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Data management plan (DMP)

1 Data collection and documentation

1.1 What data will you collect, observe, generate or reuse?

This application aims to receive ethical approval for the reuse of brain imaging- and personal, health related data of in total 300 patients with multiple sclerosis. No data will be acquired exclusively for the project.
We will also reuse an anonymized normative database containing morphometric estimates from ~380 healthy subjects who participated in earlier studies at our institute.

This project will reuse:

1. clinical MR imaging data collected by imaging techniques
2. demographic and clinical data collected by physicians

This project will generate:
3. pre-, and post-processed imaging data of the human brain
4. source codes and software

The format will be as follows:
1. DICOM
2. Excel (.xlsx) and Redcap
3. NIFTI (.nii) and .mgz
4. Octave and Matlab (.m) and Pyhon (.py)

Data volume over all are expected to remain below 1 TB (roughly 2-3 GB per patient and 0.5 GB per healthy control).

1.2 How will the data be collected, observed or generated?

Methodologies:
Imaging and clinical data of patients will be acquired following predefined protocol standards within the clinical
workup. The imaging data of healthy controls was acquired during previous studies at our institute and an anonymized database was built up, which will be reused.

1. Raw imaging data of patients will be reused from PACS (Picture Archiving and Communication System, http://www.radiologie.insel.ch/de/geraetepark/pacs/) and evaluated with FreeSurfer, FSL, SPM and self-written software.
2. clinical data from ipods

Data Management:
raw data: PACS for imaging data, ipods for clinical data as mentioned before. Each patient has a unique Patient ID (PID).
For healthy controls only age, sex, used scanner and MR sequence are known. Other information was anonymized previously and subjects cannot be identified.

All clinical and imaging data of patient will be encoded as soon as they will be used for this study. Unique subject identification codes will be generated for each patient (e.g. study code – serial subject number – sex – age - in years at MR acquisition - time point of measurement; example: MSlong_Pat001_f_31_TP1 for a 31 year old female patient's first MRI acquisition). Only the PI will have

access to the code key file linking PID and subject identification code.

Clinical data will be implemented electronically using a dedicated electronic data capturing (EDC) system (REDCap DMS, *https://www.project-redcap.org/*), hosted by server infrastructure of the Dept. Head Organs and Neurology. The base system and functionality is first tested in identical testing/developing environment. Data will be entered in REDCap using either the web based application or the REDCap mobile app for iOS/Android.

1.3 What documentation and metadata will you provide with the data?

The study will be registered in BORIS Research Data at the University of Bern.
The following information will be provided:
- name of the study
- name of the PI
- dates of study start and end
- contact address
- location of data
- number of data sets overall and in subgroups
- access conditions
- keywords: multiple sclerosis, MRI, longitudinal, morphometry, volumetry, machine learning
- aim of the study

All publications will be registered within BORIS at the University of Bern.

2 Ethics, legal and security issues

2.1 How will ethical issues be addressed and handled?

Before the study will be conducted, the protocol as well as other study-specific documents will be submitted to a properly constituted Competent Ethics Committee (CEC, KEK-Bern). This project will be conducted according to the regulatory requirements of the Human Research Act (HRA) and Human Research Ordinance (HRO).

Data of patients that were acquired between 01.02.2015 and start of the study will be used under the provision of the general consent. Only data of patients who did not refuse the general consent will be used.

Imaging and clinical data cannot be made publicly available due to the size of the data and the possibility to identify the patients. However, we are open to provide our data for reuse by other researchers if reuses apply for ethical permission and the Competent Ethics Commitee gives us the permission.

Regarding the software codes and scripts there is no need for data protection. Software developed during the project will be made freely available.

2.2 How will data access and security be managed?

The raw imaging data to be evaluated during the project will be collected on a password protected workstation at the Support Center for Advanced Neuroimaging (SCAN). Additional data that is generated during image analysis will only be identifyable by the study's subject ID and will also be stored on password protected workstations. The patient key will only be available to authorized personnel. Only personnel that is directly involved in the project will know the access codes to the workstation. All workstations used for the project are linked to a RAID system and data backups will be made every night.

Health-related data and patient identifying codes used for the analysis will be entered in a REDCap database. Daily backups are stored on two different backup systems located on the Inselspital campus, Bern. All data entered into REDCap are transferred to the database using Secure Sockets Layer (SSL) encryption. Each data point has attributes attached to it identifying the user who entered it with the exact

time and date. Retrospective alterations of data in the database are recorded in an audit table. Time, table, data field and altered value, and the person are recorded (audit trail).

For data verification purposes, authorized representatives of the applicant, a competent authority (e.g. FOPH), or an EC may require direct access to parts of the medical records relevant to the project, including participants' medical history. Nobody else from outside will have access to the clinical and imaging data.

2.3 How will you handle copyright and Intellectual Property Rights issues?

The PI will be responsible for data access.

Due too the HRA imaging data are restricted data and cannot be shared freely with third parties without explicit permission by the EC, see above.
Software will be made freely available.

The partner in Bern can rely on legal advice for issues regarding Intellectual Property Rights provided by Unitectra. Unitectra is a non-profit organization focused on issues related to technology transfer, which provides this kind of support to the University of Bern (including the University Hospital Inselspital).

3 Data storage and preservation

3.1 How will your data be stored and backed-up during the research?

Clinical data will be stored in Red-Cap, please see also 2.2. The database will be password protected and only authorized persons will have access.

Metadata will be stored in BORIS Repository for Research. Please see 1.3.

Imaging data cannot be stored in a repository due to ethical, legal and size issues. They will be stored on password protected local workstations linked to RAID systems, see above.

3.2 What is your data preservation plan?

All documents and data related to this study are archived for a period of 10 years after study termination. After this period the data will be fully anonymized according to the obligation of the HRO by destruction of the key file linking the Inselspital's patient ID with the study's subject ID.

4 Data sharing and reuse

4.1 How and where will the data be shared?

Imaging and clinical data can only be shared after permission of the EC. For this reason data will be stored locally until third parties provide ethical permission to reuse the data. A repository for imaging and clinical data will not be used.

Software developed during the project will be made freely available on BORIS Research Data, which is currently in construction and will be available 12/2019.

4.2 Are there any necessary limitations to protect sensitive data?

The investigator affirms and upholds the principle of the participants' right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals.

Metadata will be available at the BORIS Research Data Repository as mentioned under 1.3.

4.3 All digital repositories I will choose are conform to the FAIR Data Principles.

Yes

4.4 I will choose digital repositories maintained by a non-profit organisation.

Yes