responded to in a professional and timely manner and escalated to ORIC leadership as appropriate

xxii. Performing quality improvement and process improvement assessments with ORIC leadership, IRB Chair and Vice-Chairs to ensure smooth and efficient IRB operations. ORIC staff meet regularly to discuss any issues, such as the following:

a. Inconsistencies in protocol review or interpretation of IRB policies and guidelines among the IRB committees;

b. Questions related to the application of IRB policies, guidelines, and procedures;

c. Suggestions to improve services provided by ORIC staff;

d. Review of subject complaints, allegations of non-compliance, unanticipated problems, and conflict of interest management plans before forwarding the issue to the IRB for formal review, as required by regulations and Institutional policies: and/or

e. Review and revise existing IRB policies and procedures or to develop new IRB policies and procedures as needed.

H. Investigator Questions, Concerns, and Suggestions

There are several avenues through which Institutional investigators and research personnel may obtain answers to questions and bring forward concerns or suggestions regarding the HRPP.

IRB policies and procedures are posted on the ORIC website. Additionally, new policies and procedures are disseminated to investigators by email and regular educational workshops.

Investigators and research personnel should direct questions about the IRB review of particular protocols and general questions about the IRB review process to ORIC staff. However, investigators and research personnel may also consult with ORIC staff by telephone, or by making an appointment to meet with an individual staff person. Investigators should be mindful that ORIC staff and the IRB Chair or IRB Vice-Chairs cannot reverse a decision made by the convened IRB and cannot make most decisions on behalf of the IRB. However, when appropriate, ORIC staff or the IRB Chair or Vice-Chairs, will work with the investigator to bring concerns and/or suggestions to the convened IRB for consideration.

The IRB is charged with the protection of the rights and welfare of human research subjects. ORIC supports these efforts and is committed to providing excellent service to investigators and research personnel. Investigators with suggestions to improve that service or to improve the Institutional HRPP should direct their suggestions to the Director, ORIC, ORIC staff, or the IRB Chair or Vice-Chairs.

Questions, concerns, and suggestions related to the Institution's HRPP, including issues related to the IRB, may also be directed to the Senior Vice-President and Chief Operating Officer of the Research Institute (IO).

2.2 OTHER IRB MEETING ATTENDEES

A. Legal Counsel

The Office of General Counsel supports the IRB and ORIC mission in efforts to maintain an integrated Institutional compliance program and the independence and authority of the IRB under applicable law.

ORIC and the IRB Chair work closely with the Office of General Counsel on issues relating to interpretation and impact of applicable local, state and federal laws and regulations as they relate to the IRB's jurisdiction and responsibility. Counsel provides accurate and timely advice to the IRB and ORIC.

To promote this working relationship, the Assistant General Counsel regularly attends IRB meetings to address issues within the IRB's purview, assists the IRB Chair and ORIC staff in the review of policies, and provides guidance on specific issues as requested by the IRB Chair and ORIC staff.

General Counsel may also be involved in the in the review and resolution of issues concerning legal noncompliance as well as issues that arise under applicable federal laws that affect the conduct of research, such as FDA/OHRP.

General Counsel, and outside counsel if appropriate, advises on issues regarding reporting requirements.

B. Consultants, Observers, and Guests

The Institution is committed to having an IRB with the appropriate expertise to review clinical research protocols and take into consideration the medial, emotional, social, and psychological needs of the research subjects and their families. When necessary, the IRB may seek input by consultants in order to provide a comprehensive review. Consultants may be internal or external to the Institution and may be asked to assist in the review of an individual protocol and/or attend a meeting. The consultant may also provide education on a specific topic of interest to the IRB. A consultant may not have a conflict of interest as defined for IRB members. Consultants, observers, and guests do not count towards quorum and do not vote.

i. Consultants:

The Director, ORIC, and IRB Chair may determine upon the pre-review of a protocol that a consultant is needed, or any IRB member may request at any time during the review process to add a consultant to the review process. This determination is based on the topic of the protocol and expertise of the voting IRB members.

The IRB Chair selects the consultant and in doing so may consult with the department chair or any other individual as appropriate to select a suitable consultant. A consultant may be internal or external to the Institution and may be asked to review a protocol or provide education or guidance on a specific topic. The consultant provides a written report to the IRB Chair and may also be asked to attend a meeting.

Documentation of Use of Consultants:

a. Consultants are required to complete the IRB member Conflict of Interest disclosure form and the appropriate confidentiality form.

b. The use of the consultant is documented in the IRB minutes and in the IRB review for that submission.

c. The written report provided by the consultant is made available to the IRB members.

ii. Observers and Guests:

Observers and guest may attend the IRB meeting at discretion of the IRB Chair and are individuals with a particular interest and not regular attendees. Potential IRB members are invited to attend a meeting prior to joining the IRB. They are required to complete the appropriate confidentiality form, do not count towards quorum and may not vote. They are not allowed to observe the IRB final deliberation and vote for any protocols in which they may have a potential or actual conflict of interest.

iii. Investigators and Research Staff:

On occasion and by invitation from the IRB Chair, a PI and/or member of their research staff may be asked to attend the IRB meeting where their protocol will be discussed in order to address specific concerns of the IRB members. As with consultants and guest, they are also required to complete a confidentiality form. The PI/research staff will be allowed to attend only the portion of the meeting involving the discussion of their protocol and answer questions posed by the IRB. Once they have addressed the issues raised, the PI and/or research staff is dismissed from the meeting and are not present for the deliberation and vote on the protocol.