IRB Application Guidelines for Routine Functional MRI (fMRI) Studies

The IRB application for behavioral human subject studies utilizing the U-M Routine fMRI master protocol must contain the following information for IRB-HSBS review:

IRB Application Section	Question	Information Required
Section 1 (related studies)	1.1.2	Enter *HUM00093760 – Routine Functional Magnetic Resonance Imaging of the Brain* in the text box.
Section 5 (research design)	5.1.1 (stand-alone protocol)	Upload the *fMRI Master Protocol** document
	5.4 (exclusion criteria)	List the following primary exclusions: • Children under 10 (for research involving children) • Pregnancy • Claustrophobia • Uncontrollable shaking and/or cannot lie still on back for one hours • Metallic objects and/or electronic implants in the body See the *fMRI Safety Screening Form** document for detailed screening criteria.
	5-1.5	Include the study-specific plan for the reporting of incidental findings of potential brain abnormalities
Section 6 (benefits and risks)	6.3 (risks)	In additional to describing study-specific risks, state that risks associated with the fMRI scanning are described in the *Routine fMRI Master Protocol** and have been determined to be no more than minimal.
Section 8-1 (subject recruitment)	8-1.8 (recruitment materials)	Check *pre-screening questions* and upload the required *fMRI Safety Screening Form** document.
Section 9-1 (subject populations)	9-1.1 (included populations)	As applicable to the study, check: • Women of child-bearing potential (will require pregnancy screening) • Children or Viable Neonate (note: under 10 years of age not allowed) Complete application sections 33 (children) and 37 (women of childbearing potential) as applicable.
Section 10-1 (informed consent	10-1.1 (upload)	Upload the study-specific fMRI consent and/or assent informed consent documents based on the *IRB-HSBS fMRI Template**.
Section 44 (additional supporting documents)	44.1 (upload)	Upload a copy of the approved *IRBMED Routine fMRI of the Brain consent and/or assent** informed consent documents. Note: you cannot alter these consent documents.

* These documents can be found on the IRB-HSBS Website on the Routine fMRI Study Guidelines webpage.