

NORWEGIAN MOTHER AND CHILD COHORT STUDY

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 is 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 with authorization from the Norwegian Data Protection Authority.

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 Management Group (SMG) and Principal Investigator (PI).

The MoBa SMG 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.

ART 4 – Permits and approvals

The NIPH Steering Group and MoBa SMG manage and control MoBa data and material on behalf of the consenting participants within the limitations in the consent, authorization from the Norwegian Data Protection Authority, 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 SMG shall strive for efficient use of MoBa data and biological material.

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

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. It is essential that MoBa and MoBa sub-studies are 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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