DMP title

Project Name My plan (FWO DMP) - DMP title
Project Identifier FWO-SBO S006722N - 67214
Grant Title S006722N - 67214
Principal Investigator / Researcher Amaryllis Van Craenenbroeck
Institution KU Leuven

1. General Information

Name applicant

Amaryllis Van Craenenbroeck

FWO Project Number & Title

S006722N
EXercise and the GUT in liver and kidney Transplant recipients [EXGUTT]

Affiliation

- KU Leuven
- Universiteit Gent
- Other

VIB

2. Data description

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

- Generate new 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).

Samples, metadata, and results of analyses are de-identified (pseudonymized), and stored and processed in coded form. Quantitative data will be stored as electronic case report forms in REDcap.

Exercise training data are stored on a secured online platform (Coachbox)

Data(set) name	Origin of data	Type of data
Physical fitness		
Cardiorespiratory fitness	cardiopulmonary exercise test (CPET) on cycle ergometer	numerical
	The six-minute walking test: observation	numerical
Musculoskeletal fitness	Jamar Hydraulic Hand Dynamometer	numerical
	dynamometer (Biodex Medical Systems Inc., 840-000 System 4, New York, USA)	numerical
Motor fitness	The Short Physical Performance Battery test	numerical
Body morphology	Medical body weight scale	numerical
	stretch-resistant measuring tape	numerical

	DXA scan	numerical
Cardiovascular health		
Blood pressure	Omron M6	numerical
Endothelial function	Flow-mediated dilation (FMD) of the brachial artery using ultrasound (UNEX)	numerical
	Dynamic vessel analysis of the retinal microvasculature (Dynamic Vessel Analyzer Imedos GmgH Jena, Germany)	numerical
Arterial stiffness	Carotid–femoral pulse wave velocity (cf-PWV) through SphygmoCor device (AtCor Medical, Australia).	numerical
Blood markers of cardiovascular health	laboratory analysis of venous blood sample	numerical
Safety		
Graft health	urine & blood sample	numerical
	Kidney biopsy	descriptive
Adverse events	observation , medical records	
Immunity and infections	diagnosis	
	Wisconsin Upper Respiratory Symptom Survey (WURSS-21) +perceived resilience against infections	paper or electronical survey
Gut microbiome	stool sample	numerical
	Bristol Stool Score chart + data on time of sampling + questionnaire	paper/electronical
Implementation potential	administrative records	numerical
	The iMTA Medical consumption questionnaire (iMCQ) and the iMTA productivity cost questionnaire (iPCQ)	paper/electronical
Other study outcomes		

Quality of life	Surveys : The Short Form Health Survey or SF-36, EQ-5D-5L, The Ghent Participation Scale , IPA, Brussels Integrated ADL, FACIT-F + Interviews	paper/electronical, interview
Physical activity	Actigraph wGT3X-BT triaxial accelerometer	digital instrument
	Motivators and Barriers Questionnaire	paper/electronical
Healthcare use	questionnaire	paper/electronical
Frailty	Fried's Frailty Phenotype (FFP) score	numerical

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-2021-4393

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

Identification information (e.g. names, (email) addresses) Personal details (e.g. age, gender) Financial data Physical traits Leisure activities and interests Education and training Lifestyle and habits Family composition Occupation and professional activities

Fysieke kenmerken: lengte, gewicht Gezinssamenstelling: aantal kinderen Gezinssamenstelling: eigenschappen van kinderen (bv. geslacht, leeftijd) Gezinssamenstelling: aantal inwonenden Beroep: functie Beroep: anciënniteit Persoonlijke kenmerken: nationaliteit Persoonlijke kenmerken: burgerlijke staat Persoonlijke kenmerken: geboortedatum Persoonlijke kenmerken: geslacht Persoonlijke kenmerken: leeftijd Identificatiegegevens: identificatienummers (bv. studentennummer, patiëntennummer) Identificatiegegevens: elektronische locatiegegevens (bv. gps, mobiele telefoon) Identificatiegegevens: telefoonnummer Identificatiegegevens: e-mailadres Identificatiegegevens: adressen Identificatiegegevens: titels

Special categories of personal data: Data revealing racial or ethnic origin Data revealing religious or philosophical beliefs Data from or linked to the Electronic Patient Record (EPR) Data concerning (physical and/or mental) health Health: diagnoses and symptoms Health: medication use Health: medical history Health: medical images and scans (e.g. radiography, EEG, CT, etc.) Health: physiological data Health: data about mental health such as stress, depression, etc. Health: hospitalization data

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

Approval of EC Research UZ Leuven/KU Leuven will be requested

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?

Samples, metadata, and results of analyses are de-identified (pseudonymized), and stored and processed in coded form.

Data will be stored on RedCap . Using RedCap, a Data Dictionary Codebook will be generated containing variable-level information for all captured information: Variable / Field name, Field Label (including question text) and Field Attributes (including Field Type, Validation, Choices, Calculations etc.)

Survey data: Metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in RedCap

Research methods and practices will be fully documented. Details on the setting of the data collection, the selection of participants and the instructions given to researchers will be documented.

For the interviews, details on the setting of the interviews, the informed consent process, the subjects discussed and the instructions given to interviewers will be documented in a Word document. Also steps taken to remove direct identifiers in the data will be described.

Experimental protocols: description how the data are collected and generated (software, materials, set-up, settings (.docx) and how data are processed (software, protocol, guidelines, …) (.docx)

Biological sample collection registration file in software of the UZ Leuven Biobank according to the GDPR rules and only in the protected IT environment of UZ Leuven. The decoding file is a separate Excel file also in the protected IT environment of UZ Leuven.

Coded metadata and results of stool sample analyses are stored in an independent secured database, accessible by Raes Lab researchers only. This database will not contain data that would allow participant identification without decoding. Samples, derivatives thereof, and metadata can be stored for 30 years at the Raes Lab, VIB-KU Leuven (Rega Institute, Leuven, Belgium).

The progress of data collection, and final report, will be provided to the FWO and the leading ethical committee (KU Leuven).

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

Metadata (e.g. timestamp, electronic instructions) are automatically captured during survey completion in RedCap.

For imaging files, and txt documents, metadata are inherently present in the features of he files as provided by the manufacturer of the devices/software. Research data will be based on generalized metadata schema such as Dublin Core or DataCite, including the following elements:

Title: free text

Creator: Last name, first name, organization

Date and time reference

Subject: Choice of keywords and classifications

Description: Text explaining the content of the data set needed for the correct interpretation of the data, the software(s) (including version number) used to produce and to read the data, the purpose of the experiment, etc.

Format: Details of the file format,

Resource Type: data set, image, audio, etc.

Identifier: DOI (when applicable)

Access rights: closed access, embargoed access, restricted access, open access.

When depositing data in a repository (Lirias or RDR), the final dataset will be accompanied by this information under the form of a README.txt document. This file will be located in the top level directory

5. Data storage and backup during the FWO project

Where will the data be stored?

Samples, metadata, and results of analyses are de-identified (pseudonymized), and stored and processed in coded form. Quantitative data will be stored as electronic case report forms in **REDcap;** a clinical trial software for electronic data capture/management of research studies used by KU Leuven and UZGhent. This database will be hosted at a **secured server of KU Leuven,** which only the KU/UZ Leuven research team will have full access to. This server will also be used to store qualitative data & medical images.

Exercise training data are stored on a secured **online platform (Coachbox)**. At study completion, data will be removed from Coachbox and stored on a **secured server of KU Leuven**. Coachbox subscription occurs pseudo-anonymous. Raw data will remain accessible for the principal investigators at a secured KU Leuven server.

The databases will be secured with password protection in accordance with the University Hospitals' regulations. Only coded identification numbers will be entered into the database. Any electronic communication with outside collaborators will involve only unidentifiable information. Paper copies of documents from exercise testing, questionnaires, and other case report forms will be stored in a **cabinet in a locked office**. Adverse events reports and annual summaries will not include subject- or group-identifiable material.

For the , data and biological samples will be pseudonymized by a Nefro-ID. This will be assigned by Nephrology and Renal Transplantation Research Group. Only the PI and its study staff from UZ and KU Leuven are able to decode. Demographic, clinical and histology data come directly from the included patient files. These data are stored in SAS format (demographic and clinical data) on the **servers of UZ Leuven,** which benefits from the firewall and back-up services provided by the UZ Leuven IT department. Large raw data files, devoid of any reference to the clinical case, will be stored on the **Large Volume Storage or Archive Storage platform of ICTS KU Leuven**, which also incorporates back-up services. Biological sample collection registration file are currently in Excel (in the future in the registration software of the UZ Leuven Biobank) according to the GDPR rules and only in the **protected IT environment of UZ Leuven**. The decoding file is a separate Excel file also in the **protected IT environment of UZ Leuven.**

Coded metadata and results of stool sample analyses are stored in an i**ndependent secured database, accessible by Raes Lab researchers only.** This database will not contain data that would allow participant identification without decoding. Samples, derivatives thereof, and metadata can be stored for 30 years at the Raes Lab, VIB-KU Leuven (Rega Institute, Leuven, Belgium).

How is backup of the data provided?

The data will be stored on the **University's central servers and UZ leuven IT services with automatic daily back-up procedures.**

REDCap: data is backed up as follows:

- The web server backup regime is specified below:
- An hourly backup, the last 6 versions of which are saved
- A daily backup, the last 7 versions of which are saved
- A weekly backup, the last 6 versions of which are saved
- The database backup regime is specified below: -A nightly cold backup of all databases- One month's storage of the nightly cold backups

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

The university and department infrastructure is able to provide sufficient capacity

RedCap allows data storage of 2-4 MB

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

The expected total volume of data will not require a budget for data storage or preservation. The university and department infrastructure is able to provide sufficient capacity.

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

Samples, metadata, and results of analyses are de-identified (pseudonymized), and stored and processed in coded form. Quantitative data will be stored as electronic case report forms in REDcap; a clinical trial software for electronic data capture/management of research studies used by KU Leuven and UZGhent. This database will be hosted at a **secured server of KU Leuven, which only the KU/UZ Leuven research team will have full access to.** This server will also be used to store qualitative data & medical images.

Exercise training data are stored on a **secured online platform** (Coachbox). At study completion, data will be removed from Coachbox and stored on a secured server of KU Leuven. Coachbox subscription occurs pseudo-anonymous. **Raw data will remain accessible for the principal investigators at a secured KU Leuven server.**

The databases will be secured with password protection in accordance with the University Hospitals' regulations. **Only coded identification numbers will be entered into the database. Any electronic communication with outside collaborators will involve only unidentifiable information. Paper copies of documents from exercise testing, questionnaires, and other case report forms will be stored in a cabinet in a locked office. Adverse events reports and annual summaries will not include subject- or group-identifiable material.**

For the , data and biological samples will be pseudonymized by a Nefro-ID. This will be assigned by Nephrology and Renal Transplantation Research Group. **Only the PI and its study staff** from UZ and KU Leuven are able to decode. Demographic, clinical and histology data come directly from the included patient files. These data are stored in SAS format (demographic and clinical data) on the servers of UZ Leuven, which benefits from the firewall and back-up services provided by the UZ Leuven IT department. Large raw data files, devoid of any reference to the clinical case, will be stored on the Large Volume Storage or Archive Storage platform of ICTS KU Leuven, which also incorporates back-up services. Biological sample collection registration file are currently in Excel (in the future in the registration software of the UZ Leuven Biobank) according to the GDPR rules and only in the protected IT environment of UZ Leuven. The decoding file is a separate Excel file also in the **protected IT environment** of UZ Leuven.

Coded metadata and results of stool sample analyses are stored in an **independent secured database, accessible by Raes Lab researchers only.** This database will not contain data that would allow participant identification without decoding.

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, ...).

The (personal) data will be preserved for 50 years.

Samples, derivatives thereof, and metadata can be stored for 50 years at the Laboratory the Laboratory of Nephrology and Renal Transplantation research group/Laboratory of the Transplantation Research Group/Raes Lab, VIB-KU Leuven (Rega Institute, Leuven, Belgium).

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

The digital data will be stored on the university's central servers (with automatic back-up procedures) for 50 years.

Hard copies (eg. the Informed Consent forms, measurement forms and paper lab notebooks) are kept in locked cabinets in the offices of the PIs concerned

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

No additional costs are expected.

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)?

- No

Which data will be made available after the end of the project?
data are only accessible on specific requests and after signing a formal agreement.

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

- In a restricted access repository

When will the data be made available?

- Upon publication of the research results

Who will be able to access the data and under what conditions?
Everybody with a specific request, and after formal approval of all research partners/universities/hospitals.

What are the expected costs for data sharing? How will the costs be covered?
no costs

8. Responsibilities

Who will be responsible for data documentation & metadata?
Principal Investigator

Who will be responsible for data storage & back up during the project?
Principal Investigator

Who will be responsible for ensuring data preservation and reuse ?
Principal Investigator

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