FWO DMP Template - Flemish Standard Data Management Plan

Version KU Leuven

Project supervisors (from application round 2018 onwards) and fellows (from application round 2020 onwards) will, upon being awarded their project or fellowship, be invited to develop their answers to the data management related questions into a DMP. The FWO expects a **completed DMP no later than 6 months after the official start date** of the project or fellowship. The DMP should not be submitted to FWO but to the research co-ordination office of the host institute; FWO may request the DMP in a random check.

At the end of the project, the **final version of the DMP** has to be added to the final report of the project; this should be submitted to FWO by the supervisor-spokesperson through FWO's e-portal. This DMP may of course have been updated since its first version. The DMP is an element in the final evaluation of the project by the relevant expert panel. Both the DMP submitted within the first 6 months after the start date and the final DMP may use this template.

The DMP template used by the Research Foundation Flanders (FWO) corresponds with the Flemish Standard Data Management Plan. This Flemish Standard DMP was developed by the Flemish Research Data Network (FRDN) Task Force DMP which comprises representatives of all Flemish funders and research institutions. This is a standardized DMP template based on the previous FWO template that contains the core requirements for data management planning. To increase understanding and facilitate completion of the DMP, a standardized **glossary** of definitions and abbreviations is available via the following link.

1. General Project Information	
Name Grant Holder & ORCID	Kortleven Phéline 0000-0002-2206-6057
Contributor name(s) (+ ORCID) & roles	Promotor: Marianne Carlon 0000-0002-8263-0350 Co-promotor: Laurens Ceulemans 0000-0002-4261-7100 Co-promotor: Rik Gijsbers 0000-0003-0191-3904
Project number [1] & title	1SH2T24N Gene therapeutic intervention during ex vivo lung perfusion as a platform to modulate human lung disease
Funder(s) GrantID [2]	1
Affiliation(s)	Department of Chronic Diseases and Metabolism, Laboratory of Respiratory Diseases and Thoracic Surgery (BREATHE), KU Leuven, Leuven, Belgium
Please provide a short project description	Dampening ischemia-reperfusion injury (IRI) remains a major challenge in lung transplantation. IRI triggers a cellular stress response, in which the pulmonary endothelial cells play an important role, resulting in a state of sterile inflammation and acute lung injury. Ex vivo lung perfusion (EVLP) is an innovative technology in which the donor lungs are maintained in a physiologic and ventilated state outside of the body prior to transplantation. During EVLP we can selectively administer gene therapy agents (GTAs) that solely target the cells of the lung and are recirculated in the pulmonary vasculature for up to 6 hours. Since the EVLP time window is limited (6hrs), delivery of GTA should be fast and transient. Virus-like particles (VLPs) are potentially suited delivery vehicles since they deliver functional protein complexes at high efficiency and increased safety. This research aims to: 1) explore the feasibility of VLP-mediated protein delivery and uptake in target pulmonary endothelial cells during rat EVLP (by means of reporter VLPs that carry either the firefly luciferase or β-galactosidase reporter proteins) and 2) provide proof of concept of CRISPR-based gene editing during rat EVLP (by means of VLPs loaded with Cas9/sgRNA ribonucleoprotein complexes targeting IRI-related genes).

[1] "Project number" refers to the institutional project number. This question is optional. Applicants can only provide one project number.

[2] Funder(s) GrantID refers to the number of the DMP at the funder(s), here one can specify multiple GrantIDs if multiple funding sources were used.

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 [3].

				ONLY FOR DIGITAL DATA	*ONLY FOR DIGITAL DATA*	*ONLY FOR DIGITAL DATA*	*ONLY FOR PHYSICAL DATA*
Dataset Name	Description	New or Reused	Digital or Physical	Digital Data Type	Digital Data Format	Digital Data Volume (MB, GB, TB)	Physical Volume
Microscopy Images	Photos taken from (transduced) cell cultures. Fluorescent photos of stained cells or rat lung tissue. Confocal images of fluorescent staining rat lung tissue. Photos of Bioluminescent imaging.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☒ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	.tif, .jpg	☐ < 1 GB ☐ < 100 GB ☒ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	/
Gel-electrophoresis images	Imaging of agarose gel electrophoresis and Western Blot.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☒ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	.tif, .jpg	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	/
Numeric data	Data on RT-PCR outcomes, Flow Cytometry, gene editing outcomes, Elisa, bioluminescent imaging (IVIS and Envision) and transduction efficiencies.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical	.xlc, .txt, .fcs, .csv	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB	/

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

				☐ Textual ☐ Model ☐ Software ☐ Other:		☐ > 5 TB ☐ NA	
Sanger sequencing chromatograms	Outcome of gene editing experiments, control sequencing of newly generated plasmid constructs	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	.abi	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	/
Next generation sequencing	Outcomes of GUIDE-Sequencing experiments, targeted amplicon deep sequencing on/off-target sites	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	.fastaq, .zip, .fastaq.gz	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	/
Biological samples	Rat lung tissue samples, rat lung sections (cryosections and paraffin sections), RNA samples, DNA samples, samples of the EVLP perfusate solution.	☒ Generate new data ☐ Reuse existing data	☐ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software	/	☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☒ NA	Maximum of 5 boxes in the -80°C freezer and 5 boxes in cold room (4°C)

				☒ Other: Biological samples			

GUIDANCE:
The data description forms the basis of your entire DMP, so make sure it is detailed and complete. It includes digital and physical data and encompasses the whole spectrum ranging from raw data to processed and analysed data including analysis scripts and code. Physical data are all materials that need proper management because they are valuable, difficult to replace and/or ethical issues are associated. Materials that are not considered data in an RDM context include your own manuscripts, theses and presentations; documentation is an integral part of your datasets and should described under documentation/metadata.
RDM Guidance on data

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.	NA
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: ☒ Yes, animal data; provide ECD reference number: P174/2022 ☐ Yes, dual use; provide approval number: ☐ No Additional information:
Will you process personal data[4]? 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) ☒ No Additional information:

[4] 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:
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: IP protection will be prioritised before disclosure. For this matter, I can rely on the in-house expertise of IOF manager dr. F. Christ and on the IP-cell of the LRD office at KU Leuven.

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). *RDM guidance on documentation and metadata*.	For all experiments, all metadata is saved on digital files in such a way that a non-expert researcher will be able to reconstruct the experiment and analyse the data. All raw data, together with detailed annotations and techniques are stored a J drive with automatic back-up (capacity of 1 TB). Additionally, my personal data will be stored on a KU Leuven OneDrive with a capacity of 2 TB. These OneNote digital lab books contain introduction, rationale, materials & methods, execution, raw data, analysis method, results, conclusion section and rationale for future experiments. Reported metadata includes sample coding eg. "exp117-c29" and concomitant storage of experiment sheets that in detail describe how every sample was treated. For every type of experiment, standard protocols are saved and referred to in experiment descriptions. Deviations from these standard protocol versions are always mentioned. Sequencing files are always annotated according to this sample coding and include the primer that was used during sequencing. For NGS, a sample description .docx file is kept along .docx and .txt files that describe the used analysis commands. For readouts in multiwell-plates .txt files describing plate layout are saved next to the raw data files. For gel electrophoresis/Western blot/microscopy images/... .ppt files that show the location of each condition or nature of each staining on the gel/blot/image are saved in the same folder as the raw data files. For cloning/PCR procedures all details (incl. ordered DNA sequences) documented. Finally, all samples will be preserved in the appropriate freezers (-20 °C or -80 °C) and cell lines will be stored in liquid nitrogen localized in our laboratory.

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 no, please specify (where appropriate per dataset or data type) which metadata will be created: Currently, the use of metadata standards has not been implemented in the daily routine of the research group. In case this will change in the course of the project, this change and its timing will be reported at the end of the project. For all data common metadata are collected: title, author, data type, date created and data modified, file size, equipment reference (such as manufacturer and model identification). Depending on the nature of data additional metadata are collected. For instance, for Microscopy; channels used, fluorescence: wavelength.

4. Data Storage & Back-up during the Research Project	
Where will the data be stored? *Consult the interactive KU Leuven storage guide to find the most suitable storage solution for your data.*	☒ Shared network drive (J-drive) ☐ Personal network drive (I-drive) ☒ OneDrive (KU Leuven) ☐ Sharepoint online ☐ Sharepoint on-premis ☒ Large Volume Storage ☐ Digital Vault ☐ Other:

How will the data be backed up? *WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS?*	☒ Standard back-up provided by KU Leuven ICTS for my storage solution ☐ Personal back-ups I make (specify) ☐ Other (specify)
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 Daily backup is secured for all data stored on central university servers. All other data stored on the main desktop is synchronised via OneDrive. If no, please specify: NA
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.* *Guidance on security for research data*	Access to any of the locations used for data storage (KUL servers, KUL OneDrive and personal desktop) require explicit authorisation and are protected from outside access.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	OneDrive is free of use for KUL members. The pricing for large data storage (L-drive) is financed through grant applications.

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...). *Guidance on data preservation*	☒ All data will be preserved for 10 years according to KU Leuven RDM policy ☐ All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans ☐ Certain data cannot be kept for 10 years (explain)
Where will these data be archived (stored and curated for the long-term)? *Dedicated data repositories are often the best place to preserve your data. Data not suitable for preservation in a repository can be stored using a KU Leuven storage solution, consult the interactive KU Leuven storage guide.*	☐ KU Leuven RDR ☐ Large Volume Storage (longterm for large volumes) ☒ Shared network drive (J-drive) ☒ Other (specifiy): Digital versions of the lab books will be kept on OneDrive
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	These costs directly depend on the pricing of large storage drives of KU Leuven. These costs will be covered through grant applications.

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*	☐ Yes, as open data ☐ Yes, as embargoed data (temporary restriction) ☒ Yes, as restricted data (upon approval, or institutional access only) ☐ No (closed access) ☐ Other, please specify: Data will be made available after publication in peer reviewed journals. Additional data will be made available on basis of data sharing agreements if requested by third party. Additional material (and associated data) will be made available on basis of material transfer agreements (MTAs).
If access is restricted, please specify who will be able to access the data and under what conditions.	All members of the laboratory of Molecular Virology and Gene Therapy are authorized to have access to all obtained digital and physical data after the project. Due to potential commercial value of the data, no general full open access will be provided by default before IP protection and publication. Data which will be shared with third parties will exclude commercial use and will require appropriate credit to the data owners.
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.	☐ KU Leuven RDR ☒ Other data repository (specify): In a restricted access repository ☒ Other (specify): Upon request by email. Data will be available after signing a data sharing agreement which will be established with the support of KUL R&D after a request. Once KU Leuven has established a university managed and owned data repository sharing of data (or a subset of data), this repository will be evaluated for use based on policy and repository conditions. Changes to the data sharing policy will be reported in the final DMP of this project.
When will the data be made available?	☒ Upon publication of research results ☐ Specific date (specify) ☐ Other (specify)
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.* *Check the RDR guidance on licences for data and software sources code or consult the License selector tool to help you choose.*	☐ CC-BY 4.0 (data) ☒ Data Transfer Agreement (restricted data) ☐ MIT licence (code) ☐ GNU GPL-3.0 (code) ☐ Other (specify)

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, a PID will be added upon deposit in a data repository ☐ My dataset already has a PID ☐ No
What are the expected costs for data sharing? How will these costs be covered?	These costs directly depend on the pricing of large storage drives of KU Leuven. These costs will be covered through grant applications.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The individual researcher producing the data - ie. Phéline Kortleven - will have the final responsibility for data documentation and metadata. Supervision is provided by prof. Marianne Carlon and prof. Laurens Ceulemans
Who will manage data storage and backup during the research project?	Prof. Marianne Carlon and prof. Laurens Ceulemans are responsible for data preservation and reuse.
Who will manage data preservation and sharing?	Prof. Marianne Carlon and prof. Laurens Ceulemans are responsible for data preservation and reuse.
Who will update and implement this DMP?	Prof. Marianne Carlon and prof. Laurens Ceulemans bear the end responsibility for updating and implementing this Data Management Plan.