Institutional Review Board (IRB): Composition and Management

Establishment of the IRB

Woman's Hospital Foundation (WHF) IRB was established under the authority of the Woman's Hospital Foundation to protect human subjects in research.

WHF IRB has the recognized authority by the WHF Board of Directors to review, approve, require modification, disapprove, and monitor for compliance all research involving human subjects at Woman's Hospital, including exempt research activities under 45CFR46.104 for which limited IRB review is a condition of exemption, or at an entity having a contract with Woman's to provide IRB oversight for that entity and listed on WHF's Federal-Wide Assurance (FWA). Resource needs for the IRB and HRPP program are reviewed annually at fiscal year budget planning.

IRB responsibilities and review of research

The involvement of human subjects in research is not permitted until the IRB has reviewed and approved the research protocol, informed consent form(s), case report forms, advertisements, survey instruments, and any other study-related materials. The IRB will review reports from the Research and Development Committee and/or the R&D Chair regarding the scientific merit of the submitted protocols and the feasibility of conducting the studies at Woman's.

Following approval, any additions or changes to the study must be reviewed and approved by the IRB prior to implementation, except where necessary to eliminate hazards to human subjects. The IRB has the authority to suspend and/or terminate a research project in progress, or place irreversible restrictions on said project when appropriate for the protection of human subjects.

The IRB is responsible for maintaining documentation of all research proposals including minutes of IRB meetings; initial and continuing reviews; waiver of authorizations, informed consent, and waiver of documentation of informed consent; revisions to active studies; terminations; and correspondence with administration, investigators, study personnel, and federal and/or state agencies.

Pursuant to 21CFR.56.112 and 45.R.46.112, research that has been reviewed and approved by the IRB may be subject to further appropriate review by officials of Woman's. WHF Board of Directors has ultimate authority over all research conducted at Woman's, but may not reverse an IRB decision that disapproves, suspends, or terminates a research study. WHF is not allowed to approve research that has not been approved by the IRB (or the IRB of record pursuant to a reliance agreement). The IRB does not have the authority to grant retroactive approval should a research study be initiated without IRB approval.

IRB authority

The IRB has the authority to require progress reports from the investigators, conduct study audits, oversee the conduct of the study, and place restrictions on a study, including suspending or terminating approval of research not being conducted in accordance with the IRB's requirements or research that has been associated with unexpected and/or serious harm to participants. Progress reports and emergency use reports from investigators are filed with the research proposals and continuing review activities. The IRB, or a designated third party, may observe the consenting process and research conduct.

The IRB serves as a liaison for regulatory or institutional information and updates among investigators, affiliates, sponsors, institutional administration, Food and Drug Administration, and the Office for Human Research Protections, which oversees compliance of the IRB with the Common Rule (45CFR46) and other regulations.

The IRB, upon its discretion, may invite individuals with competence in special areas to assist in the review of research protocols that require expertise beyond or in addition to that on the IRB. These individuals may direct questions to the investigators and advise the IRB, but may not vote. Consultants asked to supplement the review process will be queried as to if they have a conflict of interest; if a conflict of interest exists, it will be disclosed to the convened IRB at the meeting.

IRB composition

The IRB should be comprised of a minimum of five members, with a diversity of members. The IRB shall include at least one member whose background or profession is in a non-scientific area and at least one member whose primary concerns are in a scientific area. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children or terminally ill subjects, consideration shall be given to inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. A member who is unaffiliated with the institution and a member who represents the interests of research participants should attend at least 75% of the convened meetings.

IRB liability and conflicts of interest

The WHF IRB is specifically listed as an insured on the Woman's Hospital liability policy. Members of the IRB are covered under this policy up to a limit of $10,000,000.00.

The IRB review process should be free of conflict of interest and review should not be compromised by competing business interests. IRB members will be asked to disclose any conflicts of interest at the start of each IRB meeting. Individuals responsible for business development of the organization should not serve as IRB members.

IRB review processes, and the implementation of Woman's IRB policies and procedures, are to be conducted objectively and without undue influence over deliberations or processes. IRB members, Woman's HRPP and IRB staff, investigators, or research participants who believe that

an attempt has been made to unduly influence the IRB review processes or application of policies and procedures may contact the Institutional Official (IO) or Woman's Hospital Research Center staff to report a concern. The IO or other delegated senior HRPP staff members will review reports. Outcome of the review will be documented, the complainant provided with a response, and a corrective action plan instituted if deemed necessary.

Roles and Responsibilities

IRB Chair

The Chair of WHF Board of Directors appoints the IRB Chair. Each appointment is for one year, after which the Board of Directors may reappoint the Chair for another year without term limit. The Board of Directors also has the authority to remove the Chair.

The IRB Chair is responsible for the following:

- Sharing responsibility for the protection of human subjects involved in research activities at WHF.
- Chairing the IRB and presiding at meetings.
- The application and compliance of federal regulations, state and local laws, institutional policy, and IRB procedures.
- Supporting and facilitating the IRB process.
- Ensuring compliance with the FWA.
- Ensuring training and education of IRB staff, IRB committee members, and research staff.
- Ensuring performance and documentation of audit process to assure compliance.
- Signing all official notifications from the IRB.
- Voting as a member of the IRB.
- May require study modifications, which can include suspension of enrollment, when risks/complications arise which significantly endanger the subjects until discussion by the full board.
- May request files, reports, and additional data from investigators when questions arise about any study.
- May approve responses to applications submitted to the IRB that resulted in a vote of "approved, pending revisions."
- May approve minor modifications to ongoing protocols.
- May conduct an exempt and expedited review procedure as defined in the federal regulations and exercise all of the authority of the IRB, except disapproval.
- Review off-site Adverse Events and Unanticipated Problems on behalf of the IRB, and serve on the on-site Adverse Events subcommittee.

IRB Vice chair

The WH Board of Directors appoints the IRB Vice-Chair from among the current voting IRB members. The IRB Vice-Chair can assume all of the responsibilities of the IRB Chair in the event the Chair is absent and unable to conduct the business of the IRB.

Should the IRB Vice-Chair be unable to assume the responsibilities of the IRB Chair due to unavailability or conflict of interest, another IRB member may act as Chair in this capacity.

IRB members

The WHF Board of Directors appoints IRB members. IRB members are encouraged to attend at least 50% of the IRB meetings. A member who is unaffiliated with the institution and a member who represents the interests of research participants should attend at least 75% of the convened meetings. IRB members are responsible for the following:

- Reviewing all proposed human subject research to determine that:

a. risks to subjects are minimized;
b. risks to subjects are reasonable in relation to anticipated benefits (if any);
c. selection of subjects is equitable;
d. informed consent will be adequately obtained and documented in accordance with federal regulations;
e. adequate provisions exist to protect the privacy of subjects and maintenance of confidential data (when appropriate); and
f. adequate provisions exist for monitoring data collected (when appropriate)

- Requiring additional safeguards to protect subjects that are likely to be vulnerable to coercion (when appropriate).
- Conducting timely continuing review of approved research (as appropriate).
- Reviewing all proposed human subject research in accordance with
- the basic ethical principles (respect for persons, beneficence, and justice)
- Reviewing recommendations from R&D on scientific merit.
- Acting as a rotating member of the Adverse Events subcommittee when assigned by IRB Chair.
- Submit a CV annually to the research department and notify the IRB Chair of any new conflicts of interest
- Acting as a liaison subcommittee member when assigned by the IRB Chair

Any IRB member unable to be present at a convened meeting may participate via video conference or conference telephone call provided the member received all meeting materials to be reviewed prior to the meeting.

An alternate may be appointed by the Board of Directors to serve as a substitute for an IRB member. The Board of Directors will identify which IRB member for whom the alternate may substitute. Should an alternate attend the meeting in the place of the specified IRB member, the alternate will count toward the quorum and may cast a vote. An alternate may serve as a primary reviewer, provided all meeting materials to be reviewed were received prior to the meeting.

Should both an alternate and the specified IRB member attend a convened meeting, only the IRB member may cast a vote and count toward the quorum; the alternate may participate in discussion, but will not count toward the quorum and may not vote.

Human Protections Administrator (HPA)

The HPA is responsible for the following:

- Sharing responsibility for the protection of human subjects involved in research activities at Woman's Hospital.
- Maintaining knowledge and information of pertinent federal regulations, policies, and guidelines related to the involvement of human subjects in research.
- Coordinating continuing education of IRB members, investigators, and study staff relevant to the protection of human subjects in research
- Overseeing the maintenance of IRB records (including curriculum vitae and educational training certificates) and assuring records are accessible upon request to IRB members and federal agencies
- Reporting to the IRB any immediate changes in a research study, when notified, to ensure participant safety
- Reporting to the IRB, appropriate institutional officials, OHRP, FDA, and any other federal agencies, of any unanticipated problems or serious adverse events, when required
- Reporting to appropriate institutional officials and federal agencies any serious or continued non-compliance and any suspension or termination of IRB approval of research, as required
- Implementing appropriate oversight mechanisms to ensure compliance with the decisions and policies of the IRB
- Ensuring that all investigators who rely on Woman's IRB have documented their commitment to federal human subject protection requirements
- Providing policy and oversight for all aspects of research proposal submission to the IRB for review, approval, and renewal processes, as well as post-approval monitoring and auditing for IRB compliance
- Reviewing and updating policies, forms, and all other related reports to ensure compliance with OHRP and other governing agencies
- Disseminating and maintaining IRB policies and procedures
- Filing and maintaining required documents with the federal government, including the FWA and IRB Registration with OHRP
- Serving as a resource to investigators for interpretation of R&D, IRB, and federal guidelines and policies for the conduct of research
- Overseeing day-to-day operations of the IRB, including indirectly supervising secretarial personnel and the IRB budget
- Providing orientation for new IRB members and providing them with copies of federal regulations, institutional policies, and IRB procedures relating to human subjects research

IRB secretary

The IRB Secretary is indirectly supervised by the HPA and directly supervised by the IRB Chair. The IRB Secretary is responsible for the following:

- Sharing responsibility for the protection of human subjects involved in research activities at WHF.
- Responding to each investigator's request with instructions regarding the application process for IRB review.
- Scheduling IRB meetings.
- Preparing the agenda for IRB meetings.
- Providing for the distribution of the meeting agenda and meeting packet that includes all of the study materials to be considered at the IRB meeting
- Taking minutes, filing minutes, and distributing minutes to IRB members in a timely fashion.
- Keeping an updated file on all studies submitted to the IRB.
- Maintaining a file of curriculum vitae and educational training
- certificates for all IRB members and active investigators.
- Maintaining an annual roster of all IRB members.
- Performing and documenting audits of IRB files to ensure compliance.
- Maintaining IRB records and ensure that the records are accessible upon request to IRB members and authorized federal officials. Files are kept in a locked file cabinet and have limited access.
- Maintaining the electronic database of IRB records