IRB Review and Determinations

If an investigator is uncertain if their research proposal meets the definition of human subjects research, refer to the policy Determinations of Whether or Not a Proposed Activity is Research Involving Human Subjects.

IRB Actions

The IRB will review and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by 45CFR46.111 or 21CFR56.111, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)). 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.

For initial research study proposals

In order to approve research submitted for initial review or reactivation, the IRB must determine that the following requirements are satisfied:

a). Risks to subjects are minimized by using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b). Risks to subjects are reasonable in relation to the anticipated benefits, if any, and in the importance of the knowledge that may result.

c). The selection of the subjects is equitable, taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable population (such as children, those vulnerable to societal marginalization or discrimination, and economically or educationally disadvantaged persons), the selection criteria, and the recruitment process.

d). Informed consent will be sought from each prospective subject or the subject's legally authorized representative and the informed consent will be appropriately documented.

e). Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

f). There are adequate provisions to protect the privacy of subjects and maintain the confidentiality of the data and identifiable private information (including that obtained from biospecimens).

g). When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards are implemented to protect the rights and welfare of these subjects.

For studies that require consenting of participants, the IRB will determine that the consent process incorporates all of the following:

A statement that the study involves research

An explanation of the purposes of the research

The expected duration of the participants' participation

A description of the procedures to be followed

Identification of any procedures that are experimental

A description of any reasonably foreseeable discomforts or risks to the participant

A description of any benefits to the participant or others which may be reasonably expected to result from the research

A disclosure of any alternatives, if any, that may be advantageous to the participant

A description of the extent, if any, to which confidentiality of records identifying the participant will be maintained

A contact person for questions about the research

A contact person for questions regarding research participants' rights

A contact person for any event of a research-related injury

A contact person on the research team for questions, concerns, or complaints

A contact person for someone independent of the research for problems, concerns, questions, information, or input

A statement that participation is voluntary

A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled

A statement that the participant may withdraw at any time without penalty or loss of benefits to which the participant is otherwise entitled

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
- The high-risk nature of the proposed study
- Studies with a proposed high risk / benefit ratio
- 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

The IRB will not approve, and may suspend or terminate research involving human subjects, if it finds that:

1. The information submitted to the IRB by the investigator (or sponsor) contains an untrue statement of facts pertinent to the IRB's decision-making, or omits pertinent information required by the IRB to review and evaluate the proposed research protocol.

2. The report of investigations concerning the study treatments or interventions, assessment procedures, investigational new drug (IND), medical device, or other article is inadequate to support a conclusion that it is reasonably safe to initiate or to continue the investigation.

3. The investigator does not possess the scientific or medical education or experience appropriate to qualify the investigator as a suitable expert to conduct the investigation or to assure the safety and/or effectiveness of study treatment(s), intervention, procedures, IND administration or medical device use.

4. The available facilities, including those for the clinical laboratory, inpatients, outpatients, fitness activities, affiliate or collaborative sites, and/or the medical support are inadequate to assure that the investigation will be conducted properly and in conformity with the proposed clinical protocol. Assessment of study feasibility will be considered by the Research and Development Committee and the IRB will defer to that assessment.

5. The investigational research does not conform to and/or is not being conducted in accordance with the approved protocol and/or the requirements of the IRB, FDA, Woman's Hospital, WHF, Woman's Health Research Center, or other affiliate or collaborative site pertaining to human subject research.

6. The proposed research exposes or may expose subjects to undue risks.

If the IRB disapproves research, or requires modifications, the disapproval or requirement of modifications cannot be overturned by any other authority.

For research submitted for continuing review

The criteria for approving the continuation of a study during continuing review are the same as those used in approving the research at its initial review. The IRB (or IRB Chair, in the case of expedited continuing review), will review the submitted documents to determine that:

- Risks to subjects will continue to be minimized;
- Risks to subjects continue to be reasonable in relation to anticipated benefits;
- Selection of subjects continues to be equitable;
- Informed consent continues to be adequate and appropriately documented;
- The research plan continues to make adequate provision for monitoring the data collected to ensure the safety of subjects;
- the information contained in the informed consent form remains accurate and complete
- If new information obtained during the course of the research should be added to the consent form or if currently enrolled subjects should be notified of new information;
- there continues to be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data and identifiable private information (including biospecimens); AND

- there continue to be appropriate safeguards included in the research plan to protect vulnerable subjects

Consequences of not obtaining IRB review

Failure to obtain IRB approval or an exempt determination from the IRB is considered non-compliance. The IRB will not grant post-hoc approval for research conducted without prior IRB review and approval. The IRB will not grant post-hoc exempt or not human subjects research determinations for research already conducted at the time of the determination request.

The implications of engaging in activities that qualify as research subject to WHF IRB review without obtaining such review and approval are significant. If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge or that he or she may wish to publish the results, it is important that the investigator submit a proposal to WHF IRB as soon as possible and before continuing.

Investigators who request approval to continue research that was not previously reviewed or to use data that was collected without proper WHF IRB approval face the possibility that WHF IRB will disapprove their application. WHF IRB may choose not to approve such applications where the investigator has attempted to circumvent WHF policies regarding research involving human subjects by collecting data as non-research and then applying to use them as existing data.

In addition, under WHF's FWA, investigators may have to be reported to the FDA and/or OHRP for non-compliance of IRB and/or federal policies. It is therefore in the investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future prior to commencing the work.