

Terms and conditions for access to data and/or biological material from The Norwegian Mother, Father and Child Cohort Study (MoBa)

Standard terms and conditions:

- The principal investigator (PI) is responsible for ensuring that all processing of personal data complies with the requirements of the Personal Data Act (Personopplysningsloven) and the European General Data Protection Regulation (GDPR). This includes ensuring that the information is stored safely in accordance with the institution's guidelines, ensuring measures against unauthorized disclosure and unauthorized access to personal information, as well as preventing attempts to identify individuals.
 - The PI and Data Controller must assess whether carrying out a DPIA is necessary before the processing of personal data starts.
 - The PI is obliged to assist MoBa with handling any deviations and questions from the Norwegian Data Protection Authority (Datatilsynet) and the Norwegian Board of Health Supervision (Helsetilsynet).
- The PI is responsible for entering into all necessary agreements with all research institutions where project members are employed.
- The PI is responsible for ensuring that all project members comply with terms and conditions detailed in the decision letter.
- Substantial changes to the study, such as a change of responsible institution, new project manager or prolonged project duration, will require a new approval from MoBa.
- Data access can only be given to project members who have been legally authorized to access the dataset. The PI must, at any given time, be able to provide an updated list of project members legally authorized to access the dataset.
- Data from MoBa may only be used in the approved research project and for the purpose stated in the application.
- If the project requires linkage to other data sources: No more information shall be combined than is necessary for the purpose of the project. The combinations shall comply with any consents or reservations.
- Commercial exploitation of participants, health information, and human biological material from MoBa is prohibited, following applicable Norwegian regulations (Forskrift om befolkningsbaserte helseundersøkelser § 1-4).
- Anyone with access to the dataset is bound by a duty of confidentiality in accordance with Norwegian law (Helseregisterloven § 17).
- It is not permitted to transfer or copy any data from the storage location specified in the decision letter. If a change of location is necessary, MoBa shall be notified in advance.
- Unless MoBa has explicitly approved for project members from third countries to have access to data: Employees at institutions in countries outside the EU/EEA, so-called third countries, are not allowed access to data from MoBa.
 - If personal data is to be transferred/made available to employees at institutions in third countries, the project must apply to MoBa and document that the requirements for necessary guarantees, approved transfer basis and additional measures, cf. EU's GDPR Article 46 and the Schrems II verdict, are fulfilled.

- If MoBa has approved data access for project members from third countries: MoBa will grant that access to data is given to employees in third countries only on the condition that this is done in accordance with existing permissions.
- If the project has no REK approval, or a REK approval with no storage requirement: The data material shall be deleted no later than the end of the project period.
- In the case of a REK approval with storage requirement: The data material may be stored for five years after the project ends, in accordance with the approval from REK. The data material shall then be deleted.
- When publishing or disseminating, MoBa must be cited as the source. In all publications, MoBa's official name or abbreviation must be included in the title or abstract text for PubMed searches. The project must follow the publishing guidelines available at <https://www.fhi.no/en/studies/moba/for-forskere-artikler/checklist-for-papers/>
- If the project wants to participate in national or international collaborations or consortia, where aggregated data from MoBa is included in analyses, the PI must inform MoBa in writing.
- MoBa is not responsible for interpretations or analyses of the data made by others.
- Information about the project will be published on the NIPH's website after access to the data has been granted.

Terms for access to biological material from MoBa:

- Biological material from MoBa must only be used in the approved research project and for the purpose stated in the application.
- Linkage between results from analyses of biological material and other data must only take place after analysis results/biodata have been returned to MoBa.
- It is not permitted to send biological material to third countries.
- The terms and conditions of the decision letter from MoBa will take precedence over agreements and contracts between the Data Controller and collaborating institutions in the event of conflict.
- A Material Transfer Agreement (MTA) must be entered into with the biobank in which conditions will be set forth regarding the return of analysis results.

Please note that additional project-specific conditions may be imposed, depending on the nature of the application.