

NORWEGIAN MOTHER AND CHILD COHORT STUDY (MoBa)

GUIDELINES FOR RESEARCH

1. PURPOSE

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

2. APPLICANT REQUIREMENTS

The principal investigator (PI) must have a PhD, or research experience comparable to a PhD. The PI must also be affiliated with the sub-study Institution. To qualify as a sub-study 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 sub-studies 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 sub-study.

Institutions applying from outside of Norway must have one or more Norwegian collaborators.

3. APPLICATION PROCESS

The contents of the MoBa database and the MoBa biobank are described in the MoBa study protocol (Attachment 1 <http://www.fhi.no/dokumenter/c2b3af8eb1.pdf>). Access to biological material may be restricted by accessible volumes. Submit applications via the NIPH electronic application for access to data, which is available on the NIPH website, www.fhi.no.

Applicants are encouraged to read the standard terms and conditions for MoBa material and the template for project specific access and use, available at the NIPH website www.fhi.no.

Applications are evaluated by MoBa. Applications will be processed as quickly as possible once all mandatory attachments are submitted. For applications to MoBa data linked to other registries, MoBa approval may be given, but no data will be released before all approvals from other data owners are obtained.

4. APPLICATION CONTENT

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

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- a. Sub-study protocol: The sub-study protocol must include a clear specification of research questions and scientific aims. If additional collections of data and biological material are planned, or if the sub-study requires additional contact with MoBa participants, these plans must be described in detail. Requests for linkages to other health registries must also be specified.
- b. Curriculum vitae for the PI
- 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.
- d. Copies of other regulatory approvals for linking to other data sources.
 - a. Funding for access to data and /or biological material must be in place.
 - b. Other supplementary information needed to evaluate the proposal.

Regulatory approval:

All sub-studies applying for access to MoBa questionnaire data files must obtain an approval from *the Regional Committee for Medical Research Ethics (REK)*.

All sub-studies applying for biological material must be approved by REK. If biological material is to be sent out of Norway for analysis this must be stated in the REK application.

Linkage to other registers requires approval from *REK*. Sometimes approval from the Norwegian Data directory Inspectorate is also required.

5. EVALUATION OF APPLICATION

MoBa will evaluate the application based on the following:

- a. Scientific quality, originality and feasibility.
- b. Scientific merits of the PI and the research group.
- c. The potential benefit to preventive or curative medicine.
- d. Possible conflict with ongoing sub-studies will be considered.
- e. Exclusivity
 1. Exclusivity for doctorates / PhD;
 - Maximum three specific article titles

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- Must be a funded PhD or Doctoral degree program
- Limited to 3 years. Possibility of extension to publish papers connected to the PhD.

2. Exclusivity for sub-cohorts with separate data collection can be negotiated. These must be time-limited and related to specific aims.

Appeals against a rejected application must be submitted to the Director-General of the NIPH.

6. SUB-STUDIES WITH ADDITIONAL COLLECTIONS OF DATA AND/OR BIOLOGICAL MATERIAL

Sub-studies that require additional collections of data and biological material must fall within MoBa's objectives to find the causes of diseases, to detect early signs and to describe their development. There is a high threshold for approval of such sub-studies. 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 jeopardize their future participation. All costs and expenses for additional collections must be covered by the applicant. Sub-studies with independent collections of data and biological material will need separate information brochures 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 that are collected in MoBa sub-studies will be made available for other researchers at the end of the Data/Material Transfer Agreement) period.

7. LETTER OF SUPPORT

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

8. MATERIAL TRANSFER AGREEMENT

When MoBa has approved the application for the sub-study, a Material Transfer Agreement (MTA) will be issued.

MoBa will provide the PI of the sub-study with the requested material according to the terms of the MTA. By receiving the material the PI is committed to comply with the terms and condition of the MTA.

Changes or deviations of the sub-study protocol must be submitted to and approved by MoBa.

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Once the MTA is signed, the sub-study title, name of PI, sub-study institution, a popular science summary and keywords obtained from the application form will be posted on the NIPH's website, www.fhi.no.

9. MoBa STUDY PRICES

The current prices for use of MoBa data and biological material are available on the NIPH website, www.fhi.no/moba-en. The costs applied will be those current on the effective date of the MTA.

10. MoBa PUBLICATION POLICY

All manuscripts must be presented to MoBa before submission for administrative review. This is not a scientific review, but it ensures that MoBa is described correctly, that mandatory references are included, and that the analyses are in accordance with the stated scientific aims of the approval. MoBa must be identified in the methods section, and the description of MoBa must be in accordance with the suggested standard text and references from the checklist.

Send the manuscript and completed checklist to dataaccess@fhi.no. MoBa aim to evaluate all papers within two weeks after receipt is confirmed.

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 sub-study.

Results from sub-studies must not be made publicly available until they have been published in scientific journals or as printed abstracts at scientific conferences. In all media coverage of results, MoBa must be mentioned.

Scientific credit should be provided to the MoBa Cohort and NIPH. Posters and oral power point presentations must include the logo of MoBa and NIPH. The logos for MoBa and NIPH are available on the web site. Posters and abstracts do not require approval from MoBa, but a copy of the presentation and poster must be submitted to MoBa for information purposes, at the e-mail address dataaccess@fhi.no.

If there is suspicion of violation of accordance between the manuscript and approved research questions the PI or manuscript author will be contacted for clarification. The manuscript must be revised according to the stated scientific aims. If agreement cannot be achieved, and the matter is considered to breach the Material Transfer Agreement, one or more of the following actions will be taken:

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- A written notification will be sent to the sub-study 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 Material Transfer Agreement will be terminated and further rights of analysis will be withdrawn from the sub-study.

11. OWNERSHIP AND USE OF RESULTS

11.1 Information and data

MoBa has the right to 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 destroyed.

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 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.

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11.3 Copyright

Researchers have the right to publish results from the use of 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.

Prior to publication, researchers must send a draft manuscript to MoBa to ensure that the biological material is described correctly, that mandatory references are included, and that the analyses are in accordance with the stated scientific aims approved by MoBa.

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

12. CONSORTIUM

Material can only be shared in a consortium if this is described in the study protocol and approved by MoBa.

Material can only be shared in a consortium if all parties, after written agreement, are obliged to comply with the MoBa terms and conditions.

13. GOVERNING LAW

MoBa material is collected in Norway in accordance with Norwegian legislation, and any transfer and/or use of the material will be governed by Norwegian law. This includes interpretation and enforcement of the MTA.