

MELD Protocol 1 - Patient and Control Inclusion in the MELD Project

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Abstract

The MELD Project is an international collaboration aiming to create open-access, robust and generalisable tools for FCD detection. To this end, we will train a neural network classifier on MRI features from FCD patients from multiple centres worldwide.

Protocol 1 details instructions for patient and control inclusion in the MELD Project as well as how to fill out the demographics csv file.

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Guidelines

If you have any questions or run into problems, please feel free to contact the MELD project: (meld.study@gmail.com)

Before start

Ensure that you have "cloned" the MELD file structure from github. (https://github.com/MELDProject/meld)

To do this, in a terminal window cd into the location you wish to store the data.

`cd <path>`

Then "clone" the repository using the following command:

git clone https://github.com/MELDProject/meld

This will download all of the scripts, template folder structure and template control data necessary for the MELD preprocessing.

This contains the MELD_site_code_participants.csv file that is required for this protocol.

Protocol

Review medical records and identify patients

Step 1.

Inclusion Criteria

Patients can be included in this study if they:

- have a radiological diagnosis of FCD with histopathological confirmation OR
- have a radiological diagnosis of FCD without histopathological confirmation

OR

are MRI negative with histopathological confirmation of FCD

AND

• have a 3D preoperative T1-weighted MRI scan

(this can be acquired on a 1.5T or 3T MRI scanner)

(3D FLAIR data can be included from sites where this is available)

AND

• are over age 3 years

Identify Control Participants

Step 2.

Controls can be included in this study if:

they are healthy

AND

have a 3D T1-weighted MRI scan

(this can be acquired on a 1.5T or 3T MRI scanner provided it is the same Tesla as the patients' data from your centre)

Fill in Demographic Information for Patients and Controls

Step 3.

Anonymous participant IDs

Each participant should be given an anonymous ID according to the following naming structure: MELD [site code] [scanner code] [patient/control] number

[site code] = site identifier which will be provided to you e.g. H1 for Great Ormond Street Hospital

[scanner code] = 15T if 1.5T scans or 3T if 3T scans

[patient/control] = FCD if patient, C if control

[number] = 0001, 0002 etc.

Examples of participant IDs:

MELD H1 15T FCD 0001

MELD_H1_3T_C_0002

MELD_H2_3T_FCD_0042

Please make sure to securely keep a spreadsheet at your centre which links the

anonymous IDs used in this study back to the IDENTIFIABLE patient data. THIS MUST NOT BE SHARED and should be kept securely!

Exclusion Criteria

Step 4.

Exclusion Criteria

Patients and controls cannot be included in this study if:

 they have gadolinium-enhanced T1 scans (as the gadolinium affects the cortical segmentations in FreeSurfer)

Fill in Demographic Information for Patients and Controls

Step 5.

Demographics of Patients and Controls

Open the csv file called *MELD_site code_participants.csv* (this will have been downloaded when with the MELD file structure from github. If you have not already done this, please see the guidelines for instructions on how to do so.)

Rename the csv file using your site's specific site code.

e.g. for Great Ormond Street Hospital, if the site code is H1, the csv file would be renamed

MELD H1 participants.csv

Fill in Demographic Information for Patients and Controls

Step 6.

ID

For each patient and control include participant ID - named as specified above

Fill in Demographic Information for Patients and Controls

Step 7.

Patient or Control

If patient, code as 1.

If control, code as 0.

Fill in Demographic Information for Patients and Controls

Step 8.

Age

Age of participant in years (1 decimal place) at time of pre-surgical MRI scan.

Missing data should be marked with 555

Fill in Demographic Information for Patients and Controls

Step 9.

Sex

Sex of participant.

If male, code as 1.

If female, code as 0.

Missing data should be marked with 555

Fill in Demographic Information for Patients and Controls

Step 10.

Age of onset of epilepsy

Age of onset of epilepsy in years (1 decimal place)

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 11.

Duration of epilepsy

Duration of epilepsy in years (1 decimal place)

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 12.

Radiological diagnosis

If FCD, code as 1

If MRI negative, code as 2

If any other diagnosis, code as 3 (e.g. patient with radiological diagnosis of ganglioglioma who was operated and histological diagnosis was FCD)

If control, code as 666

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 13.

If other - please provide details

If you have a patient who had any other radiological diagnosis other than FCD or MRI negative (example above in step 13), specify the details here

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 14.

Ever reported MRI negative

If the patient has ever been reported MRI negative (i.e. at some point the radiological report did not identify the FCD^*), code as 1

If lesion has always been seen on MRI, code as 0

If control, code as 666

*even if the FCD has now been identified

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 15.

Surgery

If patient has been operated, code as 1

If patient has NOT been operated, code as 2

If control, code as 666

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 16.

Histology

If patient has been operated and histological classification available please provide: e.g. FCD 1A FCD 1B FCD IIA FCD IIB FCD IIIA

If histopathology revealed lesion was NOT FCD, code as other

If patient operated but histology not available, code as 555

If control, code as 666

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 17.

If other - please provide details

If you have a patient whose histopathology was NOT FCD (i.e. other in column 9), specify the details here (e.g. Radiological diagnosis of FCD, but histopathology revealed DNET)

Fill in Demographic Information for Patients and Controls

Step 18.

Engel outcome

If patient has been operated and ENGEL outcome is available please provide: e.g. I=1, II=2, III=3, IV=4

If patient operated but Engel outcome not available, code as 555

If patient NOT operated, code as NO

If control, code as 666

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls **Step 19.**

f/u for Engel

How long in years has patient been followed up for the Engel outcome in column 11?

If patient operated, but this data is not available code as 555

If patient NOT operated, code as NO

If control, code as 666

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 20.

Lesion Mask

If lesion mask has been done, code as 1

If lesion mask has not been done, code as 0 (ideally all patient MUST have lesion masks)

If control, code as 666

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

Fill in Demographic Information for Patients and Controls

Step 21.

Scanner or Sequence

To differentiate multiple scanners or sequences used on the same field strength.

Identify how many scanners have been used to scan your patients and controls.

Identify the field strengths used.

Identify if different sequences were used on a particular scanner to acquire different patient / control data.

Each different scanner and sequence needs a unique identifier.

E.g. If two 3T scanner have been used to scan the participants the codes would be 3T1 and 3T2.

If one 3T scanner was used but 3 different T1 sequences, the codes would be 3T1, 3T2 and 3T3.

If one 3T and one 15T, code as 3T1 and 15T1.

If scanner has been upgraded, consider it as a brand new scanner i.e. If one 3T scanner but has been upgraded, code as 3T1 and 3T2

Missing data should be marked with 555

In fields irrelevant for controls, control data should be marked 666

ANNOTATIONS

MELD Project 28 Feb 2018

Mira asked: 'What about if different scanners were used and within these scanners there were different sequences....how would you like us to distinguish for that?'

We're currently not differentiating between these two. So for example, you could have, 3T1, 3T2 and 3T3 for the first scanner with three sequences, and 3T4 3T5 for the second scanner.

Fill in Demographic Information for Patients and Controls

Step 22.

3D FLAIR

If 3D FLAIR available, code as 1.

If no 3D FLAIR, code as 0.

Fill in Demographic Information for Patients and Controls

Step 23.

QC

This is filled during protocol 3

Fill in Demographic Information for Patients and Controls

Step 24.

Notes

If there is any other information that you would like to share or feel we need to know about this participant, please write in this column. REMEMBER not to include any identifiable data!

ANNOTATIONS

Konrad Wagstyl 01 Mar 2018

An extra column has been added to the demographics table for freesurfer version. Please make a note of the freesurfer version used. If you haven't already started, please use freesurfer 5.3.

Warnings

PLEASE DO NOT SHARE ANY IDENTIFIABLE DATA

Data sharing only occurs at the level of anonymised demographics information and anonymised data matrices. These are in a template space that cannot be traced back to an individual.

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