Research Security & Integrity
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Guidance Document:

Protocol and Consent Form Language for Studies Using MRI

Overview

If your study includes MRI scans at the 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 to Investigator: 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 to Investigator: 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 reviewed by a board-certified radiologist at the Anschutz Medical campus. If follow-up with the subject's clinical provider is recommended, subjects will be notified by the Principal Investigator of the results of the radiology report. Subjects will also receive a letter from the study team that includes the radiology review."

Note to Investigator: Incidental findings can be frightening and stressful for subjects so making sure the right person contacts them is important. If the study protocol builds a good rapport between subjects and someone who is not the PI (e.g., a professional research assistant), subjects may feel better getting this information from the research assistant than the PI. Be sure the language above reflects your intended protocol for contacting participants in cases of incidental findings.

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 electronically stored and analyzed using de-identified participant codes. No identifying information exists in either the MRI data or metadata. De-identified neuroimaging data and any associated behavioral data included in fMRI analysis will be stored in Flywheel, a database managed by the Intermountain Neuroimaging Consortium (INC) and Flywheel.io. Data analysis takes place within the Flywheel platform. Only study personnel with appropriate permissions may analyze and download study data via Flywheel."

Note to Investigator: No identifying information exists in either the MRI data or metadata. Strict standards of confidentiality are maintained. MRI data will be electronically collected, stored, and analyzed using de-identified participant codes.

Study teams may collect identifying information (name, address, phone number/email address) from research participants for the purpose of research logistics (e.g., to schedule MRI scans) and giving the participant any radiological review information in the rare event of an incidental finding. All documents indicating the identity of participants will be secured by the study teams.

De-identified neuroimaging data will be stored in Flywheel, a database managed by the Intermountain Neuroimaging Consortium (INC) and Flywheel.io. The INC's partnership with Flywheel.io has passed ICT review to ensure Flywheel data security and accessibility meets CU's strict standards. Behavioral data needed for fMRI analysis will also be stored using the same participant code and is also stripped of direct identifiers.

All Flywheel data and metadata are stored in a privately hosted Amazon Web Services cloud (not the public cloud). Data access is protected using CILogon dual factor authentication and only research personnel may access study information.

Data analysis takes place within the Flywheel platform. Only research staff with appropriate permissions may download data from the Flywheel database. Staff at CU Boulder's INC and CU Boulder's Research Computing will have limited access to the de-identified and coded Flywheel data for the purposes of helping researchers interpret, analyze, and debug analysis workflows. No INC or RC staff receive personal or identifiable data about the subjects. Data are kept indefinitely or until such a time that the data are no longer relevant (e.g., 7 years).

INC provides study teams with a complementary digital "brain souvenir" for each participant, consisting of single images from the scan session. Laboratory staff may send these files to participants using a secure OneDrive link.

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 technologist and can stop the MRI at any time.

Before the scan begins, you will be given a squeeze ball by the MRI technologist. 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: For Women of Childbearing Potential 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 Incidental Findings and include the following language:

"The MRI scan(s) for this study are for research purposes only. You should not expect clinical results from this study or for your MRI scan to be seen by a medical expert. If we happen to observe an abnormality, the scans will be read by a licensed radiologist at the Anschutz Medical Campus. If the abnormality would benefit from follow up or awareness by your medical provider, you will be notified by *[the principal investigator or study staff]* of the results of the radiology review. You will also receive a letter describing the observed abnormality. Further evaluation of the abnormality, and any resulting medical costs of that evaluation, will be your responsibility."