.B.4. above](#)).
 - (3) If the member(s) determine that the event was noncompliance (finding of noncompliance) and the event is possibly serious or continuing noncompliance, the issue is forwarded to the convened IRB for review (see [III.D below](#)).

- i) When appropriate, the inquiry member(s) prepare, with the assistance of an assigned OIRB staff member, a summary report. The report may consist of a summary of the allegations or report of noncompliance, interview summaries, and copies of pertinent information (correspondence such as emails). The report may or may not include recommendations for IRB action. (Note that in some cases, the IRB member simply provides the IRB with a summary of the allegations, the interview summaries, and copies of pertinent information without an accompanying written report from a review team.)
- D. Convened IRB Review Procedures for Noncompliance that is possibly Serious or Continuing
1. The Regulatory Specialist advises the convened IRB regarding the applicable institutional policy and federal regulations, assists the IRB in documenting the review, answers questions about the review process, maintains the records as required by state and federal laws, and serves as a liaison with the funding agency or agencies.
 2. The IRB reviews the material presented by the inquiry member(s) at the next convened meeting at which a quorum is present. The convened IRB is provided with the summary report from the inquiry reviewers, the report of noncompliance (if applicable) and any other documents deemed important. The convened IRB determines whether to request additional information or whether to interview additional persons of interest. The IRB may give the respondent the opportunity to meet with the convened IRB before it takes final action.
- E. Review Outcomes/IRB Actions
1. The convened IRB makes the final determination whether the noncompliance is serious or continuing based on the materials compiled during the inquiry. This determination occurs within 45 days of the IRB receiving the report of possible noncompliance.
 2. If the noncompliance is serious or continuing, the IRB, with the assistance of the OIRB, reports the incident(s) to the applicable agency following procedures outlined in [Reporting Policy and Procedure](#).
 3. The convened IRB approves a management plan that may include a variety of actions, depending on the outcome of the review, including, but not limited to, the list of actions outlined in the [Complaints Policy and Procedure](#).
 4. The IRB may require OCR to follow-up to ensure institutional requirements are met.
 5. The IRB considers the following in a determination of serious and/or continuing noncompliance:

- a) Suspend (temporary cessation of IRB approval of some or all research activities) (See [Suspension or Termination Policy and Procedure](#))
 - b) Terminate IRB approval/disapprove continuation of the study (permanent withdrawal of IRB approval) (See [Suspension or Termination Policy and Procedure](#));
 - c) Notification of current participants when such information might relate to participant's willingness to continue to take part in the research
6. The OIRB communicates (by email, or letter, contact may be made by phone but will be followed up with an email or letter) the IRB decision to the person raising the allegation (if the identity of the person is known) and in writing to the respondent or person making the report of noncompliance.
 7. The OIRB informs appropriate individuals or entities of the allegation, the review process, and the findings of the review, if appropriate, depending upon the outcome of the review (this may include the external sponsor, or applicable regulatory agencies). See [Reporting Policy and Procedure](#) for details.
 8. The IRB resolves questions or concerns raised by a PI regarding the outcome of a specific IRB noncompliance review through direct communication with the PI.
 9. If the IRB requires additional remedial actions to be taken by the PI (for a specific study or research team), the PI submits a response to IRB concerns within thirty days of the date the IRB issues the final decision. The IRB must close the issue within 120 days of the IRB decision.
 10. Remedial actions involving programmatic non-compliance must be completed within 180 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.
 11. Appeals
 - a) If the PI or complainant disagrees with the IRB's decision, the individual(s) submits response to IRB concerns in writing within thirty days of the date the IRB issues the final decision. The IRB limits concerns to a review of the procedures employed to reach the decision (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances of sanctions imposed. The PI specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued.
 - b) The IRBD or IRBAD review the response and determine whether the concern is valid and attempt to resolve the issue with the individual. If unable to resolve the concern, the issue will be processed as a new complaint.

IV. References

- A. Definitions (see [Glossary](#))

B. Regulatory (see [Policy on Policies Policy and Procedure](#))