

# Initiating and Running an MRI Study at Duke

## IRB Protocol Approval

To begin an MRI experiment at Duke, you are going to need to get your experiment approved by 2 entities, each with their own procedures and rules. They are the medical center IRB and the Brain Imaging and Analysis Center (BIAC).

First, you need to complete your CITI training /Human Subject Research Training. If you need to complete the training, go to [citiprogram.org](http://citiprogram.org). Log in with your institution (using your Duke information). When prompted, join the Duke Health portal and complete their courses: Vulnerable Subjects – Prisoners, Vulnerable Subjects – Children, Vulnerable Subjects – Pregnant Women, Biomedical Research, and CITI Good clinical practice. It should take a few hours and you need an 80% passing rate to get certification. Once completed, email [eIRB@mc.duke.edu](mailto:eIRB@mc.duke.edu) to establish a Medical Center IRB account. Once logged into <https://eirb.mc.duke.edu>, start a new IRB application with the “New Study Application” button. Once there, fill out the requested information. Remember to fill out the information for the psychiatry department as they are the hospital department that handles the MRI studies that deal with our experimental subject matters (you could also choose radiology as an alternative). It is also recommended at this time to make an appointment with the representatives at BIAC to discuss their recommendations for the MRI protocols for your experiment. Once you fill out the information (with the assistance given by BIAC), attach all relevant documents (like the summary of the research protocol, the informed consent form you plan on using, and any recruitment materials you may use) and submit the experiment for review. The process of undergoing review is time-consuming. You will likely meet with the Clinical Research Unit to discuss your IRB and make edits. You will also have to edit or clarify the protocol as deemed by the department reviewing the protocol.

## BIAC Safety Certification

Once your medical IRB has been established, you can request door access and computer access at the BIAC scanners from the BIAC help desk: [biac-help@duke.edu](mailto:biac-help@duke.edu). They will provide you with the materials you need to begin scanning. In particular, you will need to be MRI safety certified. The information about the certification can be found here: <http://www.biac.duke.edu/research/safety/>. You will need to complete the safety tutorial and complete the safety quiz.

## BIAC Protocol Approval

Once completed, go to the “getting started” page (<http://www.biac.duke.edu/research/gettingstarted.asp>) and follow their instructions on how to complete the BIAC research proposal (it will be a more condensed version of the information you filled out for the IRB). This process should go quickly as you should have met with the people at BIAC before you submitted your IRB. You will need to include information such as study personnel, which scanners you will need, how many hours you want for scanning, and experimental summary. The BIAC scientific review committee meets once near the beginning of each month to review submissions.

## Using the BIAC Calendar

To access the scanner calendar, go to the BIAC website ([www.biac.duke.edu](http://www.biac.duke.edu)) and go to their services page and select the link to the calendar. Alternatively, you can however over the services tab on the homepage and choose calendar. You will need to log in with your Duke Health Enterprise (DHE) account (established when BIAC set up your computer access; will match Duke netID and password). The calendar acts much like a typical web calendar (e.g. outlook, google, etc.). To reserve a slot, choose the room in the “scanner” field on the left. Typically, you will only be scanning in either BIAC5 or BIAC6 and possibly using the TEST1 and MOCK1 rooms for practice. Once you selected the appropriate room, choose the time you wish to reserve the room. You will be redirected to a study details page to fill out. Choose the start time, the end time, the experimenter (you), and the experimental protocol you are running. Once everything is selected, click the “add” button and your time will be allotted. Also, keep in mind the availability of the scanner techs. To check their availability, click on the “MR Tech and Pre-Sold Slots Schedule” link on the calendar main page. This will redirect you to the scanner techs’ schedules. If one of the techs is unavailable during their normal hours, there will be a note on the header of the scanner page for that day. You should be able to book the time you want as long as more than 1 tech is available. On the off chance that there is only 1 tech available, check and see if the other scanner is free. If it is free, book a scan for that room and choose the “Null.01” option for experiment. On your scanner page, book the scan using the normal procedures.

When booking a time slot, you will notice an option for “UserTest.01” in the experiment section. User tests are a way for you to book the scanner room to test out your procedures without having to pay for the time (more information in “BIAC Study Preparation” below).

TEST1 and MOCK1 are additional spaces that can be reserved to run your study. MOCK1 is equipped with a non-functioning MRI scanner and a computer that contains a few typical scanner noises. If you have a subject who has never been in an MRI scan before, it might be good practice to take them there and get them use to the scanning environment/scanner noises before the experiment. TEST1 is a small behavioral testing room. Booking and canceling either of these rooms is free of charge, but you must request hours for these rooms in your BIAC research proposal and have them approved (this will generate calendar protocols for your study that you can use to schedule on their calendars). See “BIAC Study Preparation” below for uses for these rooms.

If you cancel a scanner timeslot more than 1 day before the scan, you can cancel it and remove it from the calendar, free of charge. If you need to cancel the study the day before or the day of the scan, the funding source for the study will still be charged partially for the scan. You will not be charged anything for cancelling MOCK1 or TEST1 bookings.

After a calendar event occurs, you will need to complete the calendar entry (the slot will turn orange when you need to complete it). You will have to add the exam number (the scan number), tech information, the type of consent form signed (if you have more than 1), subject information, the amount the subject was compensated, whether there were any problems with the scan, and a pregnancy test results (if applicable). When you fill out and save all of this information, the calendar entry will return to the standard blue color.

If you would like to see some information about your experiments, click the “Experiment Info Page” on the left. You will be redirected to a page with all of your experiments. You might notice that there will be some repeat scans with different numbers as endings. This is to distinguish which hours you use in which room. For example, an experiment ending in .01 might be for BIAC6 and .61 might be for TEST1. When you click on one of the experiments, it will give you information about the study, including but not limited to the study personnel, the number of hours you have allocated, and calendar entries you need to complete. If you notice you are running low on hours, you can request more in an email to the BIAC help desk ([biac-help@duke.edu](mailto:biac-help@duke.edu)). You can also change the number of hours requested when your BIAC protocol goes through its continuing review process a year after initial approval.

## BIAC Study Preparation

Once BIAC approves your protocol, they should create directories for your study on a BIAC server (Munin3/LaBar) and the scratch drives of the BIAC room computers (their local drives), and you should be given access to these locations. If this is not done, you can contact [biac-help@duke.edu](mailto:biac-help@duke.edu).

To get your study files onto the scanner control room computers, you can upload them to your directory on Munin3 and then download them at the scanner PCs into your scratch drive directories. Information on remotely accessing the BIAC servers can be found here:

Windows - <http://wiki.biac.duke.edu/biac:sftp>

Mac - <http://wiki.biac.duke.edu/biac:macsmb>

For Windows, the software WinSCP is a reliable SFTP client option.

You will need to mount the Munin3 server onto the scanner room PCs the first time you access them. Generally, behavioral and psychophysiological data are transferred from these PCs to the server after each session, and then later downloaded to keoki.

The left workstation in each control room is for the stimulus presentation computer (has two monitors) and the right is for the BIOPAC computer.

Investigators listed on an approved imaging protocol should be able to request DukeCard access to the scanning facilities by contacting [biac-help@duke.edu](mailto:biac-help@duke.edu). You must have a DukeCard with an embedded RFID chip for this to work (not the default DukeCard type). If you need to obtain this type of DukeCard, talk to Greg to get the appropriate form (stating the lab is covering the cost of the card), and then take it to the DukeCard Office to request the new card.

Once you have calendar access, you will need to schedule UserTests to set up and test your scanning protocol on the scanner. User tests can be scheduled during empty time slots within 24 hours of the slot (essentially claiming what would have been unused scanner time) and are free. Communicate with the techs either at this point or before this point to construct a scan protocol for the study. You should request a tech's presence in the "Notes" section of the UserTest calendar entry. Things to check during UserTests include: stimulus presentation works on the scanner PC; length of task matches the functional scan length; communication between scanner, presentation PC, and BIOPAC PC is working as intended; stimulus software correctly saves necessary behavioral data; behavioral and physiological data can be transferred to the BIAC server for retrieval later; etc. Note that BIAC policy does not allow you to receive the MRI data from UserTests. If there is a specific reason why you would need to see this data to develop your protocol, you can request access to the data from Todd Harshbarger ([todd.harshbarger@duke.edu](mailto:todd.harshbarger@duke.edu)) and Chris Petty ([chris.petty@duke.edu](mailto:chris.petty@duke.edu)).

BIAC has a mock scanner room (MOCK1) that you can reserve if needed. In addition to having a mock MRI scanner, this room has a PC that is comparable to the stimulus control computers in the scanner control rooms. It can be used to test that your tasks and stimuli will present successfully. This room or TEST1 (same restrictions apply) can also be reserved for paperwork, behavioral testing, and other procedures before or after scanning sessions.

#### Study Running

You must bring a BIAC safety screening form to each session, and the subject must complete this form the day of their scan. The screening form can be found here:

[http://www.biac.duke.edu/library/forms/MR\\_Screening\\_Form.pdf](http://www.biac.duke.edu/library/forms/MR_Screening_Form.pdf)

Note that subjects in the BIAC subject pool have been pre-screened, so you can just do a screening with them the day of their scan. For subjects recruited outside of the BIAC subject pool, you are expected to pre-screen them for MRI safety before scheduling a session for them on the calendar.

Have subjects place all belongings not going into the scanner with them into the lockers near the scanner hallway entrance.

Female subjects of child-bearing potential will be required to complete a pregnancy test before entering the scanner (see age guidelines below). Before the session start time, the experimenter should obtain a urine screen kit from the scanner control room. The kit should consist of the insulated bag containing a zip-top bag contained a packaged sample cup. When entering the control room for the session, place the insulated bag with the urine sample on the papered table, and the tech will run the pregnancy test.

Age 55 or older – no test required

Age 50-54 – no test required if most recent period was more than 12 months ago

Age 45-49 – no test required if most recent period was more than 18 months ago

Remember to move data files to a secure location at the end of the session (usually to Munin3 server). Our space on Munin3 is very limited, so after BIAC QA (quality assurance) processing is completed, move files off Munin3 to keoki.

Even if the BIAC subject pool coordinator schedules a session, the researcher is responsible for completing calendar entries after the session (sometimes the techs will complete the scanner calendar entries; see "Using the BIAC Calendar" above for more information). Entries for MOCK1 and TEST1 calendars must be completed as well (sometimes this just involves opening them and saving them).