PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUBMISSION INSTRUCTIONS
Insight/eIRB

NOTE: For any study involving **cancer-related research** and/or DFCI principal investigators, co-investigators or any other DFCI resource, see the cancer-related research guidance before completing eIRB forms.

ABOUT INSIGHT/eIRB: The eIRB application is part of the Insight Humans Module. The Insight Humans Module enables the user to prepare, submit, and track IRB submissions online. Preparation of new submissions in eIRB involves using the eIRB form wizard to select the required eIRB forms, completing the selected eIRB forms, creating the study staff list, and attaching protocol-related documents.

REQUIRED SIGNATURES: Once the eIRB forms, staff list, and attachments have been completed, the submission may be submitted for required signatures. For studies involving an intervention and/or interaction with subjects, the PI and the appropriate Department Chair/Chief/Unit Chief or delegated faculty member must sign-off electronically in Insight/eIRB by entering their Partners user name and password when prompted. When the Department Chair/Chief is the Principal Investigator, the submission must be signed off on by the Institutional Official. Similarly, when the Unit Chief is the Principal Investigator the submission must be signed off on by the Department Chair/Chief. Note: Studies limited to the use of health/medical records, excess human material, or secondary use of data/samples do not require signature of Department/Unit Chair/Chief or delegate.

Once all required signatures are obtained, the submission will be routed to the PHRC to be accepted for review and then routed to any applicable ancillary committees for review. Study staff will receive an automatic email alerting them to sign-off once the submission is accepted for review by the PHRC. Note: The PHRC may decline a submission when a review of the application identifies discrepancies in the submission or the need for additional information to facilitate review.

eIRB FORMS: Forms must be completed online using eIRB. You must have a Partners username and password to access Insight and use eIRB. Contact the PHS Insight Help Desk if you do not have access to Insight/eIRB.

eIRB STUDY STAFF: Create the list of study staff by adding names from the master person data directory. The master person data directory lists all professional staff/employees that have a Partners username, as well as individuals outside Partners who have been listed as non-BWH/MGH study staff on protocols. Some of the Partners professional staff in the list will have multiple entries because they are affiliated with more than one Partners institution. Select the entry with the applicable institutional affiliation. **Only one person can be designated as the Principal Investigator. Note: Residents and Research Fellows can not be listed as the Principal Investigator.**

The study staff list should include all individuals who will be assisting the Partners Principal Investigator and/or Partners Site-Responsible Investigator(s) with the conduct of the research. This includes individuals with research study-specific roles on the protocol, such as co-investigators, research nurses, research coordinators, and research assistants who intervene and/or interact with subjects or others who have access to the subjects' identifiable health information for the purposes of the research. **Do not list individuals such as laboratory technologists/technicians, radiological technologists/technicians, phlebotomists, patient care services staff, or interviewers who do not have a research study-specific role on the protocol.**

All investigators/study staff must complete the required human-subject protection education program (the CITI Program or equivalent program). When you add an individual to the study staff, their education/training status will be displayed. Contact your protocol administrator if the education/training status in eIRB/Insight is incorrect. For more information, refer to the PHRC Education and Training web page.

If **non-BWH/non-MGH employees** will perform institutionally designated research activities or exercise institutionally delegated authority or responsibility for research, please see the policy "Non-BWH/MGH Employees As Co-Investigators/Study Staff." **Do not list research collaborators at other sites in the study staff list unless they are engaged in the conduct of the research at a Partners institution (acting as a non-employee "agent" of the institution).** For questions about engagement, contact Maria Sundquist, Assistant Director, IRB at msundquist@partners.org; 617-424-4101.

eIRB ATTACHMENTS (PROTOCOL-RELATED DOCUMENTS FOR REVIEW): eIRB submissions for studies involving an intervention and/or interaction with subjects must include the following documents, when applicable:

- ☐ Protocol Summary
- ☐ Schema, required for studies with multiple groups, treatment arms, or randomization
- ☐ Detailed Protocol (always submit the sponsor's/cooperative group's protocol if there is one) When the research is investigator-initiated, the investigator should submit a protocol prepared according to PHRC Detailed Protocol Instructions. **NIH OR OTHER GRANT APPLICATIONS CANNOT BE SUBSTITUTED FOR THE PHRC DETAILED PROTOCOL**
- ☐ DSMB/DMC Charter and Membership, if applicable
- ☐ Questionnaires, Psychological Instruments, or Patient Diaries, if applicable
- ☐ Recruitment Materials (letters, postcards, postings, advertisements, telephone scripts, etc.), if applicable Whenever possible, submit copies of print and audio/video ads in the form in which they will be used, e.g., print ads for newspapers and audio/video ads for radio/television broadcast. **Note: Audio/video ads (for radio/television broadcast) cannot be uploaded in eIRB. Contact your protocol administrator for assistance.**
- ☐ Consent Form(s), if applicable

Drug/Biologic Information

- ☐ FDA IND# and FDA IND Notification Letter (Note: For INDs held by the corporate sponsor or NIH cooperative group, the IND# must appear on the sponsor's protocol. Alternatively, the sponsor may provide equivalent documentation of IND#. For INDs held by the investigator (sponsor-investigator), the investigator must provide all correspondence with the FDA related to the IND), if applicable
- ☐ Investigational Drug Brochure (IDB), if applicable
- ☐ FDA Label Information or Package Insert for FDA-approved drugs and FDA-approved radiopharmaceuticals
- ☐ Subject Drug Diary (for take home medications only)

Medical Device Information

- ☐ FDA IDE# and FDA IDE Notification Letter (Note: For IDEs held by the corporate sponsor or NIH cooperative group, the IDE# must appear on the sponsor's protocol. Alternatively, the sponsor may provide equivalent documentation of IDE#. For IDEs held by the investigator (sponsor-investigator), the investigator must provide all correspondence with the FDA related to the IDE), if applicable
- ☐ Documentation Supporting Non-Significant Risk Status for non-significant risk device studies, if applicable. Refer to the FDA website for more information
- ☐ Device Description from PMA application or Equivalent Device Information for significant risk device studies conducted under an IDE
- ☐ Report of Prior Investigations - for significant risk device studies conducted under an IDE
- ☐ FDA 510K Summary, Letter & Indications for Use for 510K devices cleared for marketing

☐ FDA Summary of Safety & Effectiveness Data (SSED) including Labeling for FDA approved devices

Federally Funded Applications or Proposals

☐ DHHS Sample Consent Form (e.g., Cooperative Group Model Consent Form), if applicable
☐ DHHS-approved protocol (e.g., Cooperative Group Protocol), if applicable
☐ Copy of entire NIH or Federal Grant, if NIH or federally funded (see below)
NOTE: Salary information (not % effort) may be redacted (blacked out).

- If BWH/MGH/SRH is the prime awardee, submit entire copy of grant application
- If subcontract to BWH/MGH/SRH from awardee institution, submit relevant sections only
- If Cooperative Group Grant (e.g., CALGB, ACTG) and the grant does not include a description of the actual protocols, **DO NOT SUBMIT COPY OF THE GRANT – SUBMIT THE COOPERATIVE GROUP PROTOCOL AND SAMPLE CONSENT FORM**

Documents that are available electronically should be uploaded to the Attachments page in Insight/eIRB submission. Hardcopy documents should be faxed or mailed to the IRB accompanied by the eIRB Coversheet, which can be generated from the Attachments page.

STUDIES LIMITED TO HEALTH/MEDICAL RECORDS, EXCESS HUMAN MATERIAL, SECONDARY USEOF SAMPLES/DATA do not require submission of the documents listed above; however, if NIH or federally funded, a copy of the grant application or proposal is still required.

CONFLICT OF INTEREST: The Principal Investigator, Site Responsible Investigators, Co-investigators and any other member of the study staff responsible for the design, conduct, or reporting of the research (collectively 'investigators') must complete the Investigator Disclosure Form when the research involves ANY of the following:

(1) for-profit sponsor or funding source;
(2) a marketed drug, device, or other technology, or a drug, device, or other technology in development; or
(3) a new technology, software or therapeutic approach.

The Investigator Disclosure Forms should be sent under separate cover to the Human Research Office (email as pdf or fax to 617-424-4199). Investigator Disclosure Forms should **not** be attached in Insight/eIRB. Questions about Conflict of Interest should be directed to Maria Sundquist, Assistant Director, IRB at msundquist@partners.org; 617-424-4101. For more information, refer to the Partners Human Research Committee policy on Financial Conflicts of Interest.

ANCILLARY COMMITTEE REVIEW REQUIREMENTS

Non-exempt human-subjects research must be reviewed by the PHRC and, when applicable, the following ancillary committee(s):

CLINICAL TRIALS PHARMACY/INVESTIGATIONAL DRUG SERVICE REVIEW: The Clinical Trials Pharmacy (MGH) and/or the Investigational Drug Service (BWH) must review and approve:

- Protocols that direct drug administration, whether the drug is FDA-approved or not
- Protocols in which ancillary drugs are given for any procedure/test required by protocol (not for the clinical care of the patient)

BIOMEDICAL ENGINEERING REVIEW: Medical devices used in research must meet the same safety requirements as medical devices used in clinical practice. Biomedical Engineering (BME) must review and approve protocols that involve the following:

- Research activities involving clinical investigations of electrically powered devices
- Research activities involving non-standard use of hospital inventory electrically powered devices
- Research activities involving the use of non-hospital inventory electrically powered devices for research purposes (not for the clinical care of the patient)

BME does not need to review and approve protocols that involve the following:

- The use of hospital inventory devices, i.e., devices with BME control numbers (BME stickers with bar codes affixed to the device), when these devices are used according to FDA-approved labeling indications
- The use of devices being studied under an Investigational Device Exemption (IDE) that are **not** electrically powered (e.g., stents, catheters)

NOTE: Electrically-powered devices include devices that are line or battery-powered.

RADIATION SAFETY COMMITTEE (RSC) REVIEW

The RSC must review and approve protocols that involve the following:

- Research-related exposure to ionizing radiation (e.g., x-rays, fluoroscopy, CT)
- Research-related exposure to non-ionizing radiation (e.g., magnetic resonance imaging, ultrasound, and the use of lasers or other optical devices)
- Research to determine the safety and/or effectiveness of a radioactive drug (see also requirements for RDRC review below)

When the study involves the use of lasers, the Radiation Safety Committee will coordinate review by the Clinical Laser Committee. Laser operators must complete institutional training and credentialing requirements.

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC) REVIEW: The RDRC must review and approve basic science investigations of kinetics, metabolism and excretion of a radioactive drug. The RDRC does **not** review the use of radioactive drugs intended for immediate therapeutic, diagnostic or similar purposes, or to determine the safety and/or effectiveness of the drug in humans (i.e., to carry out a clinical trial).

NURSING REVIEW: The Department of Nursing must review and approve protocols that will be conducted in the Emergency Department or Inpatient Care Units (except the GCRC), or research involving the use of survey or interview procedures, or observation of Patient Care Services nurses or staff during performance of employment-related duties. Investigators must indicate whether staff of Patient Care Services may be asked to perform any of the following research-related activities:

- administering and monitoring of investigational medications and devices
- procuring any research-related specimens
- insertion of additional research-required intravenous catheters
- accompanying subjects to research-required tests
- use of research technology and equipment
- completion of survey or interviews, or observation of performance of employment-related duties

EMBRYONIC STEM CELL OVERSIGHT (ESCRO): The ESCRO Committee must review and approve research activities that involve the derivation and/or use of human embryonic stem cells (hESC).

The ESCRO Committee has its' own forms which need to be completed for their review. Refer to the ESCRO web page for forms and policy information:

Investigators proposing hESC research must receive final sign-off from the Institutional Official (IO) before they commence their research. The ESCRO Office receives all relevant approvals (PHRC, ESCRO Committee, and when applicable, Institutional Biosafety Committee). The ESCRO Office is responsible for notifying the IO when all approvals are completed.

PARTNERS INSTITUTIONAL BIOSAFETY COMMITTEE (PIBC): The PIBC must review and approve human studies involving recombinant DNA, RNA inhibition (RNAi), microbiological agents (bacteria/viruses), gene transfer or animal to human transplantation. Additionally, research laboratories utilizing unfixed human materials (tissues, blood, cells) must be registered with the PIBC. All such uses must be registered with the PIBC through the Insight eIBC module. Refer to the PIBC website for forms and policy information: http://resadmin.partners.org/RM_Home/Research_Support_Depts/Research_Oversight/PIBC/PartnersPIBC.aspx

CLINICAL TRIALS REGISTRATION

As of 07/01/11, investigator–initiated clinical trials conducted by Partners investigators that meet FDA Amendments Act (FDAAA) clinical trials registration requirements must be registered on ClinicalTrials.gov prior to IRB approval. The Clinical Trials Registration section of the eIRB form will ask investigators conducting investigator-initiated clinical trials to provide the ClinicalTrials.gov registration number (e.g., NCT00000419) and to sign the Responsible Party designation letter acknowledging responsibility for clinical trial registration and, if applicable, results and adverse event on ClinicalTrials.gov at the end of the study. For more information, see the Partners Clinical Trials Registration website.

IMPORTANT NOTE: Even if your investigator-initiated clinical trial does not meet the FDAAA clinical trials registration requirements, you are strongly advised to read the International Committee of Medical Journal Editors (ICMJE) clinical trials registration requirements and consider registering your trial to comply with the ICMJE requirements for publication.

MEDICARE COVERAGE ANALYSIS

Because clinical research often takes place in conjunction with the routine clinical care of the patient, it is important to ensure that billing for clinical and research procedures is handled appropriately and in compliance with legal requirements. A Medicare coverage analysis (MCA) is required for all clinical trials in which any tests, procedures and interventions performed on study subjects are invoiced to third party payers. The MCA involves determining the underlying eligibility of the study for Medicare coverage and a review of the clinical events specified in the protocol to determine which can be reimbursed by Medicare. Medicare's Clinical Trial Policy only allows coverage of routine costs during a qualifying clinical trial. Medicare will not cover routine costs that are paid for by the sponsor, promised free in the informed consent document, not ordinarily covered by Medicare, or solely to determine trial eligibility or for data collection or analysis. The Partners Clinical Research Office (PCRO) consults with investigators while preparing Medicare coverage analyses so that PIs' expertise and insights are reflected in the final documents.

This policy, implemented in January 2008, applies to all studies involving subject interaction or intervention reviewed by the PHRC on or after January 14, 2008, including those funded by corporate, foundation, not-for-profit and public sponsors, those funded by departmental and sundry funds and studies with no funding. When a Medicare Coverage Analysis is required, PHRC activation of the protocol will be contingent upon completion of the analysis. For more information contact PCRO at pcro@partners.org; http://www.partners.org/pcro.