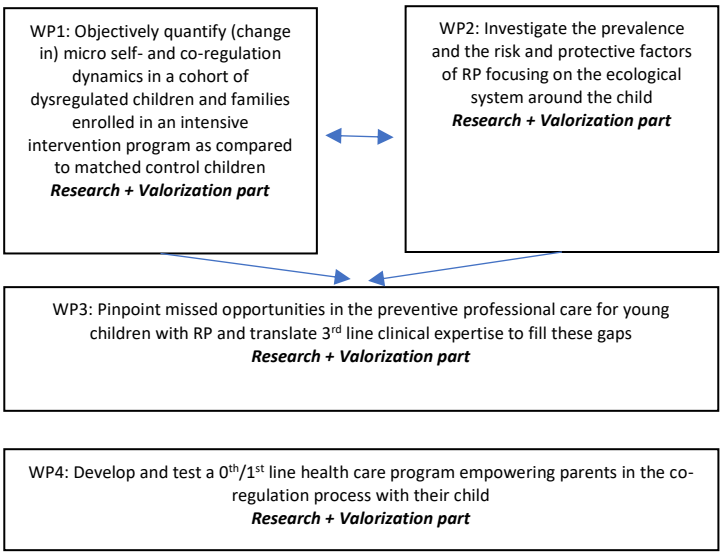
# Data Management Plan

## S003524N, Supporting the development of self-regulation in infants: a promising strategy in preventive mental health care

This is the DMP of the soc-called Co-PRIME project: "Co-regulation as the foundation of PReventive Infant MEntal health care". This SBO project comprises an interuniversity collaboration between KU Leuven, U Antwerp and U Ghent.

This project will address scientific and societal knowledge gaps throughout 4 inter-related work packages (WP):

**WP1.** Objectively quantify (change in) micro self- and co-regulation dynamics in a cohort of dysregulated children and families enrolled in an intensive intervention program as compared to matched control children
**WP2.** Investigate the prevalence and the risk and protective factors of RP focusing on the ecological system around the child
**WP3.** Pinpoint missed opportunities in the preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps
**WP4.** Develop and test a 0th/1st line health care program empowering parents in the co-regulation process with their child




KU Leuven is coordinator of the overarching project and of WP1. U Ghent coordinates WP2. U Antwerp coordinates WP3 and WP4.

The scientific team of each WP consists of:

- WP1: Boets (PI), Van den Bergh, Wass, Germeys, De Vos, Ponnet, De Bruyn, Singh, Deferm
- WP2: Ponnet (PI), Wouters, Van Hal, Boets, Germeys, Van den Bergh, De Bruyn, Hoedt
- WP3: Van Hal (PI), Ponnet, Wouters, Dhar, De Bruyn, Singh, Hertveldt
- WP4: Wouters (PI), Dhar, Boets, Van den Bergh, Ponnet, Van Hal, Singh, De Bruyn, phd

Here below, we provide the initial DMPs of the first 3 WPs which have been created in line with the requirements of the local universities. WP4 has not yet been initiated.

# 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 | Bart Boets - Promotor (0000-0002-4718-667X) |
| Contributor name(s) (+ ORCID) & roles | Binu Singh (0009-0005-0093-4078), UPC psychiatrist, PhD student<br>Ward Deferm (0009-0003-0219-8970), PhD student |
| Project number [1] & title | S003524N, Supporting the development of self-regulation in infants: a promising strategy in preventive mental health care |
| Funder(s) GrantID [2] | FWO, S003524N |
| Affiliation(s) | ☒ KU Leuven<br>x Universiteit Antwerpen<br>x Universiteit Gent<br>☐ Universiteit Hasselt<br>☐ Vrije Universiteit Brussel<br>☐ Other:<br>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.

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| Please provide a short project description | A major challenge of the newborn child is to learn to regulate internal states (physiological, emotional, and cognitive) and behavior. The child's self-regulation stems from successful co-regulation between the baby and its caregiver(s) and constitutes the basis of mental health. Regulation problems (RP) in early childhood are the seeds for emergent developmental psychopathology and for persistent mental health problems later in life. Given the increasing pressure on our mental health care system, targeting RP at an early age is a cost-effective prevention strategy. Based on growing empirical and clinical evidence, we hypothesize that child RP largely result from/persist through coregulation difficulties within the child-parent dyad, which itself is largely impacted by stress and regulation difficulties in the parent. Hence, reducing stress and enhancing parents' regulation abilities may be the most optimal gateway for improving self-regulation in the child, thereby preventing future mental health problems. Yet, the study of early RP is limited by a lack of clear concepts, objective measures and diagnostic criteria. In clinical contexts, professionals often have to rely on subjective assessments of mother, father and child problems. Furthermore, the proposed links between infant and parental self-regulation problems have not yet been established empirically.<br><br>This research project will objectively quantify self- and co-regulation dynamics in a cohort of dysregulated children and parents (and their matched controls), and we will follow them up throughout a clinically successful intensive 3rd line family-based intervention program mainly focusing on parental stress reduction. This study is highly innovative because (1) we will use state-of-the-art dual measurements in a sample of young dysregulated psychiatric patients and families, pinpointing co-fluctuations in terms of behavioral (e.g. eye gaze, facial mimicry, vocalizations, etc.), and stress physiology (heart rate and skin conductance) attunement; (2) we will not only study mother-child pairs, but also fathers will be included in all these measurements; (3) we will extend these typical laboratory measurements to the home environment, across 24-hour-long ANS and vocalization recording sessions and 14-day-long detailed diary measures, allowing us to examine how dyadic/triadic stress physiology responses and behavioral patterns interrelate in naturalistic home settings; and (4) we will administer all these measurements at multiple time-points allowing us to investigate postulated (directional) associations among parental stress and self- and co-regulation. |

## 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 |
| ICF_CO_PRIME | Informed consent forms | ☒ Generate new data | ☐ Digital<br>☒ Physical | | | | Documents of +-10 pages for each participant |
| Logbook_CO_PRIME | During the lab and follow-up sessions, annotations regarding data collection will be made on a designated worksheet (on paper). | ☒ Generate new data | ☐ Digital<br>☒ Physical | | | | 2 documents of 1 page for each participant |
| Digit_Logbook_CO_PRIME | Lab session logbook (digital versión) | ☒ Generate new data | ☒ Digital | ☒ Textual<br>☒ Other: Observational | .csv<br>.xlsx<br>.pdf | ☒ < 1 GB | |
| Pseudonomyzation_CO_PRIME | Names of included participants Will be pseudonymized using codes | ☒ Generate new data | ☒ Digital | ☒ Textual<br>☒ Other: Observational | .csv<br>.xlsx<br>.pdf | ☒ < 1 GB | |

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

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| Demographics_CO_PRIME | Participant data regarding SUBJECT_ID, age, gender, family constellation, SES. This will be collected during the first lab visit | ☒ Generate new data | ☒ Digital | ☒ Textual<br>☒ Other: Observational | . csv<br>. xlsx<br>. pdf | ☒ < 1 GB | |
| Questionaires_CO_PRIME | At both lab visits, questionnaires will be administered using REDCAP. | ☒ Generate new data | ☒ Digital | ☒ Textual<br>☒ Other: Observational | | ☒ < 1 GB | |
| Physiology | During the lab visits and follow-up sessions at Kleine K, measures of electrocardiography (ECG), Galvanic skin conductance, and respiratory rate will be collected of the infant, parent and therapist. | ☒ Generate new data | ☒ Digital | ☒ Other: Observational | . acq | ☒ < 1 TB | |

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| Biological_Samples | During the lab sessions participants will provide two saliva samples for hormonal assessment (endogenous oxytocin and cortisol levels) | ☒ Generate new data | ☒ Digital<br>☒ Physical | | .csv<br>.xlsx<br>.pdf | ☒ < 1 GB | Tubes will be labelled with Subject_ID, date, and time. |
| Video | Video data will be recorded of the parent and infant throughout all lab and follow up sessions. | ☒ Generate new data | ☒ Digital | ☒ Other: Observational | .acq<br>.mp4 | ☒ < 5 TB | |
| Home_Recordings | During the home recordings audio, ECG, proximity and location will be tracked of mother, father and infant for +-7 hours | ☒ Generate new data | ☒ Digital | ☒ Other: Observational | .csv<br>.mp3 | ☒ < 5 TB | |
| ESM_data | ESM questionnaire data of both parents | ☒ Generate new data | ☒ Digital | ☒ Other: Observational | .csv<br>.xlsx | ☒ < 100 GB | |

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| *GUIDANCE:*<br>*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.*<br>*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<br>(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: (EC application in preparation)<br>☐ Yes, animal data; provide ECD reference number:<br>☐ Yes, dual use; provide approval number:<br>☐ No<br>Additional information:<br>Only information relevant for the project's research questions will be collected. Sensitive personal data will be de-identified and pseudonymized, and will be stored and processed in coded form. |

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| 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)<br>☐ No<br>Additional information:<br>(EC application in preparation)<br><br>The project involves the collection of a broad range of multimodal data, including participant characteristics (questionnaires, clinical ratings, …), dual physiology recordings (skin conductance, heart rate, respiration recording), video and audio recordings of infant and parent during interactions, behavioral data, saliva samples and home recording data. This data will all be pseudonymized.<br><br>Personal data used for organizing the research (i.e. name, phone number, e-mail address) will not be included in the analysis and will be stored separately from the research data. |
| Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)?<br>If so, please comment per dataset or data type where appropriate. | ☐ Yes<br>☒ No<br>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)?<br>If so, please explain to what data they relate and what restrictions are in place. | ☐ Yes<br>☒ No<br>If yes, please explain: |

[4] See Glossary Flemish Standard Data Management Plan

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| Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use?<br>If so, please explain to what data they relate and which restrictions will be asserted. | ☐ Yes<br>☒ No<br>If yes, please explain: |

| **3. Documentation and Metadata** | |
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| 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).<br><br>*RDM guidance on documentation and metadata*. | We will create a separate folder on the KU Leuven L-drive (xxx) that contains the following information:<br><br>1. Readme.xlsx: In this document, the first tab will contain a table of content, furthermore we will note which researchers were involved in the collection of the data (e.g., master students), information regarding the ethical approval (reference number & institution), a short overview of the respective study experiments or questionnaires.<br>2. visit_overview.xlsx: In this document, we will provide pseudonymized information about all participants that were enrolled in the study, visit dates, and whether they completed all experiments/questionnaires or dropped-out/whether there was equipment failure.<br>3. Folder with all the study documents: Ethical application and approval, study protocol, study manual with the instructions that were given to participants, informed consent, as well as the PDF of all questionnaires.<br>4. Pre-processing documents: Comprise the very raw data (pseudonymized) and a manual with instructions to clean and (pre-)process the data. These documents will never contain sensitive (identifiable) participants information such as names, contact details, etc. |

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| Will a metadata standard be used to make it easier to **find and reuse the data**?<br><br>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.<br><br>*REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.* | ☐ Yes<br>☒ No<br>If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used:<br><br>If no, please specify (where appropriate per dataset or data type) which metadata will be created:<br><br>The metadata standard which can be found via www.FAIRsharing.org will not be used. However, within the lab, Readme files can be consulted to gather all relevant information. Regarding data-sharing repositories, metadata will be provided according to guidelines provided by the respective platforms. |

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

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| How will the data be backed up?<br><br>*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<br>☒ Personal back-ups I make (specify)<br>☐ Other (specify)<br><br>Digital documents will be digitally backed up on BIOMED L-Drive for large volume storage (secure KU Leuven facility for archiving).<br>Paper documents will be scanned and digitally backed up on BIOMED L-Drive for large volume storage (secure KU Leuven facility for archiving). |
| 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<br>☐ No<br><br>All data, except for the video recordings, will stored on the KU Leuven One Drive and L-drive. The video data will be stored on the secured KU Leuven ManGo platform. In case storage space should not be sufficient, additional space will be purchased.<br><br>If no, please specify: |
| How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?<br><br>*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.*<br>*Guidance on security for research data* | The personal nature of OneDrive ensures that files that are not explicitly shared, are not accessible to anyone else. As such, a separate folder will be created and encrypted for the current dataset. Only the PI and registered collaborating researchers will have access to this folder via the encryption key.<br>The KU Leuven network drives (e.g. L-drive) are incorporated within secured KU Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers. Only the PI can request access to the network drive for study personnel. |

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| What are the expected costs for data storage and backup during the research project? How will these costs be covered? | The OneDrive (2TB) comes free of charge for students and personnel of KU Leuven.<br>The L-drive costs about 800 EUR/year/5TB. These costs for storage and backup will be covered by project-related funding. |

| **5. Data Preservation after the end of the Research Project** | |
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| 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...).<br><br>*Guidance on data preservation* | ☐ All data will be preserved for 10 years according to KU Leuven RDM policy<br>☒ 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<br>☐ Certain data cannot be kept for 10 years (explain) |
| Where will these data be archived (stored and curated for the long-term)?<br><br>*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<br>☒ Large Volume Storage (longterm for large volumes)<br>☐ Shared network drive (J-drive)<br>☐ Other (specifiy): |

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| What are the expected costs for data preservation during the expected retention period? How will these costs be covered? | The yearly cost for L-drive storage is 800 EUR/5TB, hence annual costs for this storage are estimated at 250 EUR. This cost will be covered by current and subsequent project fundings. |

| **6. Data Sharing and Reuse** | |
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| 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.<br><br>*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<br>☐ Yes, as embargoed data (temporary restriction)<br>☒ Yes, as restricted data (upon approval, or institutional access only)<br>☐ No (closed access)<br>☐ Other, please specify: |
| If access is restricted, please specify who will be able to access the data and under what conditions. | Only published data (and associated scripts) will be available in the form of publications or other dissemination of scientific work. All data will be pseudonymized when disseminated. More data can be made available or shared after permission of the responsible person (prof. Bart Boets). Non-published data will remain confidential until a final decision on publication of the data has been taken. Data can be reused by direct colleagues, after consultation and approval of the head of CDP (prof. Bart Boets). External researchers will have to motivate why they want access to the data. When this data is being used by other researchers, they are required to give credit to the original data creators. |

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| 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<br>☐ Yes, intellectual property rights<br>☐ Yes, ethical aspects<br>☐ Yes, aspects of dual use<br>☐ Yes, other<br>☐ No<br><br>If yes, please specify:<br>We work with confidential data (e.g., name, sex, age, physiological data, video data, home recordings) |
| Where will the data be made available?<br>If already known, please provide a repository per dataset or data type. | ☐ KU Leuven RDR<br>☒ Other data repository (specify)<br>☐ Other (specify)<br>Data will be made available on a repository on the open science framework (OSF) |
| When will the data be made available? | ☒ Upon publication of research results<br>☐ Specific date (specify)<br>☐ Other (specify) |

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| Which data usage licenses are you going to provide? If none, please explain why.<br><br>*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.*<br>*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)<br>☐ Data Transfer Agreement (restricted data)<br>☐ MIT licence (code)<br>☐ GNU GPL-3.0 (code)<br>☐ Other (specify) |
| Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here.<br><br>*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<br>☐ My dataset already has a PID<br>☐ No |
| What are the expected costs for data sharing? How will these costs be covered? | Given that most data repositories are free of charge, no costs are expected for data sharing. |

| **7. Responsibilities** | |
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| Who will manage data documentation and metadata during the research project? | Ward Deferm (PhD student) will be responsible for data documentation and metadata, under supervision of principal investigator Bart Boets |
| Who will manage data storage and backup during the research project? | Data management, storage and back up will be performed by Ward Deferm under supervision of principal investigator Bart Boets, and with delegation to the dedicated data manager Dr. Wampers of the Psychiatry Research Group. |
| Who will manage data preservation and sharing? | The PI (Bart Boets) will be responsible for ensuring data preservation and sharing, with delegation to the dedicated data manager Dr. Wampers of the Psychiatry Research Group. |

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| Who will update and implement this DMP? | Ward Deferm (PhD student) will be responsible for updating and implementing this data management plan. |

# DMP WP2

*A Data Management Plan created using DMPonline.be*

**Creators:** Manon Hoedt, Sara De Bruyn https://orcid.org/0000-0003-0764-9008

**Affiliation:** Ghent University (UGent - UZ Gent)

**Funder:** Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

**Template:** FWO DMP (Flemish Standard DMP)

**ID:** 202336

**Start date:** 01-10-2023

**End date:** 30-09-2027

**Project abstract:**

The combination of the increasing pressure on mental health care and the limited HR and financial resources highlights the clear need for effective prevention strategies. It is increasingly being demonstrated that regulation problems (RP) in childhood, due to co-regulation problems within the parent(s)-child relationship are extremely important for mental health and thus setting the stage for developmental pathologies and persistent psychological problems in later life. To date, however, there is hardly any fundamental research with the aim to intervene in this vicious circle of mental health problems, especially in relation to (1) the understanding the vicious circle of regulatory problems within the broader social context, and (2) how we can prevent and treat these regulatory problems in young children.

The present study will address these gaps using a fully mixed concurrent dominant status design on 3 research goals: (1) assess the prevalence and evolution of RP (2) define the risk and protective factors of the child and the child's ecosystem in RP (3) investigate the impact of several stressors on mothers' and fathers' parenting and how this impacts RP in infants.

**Last modified:** 17-01-2024

# DMP WP2
## Application DMP

**Questionnaire**

**Describe the datatypes (surveys, sequences, manuscripts, objects … ) the research will collect and/or generate and /or (re)use. (use up to 700 characters)**

This project will use a mixed-method research design with a
- dominant longitudinal quantitative study employing questionnaires and measures with parents of young children
- qualitative study with semi-structured interviews with parents of children with regulation problems (RP)
This data will include socio-demographics and personal variables. No personal data that allows to identify a person will be linked to the respondents' answers, e.g., name, address, national register number. Analyzed data will be used for journal publications, conference presentations and public reports. Quantitative data can have the form of descriptive statistics and inferential statistics (e.g., significant relations between variables). Qualitative data can have the form of pseudonymised quotes.

**Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)**

The administrative promotor is responsible for the implementation and periodical revision of the DMP. The data collection, storage and analysis is done by the main researcher, the (co-)promotors, other researchers with whom we will closely collaborate, or students for education purposes. Data will be stored on the computers of the researchers during initial processing. The transferring of data will commence as soon as possible into a secure, shared OneDrive folder. Data will also be cyclically synced and uploaded into a personal network drive folder, provided by Ghent University's ICT Department (DICT), who is in charge of the security, maintenance and backup of the data on the project share. Once data has been manually checked for proper transfer and no loss of data is guaranteed, temporary storage of data on local drives for processing will be permanently deleted.

**What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)**

We will not deviate from the principle of preservation of data and the minimum preservation term of 5 years.

**Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)**

In line with the GDPR, we will register the use of personal information in the GDPR register, through DMPonline and prior to starting with the work packages related to the collection of personal data. Informed consent and permission for collecting, analyzing, preserving and sharing the data will be offered to all respondents. No respondents will be younger than 18 years old. The data linking and pseudonymization takes place immediately after data collection by the person responsible for the Qualtrics questionnaire at UGent, where personal data is immediately separated of the actual research data. The data analysis is therefore done on a pseudonymous basis data. After the study, the personal data will be deleted. Respondents will be informed of this procedure prior to filling out the survey.

**Which other issues related to the data management are relevant to mention? (use up to 700 characters)**

Respondents will be informed about the data collection procedure through the consent forms and an information letter. Regarding confidentiality, the data will be analysed by the research team and will be fully pseudonymised for researchers with whom we will closely collaborate, or students for education purposes.

# DMP WP2
# FWO DMP (Flemish Standard DMP)

**1. 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.**

| | | | | 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 |
| | | *Please choose from the following options:*<br>• Generate new data<br>• Reuse existing data | *Please choose from the following options:*<br>• Digital<br>• Physical | *Please choose from the following options:*<br>• Observational<br>• Experimental<br>• Compiled/aggregated data<br>• Simulation data<br>• Software<br>• Other<br>• NA | *Please choose from the following options:*<br>• .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, …<br>• NA | *Please choose from the following options:*<br>• <100MB<br>• <1GB<br>• <100GB<br>• <1TB<br>• <5TB<br>• <10TB<br>• <50TB<br>• >50TB<br>• NA | |
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**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:**

Not applicable.

**Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes, human subject data

The data linking and pseudonymization takes place immediately after data collection by a trusted person from UGent, where personal data is immediately separated of the actual research data. The data analysis is therefore done on a pseudonymous basis data. After the study, the personal data will be deleted. Respondents will be informed of this procedure prior to filling out the survey.
Ethics approval will be obtained at the '**Ethical Committee of the Faculty of Social and Political Science**' of the University of Ghent before initiating all new data
collection.

**Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes

In line with the GDPR, we will register the use of personal information in the GDPR register, through DMPonline and prior to starting with the work packages related to the
collection of personal data. Informed consent and permission for collecting, analysing, preserving and sharing the data will be offered to all respondents.
The quantitative study among parents will collect personal data,
The qualitative interviews will collect personal (and identifiable) data. The recordings and transcriptions will be digitally encrypted and will never be shared with third
parties. All data will be fully pseudonymized.
Respondents will be informed about the data collection procedure through the consent forms. Regarding confidentiality, the data will only be analysed by the research team and will not be shared with third parties/colleague researchers. For educational purposes it is possible that students gain access to analyse pseudonymized data.

**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/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

**2. 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).**

Codes of the statistical analyses (syntaxes), statistical output (graphs, summary, frequency and regression tables) and manuscripts will be generated in the current project based on the newly generated survey data as described earlier.
Codes, memos, analyses and manuscripts will be generated in the current project based on the newly generated qualitative (interviews/focus groups) as described
earlier.
The documentation (codebook, protocol, questionnaire) of all the data is available upon request. It is possible that (parts of) the quantitative data will be shared/published on established and trusted public discipline-specific data repositories and/or shared upon reasonable request.

**Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.**

- No

### 3. Data storage & back-up during the research project

**Where will the data be stored?**

The data will be stored on the computers of the researchers during intial processing. The transferring of data will commence as soon as possible into a secure, shared folder.

**How will the data be backed up?**

Data will be cyclically synced and uploaded into a personal network drive folder, provided by Ghent University's ICT Department (DICT), who is in charge of the security, maintenance and backup of the data on the project share.

**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 secured H-drive of the UGent provides sufficient storage and backup capacity during the project.

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

The storage servers can be accessed from the university network, through a VPN-connection or through a web interface, which uses SSL for transport layer encryption.
Access requires authentication through a centrally managed UAntwerpen account (Microsoft Active Directory), which uses username and password authentication with a
strong password policy. Authorization is granted by the IT department upon request by a supervising manager.
Fysical access to the servers is limited to the IT department. All access by external persons is logged and happen under supervision of the IT department.
Data at rest on the NAS is unencrypted. Off-campus data transfers have transport encryption, either through VPN or HTTPS. All files on stored on the Servers are scanned
by AV-software.

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

There are no additional costs for the data storage and backup during the project, as we use the facilities (secured network) of the UGent.

### 4. 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...).**

The survey data and qualitative data of the current project, codes (syntax) and research output (manuscripts incl. statistical output) will be retained for the expected 5-
years period after the end of the project.

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

The data and research output will be stored on servers managed by the University of Ghent IT department?

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

There are no expected costs. We use the facilities of the UGent.

**5. Data sharing and reuse**

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

- No (closed access)

During the project, all the data is available only to the research team.
After the project, the anonymous quantitative survey data can be shared upon reasonable request.
The qualitative data will not be publicly available due to privacy restrictions.

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

NA

**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 in the comment section per dataset or data type where appropriate.**

- Yes, Privacy aspects

The qualitative data will not be shared due to privacy concerns

**Where will the data be made available? If already known, please provide a repository per dataset or data type.**

The anonymous quantitative survey data can be shared upon reasonable request through a secure connection (e.g., Belnet).

**When will the data be made available?**

The data can be made available after the end of the project

**Which data usage licenses are you going to provide? If none, please explain why.**

We follow the principle that data will be as open as possible and as closed as necessary

**Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.**

- No

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

There are no costs for data sharing

**6. Responsibilities**

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

The administrative promotor (PI of the project: Prof. dr. Koen Ponnet) is responsible for the implementation and periodical revision of the DMP.

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

The data storage is done by the main researcher, the (co-)promotors, other researchers with whom we will closely collaborate. Ghent University's ICT Department (DICT) is in charge of the security, maintenance and backup of the data on the project share.

**Who will manage data preservation and sharing?**

The administrative promotor (PI of the project: Prof. dr. Koen Ponnet) is responsible for the implementation and periodical revision of the DMP.

**Who will update and implement this DMP?**

The administrative promotor (PI of the project: Prof. dr. Koen Ponnet) is responsible for the implementation and periodical revision of the DMP.

# Pinpoint missed opportunities within preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps

A Data Management Plan created using DMPonline.be

**Creator:** Febe Hertveldt

**Affiliation:** University of Antwerp

**Funder:** Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

**Template:** FWO DMP (Flemish Standard DMP)

**ID:** 203224

**Start date:** 01-10-2023

**End date:** 01-10-2027

**Project abstract:**

The combination of the growing mental health care burden and the limited human and monetary resources for health stresses the clear need for effective prevention strategies. It is increasingly demonstrated that regulatory problems (RP) in infancy – resulting from co-regulation difficulties within the caregiver(s)-child relationship – hold extreme importance for mental health, constituting the seeds for emergent developmental psychopathology and persistent mental health problems later in life. However, to date, there has been limited fundamental research which aims to intervene in this vicious cycle of mental health problems, especially with respect to (1) understanding the vicious cycle of regulatory problems within a larger social context and (2) exploring how to structurally prevent and treat infant regulatory problems. The current project is the third work package of a large-scale FWO-project "Supporting the development of self-regulation in young children: a promising strategy in preventive mental health care". By conducting qualitative interviews and focus groups with parents, professional childcare workers and healthcare providers, this third WP aims at identifying the missed opportunities in the preventive care trajectory for young children with RP, and investigate how the mechanisms of an established and clinically successful 3rd line family program can be translated to fill in the gaps within preventive infant mental health care in Flanders. We will focus on 3 research objectives to answer the research question: (1) Explore parents' health seeking behavior and care trajectory as a response to RP, (2) Examine the perspective of professional childcare workers on RP, and (3) Examine the views of health care providers on implementing a new 0th/1st line co- and self-regulation program.

**Last modified:** 08-12-2023

## Pinpoint missed opportunities within preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps Application DMP

### Questionnaire

**Describe the datatypes (surveys, sequences, manuscripts, objects … ) the research will collect and/or generate and /or (re)use. (use up to 700 characters)**

**Qualitative** data: Generate **new** interview/focus group data among parents (30-40), professional childcare workers (30-40) and infant mental health specialists (+- 30), audio-recorded and transcribed ad verbatim. Data will be fully pseudonymized for the researchers.Interviews are held online or at a a pre-arranged physical location.
Format: The data will be available in nvp (Nvivo) and docx (Microsoft Word file). The overall output of the project is reported in manuscripts (articles) available in pdf format (Adobe Acrobat document).

We will also do file analysis based on files at Little K and UKJA in which we will analyze parents' responses before admission ("anamnesis") and after admission ("feedback") in Nvivo. Parents informed consent will also be asked about this beforehand.

**Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research?
Motivate your answer. (use up to 700 characters)**

Prof. Edwin Wouters is responsible for the data preservation on the server of the University of Antwerp during and at least 5 years after the end of the research. The data will be stored on NAS-servers managed by the University of Antwerp IT department. The data is stored redundantly on two machines on separate locations approximately
6km apart. There is a maximum of 1 minute between file synchronizations. Each NAS server also provides disk redundancy through RAID 6, allowing for up to 2 simultaneous disk failures within a single machine. The data collection, storage and analysis is only done by myself, my promotor or other researchers with whom we will closely collaborate, or students for education purposes. The security of the data is ensured by the data security protocols of the University of Antwerp. This means that data is only accessible by logging into a secure university intranet, only accessible by logging in to a personal computer protected with its own account/password. The secured H-drive of the University of Antwerp provides sufficient storage and backup capacity during the project.
It is possible that (parts of) the quantitative data will be shared/published on established and trusted public discipline-specific data repositories.

**What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)**

We will not deviate from this principle.

**Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)**

Qualitative interview recordings and transcriptions will be digitally encrypted and will never be shared with third parties. All data will thus be fully pseudonymized for the researchers.

**Which other issues related to the data management are relevant to mention? (use up to 700 characters)**

Not applicable

# Pinpoint missed opportunities within preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps FWO DMP (Flemish Standard DMP)

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## Project Information

**Antigoon project ID**

48645

## 1. 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.**

| | | | | 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** |
| **Interview recordings** | Recordings of interviews of ... | Generate new data | Digital | Observational | Other: MP4 | < 10 GB | |
| **Transcripts from interviews** | Pseudomised transcripts of interviews | Generate new data | Digital | Observational | .PDF | < 1 GB | |
| **Manuscripts** | Overall output of the project | Generate new data | Digital | Compiled | .PDF | < 1 GB | |
| **(File analysis)** | | Reused data | Physical | | | | Aantal invullen |

**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:**

Not applicable

**Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes, human subject data

Qualitative interview recordings and transcriptions will be digitally encrypted and will never be shared with third parties. All data will thus be fully pseudonymized for the researchers.
Informed consent will be given by all participants.
Ethics approval will be obtained at the 'Ethische Adviescommissie Sociale en Humane Wetenschappen' of the University of Antwerp before initiating all new data collection.

**Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes

Qualitative interview recordings and transcriptions will be digitally encrypted and will never be shared with third parties. All data will thus be fully pseudonymized for the researchers.

**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/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

## 2. 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).**

Codes, memos, analyses and manuscripts will be generated in the current project based on the newly generated qualitative (interviews/focus groups) as described earlier.
Files and folders will be organized and named in a way that will provide all the necessary information about the data they contain (e.g. year, population, type, etc.). In addition, README.txt files will be added to folders where any additional data information or explanation will be necessary. Excel files with data will contain extra sheets with all the necessary information.
The documentation of all the data is available upon request.

**Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.**

- No

Metadata created for this project:
-Project identifier: Pinpoint missed opportunities within preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps, FWO-SBO project, project ID: 48645£-
Title: interview_data_WP3
-Storage link
-Format file type: MP4, .pdf, …
-Date of acquisition and last modification
-Contact: who can access and update data: Febe Hertveldt (febe.hertveldt@uantwerpen.be), Sara De Bruyn (sara.debruyn@uantwerpen.be)

## 3. Data storage & back-up during the research project

**Where will the data be stored?**

The data will be stored on NAS-servers managed by the University of Antwerp IT department. The data is stored redundantly on two machines on separate locations approximately 6km apart. There is a maximum of 1 minute between file synchronizations. Each NAS server also provides disk redundancy through RAID 6, allowing for up to 2 simultaneous disk failures within a single machine.

**How will the data be backed up?**

Snapshots are taken every two hours. These snapshots can be viewed by users with access to the shared data and individual files and folders can be restored by users with write access to the data. The snapshots are retained for a period of 52 weeks

**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 secured H-drive of the UAntwerp provides sufficient storage and backup capacity during the project.

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

The storage servers can be accessed from the university network, through a VPN-connection or through a web interface, which uses SSL for transport layer encryption. Access requires authentication through a centrally managed UAntwerpen account (Microsoft Active Directory), which uses username and password authentication with a strong password policy. Authorization is granted by the IT department upon request by a supervising manager.
Physical access to the servers is limited to the IT department. All access by external persons is logged and happen under supervision of the IT department.
Data at rest on the NAS is unencrypted. Off-campus data transfers have transport encryption, either through VPN or HTTPS. All files stored on the Servers are scanned by AV-software.

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

There are no additional costs for the data storage and backup during the project, as we use the facilities (secured network) of the UA.

## 4. 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...).**

The audio of the interviews will be deleted as soon as possible after being transcribed.

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

The data will be stored on NAS-servers managed by the University of Antwerp IT department. The data is stored redundantly on two machines on separate locations approximately 6km apart. There is a maximum of 1 minute between file synchronizations. Each NAS server also provides disk redundancy through RAID 6, allowing for up to 2 simultaneous disk failures within a single machine.

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

There are no expected costs. We use the facilities of the UA.

## 5. Data sharing and reuse

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

- No (closed access)

The original qualitative data will not be publicly available due to privacy restrictions
But the output data such as manuscripts can be published in Open Access.

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

I could create a metadata file to make datasets findable (following the FAIR principles) on Figshare without uploading the dataset

**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 in the comment section per dataset or data type where appropriate.**

- Yes, Privacy aspects

The qualitative data will not be shared due to privacy concerns.

**Where will the data be made available? If already known, please provide a repository per dataset or data type.**

The qualitative data will not be shared due to privacy concerns.

**When will the data be made available?**

Not applicable. The qualitative data will not be shared due to privacy concerns.

**Which data usage licenses are you going to provide? If none, please explain why.**

No license is granted, due to privacy concerns.

**Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.** • No

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

There are no costs for data sharing.

## 6. Responsibilities

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

The research team: supervisor Prof. dr. Guido Van Hal, Prof. dr. Edwin Wouters and postdoctoral researcher dr. Sara De Bruyn

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

The research team: supervisor Prof. dr. Guido van Hal, Prof. dr. Edwin Wouters and postdoctoral researcher dr. Sara De Bruyn

**Who will manage data preservation and sharing?**

The research team: supervisor Prof. dr. Guido van Hal, Prof. dr. Edwin Wouters and postdoctoral researcher dr. Sara De Bruyn

**Who will update and implement this DMP?**

The research team: supervisor Prof. dr. Guido van Hal, Prof. dr. Edwin Wouters and postdoctoral researcher dr. Sara De Bruyn

# Pinpoint missed opportunities within preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps GDPR

## GDPR

**Have you registered personal data processing activities for this project?**

- Yes

# Pinpoint missed opportunities within preventive professional care for young children with RP and translate 3rd line clinical expertise to fill these gaps DPIA

## DPIA

| | |
|---|---|
| **Have you performed a DPIA for the personal data processing activities for this project?** • | No |