

Neonatal Online Neuro-Analysis for Interpretation and Decision-support - Bringing automated neonatal monitoring to the bedside

Research Data Summary

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

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		<i>Indicate: N(ew data) or E(xisting data)</i>	<i>Indicate: D(igital) or P(hysical)</i>	<i>Indicate: Audiovisual Images Sound Numerical Textual Model SOftware Other (specify)</i>		<i>Indicate: <1GB <100GB <1TB <5TB >5TB NA</i>	
NeoGuard Leuven	EEG data from neonates with seizure labels, background labels, sleep labels, and outcome labels (Leuven)	E	D	N	European data format (EDF)	<1TB	
Cardiox & control	EEG data from neonates with congenital heart disease, and healthy controls (Leuven)	E	D	N	European data format (EDF)	<100GB	
HIE EEG NIRS	EEG + NIRS data from neonates with HIE with MRI outcomes (Leuven)	E	D	N	European data format (EDF)	<100GB	
Resilience artefacts	Longitudinal EEG data from preterm neonates and artefact labels (Leuven)	E	D	N	European data format (EDF)	<100GB	
HIE Cork	EEG data from neonates with HIE with background labels (Cork)	E	D	N	European data format (EDF)	<100GB	
Seizure Helsinki	EEG data from neonates with seizure labels (Helsinki)	E	D	N	European data format (EDF)	<100GB	

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

Dataset name	Source
NeoGuard Leuven	Previous collaboration with UZ Leuven (DOI: 10.1142/S0129065718500119; 10.1038/s41598-020-64211-0)
Cardiox & control	Previous collaboration with UZ Leuven (DOI: 10.1016/j.ejpn.2021.12.008)
HIE EEG NIRS	Previous collaboration with UZ Leuven (DOI: 10.1038/s41598-022-27275-8)
Resilience artefacts	Previous collaboration with UZ Leuven (DOI: 10.1088/1741-2552/acbc4b)
HIE Cork	Public dataset (DOI: 10.1038/s41597-023-02002-8)
Seizure Helsinki	Public dataset (DOI: 10.1038/sdata.2019.39)

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

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

Dataset name	S-number
NeoGuard Leuven	S54590
Cardiox & control	S54683
HIE EEG NIRS	S64831
Resilience artefacts	S58807

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

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

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HIE EEG NIRS	S64831
Resilience artefacts	S58807

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

The data will be used to develop (train and validate) machine learning algorithms for neonatal brain monitoring. The application of the trained models has valorization potential.

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

- No

There may be data transfer agreements in the future as the project progresses.

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

- No

Documentation and Metadata

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

Each dataset will be accompanied by

- a recording_data file (Excel): containing relevant (anonymized) info about each recording
- csv and/or excel files with clinical annotations for the EEG data, where available
- README text file explaining the dataset and its accompanying files.

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.

- No

Data not meant to be shared due to sensitive nature

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Other (specify below)

The data is stored on a secure SSH server at ESAT (KU Leuven).

How will the data be backed up?

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

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

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

- Yes

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

Only access to specific users that should explicitly be granted access that should connect through ssh, managed by the IT department of ESAT.

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

N/A

Data Preservation after the end of the Research Project

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

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

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

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

- Other (specify below)

secure SSH server at ESAT (KU Leuven).

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

N/A

Data Sharing and Reuse

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

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

Upon reasonable request

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

Only the involved researchers and supervisors

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

Where will the data be made available?

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

- Other (specify below)

N/A

When will the data be made available?

- Other (specify below)

N/A

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

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

- No

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

N/A

Responsibilities

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

Post-doc researcher (Tim Hermans)

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

Post-doc researcher

Who will manage data preservation and sharing?

Post-doc researcher

Who will update and implement this DMP?

Post-doc researcher