

The IRB-HSBS, IRBMED and [U-M fMRI Laboratory](http://fmri.research.umich.edu/) have worked together to formalize a process in which standard fMRI procedures are covered under a protocol approved by IRBMED (HUM00093760, Routine Functional Magnetic Resonance Imaging of the Brain). Studies conducted by IRB-HSBS investigators that employ these standard fMRI procedures therefore only require IRB approval of the behavioral component of the study (task, stimuli, responses, etc.) conducted by IRB-HSBS rather than IRBMED. See [HRPP Operations Manual Part 5](http://research-compliance.umich.edu/operations-manual-irb-jurisdiction-and-cooperative-research#irb-hsbs).

**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](http://research-compliance.umich.edu/operations-manual-irb-jurisdiction-and-cooperative-research#irb-hsbs) (not Medical School or Health System). Undergraduates may not serve as PI on an fMRI study.
2. Participants may be healthy children between the ages of 10-17 or healthy adults age 18 or older.
3. The project must be limited to the use of routine scans:
   1. No contrast agents (e.g., gadolinium) may be used.
   2. 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:
   1. The study may not involve any drugs or medical interventions.
   2. The specific study sample may not target Michigan Medicine patients.
   3. Michigan Medicine patient medical records may not be used in the study.
   4. The study may not utilize transcranial magnetic stimulation (TMS) or other external methods of disrupting brain function.
   5. 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 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 IRB-HSBS application is on the behavioral component of the research. Review and approval of the procedures associated with the fMRI scanning are in the IRBMED fMRI Master Protocol.

1. Informed Consent: The consent materials for these projects consist of two components:
   1. The IRB-HSBS consent and/or assent document that provides detailed information about the specific behavioral research study, and
   2. The IRBMED-approved Routine Functional Magnetic Resonance Imaging of the Brain (HUM00093760) Master Protocol consent and/or assent that provides information about the fMRI scanning and retention of images in a research repository. Confirm with the fMRI laboratory that you are using the most recently approved version of the consent/assent.
2. The IRB-HSBS application should contain the following specific information:
   1. **Section 1.1.2** (related studies) – include HUM00093760 – Routine Functional Magnetic Resonance Imaging of the Brain
   2. **Section 5** (research design)**/Section 5-1** (research methodology)
      1. 5.1.1 (uploaded protocol) or 5-1.5 – must cite the approved fMRI Master Protocol. Include a plan for reporting incidental findings of potential brain abnormalities (see page 3 for additional information).
      2. 5.4 (inclusion/exclusion criteria) - In addition to the specific inclusion/exclusion criteria for the research study, describe the fMRI Master Protocol required exclusion criteria:

***Excluded:***

* + children under 10
  + 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, shrapnel, or metalwork fragments)
  1. **Section 6** (benefits and risks) – Describe risks and benefits of the behavioral study and state that risks associated with fMRI scanning are described in the Master Protocol and have been determined to be no more than minimal.
  2. **Section 8-1** (subject recruitment)
     1. 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. Ensure that you are using the most recently approved version of the Safety Screener (it should contain the IRBMED finalization stamp in the header). Check with the fMRI study team to make sure you have the current version (PI Luis Hernandez-Garcia or Study Coordinator Barb Hibbard).
  3. **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. Select “children” if you will scan children.
  4. **Section 10** (informed consent type and process) – Explain that the study team will obtain consent for the behavioral component using the IRB-HSBS consent document (for the specific study research) **and** the IRBMED Master Protocol consent documents for the fMRI procedures using the currently approved IRBMED fMRI consent. The study team is responsible for providing the signed fMRI consent document to the fMRI lab staff. The study team should retain a copy of the fMRI consent for their own records.
  5. **Section 10-1** (informed consent) –Upload the IRB-HSBS fMRI consent and/or assent documents. Ensure that your consent includes information about how long the scanning process is expected to take (e.g., no more than x minutes). Upload the most recently approved IRBMED fMRI Master Protocol consent document in Section 44. Check with the fMRI study team to make sure you have the current version.
  6. **Section 33** (children) – Complete this section if you will scan children.
  7. **Section 37** (women of childbearing potential) – Describe that women who are unsure of their pregnancy status will be asked to take a urine pregnancy test provided by the fMRI lab.
  8. **Section 44** (other supporting documents)
     1. Upload the IRBMED fMRI Master Protocol consent and/or assent document(s). The IRB-HSBS does not approve this document as part of its review. It may not be edited; it must be used as approved by the IRBMED.
     2. Upload scripting for the incidental findings discussion.

**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](http://research-compliance.umich.edu/incident-reporing-aeorio). For incidents related to the fMRI process, such as mechanical issues with the scanner or with the scanning protocol, the study team should consult with the IRB-HSBS staff owner regarding these events that must be reported to the IRBMED via the Master Protocol application (HUM00093760). The IRB-HSBS staff owner will notify the Master Protocol study team and IRBMED regarding the incident and to discuss appropriate next steps.

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 must include a study-specific plan for handling incidental findings. Any abnormal finding should be immediately brought to the attention of the fMRI PI.

If the fMRI PI is available while the subject is being scanned, can assess the finding, and make a determination about informing the subject—it will be done immediately. If the fMRI PI is not available for a face-to-face meeting with the subject, study staff are instructed to complete as much of the protocol as is reasonable, without revealing the existence of an anomaly.

The intention here is to control the circumstances by which the subject is informed of the anomaly, making sure that the PI is the person who talks to the subject, can answer questions and gauge the emotional reaction of the subject to the news. The subject will be informed by the PI, personally, either through a phone call or a face-to-face meeting. While a face-to-face meeting is preferred, this may not be immediately convenient for the subject, and the PI must weigh the relative benefits of the more personal setting versus anxiety engendered by anticipating a meeting to discuss something the subject did not expect to hear.

An adverse event report of the incidental finding should be submitted to the IRB-HSBS.

1. **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 as described above.