Chapter 5
IRB Structure and Membership

I. Structure and Composition. The IRB is ultimately accountable to the Board of Directors (or Trustees). IRB committee members are appointed by the Human Subject Signatory Official.

In accordance with DHHS and FDA regulations, HSS’s IRB is comprised of persons from various disciplines and departments, including non-scientific members, and community representatives not otherwise affiliated with HSS.

HSS will have sufficient expertise to review the broad range of research in which HSS commonly becomes involved, will be knowledgeable about all relevant regulatory requirements, and will remain impartial and objective in their reviews.

II. Appointment of IRB Members, Length of Service, and Duties. HSS’s Surgeon-in-Chief will appoint IRB members to open-ended terms.

Candidates for membership on the IRB may be recommended to the Surgeon-in-Chief by the IRB Chairperson, IRB members, and IRB administrative staff, and/or officials of HSS or its components that conduct human subject research. Every effort is made to select personnel from a variety of disciplines, which represent the types of research proposals submitted for review and approval.

The IRB must comply with the membership requirements of DHHS regulations at 45 CFR 46.107 and FDA regulations at 21 CFR 56.107 as follows:

A. The IRB will have at least five members;

B. IRB members will possess varying backgrounds to promote complete and adequate review of research activities commonly conducted at HSS and institutions for which the IRB is the designated IRB;

C. IRB members will be sufficiently diverse relative to race, gender, cultural background, and sensitivity to community attitudes so as to promote respect for the IRB’s advice and counsel in safeguarding the rights and welfare of human subjects;

D. IRB members will include persons able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice;
E. One nurse must be a voting member of the IRB and there must be at least one nurse vote on nursing related protocols that require full board review at a convened IRB meeting.

F. IRBs will consist of qualified persons of both sexes;

G. No IRB will consist entirely of members of one profession;

H. Each IRB will include at least one member whose primary expertise is in a scientific area;

I. Each IRB will have at least one member whose primary concerns are in non-scientific areas; and

J. Each IRB will include at least one member who is not otherwise affiliated with HSS and who is not part of the immediate family of a person who is affiliated with HSS or other institutions for which the IRB is the designated IRB.

Members vote to approve, require modifications in, disapprove, or defer research submitted to the IRB. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their areas of expertise, and serve as general reviewers on all research discussed at convened meetings. Members are also expected to conduct expedited reviews on behalf of the IRB when so designated by the IRB Chairperson.

Scientific members will have had experience in research involving human subjects, and will be recruited from among HSS’s staff or from the community.

Non-scientific members will have had expertise in human rights issues and/or ethical or legal issues considered to be relevant to human subject research, and will be recruited from among HSS’s staff or from the community.

Unaffiliated community-based members, and members of their immediate families, may have no formal or informal affiliation with HSS, other than their service on the IRB.

Any member of the IRB may be removed by the Surgeon-in-Chief (i) for failure to perform the duties of an IRB member, including failure to attend at least 2/3 of the IRB meetings held within any 12-month period; or (ii) for scientific misconduct, conflict of interest, or argumentative behavior such that review of research by the IRB is made difficult or impossible.

III. Appointment of IRB Chairperson, Length of Service, and Duties. The IRB will have a Chairperson who is well-informed concerning regulations relevant to the involvement
of human subjects in research.

The Chairperson of the IRB is appointed by the Human Subject Signatory Official in accordance with DHHS and FDA regulatory requirements. The IRB Chairperson will be appointed to a two-year term, renewable for consecutive two-year terms without limitation.

The IRB Chairperson has the following duties:

A. Conduct each meeting in an orderly manner. The Chairperson is responsible for chairing the meeting, conducting business so that each proposal is fairly and completely reviewed, seeing that the IRB reaches a decision on the disposition of each proposal and ensuring that these decisions are communicated to the individuals who submitted the proposal.

B. Review and approve research utilizing expedited review procedures in accordance with DHHS and FDA regulations.

C. Review, as needed and as delegated by the IRB in appropriate circumstances, responses from investigators to determine if they respond sufficiently to the IRB’s concern to allow approval under expedited review procedures and without being returned to the fully convened IRB.

D. Appoint qualified IRB members to review and approve research utilizing expedited procedures in accordance with DHHS and FDA regulations.

E. Sign correspondence on behalf of the IRB.

F. Appoint a Vice Chairperson following consultation with and agreement by other members of the IRB. The Vice Chairperson will be a senior member of the IRB who will assume the responsibilities of the Chairperson during any period of the Chairperson’s absence.

G. Review IRB policies and procedures at least annually to confirm current compliance with all Federal, State, and local requirements for the protection of human subjects.

The Surgeon-in-Chief may relieve an individual as IRB Chairperson for failure to fulfill the duties listed above. The Surgeon-in-Chief may remove the Chairperson from the IRB (i) for failure to perform the duties an IRB member, including failure to attend at least 2/3 of the IRB meetings held within any 12-month period; or (ii) for scientific misconduct, conflict of interest, or argumentative behavior such that review of research by the IRB is made difficult or impossible.
IV. **Alternate IRB Members.** The IRB, at its discretion, may recruit alternate members to substitute for regular members of the IRB. Alternate members must be listed on the IRB’s official membership roster, which must specify which member (or members) the alternate is qualified to replace. (Note: Although an alternate may be qualified to replace more than one regular member, only one such member may be represented by the alternate at any convened meeting.)

Alternate members will have voting rights, except that they may not vote at meetings attended by their respective regular members. Alternate members will be included in determining or establishing quorum at meetings when their respective regular members are absent, but not when those regular members are present.

Procedures for appointment, terms of appointment, length of service, and duties are exactly as for regular IRB members.

V. **Consultants to the IRB.** At its discretion, the IRB may recruit (non-voting) Consultants (sometimes referred to as “non-voting or ex officio” members) whose presence at the meetings would aid the IRB in conducting its duties.

A. **Continuing Consultants.** Continuing Consultants serve a fixed term and generally attend all IRB meetings. They may have access to all documents submitted to the IRB, may participate in IRB deliberations, and make recommendations to influence IRB determinations. However, Continuing Consultants may not vote on IRB determinations. Continuing Consultants will not be included in determining or establishing quorum at IRB meetings.

B. **Ad Hoc Consultants.** Ad Hoc Consultants serve on an as-needed basis and generally attend IRB meeting only when their special expertise is needed. Ad Hoc Consultants may have access to all documents submitted to the IRB that are pertinent to the research under review, may participate in IRB deliberations, and make recommendations to influence IRB determinations. However, Ad Hoc Consultants may not vote on IRB determinations. Ad Hoc Consultants will not be included in determining or establishing quorum at IRB meetings.

C. **Legal Counsel.** The IRB may include an Attorney appointed by HSS’s General Counsel to serve as a Continuing Consultant (i.e., non-voting member) to the IRB. In this capacity, the attorney will advise the IRB as to fulfilling its function to protect the rights and welfare of human subjects.

D. **Chief Privacy Officer.** The IRB includes the Hospital’s Chief Privacy Officer to serve as an ex-officio member. In this capacity, the Chief Privacy Officer will advise the IRB as to fulfilling its function as the Hospital’s Privacy Board.
VI. **Conflicts of Interest.** No IRB member may participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members, including the Chairperson, who have conflicting interests are required to disclose such interests and to absent themselves from deliberations, quorum counts, and votes on the relevant protocol. Such absences are recorded in the meeting’s minutes.

While many IRB members also conduct research, it remains their ongoing responsibility to disclose any real or apparent conflicting interests to appropriate Institutional officials and to absent themselves appropriately from any IRB deliberations on which they may be conflicted. For this reason, a Conflicts of Interest Declaration must be completed by each IRB member attending each meeting.

VII. **Education and Professional Development of IRB Members.** Upon receiving an appointment to the IRB, a member receives comprehensive reference materials (including this Manual) necessary to review research from an ethical and regulatory perspective. All IRB members must complete the initial educational module available on the CITI website and all corresponding exams (see Chapter 22). New members have the opportunity to observe several IRB meetings before they are assigned studies as primary or secondary reviewer. Members will periodically be provided with continuing education opportunities within HSS or at neighbouring institutions, and resources will be made available each fiscal year for one or more IRB members to attend national or regional human subject protection meetings. Additional continuing education requirements may be established as deemed necessary by the Surgeon-in-Chief.