# HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

## 9.3 NONCOMPLIANCE REVIEW

**RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD)** **EFFECTIVE DATE: June 7, 2021**

### I. POLICY STATEMENT

A. This policy outlines responsibilities for managing issues of noncompliance with human subjects regulations, IRB requirements, institutional policies, or IRB determinations.

B. Noncompliance with the regulations, institutional human research policies, or with the requirements or determinations of the Institutional Review Board (IRB) must be reported to the UTSW IRB (or HRPP for reliance studies) (See 9.5 REPORTABLE EVENTS GUIDANCE for UT Southwestern reporting requirements).

C. Issues or events that are reported are considered apparent noncompliance until a final determination is made by the convened IRB, Institutional Official (IO), or designated HRPP reviewer.

D. Noncompliance that is determined to be serious or continuing must be promptly reported by the IRB or IO to the appropriate institutional officials, Federal Funding Agencies (if applicable), and the U.S. Food and Drug Administration (FDA) (if applicable).

E. Results of any internal or external audits that identify issues that appear to constitute serious or continuing noncompliance must be promptly reported to the reviewing IRB (and UTSW HRPP for reliance studies) according to 9.5 REPORTABLE EVENTS GUIDANCE.

F. Minor noncompliance events (e.g., deviations) that does not meet the UTSW definition of noncompliance, serious noncompliance, or continuing noncompliance do not require prompt reporting to the IRB (or UTSW HRPP for reliance studies). Instead, these events should be reported at annual update/continuing review or notice of study closure, whichever comes first. Although, when patterns emerge, these patterns may appear to constitute continuing noncompliance, which may or may not also be serious noncompliance, and therefore may require prompt reporting.

G. If the noncompliance also involves an unanticipated problem involving risks to subjects or others (UPIRSO), investigators and research staff are responsible for taking appropriate action to protect the rights, safety, and welfare of subjects or others. The IRB will review such events according to 9.2 UPIRSO and UADE.

### II. SCOPE - This policy and procedures applies to the following:

A. **Investigators and research staff** who are responsible for promptly reporting noncompliance to the IRB (and UTSW HRPP for reliance studies).

B. **The HRPPO staff, IRB Chair, or designated HRPP reviewer** who are responsible for initially reviewing allegations of noncompliance and taking appropriate action (including no action).

C. **The Office of Compliance** (at UTSW or its affiliates) who are responsible for reporting to the HRPP: 1) results of 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.

D. **Members of the UTSW Institutional Review Boards or Institutional Official (IO)** who are responsible for reviewing possibly serious and continuing noncompliance and making determinations regarding corrective action plans.

E. **The HRPPO** staff who are responsible for routing and documenting the process to include communications, determinations, reporting, and actions taken.

## III. PROCEDURES FOR POLICY IMPLEMENTATION

A. For the purpose of this policy, all sources of apparent noncompliance will be referred to as allegations until a determination is made by the IRB, IO, or designated HRPP reviewer.

B. Identifying Noncompliance. Noncompliance may be identified in a number of ways, including, for example:

a) A report by an individual can be made directly to the HRPPO.

b) Through IRB continuing reviews (including annual updates) of ongoing research.

c) Compliance reviews (audits) conducted by the Office of Compliance or one of the UTSW-affiliated institutional compliance offices.

d) A report by an individual can be made directly to the Office of Compliance (e.g., the Compliance Hotline) or one of the UTSW-affiliated institutional compliance offices.

e) 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

f) A report by another committee, department, institution, or official.

g) A report from the study sponsor or sponsor's monitoring entity.

h) Collective evaluations of all noncompliance (i.e., deviations, violations, departures) could contain instances of apparent serious or continuing noncompliance, which require prompt reporting to the IRB.

C. Prompt Reporting and Screening of Allegations of Noncompliance

1. Allegations of noncompliance by UTSW employees or affiliated personnel may be initially provided as verbal reports, but must later be submitted in writing.

2. Allegations of noncompliance by non-affiliated individuals are accepted as verbal reports; however, persons recording a complaint are encouraged to provide their concerns in writing.

3. Investigators are required to promptly submit events that appear to constitute noncompliance using the applicable eIRB Reportable Event Form.

4. Complaints that are not noncompliance are reviewed in accordance with 9.1 COMPLAINTS.

5. The PI must report noncompliance to the reviewing IRB (and UTSW HRPP for reliance studies) according to the timeframe in the 9.5 REPORTABLE EVENTS GUIDANCE.
6. The Assistant Vice President for Human Research Administration (AVPHRA), IRB Director (IRBD), or designee will determine whether allegations of noncompliance are pertinent to other research review offices (e.g., affiliated institutions) or ancillary and safety committees. If it is determined that the allegations of noncompliance are pertinent to other research review entities, appropriate coordination will occur according to the 1.5. COMMUNICATION WITH OTHER COMMITTEES AND OFFICES.

D. Evaluating Allegations of Noncompliance

1. The AVPHRA, IRBD, or designee are designated HRPP reviewers. Given their positions in HRPP, they are readily available to promptly screen and review allegations of noncompliance. The reviewers are expected to communicate with an IRB Chair or IO as appropriate.
2. The HRPP designated reviewer evaluates all allegations to determine whether they are substantiated (i.e., there are supporting documents or statements).
3. If the issue possibly involves research misconduct defined as fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting results of research, or other material deviations from accepted scientific practices such as obstruction of another's research, deliberate violations of confidentiality, and willful deception or omission, the HRPP designated reviewer will notify the IO and Research Integrity Officer (RIO). The issue will be reviewed according to the institutional policy RES-101 MISCONDUCT OR FRAUD IN RESEARCH
4. If the HRPP designated reviewer evaluates an allegation as unsubstantiated (i.e., finds no supporting documents or statements):
    a) the reviewer may dismiss the allegation as not noncompliance, and may
        (1) decide to take no action, or
        (2) continue the review as a complaint or UPIRSO (following other HRPP policies as applicable).
    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 investigator against whom the allegation was raised (respondent) or from whom the report was received.
5. If the HRPP designated reviewer determines that an allegation is noncompliance that is not serious or continuing, the reviewer may:
    a) withdraw the item and require submission at annual update/continuing review
    b) process the concern as a complaint or UPIRSO (following other HRPP policies as applicable)
    c) manage the concern through communications with the investigator (management decisions and recommendations are based on the investigator's stated plan to correct issues and prevent future occurrence), and/or

d) acknowledge the event as noncompliance that is neither serious nor continuing

6. If the HRPP designated reviewer determines that an allegation appears to constitute serious or continuing noncompliance, the reviewer may:

    a. pursue further inquiry (data gathering, interviews, etc.),

    b. acknowledge the event as noncompliance that is neither serious nor continuing after further inquiry is completed, or

    c. forward the issue to the reportable event subcommittee, IRB, and/or the IO for further consideration.

E. Subcommittee Review of an Allegation of Serious or Continuing Noncompliance

1. If an allegation or report of noncompliance appears to constitute serious or continuing noncompliance, the IRB designated reviewer may forward the allegation to an IRB subcommittee (Reportable Event (RE) Subcommittee) for further review. The RE subcommittee will consist of members of the UTSW IRBs and will be selected by the IRB Director and/or the IRB Chair(s) with consultation from the AVPHRA.

2. When the subcommittee of the IRB conducts the review, the process includes the following:

    a) If the allegation suggests subjects are at immediate risk, the IRB subcommittee may contact the IRB Chair who has the authority to immediately suspend IRB approval or take other actions as appropriate to protect the rights, safety, and welfare of subjects or integrity of the research. If research is suspended (either partially or completely), the applicable IRB policy on 9.4 SUSPENSION OR TERMINATION OF RESEARCH will be followed.

    b) If the issue possibly involves research misconduct, the inquiry may await the resolution of the assessment phase of the Research Integrity Officer or IO 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 AVPHRA, IRBD, IRB Chair may invite one or more members of the subcommittee 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 HRPP designated reviewer, may conduct the inquiry alone or with the assistance of other subcommittee members. In more serious cases, the IRB Chair, designated reviewer(s), or subcommittee (collectively referred to as *inquiry members*) may work together to gather the information.

    d) If appropriate, the RE Subcommittee may elect to interview the complainant(s), the subject of the allegation (respondent), the PI, or other individuals and may provide them with the opportunity to comment on the allegation and provide additional information.

        (1) In cases where the complainant requests anonymity, the individual who received the original allegation may interview the complainant.

(2) The interviewer prepares a summary of the interview and gives the complainant the opportunity to comment on the written summary.

e) The subcommittee member(s) may request a compliance review to be conducted by one or more of the following:

(1) The Office of Compliance,

(2) HRPP Quality Assurance and Monitoring Office,

(3) One of the UTSW-affiliated institutional compliance offices.

f) Depending on the nature of the allegation and the information collected during the review, the members may examine research data (both published and unpublished), informed consent/assent forms, medical records, inclusion/exclusion criteria, applicable approved IRB protocol(s), and any other pertinent information.

3. The subcommittee review process is complete when the members conclude that there is sufficient information related to the event to determine whether apparent serious or continuing noncompliance occurred and whether corrective actions taken and planned appear acceptable.

a) Noncompliance determination:

i. If members determine that the event was not noncompliance (i.e., dismissal of the allegation), the issue will be closed according to actions provided in the evaluation section (above) of this policy.

ii. If members determine that the event was noncompliance (finding of noncompliance) that is not serious or continuing, the issue will be closed according to actions provided in the evaluation section (above) of this policy.

iii. If members determine that the event was noncompliance (finding of noncompliance) that appears to be serious or continuing, the issue is forwarded to the convened IRB (or IO for reliance studies) for final consideration and determination.

b) Corrective and Preventative Action plan:

i. If the members agree with the actions taken and those planned to prevent recurrence, the PIs plan will be proposed to the IRB or IO (if potentially serious/continuing noncompliance) or accepted (if not serious/continuing noncompliance) as is.

ii. If the members believe additional actions should have been taken/should be taken in the future, a recommendation may be provided to the IRB/IO (if potentially serious/continuing noncompliance). The convened IRB/IO will be asked to consider appropriate actions addressing this event. For events not serious/continuing, the subcommittee will provide the PI with required actions from the subcommittee.

4. The summary of the allegations of noncompliance, interview summaries, and copies of pertinent information (e.g., correspondence such as emails) will be provided to the IRB/IO for review. The summary may or may not include recommendations for IRB/IO action.

F. IRB/IO Review Procedures

1. Following the initial review by the HRPP designated reviewer and/or RE Subcommittee, the IRB reviews the allegation at a convened meeting at which a quorum is present. If the study is relying on an external IRB, the allegation will be reviewed by the IO.
2. The IRB/IO is provided with the report of noncompliance (if applicable), summary of the event, corrective and preventative action (CAPA) plan, recommendation from the subcommittee (if applicable), and any other documents deemed relevant. The IRB/IO determines whether to request additional information or whether to interview additional persons of interest. The IRB/IO may give the respondent the opportunity to meet with the convened IRB before it takes final action.
3. The HRPP Designated Reviewer or delegate advises the IRB/IO regarding the applicable institutional policies and federal regulations, assists the IRB/IO 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.

G. IRB/IO Review Outcomes and Actions

1. The IRB/IO makes the final determination whether the noncompliance is serious or continuing based on the materials compiled during the inquiry. The IRB/IO **must** consider the following actions in a determination of serious and/or continuing noncompliance:
    a) Suspend (temporary cessation of IRB approval of some or all research activities) (see 9.4 SUSPENSION OR TERMINATION OF RESEARCH);
    b) Terminate IRB approval/disapprove continuation of the study (permanent withdrawal of IRB approval) (see 9.4 SUSPENSION OR TERMINATION OF RESEARCH);
    c) Require notification of current participants when such information might relate to participant's willingness to continue to take part in the research
2. The IRB/IO approves or requires changes to a CAPA 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 9.1 COMPLAINTS.
    a) In the review of the CAPA plan, the IRB/IO may approve (or require additional changes to) the following:
        i. Modification of the protocol
        ii. Modification of the information disclosed during the consent process
        iii. Providing additional information to past participants
        iv. Requiring current participants to re-consent to participation
        v. Modification of the annual update/continuing review schedule

vi. Monitoring of the research

vii. Referral to other organizational entities

b) In cases of serious and continuing noncompliance, the IRB/IO may recommend additional sanctions. Possible sanction recommendations include:

i. Reclassification as possible scientific misconduct

ii. Research privilege probation

iii. Suspension of research privileges

iv. Termination of research privileges

v. Embargo of publications

3. The HRPPO communicates by email or letter (contact may initially be made by phone, but will be followed up with an email or letter) the IRB/IO 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.
4. The HRPPO 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 8.2 REPORTING POLICY AND PROCEDURE for details.
5. The IRB/IO resolves questions or concerns raised by an investigator regarding the outcome of a specific IRB/IO noncompliance review through direct communication with the investigator.
6. If the IRB/IO requires additional remedial actions to be taken by the investigator (for a specific study or research team), the investigator should submit a response to IRB/IO concerns within 30 days of the date the IRB/IO issues the final decision. The HRPP should close the issue within 120 days of the IRB decision.
7. Remedial actions involving programmatic noncompliance should be completed within 180 days after the IRB's/IO's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

H. Disagreement with IRB/IO decisions

1. If an investigator or complainant disagrees with the IRB/IO's decision, a request for additional consideration must submitted to the HRPP in writing within 30 days of the date the IRB/IO issues the final decision. The HRPP limits these requests 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 request should specify the nature of any claimed procedural error or the perceived unfairness of sanctions imposed.

2. The AVPHRA, IRBD, or IRB chair reviews the response and determines whether the request is valid and attempts to resolve the issue with the individual. If unable to resolve the concern, the issue will be processed as a new complaint.

## IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

## V. REFERENCES

| Resource |
|---|
| 21 CFR 50 – PROTECTION OF HUMAN SUBJECTS |
| 45 CFR 46 – PROTECTION OF HUMAN SUBJECTS |
| 45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE) |
| 21 CFR 56 – INSTITUTIONAL REVIEW BOARDS |

## IV. REVISION AND REVIEW HISTORY

| Revision Date | Author | Description |
|---|---|---|
| June 2021 | HPPP | Separated policies. Clarified that all noncompliance should be reported to IRB/HRPP promptly. Additional grammatical/procedural edits. |
| November 2019 | HRPP | Updated references to serious/continuing noncompliance, included IO in determination process |
| August 2017 | HRPP | New Policy Development |
| March 2012 | IRB Office | IRB Written Procedures |