Data Management Plan (DMP)
Preliminary version
MODE 2020

PRELIMINARY NOTE

The present Data Management Plan (DMP) is attached to a grant application under the SNSF/DFG Lead Agency Agreement. It covers all research data generated or used during the project. Data generated or used in the present grant application can be grouped in two batches. The *clinical data* group is comprised of data generated or used from questionnaires, interviews, recordings, self-written reports and the Trust Game. The *MRI data* group is comprised of data generated or used during structural, functional and spectroscopic MRI assessments. Data will be generated or used by two participating research teams located in *Lausanne* (Switzerland) and in *Frankfurt/Bochum* (Germany). The DMP develops along the structure requested by the SNSF. Under each heading, answers present the clinical and MRI data information for Lausanne and for Frankfurt/Bochum centers. Data collection, documentation, storage, preservation, sharing and reuse as well as issues related to ethics, legal and security issues are under the responsibility of Dr G. Ambresin (Clinical data, MRI data storage, preservation, sharing and reuse, Lausanne), Prof. B. Draganski (MRI data collection and documentation, Lausanne), Prof. T. Fischmann (Clinical data, Frankfurt/Bochum), Prof. E. Hattingen (MRI data collection and documentation, Frankfurt/Bochum) and Prof.N.Axmacher (MRI data collection an documentation, Frankfurt/Bochum).

1. DATA COLLECTION AND DOCUMENTATION

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

1.1.1 Type of data

Data collected in this project include personal identifiers from patients and controls, results from self-report and hetero-report questionnaires and interviews (clinical data), video and audio data from psychological and psychoanalytic assessments, results from MRI assessments (structural, functional and spectroscopy imaging). All data available in numeric formats, questionnaires and interviews have paper copies as well when direct coding in dedicated software is not possible.

1.1.2 Format and volume of data

We list the specific types of data, equipment, software, data storage formats, and data sharing formats for all research data in this project below.

Table1: Types of data, formats and scales for new data

Types	Equipment	Software	data storage format	data archiving/sharing format	Volume
MRI images					
Raw data: Anatomical MRI Images	Siemens Prisma 3T scanner	SIEMENS MAGNETOM Prisma syngo MR D13D, VE11C	DICOM	DICOM, .tiff uncompressed, JPEG2000	20 MB per person 2*3*20*20=**2.4 GB** for Lausanne **4.8 GB** for Lausanne+ Frankfurt/Bochum
Secondary data:	Computer	FSL, Freesurfer, ITKSnapITKSnap	NIFTI	NIFTI, .png, .jpg, .tiff uncompressed, JPEG2000	400 MB per person 2*3*20*400=**48 GB** for Lausanne **96 GB** for Lausanne+ Frankfurt/Bochum
Raw data: Functional MRI Images	Siemens Prisma 3T scanner	SIEMENS MAGNETOM Prisma syngo MR D13D, VE11C	DICOM	DICOM	80 MB per person 2*3*20*80=**9.6 GB** for Lausanne **19.2 GB** for Lausanne+ Frankfurt/Bochum
Secondary data: 3D Z-stack reconstructions and processed images		FSL, Freesurfer	NIFTI	NIFTI, .png, .jpg	100 MB per person 2*3*20*100=**12 GB** for Lausanne **24 GB** for Lausanne+ Frankfurt/Bochum
Rawdata: Diffusion MR Images		SIEMENS MAGNETOM Prisma syngo MR D13D, VE11C	DICOM	DICOM	200 MB per person 2*3*20*200=**24 GB** for Lausanne **48 GB** for Lausanne+ Frankfurt/Bochum
Secondary data:		MRTRIX	NIFTI	NIFTI, .png, .jpg	20 MB per person 2*3*20*20=**2.4 GB** for Lausanne **4.8 GB** for Lausanne+ Frankfurt/Bochum
Raw data: MR spectroscopy Images	Siemens Prisma 3T scanner	SIEMENS MAGNETOM Prisma syngo MR D13D	.rda	.png, .jpg	20 MB per person 2*3*20*20=**2.4 GB** for Lausanne

					4.8 GB for Lausanne+ Frankfurt/Bochum
Secondary data: 3D Z-stack reconstructions and processed images		LC Model	NIFTI	.png, .jpg	20 MB per person 2*3*20*20=**2.4 GB** for Lausanne **4.8 GB** for Lausanne+ Frankfurt/Bochum
Recordings (interviews)					
Raw data: video recordings (OPD)		À completer?	.mpeg4	.mpeg4 (peut-être dans votre texte dire que le mpeg4 sera utilisé pour stocakage et pour archivage ?)	120 GB
Secondary data: Text transcripts		Microsoft Word, Adobe Acrobat Reader	.docx	.pdfa	1 GB (0.036 GB)
Raw data: audio recordings (Qualitative interview)		A completer?	.wav	.wav (peut-être dans votre texte dire que le wav sera utilisé pour stocakage et pour archivage ?)	96 GB
Secondary data: Text transcripts		Microsoft Word, Adobe Acrobat Reader, MaxQDA	.docx	.pdfa	
Semi-structured Interview					
Raw data: text files administered by research team members		SCID, LIFE Scanned document: Adobe Acrobat Reader	Paper form	.pdfa	1 GB (0.02 GB)
Secondary data :		Scanned document: Microsoft Word, Adobe Acrobat Reader. Results reported in spreadsheets.	.docx	.pdfa .xlsx or .csv	
Written reports					
Raw data: Self-written patient narratives (dreams diaries)		Scanned document: Adobe Acrobat Reader.	Paper form	.pdfa	1 GB
Secondary data : text transcripts			.docx	.pdfa	
Raw data: Self-written patient narratives (trauma narratives)		Scanned document: Adobe Acrobat Reader	Paper form		1 GB
Secondary data : text transcripts		Scanned document: Microsoft Word, Adobe Acrobat Reader. Results reported in spreadsheets.	.docx	.pdfa	

Questionnaires					
Raw data: self-report questionnaires filled in by participants			RedCap spreadsheet Paper form	.xlsx or .csv	1 GB (0.006 GB)
Secondary data :					
Raw data: questionnaires filled in by clinicians			RedCap spreadsheet Paper form	.xlsx or .csv	
Secondary data :					
Trust Game					
Raw data: ?????)		Dedicated software ???	. ???		120 GB
Secondary data: ?????		Microsoft Word, Adobe Acrobat Reader	.docx	.pdf	1 GB (0.036 GB)
					TOTAL = 2TB

Clinical data/Lausanne and Frankfurt/Bochum

Questionnaires

Questionnaires will be coded in RedCap spreadsheets either directly or based on paper records. Ten self-report questionnaires (BDI, MADRS, CTQ, CECA-Q, PCL-R, DEQ, IIP, SCL-90-R, OPD-Q, WAI) will be administered to each patient and healthy control at enrolment (T0) and follow-up termination (T3). Eight questionnaires will be administered to each patient only at follow-up (T1-3 months, T2-6 months). Two hetero-report questionnaires (QIDS-C and GAF) will be filled in by clinicians at all follow-up points for each patient. One hetero-report questionnaire (QIDS-C) will be filled in by a clinician at T0 and T3 for each healthy control. Spreadsheets will be archived and shared in .xlsx and/or .csv format.

Interviews

Semi-structured interviews will be coded in a dedicated software either directly or based on paper records. One semi-structured questionnaire (SCID I/II) will be administered to each patient at baseline, whereas only the subsection on major depression and/or dysthymia (SCID I) will be administered to healthy controls at baseline. At T3 follow-up, 2 semi-structured interviews (SCID I/II, LIFE) will be administered to patients. Spreadsheets will be archived and shared in .xlsx and/or .csv format.

Recordings

At T0 and T3, one qualitative interview of a duration of 1.5 hour each will be audio-recorded in 7 patients in each condition in .wav format. The interviews will be transcribed in Word text and stored in .docx format and shared in .pdfa format after anonymisation. Around all FU points, a couple of sessions will be audio-recorded in .wav format for the assessment of adherence. The adherence will be rated according to the CPPS coding system listening to interviews. Results will be stored and shared in .pdfa format after anonymisation.

At T0 and T3, one psychoanalytic diagnostic interview of 1,5 hour (OPD) will be video-recorded in .mpeg-4 format. The interviews will be coded on dedicated OPD-report forms. Report-forms will be shared in .pdfa format after anonymisation.

Written reports

Self-written trauma narratives will be collected at T0 and T3 in patients and transcribed in Word text and stored in .docx format and shared in .pdf format.

Dream diaries will be collected at each follow-up point in patients and transcribed in .docx format and shared in .pdf format.

Trust Game data

At T0 and T3, Trust Game data will be collected via Presentation or Matlab software. One Trust Game will be performed by patients at T0 and T3. Spreadsheets will be archived and shared in .xlsx and/or .csv format.

MRI data / Lausanne and Frankfurt/Bochum

Recordings and analyses

At T0 and T3, anatomical MRI, functional MRI, Diffusion MR and MR spectroscopy data will be acquired in patients and controls. This project will generate raw data images acquired using 3T MR Scans (Bochum: Philips 3T, Frankfurt and Lausanne: Siemens Prisma 3T scanner) with imaging software SIEMENS MAGNETOM Prisma syngo MR D13D, VE11C. All data will be stored in digital form, either in the format in which it was originally generated DICOM and NIFTI, or will be converted to png, .jpg, .tiff uncompressed, JPEG2000 files. The raw data files will be processed and analyzed using various software FSL, Freesurfer, ITKSnapITKSnap or MRTRIX.

Clinical data/Lausanne Total data volume will be about 200 GB

MRI data/Lausanne Total data volume will be about 2 TB.

Clinical data/ Frankfurt/Bochum Total data volume will be about 100 GB.

MRI data/Frankfurt/Bochum Total data volume will be about 2 TB.

1.1.3 Reuse of existing of data (ours or third-party)

None

1.1.4 Dataflow between participating centers

Describe the table in words and sentences.

Table 2: Types of data and formats for reused data

Types	data storage format	Original data from	Reuse of data by	Purpose
MRI images				
Anatomical MRI Images	DICOM & NIFTI	Lausanne research group Frankfurt/Bochum research group	Los Angeles Research group (Prof. Peterson)	Analysis of data
Functional MRI Images	DICOM & NIFTI	Lausanne research group Frankfurt/Bochum research group	Los Angeles research group (Prof. Peterson)	Analysis of data
MR spectroscopy Images	DICOM & NIFTI	Lausanne research group Frankfurt/Bochum research group	Frankfurt/Bochum research group (Prof Hattingen)	Analysis of data
Recordings (interviews)				
Video recordings (OPD)	.mpeg4; .docx and/or .pdf	Lausanne research group	Lausanne research group	Analysis of data
Audio recordings (Qualitative interview)	.wav; .docx and/or .pdf	Lausanne research group	Lausanne research group	Analysis of data
Semi-structured Interview				
SCID I/II	.xlsx or .csv?; .docx and/or .pdf	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group	Analysis of data
LIFE	.xlsx or .csv?; .docx and/or .pdf	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group	Analysis of data
Written reports				
Self-written patient narratives (dreams diaries)	.docx and/or .pdf	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group	Analysis of data
Self-written patient narratives (trauma narratives)	.docx and/or .pdf	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group after training or Pennebaker ?	Analysis of data

Questionnaires				
Self-report questionnaires (filled in by participants)	.xlsx or .csv	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group	Analysis of data
Questionnaires (filled in by clinicians)	.xlsx or .csv	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group	Analysis of data
Trust Game				
Data: ?????)	. ???? .docx and/or .pdf	Lausanne research group Frankfurt/Bochum research group	Lausanne research group Frankfurt/Bochum research group	Analysis of data

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

1.2.1 Methodologies for data collection / generation

Clinical data / Lausanne and Frankfurt/Bochum

Data generation and analyses from research data has been summarized above (see point 1.1)

Self-report and hetero-report data will be collected online, using the secure web application for building and managing online surveys and databases, REDCap online platform hosted on CHUV servers for Lausanne center and on International Psychoanalytic University (IPU) servers for Frankfurt/Bochum centers. The application allows to collect data without having to manually report data from paper-pencil to an electronic database, avoiding potential sources of error. Participants unable to access to the online version of the questionnaires will be provided with paper-pencil forms. The package 'REDCapR' encapsulates functions to streamline calls from R to REDCap API.

Interviews (SCID I/II and LIFE) will be collected in face-to-face setting using paper-pencil. Results will be entered in a dedicated spreadsheet via the REDCap online platform hosted on CHUV and IPU servers.

Video- and audio-recordings will be collected in face-to-face setting and coded using validated coding systems. Whenever a dedicated software for helping with data collection/observation/generation exists, it will be used.

Written reports will be collected as self-written participant narratives and transcribed in text files.

Trust Game data will be obtained via Presentation or Matlab software and collected as logfiles.

File naming & Versioning Data will be organized into folders and subfolders using a simple hierarchy of files to make navigation and location easier as well as to decrease opportunities for filing errors. Files, as well as data within files, will be named according to pre-agreed conventions. Files will be labeled using short unique identifier and summary of content. Dr Ambresin and Prof. Tamara Fischmann, principal

investigators of this project for Lausanne and Frankfurt/Bochum centers respectively, will be in charge of the setting up and the follow-up of these conventions along the project. Versioning of data subsets will be distinguished by a subscript (v01, v02, …) with date attached to the file name, as follows Date (YYYYMMDD)_DatasetName (short unique identifier_summary of content)_VersionNo. Filename will similarly appear as Date (YYYYMMDD)_FileName (short unique identifier_summary of content)_VersionNo.

All relevant data extracted from the questionnaires, interviews, recordings and Trust Game will be manually introduced in REDCap and analysed using R (.Rdata format), SPSS (.sav format) or STATA (.sav format) softwares during the course of the project, and will be converted in a .csv or .xslx format after the end of the study to be shared with the public in an online repository (see section 4.1).

MRI data / Lausanne and Frankfurt/Bochum

MRI data will be collected using 3T MR Scans (Bochum: Philips 3T, Frankfurt: Siemens 3T, Lausanne: Siemens 3T) and the SIEMENS MAGNETOM Prisma software. In Lausanne, the collection and generation of MRI data will be under the responsibility of Dr Gilles Ambresin while the MRI platform maintenance is under the responsibility of Prof. Bogdan Draganski, Head of the imaging neuroscience laboratory LREN (CHUV). In Frankfurt/Bochum, the collection and generation of MRI data will be under the responsibility of Prof. E. Hattingen and Prof. Nikolai Axmacher.

1.2.2 Methodologies for data collection / generation

Clinical and MRI data/Lausanne and Frankfurt/Bochum
Routine procedures for conducting high quality research, for publication in peer reviewed journals:
- Instrument /machine calibration and control processes for MRI data will be done by the imaging neuroscience laboratory LREN (CHUV) and Frankfurt/Bochum centers throughout the study.
- Standard protocols in the field for data collection ensuring reliability and consistency. During a pilot practicability study in Lausanne, the standard protocol for MRI data collection has been already established and controlled by an engineer from the imaging neuroscience laboratory LREN (CHUV). The same procedure has been performed in Frankfurt/Bochum centers during the pilot practicability study.

- Appropriate experimental design, data recording and data validation (controls, randomization in treatment arms, blinding of evaluators, hypothesis driven-protocol, purposeful sampling for qualitative interviews) ensuring internal validity.
- Training (techniques & data management) for research staff to ensure high quality data (PhD students and continuing education via regular workshops in *Open Science* at respective doctoral schools and libraries.
- Peer review of data: regular supervision and research meetings to ensure that procedures have been carried out correctly and that all data are properly recorded.

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

1.3.1 Data documentation

To document our research, we will use MRI logfiles, information about equipment settings & instrument calibration, method reports, references to participant and clinician questionnaires, questions and instructions for qualitative interviews, data dictionaries, DMP, all essential components of data management.

1.3.2 Metadata

Readme file All datasets generated in this study will be accompanied by a **DataCite standard metadata in a text file.** The DataCite Metadata Schema for Publication and Citation of Research Data allow data to be understood and reused by other members of the research group and add contextual value to the datasets for future publishing and data sharing. We will generate the text file automatically using the DataCite Metadata Generator after filing the form requesting intrinsic metadata.

Files with internal metadata: MRI DICOM files contain a range of metadata as defined in the DICOM standard; metadata contains information about the file, the series and study it belongs to, and the patient that it belongs to. This information is frequently parsed and used as indexing data by PACS and archive systems.

Metadata for publishing datasets on nonprofit unstructured data repositories such as Zenodo or osf (see section 4) We will use similar standard XML metadata (DataCite Metadata Schema) to publish and share unstructured datasets. The XML metadata that ensures machine readability / interoperability is generated after filing the repository submission form requesting intrinsic metadata. Metadata comprise, in addition, a persistent identifier, a publication date and conditions of access to (type of license) the dataset. We will upload, alongside the dataset, Readme files in text format with more detailed information.

Use of discipline metadata standards
- For some descriptive data such as e.g. questionnaires, DDI metadata standards will be used. https://ddialliance.org/standards
- For MRI metadata

Minimum set of metadata for T1-weighted (T1w) images in sagittal mode using a 3D Magnetization Prepared Rapid Gradient Echo (MPRAGE) sequence: TR, TE, FoV, flip angle, number of contiguous slices, voxel size, matrix size.

Minimum set of metadata for 2D echo-planar imaging: TE, slice, number of slices, volume TR, flip angle, volumes, EPI train length, field of view, bandwidth.

Minimum set of metadata for MR spectroscopy: TR, TE, Dwell Time, Number of Averages, Vector Size, Phase Encoding Steps in x and y Direction, Matrix Size in x and y Directions, Spatial Filtering: Type and Filter Width, Slice Thickness, Field of View in x and y Direction, Volume of Interest in x and y Direction, Position Vector for Slice, Row and Column Vectors for slice, Transmitter Reference Amplitude, Frequency Offset to Water.

2. ETHICS, LEGAL AND SECURITY ISSUES

2.1 How will ethical issues be addressed and handled?

2.1.1 Permission and data management of human data throughout the project

Data privacy for sensitive information related to personal and private information will be handled carefully during this research. Only absolutely necessary personal data are collected. A procedure of de-identification is introduced at the outset of the study. All personal data related with the identity of the patients and the therapists are protected. These personal data (name, date of birth, address, phone number) enabling to identify the person will be kept in a separate encrypted file on a secure NAS-CHUV and NAS-IPU storage under the responsibility of the PIs, Dr Ambresin and Prof. Tamara Fischmann respectively (see 2.2 below). No personal information can be found in any of the files or datasets. Because of this strict separation between personal and de-identified data, the risk of unforeseen usage is minimal. For the unlikely case of its occurrence, the data are regularly double-checked by the PIs for ethical problems and any problems will immediately be corrected.
The current research project with clinical and MRI approaches has been submitted to the Commission cantonale d'éthique de la recherche sur l'être humain (2019-01658) and is currently revised by the Lausanne research group. The ethics committee of the Frankfurt University Hospital has given its formal and written approval (Beschluss Nr. E 37/20; Geschäfts-Nr. 20-581, on 16.3.2020) and Bochum center is currently submitting the research project to its ethics committee. This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP, the HRA as well as other locally relevant legal and regulatory requirements.

All included subjects will be fully informed about the aims and methods of the study, as well as about what their participation entails. In accordance with the Commission cantonale d'éthique de la recherche sur l'être humain and the constraints by SwissEthics for Lausanne center and the ethics committees of the Frankfurt University Hospital and Bochum, the patients will sign an informed consent before they enter the study protocol. Participation is entirely voluntary and researchers must obtain the patient's informed consent prior to inclusion. The detailed information sheet given to patients includes the description of the aims, methods and implications of the study. There is a benefit-risk assessment where the risks of participation are considered minimal and the benefits on the personal level considered moderate. We assess the benefits for the patient group as a whole as large, because it may affect treatment strategies in the treatment of chronic depression.
Our research group will provide open-access to sensitive human data only after receiving the following explicit consent of the individuals (e.g. "Some scientific journals require the transmission of individual data (raw data). Should individual data be transmitted, it will always be encrypted and will therefore not identify you as an individual") as well as assuring privacy protection through proper data anonymization.

Audio and video-recordings are likely to generate sensitive human personal data (See 1.1.2 above) and will necessitate specific precautions to allow for anonymization prior to data sharing. We will keep limitations to data sharing as minimal as possible by sharing anonymized transcripts of the audio- and video-recordings. We consider this limitation as minimal as all the content of the anonymized interview will be

shared on the appropriate digital data repository. In this study, the data collected from audio and video-recordings will be analysed on the basis of transcripts of the verbal content of the interviews. By providing transcripts, we allow future researchers to replicate our analyses. We will restrict access to original audio and video-recordings to specific research group members involved in the process of transcription. MRI images may be partially blurred using for example the Statistical Parametric Mapping software but definitive anonymization cannot be fully guaranteed. For these reasons the scientific community working with this type of data does not share yet MRI raw data in open access but only on request during publication.

2.1.2 For research data sharing

We will ensure that shared data do not contain information that identifies, or that used i conjunction with other publicly available information to personally identify an individual, following expert recommendations from the neuroimaging platform for MRI data and from the DARIS/FORS center for clinical reports and interviews.

2.2 How will data access and security be managed?

2.2.1 Data storage and regular back-up solutions at FBM-CHUV

See 3.1 below

2.2.2 Data protection

We are aware of the SNSF Open Research Data Policy. We have provided information on Data protection for Lausanne Center. However, German study centers are facing difficulties in gathering the detailed technical information from their respective IT services. IT services of the Goethe University Frankfurt and of the Ruhr University Bochum are mainly focused on finding and implementing IT platforms for online education in these trying times of the COVID-19 pandemia. We will supplement the DMP with detailed technical information as soon as the pandemia and the process of grant reviews allow.
Data protection at Lausanne will be fulfilled according to the DSI-CHUV and DCSR-UNIL procedures.
The DSI-CHUV service provides appropriate protection of hosted data on its technical infrastructure, including confidentiality and integrity of the data. The DSI-CHUV will not modify or transmit data except under application of Swiss law and in cases of support and prevention of technical problems. For information security, the Institution mainly refers to the following international standards:
   o   **ISO 27001** – International information security standard
   o   **ISO 27002** -Code of practice for information security controls
   o   **ISO/IEC 6277** - Information security management in health
Clinical sensitive data will be stored on the NAS-CHUV (share disk for CHUV clinical data) with very high protection. For MRI data storage as well as additional analysis, sensitive data will be encoded and stored by the Division Calcul et Soutien à la Recherche - DCSR on the NAS-

JURA at UNIL. This UNIL infrastructure is managed by a team of system administrators who are the only people to have physical access and administrator rights to the machines. Remote access to the Jura infrastructure is controlled by a firewall. The access levels to the file system are configured by the system administrators. This guarantees that external individuals do not have access to our documents.

2.2.3   Transfer of data

Transfer of encrypted clinical and MRI data from Lausanne center in CHUV will use Filecare.

2.2.4   Data protection on REDCap

Data will be directly collected on the electronic Case Report Forms (eCRF) REDCap or on paper questionnaires when direct collection on eCRF is not possible. Participants will be assigned a unique coded study identifier. REDCap allows the main administrator of a project to assign specific rights to individuals to access data and create reports. All contact information and Protected Health Information will be stored on separate Data Collection Instruments (see 2.1.1). Access to these instruments will be restricted. No access will be granted to all users except for those users assigned to the site that need information to follow-up with the participant. Only "de-identified" (ie, coded) export access will be granted to project users. "De-identified" (ie, coded) data will be shared between participating centers for analysis. Access to the system is protected by a specific password and identification method.

REDCap maintains a built-in audit trail that logs all user activity and all pages viewed by every user, including contextual information (e.g. the project or record being accessed). Whether the activity be entering data, exporting data, modifying a field, running a report, or add/modifying a user, among a plethora of other activities, REDCap logs all actions. (REDCap General Security Overview, Vanderbilt University, p.3)

The institution installing REDCap will store all data captured in REDCap on its own servers. Thus, project data are stored and hosted at the local institutions (CHUV and IPU), and no project data is ever transmitted at any time by REDCap from that institution to another institution or organization.

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

2.3.1   Clinical research collaboration agreement

A clinical research collaboration agreement has been drafted by the legal service of the CHUV (Florence Nater, Florence.nater@chuv.ch). It has been submitted to all participating centers for approval. It will be binding to the signing parties and entails sections on: definition of the Principal investigators, costs of the study, study data, confidentiality, publications, intellectual property ownership, use of names, data protection and security, indemnification and insurance, and notices and communications. The agreement is attached to the current proposal.

2.3.2   Copyright and Intellectual Property Rights issues

The clinical research collaboration agreement addresses copyright and Intellectual Property Rights issues in details

According to the CHUV contract, any data created or modified in the course of our professional activity as a CHUV collaborator belongs to the CHUV (except for copyrights belonging to the creator). This means that for any use other than scientific and academic purposes, UNIL/CHUV approval is necessary (eg for patenting and commercialization).

➢ Directive du Conseil de Direction UNIL-CHUV du 02.12.2009 relative aux contrats et à la valorisation de la recherche
URL link: https://www.unil.ch/interne/files/live/sites/interne/files/textes_leg/dir_valor_UNIL_CHUV.pdf).
➢ Directive du Conseil de Direction UNIL-CHUV du 11.06.2019 relative au Traitement et gestion des données de recherche
https://www.unil.ch/interne/files/live/sites/interne/files/textes-leg/4-rech/dir4-5-donnees-rech1%20.pdf

All the information Copyright and Intellectual Property Right issues described for CHUV also apply to Frankfurt and Bochum Universities.

2.3.3 Open licenses for data

We will promote sharing and unlimited use of the data that we produced using explicit licenses. For sharing our data, we will use a creative common 'By license' that is suitable for data sharing. The CC By license allows others to distribute, remix, tweak and build upon our work, even commercially, as long as they credit us for the original creation.

Our study should not provide any concern due to commercial and patenting issues. In case of concern, we refer to the clinical research collaboration agreement and will be in contact with the CHUV legal service.

3. DATA STORAGE AND PRESERVATION

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

3.1.2 DATA storage and regular back-up at the CHUV

We are aware of the SNSF Open Research Data Policy. We have provided information on data storage and preservation at Lausanne. However, German study centers are facing difficulties in gathering the detailed technical information from their respective IT services. IT services of the Goethe University Frankfurt and of the Ruhr University Bochum are mainly focused on finding and implementing IT platforms for online education in these trying times of the COVID-19 pandemia. We will supplement the DMP with detailed technical information as soon as the pandemia and the process of grant reviews allow.

Central Storage of clinical data at the DSI service CHUV
• The person in charge of service's IT for the research at DSI: Nicolas Rosat – Contact: Service

- ➢ Appropriate data storage is the responsibility of the Principal investigator Dr Gilles Ambresin
- ➢ **Space for personal data storage** (Accessible via unit H = named "Répertoire Personnel Sécurisé (RPS)")
  - • On Network Attached Storage NAS
  - • Storage of personal information
  - • User-limited access rights management
  - • Limited amount of storage (~2 GB)
  - • Immediate and regular access to files from the CHUV
  - • Backup to the backup system by the DSI
  - • Time snapshots
  - • Available soon after disaster
  - • **Free storage**
- ➢ **Share disk for clinical data storage** (Accessible via unit L = named "stockage bureautique")
  - • On <u>Network</u> Attached <u>Storage NAS</u>
  - • Adequate protection of hosted data including confidentiality and integrity (see politique de sauvetage dans l'annexe B 4.6).
  - • NSF, SCIF, SFTP.
  - • User-limited access rights management
  - • Limited amount of storage (~1 TB)
  - • Access to files from CHUV and anywhere in the world using a vpn.
  - • Very high resistance to hardware and software failures.
  - • Security measures (protection against viruses, loss of data, etc.).
  - • **Free storage**
  - • **Data back-up and safeguarding: 3 copies of the data**
    - o Incremental snapshot backup.
    - o Full daily backup of the data on the Share Disk (1 x daily, usually overnight; retention 8 versions for daily backups, 2 versions for weekly backups)
    - o Replication of the data.
    - o Fully backup of the data on the backup disk (1 x daily, usually overnight; retention 30 versions for daily backups, 40 versions for weekly backups).

Central Storage of MRI data at the [Division Calcul et Soutien à la Recherche - DCSR](#) on the NAS-JURA at UNIL.
The person in charge of service's IT for the research at DCSR: Roberto Fabbretti PhD – Contact: help
- ➢ Appropriate data storage is the responsibility of the Principal investigator Dr Gilles Ambresin
- ➢ The JURA server comprises a parallel and distributed file system with more than 2.3PB of fast disk space, a hierarchical storage management

(HSM) system for archiving with >3.6 PB on magnetic tape and several SQL-based large-scale relational database servers. This ensures enough storage capacity for all data generated within the project. Short-term storage (3 months) is available on a fast disk and immediately accessible whereas long-term storage (up to at least 10 years) is done on magnetic tape, which can be accessible within 24 hours. For long term storage, research data are stored on disks with continuous backups on two tape copies in two different buildings.

  ➢ **Costs (1 TB, 2 copies: 500.- CHF/year)**

3.2 What is your data preservation plan?

3.2.1 Long-term data archiving

We are aware of the [SNSF Open Research Data Policy](#). We have provided information on preservation at Lausanne. However, German study centers are facing difficulties in gathering the detailed technical information from their respective IT services. IT services of the Goethe University Frankfurt and of the Ruhr University Bochum are mainly focused on finding and implementing IT platforms for online education in these trying times of the COVID-19 pandemia. We will supplement the DMP with detailed technical information as soon as the pandemia and the process of grant reviews allow.

All collected data related with the present research project will be archived on the CHUV-NAS and on the NAS-JURA at UNIL long term research storage space at least 10 years after publication.

  ➢ **Directive 4.2, art. 2.4;** URL link::
    https://www.unil.ch/interne/files/live/sites/interne/files/textes_leg/4_rech/dir4_2_integrite_scientifique3.pdf
  ➢ **Directive du Conseil de Direction UNIL-CHUV du 11.06.2019 relative au Traitement et gestion des données de recherche**
    https://www.unil.ch/interne/files/live/sites/interne/files/textes-leg/4-rech/dir4-5-donnees-rech1%20.pdf

Appropriate data archiving at Lausanne CHUV center is the responsibility of the Principal investigator Dr Gilles Ambresin.

3.2.2 Published data

Deposition and open data via Zenodo and/or OSF repositories will ensure longevity of the data in the long-term. In addition, the archiving infrastructure at UNIL_CHUV retains primary and secondary research data supporting published articles for at least 10 years after publication.

3.2.3 Unpublished data:

We will save unpublished high-quality final data generated during this project for re-use in our future projects. We will make some data available for use by researchers in future collaborations if our research group no longer uses it. Bad quality data will be permanently discarded at the end of the project.

4. DATA SHARING AND REUSE

4.1 How and where will the data be shared?

Data repository Data sharing will happen at the latest at the time of publication, via non-profit digital repositories. We will make supplementary files and key datasets accompanying a publication to demonstrate reproducibility openly available in appropriate digital data repositories that conform to the Fair Data principles and maintained by a non-profit organization:

Clinical data and secondary MRI data will be shared via the H2020 data [Zenodo-FBM/CHUV community](#) and [OSF](#) repositories. We will make a final selection depending on the type of data and specific journal's requirements. The aforementioned data repositories fulfill biomedical journals' and SNSF's requirements (allowing publishing FAIR data, non-commercial).

Data availability We will use specific formats for data sharing to ensure a file's preservation and re-usability (see DMP point 1.1 above). In some cases, we will upload the "Original" file along with the converted file. Datasets will be given a Digital Object Identifier (DOI) and associated metadata. The DOI corresponding to the datasets in the repository will be included in the article's reference list, allowing identification and access of any dataset in a publication.

Datasets visibility and valorization We will also link DOIs to appropriate records in the University's publication repository Serval, to enhance the dataset's visibility. Metadata about datasets will be publicly searchable and discoverable and will indicate how and on what terms the datasets can be accessed. We will display information about datasets on the lab's webpage, on researcher profile pages on unisciences, as well as on researchers ORCID iDs, which will increase the visibility of the datasets.

Reuse of data valorization We will share data using CC0 or CC BY licenses that will become citable products of research (see Joint Declaration of Data Citation Principles) to value the reuse of our data.

4.2 Are there any necessary limitations to protect sensitive data?

This project **will produce sensitive human personal data** and **will necessitate specific precautions and limitations for data sharing**. As mentioned in 2.1 and 2.2 above, we will share sensitive human data very carefully specifically due to legal, ethical and confidentiality issues. There are restrictions related to personal data which will never be shared, under no circumstances (according to the PI's commitment with the State of Vaud Ethics Committee and the ethics committees of the Frankfurt University Hospital and Bochum.

We do not anticipate that this study will generate patentable data or proprietary data that would need protection.

Use of the data We will share de-identified data between research members without limitation. We may make de-identified data available before publication upon demand by potential new collaborators.

Restrictions or delays to sharing We will make anonymized datasets openly available on appropriate digital data repositories (see 4.1) at the latest at the time of publication. We will restrict data sharing only in cases of concern related to commercial and patenting issues. Except for this, anonymized data with appropriate informed consent given by participants will be shared as widely as possible using Creative Commons licenses.

Primary MRI images may be partially blurred using for example the Statistical Parametric Mapping software but definitive anonymization cannot be fully guaranteed. For these reasons the scientific community working with this type of data does not share yet MRI raw data in open access but only on request during publication.

Audio and video-recordings are likely to generate sensitive human personal data (See 1.1.2 above) and will necessitate specific precautions to allow for anonymization prior to data sharing. We will keep limitations to data sharing as minimal as possible by sharing anonymized transcripts of the audio- and video-recordings. We consider this limitation as minimal as all the content of the anonymized interview will be shared on the appropriate digital data repository. In this study, the data collected from audio and video-recordings will be analysed on the basis of transcripts of the verbal content of the interviews. By providing transcripts, we allow future researchers to replicate our analyses. We will restrict access to original audio and video-recordings to specific research group members involved in the process of transcription.

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