Institutional Review Board (IRB) Meetings and Agenda

The IRB will follow written procedures for:

· conducting its initial and continuing review of research and for reporting its findings and actions to the investigator. The review of protocols and actions of the IRB will be documented and conveyed in writing to the principal investigator, the R&D Committee, (through approved minutes) and, when appropriate, the granting agency;

· determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

· ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;

· ensuring prompt reporting to the IRB, appropriate WHF officials, and the sponsoring entity or applicable federal agencies of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

IRB meetings

The IRB will meet as needed to review research proposals involving human subjects. The IRB will meet at least semi-annually, but not more frequently than monthly. Meetings will convene on the Woman's Hospital campus unless otherwise specified by the IRB Secretary in the meeting invitation. Any resources necessary for presentation of research will be provided. The IRB Secretary will distribute an agenda, official notification of the time and place of the meeting, previous month's minutes, and documents for review at least one week prior to each scheduled meeting under the direction of the IRB Chair. Volume of agenda items is controlled through deadlines for submissions established at the beginning of the calendar year.

The meeting will commence, conducted, and adjourned under the direction of the IRB Chair (or Vice Chair). The IRB Chair and Vice Chair are voting members of the IRB and their presence counts toward the quorum.

For each initial study, continuing review, and application for revisions to an existing study, the IRB may:

· Approve the application as submitted

· Approve the application with revisions, including if the revisions may be reviewed by the IRB Chair on behalf of the board or if the revisions require full board review

· Table the application and request additional information or substantial modifications. A tabled proposal requires review by the convened IRB of any additional information that was requested or any requested modifications to the study.

· Acknowledge and/or validate adverse events and/or protocol deviations as submitted

· Acknowledge and/or validate adverse events and/or protocol deviations when revisions to protocol or informed consent are required

· Acknowledge temporary or permanent closure to subject entry

· Acknowledge completions

· Disapprove the application

· Suspend or terminate any research study

The IRB Chair will notify the investigator in writing of any IRB decision (approval, acknowledgement, or disapproval), required revisions, or if the IRB requests more information for consideration at the next convened meeting.

Assignment of reviewers

The Human Protections Administrator (HPA) will assign primary and secondary reviewers for each study on the proposed agenda (initial studies, continuing reviews, and major revisions). This assignment will be based on expertise as listed in the IRB roster. If there is no member available to provide the expertise needed for a comprehensive review, then non-voting consultants may be approached to provide their expertise to the board. These consultants may review the study prior to the convened meeting and/or attend the meeting to offer their assessment to the board members.

A newly-appointed IRB member is considered experienced to be a reviewer once he/she has met with the HPA for orientation, attended a minimum of three convened IRB meetings, and completed CITI training requirements for the protection of human subjects in research.

Use of consultants

When and if is the HPA and/or IRB Chair determines that consultants or experts will be required to advise the IRB in its review of the study, the IRB Chair will distribute copies of the protocol to said consultants or experts as soon as possible or a minimum of one week prior to the next meeting. Any conflicts of interest of the consultant should be disclosed on the reviewer form. The consultant's findings will be disclosed to the board during the IRB meeting by the consultant, through a summary presentation by the HPA, or as a written summary of the consultant's findings distributed to IRB members.

Quorum

The IRB may only review proposed research at convened meetings at which a majority of the voting members of the IRB are present, including at least one member whose primary interest is in a nonscientific area. The HPA will determine if a quorum is present at the beginning of the meeting and prior to voting. A quorum determination will be recorded in the IRB meeting minutes by the IRB Secretary. No official actions may be taken at a meeting where a majority of members or a nonscientist is not present. If more than 50% of the members are present (50% +1), including a member whose primary interest is in a nonscientific area, a quorum is present.

If a quorum is lost during the meeting, including if the non-scientist leaves the meeting, no votes can be taken until a quorum is restored A physician member must be present when reviewing studies involving FDA-regulated articles. For studies on the agenda intending to enroll vulnerable subjects, a member or consultant knowledgeable of these subjects should be in attendance at the meeting.

Attendance via telephone conference call / video conference

Wherever possible, IRB meetings should take place with all participating IRB members physically present; however, circumstances sometimes warrant conducting IRB meetings via telephone conference call or video conference. Therefore, provided that each participating IRB member has received all pertinent material prior to the meeting **and** can actively and equally participate in the discussion of all proposals (each member can hear and be heard by all other participating members), then official IRB actions may be taken at a meeting in which members participate via telephone or video conference.

Conflicts of interest during a meeting

No IRB member (or consultant) may participate in the initial, continuing review, or review of an unanticipated problem or review of noncompliance of a project in which the member (or consultant) has an actual conflict of interest or the appearance of a conflict exists, except to provide information. IRB members should absent themselves from the meeting room when the IRB discusses and votes on research in which they have a conflict of interest. In order to avoid real or perceived conflicts of interest:

1. no participating IRB member will vote on a study in which he or she acts as a principal, co-investigator, or member of the study staff;

2. no participating IRB member/consultant may hold an equity interest (for example, partnership, stock, or profit-sharing) in the organization requesting IRB review;

3. no participating IRB member/consultant may be paid more than reasonable compensation or receive more than reasonable benefits for IRB-related activities; **AND**

4. no IRB member/consultant may receive compensation or benefits under arrangements that could impede or discourage objective decision-making on behalf of human subjects

5. no IRB member should vote on a study submitted by a family member

6. IRB members should abstain from voting due to any other conflict of interest, financial or nonfinancial, as appropriate

Any recusal by an IRB member/consultant due to conflict of interest will be documented in the meeting minutes. The recused member will not count toward the quorum and will abstain from discussion and voting on the research study.

Procedure for loss of a quorum

Should the quorum fail during a meeting (for example, those with conflicts being excused resulting in loss of majority, early departures, loss of a non-scientist), the meeting will be terminated from further votes until the quorum can be restored.
If there is not a quorum (50% of members + 1 and at least one nonscientist present) at a convened meeting of the IRB, all protocol submissions will be tabled until the next meeting of the IRB. No voting will be allowed. If a quorum is lost during the meeting, such as recusal of a member due to conflict of interest, no voting on any remaining protocols will be allowed until a quorum is reestablished. Discussion of the protocols and questions for investigators will be allowed, but no voting may take place until a quorum is present.

Voting requirements

Each IRB member will have one vote, indicated verbally or by show of hand, for rendering decisions upon research protocols and/or projects that come before the IRB for review and approval. Provided that any members attending via teleconference have received the meeting materials prior to the meeting and can take part in discussion and voting, their vote may be taken verbally. The IRB Secretary will record the vote. A simple majority of quorum voters, including a non-scientist, is needed to approve or disapprove a study. Consultants and non-members are not allowed to vote. Votes by proxy are not allowed.

Criteria for approval will be listed on paper in front of each member for consideration during voting. All meeting materials necessary for consideration of protocols on the meeting agenda will be mailed to all IRB members prior to the meeting.

Member Attendance

A member unaffiliated with Woman's Hospital Foundation should attend at least 75% of the IRB meetings. An IRB member who represents the perspective of research participants should be generally present at convened meetings, attending at least 75% of the meetings. This attendance will be documented in the IRB meeting minutes. If a research protocol that involves categories of participants vulnerable to undue influence or coercion (such as economically-disadvantaged persons), an IRB member knowledgeable and experienced in working with such populations should be present. A physician member should be present for voting on FDA-regulated studies.

Subcommittees

The IRB Chair will appoint a rotating Adverse Events subcommittee, who will work with the Chair, to be contacted in case of local unanticipated serious adverse events and unanticipated problems adverse device effects, major deviations from the approved protocol, problems involving the conduct of studies or subject participation, and other unexpected findings affecting risk/benefit ratio. The rotating subcommittee is selected in alphabetical order composed of three IRB members and the Chair. The term begins at the end of each meeting until the day of the next meeting. Each member of the subcommittee and the Chair are to be contacted by the IRB Secretary in the event of these types of adverse events occurring on site. The subcommittee member should refer to and follow the instructions on the Adverse Event Reporting Form.

Agenda

A meeting agenda will be distributed to all members prior to the IRB meeting in the IRB packets. The meeting agenda will contain: a determination of the roll, including non-members present, and presence of a quorum; approval of the previous meeting's minutes; request for disclosure of any conflicts of interests from board members present; a list of studies approved since the last meeting via expedited or exempt review; a call for announcements; educational materials included in the meeting packet; assignment of the Adverse Events Subcommittee; and a list of new business.

New proposals

Before a convened meeting, the HPA will assign primary and secondary reviewers based on expertise for each study to be presented for review by the full board. The reviewers will document their findings using an IRB Review Checklist, present their recommendations to the full board, and lead the discussion at the convened meeting. Packets containing review materials and reviewer forms will be distributed to all IRB members via mail at least one week prior to the IRB meeting. All members will also receive a list of initial approval criteria at the meeting.

The approval criteria are:

• Risks to subjects are minimized and reasonable in relation to anticipated benefits;
• Selection of subjects continues to be equitable;

• Informed consent is sought or waived in accordance with 45 CFR 46.116 as well as 21 CFR 50.25 for FDA-regulated research.

• Informed consent will be documented or documentation waived in accordance with 45 CFR 46.117 and 21 CFR 50.27 for FDA-regulated research.

• The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate;

- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate; and
- Appropriate safeguards for vulnerable subjects are provided.

- If multi-site research, the study management of information relevant to protection of subjects is adequate.

The R&D Committee will provide their comments, questions, conflict of interest assessment, and any controverted issues regarding scientific merit and availability of resources to the R&D Secretary prior to the meeting. The HPA, IRB Chair, or primary/secondary reviewers will present these findings to the full board prior to discussion and voting. Any reported findings from the R&D Committee will be documented in the meeting minutes.

Primary and secondary reviewers will receive and be responsible for reviewing the following materials:

a. Complete application packet;
b. Protocol
c. Case report forms;
d. Abstract or protocol summary (if available);
e. Informed consent and/or patient scripts;
f. Authorization to release protected health information form;
g. For NIH-supported clinical trials, a copy of the NIH-approved sample informed consent document(s) and the complete NIH-approved protocol;
h. Letters of Cooperation and/or IRB letters of approval from collaborating institutions;
i. Surveys, questionnaires or videotapes;
j. Financial Conflict of Interest forms and resolution plan from R&D (if a conflict of interest is determined to exist);
k. Grant applications;
l. Investigator's brochure, if applicable;
m. Advertisements
n. If applicable, outside reviewer(s)'s scientific merit report
o. The IRB may also request periodic progress reports from the investigator(s) in order to oversee the conduct of the study.

All other IRB members will receive all of the above materials, but are primarily responsible for reviewing the following materials:

a. Abstract or protocol summary, if available, otherwise objectives and study treatment schedule located within the protocol;
b. Financial Conflict of Interest forms and resolution plan from R&D (only if a conflict of interest is determined to exist);
c. Informed consent and/or patient scripts;
d. If applicable, outside reviewer(s)'s scientific merit report (given at meeting);

e. Authorization to release protected health information form.
f. For NIH-supported clinical trials, a copy of the NIH-approved sample informed consent document(s) and the full NIH-approved protocol;

Continuing review of approved research not meeting exempt or expedited criteria must occur at an interval appropriate to the degree of risk as determined by the IRB, but not less than once per year. The IRB may decide that some protocols will require review more often than annually. Some studies may require review every six months or every three months. This determination may be based on:

· Multi-center clinical trials that have a high incidence of adverse events

· Studies with a proposed high risk / benefit ratio and the nature of the risks of the study, and studies with uncertainty regarding the possible risks

· The vulnerability of the subject population

· The experience of the investigators conducting the study

· Any previous noncompliance from investigators or previous problems conducting research studies found in IRB audits

· The projected rate of enrollment of subjects

· If the study involves novel therapies

Continuing review by the full board

Before a convened meeting, for each continuing review (excluding those projects that either meet one or more of the exemption categories as authorized by 45CFR46.101(b) or one or more of the expedited categories as authorized in 45CFR46.110), the HPA will assign primary and secondary reviewers. The reviewers will document their findings using an IRB Reviewer form, present their recommendations to the full board, and lead the discussion at the convened meeting. Packets containing review materials and reviewer forms will be distributed to all IRB members via mail at least one week prior to the IRB meeting. All members will also receive a list of continuing review approval criteria distributed at the meeting.

The approval criteria are:

- The risks to the subjects continue to be minimized and reasonable in relation to anticipated benefits
- The selection of subjects continues to be reasonable in relation to the anticipated benefits
- Informed consent continues to be appropriately documented, and
- There are:
    - Provisions for safety monitoring of the data
    - Protections to ensure the privacy of subjects and confidentiality of data
    - Appropriate safeguards for vulnerable populations

If substantive changes are required that will require full board review prior to implementation, these revisions should be submitted for review at the next convened IRB meeting. If the study expires before the revisions or conditions are approved, all research activities must stop, all interventions and interactions with current participants must stop (unless the IRB determines they must continue for participant safety or their best interests), and no new participants may be enrolled until the study has been reviewed by the IRB for re-activation and approval of the requested revisions.

If there are any new significant findings, either as reported on the Continuing Review / Revision form or discussed at the convened meeting through the review process, that may affect participants' willingness to continue taking part in the study, these findings will be provided to participants.

Primary and secondary reviewers will receive the following materials:

i. Progress report form (Continuing Review Submission Form) including:
   a. a summary of the adverse events/protocol deviations/unanticipated problems for the past approval period;
   b. The number of participants enrolled
   c. The number of participants withdrawn and reasons for withdrawal
   d. Any complaints received about the study
   e. A list of any revisions or amendments
   f. A summary of any relevant recent literature
   g. Any interim findings
   h. The investigators' current risk/benefit assessment based on study results

ii. Protocol with proposed changes highlighted or summary of changes;
iii. Abstract or protocol summary if available;
iv. For NIH-supported clinical trials, a copy of the NIH-approved sample informed consent document(s) and the full NIH-approved protocol;
v. Informed consent and/or patient scripts with proposed changes highlighted;
vi. Informed consent checklist of all required elements
vii. Authorization to release protected health information form with proposed changes highlighted;
viii. Case report forms;
ix. Surveys, questionnaires or videotapes;
x. Updated Letters of Cooperation and/or IRB Letters of Approval from collaborating institutions;
xi. Grant applications;
xii. Updated Financial Conflict of Interest forms and resolution plan from R&D (if a conflict of interest is determined to exist);
xiii. Investigator's brochure;
xiv. Advertisements;
xv. If applicable, outside reviewer(s)'s scientific merit report (given at meeting);
xvi. Data Safety Monitoring Board reports; AND

xvii. Reports to or from the FDA and study sponsor.

All other IRB members will receive all of the above materials, but are primarily responsible for reviewing the following materials:

a. Progress report form including a summary of the adverse events/protocol deviations for the past approval period;
b. Abstract or protocol summary, if available, otherwise objectives and study treatment schedule located within the protocol;
c. Updated Financial Conflict of Interest form and resolution plan from R&D (if a conflict of interest is determined to exist);
d. Informed consent and/or patient scripts with proposed changes highlighted, including informed consent checklist of all required elements
e. If applicable, outside reviewer(s)'s scientific merit report (given at meeting); **AND**
f. Authorization to release protected health information form with proposed changes highlighted.

Major amendments

At a convened meeting, the IRB will review any and all proposed major changes to approved research studies. All members will receive and review any amended documents in the IRB reviewer packet prior to the meeting. This review excludes those projects that either meet one or more of the exemption categories as authorized in 45 C.F.R. 46.101(b) or more of the expedited categories as authorized in 45 C.F.R. 46.110.

The IRB will review the proposed changes to determine that:
• Risks to subjects continue to be minimized and reasonable in relation to anticipated benefits;
• Selection of subjects continues to be equitable;
• Informed consent is sought or waived in accordance with 45 CFR 46.116 as well as 21 CFR 50.25 for FDA-regulated research.
• Informed consent will be documented or documentation waived in accordance with 45 CFR 46.117 and 21 CFR 50.27 for FDA-regulated research.
• The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate;
o There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate; and
o Appropriate safeguards for vulnerable subjects are provided.
o If multi-site research, the study management of information relevant to protection of subjects is adequate.

If any significant new findings arise from the review of these revisions that might relate to participants' willingness to continue participation, these findings will be provided to participants, including participants who have completed the study, as appropriate.

If changes to the study have been implemented without IRB approval for participant safety concerns, these changes will be promptly reported to the IRB and will be reviewed at the next

convened meeting in order to determine that these changes were necessary to ensure participant welfare.

Adverse Events / Unanticipated Problems

Unanticipated serious adverse events (possibly related to the study) and unanticipated non-serious adverse events (possibly related to the study), adverse device effects, major deviations from the approved protocol, problems involving the conduct of studies or subject participation, and other unexpected findings affecting risk/benefit ratio may be reviewed by the full board. At a convened meeting, the IRB will review and acknowledge the submitted event and any R&D reports and/or validate the IRB Chair's decision regarding these reports. Factors that will be considered are as follows:

· the seriousness of the event;

· if the event is described in the protocol and informed consent;

· the investigator's recommendations as to whether the event was a direct result of a subject's participation in the research study; and

· if the facts surrounding the event might affect the risk/benefit ratio and/or the informed consent.

Closures

Investigators may submit their study for closure when the study is completed. The policies for submitting closures and permanent/temporary closure to subject entry are explained in the Completion and Closure to Entry policy.

Reporting of expedited and exempt reviews

All initial proposals, continuing review (when required by laws or regulations) of research, and revisions of previously-approved studies approved via expedited or exempt review will be listed on the agenda for the next possible convened meeting of the full board. The agenda will include the specific permissible category(ies) justifying the approvals.

Noncompliance

Any serious or continuing noncompliance with the regulations or requirements of the IRB will be reported by including an item on the agenda for the next possible convened meeting.

Audits

The results of any auditing or monitoring process will be reported on the agenda for the next possible convened meeting; however, if information gained during the auditing or monitoring process indicates that human subjects of a research study are exposed to unexpected serious harm, the IRB Chair may suspend or terminate the research study prior to the next regularly scheduled meeting.

IRB education presented at meetings

At each convened meeting, education will be provided to IRB members. The education may include, but not be limited to, the following:

a. Current federal regulations;
b. Local policies and procedures;
c. Changes in federal regulations;
d. Changes in local policies and procedures;
e. Cases of interest regarding protection of human subjects in research;
f. Other items as requested by the IRB