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Division of MRI Research

Getting Started Tips and FAQs

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This document acts as a quick guide to aid in the application process for studies planning to utilize the services of the Translational MRI Research Core.

To begin, you will need human subjects or animal research approval through the BIDMC CCI/IRB, IACUC, or another appropriate regulatory body.

- *Informed Consent Form*

The BIDMC CCI/IRB has some standard language for use in the ICF for studies involving MRI. We have developed an **IRB template** to include many of the frequently seen MRI study types.

It is easier to address MRI ICF language needs before you submit your protocol; otherwise you may need to submit an amendment to update the language. Please contact us at MRIResearch@bidmc.harvard.edu for advice on what language to include in your human subject's protocol. We are happy to review your documents before you submit to the IRB.

- *Healthy Volunteer for Sponsor Protocol*

Many industry sponsors require a phantom test to be completed with the imaging protocol. This sometimes also includes the requirement to test the protocol on a healthy volunteer. To test the protocol on a healthy volunteer, your IRB will need the following:

- Part A – Section A8 – You will need to check healthy volunteers.
- Part B – Should include a statement about scanning healthy volunteers for this purpose.
- Part D (ICF) – You can choose to include the healthy volunteer language in your overall consent, or include a separate consent for only the protocol testing/dummy run. We can share a template for a separate ICF for this.
- Part R – Section R2 –You will need to list 1+ for number of healthy volunteers.

- Screening for MRI

Implementing screening for MRI contraindications (i.e. pacemaker, some implant models, etc.) into your study's screening plan will help to prevent study delays or cancellations. In addition, you should add "MRI contraindication" to your list of exclusion criteria in your Part B. Please contact MRI Research for any questions related to MRI screening.

- *Contrast Agents*

Depending on the use of contrast agents with MRI scans, you may need to submit a Part E to the Research Pharmacy. Please contact MRI Research to discuss if this applies to you.

  - *Point-Of-Care (POC) Testing*

    Per MRI Research policy, POC urine hCG (pregnancy) and creatinine testing need to be conducted prior to the administration of a contrast agent. To add POC testing to your protocol, you will need to submit a Part H. We have template language we can share for your Part H and ICF for when pregnancy or creatinine point-of-care (POC) testing will be done in the MRI Research Suite.

- *Part R/Radiology Resources Form*

To utilize MRI, you will need to submit a Part R with your IRB application. The Part R needs to be signed by a Radiology Department designee, so you will need to send your complete CCI application to RadiologyResearch@bidmc.harvard.edu. Additionally, you will need to complete the Radiology Resources Information Form. This form is not submitted to the IRB, but it must be sent to RadiologyResearch@bidmc.harvard.edu. Please contact us if you have any questions with these forms!

- *Incidental Findings from Research MRI*

We require all studies which utilize the research MRI to include a plan in their IRB for incidental findings. Our template ICF includes example language that you can include in your study. In addition, you must denote your incidental finding plan in the Part A of your IRB application as well.

- *Orbital and body x-ray (Part F)*

If subjects have a history of metal injury to the eye or metal fragments (including shrapnel or bullet fragments) in the body, you could choose to exclude those participants or an orbital or body x-ray can be conducted to ensure that no metal remains in the body. We recommend this for patient-centered studies. These x-ray procedures will require the submission of a Part F. You will also need to include a description of the procedure as appropriate in the Part A, B, R, and ICF. We can help get you started with template language about the x-ray procedure for your ICF. The Part F needs to be signed by a Radiation Safety designee, so you will need to send your complete CCI application to RadSafety@bidmc.harvard.edu.

- *Image Transfer and Management*

Routine archiving of images and providing images via digital transfer is provided as part of the scan. For users outside of BIDMC, it is the responsibility of the study teams to set-up any needed data transfer agreements for receiving study images. Converting to other formats may be possible. Imaging data will be kept for at least 6 months from acquisition. After that point, it is the responsibility of the PI to handle and store their data. Please contact MRI Research with any questions.

- *Clinical Radiologist Read/Interpretation of Images*

Our studies do not include any professional services related to Radiologist study interpretation. As of now, Research MRI images acquired on the Research 3T MRI scanner are not allowed to be pushed to PACS or included in OMR. Therefore, they also cannot have a clinical interpretation of the images in the medical record. As an alternative, we can connect you with a Radiologist to discuss if a typed interpretation for the paper-study file would be sufficient for your study, or if other monitoring is needed.