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	**Prof. Andreas von Leupoldt, 0000-0001-8539-8131**
Contributor name(s) (+ ORCID) & roles	**Prof. Daniel Langer, 0000-0001-8738-9482, Co-PI**
Project number [1] & title	G004624N, Effectiveness and mechanisms of menthol inhalation for the relief of dyspnea in health and COPD (MENTHODYSC)
Funder(s) GrantID [2]	G004624N
Affiliation(s)	☒ **KU Leuven** ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: ROR identifier KU Leuven: 05f950310

[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.

Please provide a short project description	Dyspnea (breathlessness) is the aversive cardinal symptom in many common and debilitating diseases including chronic obstructive pulmonary disease (COPD). It is associated with severe disability, activity limitation and loss of quality of life. Since available treatment options are limited, novel and effective treatment approaches for the relief of dyspnea are urgently needed. Therefore, this project will systematically examine the effectiveness and mechanisms of menthol inhalation for dyspnea relief in healthy individuals and COPD patients. Specifically, we will investigate whether menthol inhalation (a) reliably relieves dyspnea across different stimuli and groups of individuals, (b) respective brain, breathing and receptor-related mechanisms of action and (c) potential clinical benefits in COPD patients. The multidisciplinary research team combines expertise from psychology, rehabilitation sciences, pneumology and neurosciences. In five work packages, we will use state-of-the-art scientific methods including neural, psychophysiological, behavioral and clinical measures, complemented by using innovative receptor blockades. The overarching aim is to improve the available treatment options for dyspnea by demonstrating the effectiveness of menthol inhalation as a widely available and easily applicable low cost-low risk intervention, which may be beneficial across different situations in COPD patients, but also in patients suffering from dyspnea due to other common diseases.

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
		☐ Generate new data ☐ Reuse existing data	☐ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:		☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
WP1 - Informed consent form	Signed ICF (paper)	new	physical	NA	NA	NA	1 form (=5 pages) / participant In total 30 forms
WP1 - Questionnaires and ratings	Questionnaires on personality traits and ratings of experimental stimuli	new	digital	numerical; textual	.asc; .txt; ; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav	< 1 GB	NA
WP1 - Antropometrics	height, weight, head circumference, lung function	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav;	< 1 GB	NA

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

					.spv		
WP1 - Experimental data	behavioral responses, breathing parameters and EEG recordings collected in several experimental laboratory studies (computer controlled) per participants	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 TB	NA
WP2 - Informed consent form	Signed ICF (paper)	new	physical	NA	NA	NA	1 form (=5 pages) / participant In total 30 forms
WP2 - Questionnaires and ratings	Questionnaires on personality traits and ratings of experimental stimuli	new	digital	numerical; textual	.asc; .txt; ; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav	< 1 GB	NA
WP2 - Antropometrics	height, weight, head circumference, lung function	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 GB	NA
WP2 - Experimental data	behavioral responses, breathing parameters and EEG recordings collected in several	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 TB	NA

	experimental laboratory studies (computer controlled) per participants						
WP3 - Informed consent form	Signed ICF (paper)	new	physical	NA	NA	NA	1 form (=5 pages) / participant In total 30 forms
WP3 - Questionnaires and ratings	Questionnaires on personality traits and ratings of experimental stimuli	new	digital	numerical; textual	.asc; .txt; ; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav	< 1 GB	NA
WP3 - Antropometrics	height, weight, head circumference, lung function	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 GB	NA
WP3 - Experimental data	behavioral responses, breathing parameters and EEG recordings collected in several experimental laboratory studies (computer controlled) per participants	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 TB	NA

WP4 - Informed consent form	Signed ICF (paper)	new	physical	NA	NA	NA	1 form (=5 pages) / participant In total 30 forms
WP4 - Questionnaires and ratings	Questionnaires on personality traits and ratings of experimental stimuli	new	digital	numerical; textual	.asc; .txt; ; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav	< 1 GB	NA
WP4 - Antropometrics	height, weight, head circumference, lung function	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 GB	NA
WP4 - Experimental data	behavioral responses, breathing parameters and EEG recordings collected in several experimental laboratory studies (computer controlled) per participants	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 TB	NA
WP5 - Informed consent form	Signed ICF (paper)	new	physical	NA	NA	NA	1 form (=5 pages) / participant In total 30 forms
WP5 - Questionnair	Questionnaires on personality traits	new	digital	numerical; textual	.asc; .txt; ; .tiff; .ascii; .m; .r; .xlsx; .c	< 1 GB	NA

es and ratings	and ratings of experimental stimuli				sv; .sav		
WP5 - Antropometrics	height, weight, head circumference, lung function	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 GB	NA
WP5 - Experimental data	behavioral responses, breathing parameters and EEG recordings collected in several experimental laboratory studies (computer controlled) per participants	new	digital	numerical; textual	.asc; .txt; .raw; .avg; .tiff; .ascii; .m; .r; .xlsx; .csv; .sav; .spv	< 1 TB	NA

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: S66762 ☐ Yes, animal data; provide ECD reference number: ☐ 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: S66762
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:

[4] See Glossary Flemish Standard Data Management Plan

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 each individual study of all 5 WPs, an individual README file will be created and continuously updated and stored in the main data folder for this respective study. The file will contain precise info on the: - experimental design/study protocol - technical specifications/set up details - employed questionnaires /rating scales - collected physiological outcome measures - data preprocessing pipelines and final data analyses steps In addition, individual data files (e.g., SPSS, .R, BESA, etc.) will clearly be labelled and single variables will have clear labels/headers.
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: Metadata will be stored as Microsoft Word/pdf, .txt or .csv file under each study parent folder. We are currently not using a metadata standard, but will provide the relevant metadata in a structured manner (as outlined in the paragraph above).

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: Data in paper format (i.e., informed consent forms) will be stored in a locked cabinet in a locked office of the Research Group Health Psychology (Tiensestraat 102, 3000 Leuven). All other data will be stored in electronic format during the research in pseudonymized (later in anonymized) manner on: - encrypted external hard drives - password-protected computers of the researchers - the personal KULeuven OneDrive in folders that will only be accessible to the researchers involved in the project (i.e., Andreas von Leupoldt, Daniel Langer, PhD student, MA student, technician) and - on secured and encrypted servers of the Research Group Health Psychology (with backups) - on L-drives of the Department of Rehabilitation Sciences (with back-ups).
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) Encrypted external hard drives and password-protected computers of the researchers will be backuped regularly by the individual researchers. Data stored on secured and encrypted servers of a) the Research Group Health Psychology (responsible: Dr. Mathijs Franssen) and b) the KU Leuven (responsible: ICTS) receive automatic daily backups. If data on one storage medium should get lost, this data can be retrieved from the other storage media (simple copy & paste).

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: All KU Leuven personnel has access to 2 TB of data storage on OneDrive. As the estimated sizes of the datasets are < 2 TB, sufficient storage and backup capacity is available. Moreover, additional secured and encrypted servers of the Research Group Health Psychology offer further storage and backup options (> 500 TB).
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*	Since we will be working with sensitive personal data, the data will be stored and analyzed in pseudonymized manner using a numeric code instead of personal data for each participant. A decoding key (relating data to a specific person), will be saved separately from the personal data. As soon as possible, but the latest after final data analyses, the personal data will be fully anonymized by deleting the decoding key. All pseudonymized/anonymized data will be securely stored on password protected and/or encrypted hard drives, computers, and servers of KU Leuven. Only the involved researchers of this project will have access to the personal data, whenever possible exclusively in pseudonymized format.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	None expected

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): The research data will be archived in electronic format (in anonymized format) on: - encrypted external hard drives and on secured and encrypted servers of the Research Group Health Psychology and - the KU Leuven central servers (both with backups).
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	None expected

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: - Fully anonymized datasets with documentation can be uploaded in a .csv format in an open access repository (i.e. linked to the publication). - Fully anonymized datasets with documentation can be made available on request after signing a data sharing agreement.
If access is restricted, please specify who will be able to access the data and under what conditions.	Clinicians /researchers will be able to access the anonymized data. They will have to motivate why they want access to the data and that it is solely for professional and non-commercial reasons (research, clinical).
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) ☐ Other (specify) This repository is currently not specified, but may include Open Science Framework (osf).
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?	None expected

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The involved PIs of this project (Andreas von Leupoldt, Daniel Langer) supported by the involved researchers.
Who will manage data storage and backup during the research project?	The involved PIs of this project (Andreas von Leupoldt, Daniel Langer) supported by the involved researchers.
Who will manage data preservation and sharing?	The involved PIs of this project (Andreas von Leupoldt, Daniel Langer) supported by the involved researchers.
Who will update and implement this DMP?	The involved PIs of this project (Andreas von Leupoldt, Daniel Langer).