HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

1.5 COMMUNICATION WITH OTHER COMMITTEES AND OFFICES

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

I. **POLICY STATEMENT**

A. The Human Research Protection Program Department (HRPPD) and other organizational components integral to the Human Research Protection Program (HRPPD) will establish working relations to coordinate research protection related activities within UT Southwestern.

B. The Human Research Protection Program Department (HRPPD) and the Human Research Offices of other affiliated institutions will establish working relations to coordinate research protection related activities between applicable institutions

II. **SCOPE**

A. This policy and procedure applies to the Human Research Protection Program Department (HRPPD), affiliated institutions, and other Committees and Offices at UT Southwestern which are integral to the review and oversight of human subjects' research.

III. **PROCEDURES FOR POLICY IMPLEMENTATION**

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

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

a) If the coordinating committees or offices (CCOs) of the UT Southwestern HRPPD 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 HRPPD (e.g., the safety, rights or welfare of research participants), the CCO POC (point of contact) will promptly notify the Assistant Vice President for Human Research Administration (AVPHRA) or Institutional Review Board Director (IRBD). The CCO POC may confer with the AVPHRA or IRBD to assess whether the complaint/alleged noncompliance falls under the purview of the HRPPD, CCO or both.

b) If the HRPPD 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 AVPHRA, IRBD or designee will promptly notify the CCO POC. The AVPHRA, IRBD or designee may confer with the CCO POC to assess whether the complaint issue falls under the purview of the HRPPD, CCO or both.

c) If an issue overlaps with the HRPPD, the appropriate CCO will provide the AVPHRA or IRBD 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 AVPHRA or IRBD.

d) See 9.1 COMPLAINTS, 9.2 UPIRSO and UADE, 9.3 NONCOMPLIANCE REVIEW AND 8.2 REPORTING POLICY AND PROCEDURE for further details.

2. Quality Assurance/Improvement Findings

a) If the HRPPD Quality Improvement Program, identifies issues pertinent to the responsibilities of the CCOs listed above, the AVPHRA, IRBD, or designee will promptly notify the appropriate CCO POC.

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

3. Joint Policy/Procedures Development and Improvement

a) The AVPHRA in consultation with the HRPP Steering Committee, 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 AVPHRA.

B. Institutional Affiliates: Parkland Health & Hospital System (PHHS), Children's Health, Scottish Rite for Children (SRC), The Retina Foundation of the Southwest (RFS) – Research Offices - CCO Point of Contact (POC) with HRPPO: Vice President for Research Administration (PHHS); Vice President for Research Administration (Children's Health), Administrator (SRC); Research Administration (RFS)

1. Protocol Review Procedures

a) Upon submission of a new protocol, the PI prepares and submits a Performance Site Review form in Velos (prior to eIRB submission) which notifies the applicable sites of the new submission.

b) The affiliate research staff have access to the eIRB electronic files and are able to screen the submission documents. Screening by the affiliate research staff may streamline the review process by identifying significant issues as early as possible.

c) If the affiliate research staff identifies any issues, he/she may contact the PI or HRPPO staff to ensure that required changes are made.

d) For affiliate studies, the affiliate Research Department staff have access to the electronic copies of the following:

i. All IRB applications;

ii. Findings of initial and continuing review approvals;

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

iv. Other pertinent correspondence, as appropriate.

2. The HRPPO or Office of Compliance may request assistance with audits of research records for affiliate studies. The IRB/HRPPO, through the POC, may request the affiliate Compliance Office(s) perform a review of ongoing human research. In addition to the reviews requested by the IRB/HRPPO, the affiliate Compliance offices conduct regular audits of research.

   a) The affiliate Compliance Office will promptly notify the AVPHRA and Affiliate POC of any audit findings that may indicate possible serious or continuing noncompliance.

   b) The AVPHRA 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.

3. The Affiliate POC or designee will provide updated information on affiliate requirements, policies, and procedures related to human research protection to the AVPHRA and Chairs. Assurances and the Memorandum of Understanding/Research Services Agreement are updated, as appropriate.

   a) The Affiliate POC or designee disseminates information to researchers and the HRPPD about affiliate requirements and policy. The HRPPD provides assistance upon request.

   b) See 8.2 REPORTING POLICY AND PROCEDURE for specifics on reporting between IRB and Affiliates.

4. Investigator and Study Personnel Education

   a) The affiliate Research Departments ensures that the PI and all others engaged in the proposed research activity have met current affiliate education requirements for the protection of human subjects, when the PI or engaged personnel are employed by the affiliate. The eIRB Parent Smart Form lists all study staff engaged in research.

C. Conflict of Interest Committee (COIC) - CCO Point of Contact (POC) with HRPPD: Assistant Vice President of Conflict of Interest and Institutional Animal Care and Use Committee or designee

1. Disclosure of Investigator and study staff Conflict of Interest for Research

   a) All UT Southwestern IRB members, faculty, as well as any staff or students conducting research must complete a statement of outside activities in accordance with ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities.

   b) The COI Office will review and process all statements of outside activates according to RES-401 FINANCIAL CONFLICTS OF INTEREST IN RESEARCH: DISCLOSURE, MANAGEMENT, AND REPORTING

   c) The COI disclosure form is designed to determine whether a conflict of interest or commitment exists related to the research.

2. Disclosure of Financial Conflict of Interest to the IRB

a) The IRB Application Smart Form prompts the investigator to declare whether a Financial Interests exists for any personnel on the research proposal.

b) The eIRB Continuing Review Smart Form includes a question for the Investigator to declare any changes to Financial Conflicts of Interest for any personnel on the research proposal.

c) If a Financial Conflict of Interest exists, the HRPPD staff follows the HRPP Policy 5.3 FINANCIAL CONFLICT OF INTEREST MANAGEMENT

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

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

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

c) 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.

d) If the IRB has additional requirement to add to the COI management plan, the HRPPD informs the PI in writing of any additional IRB requirements or recommendations. The COI Office is provided a copy of the IRBs determination.

e) The IRB has the final authority to determine if the COI Management Plan is sufficient or if any further action is needed to adequately protect the rights and welfare of human subjects.

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

D. Radiation Safety Committee (RSC)/ Radioactive Drug Research Committee (RDRC) - CCO Point of Contact (POC) with HRPPD: Radiation Safety Officer (RSO) or Chair

1. Protocol Review Procedures

a) All new protocols involving the use of investigational procedures involving radiation or radioactive drugs are submitted to the RSC/RDRC for review, preferably prior to protocol submission to the HRPPD. The IRB reviews new studies involving research-only radiation concurrently with the RSO/RDRC. The HRPPD and/or RSO will determine whether additional RSC/RDRC approval is required.

b) Final approval to implement the study is not granted until the PI provides documentation indicating the RSC and, if applicable, the RDRC has reviewed and approved the protocol.

c) For research approved by the IRB that has not yet received final approval from RSC/RDRC, the HRPPD is responsible for ensuring the final approval is received and is not based on a different radiation exposure than was originally reviewed by the IRB. If the radiation exposure provided on the RSC/RDRC approval is higher than originally approved by the IRB, the protocol must be re-reviewed by the IRB.

d) Any requests to modify an already approved study (IRB modification) that adds investigational radiation exposure is reviewed in a similar manner.

e) The Smart Form questions on Radiation Exposure provide a framework for quantifying research-related and standard of care radiation exposure. The questions on the Smart Form provides a method to quantify the number of radiation-related procedures and calculates the grand total effective dose of radiation. The RSO has also provided suggested wording for use in the risks section of the consent form.

f) RSC/RDRC may make initial decisions that procedures are/are not medically indicated. The IRB will have the final authority on this decision. The IRB may review the draft or final coverage analysis for additional information regarding research-only versus standard of care procedures.

g) The RSO may act 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.

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

i) The IRB has membership including Radiologists and Medical Physicists (with dosimetry expertise) to facilitate reviews of research involving radiation.

E. Institutional Biosafety Committee - CCO Point of Contact (POC) with HRPPD: Assistant Director, Office of Safety and Business Continuity

1. Protocol Review

a) When a PI proposes research which falls under the purview of the IBC (Recombinant DNA/Human Gene Transfer into human research participants), the PI must obtain approval from IBC before receiving final IRB approval. IBC is typically a "blocking review," which means that the study is reviewed by the IBC prior to submission to the eIRB system. However, when studies are not routed to IBC prior to IBC submission, the reviews may occur simultaneously. The IRB will not issue final approval for new protocols falling under IBC purview unless the PI has obtained IBC review first and has received the required IBC review documentation.

b) If HRPPD 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, HRPPD staff contact the IBC for assistance in determining whether IBC review is required. If HRPPD staff determines that the proposal does fall under the purview of the IBC, HRPPD staff informs the PI of the IBC/IRB requirement.

c) The IBC or his/her designee provides the IRB with data safety expertise, especially with respect to risk assessment. The Biosafety Officer may either attend the convened IRB meeting or send comments in writing.

d) Final approval by the IRB to implement the study is not granted until the PI provides documentation indicating the IBC has reviewed and approved the protocol.

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

f) The HRPP Director serves as a member of the IBC to facilitate communications.

F. Office of the Dean, Southwestern Medical School – Point of Contacts (POCs) with HRPPD: Dean of Medical Students & Associate Dean Student Affairs (for Medical Students); Dean, UT Southwestern Graduate School of Biomedical Sciences (Graduate Students or Postdoctoral Fellow); Scott Smith - Office of Dean- UT Southwestern School of Health Professions (Health Professions Students); Assistant Dean, Office of the Dean (Residents/Clinical Fellows).

1. Research involving the inclusion of Medical students, Health Professions students, Graduate students, Postdoctoral Fellows, Residents or Clinical Fellows as research subjects requires prior approval.

2. The PI should include a completed, approved, Form N in the application. The Form N documents prior approval to recruit students/fellows and residents. If the Form N was not completed, HRPPD staff sends a completed Form N, the protocol and consent form (if applicable) to the appropriate POC to request review the inclusion of students/fellows/residents as research subjects.

3. The POC will review the proposal and justification for the inclusion of residents and may request changes or disallow the inclusion of students/fellows/residents in the research.

4. Upon final approval from POC, the communication will be uploaded to the study Smart Form in eIRB and the research may proceed for review by the IRB.

G. Laser Committee (LC) – LC Point of Contact (POC) with HRPPD: Assistant Director, Laser Safety Officer

1. Research involving the use of lasers is required to receive approval from the Laser Safety Committee. The Laser Safety staff oversee all aspects of laser purchase, use, maintenance, and operations of all Lasers at UT Southwestern and affiliates.

2. When a PI proposes research involving lasers, Laser Safety approval form must be obtained prior to final IRB approval. A Form X may be submitted at initial submission indicating approval from the Laser Safety office.

3. If HRPPD staff receive an IRB application, which in their judgment may require Laser Safety approval and the PI has not included the required Form X in the submission, HRPPD staff contact the Laser Safety Office for assistance in determining whether the review is required. If HRPPD staff determines that the proposal does fall under the purview of the Laser Safety, HRPPD staff informs the PI of the requirement and requests the Form X to be completed and submitted to the Laser Safety Office.

4. Final approval by the IRB to implement the study is not granted until the PI provides documentation indicating the Laser Safety has reviewed and approved the protocol.

H. Information Systems Acquisition Committee (ISAC) – ISAC Point of Contact (POC) with HRPPD: Associate Vice President of Information Security and Chief Information Security Officer or designee

1. ISAC approval is required for research which requires the acquisition/use of software or other applications that meet the following requirements:

   a) All IT asset or software acquisitions greater than $25,000

   b) Any non-IR acquisition of networking, payment card processing, or teleconferencing equipment

   c) All acquisitions of any 3rd party technology service requiring a HIPAA BAA

   d) Any technology storing UTSW data offsite (e.g., Dropbox, Google Drive, GoDaddy, Network Solutions)

   e) Any technology processing UTSW data offsite (e.g., Rackspace, Amazon EC2)

2. Investigators are required to submit the ISAC Approval form to the ISAC and receive committee approval prior to acquiring/using technology as described above.

I. Office of Sponsored Programs Administration (SPA) - CCO Point of Contact (POC) with HRPPD: Assistant Vice President of Sponsored Programs Administration or designee

1. Proposal Submission

   a) An eGrants Funding Proposal (FP) must be completed for all research applications that request funding from 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 FP to SPA.

   b) The FP includes questions designed to verify whether the project involves human subjects and whether the PI has obtained IRB approval, if required.

c) The SPA staff reviews each externally sponsored grant proposal/agreement and the associated FP . When appropriate, the SPA 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 SPA staff refers the PI to the HRPPD in cases where the PI requires additional clarification or assistance with human research protections.

d) The PI submits certifications of IRB approval or mandatory education requirements to SPA and the SPA Institutional Official will submit the required information to the sponsor in accordance with agency requirements. The HRPPD staff prepares agency certifications for the PI upon request.

2. Negotiation of Award Agreements

a) SPA provides investigators with up-to-date information on sponsor requirements and institutional policy. This information is required in negotiating the terms of research agreements to ensure compliance with applicable law, university policy, and good business practice. For transparency, SPA publishes information resources on the SPA website, including regulatory resources, agreements matrix, and specific information on all research agreements including clinical trial agreements.

b) Once UT Southwestern receives an extramural award, SPA 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, as applicable. The PI receives a copy of the completed agreement from SPA.

c) The SPA staff includes provisions in the research agreement outlining the plans for disseminating research findings in alignment with the UT Southwestern policies and the roles of the PI and the sponsor in publication or disclosure of research results.

3. Negotiation of Clinical Trial Agreements

a) Additional award negotiation procedures beyond those outlined above apply to industry sponsored research designated as a clinical trial. Current institution policy related to industry sponsored agreements requires the following language be included or waived by the Clinical Research Services (CRS) Director with consultation from the HRPP Director:

i. 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.

ii. 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.

b) The PI provides the Contract Intake through Velos with a copy of the proposed agreement and a sponsor contact as early in the process as possible.

c) The SPA staff reviews the terms of clinical trial agreement (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/SPA 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:

i. Rights/permissions to subject samples and prior medical records; and

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

d) When appropriate, the SPA staff notifies the HRPPD staff and provides a copy of the contract language in question. HRPPD staff advises SPA 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 HRPPD staff act as a liaison between the IRB and SPA and respond to SPA requests on a case-by-case basis. SPA ensures that the resulting provisions incorporated into the CTA comply with the guidance obtained from the IRB/HRPPD.

e) 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 HRPPD staff will contact SPA 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 HRPPD staff forward required changes to the PI and the IRB for review and approval.

f) The SPA staff reviews Velos and eIRB for the current IRB approval letter. The electronic record in Velos contains all the following information:

i. A copy of the research protocol (becomes a part of the CTA by attachment if required by sponsor);

ii. The fully signed agreement;

iii. The IRB approval letter.

4. Terminations or Lapses in IRB Approval

a) If the IRB terminates IRB approval of a sponsored project due to non-compliance, the IRB Director notifies the SPA Director.

b) SPA takes the appropriate action in accordance with the sponsor requirements.

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

J. Office of Compliance (OoC) - CCO Point of Contact (POC) with HRPPD: Chief Compliance Officer or Research Compliance Assistant Director

1. The Office Compliance performs reviews of ongoing human research for the IRB/HRPPD. The reviews are conducted for cause, at the request of the IRB or HRPPD, or according to the annual Compliance monitoring plan.

2. HRPPD is provided with reports of the audit findings for each operating quarter.

K. Simmons Comprehensive Cancer Center (SCCC) Protocol Review Monitoring Committee (PRMC) - CCO Point of Contact (POC) with HRPPD: Chair or designee

1. Protocol Review Procedures

a) All Simmons Cancer Center protocols are submitted to the SCCC Protocol Review Monitoring Committee (PRMC) for scientific review, preferably prior to protocol submission to the HRPPD. Occasionally, the IRB may review a cancer protocol concurrently with the PRMC. HRPPD staff notifies PRMC of any cancer related protocols that are submitted to the HRPPD without PRMC approval. The IRB is provided a copy of the disapproval, conditional approval with stipulations, and/or approval letter from the PRMC.

b) Research protocols that have not yet received final approval from PRMC 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 PRMC approval prior to the HRPPD determination. Final approval by the IRB/HRPPD to implement these types of studies is not granted until the PI and/or PRMC provides documentation indicating PRMC final approval has been granted.

c) The PRMC Chair or designee 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 PRMC review is needed. The PRMC Chair or designee may attend the IRB meeting or send comments in writing.

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

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

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

VI. REVISION AND REVIEW HISTORY

REVISION DATE	AUTHOR	DESCRIPTION
JUNE 2021	**HRPP**	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
MAY 2019	**HRPP**	Updated Joint Policy/Procedures Development to remove reference to "Research Administration Leadership" as it is no longer a valid department at UTSW
JULY 2018	**HRPP**	Update COI POC, minor COI process clarification; revision to RSC (dissolved SHUR); clarifications to IBC review process and requirement for IBC approval prior to IRB final approval, updated approval process and POCs to approve inclusion of medical students/residents and fellows; updated Laser Safety Review process
AUGUST 2017	**HRPP**	New Policy Development
MARCH 2012	**IRB OFFICE**	IRB Written Procedures