MEMORANDUM

To: PRINCIPAL INVESTIGATOR

From: Maria Sundquist

PHRC IRB Liaison

Date: DATE

Re: PROTOCOL TITLE/CEDE REVIEW RECORD NUMBER

The protocol is eligible for independent/commercial IRB review. The following institutional requirements must be fulfilled **prior** to submission of an application to the independent IRB.

1. Ancillary Committee Review
2. Administrative Requirements
3. Completion of Independent IRB Forms

**Ancillary Committee Review**

The protocol must be reviewed by the ancillary committee(s) listed below **prior** to submission to the independent IRB. We have forwarded the protocol, model consent form and, when applicable, drug/device brochure, to them for their review. The ancillary committees will notify us when they have completed their review and will provide us with any changes they require to the protocol and/or consent form.

[ ]  MGH Clinical Trials Pharmacy

[ ]  BWH Investigational Drug Service

[ ]  MGH Radiation Safety Committee

[ ]  BWH Radiation Safety Committee

[ ]  MGH Biomedical Engineering

[ ]  BWH Biomedical Engineering

[ ]  MGH Nursing

[ ]  BWH Nursing

[ ]  PHS Biosafety

[ ]  PHS Medicare Coverage Analysis (MCA)

**Administrative Requirements**

You are responsible for completing the administrative requirements listed below **prior** to submitting the IRB application forms to the independent IRB.

1. Complete, Sign and Submit the Partners Cede Review Principal Investigator and Department Chair Certification Form
2. Submit Completed and Signed Partners Cede Review Study Staff Certification Forms
3. Submit Completed and Signed Financial Disclosure Forms for Study Staff Identified as Responsible for the Design, Conduct, or Reporting of the Research
4. Complete and Submit Documentation of Completion of Administrative Requirements Listed Below:

[ ]  Emergency Department Review

1. Any protocol that involves the Department of Emergency Services at MGH must be reviewed by Dr. Nagurney’s Department of Emergency Services Committee. Please ensure that Dr. Nagurney is fully apprised of the protocol and has signed off on it.
2. Any protocol that involves the Department of Emergency Medicine at BWH must be reviewed by Dr. Danny Pallin, Director of Clinical Research in the Department of Emergency Medicine. Please ensure that Dr. Pallin is fully apprised of the protocol and has signed off on it.

[ ]  Operating Room/Recovery Room Instructions

1. The BWH OR Products Committee must approve any protocol that involves the use of a medical device and/or product in the Operating Room. Approval from the OR Products Committee must be obtained prior to scheduling the first patient. Please contact Maureen Kelly Fitzgerald, Director, Operating Rooms at (617) 732-7280 to facilitate the approval process.
2. Any protocol that involves any intervention in patient carebefore, during or after their surgical procedure, whether it is the use of a medical device and/or product (e.g., drugs, instruments, equipment or other research tools) in the Operating Room at MGH, must be approved by the MGH OR Products Committee. You must obtain approval from the OR Products Committee before scheduling the first subject. Please contact Dr. Peter Dunn, Medical Director of the Operating Room at (617) 726-7542 to facilitate the approval process.

[ ]  Labor & Delivery Instructions

1. Any protocol at MGH that involves pregnant women should be reviewed by the MGH Obstetrics Review Committee. Please contact Jeff Ecker, MD directly regarding this review.
2. Any protocol at BWH that involves pregnant women should be reviewed by the BWH Obstetrics Review Committee. Please contact Tom McElrath, MD, PhD directly regarding this review.

[ ]  Conscious Sedation Instructions

1. Any protocol that involves conscious sedation done for research at MGH only must be forwarded to Richard Pino, MD, medical director for conscious sedation at MGH for approval. He will ensure that the plans for conscious sedation adhere to the institutional policies. Please forward this protocol to Dr. Pino for review.
2. We expect that those administering conscious sedation at BWH are institutionally credentialed to do so.  Please confirm and specify who will be administering conscious sedation.

[ ]  CMS Category B Device and Medicare Intermediary Instructions

1. This protocol proposes the use of a Category B investigational device. In order to petition the Medicare Intermediary and other third party payers for coverage of an investigational device and related service, special handling is required. Please contact Jennifer Meneses at 617-954-9368 to provide the information necessary to allow determination of coverage. **Please be advised it may take up to 6 weeks from IRB approval to obtain determination of coverage from the Medicare Intermediary. Coverage for the cost of the device and related care may be denied if the device is used before the determination is made.**

[ ]  BWH Radiology Review

**Any protocol that involves imaging or image guidance that deviates in any way from routine clinical imaging (including specific requirements for image acquisition or reconstruction) must have a BWH Radiologist Co-Investigator and must be reviewed by a member of the relevant radiology modality operations team.  Contact** **Patti Goldberger****, Administrative Director of Radiology Research (617-525-8758) to arrange for review by the relevant radiology modality operations team.**

[ ]  Payments to Subjects and Cash Control Policy Instructions

**Payments to research subjects must be made by Partners Accounts Payable (AP) check when the study involves a single one-time payment of greater than $50 OR multiple payments over time. See policies** [**Payments to Human Subjects for Participation in Research**](http://healthcare.partners.org/phsirb/Guidance/Payments_to_Human_Subjects_for_Participation_in_Research.4.12.pdf) **and** [**Cash Control and Accountability for Payments to Human Subjects for Participation in Research**](http://healthcare.partners.org/phsirb/Guidance/Cash_Control_for_Subj_Pymts.4.12.pdf)**.**

[ ]  Zero Dollar Purchase Order Instructions (for bringing in devices provided by sponsor)

**When the sponsor (or another party) provides a medical device for use to obtain measurements, collect data, or monitor subjects, the investigator must request a zero dollar purchase order to track receipt of the medical device and to document BME inspection for electrical safety, when necessary. For more information, refer to the** [**Zero Dollar Purchase Order Policy**](http://biomed.partners.org/main/Policies/PartnersZeroDollarPOPolicy.pdf)**.**

**Completion of Independent IRB Forms**

You may complete the independent IRB submission forms when all administrative requirements and ancillary committee reviews have been completed. We will notify you when these are complete and you can submit to the independent IRB.

**Record Keeping Responsibilities and Insight**

We will create a cede review protocol record in Insight for tracking and reporting purposes. However, the Insight cede review protocol record will not contain copies of all independent IRB submissions and correspondence; these are available in the independent IRB’s research portal. You will be responsible for creating and maintaining a regulatory binder for this protocol and for complying with all regulatory and institutional record keeping requirements.

**Study Staff Changes**

You are responsible for reporting changes in study staff to the Partners IRB and for requiring new study staff to submit completed and signed study staff certification forms, and when applicable, completed and signed financial disclosure forms.

**Questions**

Contact me by phone 617-424-4101 or by email msundquist@partners.org with questions about the institutional requirements in this memo or the policies and procedures for use of an independent IRB.