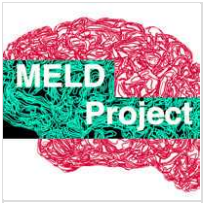

Feb 08, 2022

Protocol 1: Clinical and demographic information

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Meld Project
University College London, University of London

The MELD Project is an international collaboration aiming to create open-access, robust and generalisable tools for FCD detection.

This MRI data protocol details
1) How to get access to the MELD Focal Epilepsies Redcap database
2) Inclusion criteria for the study
3) How to fill in the participant information questionnaire

PLEASE NOTE: To take part in the MELD Project each site will be required to 1) sign our memorandum of understanding and 2) provide a letter from the head of department or local R&D office confirming that they have obtained appropriate ethical approval to share the anonymised data with UCL.

DOI

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Grant ID: A2665

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Feb 08, 2022

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

:

Contact the meld.study@gmail.com in order to
1) Ensure you have the necessary ethical approval to take part in the study
2) Obtain you site code
3) Get access to the RedCap questionnaire

Access to the RedCap Database

1 Anonymised clinical and demographic information for all participants should be entered by filling in the participant information survey on Redcap.

Each participating site needs to send us the institutional email addresses of the individuals who will be carrying out data entry. Accounts on RedCap will be set up by the study co-ordinators to give you access to the participant questionnaire.

Please note researchers at your institution will only be able to see / review / edit records that have been created by your site.

Inclusion criteria

2 **Inclusion criteria:**

- Any age > 0
- 3D T1-weighted MRI scan (either 1.5T, 3T or 7T)
- A radiological and / or histopathological diagnosis of:
  - Focal cortical dysplasia
  - Hippocampal sclerosis / granule cell dispersion
  - DNET / ganglioglioma / other low-grade tumour
  - Polymicrogyria
  - Periventricular nodular heterotopia
  - Cavernoma
  - Gliosis
  - Non-specific pathology
  - mild malformation of cortical development

OR

- MRI-negative, unoperated focal epilepsy

Controls can be healthy controls or patients scanned for headache with a normal MRI

2.1 **Exclusion criteria:**

- Meningoangiomatosis
- Hemimegalencephaly
- Sturge-Weber Syndrome
- Infarcts
- Rasmussen's encephalitis
- Tuberous sclerosis

MELD anonymous IDs

3 Each participant should have been given an anonymous ID according to the following naming structure:
MELD_[site code]_[patient/control]_number

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

[patient/control] = P if patient, C if control.

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Examples of IDs:
MELD_H1_P_0001
MELD_H1_C_0001

If participant was included in the FCD study and has an ID such as MELD_H1_15T_FCD_0001, the ID should be kept the same. I.e. Use the original FCD flag and scanner flag
If control was included in the FCD study and has an ID such as MELD_H1_3T_C_0001, the ID should be kept the same.

[number] = 0001, 0002 etc.

Examples of old participant IDs from the FCD study :
MELD_H1_15T_P_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

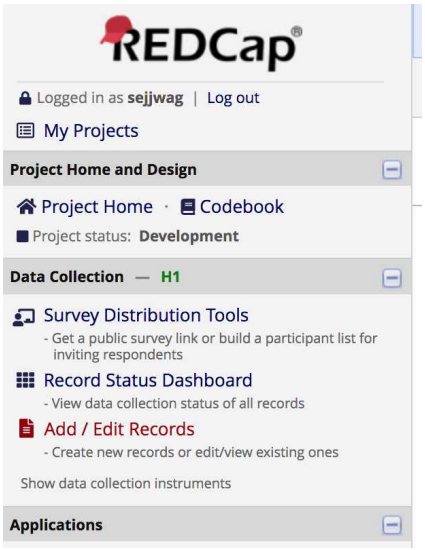
Filling in Participant information on the RedCap Database

4 Login to UCL RedCap (**redcap.slms.ucl.ac.uk**) using your login details

Click on My Projects

Click on MELD Project: Focal Epilepsies

Click on Add / Edit Records



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5 Under "Enter a new or existing MELD Project Anonymous Participant ID" type the anonymous ID of the participant you want to enter data for

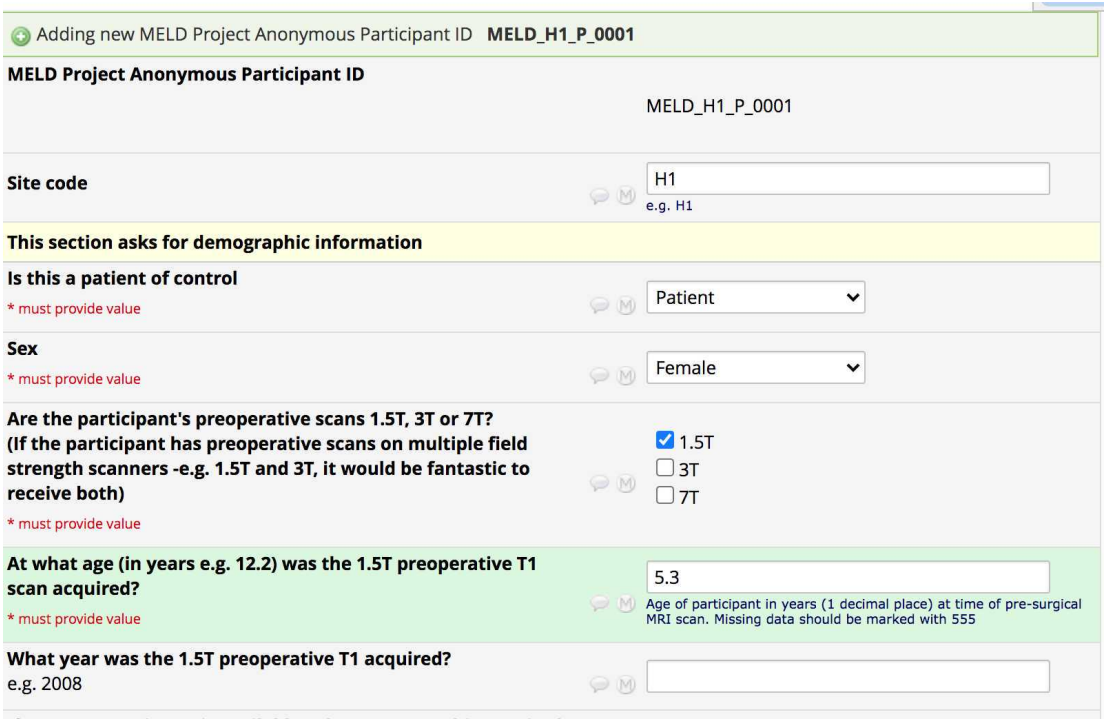
e.g. MELD_H1_P_0001

This can either be a new participant or you can edit the information of a previously entered participant.

To edit the participant, you will need to click "status"

6 You will now be able to fill in the questionnaire:

Here is an example



7 Filling out seizure outcome data:

Some centres use ENGEL outcome and others use the ILAE classification system. Please fill in

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1. Whether the patient was seizure free (no auras) at 1 year follow-up
2. Whether the patient was seizure free (with auras) at 1 year follow-up
3. ENGEL or ILAE outcome at 1 year follow-up
4. ENGEL or ILAE outcome at most recent follow-up

There is no need to provide both ENGEL and ILAE unless you easily have this information.

8 When you have finished filling out the questionnaire, save and exit the form.

If you partially fill out a form, under form status ensure the box states "incomplete". This will allow you to reenter the record and edit the information at a later date.

Do not click complete until you have filled in all information.

9 If you have any questions about how to fill out the questionnaire - please contact **meld.study@gmail.com**
or post a comment on this protocol!

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