FWO DMP Template - Flemish Standard Data Management Plan

1. General Project Information	
Name Grant Holder & ORCID	Bart Depreitere 0000-0002-7458-0648
Contributor name(s) (+ ORCID) & roles	Alan Urban 0000-0002-6460-2364
Project number & title	G0C9923N Ultrasound hemodynamic neuroimaging to improve monitored management in patients with traumatic brain injury (USNI4TBI)
Funder(s) GrantID	FWO
Affiliation(s)	● KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: Provide ROR identifier when possible:

| Please provide a short project description | Traumatic brain injury (TBI) is a major worldwide cause of mortality and lifelong morbidity. In TBI and other causes of acute brain injury, primary damage is followed by a cascade of secondary events with brain ischemia as a final common result. Providing oxygen and energy to the brain through adequate cerebral blood flow (CBF) is critical in managing patients. Real-time monitoring of CBF and the status of its protective autoregulatory mechanisms – that are often impaired following injury – is still impossible to date. It leaves clinicians uncertain with only indirect assessments and no proactive or swift means of therapeutic action. Through a collaborative effort, we have recently demonstrated using ultrasound neuroimaging (USNI) that high-resolution hemodynamic measurements in a porcine cranial window model are strongly correlated with CBF changes. We have also performed a complete characterization of the cerebrovascular autoregulation curve. Our project aims at establishing the complex links between CBF, autoregulation status, currently monitored physiological variables in TBI patients in the intensive care unit (ICP, CPP, PbO2), brain activity and brain ischemia. We will investigate the efficiency of USNI for decision support and prediction of ischemia in a translational TBI pig model. We will also evaluate the effect on ischemia of distinct therapies to aim to improve CBF. If successful, our results are highly transferrable to patients. |

2. 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[1].

Dataset Name	Description	New or Reused	Digital or Physical	*ONLY FOR DIGITAL DATA* Digital Data Type	*ONLY FOR DIGITAL DATA* Digital Data Format	*ONLY FOR DIGITAL DATA* Digital Data Volume (MB, GB, TB)	*ONLY FOR PHYSICAL DATA* Physical Volume
Healthy + USNI	USNI monitoring integrated with the healthy porcine cranial window model	Generate new data	Digital	Experimental	.csv, .dta, .hdf5, NII	< 5 TB	
CBF & CA monitor algorithm	software algorithms for both continuous CBF monitoring and CA status monitoring	Generate new data	Digital	Software	Matlab and other alike	<1 GB	
TBI + USNI	TBI piglet model equipped with cranial window + USNI	Generate new data	Digital	Experimental	.csv, .dta, .hdf5, NII	< 5 TB	
TBI + USNI + treatments	TBI piglet model equipped with	Generate new data	Digital	Experimental	.csv, .dta, .hdf5, NII	< 5 TB	

---

[1] Add rows for each dataset you want to describe.

	cranial window + USNI and subjected to CA treatments						

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.	N/A
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, please describe these issues further and refer to specific datasets or data types when appropriate.	☐ Yes, human subject data ☒ Yes, animal data ☐ Yes, dual use ☐ No If yes, please describe: ethical approval is requested from the ECD for every experimental setting.
Will you process personal data[2]? If so, briefly describe the kind of personal data you will use. Please refer to specific datasets or data types when appropriate. If available, add the reference to your file in your host institution's privacy register.	☐ Yes ☒ No If yes: - Short description of the kind of personal data that will be used: - Privacy Registry Reference:

---

[2] See Glossary Flemish Standard Data Management Plan

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.	☒ Yes ☐ No If yes, please comment: If USNI based CBF & CA monitor is validated in patient studies (not part of the present project), this may be amenable to commercial exploitation. Relates to all databases of the current project.
Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements, research collaboration agreements)? If so, please explain to what data they relate and what restrictions are in place.	☐ Yes ☒ No If yes, please explain:
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 to what data they relate and which restrictions will be asserted.	☒ Yes ☐ No If yes, please explain: USNI algorithms and USNI-based CBF- & CA- monitor tools are patentable.

3. 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).	Each experiment is logged in an Electronic Lab Notebook, including type of experiment, particularities, researcher involved, exact type of data involved and exact location of each type of data

| 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.

REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS. | ☐ Yes
☒ No
If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used:

If no, please specify (where appropriate per dataset or data type) which metadata will be created:
type of experiment, particularities, researcher involved, exact type of data involved (files created) and exact location of each type of data |

4. Data Storage & Back-up during the Research Project

| Where will the data be stored? | - USNI data in a cloudian server at NERF
- Physiological & monitor & microscopy data + metadata on KUL server and on local server owned by the research group (NAS-Synology) |

How will the data be backed up? *WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS? DESCRIBE THE LOCATIONS, STORAGE MEDIA AND PROCEDURES THAT WILL BE USED FOR STORING AND BACKING UP DIGITAL AND NON-DIGITAL DATA DURING RESEARCH.[3]* *REFER TO INSTITUTION-SPECIFIC POLICIES REGARDING BACKUP PROCEDURES WHEN APPROPRIATE.*	Raw digital data is saved in multiple online and local servers at the same time.
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 ☐ No If yes, please specify concisely: KUL: distributed system of local servers allow for storage and backup of all the projects' data. NERF: Cloudian is supporting logical storage policies that can be configured with replication or erasure coding. 10TB will be stored with full on-line access and then archived at the end of each year to a cold-storage solution in a SYNOLOGY Disk Station NAS located at NERF/imec. If no, please specify:
How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons? *CLEARLY DESCRIBE THE MEASURES (IN TERMS OF PHYSICAL SECURITY, NETWORK SECURITY, AND SECURITY OF COMPUTER SYSTEMS AND FILES) THAT WILL BE TAKEN TO ENSURE THAT STORED AND TRANSFERRED DATA ARE SAFE.*	KUL: Data is protected with 2FA. Servers are also within a locked office space. NERF: Data is protected following specific standards.

[3]

What are the expected costs for data storage and backup during the research project? How will these costs be covered?	Both at KUL and NERF storage solutions and backups have been purchased and come with no extra cost.

5. Data Preservation after the end of the Research Project

Which data will be retained for at least five 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 experimental data will be retained for reasons of reproducibility and to be used in further hypothesis development and testing.
Where will these data be archived (stored and curated for the long-term)?	KUL and NERF long term storage solutions (in place)
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	Both labs pay a licence fee for the current and other projects.

6. 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. *Note that 'available' does not necessarily mean that the data set becomes openly available, conditions for access and use may apply. Availability in this question thus entails both open & restricted access. For more information:* [*https://wiki.surfnet.nl/display/standards/info-eu-repo/#infoeurepo-AccessRights*](https://wiki.surfnet.nl/display/standards/info-eu-repo/#infoeurepo-AccessRights)	☐ Yes, in an Open Access repository ☒ Yes, in a restricted access repository (after approval, institutional access only, …) ☐ No (closed access) ☐ Other, please specify:
If access is restricted, please specify who will be able to access the data and under what conditions.	Bart Depreitere & collaborators Alan Urban & collaborators
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.	☐ Yes, privacy aspects ☒ Yes, intellectual property rights ☐ Yes, ethical aspects ☐ Yes, aspects of dual use ☐ Yes, other ☐ No If yes, please specify:
Where will the data be made available? If already known, please provide a repository per dataset or data type.	N/A

When will the data be made available? *THIS COULD BE A SPECIFIC DATE (DD/MM/YYYY) OR AN INDICATION SUCH AS 'UPON PUBLICATION OF RESEARCH RESULTS'.*	N/A
Which data usage licenses are you going to provide? If none, please explain why. *A DATA USAGE LICENSE INDICATES WHETHER THE DATA CAN BE REUSED OR NOT AND UNDER WHAT CONDITIONS. IF NO LICENCE IS GRANTED, THE DATA ARE IN A GREY ZONE AND CANNOT BE LEGALLY REUSED. DO NOTE THAT YOU MAY ONLY RELEASE DATA UNDER A LICENCE CHOSEN BY YOURSELF IF IT DOES NOT ALREADY FALL UNDER ANOTHER LICENCE THAT MIGHT PROHIBIT THAT.* *EXAMPLE ANSWER: E.G. "DATA FROM THE PROJECT THAT CAN BE SHARED WILL BE MADE AVAILABLE UNDER A CREATIVE COMMONS ATTRIBUTION LICENSE (CC-BY 4.0), SO THAT USERS HAVE TO GIVE CREDIT TO THE ORIGINAL DATA CREATORS." [4]*	N/A
Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here. *INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.*	☐ Yes ☒ No If yes:
What are the expected costs for data sharing? How will these costs be covered?	N/A

---

[4] Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	PhD student Bart Depreitere under his supervision Postdoc fellow Alan Urban under his supervision
Who will manage data storage and backup during the research project?	PhD student Bart Depreitere under his supervision Postdoc fellow Alan Urban under his supervision
Who will manage data preservation and sharing?	PhD student Bart Depreitere under his supervision Postdoc fellow Alan Urban under his supervision
Who will update and implement this DMP?	Bart Depreitere and Alan Urban