University of Colorado Boulder

Institutional Review Board
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Guidance Document:

Protocol and Consent Form Language for Studies Using MRI

Overview

If your study will include MRI scans at Intermountain Neuroimaging Consortium (INC), the quoted information in this document should be included in your protocol and consent form documents.

Protocol Document

Exclusion Criterion Language:

"Inability to undergo MRI as determined by MRI safety screen (e.g., pregnancy, metal in body, claustrophobia, using the standard screen conducted by the MRI imaging facility)."

Note: If pregnancy is an exclusion criterion because of the MRI procedure only, pregnancy verification will be in accordance with the INC's policies and procedures. If there are other, non-MRI, study-related procedures that necessitate excluding pregnant women, pregnancy verification is a research procedure and should be listed in the procedures section of the protocol and consent form.

Procedures Section Language:

"MRIs will be conducted according to the policies and procedures of Intermountain Neuroimaging Consortium at the Center for Innovation and Creativity in Boulder Colorado."

Note: Describe the expected duration of the MRI and any tasks or activities subjects will perform during MRI scans.

If you will utilize the mock scanner, include a description of the circumstances under which it will be used (e.g., will all subjects visit the mock scanner or only children or only those who have never had an MRI before?), how the visits will be scheduled, and what subjects will do (e.g., mimic fMRI activities or merely remain still in the mock scanner).

"INC MRI technologists are not trained to read the scans for abnormalities; however, should an anomaly be observed, these images will be flagged and read by a neurologist or licensed radiologist at the Mind Research Network. Subjects will be notified by *[the Principal Investigator or INC staff – chose one]* of the results of the radiology report, regardless of the outcome. Subjects will also receive a letter from the Mind Research Network that includes the radiology report."

Note: Incidental findings can be frightening and stressful for subjects so making sure the right person contacts them is important. If, during the course of your study, you have the opportunity to build a good rapport with subjects (e.g., they have several study visits with you before the MRI is performed) subjects may feel better getting this information from you. If you are uncomfortable contacting subjects about incidental findings INC

staff can contact subjects with the results. Be sure to change the text above to reflect who will contact participants.

Risks Section Language:

"Subjects may experience nervousness and/or claustrophobia during the MRI. While generally safe, it is not known whether an MRI would harm a fetus."

Data Management Section Language:

"MRI data will be stored according to standard INC data management procedures. MRI images will be housed on a CU Boulder server. Metadata (name and contact information) will be entered into the COINS database by study personnel. Each COIN entry will receive a unique research subject identifier. This code will be associated with the images. A copy of the MRI images will be sent to the Mind Research Network for data sharing and storage. No identifying information is included in the images."

Consent Form

Procedures Section Language:

Clearly explain the location, frequency, and duration of the MRI scan(s) subjects will undergo. If an fMRI will be done, describe the activities subjects will perform during the scan.

Risks Section Language:

"You may experience nervousness and/or feelings of claustrophobia during the MRI scan. Should this occur, you will be able to communicate with the MRI technician and can stop the MRI at any time.

Before the scan begins, you will be given a squeeze ball. Should you wish to stop the scan for any reason, you can do so by squeezing the ball."

If applicable, add a sub-section to the Risk section titled: <u>For Women of Childbearing Potential</u> and include the following language:

"While generally safe, it is not known whether an MRI would harm a fetus. You will be screened prior to the procedure and specifically asked whether you could be pregnant. If you are pregnant, you cannot participant in the MRI."

For all studies, add a new section (just after the Risks section) titled <u>Incidental Findings</u> and include the following language:

“The MRI scan(s) for this study are for research purposes only; however, should we observe an abnormality, the scans will be read by a licensed radiologist or neurologist at the Mind Research Network. You will be notified by *[the principal investigator or INC staff – choose one]* of the results of the radiology report. You will also receive a letter from the Mind Research Network that includes the radiology report. Any resulting medical costs will be your responsibility.”