Chapter 21
External Institutional Review Board Approval

All research projects conducted at Hospital for Special Surgery (HSS) involving human subjects requires review and approval by HSS. Under some circumstances, protocols may be referred to an external Institutional Review Board (IRB).

I. External Institutional Review Board Approval. Under some circumstances, defined below, the Chair of the HSS IRB may determine that a submitted research protocol that involves human subjects may be referred to an external IRB contracted with by HSS for review and approval. No research protocol will be authorized to begin at HSS unless prior review by the Chair of the HSS IRB has occurred and the protocol has been approved by an authorized IRB.

II. Protocols to be considered for external IRB review must fall into one of the following categories:
   A. Industry-sponsored trials;
   B. Studies involving greater than minimal risk;
   C. Studies that involve potential or perceived investigator and/or institutional conflict of interest;
   D. Other studies that are determined, by the Chair of the HSS IRB, to be more effectively reviewed by an external IRB.

III. HSS Review of protocols eligible for external review:
   A. The following documents must be submitted to the HSS IRB office to be considered for external review:
      1. Page 1 of the HSS IRB Application (to verify ancillary department approvals);
      2. Documentation of Clinical Review Panel (CRP) approval;
      3. A short summary/abstract of the proposed research;
      4. Completed Conflict of Interest forms;
      5. Five (5) copies of the protocol.
   B. All research protocols proposed for activity at HSS must be reviewed by both the appropriate specialty section Clinical Review Panel (CRP) and the HSS IRB office.
      1. CRP assessment of protocols destined for external IRB review will not require a complete appraisal of methodology and consenting process, as this will be the charter of the outside review agency. The purpose of this internal review is to understand the objectives of the protocol and address any local context issues – duplicate or past studies that may have some bearing, practical matters dealing with conduct of the study and resources required, such as patient population, HSS ancillary services, etc. Studies requiring additional imaging services at HSS will require an approved radiology research form (Refer to the Radiology Research Policy). If the study is controversial, involves high risk, unacceptable exposure to litigation, or may be inappropriate for HSS, the CRP will raise this issue with the HSS IRB Chairperson. If the CRP recommends the protocol for external IRB review, the investigator and HSS IRB Chairperson will be notified.
2. The HSS IRB office will perform an appraisal of the submitted protocol to insure that required reviews are in place, including but not limited to: Conflict of Interest, CRP, Ancillary Services, and Research Administration.

3. After the above has been completed the HSS IRB Chairperson will determine if the protocol should be directed to any external IRB for review.

IV. Protocol Monitoring:
A. The HSS IRB is responsible for monitoring protocol approval and implementation. The HSS IRB must be copied and receive all correspondence between the investigator and the external IRB.

B. Compliance monitoring for active protocols will be determined on a protocol-by-protocol basis by the HSS IRB office. A review could include:
   1. Observation of informed consent procedures;
   2. Review of investigative site records;
   3. Good Clinical Practice reviews;
   4. Certification of investigator and/or clinical research staff to perform research at HSS.

V. Process for Protocol Submissions to an external IRB.
A. Western Institutional Review Board (WIRB) (See Appendix 1 at the end of this chapter.)
B. Biomedical Research Alliance of NY (BRANY) (See Appendix 2 at the end of this chapter.)
C. The required external IRB Authorization Agreement (Appendix 3) requires the signature of the Vice President of Research or his/her designee and must be submitted to the HSS IRB office along with the appropriate HSS designated CRP approval;
D. The Principal Investigator and/or protocol funds are responsible for the cost of submitting a protocol for external review. The current fee schedules are available through WIRB and BRANY.
Appendix 1.

Western Institutional Review Board (WIRB)

Instructions for submitting protocols to WIRB can be found at http://www.wirb.com. Once at the website, click on submission requirement for instructions. Click on ‘Download Forms” which has all of the necessary forms for the life of the study.

OHRP IRB Registration #: IRB00000533

I. Submission Requirements. The following items are needed to begin the WIRB review process for your research study. If you have questions, call (800) 562-4789 and a staff member will help you.

II. All requests for review must include copies of the following:

A. Protocol (if previously received by WIRB, you may submit the protocol title page and signature page only)
B. Current professional license (for Principal Investigator, if not already submitted to WIRB in current year, showing expiration date)
C. Consent form (see item III in Submission Form for details) There may be a previously approved consent form on record for this protocol. Please contact WIRB if you would be interested in using the previously approved form.
D. Curriculum Vitae (CV) for Principal Investigator and each Sub-Investigator (if not submitted to WIRB within the past year)
E. Completed WIRB Research Review Submission Form (following one of the two options below)
   1. Form may be submitted over the internet
   2. Form may be downloaded and submitted via mail or fax

III. A Drug/Biologic study review requires a copy of the following:

A. Investigator Drug Brochure (for research drug unless previously received by WIRB)
B. Investigator Drug Brochure (for research drug unless previously received by WIRB)
C. Background Information for Food Supplements
D. FDA Form 1572 (when applicable)
E. Research Ethics Board Attestation Form (Canadian sites)
F. Gene Therapy Protocols: (if applicable) either a request for WIRB Institutional BioSafety Committee (IBC) review or the IBC approval information from the review of your study.
IV. If a DEVICE study, a copy of the signed Investigator Agreement for protocols with an IDE, and ONE of the following:

A. FDA Letter approving the Investigational Device Exemption (IDE); OR
B. 510(k) clearance; OR
C. Letter from sponsor stating significant or non-significant risk; OR
D. If the device is cleared for marketing, but the study involves a new investigational use, then

1. A Pre-Market Approval (PMA) letter; OR
2. A PMA supplement letter; OR
3. A PMA amendment letter.

For other submissions, please describe the specific request in your cover letter.

Print this page and go the Download Forms section to download the Research Review Submission Form.

For more information: Contact WIRB or E-mail WIRB.
Appendix 2.

Biomedical Research Alliance of New York (BRANY)

Instructions for submitting protocols to BRANY can be found at http://www.branyirb.com/irb_resources.html. Once at the website, all required forms and submission instruction are posted on the left.

OHRP Federalwide Assurance (FWA) #: FWA0000037

OHRP IRB Registration #: IRB00000080 or IRB00000738

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK
Institutional Review Board
Summary of IRB Submission Requirements

FOR RESEARCH PRESENTING POSSIBLE RISK TO SUBJECTS
(drug and medical device trials, surgical and other invasive procedures, placebo controls, etc.)

Please submit for the first Principal Investigator:

- Three (3) copies of the complete protocol
- Five (5) copies of a summary of the project – i.e. an explanation of the study in non medical terminology not to exceed one page
- Four (4) copies of a properly executed consent form in simple, non medical terminology
- Four (4) copies of assent form, if applicable
- Three (3) copies of the Investigator Drug Brochure
- Three (3) copies of any IND Safety Reports, Drug Inserts or documents relating to the IDB
- Five (5) copies of any advertisement of the study
- One (1) copy of FDA 1572 Form
- One (1) copy of signed “Application for Review of a Research Project” *(need original for IRB files)
- Four (4) copies of the Curriculum Vitae
- Three (3) copies of any other related documents (i.e. –Amendments, Subject Diaries, etc…)

Please submit for each additional Principal Investigator:

- One (1) copy of the complete protocol
- One (1) copy of the summary
- One (1) copy of the informed consent form
- One (1) copy of the assent form, if applicable
- One (1) copy of any advertisement of the study
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<tr>
<td>One (1) copy of any other related documents (i.e. – IND Safety Reports, Amendments, Subject Diaries, etc…)</td>
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<tr>
<td>Four (4) copies of the Curriculum Vitae</td>
<td>4</td>
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<tr>
<td>One (1) copy of the FDA 1572 Form</td>
<td>1</td>
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<tr>
<td>One (1) copy signed “Application for Review of a Research Project” *(need original for IRB files)</td>
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**FOR RESEARCH QUALIFYING FOR EXPEDITED REVIEW**

Please submit for each Investigator:

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<tr>
<td>Two (2) copies of the complete protocol</td>
<td>2</td>
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<td>Two (2) copies of the summary</td>
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<tr>
<td>Two (2) copies of the informed consent form</td>
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<tr>
<td>Two (2) copies of the assent form, <em>if applicable</em></td>
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<tr>
<td>One (1) copy of the FDA 1572 Form</td>
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<tr>
<td>Two (2) copies of signed “Application for Review of a Research Project – Research Qualifying for Expedited Review” *(need original for IRB files)</td>
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Appendix 3.

IRB Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):
Western Institutional Review Board (WIRB) or Biomedical Research Alliance of NY (BRANY)

IRB Registration #: BRANY: IRB00000080 WIRB: IRB00000533
Federalwide Assurance (FWA) #, if any: BRANY: FWA0000037

Name of Institution Relying on the Designated IRB (Institution B):
Hospital for Special Surgery

OHRP Federalwide Assurance (FWA) #: 00000676

The Officials signing below agree that Hospital for Special Surgery may rely on the designated IRB for review and continuing oversight of its human subject research described below: (check one)

(___) This agreement applies to all human subject research covered by Institution B’s FWA.

(_X_) This agreement is limited to the following specific protocol(s):

Name of Research Project:
Name of Principal Investigator:
Sponsor or Funding Agency: ___________________ Award Number, if any: ___________________

(__) Other (describe):

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Institution B’s OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

Signature of Signatory Official (Institution A): ___________________________ Date: ___________
Print Full Name: ________________________________ Institutional Title: _____________________

Signature of Signatory Official (Institution B): ___________________________ Date: ___________

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