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I. Policy

A. IRB Chairs and members (primary, alternate and ex officio) are evaluated at least annually

B. The membership of the IRB is evaluated at least annually

C. The composition of the IRB is evaluated at least annually.

II. Overview

A. This procedure is ongoing

B. Summary of responsibilities

1. The IRB Director is responsible for evaluating the IRB Chairs and members on at least an annual basis.

2. The IRB Chairs are responsible for assisting the IRB Director in evaluating IRB members on at least an annual basis.

3. IRB Director and Chair collaborate to adjust the IRB membership to ensure ethical and regulatory review of research and appropriate representation at convened meetings.

III. Procedure

A. On-going assessment and evaluation of IRB members

1. The IRB Director and Chairs meet on a regular basis. As part of the agenda, the Director 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.

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

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

   a) the quality of the member’s pre-review and/or review for the convened meeting in identifying substantive scientific and ethical issues,
b) meeting attendance,

c) being adequately prepared for the meeting,

d) knowledge of regulatory criteria for approval,

e) knowledge of other clinical, ethical and institutional issues.

f) contributions to the board (i.e. number reviews conducted, subcommittee attendance)

4. As needed, the Director 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.)

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

6. Ongoing assessment of VA representative board members is shared with the South Texas Veterans Health Care System (STVHCS) Associate Chief of Staff for Research and Development (ACOS R&D).

B. On-going assessment and evaluation of IRB Chairs

1. The IRB Director and Assistant VP for Research Administration (AVPRA) meet on a regular basis. As part of the agenda, the Director and AVPRA 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 (as outlined in HOP 1.6.6.) are discussed.

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

3. As needed, the Director and AVPRA 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.)

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

C. Annual assessment of Membership

1. 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.

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

a) For the comprehensive evaluation:

(1) the Director determines whether the membership, collectively has the appropriate:
(a) knowledge of applicable regulatory and legal requirements;

(b) knowledge of professional standards and practices;

(c) knowledge of the local research context and research sites and their capabilities;

(d) knowledge of community standards and attitudes;

(e) scientific, scholarly, clinical, and professional expertise;

(f) racial, ethnic, and cultural diversity; and

(g) representation of participants' perspectives.

(2) 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 IRB Director, assisted by the IRB Chairs and the South Texas Veterans Health Care System (STVHCS) Associate Chief of Staff for Research and Development (ACOS R&D).

(3) Each prospective IRB member’s qualifications are reviewed during the recruitment process by a working group lead by the IRB Director and attended by the IRB Chairs, IRB Associate Director and the Institutional Reviewer. Prospective members are recommended for appointment to fulfill the needs of the IRB identified during the comprehensive evaluation of the membership.

b) For the individual evaluations

(1) Current IRB members are evaluated by the IRB Director and Chairs (and STVHCS ACOS R&D as appropriate) to ensure their understanding of the HRPP (ethical principles, policies and procedures, and regulations) and 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 obtained during the ongoing review process listed above is also used in making decisions about continued service on the IRB.

(a) IRB Chairs will provide performance feedback to all board members annually. Generally, the feedback is provided via email.

(2) Current Chairs are evaluated by the IRB Director and AVPRA (and STVHCS ACOS R&D as appropriate) 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 above is also used in making decisions about continued service on the IRB.

(a) The IRB Director will provide performance feedback to all IRB Chairs annually. Generally, the feedback is provided via email.

IV. References

A. Definitions (see Glossary)

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