The Gut-Immune-Brain axis: the key to understanding fatigue in inflammatory bowel disease?

Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Saliva	collected during MAST, n=8	**N**	**P**				1000 aliquots (0.5-1 mL)
Biological samples	Whole blood, serum, faecal	**N**	**P**				Whole blood: 75 (10 mL) Serum: 125 (8 mL) Stool: 125 (1 mat)
Raw ECG	HRV	**N**	**D**	**N**	.txt	<100GB	
Structural MRI, MRS, DW-MRI, QSM	raw images	**N**	**D**	**I**	DICOM	<5TB	
PET	raw images	**N**	**D**	**I**	DICOM	<100GB	
MRS, DW-MRI, QSM	processed images	**N**	**D**	**I**	NIfTI (.nii)	>5TB	
PET	processed images	**N**	**D**	**I**	NIfTI (.nii)	<1TB	
Wearables (chest- and wristband	raw data	**N**	**D**	**N**	.txt	<5TB	
ESM (m-path)	raw data	**N**	**D**	**N**	.txt	<1GB	
food diary	raw data	**N**	**D**	**N**	REDCap	<1GB	
Numerical data	biological sample values, processed wearable data, processed HRV, behavioral data, questionnaires	**N**	**D**	**N**	REDCap	<100GB	

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

We do not use existing 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, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

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Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

PRET G-number: G-2025-9292

Personal data (as described above, as well as identifiable images of skull/face recorded during MRI scanning) will be collected in accordance with GDPR and KU Leuven guidelines. The reference to the file in KU Leuven's Record of Processing Activities will be provided when it is available.

We will collect the following: signed informed consent forms, contact information and account number (for reimbursement), a log file linking participants' name to participant ID (password-protected), identifiable images of skull/face recorded during (PET)-MRI brain scanning. These data will be considered as restricted throughout the entire project. This means that they will only be accessible to authorized individuals and stored (excl. informed consent forms, see further) at restricted, encrypted, password-protected network drives managed by the KU Leuven ICT facility, bound by the KUL ICT code of conduct. Offline copies of restricted data and the informed consent forms will be separately archived in a restricted-access and locked room.

We will collect the following: sensitive personal data, demographic data, health data, questionnaire data, and derived imaging and biological data (see above). These data will be coded and thus pseudonymized, and stored on encrypted, password-protected KU Leuven restricted network, laptop, and/or backup hard-drives managed by the KU Leuven ICT facility.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

Raw data files will be kept in a common structure with individual data-files stored within participant sub-folders per experiment. Derived data will be stored within separate participant sub-folders and aggregated data will be stored under the experiment parent-folder.

We will extensively document study design and research procedures, including the settings of data collection, participant selection, equipment details and settings, sampling methodology, specification of the raw data file names (which measures they refer to), information that describes the variable codes (referring to type and time of specific measurements) and used analyses methods, as well as any other information necessary for a secondary analysis to use the data accurately and effectively.

Will a metadata standard be used to make it easier to find and reuse the data?

If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- Yes

Where possible, metadata standards will be used, or if unavailable, the experimental and data analysis metadata will be stored in a structured manner alongside our research data in .csv, .docx, .xslx or .txt files (e.g. “README” files for each distinct dataset), based on commonly used terminology in the relevant fields. For the MRI and PET data, metadata are included in the BIDS file format.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Other (specify below)
- Shared network drive (J-drive)
- ManGO

Additionally, data will be stored in the REDCap data management system, KU Leuven Onedrive, LaBGAS server and IBD genemod.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

The researchers each have a personal OneDrive with each 250G B capacity to store the data. The network drive at the level of the research group has 4 TB of storage space as well as 3 TB on Mango, which both can be extended flexibly if needed. Storage for biological samples is guaranteed by dedicated freezer space at a PI-owned freezer in the KU Leuven Biobank.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All data will be managed, processed and stored on secure, password-protected and encrypted network drives managed by the KU Leuven ICT facility and in restricted-access. Access to the network drives is only possible for registered KUL personnel and the PI will determine access rights to dedicated project folders. All personal laptops and external drives will be password-protected and encrypted.

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

Storage on the central KU Leuven servers is 156,60 EUR/TB/year, with an estimated total data size of 4 TB. Mango is 70 EUR + 35 EUR/TB/year. This will be paid from the study budget. The freezer to store the biological samples has already been purchased by the PI and is located in the biobank at no additional cost.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- Shared network drive (J-drive)

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

N/A

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

Pseudonymized data can be shared within the research unit or shared upon request.

If access is restricted, please specify who will be able to access the data and under what conditions.

Access to the data may be granted to other researchers upon submission of a well-defined research question and proof of ethical approval.

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

Please explain per dataset or data type where appropriate.

- No

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

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

N/A

Responsibilities

Who will manage data documentation and metadata during the research project?

Data documentation and metadata will managed by the PhD students, postdoctoral researchers, administrative and technical staff, and (co-)PIs involved in this project in accordance with KU Leuven's Research Data Management (RDM) policy.

Who will manage data storage and backup during the research project?

PhD students, postdoctoral researchers, administrative and technical staff, and (co-)PIs involved in this project are responsible for data storage and backup. All data will be securely managed, processed, and stored on KU Leuven ICT-managed network drives in accordance with KU Leuven's Research Data Management (RDM) policy.

Who will manage data preservation and sharing?

The PIs involved in the research project are responsible for data preservation and sharing, ensuring that all data is retained for 10 years in accordance with KU Leuven's Research Data Management (RDM) policy.

Who will update and implement this DMP?

The PI (Bram Verstockt) bears the end responsibility of updating & implementing this DMP in accordance with KU Leuven's Research Data Management (RDM) policy.