

HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

9.1 COMPLAINTS

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD)

EFFECTIVE DATE: June 7, 2021

I. POLICY STATEMENT

- A. The purpose of this policy and procedure is to document the responsibilities of the Human Research Protection Program Department (HRPPD), the Institutional Official, the convened IRBs, principal investigators and UT Southwestern employees for handling complaints regarding research.
- B. Complaints that are reported are considered sensitive issues and the relative information and identities of individuals named in a complaint will be handled appropriately until a final determination is made by the appropriate reviewer.
- C. Complaints that may indicate that a research subject's rights, safety or welfare may have been or were at risk of being adversely affected shall be promptly reported to the HRPP Office and are forwarded to the convened IRB if substantiated.
- D. Complaints that are substantiated may be further investigated through a directed compliance review, and actions will be taken as deemed appropriate by the IRB.
- E. A complaint that is determined to also involve serious and/or continuing noncompliance, or an unanticipated problem involving risk to subjects or others (UPIRSO) must be promptly reported to the appropriate institutional officials, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (if applicable) following applicable policy.

II. SCOPE

- A. This policy and procedure applies to all complaints regarding human subjects' research conducted under the jurisdiction of UT Southwestern HRPP.
- B. Summary of responsibilities include:
 - 1. Investigators are responsible for addressing all complaints they receive. Investigators should attempt to find a suitable resolution and respond to the complainant in a timely manner.
 - 2. The HRPPD staff is responsible for documenting any complaints that are received and promptly forwarding the information to the Assistant Vice President for Human Research Administration (AVPHRA), IRB Director (IRBD), IRB Chair or designee.
 - 3. The Office of Compliance is responsible for reporting complaints identified during compliance reviews or human research concerns from the hotline.

4. Other institutional committees and offices that oversee research activities are responsible for reporting complaints (further details are provided in the 1.5. COMMUNICATION WITH OTHER COMMITTEES AND OFFICES).
5. AVPHRA, IRBD, Chair or designee is responsible for reviewing any complaint, collecting necessary information and resolving the issue, if possible, or forwarding the complaint for review by the convened IRB.
6. The IRB reviews complaints and determines whether the complaint is justified and recommends appropriate action.

III. PROCEDURES FOR POLICY IMPLEMENTATION

- A. This procedure starts upon initial notification of a complaint. Complaints may be identified in a number of ways including the following:
 1. A complaint by an individual can be made directly to the HRPP Office,
 2. The IRB may learn of a complaint through its continuing review of ongoing research
 3. During compliance reviews (audits) conducted by the Office of Compliance or one of the Affiliate Institutional compliance offices (e.g., Children's, Parkland, etc.)
 4. A complaint by an individual can be made directly to the Office of Compliance (Hotline)
 5. A complaint by or to another committee, department or official
 6. A complaint from the study sponsor's monitoring entity
- B. This procedure ends when a final determination is made by the IRB or appropriate reviewer and final determination has been communicated to the Principal Investigator.
 - A. Receipt and Screening of Complaints
 - a. The Principal Investigator (PI) is responsible for reviewing all complaints from research participants or others associated with the participant (i.e., family, care givers). The PI will attempt to resolve the complaint and will respond to the complainant in a timely manner
 2. All complaints are summarized in the next progress report submitted as part of continuation review or in the final report submitted to inactivate the study
 - a. Complaints that may indicate that a research subject's rights, safety or welfare may have been or were at risk of being adversely affected shall be promptly reported to the IRB (see 9.2 UPIRSO and UADE and 9.3 NONCOMPLIANCE REVIEW).
 3. Complaints from research participants or family members of research participants, members of the research team, or individuals not otherwise affiliated with the institution are accepted as verbal reports; however, persons recording a complaint are encouraged to provide their concerns in writing.
 4. The AVPHRA and IRBD are designated as the administrative reviewers for this process. Given their positions in the HRPP Office, these individuals are readily available to

promptly review complaints. The reviewers are expected to communicate with the appropriate IRB Chair. The reviewers screen the complaint to determine whether the protocol has issues pertinent to other research review offices or committees, i.e., Institutional Research Offices at affiliate hospitals, the Protocol Review Monitoring Committee (PRMC), Institutional Biosafety Committee (IBC), Radiation Safety Office (RSO), Sponsored Programs Administration (SPA), Conflict of Interest Committee (COIC) and other affiliated groups. If it is determined that the complaint is pertinent to other research review entities, appropriate coordination will be planned (see 1.5. COMMUNICATION WITH OTHER COMMITTEES AND OFFICES).

- B. Review of a Complaint. The AVPHRA or IRBD reviews all complaints to determine whether they can be resolved or whether further inquiry is necessary
1. If the reviewer is able to resolve the complaint, the reviewer may:
 - a) decide to take no action, or
 - b) communicate the complaint to the principal investigator to develop an appropriate response or corrective action
 2. If the reviewer determines further inquiry is necessary, the reviewer may:
 - a) require the PI to submit documentation following the applicable policy (if the complaint involves possible noncompliance or unanticipated problems)
 - b) Otherwise, the reviewer will continue to collect information related to the complaint to determine whether the issue should be forwarded to the convened IRB. The reviewer:
 - (1) will initiate data gathering, interview, and summary report with opportunity to comment, as applicable;
 - (2) may request a compliance review (audit) be conducted by the Office of Compliance or one an affiliated Institutional compliance office(s);
 - (3) communicate with the IRB Chair and request assistance from the Board members as needed;
 - (4) will communicate (by email, or letter, contact may be made by phone but will be followed up with an email or letter) the decision to take further action in writing to the complainant (if the identity of the person is known) and to the PI of the research against whom the complaint was made or from whom the report was received. If the complaint involves a co-investigator or a research assistant, these individuals may also be notified in writing.

3. If the complaint involves allegations of research misconduct defined as fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results, the Designated Reviewer notifies the Institutional Official.
4. If the complaint suggests that a research subject's rights, safety or welfare may have been or were at risk of being adversely affected
 - a) The reviewer 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.
 - b) The IRB reviews the material presented by the reviewer at a convened meeting at which a quorum is present. 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.

C. Review Outcomes and IRB Actions

1. The convened IRB makes the final determination whether the research subject's rights, safety or welfare may have been or were at risk of being adversely affected, and if so, the IRB, with the assistance of the HRPPD, reports the incident(s) to the applicable agency following procedures outlined in 8.2 REPORTING POLICY AND PROCEDURE.
2. The convened IRB may take a variety of actions, depending on the outcome of the review, including, but not limited to, the following:
 - a) No action
 - b) Approve continuation of research without changes with a cautionary reminder to the PI. If the event is a UPIRSO/UADE, this will include clarification to the PI explaining why no changes are necessary;
 - c) Require formal educational intervention;
 - d) Require minor or major changes in the research procedures and /or consent documents;
 - e) Modify the current approval period;
 - f) Require monitoring of research;
 - g) Require monitoring of the consent process;

- h) Require audits of other active protocols of the individual(s) involved;
 - i) Recommend disqualification of the individual(s) from conducting research involving human subjects at the institution;
 - j) Determine that the data collected cannot be used for publication;
 - k) Require that subjects previously enrolled in the study be contacted and provided with additional information and/or re-consented;
 - l) Request that publishers and editors be informed if manuscripts emanating from the research have been submitted or published;
 - m) Recommend to the appropriate officials of the institutions engaged in the research that further administrative or disciplinary action be taken.
3. The IRB considers Suspension, Termination, notification of participants and/or modification to the study procedures/protocol if the complaint results in a determination of serious and/or continuing noncompliance (See 9.3 NONCOMPLIANCE REVIEW and 9.4 SUSPENSION OR TERMINATION OF RESEARCH).
4. The HRPPD will communicate (see 8.2 REPORTING POLICY AND PROCEDURE) the IRB decision in writing to the PI of the research against whom the complaint was made or from whom the report was received. If the complaint involves a co-investigator or a research assistant, these individuals may also be notified in writing.
5. The HRPPD communicates as with other institutions and offices following the guidance provided in the 1.5. COMMUNICATION WITH OTHER COMMITTEES AND OFFICES.
6. The AVPHRA or IRBD may communicate (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(s) who submitted the complaint, if appropriate and if the identity of the person is known.
7. The IRB resolves questions or concerns raised by the individuals involved regarding the outcome of a specific IRB complaint review through direct communication with the individual.
8. Challenging IRB Decision
- 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 AVPHRA or IRBD 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.
- c) If the IRB votes to uphold its original decision once an appeal has been processed through the complaints process the decision may not be appealed again. Nor may it be reversed by any administrator, other officer or agent of UT Southwestern Medical Center, state government or federal government.

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

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
July 2018	HRPP	Revision to RSO (dissolved SHUR)
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures