**Human Research Protection Program Departmental Policy and Procedure**

# 8.2 Reporting Policy and Procedure

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: June 12, 2026

## I. Policy Statement

a. This policy and procedures outlines specific actions and responsibilities of the Principal Investigator, HRPPD and convened IRB's for ensuring prompt reporting of required activities, circumstances and results involving the conduct and monitoring of research involving human subjects.

## II. Scope

a. This policy and procedure applies to the convened IRB or the HRPPD making a determination that requires reporting in accordance with this policy

b. Summary of responsibilities

i. HRPPD staff are responsible for collecting or recording determinations of the IRB in accordance with UT Southwestern (UTSW) policy, creating appropriate reporting documents, obtaining appropriate signatures and sending reports/making reports available to applicable individuals, institutions, departments or agencies.

ii. Appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.).

1. If the research is also regulated by other involved institutions, HRPPD staff also send specific reports to the appropriate institutional officials at involved institutions. Each of the Institutional Officials is responsible for sending those reports throughout their institution, as they consider appropriate (e.g., if an unauthorized use, loss, or disclosure of individually identifiable patient information resulted, the institution's

Privacy Officer would be notified).

## III. Procedures For Policy Implementation

a. Problem Reports

i. The IRB reports unanticipated problems involving risks to participants or others (UPIRSOs), unanticipated adverse device effects (UADEs) (and if appropriate, depending upon the outcome of the review, external sponsor reviews for UADE's), serious or continuing noncompliance, and suspensions or terminations, of research to internal entities (such as Principal Investigators and other appropriate UTSW officials) and external entities (such as department or agency heads, OHRP, and the FDA) as required by federal regulations. For FDA–regulated research, any reported events that the IRB determines to be internal unanticipated problems involving risks to subjects or others will be reported to the FDA by the HRPPD will be reported to the FDA by the HRPPD.

ii. IRB determinations of serious or continuing non-compliance in accordance with the non- compliance policy will be reported to the following entities. Please note that additional notifications of serious or continuing noncompliance will occur according to specific local institutional requirements (e.g., UTSW, Parkland, Children's) as soon as possible:

1. Principal Investigator;
2. Person(s) involved in the noncompliance;
3. Department Chair (or equivalent);
4. Dean or unit Director, if appropriate;
5. Institutional Official;
6. Compliance Office, Sponsored Program Administration (SPA), and other institutional entities as appropriate;

7. OHRP (incident report) (if federally funded);
8. FDA, if applicable;
9. DoD funding agency, if applicable, when research is funded by the Department of Defense
10. Sponsor coordinated through Sponsored Program Administration (SPA), if appropriate;
11. Other appropriate institutional officials at involved institutions (e.g., Children's, Parkland, etc.) for which the UTSW IRB is serving as the IRB of record.
12. The person raising the allegation (if the identity of the person is known and the feedback is deemed appropriate) (This notification is communicated by the HRPP Director/HRPP Associate Director).

iii. Policies and procedures describe the reporting to AAHRPP as soon as possible but generally within 48 hours after the organization or any researcher becomes aware of:

1. Any negative actions by a government oversight office, including, but not limited to,
   a. OHRP Determination Letters,
   b. FDA Warning Letters,
   c. FDA 483 Inspection Reports with official action indicated,
   d. FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
2. Any litigation, arbitration, or settlements initiated related to human research protections.
3. Any press coverage (including but not limited to radio, TV, newspaper,

online publications) of a negative nature regarding the Organization's HRPP.

iv. The determinations of UPIRSO, UADE (and if appropriate, depending upon the outcome of the review, external sponsor reviews for UADE) in accordance with the unanticipated problems policy will be reported to the following entities following the IRB's determination. Please note that additional notifications of UPIRSO, UADE (depending upon the outcome of the review, external sponsor reviews for UADE) will occur according to specific local institutional requirements (e.g., UTSW, Parkland, Children's):

1. Principal Investigator;
2. The Department Chair;
3. Dean or unit Director, if appropriate;
4. Institutional Official;
5. Compliance Office, Sponsored Program Administration (SPA), and other institutional entities as appropriate;
6. OHRP (incident report); federally funded studies in which a UPIRSO occurred that was based on an internal UPIRSO and/or based on an external UPIRSO only if the local PI identified the problem, the HRPPD promptly submits an incident report to Applicable Federal Department or Agency head if funded by a department or agency including OHRP.
7. FDA, if applicable; when research is FDA regulated and the UPIRSO is an internal UPIRSO and/or based on an external UPIRSO only if the local PI identified the problem: The IRB requires that the PI reports the UPIRSO to the sponsor (as applicable), who must report to the FDA. If the PI is also the sponsor, then the IRB requires that the sponsor-investigator report to the FDA. Regardless of whether such reporting

has occurred as indicated by the PI for Initial determination or resolution of UPIRSOs the HRPPD will report to the FDA.

8. DoD funding agency, if applicable, when research is funded by the Department of Defense
9. Sponsor coordinated through Sponsored Program Administration (SPA), if appropriate;
10. Other appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.)

v. The IRB's decision to suspend or terminate research in accordance with the Suspensions and Terminations Policy and/or notification to the IRB of the IO's decision to suspend or terminate research will be reported to the following entities after the IRB's determination. Please note that additional notifications of the IRB's decision to suspend or terminate research will occur according to specific local institutional requirements (e.g., UTSW, Parkland, Children's):

1. Principal Investigator;
2. Department Chair (or equivalent);
3. Dean or unit Director, if appropriate;
4. Institutional Official;
5. Compliance Office, Sponsored Program Administration (SPA), and other institutional entities as appropriate;
6. OHRP (incident report) (if federally funded);
7. DoD funding agency, if applicable, when research is funded by the Department of Defense
8. FDA, if applicable;

9. Sponsor coordinated through Sponsored Program Administration (SPA), if appropriate;
10. Other appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.). If the IRB decides to suspend or terminate a research activity, it will include in its written notification a statement of the reasons for the IRB's action.

vi. Appeals to reports

1. The PI may appeal the IRB's decision regarding determinations of unanticipated problems involving risks to participants or others, serious or continuing non- compliance, and suspensions or terminations of research. The PI specifies the nature of any claimed procedural error or the perceived unfairness of action taken by the IRB.
2. The appeal will go before the convened IRB for review and consideration.
3. The IRB determination following a review of an appeal is considered final.

vii. Responses or reports from federal departments

1. HRPPD presents responses or other reports from federal departments or agency heads (generally OHRP or FDA) to:
   a. UT Southwestern Institutional Official (IO)
   b. the IRB,
   c. appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.)
   d. the PI, and

e. AAHRPP

i. UTSW will report to AAHRPP within 24 hours of becoming aware of any sanctions taken by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, and FDA Restrictions placed on an IRB or investigator or any lawsuits related to human research protection.

ii. UTSW will consult the AAHRPP office for further advice if in doubt about whether a particular item is immediately reportable.

b. Other Reports

i. The HRPP reports to internal entities (such as Principal Investigators and other appropriate UTSW officials) and as appropriate external entities (such as department or agency heads, OHRP and the FDA) as required by federal regulations:

1. inclusion of certain vulnerable populations,
2. IRB Membership and Certification changes,
3. Emergency Medical Research requesting Exception to Informed Consent, and
4. determinations made by the IRB following initial and continuing review and as appropriate during review of modifications to previously approved research.

ii. Determinations made by the IRB/HRPPD following review (initial and continuing review, review of modifications to previously approved research, and responses to contingencies for research which was conditionally approved) by the convened IRB, expedited review, or administrative HRPPD review will be reported by the HRPPD to the PI and the appropriate officials at affiliated institutions of the following:

1. For each research item reviewed by the convened IRB, the HRPPD will report the following determinations to the appropriate institutions for which the UTSW IRB is serving as the IRB of record:
    a. Approve the research activities as written,
    b. Require minor modifications to secure IRB approval (conditional approval),
    c. Defer review to another convened meeting pending resolution of major issues/modifications (tabled item), or
    d. Inactivate.
    e. Disapproval: In the case that research is disapproved (for convened meetings only) by the IRB during initial or continuing review, a written notification containing a statement of the reasons for the decision, and a list of the required modifications or clarifications for re-consideration of the item for approval by a subsequent convened IRB is forwarded to the Principal Investigator and the appropriate officials at affiliated institutions. If the disapproval leads to a suspension of research activities or lapse in IRB approval, the IRB follows the appropriate guidance in either Suspension or Termination of Research Policy and Procedure or Continuation Review Policy and Procedure.
2. For each research item reviewed under an expedited review procedure the HRPPD will report the determinations to the following:
    a. The PI
    b. Affiliated institutions relying on the UTSW IRB
    c. The convened IRB. The Expedited Actions report constitutes documentation of approval and is available to members of all convened IRBs prior to and during each IRB meeting.

3. For each item reviewed under HRPPD Administrative review (not requiring IRB review), the HRPPD will report the results of the action to:

    a. The PI

    b. Appropriate institutions engaged in the research for which the UTSW IRB is serving as the IRB of record

iii. Reporting research involving Pregnant Women, Fetuses, and Neonates where the IRB finds that the research is not otherwise approvable for pregnant women, nonviable neonates, or neonates of uncertain viability under 45 CFR 46 Subpart B and the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates - the HRPPD reports to:

    1. PI

    2. OHRP

iv. Reporting research involving Prisoners where the PI has submitted the protocol to the State, County or DHHS or where the research is DHHS funded and includes prisoners - the HRPPD reports to:

    1. PI

    2. OHRP

v. Reporting research involving Children, if the IRB finds that the research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children under the applicable FDA, DHHS, or U.S. Department of Education subpart - the HRPPD reports to:

    1. The PI

2. With a copy to the applicable federal agency (e.g., Secretary of DHHS through OHRP, Secretary of U.S. Department of Education, or Commissioner of FDA).

vi. Reporting changes in IRB membership - the HRPPD reports to: OHRP.

vii. Reporting Certification of IRB Approval - the HRPPD reports upon request to: The funding agency either directly or through the PI.

viii. Reporting Emergency Medical Research requesting Exception to Informed Consent when the IRB does not approve an exception from the general informed consent requirements for emergency research under FDA and DHHS requirements - the HRPPD reports to:

1. The PI

2. The sponsor

c. Serious or Continuing Noncompliance – Reporting Procedure

i. HRPPD Staff reports determinations of Serious or Continuing Noncompliance via informal means and formal official notices

1. Informal notification is made via telephone or encrypted email, as necessary to satisfy specific institutional requirements.

2. The HRPPD prepares official notifications of serious or continuing noncompliance within the timeframe required from the date an event is determined to be serious and/or continuing noncompliance by the IRB, if the event is a more serious incident, this may mean reporting to OHRP within days. In all cases, incident reporting will occur within the timeframe required above of determining the event is a serious and/or continuing noncompliance.

a. The IRB Chair or designee , reviews the determination letter (report), which the HRPPD sends to the PI with a copy to the appropriate federal agency, department chair, and appropriate

institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.)

b. If the DHHS conducts or funds the research, the HRPPD sends the report to OHRP in accordance with current OHRP guidance on incident reporting http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html.

c. If an agency that is subject to the "Common Rule," other than the DHHS, conducts or funds the research, the HRPPD sends the report to the agency as required by the agency and OHRP.

d. For FDA-regulated research, any IRB determinations of serious or continuing non-compliance will be reported to the FDA by the HRPPD as outlined in "when reporting to the FDA" (below).

ii. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the grant/award number of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; and the findings of UTSW or the IRB; actions taken by the PI, UTSW, and/or the IRB to address the issue.

iii. The HRPPD files a copy of the federal report(s) and any final IRB actions in the IRB study file.

iv. All reports made by the HRPPD to federal agencies pertaining to serious or continuing non- compliance will be made available to the convened IRBs.

d. Unanticipated Problems Involving Risks to Subjects (UPIRSO), Unanticipated Adverse Device Effects (UADE) – Reporting Procedure after a UPIRSO/UADE determination is made by designated reviewers or the convened IRB

i. HRPPD Staff reports UPIRSO/UADE determinations and the specified

resolution via informal means (initial notification) and formal official notifications (notices of determination and notices of resolution)

1. Informal notification is made via telephone or encrypted email, as necessary to satisfy specific local institutional requirements. Generally, initial notices are sent locally pending IRB review.
    a. The initial notification will identify:
        i. Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
        ii. Title of the research project and/or grant proposal in which the problem occurred;
        iii. Name of the principal investigator on the protocol;
        iv. The grant/award number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
        v. A description of the problem; and
    b. If substantive issues remain (e.g., additions to the action plan to account for issue(s) identified as conditions of continued approval to conduct research at any of the involved institutions) a follow-up notice requesting further input from the appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record, PI's department chair or PI may be necessary or an appointment may be set to meet with the PI to determine the status of the UPIRSO/UADE.
2. Official notifications are made as determination notices. Determination notices are sent following IRB/designated reviewer review. However, if the event is a more serious incident, this may mean reporting to applicable federal department or agency head including OHRP days

prior to an IRB determination. In all cases, incident reporting of IRB determinations to the applicable federal department or agency heads including OHRP will occur within the timeframe required above.

a. The Determination notice will identify:

   i. Name of the institution(s) (e.g., university, hospital, foundation, school, etc.) conducting the research;

   ii. Title of the research project and/or grant proposal in which the problem occurred;

   iii. Name of the principal investigator on the protocol;

   iv. The grant/award number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);

   v. IND or IDE number (if applicable)

   vi. A detailed description of the problem;

   vii. Actions the IRB, PI, sponsor and institution(s) are taking or plan to take to address the problem (e.g., educate the investigator, educate all research staff, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.); and

   viii. Any additional actions requested of the PI by the IRB to resolve the problem (if applicable).

b. Concerning follow-up reports (if required by the IRB).

   i. If the follow-up report has not been received within

approximately 30 days following the meeting, HRPPD Staff prepare follow-up correspondence to the PI and coordinator requesting any information necessary for resolution

c. The Assistant Vice President for Human Research Administration (AVPHRA), IRB Director, or IRB Chair approves all official notices.

ii. HRPPD Staff reports determinations to all required entities as indicated below:

1. Appropriate officials at UTSW including:

a. Compliance Officer (for all reports involving privacy issues),

b. Institutional Official

i. for UPIRSO based on Internal Adverse Events

ii. UPIRSO based on non-adverse events where:

iii. a local incident, experience or outcome or

iv. where external incident, experience or outcome was identified by local PI

v. UADE reports

c. IRB Chair (as appropriate, e.g., for designated reviewer determinations)

i. for UPIRSO based on External Adverse Events, and

ii. UPIRSO based on non-adverse events where:

iii. A determination of incident, experience or outcome was not made by local PI (e.g., sponsor or DSMC via sponsor identified the external information that was determined to represent a possible UPIRSO).

d. IRB (as appropriate, e.g., for determinations)

i. Each IRB reviews UPIRSO related documents placed on the meeting agenda.

2. Appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.). Appropriate organizational representatives then disseminate as needed within their organization and gather any additional institutional requirements and forward any such requirements to the PI to be incorporated into the action plan if necessary.

3. Applicable Federal Department or Agency head if funded by a department or agency including OHRP

   a. OHRP is only notified for:

      i. UPIRSO based on Internal Adverse Events

      ii. UADE reports may meet this criteria

      iii. And when deemed appropriate by the HRPP Director, HRPP Associate Director or IO any UPIRSO based on non-adverse events where OHRP would not otherwise be notified by another entity:

      iv. a local incident, experience or outcome or

      v. external incident, experience or outcome identified by local PI

   b. If the DHHS conducts or funds the research, the HRPPD sends the report to the Office for Human Research Protections (OHRP) in accordance with current OHRP guidance on incident reporting

   c. If an agency that is subject to the "Common Rule", other than the DHHS, conducts or funds the research, the HRPPD sends the report to the agency as required by the agency and OHRP.

4. For FDA-regulated research, any reported event that the IRB

determines to be a UPIRSO (UPIRSOs based on an internal event and/or based on an external event in which the local PI identified the issue) will be reported to the FDA by the HRPPD as outlined in "when reporting to the FDA" (below).

iii. 3. The HRPPD files a copy of the notices, federal reports and reports of any final IRB actions in the IRB study file.

e. Suspension or Termination of Research – Reporting Procedure

i. HRPPD Staff reports determinations of suspension and termination via informal means and formal official notices

1. Informal notification is made via email or telephone, as necessary to satisfy specific local institutional requirements.

2. The HRPPD prepares official notification, a summary report of suspension and termination, within the timeframe required above. However, if the event is a more serious incident, this may mean reporting to appropriate federal agencies (e.g., OHRP) within days. In all cases, incident reporting will occur within the timeframe required above.

a. The AVPHRA or IRB Director, in consultation with the IRB Chair, approves the report, which the HRPPD sends to the PI with a copy to the appropriate federal agency, department chair, and appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.)

b. If the DHHS conducts or funds the research, the HRPPD sends the report to OHRP in accordance with current OHRP guidance on incident reporting http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html.

c. If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the HRPPD sends the report to the agency as required by the agency and OHRP.

d. For FDA-regulated research, any suspensions or terminations of IRB approval will be reported to the FDA by the HRPPD as outlined in "when reporting to the FDA" (below).

ii. The report includes:

1. the title of the research protocol and/or grant proposal;
2. name of the PI on the protocol;
3. IRB number assigned to the research protocol;
4. the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
5. the nature of the event; and
6. the findings of UTSW. IO, or the IRB;
7. actions taken by the PI, UTSW, IO, and/or the IRB to address the issue.

iii. The HRPPD files a copy of the federal report(s) and any final IO or IRB actions in the IRB study file.

iv. All reports made by the HRPPD to federal agencies pertaining to suspensions or terminations of research will be made available to the convened IRBs.

f. Determinations of the IRB/HRPPD – Reporting Procedure. Following review of the following items by either the HRPPD or IRB: initial review, continuing review, review of modifications to previously approved research, inactivation requests, response to IRB stipulations and administrative changes. HRPPD staff:

i. Draft convened IRB minutes. See IRB Minutes Policy and Procedures.

ii. Draft notification letters or emails for all levels of review – HRPPD, Expedited Review, Convened IRB review. These letters indicate the following actions:

1. Approved,
2. Conditionally Approved,
3. Deferred,
4. Disapproved, or
5. Inactivated

iii. Send the notification to the Principal Investigator and any officials at other institutions engaged in research for which the UTSW IRB is serving as the IRB of record (e.g., Children's Parkland, etc.). It is the PIs responsibility to report to any institutions where research activities are being performed and UTSW is not the reviewing IRB.

1. If conditionally approved, the notification details the reasons for conditional approval and actions necessary to resolve the non-substantive issues and that research may not start until receipt of final approval.
2. If deferred, the notification details the substantive reasons for deferral and actions necessary to resolve the substantive issues as well as detailing other non-substantive issues. Generally investigators are given the opportunity to respond to the IRB at a subsequent convened meeting of the same IRB panel if the PI disagrees with the actions outlined by the IRB.
3. If disapproved, the notification details the substantive reasons for disapproval and details other non-substantive issues. This notification includes a statement that provides the PI an opportunity to respond to

the IRB decision in person or in writing.

4. The letter will include the following:
    a. the title of the research protocol and/or grant proposal;
    b. name of the PI on the protocol;
    c. IRB number assigned to the research protocol;
    d. Expiration date (for initial and continuing review notifications)
    e. The grant/award number of any applicable federal award(s) (grant, contract, or cooperative agreement), if available;
    f. the findings of HRPPD or the IRB including:
        i. Date of approval
        ii. Expedited review categories for new studies that were not reviewed by the convened IRB.
        iii. Exempt review categories for new studies determined exempt from IRB review
        iv. Determination of non-human research or non-regulated research for those studies determined not to meet the definition of human subjects' research.
        v. Approval of the inclusion of any vulnerable populations
        vi. Approval of any waivers or alterations of informed consent or HIPAA authorizations.
5. Research proposals/activities that have been approved under an expedited review procedure (initial review, continuing review, modifications to existing studies and responses to contingencies for research which was conditionally approved) will be reported to the IRB within one month following the date the determinations were made. This report will contain the following information and will be organized

according to the types of items reviewed:

a. ETHOS tracking number (STU number);

b. PI;

c. Study/project title;

d. Sites engaged in research;

e. IRB documents reviewed;

f. Date of review;

g. Description of the modification(s) to the study (if modification(s) requested).

g. Pregnant Women, Fetuses, and Neonates – Reporting Procedure

i. Upon receipt of an IRB application or request, HRPPD staff screen protocols for any inclusion of pregnant women, fetuses, or nonviable neonates, or neonates of uncertain viability in research submitted to or funded by the DHHS as part of Administrative/Regulatory Pre-review (See Receiving, Routing, and Administrative Review of Submissions Policy and Procedure).

ii. When required under this policy, HRPPD staff, with input from the IRB and the PI, prepares a report to the DHHS based on the current guidance from OHRP. The IRB, in consultation with the AVPHRA or IRB Director, approves the report, which HRPPD staff sends through the IO, with a copy to the PI and to OHRP per OHRP guidance following IRB approval of the report.

iii. HRPPD staff file a copy of all correspondence in the IRB protocol file and database, if applicable.

iv. If the OHRP disagrees with the IRB findings on the research involving pregnant women, fetuses, nonviable neonates, or neonates of uncertain

viability, HRPPD staff present the information from OHRP to the IRB and the PI.

h. Prisoners – Reporting Procedure

i. Upon receipt of an IRB application or request, HRPPD staff screen protocols for any inclusion of prisoners in research submitted to or funded by DHHS as part of Administrative/Regulatory Pre-review (See Receiving, Routing, and Administrative Review of Submissions Policy and Procedure).

ii. HRPPD staff notifies the PI of the State, County or DHHS reporting requirements.

iii. With input from the IRB and the PI, for DHHS-funded research, HRPPD staff prepares a prisoner certification report certifying to OHRP that the duties of the IRB have been fulfilled to the DHHS based on the current guidance from OHRP on research which includes prisoners. The AVPHRA or IRB Director approves the report and HRPPD sends it through the IO to OHRP following approval of the report. HRPPD staff file a copy of all correspondence in the IRB protocol file.

iv. If the OHRP disagrees with the UTSW IRB classification of the research involving prisoner(s), HRPPD staff present the information from OHRP to the IRB and the PI.

i. Children – Reporting Procedure

i. Upon receipt of an IRB application or request, HRPPD staff screen protocols for inclusion of children in research submitted to or funded by DHHS or the U.S. Department of Education; or regulated by FDA as part of Administrative/Regulatory Pre-review (See 1.1. Receiving, Routing, And Administrative Review Of IRB Submissions).

ii. The HRPPD staff, with input from the IRB and the PI, prepares a report

summarizing the research that is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate serious problems to the DHHS based on the current guidance from the applicable agency. The IRB, in consultation with the HRPP Director or HRPP Associate Director, approves the report and sends it through the IO with a copy to the PI. HRPPD staff forward the report to the institutional official of the applicable federal agency (e.g., Secretary of DHHS through OHRP, Secretary of U.S. Department of Education, or Commissioner of FDA) based on current guidance from the agency. The HRPPD staff place a copy of all correspondence in the IRB protocol file and database, if applicable.

iii. If the applicable federal agency disagrees with the IRB findings on the research involving children, the HRPPD staff present the information from the agency to the IRB and the PI.

j. Changes in IRB Membership – Reporting Procedure

i. When a change in IRB membership occurs, HRPPD staff notifies OHRP. The AVPHRA, IRB Director or designee enters the required information regarding the changes in membership and submits the data to OHRP according to OHRP's policy requirements following receipt of approval of the membership in accordance with IRB Membership Policy and Procedure

k. Certification of IRB Approval – Reporting Procedure

i. When a funding agency requires certification of IRB approval, the PI contacts the HRPPD to request that HRPPD staff prepare the certification document. The PI is responsible for requesting HRPPD documentation of IRB approval in accordance with the funding agency requirements.

ii. The PI may provide HRPPD staff with a copy of the agency certification form. HRPPD staff prepares the required agency form(s) and obtain the signature of the UTSW authorized organizational representative for

sponsored research, or authorized IRB member.

iii. The HRPPD staff files a copy of the certification form in the IRB protocol file and forwards the original certification form to the investigator.

iv. The PI transmits the certification of IRB approval to the funding agency within the time period specified by the agency and provides a copy to appropriate organizational representatives at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., the Sponsored Program Administration (SPA)).

v. To prepare a certification form for grants/contracts that fund more than one IRB protocol, the PI provides the HRPPD with a list of pertinent IRB protocol numbers. HRPPD staff verifies the IRB numbers and IRB approval prior to preparing and issuing the certification document. The PI transmits the certification to the agency and provides appropriate institutional officials at involved institutions (e.g., the Sponsored Program Administration (SPA)) with a copy.

l. Exception to Informed Consent in Planned Emergency Research – Reporting Procedure

i. When the IRB approves an exception from the general informed consent requirements for planned emergency research under FDA and DHHS regulations, the PI provides the sponsor with a copy of the information publicly disclosed prior to the initiation and at the completion of the study. The PI is responsible for maintaining a copy of the report.

ii. If the IRB does not approve a request for exception to informed consent for planned emergency research under FDA and DHHS regulations, the HRPPD staff, with input from the IRB, prepares a report of the reasons why the IRB did not approve the exception. The IRB Chair, in consultation with the HRPP Director or HRPP Associate Director, approves the report. The HRPPD staff submits the report to the sponsor and the PI.

iii. When the IRB approves an exception from the general informed consent requirements for planned emergency research under DHHS regulations and not under FDA regulations (21 CFR part 50), the HRPPD provides the Office for Human Research Protections (OHRP) with a report that the conditions of approval have been met in accordance with the HHS Secretarial waiver under (45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings [Federal Register: Oct 2, 1996 (Vol. 61, Num. 192)].

iv. HRPPD staff file a copy of the reports in the IRB files.

v. Agency-Requested Reports

1. A federal agency may periodically ask the IRB or the UTSW for a specific report on a variety of issues (e.g., alleged noncompliance submitted to a federal agency). The AVPHRA or designee will review the request and designate an HRPPD staff member to assist the IRB/UTSW with preparation of the report

2. The designated HRPPD staff member prepares the report in accordance with the agency's request relative to content and timing.

3. The AVPHRA or IR Director approves the report. The AVPHRA, IRB Director, and/or IRB Chair or IO determines who receives a copy of the report depending on the nature of the request.

m. Procedure for Determining Which UTSW Officials Will Receive Copy of IRB Reports

i. The AVPHRA or designee recommends the UTSW and affiliated institutional officials or offices that should be included in reporting notifications to a federal agency for any of the federally mandated reports contained in this policy. The IO makes the final determination on a case-by-case basis. The determination is in accordance with applicable federal

requirements and in accordance with the policies outlined in the applicable institutional policies and memorandums of understanding/agreement (e.g., Parkland)

ii. Appropriate institutional officials then disseminate as needed within their organization and gather any additional institutional requirements and forward any such requirements to the PI to be incorporated into the action plan if necessary

iii. Examples of organizational representatives who may receive copies of a report include, but are not limited to, the following:

1. Institutional Official;
2. Dean of a University School;
3. Associate Dean;
4. Department or Division Chair;
5. Legal Counsel;
6. Assistant Vice President of Sponsored Programs Administration;
7. Privacy Officer;
8. Compliance Officer;
9. Other appropriate institutional officials at involved institutions for which the UTSW IRB is serving as the IRB of record (e.g., Children's, Parkland, etc.)

n. When reporting to the FDA:

i. For suspensions or terminations of IRB approval, include the IND or IDE number, the full name of the research protocol, the name(s) of the clinical investigators, and the reason(s) for the suspension or termination.

ii. These reports may be submitted via e-mail or in hard copy by FAX or mail. Information will be submitted to the following locations/contacts:

iii. Report suspension or termination of IRB approval; serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB; or internal unanticipated problems involving risks to human subjects (if not already reported by PI) to appropriate officials.

## IV. Definitions

See glossary of human research terms

## V. References

a. 21 CFR 50: Protection Of Human Subjects

b. 45 CFR 46: Protection Of Human Subjects

c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56: Institutional Review Boards

## VI. Revision and Review History

a. Revision Date: June 2026; Author: HRPP; Description: Reference to eIRB revised to include ETHOS and other minor clarifications

b. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

c. Revision Date: November 2019; Author: HRPP; Description: Updated reference to AAHRPP accreditation

d. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

e. Revision Date: March 2012; Author: IRB Office; Description: IRB Written Procedures