Overview

• How to accurately create a budget for your Radiology research exams inclusive of either X-Ray, CT, MRI or PET/CT.

• How to successfully schedule and logistically plan for your Radiology research studies.

• How to incorporate appropriate IRB Informed Consent language into your study ICF documents.
Steps to Creating an Accurate BMC Imaging Study Budget

Before your study budget is finalized with the sponsor:

- Contact Both Radiology Research Administrator, Jacqueline Jordan-Gray, at ext. 4-4631 and Alexandra Hui in Grants Administration at ext. 4-5110 to inform them of your new study.

- Your budget, including technical reimbursement for each scan and faculty and ancillary salary support, will be reviewed and established by Alex Hui working with the P.I. and study coordinator.

- Professional fees (fees for the Radiologist read of the scans) are pre-set fees established by the Radiology Department and will be provided to you by Jacqueline Jordan-Gray. (The technical fees agreed upon will not be inclusive of professional fees). Should your study require clinical reads, your office will be invoiced directly for them by the office of Radiology Research.
Scheduling Radiology Research Scans @ BMC

*Research scanning cannot begin until the following:*

- A BMC registration grant account is set up as an insurance carrier in SDK by the BMC Grants Admin. Post-Awards office – Alex Hui (4-5110). *(SDK is the BMC registration system for all non-standard of care procedures).*
- Study imaging acquisition parameters, imaging transfer guidelines, special scheduling instructions, clinical read requirements, and the CRF, source document, and volunteer or phantom scan requirements are outlined in the Office of Radiology Research fax form. This must be completed and reviewed by the research office.
- A pre-initiation meeting is required to be held prior to the first research subject visit and must be attended by the PI, his/her Study Coordinator, all Radiology co-investigators, the modality supervisor and the Office of Radiology Research representatives.
- A Radiology research code is assigned to your study. *This will ensure that your subjects will not receive bills for the technical and professional fees.*
Scheduling Radiology Research Scans @ BMC (continued)

- Your research subjects must be registered with Central Registration. Contact Meaghan Whalen in Radiology (tel: 4-2737) for CT, MRI and PET/CT availability and review appointment dates/times. Register your subject with Central Registration immediately after.

- Register them by completing and faxing the form labeled “BMC Research Subject Registration/Outpatient Billing Form” found on the Radiology intranet site under “Registration and Education” under Step-by-Step Guide. (Attn: Allan Reddrick fax: 4-5871, tel: 4-4155).

- **The form must include**: Subject Name, DOB, and date and time of appointment. In SS # field write: denied. If your subject is not a patient of BMC, then write the address of your P.I.’s office. If your subject is a patient, do not change their home address. This will provide an additional check and balance for patients who would not normally come to BMC so they aren’t billed.
Scheduling Radiology Research Scans @ BMC (continued)

Within 48-72 hours, Central Registration should fax you back 2 numbers:

1. Medical Record Number (MRN) – if your subject has never been a patient @ BMC (No Radiology research appointment can be booked without a MRN).

2. Episode or Billing Number – This number ensures that the research visit has been built in SDK and that the study scan will be billed to the grant and not your subject’s insurance.
   (See Federal False Claims Act – prohibits submitting false information)

If 2 days before the study visit you do not have a MRN and or Billing Number, call Allan at 4-4155 ASAP. If you cannot reach him, PAGE Meaghan Whalen (pager # 2784) or Kirise Kramer (pager #4800).

A unique episode/billing number must be created for each research visit to Radiology via the “BMC Registration Form for Research Subject” form
Scheduling Radiology Research Scans @ BMC (continued)

Appointment day/time scheduling arrangements

- There are two dedicated MRI research slots available Monday-Friday on ENC. They are 10:45 and 11:30 a.m. There are NO blocked slots for Research CT and Nuclear Radiology.
- Should your study require specific times other than the existing blocked slots, contact Jacqueline Jordan-Gray.
- You must book a study within 7 business days of the designated time slot. If not, it will be released for clinical purposes.
- To schedule an appointment day/time for your subject, contact Meaghan via email at Meaghan.Whalen@bmc.org with the following information: name of study, subject name, subject DOB and subject MRN.
Scheduling Radiology Research Scans @ BMC (continued)

• Provide Meaghan a few requested dates/times in case some slots have already filled.
• You will know availability via email within 24 hours or sooner.
• Slots fill quickly so it’s best to have all requested information to Meaghan at first time of contact.
• Research appointments cannot be booked without a MRN.
• We cannot “hold slots” for more than one day.
• We will do our best to accommodate your subject’s availability.
Navigating Radiology on the Study Day

*It is HIGHLY SUGGESTED that someone from your research staff accompany each study subject to every scheduled research appointment.*

- Report with your subject to either ENC or HAC campus Radiology Department 15-30 minutes before your scheduled scan time.
- Radiology on ENC is located on the first floor of the 88 East Newton Pavilion past the old gift shop location. Radiology on HAC is located on the 1st floor of the Menino Pavilion to the left of the main entrance. (The Radiology research staff is happy to show you these locations before your first subject is enrolled).
- Provide the check-in receptionist in Radiology with the subject’s central registration form (mentioned earlier).
Navigating Radiology on the Study Day (continued)

• Your study patient will be asked specific questions (Name, DOB and Soc Sec #) in an effort to correctly identify them. Please inform them of this process which is hospital policy.

• A wristband will be placed on your subject.

• Please arrive with all study related materials such as CRFs, source docs, labeled CDs or DVDs, etc. (Some study coordinators have made their own). You will not have to wait for your CDs or DVDs to be burned. They will be collected and distributed to you by our research staff.

Daily Radiology Schedule delays will almost always occur

• Manage your subject’s expectations and factor this into post-Radiology study activities.
Navigating Radiology on the Study Day (continued)

Cancellations and Lateness

• For cancellations or late appointments of more than 30 minutes on the day of the study scan please call the applicable modality tech room AND page Meaghan Whalen at 4-2784.

  MRI tech room on ENC: 8-6054
  CT tech room on ENC: 8-6564
  CT tech room on HAC: 4-7631
  Nuclear Medicine on ENC: 8-6625
  Nuclear Medicine at Moakley: 4-6440
Navigating Radiology on the Study Day (continued)

• For cancellations 24 hours or more prior to your study appointment, please call AND email
  Meaghan Whalen @ 4-2737;
  meaghan.whalen@bmc.org
Template ICF Language for Studies Involving Contrast Agents

CT with IV Contrast

**Background:**
A CT scan is a type of x-ray used to evaluate _______________. Here at Boston Medical Center, CT is the standard method finding out _______________ Before a CT Scan, an x-ray dye (called "contrast") is injected through a needle in your vein to be able to tell the difference between blood vessels and other tissues on the scan.

**What Happens in this Research Study:**
When you enter the CT scanner, special lights may be used to ensure you are properly positioned. You will hear only slight buzzing, clicking and whirring sounds as the CT scanner revolves around you.

If IV contrast is used, you will feel a slight pin prick when the needle is inserted into your vein. You may have a warm, flushed sensation during the injection and a metallic taste in your mouth that lasts for a few minutes. Occasionally, a patient will develop itching and hives, which can be relieved with medication. If you become light-headed or experience difficulty breathing, you should notify the technologist as you may be having a severe allergic reaction.

**Risks and Discomforts:**
The risks of the procedure include an allergic reaction and/or decreased kidney function from the standard contrast administration. Without history of previous adverse reactions to contrast material, or abnormal kidney function, such risks are minimal. If a reaction should occur, you will receive appropriate medical care immediately.

A CT scan gives an added dose of radiation. The total dose of additional radiation you will receive from all CT during the entire study is about _______ [check with Radiation Safety Office – Chris Martel – as it depends on the area to be scanned and number of scans].
Template ICF Language for Studies Involving Contrast Agents

- More ICF templates inclusive of MRI and PET/CT can be found on our Radiology web site at:

http://internal.bmc.org/radiology/ResearchEducation.html
Radiology Research Resources @ BMC

- **Research Instructions:** [Introduction to Radiology Research Funding](http://internal.bmc.org/radiology/PoliciesandProcedures.html)

- **Step-By-Step Guide to Initiating Your Study in Radiology**

- **Human Subject Protection Training & INSPIR Registration Instructions**

- **How to Submit and IRB Protocol via INSPIR**

Policies and Procedures of Radiology and Radiology Research can be found here: [http://internal.bmc.org/radiology/PoliciesandProcedures.html](http://internal.bmc.org/radiology/PoliciesandProcedures.html)
Radiology Research Resources @ BMC

Research Instructions:
- Introduction to Radiology Research Funding
- Step-By-Step Guide to Initiating Your Study in Radiology
- Human Subject Protection Training & INSPIR Registration Instructions
- How to Submit and IRB Protocol via INSPIR

On-Going Research:
- List of IRB-Approved Radiology Research Projects
- List of Active Research Projects in Radiology with and without Radiology P.I.s
The Office of Radiology Research is located at:
820 Harrison Avenue
FGH Building, 3rd Floor
Main phone: 617-638-6610
Main Facsimile: 617-638-6616

- Jacqueline Jordan-Gray, Research Administrator
  Phone: 617-414-4631, pager #4879
- Kirise Kramer, Research Coordinator,
  Phone: 617-638-6591, pager #4880
- Meaghan Whalen, Research Assistant
  Phone: 617-414-2727, pager #2784