Research and Development Committee

Policy and Procedures
Woman's Hospital
Baton Rouge, LA

The following policy and procedures shall define the structure and function of the Research and Development Committee (R&D) and the mechanism through which this committee will review, approve, and monitor 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 of the WHF and is designated as a committee under WHF.

A. Roles and Responsibilities

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, conflict of interest assessment, adherence to Woman's Hospital's Foundation (WHF) mission and core values, and resource availability based on administrative or external funding.

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 (IRB) or an approved external IRB.

B. Annual Report

The medical director of research will present an annual report of research at Woman's Hospital. The report will be written and given orally to the:

1. R & D Committee
2. Medical Staff

3. Board of Directors (upon request)

The report will contain, at a minimum:

1. A summary of all research projects that was active during the reporting period. The summary will include the names of the principal investigator, title, start date, and current status of the project.
2. A summary of publications and presentations of all research projects that was active during the reporting period.

The R&D will review the annual research report and make any additional corrections or recommendations before it is presented to the Medical Staff.

C. Research and Development Committee Membership

The R&D Committee shall be composed of doctors, nurses, and VP's with various backgrounds and areas of expertise. There is no maximum term limit for membership. The R&D members are appointed by the Vice President of Research and the R&D Chair.

The R&D Chair and/or Committee may assign additional non-member resource persons to review proposed projects who will attend the R&D Committee meeting at which the proposed project is presented.

The R&D Chair will direct the activities of the R&D Committee. The R&D Chair is responsible for the conduct of the monthly R&D Committee meetings and for the day-to-day execution of Committee business. The R&D chair reviews all research projects submitted to WHRC.

The R&D Chair reviews and approves minutes from the R&D Committee meeting. The previous R&D minutes will be included in the R&D meeting reminder forwarded to R&D Committee members, via email, a week prior to the next convened meeting.

D. Research and Development Committee Meetings

The R&D meets on the 3rd Tuesday of every month at the discretion of the R&D Chair. The monthly meeting will review:

1) Agenda Items
   a. Summary of current research activities
   b. Funding and grant report
   c. IRB minutes

2) New Business
   a. New protocols
   b. Other new business
3) Old business.
4) Adjournment

E. Research and Development Committee Review

1) Initial Submission

New proposals submitted to the research department for review are first submitted to R&D for review of scientific merit, resource availability, and adherence to WHF mission and core values. All projects shall be handled in the same manner, even if the research fulfills the criteria for expedited or exempt IRB review as defined by 45CFR46, or does not involve human subjects.

R&D reviews may be conducted by the R&D Chair, selected members of the R&D Committee as determined by the R&D Chair, based on area of expertise, or by the entire R&D Committee. At least one of the reviewers shall hold an MD or Ph.D. degree.

Exempt and/or expedited projects as defined by 45CFR46, may be reviewed by the R&D Chair only and assessment forward to the IRB Chair. Full Board projects as defined by 45CRF46, are reviewed by the R&D Committee and presented to the full board R&D Committee (reference R&D submission deadlines and current meeting schedule). After full board R&D Committee, a letter and/or an assessment will be forwarded to the IRB to include in the IRB submission packets.

The reviewer(s) shall complete the R&D Committee Reviewer form and return to the Woman's Hospital Research Center (WHRC) by the indicated deadline.

Questions and concerns from the R&D may be forwarded to the investigators for response or correction prior to submission of the project for IRB review. Minor revisions may be verified by WHRC. Major revisions shall be submitted by the WHRC to the R&D chair and the same R&D Committee reviewer(s), if necessary.

If applicable, the principal investigator shall present the proposed protocol at the R&D Committee meeting at which proposed project is scheduled for presentation. If an individual other than the principal investigator presents the study and is unable to answer questions posed by the Committee, there is increased risk the proposed project will be tabled until all issues are resolved.

After presenting, the principal investigator and/or representative shall leave the room after any questions posed by the R&D Committee have been answered. The R&D Committee shall provide comments on the feasibility, conflict of interest assessment, and scientific validity of the proposed project. The R&D Committee may then decide upon on of the following actions:

a) Pass the proposal
b) Pass the proposal with suggested changes not requiring re-review
c) Table the proposal for re-review at a future meeting
d) Reject the proposal with the suggestion of resubmission or
e) Reject the proposal without the potential of resubmission.

2) Annual Review / Amendments of Previously Approved Projects

a) Annual reviews require R&D approval. Investigators should submit a complete Continuing Review / Revision Application form and supporting documents to WHRC at least three months prior to the designated project expiration date. The R&D Secretary shall send the continuing review to the R&D Chair for review.

After R&D review, the R&D Secretary shall send a letter of approval or a letter documenting concerns and/or assessment to the IRB.

b) Projects that do not require an IRB annual review shall be reviewed annually by the R&D Committee. The investigator will be notified by the R&D Secretary for an annual update of the approved project. The R&D chair will review submitted materials. Documentation of the R&D review shall be filed in the retrospective project folder and update the Research Protocol Database.

c) For exempt projects, the R&D Secretary will notify the investigator annually for an update on the exempt project. The R&D Secretary will update the Research Protocol Database.

d) Projects that have an outside IRB of record shall be reviewed annually by R&D Chair. When annual documents are received from the outside IRB, the R&D Chair will review.

Previously approved projects that are permanently closed to enrollment of new subjects, and the research remains active only for data analysis or long-term follow-up of subjects, do not require an R&D review. Projects will remain in the Research and Development Protocol Database until completion.

e) When changes to the protocol and/or consent are requested, the investigator should submit a completed Continuing Review / Revision Application form and supporting documents to WHRC.

If requested changes are minor (reference IRB Policy XII, Section A.), and do not involve an increase in institutional resources (at the discretion of WHRC) the documents should be submitted to the IRB Secretary for review and retrospectively reported to the R&D Committee. If major changes are requested (reference IRB Policy Revisions and Amendments to Research Studies, Section B.), and/or involve increased institutional resources (at the discretion of WHRC) requires R&D review prior to submission to the IRB and implementation. Following R&D review, the R&D secretary shall arrange for the documents to be submitted to the IRB before the next IRB deadline date.

b) Changes to the protocol and/or consent form necessary to protect subject rights and/or safety shall be submitted to WHRC. The R&D Secretary shall arrange for the changes to be placed on the agenda of the next scheduled R&D Committee meeting and may be reported retrospectively to the R&D Committee.

3) R&D Review – of Studies with Outside IRBs

The R&D will review all multi-site research activities with an outside IRB of record. All study related materials (e.g.., protocol, informed consent form, case report forms, adverse events etc.), will be reviewed initially, annually, and for all revisions. The R&D may choose to forward study to Woman's IRB for review if there are concerns and/or issues with subject rights and/or safety. The R&D will forward a letter to the IRB documenting the R&D Committee concerns and/or issues.

If Woman's ceases participation in a multi-site study where Woman's is not the IRB of record the principal investigator shall notify the R&D Chair.

4) Closure / Complete / Publications

a) When a project is submitted for closure / complete/ or termination, the investigator should submit a completed Continuing Review / Revision Application form and supporting documents to the WHRC. The R&D Secretary shall arrange for the closure to be submitted to the IRB by the next IRB deadline date. The R&D Secretary shall also update the Research and Development Protocol database.

b) Any publications resulting from human subjects research conducted at Woman's or using Woman's as a site in a multi-site project. All publication must be reviewed by the Research and Development Committee prior to publication from R&D. The R&D Secretary will notify the investigator of any revisions and/or concerns from the R&D Committee. After all revisions and/or concerns are addressed the investigator will receive a decision letter from the R&D.

F. Quorum

The R&D Committee does not require a quorum to approve or forward a project to the IRB.

G. Retention of Records

The WHRC shall retain all R&D Committee meeting minutes in a permanent file. The records / documents for each research project shall be retained for a period of at least three years or longer, if federally mandated, after the completion of a research project. No records / documents for research projects shall be in the possession of R&D Committee members after a proposal has been approved. All printed materials of R&D projects that have been distributed to the R&D Committee members shall be destroyed at the end of each R&D meeting.

H. Confidentiality Statement

All information to which R&D Committee members and any individual attending a R&D Committee meeting may have access to regarding research projects at Woman's Hospital is strictly confidential. R&D Committee members may not discuss, reveal, or in any way disclose any information obtained during a R&D Committee meeting to any person(s) other than those directly involved with the specific research study. To release any information obtained to unauthorized individuals would be a breach of confidentiality.

I. Relationship of the R&D Committee and WHRC

The staff of the WHRC functions as the interface between the principal investigator (PI) and the R&D Committee. Materials/documents required for the submission of a proposal to the R&D Committee by an investigator will be collected and initially examined by WHRC. When the WHRC has determined that all documents have been compiled, the proposal is submitted for R&D review. In order for a proposal to be reviewed by the R&D, a complete proposal shall be submitted by the PI to the WHRC three weeks before the monthly R&D Committee meeting. In exceptional cases, proposals may be submitted 2 weeks

before the R&D Committee meeting at the discretion of the WHRC and R&D Chair.

J. Relationship between the R&D and IRB

In addition to R&D review, all research conducted at Woman's Hospital that involves human subject shall also be reviewed by the Woman's Hospital IRB. Projects that have been reviewed by the R&D Committee shall automatically be submitted to the IRB with the aide of the investigator. The R&D secretary will forward R&D approval and/or assessment to the IRB. A research project involving humans cannot be initiated until both R&D and IRB approval have been granted.

Projects that require IRB approval prior to submission to a granting agency, in the case where the R&D deadline date has passed, may qualify for parallel tracking(ref. section K).

K. Parallel Tracking Approval

Parallel tracking is the simultaneous submission of a project to the R&D Chair and the IRB.

A parallel tracked proposal will first be reviewed by the WHRC for completeness and submitted to the R&D Chair. If the R&D Chair feels the proposal meets the criteria for acceptance (section L below) then it may be submitted to the IRB before R&D Committee review. If the IRB approves the parallel tracked proposal it shall be presented as a new grant retrospectively at the next R&D meeting.

Proposals that are parallel tracked require the PI to submit written evidence from the granting agency delineating the grant's time restraints.

L. Principal Investigator Requirements

The following individuals may submit proposals to the R & D Committee:

1. Woman's Hospital Medical staff
2. Woman's Hospital Staff researchers
3. Woman's Hospital Allied Health and nursing staff
4. Researchers from other accredited institutions, universities or industries wishing to collaborate must have a principal investigator or co-investigator who is a WH medical staff appointee, a WH staff scientist, or an employee of WHF.

M. Study Requirements

The following are requirements for submission of a project to R&D:

1. The project must meet the ethical standards of Woman's Hospital.
2. All required documents, as outlined in the IRB Policy and guidelines for submission of a project, must be completed.
3. If human subjects are involved in the project, all of the requirements and forms established by the IRB must be met.
4. The project must conform to all state and federal regulations and all applicable WHF guidelines.

N. Conflict of Interest

The R&D members who have research projects under consideration or who have a conflict of interest with a project may be allowed to discuss such projects at committee meetings but will be excused during voting and discussions.

The R&D Committee will follow the Human Protection Research Program Conflict of Interest Policy for disclosures and identifying potential conflict of interest.