DMP title

Project Name My plan (KU Leuven DMP)

Grant Title 1830722N

Principal Investigator / Researcher Tom Theys

Description Our understanding of the human brain is hampered by the limitations we face with respect to the research techniques we can apply. We propose an approach to unravel neuronal selectivity underlying cognitive processing by implementing invasive recordings in neurosurgical patients. Recordings from intracranial micro-electrodes will be combined with microstimulation to study the functional network underlying image and action processing, as well as the influence of reward computation and working memory load on decision-making. We complement microscale investigations with fMRI to integrate our findings in a larger network perspective.

Institution KU Leuven

1. Data Description

What data will you collect or create? Fill out the table below and/or describe.

Type of data	Format	Volume	How created?
e.g observational, experimental, reference data,...	e.g. textual, numerical, multimedia	e.g 200MB, 1GB	Computer task, observations, blood sample, ...
Electrophysiological data in patients	ns6, .nev, .ns2 files, MAT files	20-100 GB	clinical and experimental recordings
Functional and anatomical imaging data	dicom; Nifti	5-20 GB	human brain imaging
Psychometric functions and behavioral data	MAT files	1-5 GB	behavioral assessment
Patient information: decoded personal data, clinical parameters and longitudinal follow-up (text fields in Redcap database)	REDCAP eCRF	1-5 GB	patient records

Do you intend to reuse existing data?

Collect and generate new data, there will be **no** use of existing data

Do you use personal data (i.e. all data possibly identifying an individual)?

- Yes

Yes, data on age, sex, disease of the human participants

All human data will be anonymized and stored at the hospital.

2. Documentation and Metadata

Describe the documentation that will be created for the data. This section deals with the way in which you will document how the dataset was created and subsequently processed.

We will acquire electrophysiological data (LFP-MUA_SUA) and behavioral data. Data are stored as Matlab files. New data is generated in several work packages. **For human recordings**, we will obtain:

1. Electrophysiological data in neurosurgical patient: ns6, .nev, .ns2 files, MAT files. Electrophysiological data (digitally - the raw recording data will be saved together with the processed data) as .MAT files
2. Functional and anatomical imaging data. Data (DICOM) will be finally converted in Nifti file format (for statistical analyses).
3. Psychometric functions and behavioural data will be saved in matlab files.
4. Patient information: decoded personal data, clinical parameters and longitudinal follow-up (text fields in Redcap database): For the clinical trials, data will be collected by reviewing the participant and from experiments performed by the investigators. Baseline, demographic, health and research data will be documented on source documents and in an electronic Case Report Form (eCRF), with the exception of personal data which will be collected
5. Manuscripts (papers: .doc, .pdf) will be saved as PDF and in a Word document. Figures as .PNG file (from programs such as Illustrator/Photoshop and Powerpoint).

Describe the metadata for the data. This section deals with metadata: information contained in your dataset about the research data.

Files with names that include the experimental data. The folder structure is organized according to experiment type and will be accessible by all researchers on the delegation log. We are using detailed lab notebooks. The data will be annotated during the acquisition phase of the experiments.

Metadata will be provided as readme, csv, word or excel files, containing all settings and technical descriptions of the experiment. Header files of the imaging data, including all the relevant imaging parameters will be automatically extracted during scanning and stored in automatically created directory structures. The metadata will be provided in a structured manner.

3. Ethical, Legal and Privacy Issues

Are there any ethical issues concerning the creation and/or use of the data?

Creation:

Ethical considerations

- Ethical approval is obtained from the Medical Ethical Committee from UZ/KU Leuven – file S53216 and S60399 was approved and the included informed consent is used for every patient.
- All human data will be anonymized and stored at the hospital.

Did you consider all issues about copyrights and IPR?

If the obtained data have potential for tech transfer and valorization, LRD will be contacted to offer guidance.

Are the collected data considered to be â€œdata containing personal informationâ€ and are all the requirements about the collection of these data met?

Yes, data on age, sex, disease of the human participants

All human data will be anonymized and stored at the hospital.

4. Data storage and Backup during Research

How and where will the data be stored during research?

- Centrally on storage facilities of the research unit

All human data will be anonymized and stored at the hospital.

Neurophysiological, imaging and behavioural data is recorded on the internal and external storage of the computers attached to equipment and is duplicated on the storage facilities of the research unit (UZ Leuven).

Which back-up procedures are in place?

Neurophysiological, imaging and behavioural data is recorded on the internal and external storage of the computers attached to equipment and is duplicated on the storage facilities of the research unit (UZ Leuven).

Describe the data security procedures and who has access to the data.

For the human data, data can only be accessed by personal login by the principal investigator and delegates involved in the conduct of this trial, as mentioned on the research protocol. The file containing the identification code will be secured with a password only available for the investigators involved in this trial. If correction of the data is required, the time, date and initials of the investigator will be written next to the correction.

5. Data selection and Preservation after Research

What is the long-term preservation plan for these dataset(s)?

All data related to the clinical aspects will be retained for at least 20 years after completing the study, as required by law. Data collection has been defined in the informed consent. The data will be stored on labeled pairs of high capacity hard drives within the research facility.

Data Selection: Which data will have long time value for the research and will be preserved?

All data related to the clinical aspects will be retained for at least 20 years after completing the study, as required by law. Data collection has been defined in the informed consent. The data will be stored on labeled pairs of high capacity hard drives within the research facility.

6. Data Sharing

Are there any restrictions for sharing the data?

There is a research agreement (document) for clinical trials: personal data will not be made available under any circumstance, as required by law.

If there are no restrictions, which mechanisms will be in place to assure that the data are discoverable, accessible and intelligible?

Data without legal or contractual restrictions will be made available after the end of the project.

External users will have access to our database through our publications Internal users (UZ/KU Leuven) can access the server. For human data, only people on the delegation log can access the acquired data.

Human data: All people defined on the delegation log (s53126 and s60399) will be able to access the data with the approval of the PI and head of the department. Data can be shared with academic researchers, upon request, after publication and after discussing the purpose and possible collaborations..

How will you share the data?

- Repository

HBP project related data will be uploaded to EBRAINS.

With whom will the data be shared?

- On request

For human data, only people on the delegation log can access the acquired data.

All people defined on the delegation log (s53126 and s60399) will be able to access the data with the approval of the PI and head of the department. Data can be shared with academic researchers, upon request, after publication and after discussing the purpose and possible collaborations.

7. Responsabilities and Resources

Who is responsible for Data Management during the project? This will be the person

who might receive questions on the data management aspects of the research project.

The PI bears the end responsibility of updating & implementing this DMP.

Which additional resources are needed for the execution of the Data Management Plan?

N/A

Did you read the KU Leuven Data Management Policy? (find the link to the policy in the guidance).

- Yes

N/A