



## INSTITUTIONAL REVIEW COMMITTEE POLICIES AND PROCEDURES

### **I. Ethical and Regulatory Mandates to Protect Human Research Participants:**

#### **A. Ethical Foundation for Human Subject Protections:**

The Washington Hospital is committed to ensuring that all human subject research in which it is engaged is conducted in accordance with the ethical principles stated in the Belmont Report (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>). The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provides the ethical foundation for the federal regulations for the protection of human research subjects. Three fundamental principles are articulated:

##### 1. Respect for Persons

Individuals should be treated as autonomous agents afforded the right to make decisions for themselves. Those with diminished autonomy (e.g. minors, prisoners, persons who are mentally disabled) are entitled to additional protections. Application of this principle requires that human subjects are enrolled into research studies only under the conditions of effective informed consent. This involves a process in which participation in the research is acknowledged by the research subject (or by a legally authorized representative) as a voluntary act free from coercion or undue influence from the investigator or members of the research team. Exceptions to this informed consent requirement must be outlined in the federal regulations and subsequently approved by the IRC.

##### 2. Beneficence

The research study must be designed and implemented so as to maximize possible benefits and minimize possible harms. Application of this principle involves a risk/benefit analysis in which the risks to subjects must be reasonable compared to the potential for benefit either to subjects directly or to society. Risk evaluation must include the consideration of both the probability and magnitude of harm, including psychological, physical, legal, social, and economic harm.

##### 3. Justice

The possibility for benefits and the potential burdens of the research should be equitably distributed among the potential research subjects. Application of this principle requires the close scrutiny of the enrollment process to ensure that particular classes (welfare patients, racial and ethnic minorities, or persons confined to institutions) are not selected for their compromised position or convenience to the research investigator.

#### **B. Regulatory Mandates:**

The IRC adheres to the following regulations and policies for human subject research activities that fall under its authority:

1. The Federal Policy regulations for the protection of human research subjects (45 CFR Part 46; “Common Rule”) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> )
2. When research involves articles subject to regulation by the FDA, the FDA regulations for the protection of human subjects (21 CFR Parts 50) and Institutional Review Boards (21 CFR Parts 56) (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>)
3. Where applicable, other federal, state and local regulations regarding research involving human subjects
4. The provisions of the Federal Wide Assurance Agreements (FWA) for The Washington Hospital (FWA #00009429)

## **II. Purpose of the IRC:**

The primary purpose of the IRC is to protect the rights and welfare of human subjects involved in research activities being conducted under its authority. In so doing, the IRC shall ensure adherence to the criteria for IRC approval as listed in 45 CFR 46.111 and 21 CFR 56.111 i.e., that:

- A. the risks to human research subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk, and whenever appropriate, by using procedures already being performed on subjects for diagnosis or treatment purposes.
- B. the risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.
  1. For the purpose of IRC consideration, “benefit” is defined as a valued or desired outcome; an advantage.
  2. For the purpose of IRC consideration, “risk” is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. In evaluating risk, the IRC is to consider the conditions that make the situation dangerous, per se (i.e., as opposed to those chances that specific individuals are willing to undertake for some desired goals).
  3. In evaluating risks and benefits, the IRC considers only those risks and benefits that may result from the research (i.e., as distinguished from risks and benefits of treatments or procedures that the patient would undergo if not participating in the research).
  4. In evaluating risks and benefits, the IRC does not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of research on public policy).
- C. the selection of human subjects for research participation is equitable.
- D. human research subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research; and that informed consent is obtained from each prospective human research subject, or his/her legally authorized representative, in accordance with, and to the extent required by federal

regulations and IRC policies.

- E. informed consent of human research subjects is obtained in advance of research participation and appropriately documented in accordance with, and to the extent required by federal regulations and IRC policies.
- F. the research plan, when appropriate, makes adequate provisions for monitoring the data collected to ensure the safety of human research subjects.
- G. there are adequate provisions to protect the privacy of human research subjects and to maintain the confidentiality of research data.
- H. appropriate additional safeguards have been included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, decisionally impaired persons, or economically or educationally disadvantaged persons).

As a secondary purpose, the IRC must seek to ensure that the Hospital, affiliate institutions, and the investigators that it serves are compliant with the ethical standards and regulations governing human subject research. The IRC also serve to assist investigators in the design of ethical and regulatory compliant human subject research studies.

**III. Institutional Authority under which The Washington Hospital IRC is Established and Empowered:**

A. The Washington Hospital:

The Washington Hospital has delegated authority, through the President & CEO (the designated Institutional Official), to The Washington Hospital Institutional Review Committee (IRC) to review initially and periodically and to approve, require modifications to (to secure approval) or disapprove all research activities falling under the human research protection program of The Washington Hospital.

The Washington Hospital human research protection program encompasses all human subject research wherein The Washington Hospital medical staff, employees, students or facilities are engaged in the conduct of the research or the human subject research involves the private records of The Washington Hospital.

**IV. The Authority of the IRC:**

- A. The IRC shall review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities involving human subjects that fall under its authority, including research that qualifies for “exempt” status under the provisions of 45 CFR 46.
  - 1. Research activities approved by the IRC are subject to further appropriate review and approval or disapproval by the Institutional Official (President and CEO of The Washington Hospital). However, the Institutional Official may not approve human subject research to be conducted within the institution if such research has not been prior approved by the IRC.
  - 2. Unresolved questions or issues between the IRC and human subject investigators shall be referred to the Institutional Official for additional discussion. Comments and recommendations of the Institutional Official shall be considered by the IRC in

its subsequent decision to approve or disapprove the respective human subject research.

- B. The IRC shall have the authority to determine that a project submitted by an investigator does not meet the regulatory definition of human subject research under 45 CFR 46.102(f) and 21 CFR 56.102(f).
- C. The IRC shall have the authority to require progress reports from investigators and to conduct continuing reviews of approved human subject research studies at intervals appropriate to the degree of risk, but not less than once per year. Research studies qualifying for “exempt” status in accordance with 45 CFR 46.101(b) will not be subject to continuing review.
- D. The IRC shall have the authority to approve prospectively all modifications to previously approved research protocols and/or informed consent documents; the only exception being a protocol deviation that may be necessary to eliminate an apparent immediate hazard to a given research subject.
- E. The IRC shall have the authority to observe or have a third party observe the conduct of approved human subject research studies, including the informed consent process.
- F. The IRC shall have the authority to suspend or terminate the approval of, human subject research activities that are not being conducted in accordance with the IRC’s requirements or have been associated with unexpected serious harm to subjects.
- G. The IRC shall have the authority to place restrictions on human subject research activities.
- H. Cooperative Research:

The IRC may agree to delegate the responsibility for initial and continuing review to another institution’s IRB. In turn, the IRB agrees to assume responsibility for initial and continuing review.

The agreement for IRB review of cooperative research shall be documented.

**V. Management of the IRC:**

A. Appointment of IRC Chair:

1. Appointment:

The IRC Chair shall be appointed by the Institutional Official.

- a. In appointing the IRC Chair, primary consideration shall be given to current or past members of the IRC.
- b. The IRC Chair should be a highly respected individual fully capable of managing the IRC and the matters brought before it with fairness and impartiality. The task of making the IRC a respected part of the institutional community will fall primarily on the shoulders of this individual.
- c. Vice Chairs shall be appointed based on previous experience as an IRC member and/or past experience in the conduct of human subject research.

2. Term:

The term of appointment of the IRC Chair shall be indefinite.

B. Responsibilities of the IRC Chair:

The IRC Chair shall hold leadership responsibility for IRC review and approval of human subject research in accordance with current guidelines, institutional policies, and federal and state regulations governing human subject protections. In addition, the IRC Chair shall:

1. oversee the recruitment, orientation, continuing education and retention of IRC members
2. oversee the development and implementation of appropriate policies, procedures and guidelines directed at human subject protections and the functions and activities of the IRC. The IRC Chair is responsible for reviewing the IRC's policies and procedures for currency, accuracy and consistency on an ongoing basis.
3. have authority to request audits of human subject research activities
4. have the authority to suspend some or all research activities if exceptional human subject safety issues are identified. (Note that this authority is only exercised if an action is required prior to a convened meeting and it is not feasible to assemble an emergency meeting) When this authority is exercised, it shall be reported at the next convened IRC meeting.

C. Termination of IRC Chair:

1. Only the Institutional Official has the authority to terminate the appointment of the IRC Chair.

**VI. IRC Committee Membership:**

A. Composition of IRC:

1. The IRC will be comprised of at least seven (7) members, with varying background and expertise to provide complete and thorough review of research activities commonly conducted by the Institution.
2. The membership of the IRC will be sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human research subjects.
3. The IRC includes persons able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
4. The IRC includes members of more than one profession.
5. The IRC includes at least two members who are physicians.

B. Alternates:

The IRC maintains a roster of alternates whom may vote in place of an absent voting member.

1. The alternate member shall have similar expertise as the regular committee member for whom s/he is serving as a replacement (physician to physician; other scientific to other scientific; and non-scientific to non-scientific).
2. The alternate member shall assume all of the responsibilities of the committee member for whom s/he is serving as a replacement.
3. Alternate members may attend IRC meetings without serving as a replacement for a regular committee member; however, in this capacity, the alternate member may not participate in any of the final approval decisions of the committee.
4. IRC minutes shall document if a member present at the meeting is an alternate as well as the IRC member for whom the alternate is substituting.

C. Responsibilities of IRC Members:

General Responsibilities of all IRC Members include:

1. Reviewing research study proposals and evaluating them from the perspective of the regulatory criteria for approval addressed under 45 CFR 46.111, 21 CFR 56.111 (if applicable); and any other relevant ethical, scientific or compliance considerations.
2. Reviewing informed consent documents and evaluating them from the perspective of addressing the required and additional elements of informed consent addressed under 45 CFR 46.116, 21 CFR 50.20 (if applicable) and any other relevant ethical or compliance considerations.
3. Attending IRC meetings in person, unless exigent circumstances prevent such attendance on an occasional basis; reporting promptly at the designated time that the meeting convenes; and remaining in attendance at the meeting until the full agenda has been addressed.
4. Participating in IRC deliberations concerning issues inherent to proposed research studies and related informed consent documents, and making recommendations for reducing risk and improving the informed consent process and otherwise for improving human subject protections.
5. Voting for full approval, approval subject to modification(s), reconsideration, or disapproval of the human subject research as outlined in Section X.I.3.
6. Evaluating the risk level (i.e., minimal or greater than minimal) of the proposed research. In performing this evaluation, IRC members shall use the following absolute definition for “minimal risk” at 45 CFR 46.102(i).
  - “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population) or during the performance of routine physical or psychological examinations or tests.”
7. Deciding, for research studies of greater than minimal risk, if IRC continuing review of the research is warranted on a more frequent basis than the requisite annual review. In making this determination, IRC members shall follow the procedure outlined in Section X.I.2.

8. Conforming, at all times, their behavior to be within legal and ethical principles accepted by the IRC; including, but not limited to, maintaining confidentiality/non-disclosure of human subject research submitted for IRC review and approval, and good faith participation in IRC deliberations without appearance of discrimination or conflict-of-interest.

D. IRC Roster:

1. Information on the IRC Roster

The IRC membership roster will include the following information:

- a. Names of members;
- b. Earned degrees
- c. Representative capacities
- d. Scientific/nonscientific status
- e. Affiliation status (whether the IRC member or an immediate family member of the IRC member is affiliated with the organization)
- f. Indications of experience sufficient to describe each IRC member's chief anticipated contributions
- g. Employment or other relationship between each IRC member and the organization
- h. Alternate members including the primary members or class of primary members for whom each alternate can substitute

2. Maintenance of the IRC Roster

- a. The IRC Chair is responsible for maintaining an updated membership roster.

E. Resignation and Termination of IRC Members:

1. Resignation of IRC membership status, based on the wishes of the IRC member, shall be submitted, in writing, to the IRC Chair.
2. IRC membership status may be terminated by the Institutional Official due to failure to attend and/or otherwise actively participate in IRC functions.

**VII. General Procedures for All IRC Submissions:**

Investigators involved in the conduct of human subject research that falls under the authority of the IRC shall submit all protocols, informed consent documents, determinations from other IRC's, brochures to be given to research subjects and other pertinent information to the IRC chair.

A. Assignment of IRC Number:

1. New Protocols

All new protocols will be assigned an eight-digit number. The number assigned reflects the year and month of submission with consecutive numbers thereafter (e.g., 20070601 would mean the protocol was submitted in June 2007 and was the 1<sup>st</sup>

protocol submitted in the month).

2. Renewals

Renewals that are currently being reviewed in a paper format will retain the number originally assigned with the addition of a four digit suffix to indicate the most recent date (i.e., year/month) of IRC continuation approval (e.g., 20070601-0803 for IRC continuation approval of this research granted in March 2008).

3. Modifications

Modifications will retain the number originally assigned to the study.

B. Fees:

Fees are charged for review of industry-sponsored research studies. Industry sponsorship includes pharmaceutical companies, medical device manufacturers and other for-profit companies sponsoring medical research. Fees may be waived by the chairman if unusual hardship is demonstrated. Fees are not charged for studies sponsored by non-profit organizations, data registries, students, or physicians affiliated with The Washington Hospital.

Fees must be paid prior to review by the IRC. The Fee Schedule is listed in Appendix A.

C. Initial Screening:

All submissions are initially screened by the IRC Chair to ensure completeness of the application and to determine whether the submission can be granted expedited review or go to the appropriate full board meeting.

Incomplete submissions will be returned to the principal investigator for correction. Once all required elements are present, the IRC Chair will forward the study appropriately.

D. Calculation of Initial Approval Date:

The IRC shall calculate the date of initial IRC approval in the following manner:

1. When a research study is approved at a convened meeting, the date of the convened meeting shall be the date of IRC approval.
2. When the research study is approved subject to modifications at a convened meeting, the date of IRC approval shall be the date that the requested changes are verified by the Chair.
3. When a research study is reviewed and approved through an expedited review process, the date that approval is extended by the Chair shall be the date of IRC approval.

E. Calculation of Expiration Date:

The IRC shall calculate the date of expiration in the following manner:

1. When a research study is fully approved at a convened meeting, the date of expiration shall be based on the date of the convened meeting (minus one day). For example, if the committee meeting date is 10/17/06, then the date of IRC expiration



is 10/16/07 for an annual approval or 4/16/07 for a six month approval.

2. When a research study is approved subject to modifications, the date of expiration shall be one year from the date of the convened meeting (minus one day). It is not calculated from the date that the Chair verifies the requested changes and grants final approval. For example, if the committee approves a research study subject to modifications on 10/17/06 and the response is verified by the Chair on 10/20/06, then the date of IRC approval is 10/20/06 and the expiration is 10/16/07 for an annual approval or 4/16/07 for a six month approval.
3. When a research study is reviewed and approved by expedited review, the date of expiration shall be based on the date that the Chair verifies any requested changes and grants final approval (minus one day).

F. Modification Dates:

The IRC shall calculate the date of modification approval in the following manner:

1. When a modification is approved through an expedited review mechanism, the modification approval date shall be the date that the Chair reviews and approves the modification.
2. When a modification is reviewed at a full board meeting and is approved at the meeting, the modification approval date shall be the date of the IRC meeting.
3. When a modification is reviewed at a full board meeting and is approved subject to modifications, the modification approval date shall be the date that the response is verified by the Chair.

Expiration dates are maintained as the date assigned upon initial or continuing review unless the IRC determines that there has been a significant change to the risk/benefit ratio which would require a more frequent continuing review. If this change occurs, the IRC will notify the principal investigator of the study of the new expiration date. The new date must never exceed the original expiration date.

G. Investigator Communications:

1. Initial Comments from the IRC – General Information

The principal investigator shall be notified, in writing, of the IRC's decision to approve, reconsider, or disapprove the proposed research, or of the modifications required to secure IRC approval of the research study. Comments will be issued to investigators once either the minutes from the full board meeting have been accepted by the IRC Chair, or the comments have been finalized for expedited or exempt submissions. Correspondence will contain, at a minimum:

- a. the name of the principal investigator
- b. the title of the project
- c. the IRC number assigned to the submission
- d. the decision of the IRC

2. Full Board Decisions

The IRC full board decisions will be outlined in the investigator communications as follows:

a. Full Approval

If a convened IRC determines that the study can be approved as submitted, the investigator will be issued a full approval letter.

b. Approved subject to minor modifications (comments must be directive)

If the IRC decides to approve a research study subject to modifications, it shall include in its written notification the specific revisions stipulated by the IRC in order to obtain full approval to conduct the research.

- (1) The written notification shall instruct the investigators to revise the research and informed consent document(s) in accordance with the specific revisions stipulated by the IRC and to resubmit for final IRC approval.

c. Reconsideration or Disapproval

If a convened IRC decides to reconsider or disapprove a research activity, the written notification to the investigator shall include:

- (1) a statement of the primary reason(s) for the IRC's decision to reconsider or disapprove the research;
- (2) a listing of additional problems and/or deficiencies identified by the IRC;
- (3) instructions relating to resubmission of the research for full-board IRC review, including statements that the principal investigator should address in writing the comments and concerns of the first IRC review and that s/he may appear in person to address additional questions or concerns related to full-board IRC review of the resubmitted protocol.

3. Expedited Submissions

Submissions that are reviewed on an expedited basis can either receive full approval or approval subject to minor modifications. In the event that directive comments cannot be provided or if the study does not meet a regulatory category which would permit an expedited review, the investigator will be notified that the study will be reviewed by the convened IRC.

4. Investigator Responses

Responses of the principal investigator shall be returned to the IRC Chair for final approval.

In the event of a failure to resolve problems or concerns related to the investigator's response(s), the IRC submission (to include prior correspondence between the IRC Chair and investigator) shall be reviewed at a convened meeting of the IRC (i.e., full-board IRC review).

5. Response Deadline

The communication to the principal investigator shall specify that s/he must respond to the comments or concerns of the IRC within 6 weeks of the date of the communication, and that failure to respond within this 6-week period may result in withdrawal of the project by the IRC.

6. Content of IRC Concurrence/Approval

The principal investigator shall be notified of IRC concurrence/approval through written correspondence prepared and discharged by the IRC Chair. All correspondence shall contain:

- the name of the principal investigator
- the title of the project
- the IRC number assigned to the submission
- the name of the non-conflicted IRC Chair granting final concurrence / approval
- the date of IRC approval/concurrence
- the date of IRC expiration (for expedited and full board studies only)
- the date of IRC modifications (for modification requests only)
- a statement that modifications to the IRC approved research study will require either notification to the IRC (for no human subjects research or exempt determinations) or approval by the IRC (for expedited or full board studies)

For studies that are designated as “no human subject research” the correspondence shall indicate a concurrence that the project does not meet either the definition of “research” at 45 CFR 46.102(d) or “clinical investigation” at 21 CFR 56.102(c); or the definition of “human subject” at 45 CFR 46.102(f) or 21 CFR 56.102(e). For activities determined by the IRC Reviewer to meet either the DHHS or FDA definition of “human subject research,” the principal investigator shall be advised to resubmit the project for exempt, expedited or full-board IRC review as appropriate.

For studies that are designated as “exempt” the correspondence shall include the basis for granting exempt status (i.e., 45 CFR 46.101(b)(1-6) and/or 21 CFR 56.104(d)). For research activities that involve human subjects but are determined to not qualify for exempt status, the principal investigator shall be advised to resubmit the research for expedited or full-board IRC review as appropriate.

For studies that are approved as “expedited” the correspondence shall include the basis for granting expedited approval of the research (i.e., the minimal risk status of the research and the applicable category or categories of research activities listed in the OHRP and FDA document, “Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure”) shall be documented, with justification, within the IRC Research Protocol and/or review materials. For research activities that are determined to not qualify for expedited review status, the principal investigator shall be advised to resubmit the research for full-board IRC review.

For studies involving the use of a Humanitarian Use Device the correspondence must include the following statement:

“Clinical use of the HUD must be limited to the manufacturer’s product labeling and

the clinical protocol approved by the IRC.”

7. Lapses in IRC Approval

If the study is not reviewed and approved by the IRC prior to the expiration date of the previous IRC approval, the principal investigator will be required to cease all research activities described in the IRC protocol (including data analysis) until notification of final IRC approval for continuation of the research has been issued. In this circumstance, the principal investigator shall be advised that, if it is felt that there is an overriding safety concern or ethical issue, s/he may petition the IRC Chair for permission to continue certain research activities that impact the rights and welfare of current research subjects. However, under no circumstances can new subjects be enrolled into a research study after expiration of IRC approval.

If the investigator wishes to continue the study, a new submission to the IRC Chair is required. The investigator will be required to submit information related to conduct of the study to date.

***To access the remainder of the IRC Policies and Procedures,  
please contact the Administration Office.***

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