

**NORWEGIAN MOTHER AND CHILD
COHORT STUDY - STATUTES**

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STATUTES

ART 1 – The Norwegian Mother and Child Cohort Study

The Norwegian Mother and Child Cohort Study (MoBa) is a prospective population-based pregnancy cohort study conducted by the Norwegian Institute of Public Health. Participants were recruited from all over Norway from 1999-2008.

All data and material in MoBa are collected with informed consent from participants in the study.

Participants are entitled to withdraw their consent at any time.

ART 2 – Objective

The objective of MoBa is to test specific hypotheses about the causes of a number of diseases in order to improve health for families. The main aim is to prevent disease.

ART 3 – Organization and management

MoBa is organized as a health registry. Until July 20, 2018, MoBa had authorization from the Norwegian Data Protection Authority. After the implementation of the EU General Data Protection Regulation (GDPR) in Norwegian law, MoBa is regulated under “Forskrift for befolkningsbaserte helseundersøkelser”

MoBa is a part of, and is managed by, the Norwegian Institute of Public Health. It is not a separate legal entity.

The NIPH Steering Group approves the MoBa budget and semiannual accounts and appoints the MoBa Scientific Advisory Board (SAB) and Principal Investigator (PI).

The MoBa SAB is responsible for the strategy for research, dissemination and further development of MoBa.

The MoBa administration group is responsible for the day-to-day business, and approves applications and publications.

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The NIPH Steering Group and MoBa administration group manage and control MoBa data and material on behalf of the consenting participants within the limitations in the consent, regulations in the "Forskrift for befolkningsbaserte helseundersøkelser", the ethical approvals of the specific research projects and Norwegian law.

ART 5 – Access to data

All transfer of data and material must be in accordance with applicable laws and regulations.

Access to MoBa data and material requires a written agreement between NIPH and the recipient institution.

ART 6 – Usage

MoBa data and material are to be used for non-profit research purposes only.

Research on MoBa data and biological material shall be conducted according to scientific standards.

The MoBa SAB shall strive for efficient use of MoBa data and biological material.

MoBa data and material are to be non-identifiable in research projects, and any attempt to identify MoBa participants in a research project is strictly prohibited.

ART 7 – Data handling and security

MoBa data and material are highly sensitive information and, as such, need to be handled with the greatest care. Security is a prime concern. MoBa research projects must be compliant with the requirements of relevant legislation, such as the Data Protection Act.

Key aspects of the control required include identity and identifier management, ensuring the accuracy of the data collected, inclusion of comprehensive audit data and strict controls on data access.

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Version	Date	Changes	Document owner
1.0	October 26, 2015		FHI/MoBa/
1.1	March 19, 2019	Updates in accordance to new legislation/GDPR	FHI/MoBa