Information for Investigators
IRB-HSBS Review of Studies using the Routine fMRI Master Protocol
September 2015

Introduction

In the past, all research projects involving the use of functional magnetic resonance imaging (fMRI) have been reviewed by the IRBMED. The IRB-HSBS, IRBMED and U-M fMRI Laboratory have worked together to formalize a new system in which all standard fMRI studies conducted by any eligible investigator are covered under a single, recently approved IRBMED protocol (HUM93760 Routine Functional Magnetic Resonance Imaging of the Brain), Such standard fMRI studies will therefore only require IRB approval of the behavioral component of the study (task, stimuli, responses, etc.) and that review will be conducted by IRB-HSBS rather than IRBMED. See HRPP Operations Manual Part 5.

Criteria for Review by IRB-HSBS

In order for a study to be eligible for IRB-HSBS review, the following criteria must be satisfied:

1. The principal Investigator must be associated with a unit that is typically subject to IRB-HSBS jurisdiction (not Medical School or Health System). Undergraduates may not serve as PI on an fMRI study.
2. Participants must be healthy adults age 18 or older.
3. The project must be limited to the use of routine scans:
    a. No contrast agents (e.g., gadolinium) may be used.
    b. The MRI pulse sequences will not use gradients that exceed 120 mT/m/s or RF pulses that exceed 1 Watt/kg. No other scanning protocols may be used.
4. Other limitations:
    a. The study may not involve any drugs or medical interventions.
    b. The specific study sample may not include UMHS patients.
    c. UMHS patient medical records may not be used in the study.
    d. The study may not utilize transcranial magnetic stimulation (TMS) or other external methods of disrupting brain function.
    e. The study may not involve the use of unique or unusual equipment not already in use in the fMRI Laboratory.

Any projects not meeting the criteria for review by IRB-HSBS must still be reviewed and approved by the IRBMED.

Preparing the IRB Application

Investigators submitting IRB applications to IRB-HSBS that utilize fMRI scanning procedures outlined in the Master Protocol must consider the following:

1. The focus of the application should be on the behavioral component of the research. The procedures associated with the fMRI scanning have already been reviewed and approved in the Master Protocol.
2. Informed Consent: The consent materials for these projects consist of two components:
    a. The IRB-HSBS fMRI Consent that provides information about the specific research study
    b. The IRBMED-approved fMRI Lab Umbrella Consent that provides information about the fMRI scanning and retention of images in a research repository.
3. The application should contain the following specific information:
    a. Section 1.1.2 (related studies) – include HUM00093760 – Routine Functional Magnetic Resonance Imaging of the Brain
    b. Section 5 (research design)

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i. 5.1.1 or 5-1.5 (protocol) – must cite the approved fMRI Master Protocol. Include a plan for reporting incidential findings of potential brain abnormalities.
ii. 5.4 (inclusion/exclusion criteria) - In addition to the specific inclusion/exclusion criteria for the specific research study, the fMRI Master Protocol requires the following:
- Exclusion:
  - Individuals under 18
  - pregnancy
  - claustrophobia
  - uncontrollable shaking
  - can't lie still for one hour
  - metallic or electronic implants in the body (pacemakers or pacemaker wires, open heart surgery, artificial heart valve, brain aneurysm surgery, middle ear implant, hearing aid, braces or extensive dental work, cataract surgery or lens implant, implanted mechanical or electrical device, or artificial limb or joint
  - foreign metallic objects in the body (bullets, BBs, pellets, schrapnel, or metalwork fragments)
  - current or past employment as machinists, welders or metal workers

c. Section 6 (benefits and risks) – Describe risks and benefits of the behavioral study and note that risks associated with fMRI scanning are described in the Master Protocol and have been determined to be no more than minimal.
d. Section 8-1 (subject recruitment)
   i. 8-1.8 (recruitment materials) – Check "pre-screening questions" and upload the approved Safety Screening document that is required for all projects involving fMRI scanning.
e. Section 9-1 (subject populations) - If the study includes women, be sure to select "women of child-bearing potential" as they must be screened for pregnancy.
f. Section 10-1 (informed consent) –Upload the IRB-HSBS fMRI consent document. Upload the IRBMED consent document in Section 44.
g. Section 37 (women of child-bearing potential) – Note that women who are unsure of their pregnancy status will be asked to take a urine pregnancy test provided by the fMRI lab.
h. Section 44 (other supporting documents) – Upload the IRBMED fMRI Umbrella Consent. This document is uploaded here as the IRB-HSBS is not approving this document as part of its review.

Incident Reporting – Adverse Events/ORIOs/Unanticipated Problems
Investigators should report any adverse events and ORIOs (Other Reportable Information or Occurrences) such as protocol deviations or accidents/incidents to the IRB-HSBS in accordance with standard reporting requirements. Incidents related to the fMRI process, such as mechanical issues with the scanner or with the scanning protocol, will be reported to the IRBMED via the Master Protocol for review.

1. **Incidental Findings**
   fMRI scans used for research purposes are different from clinical MRI scans and are not intended to be used to detect brain abnormalities. Occasionally a researcher or the MRI technician, who are not neuroradiologists, may detect something that appears to be an abnormality (such as a cyst or tumor) in a research scan. The Master Protocol outlines the general process regarding reporting of incidental findings; the IRB-HSBS protocol includes a study-specific plan for handling

incidental findings. Any abnormal finding should be immediately brought to the attention of the study PI or faculty advisor for projects being conducted by graduate students or post docs. The PI will inform the participant either through a phone call or face-to-face meeting, make a recommendation that the participant follow up with their personal physician and make arrangements to provide a summary of the finding to the participant's personal physician, with the permission of the participant. An adverse event report of the incidental finding should be submitted to the IRB-HSBS.

2. **Subject Complaints**
   Participants are provided with contact information for both IRB-HSBS and IRBMED in the consent materials. Generally ORIOs reporting subject complaints should be submitted to IRB-HSBS unless they deal specifically with the fMRI scanning component of the research, which should be reported to IRBMED via the Master Protocol.