Research Submission Requirements

Submission of proposals to the IRB is limited to:

- Woman's Hospital Foundation (WHF) employees
- active medical staff
- investigators outside the institution collaborating with WHF employees and/or active medical staff

Proposals that are clinical in nature and have investigators that are not WHF active medical staff members or employees must have a WHF active medical staff member serve as a co-investigator or medical monitor. No subjects may be enrolled or recruited prior to receipt of written final approval of the application from the IRB.

Research involving human subjects may not commence until the following approvals are obtained:

- Research and Development Committee (R&D)
- Any hospital departments involved in the research (via a Department Approval Form)
- Institutional Review Board (IRB)

All submitted research studies for will be reviewed by the R&D prior to IRB submission. Some studies may be reviewed by the R&D Chair on behalf of the full committee, and may be sent to additional R&D Committee members or consultations at the discretion of the R&D Chair. Any comments or questions from the R&D may be submitted to the IRB for inclusion in the IRB reviewer packets, emailed to the primary and secondary IRB reviewers, or may be conveyed by the HPA during discussion at the IRB meeting. Comments and questions from the R&D may also be addressed by the investigators prior to the IRB meeting or expedited/exempt IRB review.

General requirements for submission of research proposals

The IRB requires that researchers submit their applications in a uniform format to facilitate review. This format may be substantially different from that which is prepared for other purposes (e.g., applying for funding or submitting for publication). Pages should be numbered consecutively.

For guidance on requirements for informed consent forms, refer to the policy Informed Consent Elements and Requirements.

All initial and continuing review applications should include the IRB submission form and:

- the most recent version of the protocol
- informed consent form
- HIPAA authorization form

- any associated study materials: advertisements, case report forms, logs, scripts

The HPA and/or IRB Secretary will review all research submissions prior to submitting them to the IRB Chair for exempt/expedited review or to the IRB for full board review. Incomplete proposals will be returned to the investigator, delaying review of the application. If the submission is incomplete or requires revisions, the HPA will communicate with the investigators to resolve any discrepancies prior to submission for R&D and IRB review.

The HPA and/or IRB Secretary will review submissions to ascertain that:

- all study materials have been included in the submission
- information and documents are consistent with the previously approved protocol (for continuing review submissions)
- the current informed consent form is submitted (for continuing review submissions)
- the informed consent form contains all required elements of 45CFR46
- any important matters regarding the study that may be to the interest of the IRB that should be discussed at the convened meeting are addressed
- all hospital departments involved in the study have given their approval and support to the study
- all investigators and coordinators are current on CITI education

Submission materials for initial research proposals

All initial research proposals should be submitted to the Woman's Health Research Center with an Initial Study Application and:

- A written protocol with title and version date. Protocol requirements are listed separately in this policy. If the protocol covers multiple sites, a site-specific protocol should be included detailing what will be done specifically at Woman's Hospital. Include the complete DHHS-approved protocol, if applicable.
- Copies of any screening forms, surveys, questionnaires, advertisements, demographic forms, and case report forms / data collection forms
- A signed Investigator Agreement for each investigator (for full board and expedited studies)
- A signed Financial Interests Disclosure form for each investigator, if the study is funded
- Curriculum Vitae for each investigator, including copies of licenses and degrees (for full board and expedited studies)
- Certificate of completion of CITI training for each investigator, found online at citiprogram.org, if not previously submitted (for full board and expedited studies)

- Department Approval Forms from each department involved in the study, signed by the director and VP from each department
- Human Resources requirements for non-employee study personnel, which may include confidentiality statements, proof of training, and appropriate blood tests and vaccinations. TB skin testing documentation (within the past 365 days) is required for non-employees that will be on Woman's campus conducting research.
- Informed consent form (including the cover sheet) or subject information sheet, unless requesting a waiver
- Completed informed consent checklist
- Suggested/Sample informed consent form (for NIH studies)
- Patient scripts for recruiting/enrollment, if applicable
- An electronic copy of the informed consent form sent via email to the HPA
- Authorization form (HIPAA form), unless requesting a waiver
- Radiation Safety Committee approval for studies involving radiation exposure, other than for diagnostic or treatment procedures

Additional requirements for studies using investigational drugs or devices:

- Two copies of the Investigational Brochure
- Proof of IDE/IND (for investigational drug or device studies, and studies involving dietary supplements). The HPA will verify the IDE/IND with FDA.

Information to include in the research protocol

The following elements should be included in the study protocol:

- Names of the Principal Investigator and co-investigators, including addresses and phone numbers on the title page
- Literature review (if applicable) and purpose of the study
- Study procedures, including design and methodology
- Study subject population and recruitment plan
- Procedure for consenting subjects: who will perform the consent process, including use of translated consent forms (if applicable) and obtaining assent from minors, how coercion will be minimized, and if there is any waiting period between informing the participant and obtaining consent
- Study subject inclusion/exclusion criteria

- Which hospital departments will be involved and what they will contribute
- Risks and benefits for study participants
- Anticipated number of subjects to be enrolled, duration of subjects' participation in the study, if there is a follow-up period, and for how long
- Justification for use of special or vulnerable populations
- How data will be analyzed and what will be done with the data upon study completion (submitted for publication, dissertation only, etc.), how the data will be stored and for how long
- How adverse events will be handled and reported
- Study sponsor information and what they are providing
- A plan for keeping records and data confidential
- For investigational drug studies (IND and FDA-approved drugs), drug information should include: drug name, drug classification, dosage form available, normal dose ranges, pharmacological action of the drug, contraindications, potential side effects or adverse reactions, symptoms of toxicity, rationale for dosage used in the study, a plan for drug administration, procedure for breaking code or double-blinded studies in an emergency
- For investigational device studies, device information should include a description of the device and how it works and a determination from the sponsor of significant risk (SR) or non-significant risk (NSR)
- Bibliography or Works Cited

Human Resources requirements for non-employees

Any non-employee that will be on campus to conduct research should complete the following human resources requirements and submit them to the HPA for forwarding to the HR Department:

- The HR Approval form from Research
- Copy of driver's licenses
- Contact information (including an e-mail address) so Woman's can initiate the background screening process with a third party background check company
- Complete, sign, date, and return the last two pages of the Non-Employee Service Provider Agreement and Non-Employee Confidentiality Agreement from the non-employee packet.
- Arrange a drug screening with the Employee Health Services department
- Documentation of a TB skin test (within the last 12 months). A TB skin test can be done through Woman's Employee Health or through the investigators' institution, if available.

Submission of research for continuing review

For continuing review to a previously approved study, the investigator should submit a Continuing Review / Revision application and all requirements for an initial submission as listed above. All documents should be the most recent IRB-approved versions, and consent forms submitted should be current, clean copies with no approval stamp.

Additional requirements:

- a summary list of any adverse advents and minor protocol deviations that occurred during the previous period of approval
- a summary list of any serious adverse events or unanticipated problems reported to the IRB during the previous period of approval
- updated, signed Conflict of Interest Disclosure forms for each investigator and study coordinator
- any updated/renewal CITI training certificates
- any publications or abstracts in progress
- Any requested revisions included in the submission should be submitted with tracked/red-lined copies of the revised documents

Submission of research for revisions

For review of revisions to a previously approved study, the investigator should submit:

- A Continuing Review / Revision application
- Tracked/red-lined copies of any revised materials
- Clean copies of any revised materials
- If the revision includes the addition of any investigators: CVs, copies of licenses, CITI training certificates, Investigator Agreements, and Financial Conflict of Interest forms

Reactivation or research previously terminated

A reactivation of a previously approved and terminated protocol will be reviewed as an initial submission. All materials related to the study (e. g., protocol, informed consent, authorization form, advertisements, etc.) should be submitted along with an IRB Initial Study submission form.