*(EHS use only)* MRISC Protocol#:

Form Completed by:

Name:

Your email address

Phone Number:

Section I: General Information:

Protocol Title:

Synopsis: Provide a brief (2-3 sentences) lay-language synopsis of the study

Principal Investigator:

Principal Investigator Phone Number:

Principal Investigator Email Address:

Department:

Is this project a part of an approved IRB protocol?

[ ]  Yes

[ ]  No

Is the PI the author of the protocol/study?

[ ]  Yes

[ ]  No

IRB Protocol # and Title (N/A if not yet approved)

*Note: Submit the approved IRB protocol or draft IRB protocol and associated documents with this form.*

Section II: Imaging Payment Information

FAU Tag #:

Cost Center Manager:

Cost Center Manager email:

Cost Center Manager phone number:

Granting Agency (N/A if not applicable):

Section III: Study Details

For this study, subjects are (Check and explain):

[ ]  Healthy controls

[ ]  Patients with specific symptoms or disorders. Please explain:

[ ]  Other. Please explain:

What phase is the trial in?

[ ]  Phase 1

[ ]  Phase 2

[ ]  Phase 3

[ ]  Not applicable

[ ]  Other (please explain)

REALISTIC estimated number of patients to undergo MRI scanning

Estimated number of radiology visits per patient

Estimated start date of study

Estimated end date of study

Section IV: Imaging Details

Please briefly (1-2 sentences) identify specifically what the Sponsor/Principal Investigator is looking for on the imaging exam (why the study is being requested, what specific issues need to be addressed in the radiology report, etc.).

Are standard clinical imaging protocols acceptable for this study?

[ ]  Yes

[ ]  No

Describe the MRI protocol with specific sequences that is expected to be used in this study (e.g. T1, T2, BOLD, ASL, MRA, MRS, other). Please be as specific as possible and include duration of each sequence.

Is this a functional MRI scan?

[ ]  Yes

[ ]  No

If Yes, please specify what functional components will be needed (e.g. visual stimulation, auditory stimulation, etc.)

Who will provide the activation stimuli (MRI technologist vs member of the research team)?

Will a member of the research team need to be present for the scanning?

[ ]  Yes

[ ]  No

Is there any phantom imaging or a volunteer imaging required?

[ ]  Yes\*

[ ]  No

\*You may be required to supply a volunteer for imaging.

If Yes, please specify the requirement?

Is there specific online training required for imaging team?

[ ]  Yes

[ ]  No

If Yes, please specify the online training requirement?

Is there a questionnaire to be completed?

[ ]  Yes

[ ]  No

If Yes, please list the questionnaire.

Will other study related equipment need to be brought into the MRI control room or scanner room?

[ ]  Yes

[ ]  No

If Yes, please explain.

Will specific patient populations be studied that might require additional care? (check all that apply or select that none of these populations will be included in the MRI procedures)

[ ]  Minors (0-9 years)

[ ]  Minors (10-17 years)

[ ]  Adults (18-=70 years)

[ ]  Elderly (age >70 years)

[ ]  Individuals with a condition or disease that requires additional support or attention during the scan. Please explain:

Are there any modifications to the standard screening and imaging support process that will be needed for this subject population?

[ ]  Yes

[ ]  No

If Yes, please explain.

Is contrast required for study?

[ ]  Yes\*

[ ]  No

\*If yes, you must contact MRMD to discuss (anewberg@health.fau.edu)

Section V: Staff Resources

Are there any special instructions or specification for conducting or interpreting the images?

Identify if additional Radiologist support for this study is required. (check all that are needed)

[ ]  Dual Reads

[ ]  Blind Reads

[ ]  Utilizing specific measurement tools

[ ]  3D volumetric evaluation

[ ]  RECIST

[ ]  RANO

[ ]  modified RECIST

[ ]  Not applicable

[ ]  Other. Please explain:

Has a radiologist with knowledge of the protocol been identified as a co-investigator?

[ ]  Yes

[ ]  No

Radiologist Name (N/A if not applicable)

Radiologist Phone Number (N/A if not applicable

Radiologist Email Address (N/A if not applicable)

Clinical/Regulatory Research Coordinator Name (N/A if not applicable)

Clinical/Regulatory Research Coordinator's Phone Number (N/A if not applicable)

Clinical/Regulatory Research Coordinator's Email Address (N/A if not applicable)

Section VI: Additional Comments

Please provide any additional information you deem applicable to our assessment of the feasibility of your study:

Section VII: Acknowledgement

**Check to indicate agreement:**

[ ]  I acknowledge responsibility for the conduct of the research study and procedures involving MRI scanning at the FAU MRI Facility

[ ]  I am familiar with the potential hazards in the magnetic environment and agree to fully adhere to the requirements delineated in this application

[ ]  I have read and understand the FAU MRI Safety procedures and agree that they will be followed by study team members

[ ]  I agree that all study team members who enter the MRI Facility will be compliant with MRI Safety Training requirements

List names of all team members:

[ ]  I agree that all subjects and items will be screened for safety prior to entering the magnet room

Principal Investigator Name Email/phone

Principal Investigator Signature Date