DMP title

Project Name DMP FWO SB - DMP title

Project Identifier 1SD3322N

Principal Investigator / Researcher Alexander Geerardyn

Project Data Contact alexander.geerardyn@kuleuven.be

Description DMP on PhD project funded by FWO Predoctoral Strategic Basic grant. This project aims to improve speech and music perception for future cochlear implant users. We will investigate an innovative stimulation strategy that excites the inner ear both electrically and vibrationally, all at once. This project includes behavioral experiments with people with a cochlear implant, a histological study of human temporal bone specimens and experimental procedures in human cadaveric specimens.

Institution KU Leuven

1. General Information

Name applicant

Alexander Geerardyn

FWO Project Number & Title

Project number: 1SD3322N

Project title: "ELVIS: ELectro-Vibrational Stimulation to exploit the full potential of the human cochlea"

Affiliation

- KU Leuven

Research Fellowship Harvard Medical School 2021-2022.

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data
- Reuse existing data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

1. Behavioral Experiments

Dataset Name	Origin	How Created	Data Type	File Format	Volume
1. Observational numeric data on behavioral measurements of speech & music perception	Newly generated	Generated during behavioral experiments with CI users	Numerical	Raw: .apx Processed: .xlsx	30 spreadsheets
2. Qualitative data on a survey of music perception with CI	Newly Generated	Generated during behavioral experiments with CI users	Textual	Raw: .pdf (scans of written documents) Processed: .docx	30 documents
3. Patient data	Newly generated	Generated from medical file	Combination Numerical & textual	.xlsx	1 spreadsheet
4. Experimental protocol scripts	Newly generated	Generated with APEX software tool	Software	.apx	30 * 25 scripts (58 kb each)

2. Histological Study

Dataset Name	Origin	How Created	Data Type	File Format	Volume
1. NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry https://national-tb-database.meei.harvard.edu/	Reused	Scanning histological sections of human temporal bones	Images	.svs	1 TB
2. Patient data	Reused	Upon inclusion into database	Combination Numerical & textual	.xlsx	1 spreadsheet
3. Segmentations of histological images	Newly generated	Segmentations made during research stay in Mass Eye and Ear Boston, with the use of Amira software	Numerical	.am	About 1 GB
4. Scripts for export & analysis of segmentations	Newly generated	Code written in MATLAB & AMIRA	Software	.txt; .m	< 5 MB
5. Data exports from raw segmentation data	Newly generated	Generated using scripts	Numerical	.csv	100 MB

3. Cadaveric Studies

Dataset Name	Origin	How Created	Data Type	File Format	Volume
1. Data Acquisition Scripts	Newly Generated	Written in MATLAB (with colleague Irina Wils)	Software	.m	< 50 MB
2. Experimental Protocol & Surgical notes	Newly Generated	Generated during cadaveric experiment	Textual + Images	.docx	100 MB
3. Experimental data	Newly Generated	Generated during cadaveric experiments	Numerical	.csv	5-10 GB
4. Specimens	Newly Generated	Surgical preparations before/during experiments	Human Tissue	-	-

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference:G-2021-3770-R3(AMD)

Short description of the kind of personal data that will be used:

In the behavioral experiments we will observe the speech & music perception of cochlear implant users (patients). These data will be combined with data from the medical file of these patients.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

G-2021-3770-R3(AMD)

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

Behavioral Experiments

1. For each of the speech and music test, metadata (e.g. date, subject identifier, stimuli presented, intensities...) are saved with the raw data (.apx format). Moreover, we will generate an individual protocol (word document) for each experiment that will be annotated during the experiment.

2. The experimental protocol scripts will be accompanied by a ReadMe.txt file that describes the

goal of each script and keeps track of updates.

Histological study

1. The digitized histological sections are saved as .svs files and contain metadata such as voxel sizes.

2. Segmentations are accompanied by a detailed Word Document on the exact methodology applied to generate the segmentations.

3. The scripts for export & analysis are accompanied by a ReadMe.txt file that describes the goal of each script and keeps track of updates.

Cadaveric studies

1. Data Acquistion scripts are extensively commented inside the script and accompanied by a ReadMe.txt file that describes the goal of each script and keeps track of updates.

2. For each experimental session,an individual protocol (word document) will be generated and annotated during the experiment. This will be supplied with images form the day of the experiment.

3. The specimens are labelled with an identifier and kept track of in a spreadsheet. Metadata such as side, date of freezing, thawing, surgical preparations are kept track of.

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

5. Data storage and backup during the FWO project

Where will the data be stored?

Behavioral experiments & Cadaveric studies

Except for personal data, all data will be stored on the KU Leuven OneDrive.

Personal data will be stored pseudonimizyed on a REDCAP database (see PRET).

Histological study

Digitized sections are kept secure on the servers of Mass Eye and Ear and cannote be accessed after the end of the research stay.

Newly generated data (segmentations & exports) are stored on the KU Leuven OneDrive.

How is backup of the data provided?

Data on the KU Leuven OneDrive are subject to automatic backups. Once every month additional backups are made on a physical external hard drive (encrypted).

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

Storage & backup capacity:
- OneDrive 2TB
- External Hard Drive 5 TB
- Laptop Hard drive 0.5 TB

Excluding the digitized histological images that are stored at the internal servers of Mass Eye and Ear (Harvard University), expected data capacity needed is limited (<1 TB).

The avaialbel storage and backup capacity is sufficient.

What are the expected costs for data storage and back up during the project? How will these costs be covered?

OneDrive storage is complementary withing KU Leuven

External Hard Drive has been purchased before with bench fee.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Data will be stored according to KU Leuven Policy.

Hard drives used for storage are encrypted.

Personal data (see PRET)

All participant data will be pseudonymised by using a random generated subject-session identifier. Only the handling researcher and the applicant will have the metadata to link an identifier to a session and/or participant. This metadata will be stored secure and separate from the pseudonymized data.

The pseudonynmised data itself will be stored on the REDCAP database as suggested by KU Leuven.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

Except for the human cadaveric specimens, all data will be retained for the expected 5 year period. The designated responsible person is Nicolas Verhaert.

Due to legal and ethical restrictions, the human cadaveric specimens can only be stored for a limited time (2-3 months) before the specimens will be collected for funeral with other pieces of the cadavre.

Where will the data be archived (= stored for the longer term)?

The data will be stored on the university's central servers and/or OneDrive (with automatic back-up procedures) for at least 5 years, conform the FWO RDM policy.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

The total size of the data generated is expected to be within the limit of 2TB that is included for storage space in KU Leuven.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- Yes. Specify:

Original digitized images used in the Histological study are property of the Mass Eye and Ear and cannot be shared without their permission.

Which data will be made available after the end of the project?

None, only on request.

Where/how will the data be made available for reuse?

Data will be available on request after signing a data sharing agreement.

When will the data be made available?

Data will be available on request after publication of the research results.

Who will be able to access the data and under what conditions?

Only uses for research purposes will be allowed and commercial reuse will be excluded.

What are the expected costs for data sharing? How will the costs be covered?

No costs expected.

8. Responsibilities

Who will be responsible for data documentation & metadata?

Alexander Geerardyn (+ Irina Wils co-responsible for scripts Cadaveric Studies)

Who will be responsible for data storage & back up during the project?
Alexander Geerardyn

Who will be responsible for ensuring data preservation and reuse ?
Nicolas Verhaert

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