Coordination with Other Committees or Offices Policy and Procedure

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I. Policy

A. The Institutional Review Board (IRB) / the Office of the IRB (OIRB) and other organizational components integral to the Human Research Protection Program (HRPP) will establish working relations to coordinate research protection related activities within UTHSCSA.

B. The Institutional Review Board (IRB) / the Office of the IRB (OIRB) and the Human Research Protection Program (HRPP) contacts of other affiliated institutions will establish working relations to coordinate research protection related activities between applicable institutions.

II. Coordination procedures common to all research related committees and offices

A. Complaints, Concerns, Comments or Questions and Possible UPIRSO or Alleged Noncompliance

1. If the coordinating committees or offices (CCOs) of the UTHSCSA HRPP or that of an affiliated institution receive a complaint, concern, comment, or question that may indicate possible noncompliance or other issues related to the responsibilities of the IRB (e.g., the safety, rights or welfare of research participants), the CCO POC (point of contact) will promptly (i.e. within 2 business days) notify the IRB Director or Chair. The CCO POC may confer with the IRB Director or Chair to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, CCO or both.

2. If the IRB receives a complaint, concern, comment, or question that may indicate possible noncompliance or other issues pertinent to the responsibilities of the CCOs listed above, the IRB

Director, Chair or designee will promptly (i.e. within 2 business days) notify the CCO POC. The IRB Director, Chair or designee may confer with the CCO POC to assess whether the complaint issue falls under the purview of the IRB, CCO or both.

3. If an issue overlaps with the IRB, the appropriate CCO will provide the IRB Director pertinent information from the review. If the issue is determined to be reportable to a federal regulatory agency, the CCO POC will provide a copy of the federal report to the IRB Director.

4. See Complaints Policy and Procedure, Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) Policy and Procedure, Noncompliance Policy and Procedure, and Reporting Policy and Procedure for further details.

B. Quality Assurance/Improvement Findings

1. If the OIRB Quality Improvement Program, identifies issues pertinent to the responsibilities of the CCOs listed above, the IRB Director, or designee will promptly (i.e. within 2 business days) notify the appropriate CCO POC.

2. If the CCOs listed above receive audit or inspection reports that indicate issues pertinent to the IRB's responsibility for the protection of human subjects, the CCO POC is responsible for providing the IRB Director, Chair, or designee with a summary of the issues. The IRB Director or Chair will determine the appropriate process for review of the issue.

C. Joint Policy/Procedures Development and Improvement

1. The IRB Director assisted by the Research Protection Program leadership, when appropriate, is responsible for initiating efforts to establish joint policy, procedures and submission forms with the CCOs listed above. Suggestions or recommendations for the joint policy/procedure/form initiatives may be submitted to IRB Director.

III. Radiation Safety Committee (RSC)/Medical Radioisotope and Radiation Control Committee (MRRCC-VA studies only)/Radioactive Drug Research Committee (RDRC) - CCO Point of Contact (POC) with IRB: Radiation Safety Officer (RSO) or Chair – MRRCC RSC

A. Protocol Review Procedures

1. All new protocols involving the use of radiation for purposes of research or radioactive drugs not requiring an IND are submitted to the RSC/RDRC for review, preferably prior to protocol submission to the OIRB. The IRB may review a new study involving radiation concurrently with the RSC/RDRC. The IRB is provided a copy of the Radiation Worksheet and informed consent document language submitted to the RSC/RDRC to assist with understanding the research related risks. The OIRB and/or RSO will determine whether additional RSC/RDRC approval is required.

2. Final approval by the institution is not granted until the PI provides OCR documentation indicating the RSC (or MRRCC, if VA) and, if applicable, the RDRC has reviewed and approved the protocol.

3. For research approved by the IRB that has not yet received final approval from RSC/MRRCC/RDRC, the OCR is responsible for ensuring the final approval is received and is not based on a different radiation exposure than was reviewed by the IRB. If the radiation exposure information provided on the

worksheet is changed to a different dose of radiation during the RSC/MRRCC/RDRC an IRB amendment must be returned to the convened IRB for review prior to institutional activation.

4. Any requests to modify an already approved study (IRB amendment) that adds radiation exposure is reviewed in a similar manner, however, the IRB will not approve the amendment without final RDRC approval.

5. The Radiation Worksheet is a form developed by both committees to provide a framework for measuring radiation exposure. The worksheet provides a method to categorize the total exposure level as low, medium and high (categories I, II, or III). The worksheet also provides suggested wording for use in the risks section of the consent form. The comparative risks statements were jointly developed and agreed upon by both the IRB and RSC/MRRCC/RDRC.

6. The RSO acts as a consultant to the IRB in the area of radiation safety, the adequacy of the information in the informed consent form pertaining to radiation risks, and may advise the IRB regarding whether Radiation Safety review is needed. The RSO may attend the IRB meeting or send comments in writing.

7. If the RSC/RDRC requires other IRB documents for its review of radiation safety applications, the RSO has access to the IRB electronic files.

IV. South Texas Veteran's Health Care System (STVHCS) - VA R&D Committee - CCO Point of Contact (POC) with IRB: STVHCS Associate Chief of Staff (ACOS) for Research

A. Protocol Review Procedures

1. The PI is responsible for following the applicable VHA Handbook 1200.05 and other applicable VA requirements. Examples include, but are not limited to, the following:

   a) Payment to subjects;

   b) Informed consent (e.g., VA medical treatment, co-pay statements, research records, and specimens);

   c) Use of Legally authorized representatives;

   d) Inclusion of individuals with impaired decision-making;

   e) Use of investigational drugs and devices;

   f) Declaration of conflict of interest.

2. Upon receipt of an IRB initial review application, the OCR staff in-processes the application and the IRB review it in accordance with applicable procedures (see the Receiving, Routing, and Administration Review Policy). In addition, the OCR staff informs the STVHCS ACOS or designee (generally the staff of the VA R&D Service or the HSC IRB-VA R&D Liaison) which studies include the VA. The VA R&D Service staff or the HSC IRB-VA R&D Liaison have access to the IRB electronic files and are able to screen and make changes to the submission documents to ensure compliance with VA Handbook 1200.05 requirements and any other applicable VA regulations or policies during the institutional pre-

review process. Screening by the VA staff or the HSC IRB-VA R&D Liaison is intended to streamline the IRB/VA R&D Committee review process by identifying significant issues as early as possible.

3. If the STVHCS ACOS or designee identifies any VA regulatory issues, he/she may contact the PI, OCR, and/or OIRB staff to ensure that required changes are made. The STVHCS ACOS serves as the HSC IRB's primary consultant on matters related to the VA population and facilities. The STVHCS ACOS or designee may attend IRB meetings and/or send comments in writing.

4. STVHCS ACOS or designee ensures that research supports the mission of VHA and enhances the quality of health care delivery to Veterans and is relevant to the VA mission during the institutional pre-review process.

5. The STVHCS ACOS or designee and the IRB primary and secondary reviewers screen for the following types of issues including, but not limited to: variety of informed consent statements (e.g, legally authorized representatives, medical injury payment, co-pays, specimen banking, payment to subjects; investigational drug and device controls; and conflict of interest).

6. The VA R&D Staff or the HSC IRB-VA R&D Liaison sends VA Form 10-9012, Investigational Drug Information Record, to the OIRB for investigational drug studies. The OIRB forwards Form 10-9012 to the IRB Chair or designee, who reviews and signs it. The OIRB staff returns the form to the VA R&D Service after obtaining the IRB Chair or designee's signature.

7. After the IRB has completed its review in accordance with the procedures outlined in the HSC policies, the STVHCS ACOS or designee and PI forward the IRB approval and the application to the VA R&D Committee in accordance with the procedures outlined in the STVHCS policy. The application may be forwarded to the VA prior to IRB approval; however, the R&D Committee does not issue final approval without prior IRB approval.

8. If the VA R&D Committee requires changes in the protocol or the COI management plan (if applicable), the R&D Committee requires the PI to send a modification request to the IRB. The R&D Committee does not issue final approval without prior IRB approval of the modification.

B. Communication

1. For STVHCS studies, the VA R&D Service staff or the HSC IRB-VA R&D Liaison have access to the electronic copies of the following:

   a) All IRB applications;

   b) IRB meeting minutes (with non-VA studies redacted);

   c) Reportable events on VA protocols as included in the report to the IRB and initial notifications reported by OIRB staff (AE UPIRSOs, non-AE UPIRSOs, possible serious or continuing noncompliance; suspension or termination);

   d) Quality Improvement Reviews;

   e) Other pertinent correspondence, as appropriate.

2. The ACOS or designee notifies the appropriate STVHCS officials (e.g., Chair of VA R&D Committee, VA Privacy Officer, VHA Information Security Officer, and others when applicable) and the VA Regional Office of Research Oversight (e.g., in case of unanticipated problems involving risks to subjects) and others, when applicable, of all of the reportable items listed above, in accordance with standard VA and IRB operating procedures. The ACOS or designee copies the IRB/OIRB on the notifications of these items to VA offices.

3. The IRB may request assistance with audits of research records for VA studies. The IRB, through the ACOS, may request the VA Compliance Office perform a review of ongoing human research. In addition to the reviews requested by the IRB, the VA Compliance office conducts regular audits of research.

    a) The VA Compliance Office will promptly notify the IRB Director and ACOS of any audit findings that may indicate possible serious or continuing noncompliance.

    b) The IRB Director or designee are available to attend the compliance auditor's exit conference with the Principal Investigator to improve communication and identify issues of possible noncompliance.

4. The STVHCS ACOS or designee will provide updated information on VA requirements, policies, and procedures related to human research protection to the IRB Director. Assurances and the Memorandum of Understanding are updated, as appropriate.

5. The STVHCS ACOS or designee disseminates information to researchers and the IRB about VA requirements and policy. The OIRB provides assistance upon request.

6. See the Reporting Policy and Procedure for specifics on reporting between IRB and STVHCS.

C. Investigator and Study Personnel Education

1. The VA R&D Service staff or the HSC IRB-VA R&D Liaison ensures that the PI and all others engaged in the proposed research activity have met current VA education requirements for the protection of human subjects. The Research Common Application, Form Inst M or Form B-2 lists all study staff engaged in research and designates those subject to VA training requirements. The VA R&D Service maintains records documenting completion of mandatory VA training in accordance with standard VA operating procedures.

D. Standard OIRB/IRB Operating Procedures

1. All OIRB staff, the IRB Members, the IRB Chairs, the VA investigators and study personnel, and the VA ACOS comply with the standard OIRB/IRB operating procedures which apply to VA studies. These policies and procedures are outlined in OIRB/IRB policies including, but not limited to, those for review process and procedures, outcome, special requirements, recordkeeping and external reporting, and quality improvement and assessment policies.

2. The VA ACOS or designee educates the IRB, IRB Chair, OIRB staff, Chair of the VA R&D Committee, VA investigators and study personnel, and other STVHCS personnel in the applicable VA procedures and VA requirements. OIRB staff assists in education efforts as needed or appropriate.

E. The provision of services by the IRB is established through a memorandum of understanding or other written agreement that outlines the responsibilities of the VA facility and the academic affiliate.

V. University Health System (UHS) – Research Office - CCO Point of Contact (POC) with IRB: Senior Research Director

A. Protocol Review Procedures

1. Upon receipt of an IRB initial review application, the OCR staff process and the IRB reviews the application in accordance with applicable procedures (see Receiving, Routing, and Administrative Review Policy). In addition, the OCR staff informs the Senior Research Director or designee (generally the staff of the UHS Research Department) which studies include UHS. The UHS research staff have access to the IRB electronic files and are able to screen and make changes to the submission documents. Screening by the UHS Research staff is intended to streamline the review process by identifying significant issues as early as possible.

2. If the Senior Research Director or designee identifies any issues, he/she may contact the PI, OCR and/or OIRB staff to ensure that required changes are made.

3. For UHS studies, the UHS Research Department staff have access to the electronic copies of the following:

   a) All IRB applications;

   b) Findings of initial and continuing review approvals;

   c) Reportable events on UHS protocols as included in the report to the IRB and initial notifications reported by OIRB staff (AE UPIRSOs, non-AE UPIRSOs, possible serious or continuing noncompliance; suspension or termination);

   d) Quality Improvement Reviews;

   e) Other pertinent correspondence, as appropriate.

4. The IRB may request assistance with audits of research records for UHS studies. The IRB, through the Clinical Research Director, may request the UHS Compliance Office perform a review of ongoing human research. In addition to the reviews requested by the IRB, the UHS Compliance office conducts regular audits of research.

   a) The UHS Compliance Office will promptly notify the IRB Director and Clinical Research Director of any audit findings that may indicate possible serious or continuing noncompliance.

   b) The IRB Director or designee are available to attend the compliance auditor's exit conference with the Principal Investigator to improve communication and identify issues of possible noncompliance.

5. The UHS Clinical Research Director or designee will provide updated information on UHS requirements, policies, and procedures related to human research protection to the IRB Director and Chairs. Assurances and the Memorandum of Understanding are updated, as appropriate.

6. The UHS Clinical Research Director or designee disseminates information to researchers and the IRB about UHS requirements and policy. The OIRB provides assistance upon request.

7. See the Reporting Policy and Procedure for specifics on reporting between IRB and UHS.

B. Investigator and Study Personnel Education

1. The UHS Research Department ensures that the PI and all others engaged in the proposed research activity have met current UHS education requirements for the protection of human subjects, when the PI or engaged personnel are employed by UHS. The Research Common Application, Form Inst M or Form B-2 lists all study staff engaged in research and designates those subject to UHS training requirements.

VI. Conflict of Interest Committee (COIC) - CCO Point of Contact (POC) with IRB: Assistant Vice President for Research Administration (AVPRA) and COI Manager or COIC Chair

A. Disclosure of Investigator and study staff Conflict of Interest for Externally Funded Research

1. All HSC principal investigators conducting externally funded research must complete a Certificate of Proposal (COP) prior to submission of a proposal for external funding, disclosing any significant financial interest, as defined in the HOP 10.1.6 Conflicts of Interest in Scholarly, Research, and Clinical Activity.

2. The COP contains a question designed to ensure a recent Disclosure Statement of Conflicts of Interest and Commitment has been submitted. The disclosure form is designed to determine whether a conflict of interest or commitment exists related to the research. OSP ensures that PIs and research personnel responsible for the design, conduct, or reporting of sponsored research complete financial disclosure statements and certify that they have completed the HSC Conflict of Interest training prior to grant proposal submission.

3. If a PI (or other research personnel) has a declared conflict of interest in a proposed sponsored research project involving human subjects, the OSP staff notifies the COI Manager. The PI is responsible for declaring any conflicts on the IRB application.

4. All full-time HSC faculty and staff complete a Conflict Of Interest Report (COI Report) within 30 days of employment, annually and for new or changing activities. Activities such as outside employment, other compensated activities, service on a Board, or reimbursed travel expenses from sources other than the HSC must be approved by the department chair, Dean (or VP) and the President's delegate before the activity begins.

5. The COI Reports are reviewed by the COI Manager and the appropriate academic department chair and/or Dean. The COI Manager performs an initial review of all COI Reports submitted. The COI Manager will create a Conflict Management Plan or Expedited Conflict of Interest Approval form, as applicable, for those individuals that submit identifying real or potential conflicts of interest or commitment. If the conflict can be adequately managed through the expedited approval process, the Conflict of Interest Committee Chair will review and approve the conflicted investigator's activities.

However, if a Conflict Management Plan is required, it will be submitted to the COIC for review and disposition.

6. If the research involves human subjects, the COI Manager is responsible for informing the OIRB. The IRB Director serves as an *Ex Officio* member of the COIC to facilitate communications.

B. Disclosure of Financial Conflict of Interest to the IRB

1. The IRB application submitted for a new study includes a section which requires investigators to answer the question, "Do any of the investigators and study staff who are or will be responsible for the design, conduct, or reporting of activities under this research or their immediate family members have income or relationships to disclose?" The IRB Progress Report, submitted as part of continuation review, requires that the PI attests to whether there have been any changes to the status of possible financial conflict of interest for any of the study staff members, or their families, with respect to the study. OCR notifies the IRB when a new or updated financial conflict of interest disclosure is identified on the personnel form.

2. If appropriate, these forms prompt the investigator to complete and attach the Protocol Related Conflict of Interest form for each key personnel disclosing a possible COI with the research proposal.

3. The conflict of interest reporting form is designed to provide additional information about the possible conflict of interest for review by the COI Committee.

4. The OIRB/OCR forwards a copy of the form(s) to the COI Manager for concurrent review by the COIC. The COI Manager provides the review outcomes to the IRB/OCR. The OIRB/OCR ensures that COI management plans are provided to the IRB for review.

C. IRB Review and Oversight of Research with a Conflict of Interest

1. In reviewing research protocols in which an investigator has disclosed a COI, the IRB relies on recommendations from the Conflict of Interest Committee, applicable regulatory guidance, and federal and state law and the HSC policy on COI to ensure the protection of human subjects.

2. The IRB determines whether the recommendations from the COIC and the Conflict Management Plan (if applicable) adequately protect the rights and welfare of human subjects or whether other actions are necessary.

3. The IRB determines the kind, amount, and level of detail of information to be provided to subjects in the informed consent process regarding source of funding, funding arrangements, financial interests of parties involved in research, and any techniques applied to manage financial COI.

4. The OIRB informs the PI in writing of any additional IRB requirements or recommendations. The COI manager is provided a copy of the IRBs determination. The IRB has the final authority to determine if the management plan is sufficient or if any further action is needed to adequately protect the rights and welfare of human subjects.

5. The investigator or other key research personnel and/or the COI Manager provides the IRB updated disclosures relating to ongoing research any time a relevant significant financial interest, not originally disclosed, develops or is acquired.

VII. Institutional Biosafety Committee - CCO Point of Contact (POC) with IRB: Assistant Vice President for Risk Management & Safety (AVP RM&S)

A. Protocol Review

1. When a PI proposes research which falls under the purview of the IBC, the PI must submit the protocol to the IBC and obtain provisional approval before submitting the IRB initial review application. The IRB will not review new protocols falling under IBC purview unless the PI has obtained IBC review and provisional approval first and has included the completed Gene Therapy Worksheet and the required IBC review documentation.

2. If OIRB staff receive an IRB application, which in their judgment may require IBC approval and the PI has not included the required IBC documentation in the submission, OIRB staff contact the Biological Safety Manager (BSM) for assistance in determining whether IBC review is required. If OIRB staff determines that the proposal does fall under the purview of the IBC, OIRB staff informs the PI of the IBC/IRB requirement.

3. The BSM or his/her designee provides the IRB with data safety expertise, especially with respect to risk assessment. The BSM will either attend the convened IRB meeting or send comments in writing.

4. Final approval by the institution is not granted until the PI provides documentation indicating the IBC has reviewed and approved the protocol.

5. Any requests to modify an already approved study (IRB amendment) that requires IBC purview will be reviewed in a similar manner, however, the IRB will not approve the amendment without final IBC approval.

VIII. Office of Sponsored Programs (OSP) - CCO Point of Contact (POC) with IRB: Director of Sponsored Programs

A. Proposal Submission

1. A HSC Certificate of Proposal (COP) must be completed for all proposals and applications that request funding to outside sponsors that may result in a grant, contract, or other agreement. As part of the grant, contract or agreement review process, the PI submits the COP to the OSP.

2. The OSP staff ensures that no contracts, grants, or agreements contain language authorizing the payment of finder's fees.

3. The COP includes questions designed to verify whether the project involves human subjects and whether the PI has obtained IRB approval.

4. The OSP staff screens each externally sponsored grant proposal/agreement and the associated COP. When appropriate, the OSP staff advises the PI of sponsor requirements for submission, of the certification of IRB approval, and/or completion of mandatory human research training, as required by the sponsor. The OSP staff refers the PI to the OIRB in cases where the PI requires additional clarification or assistance with human research protections.

5. The PI submits certifications of IRB approval or mandatory education requirements to the agency in accordance with agency requirements. The OIRB staff prepares agency certifications for the PI upon request.

6. Initial IRB review and continuation review applications require the PI to provide information on the sponsor. The OIRB or OCR staff enters this information into the Research database.

B. Negotiation of Award Agreements

1. The OSP provides investigators with up-to-date information on institutional policy in negotiating the terms of sponsored research agreements to ensure compliance with applicable law, university policy, and good business practice. The OSP publishes information resources on the OSP web site, including regulatory resources, sample research study agreements, and specific information on clinical trial agreements.

2. Once the HSC receives an extramural award, the OSP staff reviews the proposed research agreement and negotiates acceptable terms between the sponsor and the institution. The agreement includes provisions for human research protections in compliance with all applicable laws, institutional policies for ethical conduct of research, and the written research protocol. The PI receives a copy of the completed agreement from OSP.

3. The OSP staff includes provisions in the research agreement outlining the plans for disseminating research findings in alignment with the HSC policies and the roles of the PI and the sponsor in publication or disclosure of research results.

C. Negotiation of Clinical Trial Agreements

1. Additional award negotiation procedures beyond those outlined above apply to sponsored research designated as a clinical trial. Current institution policy related to sponsored research agreements requires the following language be included or waived by the OSP Director with consultation from the IRB Director:

   a) If a study participant is injured as a result of the study drug or procedure that is required solely for study purposes, the sponsor will be responsible to cover the cost of treating the injury. Full financial responsibility for payment of such expenses resulting from an injury or illness suffered in the course of the study will rest with the sponsor, except to the extent that such expenses are attributable to the negligence or willful misconduct of the Institution.

   b) The sponsor will promptly provide notice to the Institution and/or Principal Investigator of any information discovered through monitoring and audit efforts or through analysis of study results and for a minimum of two years after completion of the study, if such information could:

      (1) adversely affect the safety of current or former study participants;

      (2) adversely affect the willingness of study participants to continue participation;

      (3) influence the conduct of the study; or

      (4) alter the IRB approval to continue the study.

2. The PI provides the appropriate OSP staff with a copy of the proposed agreement and a sponsor contact as early in the process as possible.

3. The OSP staff screens the terms of clinical trial agreements (CTA) for specific provisions related to IRB or Health Insurance Portability and Accountability Act (HIPAA) issues which need coordination with the IRB. Types of issues that may require IRB/OSP coordination include additional university/sponsor certifications or requirements related to human research protections, applicable federal assurances, and sponsor access to protected health information. Specific examples include, but are not limited to, the following:

    a) Rights/permissions to subject samples and prior medical records; and

    b) Use of participant data in future sponsor reviews only as approved by the IRB.

4. When appropriate, the OSP staff notifies the OIRB staff and provides a copy of the contract language in question. OIRB staff advises the OSP staff on pertinent existing regulatory and institutional policy, provides requested documentation or certifications, or refer the request to the IRB for review, as appropriate. The OIRB staff act as a liaison between the IRB and the OSP and respond to the OSP requests on a case-by-case basis. The OSP ensures that the resulting provisions incorporated into the CTA comply with the guidance obtained from the IRB/OIRB.

5. As part of the IRB application, the PI submits the informed consent document consistent with the proposed contract language related to provisions for payment of injury related care and research costs to the subject. If the language in the informed consent document differs from the template language provided by the IRB, the OIRB staff will contact OSP to confirm the language in the submitted consent(s) is consistent with the CTA prior to final IRB approval. If changes are needed in the informed consent document, the OIRB staff forward required changes to the PI and the IRB for review and approval.

6. The OSP staff also obtains a copy of the IRB approval letter from the PI or from the OIRB and places it in the physical file. The OSP staff maintains a checklist of documents required to complete a clinical trial file, including the following:

    a) A copy of the research protocol (becomes a part of the CTA by attachment);

    b) The fully signed agreement;

    c) The IRB approval letter.

D. Genomic Data Sharing Certification

1. Institutions are responsible for assuring, through an Institutional Certification, to the National Institutes of Health (NIH) that plans for the submission of genomic and phenotypic data from research studies to NIH designated data repositories meet the expectations of the NIH Genomic Data Sharing (GDS) Policy.

2. When a PI proposes research which falls under the purview of the NIH GDS Policy, the PI must submit the protocol or a protocol amendment to the IRB/OCR as part of the institutional research application.

3. Institutional Certifications received directly by OSP will be routed to the IRB/OCR for processing outlined above.

4. The IRB/OCR ensures GDS Policy requirements are met.

5. The certification document is then routed for signature by Research Protection Program Director or designee to the institutional official.

6. A signed copy will be returned to the PI and OSP to meet Just-in-Time requirements for an initial approval or by an amendment to an existing study.

E. Terminations or Lapses in IRB Approval

1. If the IRB terminates IRB approval of a sponsored project due to noncompliance, the OIRB Director notifies the OSP Director.

2. OSP takes the appropriate action in accordance with the sponsor requirements.

3. If an IRB approval lapses due to failure of the PI to submit a continuation review application, the OIRB staff sends the PI a lapse of approval notice. The IRB notifies OSP that IRB approval has expired. The PI is responsible for notifying the sponsor of the lapse.

IX. Office of Regulatory Affairs & Compliance (ORAC) - CCO Point of Contact (POC) with IRB: Chief Compliance Officer or Research Compliance Manager

A. The Office of Regulatory Affairs & Compliance performs reviews of ongoing human research for the IRB. The reviews are conducted for cause, at the request of the IRB/OIRB, or randomly. Details of how ORAC and IRB coordinate reviews can be found in the Study Reviews for Human Research Policy.

X. Mays Cancer Center Protocol Review Committee - CCO Point of Contact (POC) with IRB: Chair or designee

A. Protocol Review Procedures

1. All Health Science Center cancer protocols are submitted to the Mays Cancer Center (MCC) Protocol Review Committee (PRC) for scientific review, preferably prior to protocol submission to the OIRB. The IRB may review a cancer protocol concurrently with the PRC. OCR notifies MCC PRC of any cancer related protocols that are submitted to the OIRB without PRC approval. The IRB is provided a copy of the PRC disapproval, conditional approval with stipulations, and/or approval letter from the PRC.

2. Research protocols that have not yet received final approval from PRC because non-scientific design stipulations are outstanding may be approved by the IRB if all regulatory criteria for approval are met. Cancer related protocols that meet the regulatory criteria for exemption do not require PRC approval prior to the IRB determination. Final approval by the institution to implement these types of studies is not granted until the PI and/or PRC provides OCR documentation indicating PRC final approval has been received.

3. The PRC Chair may act as a consultant to the IRB in the area of cancer clinical trials, the adequacy of the information in the informed consent form pertaining to acceptable medical practice, and may advise the IRB regarding whether PRC review is needed. The PRC Chair may attend the IRB meeting or send comments in writing.

4. Any requests to modify an already approved cancer related study (IRB amendment) with significant changes is reviewed in a similar manner.

XI. Office of Clinical Research (OCR) - CCO Point of Contact (POC) with IRB: OCR Manager

A. The OCR performs review of new human subjects research applications for institutional requirements. Details of how OCR coordinates reviews with the IRB and other committees and offices can be found in the Institutional Review Policy.

XII. Clinical Trials Office - CCO Point of Contact (POC) with IRB/OCR: Financial Planning Manager

A. Participant Payment Review Procedures

1. OCR notifies the Clinical Trials Office (CTO) of all Health Science Center human subject protocols containing plans to pay participants.

2. Following CTO review of the participant payment form, CTO provides a copy of the final form to OIRB or OCR (for external IRB studies).

3. The OIRB analyst confirms the information on the final participant payment form is consistent with the informed consent for the study.

4. The OIRB analyst provide the final participant payment form to the IRB for review with the protocol.

B. Protocol Review Procedures

1. OCR notifies the CTO of all human subject protocols for the UT Health Science Center to conduct a billing review (see Research Billing Risk Questionnaire Standard Operating Procedure).

2. Final approval by the institution to implement the study is not granted until the CTO provides documentation indicating their review is complete (see Institutional Review Policy).

XIII. Patient Data Governance Committee (PDGC) – CCO POC with IRB/OCR: is through representation of the IRB/OCR on the CISIL Committee

A. The PDGC reviews all requests for UTHSA data that are referred by the Compliance, Information Security IRB, Legal, CISIL committee.

1. The CISIL committee reviews the data acquisition and use request (DAUR) form.to discuss requests for data.

2. The CISIL meets weekly to review the DAUR form.

3. The DAUR form is provided to the IRB/OCR as part of the research application.

4. The IRB/OCR analyst confirms information on the DAUR form is consistent with the other application documents.

5. This process applies to new studies or requests to modify an already approved study through an IRB/OCR amendment.

6. Final approval by the institution to implement the study is not granted until the PDGC provides documentation indicating their review is complete (see Institutional Review Policy).

XIV. References

A. Definitions (see Glossary)

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