

NORWEGIAN MOTHER, FATHER AND CHILD COHORT STUDY (MoBa)  
GUIDELINES FOR RESEARCH

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## 1. PURPOSE AND GENERAL INFORMATION

The MoBa Guidelines provide the framework for access to and use of data and biological material, including data derived from use of the MoBa resource, to ensure high-quality research based on MoBa.

All relevant documents including the MoBa study protocol, standard terms and conditions for access to and use of MoBa and information about the application process may be found at the NIHP website (<https://www.fhi.no/en/studies/moba/for-forskere-artikler/viktige-dokumenter-for-moba-forskere/>). All applicants are encouraged to read the following articles and the standard terms prior to applying:

- Magnus P, Birke C, Vejrup K, Haugan A, Alsaker E, Daltveit AK, Handal M, Haugen M, Hoiseth G, Knudsen GP, Paltiel L, Schreuder P; Tambs K, Vold L, Stoltenberg C. Cohort Profile Update: The Norwegian Mother and Child Cohort Study (MoBa). *Int J Epidemiol* 2016; 45:382-8.
- Liv Paltiel, Anita Haugan, Trine Skjerden, Kari Harbak, Siri Bækken, Nina Kristin Stensrud, Gun Peggy Knudsen and Per Magnus. The biobank of the Norwegian Mother and Child Cohort Study – present status *Nor J Epidemiol* 2014; 24 (1-2): 29-35

The articles describe the contents of the MoBa database and the MoBa biobank. Access to biological material may be restricted by accessible volumes.

If a research project wants to explore objectives, where the Norwegian Institute of Public Health (NIPH) has national responsibility and experienced researchers, MoBa may propose that a researcher from NIPH is included in the research project.

The following contributors must, until 2025 be invited to participate in any study using GWAS data (MoBa Genetics) from MoBa: Per Minor Magnus, Pål Njølstad and Ole Andreassen.

All research projects must apply for ethical approval from *the Regional Committee for Medical and Health Research Ethics (REK)*. This must be obtained before MoBa can approve the project. If applicable, approval to send biological materials abroad must be stated in the REK decision letter.

No exclusive rights to the scientific aims covered is given. MoBa encourage scientific collaboration with other MoBa research projects to avoid conflicts of interest.

## 2. APPLICANT REQUIREMENTS

The principal investigator (PI) must have a PhD, or research experience equivalent to a PhD. The PI must be affiliated with a Norwegian research institution. To qualify as a research institution, the institution must have the necessary infrastructure to conduct research of high

quality and to store MoBa data and biological material securely and in accordance with Norwegian law and regulatory requirements.

The PI is responsible for obtaining national approvals, in compliance with Norwegian law and regulatory requirements.

### **3. APPLICATION PROCESS**

Applications for access to data and biological material must be submitted through [www.helsedata.no](http://www.helsedata.no), and will be processed once all mandatory documents (listed in section 4 below) are submitted. For applications where linkage to other registries or data sources are required, MoBa approval may be given, but access to data may be conditional on approvals from other data owners.

### **4. APPLICATION CONTENT**

In addition to the completed application form, the following are required:

- a. Research protocol: The protocol must include specific research questions and scientific aims. If additional collections of data and biological material is planned, or if the project requires to contact MoBa participants, the MoBa administration should be contacted prior to finalisation of the research protocol. See paragraph 6 for more information.
- b. Information about planned publications.
- c. A completed variable list and, if relevant, the request form for biological material.
- d. A copy of REK application and decision letters, as well as any temporary decisions and change notices.
- e. Approved Data Protection Impact Assessment (DPIA) or justification for why DPIA is not required, as well as information on the legal basis for handling personal data according to articles 6 and 9 of the General Data Protection Regulation (GDPR).
- f. Copies of approvals from other data owners for linkage to other data sources, as well as a linkage flow chart, if applicable.
- g. For projects using MoBa Genetics, a confirmation that the contributors have been invited to participate in the research project.

Curriculum vitae for the PI focusing on the research conducted during the last 5 years must be provided upon request.

### **5. EVALUATION OF APPLICATION**

MoBa will evaluate the application based on the following:

- a. The project aims must be within the objectives of MoBa, which are to find causes of diseases, to detect early signs of disease and to describe the development of diseases. The project must also comply with the consents given by the participants.
- b. Scientific quality, originality, and feasibility.
- c. Scientific merits of the PI and the research group.

- d. The potential benefit to preventive or curative medicine.
- e. Whether the research is approved by REK
- f. Whether the application is in accordance with GDPR and Norwegian legislation.
- g. Emphasis is placed on how the PIs previous projects have proceeded, including whether conditions have been violated.

NIPHs decision can be appealed in accordance with the Public Administration Act §28. An appeal against the decision shall be sent to [mobaadm@fhi.no](mailto:mobaadm@fhi.no).

## **6. PROJECTS INTENDING TO COLLECT NEW DATA AND/OR BIOLOGICAL MATERIAL FROM MOBA PARTICIPANTS**

Researchers who want to contact participants to collect additional data and/or biological material should contact the MoBa administration at an early planning stage. MoBa may be able to provide advice and guidance before the application is sent to MoBa for evaluation. Involvement by MoBa at an early stage does not guarantee that the project will be approved. When the application is submitted it will go through regular processing.

The threshold for approval of such research projects is high. Additional collection of data and/or biological material will not be permitted if the burden on the participants could risk their future participation in MoBa. The applicant must cover all costs and expenses for new collections. Research projects with independent collections of data and biological material will need separate information material and consent forms, which must be approved by MoBa prior to submission of applications to REK and other regulatory bodies. All results from biological material and additional data collected in MoBa research projects must be returned to MoBa and may be made available for other research projects.

Read more about the application process and special conditions for new collection of data and / or biological material in MoBa the NIPH website (<https://www.fhi.no/en/studies/moba/for-forskere-artikler/new-collection-in-moba/>).

## **7. LETTER OF SUPPORT**

Upon request, MoBa may issue a letter of support to researchers. This can be used to support applications for funding or regulatory approval. Letters of support are not legally binding for MoBa / NIPH.

## **8. AGREEMENTS OR DECISION LETTERS**

When MoBa has approved the application for the research project, an Agreement will be made, or a decision letter will be issued.

The Agreement or decision letter will define the terms and conditions for access to and use of MoBa data and/ or biological material in the research project.

Substantial changes of the research protocol must be submitted to and approved by MoBa.

Once an Agreement is signed or a decision letter is issued, information about the project including the project title, name of PI, project institution, a popular science summary and keywords will be posted on the NIPH website (<https://www.fhi.no/en>).

## **9. MoBa STUDY COSTS**

The list of prices for the access and use of MoBa data and biological material is available on the NIPH website (<https://www.fhi.no/en/publ/forms/price-list-for-moba/>). The costs will be as stated in the signed Agreement.

## **10. MoBa PUBLICATION POLICY**

Prior to publication, researchers must send a draft of the manuscript to MoBa. This is not a scientific review, but the manuscript will be revised to protect confidentiality as needed; to ensure that the data and biological material are described correctly, that mandatory references are included, and that the analyses are in accordance with the stated scientific aims approved by MoBa. MoBa does not take responsibility for the scientific content of the manuscript.

MoBa must be referred to in the methods section, and the description of MoBa must be in accordance with the suggested standard text and references from the checklist, which can be found at the NIPH website (<https://www.fhi.no/en/studies/moba/for-forskere-artikler/checklist-for-papers/>). The manuscript and completed checklist must be sent to [mobaadm@fhi.no](mailto:mobaadm@fhi.no). MoBa aims at evaluating all papers within two weeks after receipt is confirmed.

If a journal requires publication of summarized data, this must be stated when sending the draft of the manuscript to MoBa.

The manuscript must be accompanied by a syntax file showing how the study population was selected and how the main variables were defined. The syntax will only be used to reproduce the results or to comment on them in a letter to the editor of the journal in which the manuscript is published. Stored syntax files will be treated confidentially and will not be distributed to others without written permission from the PI of the research project.

After publication, NIPH have the right to reproduce, translate and publish abstracts of the publications.

Results from research projects must not be made publicly available until they have been published in scientific journals or as printed abstracts at scientific conferences. Scientific credit must be provided in all media coverage of results, and posters and oral power point presentations must include the logo of MoBa, available on the website. Posters and abstracts do not require approval from MoBa. A copy of the presentation or poster may be submitted to MoBa at [mobaadm@fhi.no](mailto:mobaadm@fhi.no) for information purposes.

## 11. PRICIPAL INVESTIGATORS RESPONSABILITY

The PI is responsible for data (personal information) and / or biological material lent from MoBa to the project. Furthermore, the PI is responsible for following up obligations set in the Agreement with FHI / MoBa, or in the decision letter issued from MoBa, as well as ensuring that all project members also follow these. The PI is the person specified as the project leader in the decision letter from REK. This applies regardless of at which institution or in what country the research is carried out.

If MoBa suspects that the project has violated terms and conditions stated in the Agreement or decision letter, the PI will be contacted for clarification. If the matter cannot be resolved and is considered to breach the conditions, one or more of the following actions may be taken:

- A written notification will be sent to the research project institutions data protection officer (DPO) as well as the PI's leader to inform that the agreement has been breached.
- If the violation is related to a manuscript, a written notification will be sent to the journal editors where the manuscript has been submitted, informing them of the breach.
- The approval of the project will be withdrawn.

Regardless of severity, the violation will be registered as a deviation in NIPHs improvement system.

## 12. OWNERSHIP AND USE OF RESULTS

### *12.1 Information and data*

MoBa shall receive copies of all recorded information or data derived from analysis of biological material from MoBa, accompanied by a written description of the process and techniques used to extract such information.

The researchers analysing MoBa material have the right to use this information for the purpose and duration of the research project, in accordance with the applicable regulatory approvals. The information must subsequently be deleted or destructed.

Data received from MoBa or new data collected may not under any circumstances be uploaded to public repositories or databases.

Data (including analytical results) derived from MoBa biological material must be transferred to MoBa as soon as the analyses and QC are completed. Data collected in projects and generated variables must be transferred to MoBa in accordance with the agreement entered into with MoBa. The PI is responsible for ensuring that the data are transferred. Information on how to transfer results to MoBa is available at the NIPH website (<https://www.fhi.no/en/studies/moba/for-forskere-artikler/tilbakeforing-av-resultater-og-data-til-MoBa/>).

MoBa has the right to retain, use, duplicate or disclose the information, in whole or in part, for any other research than the research project, including the right to make the information and data available to other researchers.

### *12.2 Inventions*

Inventions in the form of substances, procedures or products, which are conceived and first used in the research project on biological material, whether patentable or not, shall be owned by the inventors' employer. Inventions made by employees from both external researchers and researchers at NIPH shall be jointly owned, with ownership reflecting each party's contribution to the invention.

The institutions collaborating in research shall disclose to each other, on a confidential basis, all inventions made by their employees in the research project, in order to determine ownership and the legal protection of the invention as applicable.

Regardless of ownership, NIPH is entitled to a non-exclusive, royalty-free licence to use any inventions based on the use of the biological material. This licence does not include the right to sub-license the invention to third parties.

In the event that an institution does not maintain or actively develop the substance, process or product described in a patent or patent application, which is based on the use of the biological material, NIPH are entitled to have such patent or patent application assigned at no cost.

### *12.3 Copyright*

Researchers have the right to publish results from the use of data and biological material in their research projects in scientific journals, in accordance with the Vancouver Guidelines on authorship and contribution, and the authors will have the copyright to such publications.

## **13. META-ANALYSES**

Aggregated data may be shared for the use in a meta-analysis if the research purpose for the meta-analysis falls within the scientific scope of MoBa and is consistent with the participants' given consent and obtained approvals for the research project. The PI in the project participating in the meta-analysis is responsible for ensuring that the meta-analysis is consistent with the scope and objectives of the project and is responsible for ensuring that the use of MoBa data is covered by the existing regulatory approvals.

MoBa must be informed of the meta-analysis. Information regarding the use of MoBa data in meta-analyses may be found on the NIPH website (<https://www.fhi.no/en/studies/moba/for-forskere-artikler/use-data-metaanalyses/>).

## **14. GOVERNING LAW**

MoBa data and biological material are collected from Norwegian participants in Norway in accordance with Norwegian legislation. Any access to and use of MoBa data and/ or biological material will be governed by Norwegian law.