HUMAN RESEARCH PROTECTIONS PROGRAM (HRPP)

SCOPE AND COMPONENTS

Woman's Hospital Foundation Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in human research. The Human Research Protection Program encompasses all employees, particularly certain departments and key personnel, fulfilling their roles and responsibilities described in this plan. Throughout this document "Institution" refers to Woman's Hospital Foundation.

Woman's Hospital conducts human subjects research under its Federal-wide Assurance (FWA) issued by the Office of Human Research Protections (OHRP). The Woman's Institutional Review Board (IRB) registration number is IORG0003155 and its FWA# is 00005699. Both can be located on the OHRP Web site at https://ohrp.cit.nih.gov/.

Definitions

I. Research

Research is defined by the Department of Health and Human Services (DHHS) federal regulations at 45CFR46.102(d) as:

> a "systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge."

To be considered a "**systematic investigation**," a study should:

- Attempt to answer research questions
- Be methodologically driven and collect data in an organized and consistent way
- Analyze data with quantitative or qualitative analysis
- Draw conclusions from results

To be considered "**generalizable knowledge**," the activity would include the following concepts:

- Knowledge contributes to a theoretical framework of an established body of knowledge
- Results are expected to be generalizable to a larger population beyond the site of data collection or population studied
- Results are intended to be replicated in other settings

HIPAA (Health Insurance Portability and Accountability Act) definition of research follows the DHHS definition.

Research is defined by Food and Drug Administration (FDA) as:

> any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to

the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for the purposes of FDA regulations. [21 CFR 50.3(c) and 21 CFR 56.102(c)]

II. Clinical Trial

FDA has defined "**clinical investigation**" to be synonymous with "research". "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

A "**clinical trial**" is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

III. Human subject

DHHS defines "human subject" as a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

FDA defines "human subject" as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. Research involving a human being as an **experimental subject** is an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction [32 CFR.210.102 (f) reference (c)].

For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is use. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

Research involving human subjects

Any activity that either:

- Is "research" as defined by DHHS and involves "human subjects" as defined by DHHS ("DHHS Human Research"); or DHHS 45 CFR 46.102

- Is "research" as defined by FDA and involves "human subjects" as defined by FDA ("FDA Human Research"). FDA 21 CFR 56.102.22(c); 21 CFR 50.3.25 (c)

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen is a biospecimen for which the identity of the subject may readily be ascertained by the investigator or associated with the biospecimen.

Therefore, research activities involving data obtained through intervention or interaction with a living individual or identifiable private information regarding a living individual must be reviewed by the IRB.

Interventions may include physical or medical procedures, as well as manipulations of the subject and his/her environment.

Interaction may include direct communication between the subject and the investigator, as well as telephone or mail interaction.

Private information includes gathering of information for specific purposes (including medical records) or observation of a subject without his or her knowledge.

IV. Principal Investigator, Co-Investigator, Investigator

Principal Investigator (PI), Co-Investigator (Co-I), or Investigator is an individual who conducts research or under whose immediate direction research is conducted; or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. (NIH PHS 398)

Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject,

or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. FDA 21 CFR 50.3.25(d)

For the purposes of this Institution, Principal Investigators must be a WHF employee or WHF active medical staff. Medical and Pharmacy residents are not permitted to be Principal Investigators but may serve as co-investigators with a mentor (LSU clinic faculty member or pharmacist employed at Woman's, respectively) serving as the Principal Investigator.

Scope of the Human Research Protection Program

The categories of research overseen by Woman's IRB include:

- FDA-regulated research
- Research involving drugs that require an IND
- Research involving devices that require an IDE issued by FDA
- Research involving pregnant women as subjects
- Research involving non-viable neonates
- Research involving neonates of uncertain viability
- Research involving children, pregnant women, fetuses, or neonates
- Investigator-held IND or IDE
- Research involving devices that require an abbreviated IDE.
- Investigator held abbreviated IDE.
- Activities involving humanitarian use devices (HUDs)
- Research using the short form consent form for non-English speakers
- Research using dietary supplements, with or without an IND

Categories of research **not** conducted at Woman's and not overseen by Woman's IRB include:

- Research conducted or funded by the Veteran Administration (VA)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted or funded by the Department of Education (ED)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Research involving in vitro fertilization.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving a waiver of consent for planned emergency research.

- Research involving participants with limited decision-making capacity
- Planned Emergency Use research
- International research as the IRB of record

If at any time research studies from federal agencies that are not currently overseen by Woman's IRB are proposed that adhere to Woman's mission, and the institution decides to take part, the Human Research Protection Plan and research policies will be revised to accommodate the agency's requirements.

Federal Regulations and Woman's Hospital Human Research Protection Program policies

The following policy and guidelines were prepared to help researchers, Research and Development Committee (R&D) members, Institutional Review Board (IRB) members, and IRB staff comply with the overall mission, philosophy, and policies of Woman's Hospital Foundation (WHF) and with the federal regulations concerning the use of human subjects in research. Any updates or changes to HRPP policies will be communicated to all researchers, IRB and R&D members, and IRB staff. The policies are available on the Woman's intranet and online at womans.org/about-womans/research.

The policy and guidelines include detailed information concerning:

- federal and institutional requirements for the protection of human subjects;
- the IRB's role and responsibilities;
- the requirements and procedures for initial and continuing IRB review and approval of research;
- the requirements and procedures for expedited review;
- the requirements and procedures for verifying that research is exempt from IRB review;
- the responsibilities of investigators during the review and conduct of research;
- requirements and procedures for notifying the IRB of unanticipated problems or events involving risks to the subjects, protocol deviations, as well as any other expected or unexpected adverse events;
- informed consent requirements;
- authorization to release protected health information requirements; and
- issues to consider regarding vulnerable populations of subjects.

45CFR46 – The Common Rule

All DHHS federal regulations (45CFR46, the Common Rule, Subparts A, B, D, and E) concerning human subject research are applied to all research conducted at Woman's, regardless of funding.

The revised Common Rule, effective January 21, 2019, will apply to all research approved after the effective date. Research approved prior to January 21, 2019, will be subject to the pre-2019 Common Rule regulations.

The definitions set forth in the final rules issued by DHHS 45 CFR Parts 160 (The Privacy Rule) and 164 (The Privacy Rule, subparts A and E) will also be applicable to these research guidelines.

FDA Regulations

The definitions set forth in the final rules issued by the Food and Drug Administration (FDA) 21 Code of Federal Regulations CFR Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), 312 (Investigational New Drugs), 812 (Investigational Devices), and 814 (Premarket Approval of Medical Devices) will be applicable to these research guidelines.

Ethical Principles

All researchers and research staff (including students), IRB members and staff, Research and Development Committee members, the organizational and institutional officials, other components of the HRPP, and any employee involved in human subjects research at Woman's is expected to adhere to the following ethical principles:

1). Mission and philosophy of Woman's Hospital Foundation

a). Mission statement

The protection of human subjects in all research is encompassed in the overall mission and philosophy of WHF. The mission of Woman's Hospital is to improve the health of women and infants.

b). Core Values of WHF

Respect – Accepting and appreciating differences
We welcome diversity and seek to understand differences in cultures, opinions and perspectives.

Innovation – Creating and embracing change to improve outcomes
We improve lives by accepting challenges, never giving up, and relentlessly nurturing new ideas.

Compassion – Showing kindness to and caring for one another
We are gentle and considerate through our actions and expressions.

Excellence – Being the best at what we do
We continue to exceed the expectations of our co-workers, patients, and guests

2). The Belmont Report

The three basic principles that govern the protection of human subjects in biomedical and behavioral research as set forth in the Belmont Report and adhered to by WHF are:

RESPECT FOR PERSONS
Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy

BENEFICENCE
Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and

JUSTICE
Fairness in the distribution of research benefits and burdens

3). List of ethical principles

The WHF IRB policies are based on the following general ethical principles:

1. The rights and welfare of subjects must be adequately protected to safeguard the physical and psychological well-being of a subject and to preserve the subject's rights of privacy and self-determination.

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

3. Risks must be reasonable in relation to anticipated benefits to subjects or to the importance of the knowledge that may be gained. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

4. Recruitment and selection of subjects must be equitable within the confines of the purposes and design of the study. Subjects must not be arbitrarily excluded on the basis of gender, race, national origin, religion, creed, education or socio-economic status. In making this assessment, the IRB will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, terminally ill, or economically or educationally disadvantaged persons.

4). International Conference on Harmonization – Good Clinical Practice (E6)

All clinical trials at WH will adhere to the International Conference on Harmonization – Good Clinical Practice (ICH-GCP) (E6) where it is consistent with FDA regulations. Compliance with

this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected and consistent with the principles that have their origin in the Declaration of Helsinki, and that clinical trial data are credible.

Components of the HRPP

Institutional Official

The Executive Vice President / Chief Operating Officer of the institution is designated as the Institutional Official (IO). The IO is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the Federal-wide Assurance.

The general administrative obligations of the Institutional Official are:

- Designating one or more Institutional Review Boards (IRBs) that will review research covered by the institution's FWA;
- Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties;
- Providing training and educational opportunities for the IRB and investigators;
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP;
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Serving as a knowledgeable point of contact for OHRP and other federal agencies, or delegating the responsibility to another appropriate individual;
- Supports the independent authority of the IRB as required under federal regulations;

Some responsibilities may be delegated to a designee, such as the HRPP Organizational Official. This designation of duties must be in writing. Upon designation of a new IO, all delegation letters must be reviewed and renewed by the new IO if the new IO chooses to maintain delegation. The Institutional Official or the designee cannot approve research that has been disapproved (or not yet approved) by the IRB.

The following responsibilities may be delegated by the IO to a designee:

- Appointing IRB members, and suspending or terminating IRB membership of any individual for whom it has been determined is not fulfilling membership responsibilities or obligations;
- Appointing IRB chairs and co-chair(s), and suspending or terminating the appointment of any chair or co-chair for whom it has been determined is not fulfilling the responsibilities or obligations of their position Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;
- Managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA, and other agencies as applicable, including reports to federal agencies;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an educational plan for IRB members, staff and investigators;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Performing periodic evaluation of the performance of the IRB members and administrative staff;
- Recruiting qualified members to include expert, non-scientific, and unaffiliated representation on the IRB;
- Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP;
- Overseeing daily operations of the IRB and HRPP in accordance with the SOPs.
- Assessing this plan periodically to determine whether it is providing the desired results and recommending amendments as needed.
- Establishing policies and procedures designed to increase the likelihood that human research will be conducted in accordance with ethical and legal requirements.

The following responsibilities of the Institutional Official should not be delegated to a designee:

- Signatory authority for the FWA;
- Ensuring that the IRB functions independently and that its chair or chairs and members have direct access to the Institutional Official for appeal if they experience undue influence or if they have concerns about the function of the IRB;
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP;

Woman's Hospital Foundation Board of Directors

The WHF Board of Directors will appoint the members of the IRB, including alternates, the IRB Chair, and the IRB Vice-Chair. The Board of Directors will also be responsible for suspending or terminating IRB membership of any individual for whom it has been determined is not fulfilling membership responsibilities or obligations. The appointments will be made annually and members will be notified of their appointments via written correspondence. The WHF Board of Directors recognizes the authority of the IRB 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).

HRPP Organizational Official

The Organizational Official will oversee the day-to-day operations of the Human Research Protection Program in accordance with the written policies and procedures. In addition, the following duties of the IO have been designated to the Organizational Official:

- Managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP;
- Performing periodic evaluation of the performance of the IRB members and administrative staff (with input and review from the IRB Chair);

Institutional Review Board (IRB)

The IRB at WHF is designated by the Woman's Board of Directors. In order to avoid conflicts of interest and undue influence, no individual responsible for raising funds or garnering support for research should serve as an IRB member. 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.

The IRB functions independently of, but in coordination with, other hospital departments, particularly the Research and Development Committee, which provides review of all research for scientific merit, alignment with the mission of the hospital, and availability of resources.

The IRB makes an independent determination to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects, conducted, supported or otherwise subject to regulation by any federal department or agency that has adopted the human subject regulations. Consistent with federal regulations, no one within the institution may approve human subjects research that has not been approved by the IRB.

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 under the supervision of the Institutional Official and/or the Organizational Official.

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, the feasibility of conducting the studies at Woman's, adherence to Woman's mission, and management of any conflicts of interest.

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. 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. 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.

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. The IRB does not have the authority to grant retroactive approval should a research study be initiated without IRB approval.

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. 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 as consultants for the review process 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 members, IRB Chair, IRB Vice Chair, and alternate members are appointed by the WHF Board of Directors; there is no selection of IRB members by investigators. IRB appointments are for one-year terms with no maximum number of terms. Membership is evaluated and reassessed annually. The Human Protections Administrator is responsible for annually evaluating the composition of the IRB and providing orientation to new members to familiarize them with the federal regulations and ethical principles, as well as IRB meeting procedures and the review process. All IRB members must complete the CITI training provided online at: http://citiprogram.org. Members are subject to removal without cause by the Board of Directors.

The WHF IRB is specifically listed as an insured on the Woman's Hospital liability policy.

Research and Development Committee

The Research and Development Committee (R&D) reviews, approves, and monitors all research at Woman's Hospital Foundation (WHF) and any affiliate or collaborative sites utilizing the

institution, staff, equipment, or supplies. The R&D shall act by authority of the Board of Directors and is designated as a committee under Woman's Hospital Foundation.

The R&D of Woman's Hospital (WH) is responsible for stimulating and monitoring all research activities at WH and any research at affiliated or collaborative sites. The R&D promotes interdepartmental research collaborations, facilitates support of research by hospital departments and physicians, facilitates support of the research requirements of residency and fellowship programs, and identifies research initiatives in support of existing programs and new initiatives.

The R&D reviews research activities for scientific validity, conflicts of interest, adherence to WHF's mission and core values, and resource availability based on administrative or external funding. All research studies in which the institution is engaged are first reviewed by R&D and the results of the R&D review are forwarded to the IRB to supplement the board's review.

The R&D is a multidisciplinary group of individuals appointed by the R&D Chair and the Vice President of Research. The R&D ensures that the research conducted at Woman's Hospital follows all federal and state regulations and institutional policies. It is also entrusted with the responsibility of ensuring that all research involving human subjects is reviewed by the Woman's Hospital's Institutional Review Board or an approved external IRB.

Woman's Hospital Research Center Staff

The Woman's Hospital Research Center (WHRC) staff facilitates the processing of research studies submitted for Research and Development Committee and Institutional Review Board review. Staff duties include: office pre-review of submitted research proposals, maintaining HRPP policies and adherence to federal regulations at 45CFR46, assisting investigators with federal regulations and HRPP policy interpretation and application to research studies, maintaining IRB/R&D records, and communicating with IRB/R&D members, research participants, investigators, and federal agencies regarding human subjects research conducted at Woman's Hospital.

Investigators and Research Study Staff

Investigators and research staff conducting research at Woman's have the responsibility to:

- Follow the ethical principles as outlined in the Belmont Report
- Comply with the Human Research Program Policies at Woman's Hospital
- Adhere to federal regulations regarding research with human subjects at 45CFR46 and 21CFR56
- protect the rights and welfare of human subjects involved in research and oversee the research process on a day-to-day basis

- forward any complaints regarding the conduct of research to the Woman's Hospital Research Center office
- adhere to local and state laws for human subjects in research
- abide by all determinations of the IRB of record for their research study(ies) and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities
- complete and maintain any educational requirements, including CITI training, as required by their institution
- maintain documents as required by federal, state, WHF, and sponsor policies/procedures. At a minimum, investigators must maintain research records for at least three years after completion of the research. Beyond three years, requirements for record retention vary with the type of research conducted and provisions of the investigators funding source. It is the investigator's responsibility to clearly understand the retention requirements of their sponsor.
- report promptly to the IRB any proposed changes in the research and not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects
- report immediately to the IRB, sponsor, and federal agencies (as applicable), any unanticipated problems or serious adverse events to subjects or others in research
- ensure an accurate and thorough informed consent process and obtain, document, and maintain records of informed consent/assent from each subject or the subject's legally authorized representative, as required

Legal Counsel

Legal counsel employed by WHF will provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program regarding the interpretation and application of federal and Louisiana state law relevant to human subject research and as an initial point of contact about the laws of other jurisdictions where research is conducted as they may apply to human subject research.

Any new IRB Reliance Agreements or contracts with outside institutions may be reviewed by legal counsel. Legal counsel may also be consulted to resolve conflicts among applicable laws.

Radiation Safety Committee

The Radiation Safety Committee (RSC) oversees the use of radioactive materials and radiation-producing devices at the institution. All human subject research involving radiation must have RSC approval before research activities may commence. If the study involves radiation

exposure, other than for the use of standard diagnostic or treatment procedures for screening or medical management purposes, the protocol will be forwarded for review at the next meeting of the RSC. Approval of research by the RSC will be forwarded to the IRB to supplement the board's review. Examples of uses of these sources include, but are not limited to, x-rays, DXA scans, CT scans, fluoroscopy, and nuclear medicine procedures.

Health Information Management (HIM)

Health Information Management oversees HIPAA privacy protections for any research studies using protected health information for research subjects. HIM provides guidance regarding any identifiable information that is used, maintained, stored, or transmitted by WHF for research purposes, including reviewing and maintaining information regarding medical records accessed for research purposes under a waiver of authorization.

Information Systems (IS)

IS may be consulted for research studies that may require storing data on laptops, thumb drives, or mobile devices for data security. Studies using online Web platforms to enter and/or record data, such as REDCap, may also require IS review and approval prior to forwarding to IRB for review. IS may be asked to review and/or support research studies involving, but not limited to, questions of cybersecurity, online questionnaires/surveys, electronic transfer of data, or any use of any internal or external information systems technology. IS will also help with the maintenance of research information on the Woman's intranet and Woman's internet Web pages.

Pharmacy

The Pharmacy department ensures that procedures for the control of drugs used in clinical research are developed and implemented. Pharmacists are available to support investigators' research staff in management of study drugs and other medication related issues. Study drugs stored outside Pharmacy are audited by Pharmacy staff to ensure storage, dispensing, accountability, and security comply with federal and state laws and regulations, institutional policies, and ICH-GCP recommendations.

Information on all studies involving the use of drugs, such as the IRB-approved research protocol and investigator's brochure, is shared with Pharmacy staff as needed. Pharmacy will follow the American Society of Health-System Pharmacists (ASHP) Guidelines on Clinical Drug Research.

Laboratory / Outpatient laboratory

The laboratory and outpatient laboratory are available to assist investigators with any research laboratory testing required by the protocols as well as any cost analysis associated with lab procedures for research grants and/or funding planning.

Human Resources (HR)

Human Resources at WHF supports research in assuring that all off-site investigators coming to WH to conduct research obtain the proper immunizations, drug screening, TB skin testing, and identification to be on campus. Investigators outside the institution conducting research on WH campus will be given a non-employee service provider orientation packet and asked to sign a non-employee service provider agreement and a non-employee confidentiality agreement. Contact information and a copy of a driver's license may be required to initiate the background screening process with a third party background check company for outside investigators.

Other hospital departments involved in research

Any hospital departments allowing a research study to be conducted in their department will be asked to provide their approval and support via the completion of a Department Approval Form.

Scope of IRB Review

All research activities conducted at Woman's that involve human subjects, regardless of funding source, must be reviewed by the IRB if one or more of the following apply:

1. A single-site study sponsored by WHF or any WHF affiliate site (any entity that is wholly owned by WHF);
2. A single-site study conducted at WHF or at any WHF affiliate;
3. A single-site study conducted by or under the direction of any person who is employed by WHF or any WHF affiliates while acting in their capacity as an employee;
4. A single-site study conducted by or under the direction of any person using any property or facility of WHF or any WHF affiliate;
5. A single-site study involving the use of WHF or any of WHF affiliate's non-public information to identify or contact human research subjects or prospective subjects;
6. any entity having a contract with WHF to provide IRB oversight for that entity and added to that entity's FWA;
7. A multi-site study in which Woman's IRB is the IRB of record.

Specific examples of IRB jurisdiction:

a). Cooperative research

Any institution located in the United States that is engaged in cooperative federally-funded research must rely upon approval by a single IRB for that portion of the research that is

conducted in the United States (45CFR46.114); however, Woman's Research and Development Committee will review the study and the IRB may still choose to conduct an institutional review to ascertain adherence to Woman's mission and goals and ensure participant safety. Such a review will not have any regulatory status in terms of compliance with the Common Rule.

b). Standard diagnostic or therapeutic procedures

The distinction between research and treatment can become blurred in patient care settings, as well as in some educational and training settings. An established and accepted diagnostic or therapeutic procedure that is performed only for the benefit of a patient is not subject to IRB review. However, collection of data about a series of such procedures or treatments for dissemination or generalization does constitute research that requires IRB review. Additionally, if patient care or assignment to intervention is altered for research purposes in any way, the activity must be submitted for IRB review. Also, a diagnostic procedure for research purposes that is added to a standard treatment requires WHF IRB review.

c). Innovative procedures or treatments

Innovations in diagnosis or therapy are not generally subject to IRB review if they are applied to a patient for the sole purpose of aiding that individual, although such innovations are governed by the appropriate professional ethics (for example, obtaining informed consent). IRB review is required when a "systematic investigation" of such innovations is considered. For example, if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to standard treatment, the physician must receive prior IRB review and approval.

d). Emergency use of an investigational drug or device

Notification of one-time compassionate emergency use of an investigational drug or device to the IRB is required within five business days. Continuing or planned emergency use research is not allowed under Woman's IRB.

e). Student-conducted research

All activities that meet the definition of research with human subjects and are conducted by students for a class project or for work toward a degree must be reviewed by the IRB. may be published, publicly presented, or otherwise disseminated. Investigators who are students must submit a letter of support for the project from the major professor on school letterhead and a copy of the approval letter from the school's IRB, if that IRB is to be the IRB of record. The letter of support must verify that the purpose of the project is to fulfill the requirement for a degree. In addition, it is strongly recommended that the major professor attend the IRB meetings at which the proposal is presented for initial and continuing review.

g). Reviews preparatory to research

If an investigator wishes to review protected health information (PHI) to determine the feasibility of a research study, the IRB should be notified using a "Representation of Activities Preparatory to Research" form (45CFR164.512(i)(1)(ii)). Reviews preparatory to research that involve human subjects require IRB review and approval. As a covered entity under HIPAA, Woman's IRB must obtain from the researcher representations that:

- Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
- No protected health information is to be removed from the covered entity by the researcher in the course of the review; and
- The protected health information for which use or access is sought is necessary for the research purposes.

The Review Preparatory to Research may be used by an investigator in order to review PHI of potential research subjects, but may not contact the potential subjects to ask them to participate in a research study until IRB approval of the research study is granted. HIPAA does allow investigators to retain lists of prospective subjects obtained during Review Preparatory to Research, provided that the data does not leave the covered entity. Refer to the Review of Data Preparatory to Research Policy.