

# MELD Protocol 1 - Patient and Control Inclusion in the MELD Project Version 2

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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

## ■ ANNOTATIONS

**MELD Project** 05 May 2018

Remember to read the guidelines before starting this protocol!

### 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

***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**

#### ■ ANNOTATIONS

**Nuria Bargallo** 07 Jun 2018

Hi, I am Nuria from Hospital Clinic. I do not understand this Lesion Mask question. Could you explain it?.

## 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*

*We are not differentiating between different scanners and different sequences. So for example, you could have, 3T1, 3T2 and 3T3 for the first scanner with three sequences, and 3T4 3T5 for the second scanner.*

**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 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!*

Fill in Demographic Information for Patients and Controls

### Step 25.

#### FreeSurfer version

*Please make a note of the freesurfer version used. If you haven't already run FreeSurfer, please use freesurfer 5.3.*

*If version 5.3, code as 5.3*

*If version 6.0, code as 6.0*

## 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.