HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

6.1 APPOINTMENT AND EVALUATION OF IRB MEMBERS AND CHAIRS

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

I. POLICY STATEMENT

A. This policy describes the regulations and requirements for establishing, maintaining and utilizing IRBs at UT Southwestern. The UT Southwestern Medical Center has assured the Department of Health and Human Services (DHHS) of compliance with DHHS regulations (45 CFR 46.103) for the protection of human subjects, through an Office of Human Research Protection (OHRP) approved Federalwide Assurance (FWA00005087). The FWA covers the UT Southwestern Medical Center, inclusive of the Graduate School of Biomedical Sciences, Medical School, School of Allied Health Sciences, UT Southwestern Moncrief Cancer Center, Zale Lipshy University Hospital, and William P. Clements Jr. University Hospital, centers and organized research units.

B. Each IRB individually shall meet the following membership requirements:

1. A minimum of five members.
2. At least one member whose primary concerns are in scientific areas.
3. At least one member whose primary concerns are in nonscientific areas.
4. The IRB may not consist entirely of members of one profession.
5. Every effort will be made to ensure that each IRB does not consist entirely of men or entirely of women.
6. Each IRB shall include one or more individuals who are knowledgeable about and experienced in working with vulnerable human subject population (such as children, prisoners, pregnant women, or physically or mentally disabled persons) in which research is regularly reviewed.
7. Each IRB shall have at least one member not affiliated with the institution and not an immediate member of a family affiliated with the institution (such individuals should be drawn from and represent the community). Individuals with no affiliation to the institution other than by serving on the IRB or another committee as a community member are considered unaffiliated.

C. The IRB Chairs, members (primary, alternate, and ex-officio), Assistant Vice President for Human Research Administration (AVPHRA), IRB Director (IRBD), and staff must be familiar with the ethical principles guiding human research; the requirements of federal regulations, applicable state law, the institution's FWA; and, institutional policies and procedures established for the protection of human subjects. The IRB as a whole must also have effective knowledge of subject populations and other factors which can potentially contribute to a determination of risks and benefits to subjects and which can impact participants' informed consent.

D. Evaluations of IRB Chairs and members (primary, alternate and ex-officio), membership and composition of the IRB are completed at least annually.

II. SCOPE

A. This policy and procedures applies to IRB members (primary, alternate and ex-officio), IRB Chairs and vice-Chairs.

III. PROCEDURES FOR POLICY IMPLEMENTATION

A. Appointment Procedures/Terms of Membership

1. IRB Chairs, Vice Chairs, members, and alternates are responsible for providing the HRPPD their curriculum vitae to document each member's expertise, degrees, and/or license number. The HRPPD maintains a copy of the curriculum vitae for each member during their term on the IRB and periodically requests updates, as appropriate.

2. Alternate IRB members replace regular IRB members who are unable to attend convened meetings of the IRB. Alternate members have qualifications comparable to the applicable regular member and may be alternates for more than one IRB member. The IRBD or designee maintains lists of alternate members on the official membership list approved by the Office for Human Research Protections (OHRP). The membership list specifies which members the alternate is qualified to replace. The duties are the same as those of regular IRB members.

3. Alternates attending a meeting or conducting a protocol review have all the authority of regular IRB members and receive the same training and protocol review application materials as the regular members. If the regular member and his/her alternate attend the same convened meeting, only one individual may vote depending upon roles.

4. Institutional liaisons may attend IRB meetings to ensure coordination among other research administrative units. Examples include but are not limited to: Radiation Safety Officer, Legal Counsel, and Institutional Biosafety Officer.

5. Affiliate Institutions are represented with assigned voting/alternate voting members. Examples include but are not limited to: Parkland, Children's Health, Texas Health Resources, and Scottish Rite for Children.

6. The HRPPD staff recruit ad hoc and cultural consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available among the IRB membership. These ad hoc and cultural consultants do not vote with the IRB and do not count toward a quorum at a convened meeting. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. The procedures for contacting consultants are described in 2.1. INITIAL REVIEW OF RESEARCH.

B. When the IRB reviews research that involves prisoners, both of the following must be true:

1. A majority of the IRB (exclusive of the prisoner representative) must have no association with the prison involved, apart from their relationship on the IRB.

2. At least one voting member at the IRB meeting must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

C. Filling Appointments

1. The IRB Chairs, IRBD, or delegate solicit recommendations from a variety of sources and recruits potential members.

   a. Potential members who are faculty at UT Southwestern Medical Center should also provide proof of support for appointment to the IRB from their respective Department Chair or leadership.

   b. The IRBD makes recommendations for appointments to the Boards. Prior to making the recommendation, the IRBD ensures no individual from a developmental or business office is appointed as an IRB member. The HRPPD staff send a copy of the recommendations and letters of support (if applicable) to the Institutional Official for appointment of new members. The Institutional Official has been delegated the authority from the President of the University to appoint individual members and chairs to the IRBs. The President has the ultimate authority to appoint the Institutional Official and the IRB committee as one of the President's Institutional Standing Committees (see RES-151 Human Research Protection Program).

   c. A letter from the Institutional Official to the Chair(s) or member(s) confirming appointments to the Board signifies such appointment.

   d. IRB Chairs are appointed in the same way; however, they should have at least an Associate Professor title.

   e. All IRB Chair and member appointments are for a period of 3 years and may be renewed indefinitely.

   f. New members to the IRB shall receive orientation from the IRB Chairs, IRBD, or designee. Members must complete required training as outlined in applicable IRB education policies. Members will also receive continuing education on current topics of human research as outlined in applicable IRB education policies. Members are educated on topics, such as ethics, applicable regulations, policies, etc. Each member shall receive continuing education information as part of the monthly IRB packets. Pertinent issues are discussed at meetings and documented in the minutes as appropriate.

D. OHRP IRB Registration/IRB Membership Roster

1. The IRBD or his/her designee completes the Office for Human Research Protections (OHRP) IRB registration forms and updates the registration in a timely manner when membership changes are made. The OHRP registration form serves as the official IRB roster and denotes in which scientific capacity each member serves.

2. The IRBD or his/her designee maintains membership records. HRPPD staff use the IRB Membership Roster to determine who may attend IRB meetings and count toward the quorum. It includes a list of regular members, their designated alternates and indicates the scientific status and issue specific knowledge of all members.

3. To meet OHRP registration requirements and in order to hold convened meetings, the scientist and nonscientist member designations are as follows:

    a. Nonscientific: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose:

        i. education, work, or interests are not solely in medical, behavioral or social science areas.

        ii. little or no scientific or medical training or experience.

        iii. individuals with advanced or professional training in both scientific and non-scientific areas should not be classified as non-scientists.

    b. Scientific: members whose primary interests are scientific. These individuals generally have substantial scientific or medical training. For example:

        i. academic degrees in science-related fields;

        ii. Medically-related practice degrees (e.g. nursing, pharmacy, physicians assistants, etc.); or

        iii. Other roles/positions actively engaged in medically-related research in the physical, educational, social, behavioral or biological sciences and disciplines and/or hold regular faculty appointments.

4. After appointments and changes, IRB Membership is reported in accordance with the 8.2 REPORTING POLICY AND PROCEDURE.

E. Removal of IRB Members

1. Members may be disqualified from the IRB for scientific misconduct, unethical behavior, conflict of interest, or non-compliance with the rules governing the IRB or failure to actively participate.

2. Such concerns are forwarded to the Institutional Official (IO) for review and action, as appropriate.

F. Evaluation of IRB Membership

1. IRB members

    a. The IRBD and the IRB Chairs are responsible for evaluating the IRB members on at least an annual basis.

    b. Annual assessment of IRB members

        i. IRB Member self-evaluations are sent to IRB members annually. The IRBD and Chairs discuss the results of the self-evaluations annually.

        ii. The AVPHRA, IRBD, and Chairs meet annually to discuss IRB members understanding of the HRPP (ethical principles, policies and procedures, and regulations) and to ensure that their service on the IRB will continue to contribute to the ethical and regulatory review of research. Information about an individual member's performance (including attendance and quality of

reviews) obtained during the ongoing review process listed below is also used in making decisions about continued service on the IRB.

iii. Results of the annual evaluation process will be provided to members at a convened IRB meeting at the end of the fiscal year (generally August). Based on the information obtained from the self-evaluation and the annual evaluation process, individual members or IRBs may be provided additional guidance or further education.

c. The report of the annual evaluations will be shared with the IO at the end of each fiscal year. On-going assessment and evaluation of IRB members

i. The AVPHRA, IRBD, and Chairs meet on a regular basis. As part of the agenda, the AVPHRA, IRBD, and Chairs evaluate previous board meeting(s). As appropriate, issues related to a specific member's performance as a primary or secondary reviewer or other roles are discussed.

ii. In addition, the performance of all members during the meeting that were notable (i.e., problematic or done well) are discussed.

iii. The goal of this ongoing evaluation process is to promptly identify areas for improvement of individual board members. Areas of evaluation include:

1. The quality of the member's pre-review and/or review for the convened meeting in identifying substantive scientific and ethical issues,
2. Meeting attendance,
3. Being adequately prepared for the meeting,
4. Knowledge of regulatory criteria for approval,
5. Knowledge of other clinical, ethical and institutional issues,
6. Contributions to the board (i.e. number reviews conducted, subcommittee attendance).

iv. As needed, the IRBD and Chairs develop an informal plan to address areas for improvement (e.g., provide additional education, meet with the board member to discuss specific issues, provide feedback to board members as appropriate, etc.).

v. If the informal improvement plan does not result in improved performance for the members identified during this process the IRBD may take other actions (e.g., not reappointing the member at the next scheduled period, dismissing the member from the board).

2. Evaluation of IRB Chairs

a. Annual Evaluation

i. IRB Member and Chair self-evaluations are sent to IRB Members and Chairs annually. The AVPHRA and IO discuss the results of the self-evaluations annually.

ii. Current Chairs are evaluated by the AVPHRA and Institutional Official annually to ensure that their service as Chair will continue to contribute to the ethical and regulatory review of research. Information about a chair's performance obtained during the ongoing review process listed below is also used in making decisions about continued service on the IRB.

iii. Results of the annual evaluation process will be provided to Chairs at an IRB Chair meeting near the end of the fiscal year (generally August). Based on the information obtained from the self-evaluation and the annual evaluation process, individual Chairs may be provided additional guidance or further education.

iv. The report of the annual evaluations will be shared with the IO at the end of each fiscal year.

b. On-going assessment and evaluation of IRB Chairs

i. The AVPHRA and Institutional Official (IO) meet on a regular basis. As part of the agenda, the AVPHRA and IO discuss previous board meetings. As appropriate, issues related to a specific Chair's performance (e.g., notable issues with regulatory knowledge, meeting management, resolution of problems, consensus building, or other issues related to the Chair's responsibilities are discussed.

ii. The goal of this ongoing evaluation process is to promptly identify areas for improvement of an individual Chair.

iii. As needed, the AVPHRA and Institutional Official develop an informal plan to address areas for improvement (e.g., provide additional education, meet with the chair to discuss specific issues, provide feedback as appropriate, etc.).

iv. If the informal improvement plan does not result in improved performance by the chair identified during this process, the IO may take other actions (e.g., not reappointing the chair at the next scheduled period, dismissing the chair form the board IRB).

G. Annual assessment of Membership

1. The IRBD and Chairs collaborate to adjust the IRB membership to ensure ethical and regulatory review of research and appropriate representation at convened meetings.

2. University committee assignment of members generally occurs at the beginning of the fiscal year. Several months prior to this date, the university solicits faculty and staff to volunteer for service on each of the committees, including the IRB.

3. As part of this process, the IRBD completes a comprehensive evaluation of the IRB membership and individual evaluations of each Board member including the chairs.

4. For the comprehensive evaluation the IRBD determines whether the membership, collectively, has the appropriate:

i. Knowledge of applicable regulatory and legal requirements;

ii. Knowledge of professional standards and practices;

iii. Knowledge of the local research context and research sites and their capabilities;

iv. Knowledge of community standards and attitudes;

v. Scientific, scholarly, clinical, and professional expertise;

vi. Racial, ethnic, and cultural diversity; and

vii. Representation of participants' perspectives.

5. Based on these assessments and taking into consideration the nature and volume of research reviewed, the composition and membership of each IRB is adjusted by the IRBD, assisted by the IRB Chairs.

6. Each prospective IRB member's qualifications are reviewed during the recruitment process by a working group led by the IRBD. Prospective members are recommended for appointment to fulfill the needs of the IRB identified during the comprehensive evaluation of the membership.

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 IRB Member and Chair Feedback process
July 2018	HRPP	Update Member appointment process
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures