Protocol title

WPXX: Title of WP

Task X.X: Title of task

Substance group X

|  |  |
| --- | --- |
| Date |  |
| Responsible author |  | E-mail |  |
| Short name of institution |  | Phone |  |
| Co-authors |  |

# Background

Provide background literature regarding the research hypothesis.

# Objective

Explain the objective of the study protocol with stating the specific research question.

# Methods

## Study design

Select the sub-datasets of the aligned studies that are needed for this study protocol in the table below:

|  |  |  |
| --- | --- | --- |
| **CHILDREN** | **TEENAGERS** | **ADULTS** |
| [ ] Odense Child cohort | [ ] Riksmaten Ungdom | [ ] CPHMINIPUB |
| [ ] NEB II  | [ ] NEB II | [ ] Diet\_HBM |
| [ ] Indoor Air Quality | [ ] Pilot study in Czech school children | [ ] FinHealth |
| [ ] PCB cohort | [ ] PCB cohort follow-up | [ ] (C)ELSPAC |
| [ ] POLAES | [ ] POLAES | [ ] POLAES |
| [ ] SLO CRP | [ ] SLO CRP | [ ] HBM in Croatia |
| [ ] CROME | [ ] CROME | [ ]  INSEF-ExpoQuim |
| [ ] Northern Adriatic Cohort II | [ ] BEA | [ ] SHeS-pp |
| [ ] ESTEBAN | [ ] ESTEBAN | [ ] ESTEBAN |
| [ ] GerES V | [ ] GerES V | [ ] ESB |
|  | [ ] FLEHS IV | [ ] Oriscav-Lux2 |

*Remark: More information about available data for each of the sub-datasets is available in the appendix of this template. The information is currently available on substance group level. The list of specific metabolites available per sub-dataset depends on the qualifications of the analyzing lab. A complete list of available data per sub-dataset on metabolite level will be made available through the HBM4EU website in the online library.*

Describe the overall study design: e.g. meta-analysis, pooled analysis,…

Describe the target group: age (children/teenagers/adults), sex,…

## Exposure variables and accompanying variables

Describe the exposure variables (specific metabolites) and accompanying variables (age, sex, SES, NUTS,…) needed to explore this specific research hypothesis.

All variables should be listed in “[Annex 1: Research protocol aligned studies variable list](https://www.hbm4eu.eu/mdocs-posts/annex1-research-protocol-aligned-studies-variable-list/)” of this research protocol. The full list of harmonized variables available from the aligned studies is detailed in the codebooks of the aligned studies that can be obtained upon request through the data management helpdesk (HBM4EU.DATAMANAGEMENT@vito.be).

## Statistical analysis

Explain the statistical methods that will be used.

Describe the analytical models you will use, the sensitivity analysis you will perform,…

Specify if you will do meta- and/or pooled analysis, and set out the minimal requirements of data comparability to enable these analyses.

Guidance on how to deal with substance specific issues common to the aligned studies (e.g. dealing with a combination of spot-urine and morning urine samples) can be found in D10.10 Statistical Analysis plan for aligned studies.

# Organisation, publication and time schedule

## Organisation

Specify the responsible person who will coordinate the study protocol and in which WP the statistical analysis is framed.

|  |  |
| --- | --- |
| **Responsible person:** | ………….. |
| **WP:** | ………….. |

For each sub-dataset used in the research protocol a representative researcher of that sub-dataset should be assigned to join the study protocol working group.

State who will do the statistical analyses. Only these nominated persons will be granted access to the data:

|  |  |
| --- | --- |
| **Name:** | **Institute:** |
|  |  |
|  |  |
|  |  |
|  |  |

The source data of the aligned studies is stored in a central database at VITO. Access to extracts of the data will be provided through this data platform after signing Supplying data controller – Receiving data controller agreements with each of the aligned studies from which data is requested. A [template](https://www.hbm4eu.eu/mdocs-posts/guidance-supplying-dc-receiving-dc-agreement/) Data controller – Data controller Agreement is available on the project website.

## Publication

The procedures described in the HBM4EU publication policy shall be followed considering submission of any papers for publication and/or abstracts for conferences. Considering data use, the HBM4EU data policy sets the requirements of acknowledgement of the Data Owner/Data Provider. At latest 30 calendar days prior to submission of any papers for publication considering data that are provided to HBM4EU partners via the central database at VITO, the lead author shall contact the Data Provider by sending a title, abstract, and author list. The Data Provider is entitled to request to include 2 co-authors in scientific publications of results considering the provided data. It is advised to consult the Data Provider as early as possible.

Specify which publication(s) will results from this study protocol.

List of potential co-authors and their contribution to the manuscript.

## Time schedule

Clarify the working plan in a time schedule, e.g. describe the different steps that will be taken and put a timing on it, including a timing for writing a paper of the results.

## Permissions and ethical issues

To obtain permission to use the data, the lead data user has to submit a proposal, containing among others the purpose of data use, named lead data user and other data users, the required studies, variables, sampling time frame, a start and end data to perform the analyses,…

The WP leader verifies the fit of the purpose with HBM4EU objectives and checks whether the same analyses are not yet performed by other consortium partners. Upon approval of the proposal, the lead data user and each other data user shall complete and sign the HBM4EU supplying data controller – receiving data controller agreement. Upon signed agreement, the lead data user and other data users obtain the necessary permissions to access the data through the VITO data platform and to perform the data analyses for the purpose specified in the approved research protocol. Data analyses and presentation of papers should adhere to good epidemiological practice and the STROBE guidelines. By receiving and using data within the frame of HBM4EU all involved parties accept the HBM4EU Data Policy. This includes, but is not limited to, protection of the study participants identity, safeguard to not share the data with unauthorized people, commitment to not store the data on any place that is accessible by others (unauthorized people), commitment to follow the procedures regarding publication and/or dissemination of results. All details are available in the documents mentioned above.

# References

Reference list

# Appendix





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