I. Policy

A. Problem Reports - 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 HSC 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 OIRB.

1. IRB determinations of serious or continuing non-compliance in accordance with the non-compliance policy will be reported to the following entities within 15 days of the IRB’s determination. Please note that additional notifications of serious or continuing non-compliance will occur according to specific local institutional requirements (e.g., HSC, STVHCS as soon as possible but no later than 5 business days):

   a) Principal Investigator;

   b) Person(s) involved in the noncompliance;

   c) Department Chair (or equivalent);

   d) Dean or unit Director, if appropriate;

   e) Vice President for Research through the AVPRA;
f) Compliance Office, Office of Sponsored Programs, and other institutional entities as appropriate;

g) OHRP (incident report) (if federally funded);

h) FDA, if applicable;

i) DoD funding agency, if applicable, when research is funded by the Department of Defense

j) Sponsor coordinated through Office of Sponsored Programs, if appropriate;

k) Other appropriate institutional officials at involved institutions (e.g., STVHCS, UHS, etc.) for which the UTHSCSA IRB is serving as the IRB of record.

For VA research the STVHCS facility Director and the ACOS/R&D will be notified.

l) 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 IRB Director/Associate Director).

2. 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 within 15 days of 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., HSC, STVHCS as soon as possible but no later than 5 business days):

a) Principal Investigator;

b) The Department Chair;

c) Dean or unit Director, if appropriate;

d) Vice President for Research through the AVPRA;

e) Compliance Office, Office of Sponsored Programs, and other institutional entities as appropriate;

f) 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 OIRB promptly submits an incident report to Applicable Federal Department or Agency head if funded by a department or agency including OHRP.

g) 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 OIRB will report to the FDA.

h) DoD funding agency, if applicable, when research is funded by the Department of Defense

i) Sponsor coordinated through Office of Sponsored Programs, if appropriate;

j) Other appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.) For VA research the STVHCS...
facility Director and the ACOS/R&D will be notified.

k) For local research deaths that meet criteria as an UPIRSO, the IRB will alert by email or phone within 2 business days after receiving such notification and provide relevant information as requested to VA ORO with concurrent notification to STVHCS facility Director and the ACOS/R&D

3. 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 within 15 days of 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., HSC, STVHCS, as soon as possible but no later than 5 business days.):

   a) Principal Investigator;

   b) Department Chair (or equivalent);

   c) Dean or unit Director, if appropriate;

   d) Vice President for Research through the AVPRA;

   e) Compliance Office, Office of Sponsored Programs, and other institutional entities as appropriate;

   f) OHRP (incident report) (if federally funded);

   g) DoD funding agency, if applicable, when research is funded by the Department of Defense

   h) FDA, if applicable;

   i) Sponsor coordinated through Office of Sponsored Programs, if appropriate;

   j) Other appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.). For VA research the STVHCS facility Director and the ACOS/R&D will be notified.

   k) 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.

4. Appeals to reports

   a) 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.

   b) The appeal will go before the convened IRB for review and consideration.

5. Responses or reports from federal departments

   a) OIRB presents responses or other reports from federal departments or agency heads (generally OHRP or FDA) to:

      (1) the IRB,
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b) appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.) For VA research the STVHCS facility Director and the ACOS/R&D will be notified.

(1) the PI, and

(2) AAHRPP. UTHSCSA will:

(a) Report to AAHRPP within 24 hours of becoming aware of:

(i) Catastrophic event that results in an interruption or discontinuance in a component of or the entire human research protection program;

(ii) Any sanctions taken by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports, FDA Restrictions placed on an IRB or Investigator, and corresponding compliance actions taken under non-US authorities related to human research protections;

(iii) Any litigation, arbitration, or settlements initiated related to human research protections;

(iv) Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the organization’s human research protection program.

(b) Consult the AAHRPP office for further advice if in doubt about whether a particular item is immediately reportable.

B. Other Reports - The IRB reports inclusion of certain vulnerable populations, IRB Membership and Certification changes, Emergency Medical Research requesting Exception to Informed Consent, and determinations made by the IRB following initial and continuing review and as appropriate during review of modifications to previously approved research, to internal entities (such as Principal Investigators and other appropriate HSC officials) and as appropriate external entities (such as department or agency heads, OHRP and the FDA) as required by federal regulations.

1. Determinations made by the IRB/OIRB 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 OIRB review will be reported by the OIRB to the PI and the appropriate officials at affiliated institutions of the following:

a) For each research item reviewed by the convened IRB, the OIRB will report the following determinations to the appropriate institutions for which the UTHSCSA IRB is serving as the IRB of record:

(1) Approve the research activities as written,

(2) Require minor modifications to secure IRB approval (conditional approval),

(3) Defer review to another convened meeting pending resolution of major issues/modifications (tabled item), or

(4) Inactivate.

(5) 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.

b) For each research item reviewed under an expedited review procedure the OIRB will report the determinations to the following:

(1) The PI

(2) Affiliated institutions relying on the HSC IRB

(3) 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.

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

(1) The PI

(2) Appropriate institutions engaged in the research for which the UTHSCSA IRB is serving as the IRB of record

2. 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 OIRB reports to:

a) The PI

b) With a copy to OHRP.

3. 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 OIRB reports to:

a) The PI

b) With a copy to OHRP.

4. 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 OIRB reports to:

a) The PI

b) 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).

5. Reporting changes in IRB membership - the OIRB maintains a current copy of IRB members.
6. Reporting **Certification of IRB Approval** - the OIRB reports upon request to: The funding agency either directly or through the PI.

7. 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 OIRB reports to:

   a) The PI

   b) The sponsor.

II. **Overview**

   A. This procedure starts upon the IRB or the OIRB making a determination that requires reporting in accordance with this policy

   B. This procedure ends when reporting has been carried out in accordance with this policy.

   C. Summary of responsibilities

      1. OIRB staff are responsible for collecting or recording determinations of the IRB in accordance with UTHSCSA policy, creating appropriate reporting documents, obtained appropriate signatures and sending reports/making reports available to applicable individuals, institutions, departments or agencies.

      2. Appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.) If the research is regulated by other involved institutions OIRB staff also send specific reports to the appropriate institutional officials at involved institutions. Each of these individuals is responsible for sending those reports throughout their institution as they consider appropriate. (e.g., STVHCS ACOS, forwards certain reports to: the Chair of the Research and Development Committee; the Regional Office of Research Oversight; the VA Privacy Officer (e.g., if an unauthorized use, loss, or disclosure of individually identifiable patient information resulted); and the VA Information Security Officer (e.g., if a violation of VA information security requirements resulted)).

III. **Procedure**

   A. **Serious or Continuing Noncompliance – Reporting Procedure**

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

         a) Informal notification is made via telephone or encrypted email, as necessary to satisfy specific institutional requirements (e.g., STVHCS, as soon as possible within the timeframe required by I.A.1.1).

         b) The OIRB 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 by I.A.1 above of determining the event is a serious and/or continuing noncompliance.

         (1) The IRB Chair or designee, reviews the determination letter (report), which the OIRB sends to the PI with a copy to the appropriate federal agency, department chair, and appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.)
(2) If the DHHS conducts or funds the research, the OIRB sends the report to OHRP in accordance with current OHRP guidance on incident reporting http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html.

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

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

2. 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 UTHSCSA or the IRB; actions taken by the PI, UTHSCSA, and/or the IRB to address the issue.

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

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

B. 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

1. OIRB 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)

   a) Informal notification is made via telephone or encrypted email, as necessary to satisfy specific local institutional requirements (e.g., STVHCS, as soon as possible within the timeframe required by I.A.2). Generally, initial notices are sent locally pending IRB review.

   (1) The initial notification will identify:

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

      (b) Title of the research project and/or grant proposal in which the problem occurred;

      (c) Name of the principal investigator on the protocol;

      (d) 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);

      (e) A description of the problem; and

   (2) 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 UTHSCSA 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:
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(a) If 15 days have passed since initial notice, OIRB Staff prepare follow-up correspondence to the PI and coordinator requesting any information necessary

(b) If 22 days have passed since initial notice without resolution, OIRB Staff prepare a Letter to Department Chair with a copy to PI and coordinator. Letter should state if the required information is not received within 7-10 days the issue will be forwarded to the Convened IRB as a matter of noncompliance.

b) Official notifications are made as determination notices and notices of resolution. Determination notices are sent following IRB/designated reviewer review, and notices of resolution are generally sent after the action plan is fully implemented. However, if the event is a more serious incident, this may mean reporting to applicable federal department or agency head including OHRP within days. In all cases, incident reporting of IRB determinations to the applicable federal department or agency heads including OHRP will occur within the timeframe required by I.A.2 above.

(1) The Determination notice will identify:

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

(b) Title of the research project and/or grant proposal in which the problem occurred;

(c) Name of the principal investigator on the protocol;

(d) 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);

(e) IND or IDE number (if applicable)

(f) A detailed description of the problem;

(g) 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

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

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

(a) If the follow-up report has not been received within approximately 30 days following the meeting, OIRB Staff prepare follow-up correspondence to the PI and coordinator requesting any information necessary for resolution

(b) If approximately 45 days have passed since initial notice without a response to the IRB determination, OIRB Staff may prepare a Letter to Department Chair with a copy to PI and coordinator. Letter should state if the required information is not received within 7-10 days the issue will be forwarded to the Convened IRB as a matter of noncompliance.

(3) The IRBD, IRBAD or IRB Chair approves all official notices.
2. OIRB Staff reports determinations to all entities listed in I.A.2 above as indicated below:

a) Appropriate officials at UTHSCSA including:

   (1) Compliance Officer (for all reports involving privacy issues),

   (2) AVPRA

      (a) for UPIRSO based on Internal Adverse Events

      (b) UPIRSO based on non-adverse events where:

          (i) a local incident, experience or outcome or

          (ii) where external incident, experience or outcome was identified by local PI

   (c) UADE reports

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

   (a) for UPIRSO based on External Adverse Events, and

   (b) UPIRSO based on non-adverse events where:

      (i) 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).

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

   (a) Each IRB reviews UPIRSO related documents placed on the meeting agenda.

b) Appropriate institutional officials at involved institutions for which the UTHSCSA IRB is
   serving as the IRB of record (e.g., STVHCS, UHS, etc.). 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.

c) Applicable Federal Department or Agency head if funded by a department or agency
   including OHRP

   (1) OHRP is only notified for:

      (a) UPIRSO based on Internal Adverse Events

          (i) UADE reports may meet this criteria

      (b) And when deemed appropriate by the IRB Director, Associate Director or AVPRA

          any UPIRSO based on non-adverse events where OHRP would not otherwise be

          notified by another entity:

          (i) a local incident, experience or outcome or

          (ii) external incident, experience or outcome identified by local PI
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(2) If the DHHS conducts or funds the research, the OIRB sends the report to the Office for Human Research Protections (OHRP) in accordance with current OHRP guidance on incident reporting http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html

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

d) 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 OIRB as outlined in “when reporting to the FDA” (below).

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

C. Suspension or Termination of Research – Reporting Procedure

1. OIRB Staff reports determinations of suspension and termination via informal means and formal official notices

   a) Informal notification is made via email or telephone, as necessary to satisfy specific local institutional requirements (e.g., STVHCS, as soon as possible within the timeframe required by I.A.3).

   b) The OIRB prepares official notification, a summary report of suspension and termination, within the timeframe required by I.A.3 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 by I.A.3 above.

   (1) The IRB Director or Associate Director, in consultation with the IRB Chair, approves the report, which the OIRB sends to the PI with a copy to the appropriate federal agency, department chair, and appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.)

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

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

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

2. The report includes:

   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) the number of any applicable federal award(s) (grant, contract, or cooperative agreement);

e) the nature of the event; and

f) the findings of UTHSCSA, IO, or the IRB;

g) actions taken by the PI, UTHSCSA, IO, and/or the IRB to address the issue.

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

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

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

OIRB staff:


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

   a) Approved,

   b) Conditionally Approved,

   c) Deferred,

   d) Disapproved, or

   e) Inactivated

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

   a) 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.

   b) 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.

   c) 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 OIRB or the IRB including:

(1) Date of approval

(2) Expedited review categories for new studies that were not reviewed by the convened IRB.

(3) Exempt review categories for new studies determined exempt from IRB review

(4) Determination of non-human research or non-regulated research for those studies determined not to meet the definition of human subjects’ research.

(5) Approval of the inclusion of any vulnerable populations

(6) 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 at the first Board meeting following the end of a calendar month during which such determinations were made, e.g., determinations in January will be reported to the first Board meeting in February. This report will contain the following information and will be organized according to the types of items reviewed:

a) IRB tracking 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).

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

1. Upon receipt of an IRB application or request, OIRB 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).

2. When required under this policy (I.B.2), OIRB 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 IRB Director or Associate Director, approves the report, which OIRB staff sends through the AVPRA and VPR/IO, with a copy to the PI, to OHRP per OHRP guidance within fifteen days of IRB approval of the report.

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

4. If the OHRP disagrees with the IRB findings on the research involving pregnant women, fetuses, nonviable neonates, or neonates of uncertain viability, OIRB staff present the information from OHRP to the IRB and the PI.

F. Prisoners – Reporting Procedure

1. Upon receipt of an IRB application or request, OIRB 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).

2. OIRB staff notifies the PI of the State, County or DHHS reporting requirements.

3. With input from the IRB and the PI, for DHHS-funded research, OIRB 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 IRB Director or Associate Director approves the report and OIRB sends it through the AVPRA and VPR/IO to OHRP within fifteen days of approval of the report. OIRB staff file a copy of all correspondence in the IRB protocol file.

4. If the OHRP disagrees with the UTHSCSA IRB classification of the research involving prisoner(s), OIRB staff present the information from OHRP to the IRB and the PI.

G. Children – Reporting Procedure

1. Upon receipt of an IRB application or request, OIRB staff screen protocols for any 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 Receiving, Routing, and Administrative Review of Submissions Policy and Procedure).

2. The OIRB 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 IRB Director or Associate Director, approves the report and sends it through the AVPRA and VPR/IO with a copy to the PI within fifteen days of IRB approval of the report. OIRB 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 OIRB staff place a copy of all correspondence in the IRB protocol file and database, if applicable.

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

H. Changes in IRB Membership – Reporting Procedure

1. When a change in IRB membership occurs, the IRB Director, Associate Director or designee enters the required information regarding the changes in the institutional membership records and according to OHRP’s policy requirements in accordance with HOP 1.6.6 (See IRB Membership Policy and Procedure for further detailed procedures)
I. Certification of IRB Approval – Reporting Procedure

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

2. The PI may provide OIRB staff with a copy of the agency certification form. OIRB staff prepares the required agency form(s) and obtain the signature of the UTHSCSA authorized organizational representative for sponsored research, or authorized IRB member.

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

4. The PI transmits the certification of IRB approval to the funding agency within the time period specified by the agency and provides appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., the Office of Sponsored Programs) a copy.

5. To prepare a certification form for grants/contracts that fund more than one IRB protocol, the PI provides the OIRB with a list of pertinent IRB protocol numbers. OIRB 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 Office of Sponsored Programs) with a copy.

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

1. 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.

2. If the IRB does not approve a request for exception to informed consent for planned emergency research under FDA and DHHS regulations, the OIRB 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 IRB Director or Associate Director, approves the report. The OIRB staff submits the report to the sponsor and the PI within fifteen days of disapproval.

3. 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 OIRB 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)].

4. OIRB staff file a copy of the reports in the IRB files.

K. STVHCS Reporting Requirements – Reporting Procedure

1. The HSC IRB minutes are sent to the STVHCS R&D Service via secure email allowing the VA staff access to the minutes.

2. An initial report of an IRB determination that serious non-compliance or continuing non-compliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.

3. Procedures for STVHCS reporting are outlined above in the procedures for reporting unanticipated problems, serious or continuing noncompliance, and suspension or termination.
of research.

4. Agency-Requested Reports

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

b) The designated OIRB staff member prepares the report in accordance with the agency’s request relative to content and timing.

c) The IRB Director or Associate Director approves the report. The IRB Director, Associate Director and/or IRB Chair or AVPRA determines who receives a copy of the report depending on the nature of the request.

L. Procedure for Determining Which HSC or VA Officials Will Receive Copy of IRB Reports

1. The IRB Director or designee recommends the HSC 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 AVPRA or the VPR/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., STVHCS, UHS).

2. 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.

3. Examples of institutional officials who may receive copies of a report include, but are not limited to, the following:

   a) Vice President for Research;
   b) Dean of a University School;
   c) Associate Dean;
   d) Department or Division Chair;
   e) STVHCS Associate Chief of Staff for Research and Administrative Officer (if study involves STVHCS);
   f) Legal Counsel;
   g) Director of the Office of Sponsored Programs;
   h) Privacy Officer;
   i) Compliance Officer;
   j) Other appropriate institutional officials at involved institutions for which the UTHSCSA IRB is serving as the IRB of record (e.g., STVHCS, UHS, etc.)

M. When reporting to the FDA:
1. 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.

2. 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:

3. 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.

(See other UTHSCSA policies for investigator reporting responsibilities.)

IV. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)