

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

ART 1 – The Norwegian Mother, Father and Child Cohort Study

The Norwegian Mother, Father 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 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 om befolkningsbaserte helseundersøkelser](#).

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

The role as Data controller, according to GDPR art 4 number 7, is delegated to the Director of Division of Health Data and Digitalisation, and further delegated to the leader of the MoBa-cluster.

Decisions about MoBa are made in The MoBa Operations Board. In complicated matters the Division Director may escalate the cases to the NIPH Steering Group.

The MoBa Scientific Advisory Board's role is to give strategic and scientific advice to The MoBa Operations Board, to promote use of MoBa in research and manage a scientific strategy for developing MoBa.

ART 4 – Permits and approvals

The legal basis for MoBa is GDPR article 6.1.e and article 9.2.g with a supplementary legal basis in [forskrift om befolkningsbaserte helseundersøkelser](#). The Division of Health Data and Digitalisation manage and control MoBa data and material on behalf of the consenting participants within the limitations in the consentthe ethical approvals of the specific research projects, GDPR and Norwegian law.

ART 5 – Access to data

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

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

ART 6 – Usage

MoBa data and material may only be used for non-profit research purposes. Research on MoBa data and biological material shall be conducted according to scientific standards.

MoBa data and material must 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 General 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.