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I. Policy
   A. See HOP Policy 7.2.2:

II. Procedure
   A. Appointment Procedures/Terms of Membership
   B. IRB membership and Chair appointments are addressed in HOP policy 1.6.6, Institutional Review Board (IRB).

1. IRB Chairs, Alternate Chairs, members, and alternates are responsible for providing the IRB Office a curriculum vitae to document each member’s expertise, degrees, and/or license number. The IRB Office maintains a copy of the 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 Research Protection Programs Director 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 alternate voting members. Examples include but are not limited to: Christus Santa Rosa Healthcare, University Hospital, University of Texas San Antonio,
6. The OIRB 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 the Initial Review of Research Policy and Procedure.

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

   a) 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.

   b) 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.

8. When the IRB reviews VA research that involves mentally disabled persons or persons with impaired decision-making capacity, there is at least one IRB member who is an expert in the area of the research involved in the review.

C. Filling Appointments

1. The IRB Director or Chairs solicit recommendations from a variety of sources, recruits potential members, and makes recommendations for appointments to the Boards. Prior to making the recommendation, the IRB Director ensures no individual from a developmental or business office is appointed as an IRB member. The OIRB staff send a copy of the recommendations through the VPR to the President who makes all final appointments (see HOP 1.6.6.).

D. OHRP IRB Registration/IRB Membership Roster

1. The Research Protection Programs Director, 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 IRB roster and denotes in which scientific capacity each member serves.

2. The Research Protection Programs Director or his/her designee makes a copy of the IRB Membership Roster available to the STVHCs R&D office. The Research Protection Programs Director or his/her designee maintains membership records. OIRB 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:

      (1) education, work, or interests are not solely in medical, behavioral or social science areas.

      (2) little or no scientific or medical training or experience

      (3) 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:

(1) academic degrees in science-related fields;

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

(3) 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.

E. After appointments and changes, IRB Membership is reported in accordance with the Reporting Policy and Procedure.

III. References

A. Definitions (see Glossary)

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