

## NORWEGIAN MOTHER AND CHILD COHORT STUDY (MoBa)

GUIDELINES FOR RESEARCH

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**1. PURPOSE**

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

**2. APPLICANT REQUIREMENTS**

The principal investigator (PI) must have a PhD, or research experience equivalent to a PhD. The PI must also be affiliated with the research project Institution. To qualify as a research project institution, a research institution must document that it has the necessary infrastructure to conduct research of high quality and to ensure that MoBa data and biological material are stored securely and in accordance with Norwegian law and regulatory requirements.

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

Institutions applying from outside of Norway must have one or more Norwegian collaborators acting as a site-PI responsible for obtaining national approvals, in compliance with Norwegian law and regulations.

**3. APPLICATION PROCESS**

The contents of the MoBa database and the MoBa biobank are described in the MoBa study protocol. Access to biological material may be restricted by accessible volumes. Submit applications via the NIPH electronic application for access to data and biological material. The application form is available on the NIPH website.

**The Norwegian Mother and Child  
Cohort study - Guidelines**

Applicants are encouraged to read the standard terms and conditions for access to and use of MoBa and the template for project specific access and use, is available at the NIPH website.

Applications will be processed as quickly as possible 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.

All relevant documents including the MoBa study protocol, standard terms and conditions and information about the application process may be found at the NIPH website (<https://www.fhi.no/en/op/data-access-from-health-registries-health-studies-and-biobanks/data-from-moba/research-and-data-access/>).

**4. APPLICATION CONTENT**

Documents must be submitted in English. In addition to the completed application form, the following are required:

- a. Research protocol: The protocol must include a clear specification of research questions and scientific aims. Requests for linkages to other registries must be specified.

If additional collections of data and biological material is planned, or if the project requires contact with MoBa participants, the MoBa administration should be contacted prior to finalisation of the research protocol.

- b. Curriculum vitae for the PI focusing on the research conducted during the last 5 years.
- c. All research projects must apply for ethical approval from *the Regional Committee for Medical Research Ethics (REK)*. This approval must be in place before MoBa can approve the project, including approval to send biological materials abroad if applicable.
- d. Copies of other regulatory approvals for linking to other data sources.
- e. Funding for access to data and /or biological material must be in place.

**The Norwegian Mother and Child  
Cohort study - Guidelines**

- f. Other supplementary information needed to evaluate the proposal including confirmations of compliance with the EU General Data Protection Regulation (GDPR).

**5. EVALUATION OF APPLICATION**

MoBa will evaluate the application based on the following:

- a. If the research projects aims are within MoBa's objectives, which are to find causes of diseases, to detect early signs of disease and to describe the development of diseases. The project must also be compatible 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. Possible conflict of interest with ongoing research projects will be considered.

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. RESEARCH PROJECTS WITH ADDITIONAL COLLECTIONS OF DATA AND/OR BIOLOGICAL MATERIAL**

Research projects that require additional collections of data and biological material must be within MoBa's objectives. The threshold for approval of such research projects is high. Researchers who want to establish a sub-cohort in MoBa should contact the MoBa administration at an early planning stage. A close collaboration between researchers and the MoBa administration is important from the start to ensure that any technical issues are taken into consideration. Additional data collection will not be permitted if the burden on the participants could risk their future participation. The applicant must cover all costs and expenses for additional collections. Research projects with independent collections of data and biological material will need separate information material and consent forms, which

**The Norwegian Mother and Child  
Cohort study - Guidelines**

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 may be made available for other researchers.

**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 the NIPH.

**8. AGREEMENTS**

When MoBa has approved the application for the research project, an Agreement will be issued.

The Agreement will define the terms and conditions for access to and used 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 the Agreement is signed, the project title, name of PI, project institution, a popular science summary and keywords obtained from the application form will be posted on the NIPH website,

(<https://www.fhi.no/en/sys/news/?blockId=75238&ownerPage=45258&language=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/globalassets/dokumenterfiler/studier/moba/dokumenter/price-list-moba.pdf>). The costs will be those 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. NIPH 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/studier/moba/forskere/check-list-for-papers/>). The manuscript and completed checklist must be sent to [mobaadm@fhi.no](mailto:mobaadm@fhi.no). MoBa aims to evaluate 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.

If MoBa suspects that the project has violated the approved scientific aims as stated in the Agreement, the PI or manuscript author will be contacted for clarification. If the matter

cannot be resolved and is considered to breach the Agreement, one or more of the following actions may be taken:

- A written notification will be sent to the research project institution to inform that the agreement has been breached.
- A written notification will be sent to the journal editors where the manuscript has been submitted, informing them of the breach.
- The Agreement will be terminated and further rights of analysis will be withdrawn from the research project.

## **11. OWNERSHIP AND USE OF RESULTS**

### *11.1 Information and data*

MoBa shall receive copies of all recorded information or data extracted from the 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.

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 after the expiry of an embargo period defined for each set of data.

### *11.2 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

**The Norwegian Mother and Child  
Cohort study - Guidelines**

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.

### *11.3 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.

## **12. CONSORTIUM**

Data can only be shared in a consortium if this is described in the study protocol and approved by MoBa, and all parties, after written agreement, are obliged to comply with the MoBa terms and conditions as stated in the Agreement.

## **13. 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.

**The Norwegian Mother and Child  
Cohort study - Guidelines**

Version	Date	Changes	Document owner
1.0	October 26, 2015		FHI/MoBa/
2.0	March, 2019	Technical changes and update in accordance to GDPR.	FHI/MoBa