

Terms of Use for Research Collaboration using Data from the 'KISO'¹ Survey Cohort'

Access to data through UCPH (for a collaboration partner in a concrete sub-research project)

History

To shed light on menopause, Associate Professor at the University of Copenhagen, Maria Hybholt, initiated the KISO Survey, a longitudinal questionnaire survey of women aged 45-59 with a Danish civil registration number in 2024. In collaboration with Associate Professor Terese Høj Jørgensen and PhD student Sigrid Normann Biener, the questionnaire was developed and tested; data was collected electronically via eBoks, and the cohort data was cleaned and analyzed. The 'KISO Survey Cohort' is based on University of Copenhagen. This document describes the terms of use for research collaborations using data from the 'KISO Survey Cohort' and Dataset.

Description of the Project – 'KISO Survey Cohort'

The project is registered in the University of Copenhagen's register under journal number 514-0965/24-3000. The data controller is Copenhagen University.

The 'KISO Survey Cohort' refers to a research project with electronic questionnaire responses from women aged 45-59 with a Danish civil registration number. From July to November 2024 the questionnaire was sent to 575,863 women. The response rate is 27% for complete responses. A follow-up survey is anticipated every three years, with the initial follow-up scheduled for 2027. The 'KISO Survey Cohort 2024' is a research project with questionnaire responses from 153.800 women born between 1964 and 1979, identified with a civil registration number. The project currently includes:

1. Responses from the questionnaire survey among participants in 2024
2. Documentation and codebook for the KISO survey and its variables
3. A dataset with a key to link the data to CPR.

The information about variables and responses is only available in electronic form.

The purpose of the research project, 'KISO Survey Cohort', is to uncover the challenges and opportunities that women in Denmark experience before, during, and after menopause. The knowledge gained from the study will be used to map the symptoms women experience in the different stages of menopause, and to identify the causes and consequences associated with these symptoms over time. The results of the study will contribute to creating new knowledge in this field and form the basis for recommendations on how the healthcare system,

¹ KISO is an acronym for the Danish research project Women in Healthy Transition (Kvinder i Sund Overgang).

workplaces, and women themselves can prevent and manage symptoms related to this phase of life.

Legal basis

The legal basis for the processing of the collected data is the General Data Protection Regulation, Article 6(1)(e) and Article 9(2)(J) and Section 10 of the Data Protection Act, which allows the processing of personal data, but only for statistical and scientific purposes.

KISO Survey Dataset

Based on the information that the data subjects received prior to data collection - *Data may be disclosed and linked with other data sources for statistical and scientific purposes in other studies, e.g. at other research institutions.* - the research group have established a dataset for use in related research projects, consistent with the overall purpose of the KiSO Survey Cohort.

The dataset is registered in the University of Copenhagen's register under journal number 514-1179/25-3000. The data controller is Copenhagen University.

KiSO Survey Steering Committee

The 'KISO Survey Cohort' and the dataset is managed by a Steering committee of 4-6 members. Maria Hybholt is chairman and Terese Høj Jørgensen is vice-chairman. Steering committee members are selected for a four-year term and may be reappointed. New members will be admitted through a process where the steering committee seeks consensus. Once consensus is reached, approval is required from the Head of Department at IFSV. If consensus cannot be achieved, the decision-making authority rests with Head of Department at IFSV. Members can resign from the steering committee if requested. Members are senior researchers with an interest in and insight into the KISO Survey. At least 50% of the members, including the chairman and vice-chairman, must be employed at UCPH. New members commit to complying with this agreement.

The chairman and vice-chairman, who were founder of the dataset, may, however, continue in the steering committee as long as they work on tasks that are relevant to the 'KISO Survey Cohort'. No remuneration is paid to the members of the steering committee. Rules of procedure must be drawn up for the activities of the steering committee, which, among other things, deal with the convening of meetings, minutes of negotiations, disqualification, expiry and rules for the content of the 'KISO Survey Cohort' website.

On a meeting in February 2025, the steering committee for the 'KISO Survey Cohort' was established, with the following members:

- Associate Professor Maria Hybholt, PhD, (Principal Investigator (PI) of KISO Survey Cohort), Section of Social Medicine, Department of Public Health, University of Copenhagen - Chairman
- Associate Professor Terese Høj Jørgensen, PhD, (Project Manager of KISO Survey Cohort), Section of Social Medicine, Department of Public Health, University of Copenhagen – Vice-chairman
- Associate Professor Lasse Gliemann, Promotion Programme, Deputy Head of Department, Department of Nutrition, Exercise and Sports, University of Copenhagen
- Amani Meaidi, Medical Doctor, Visiting Researcher, Herlev Hospital, Danish Cancer Society and North Zealand Hospital

Composition and Tasks of the Steering Committee

The steering committee aims to ensure that data from 'KISO Survey Cohort' is developed and utilized for research to improve and develop the scientific knowledge about factors affecting public health - within the purposes;

- to uncover the challenges and opportunities that women in Denmark experience before, during and after menopause
- to map the symptoms that women experience in the different phases of menopause
- to map the causes and consequences that these are associated with over time
- to form the basis for recommendations on how the healthcare system, workplaces and women themselves can prevent and manage symptoms related to this phase of life.

The steering committee is responsible to IFSV for the overall management of the 'KISO Survey Cohort' and Dataset. The steering committee is responsible for ensuring that the research use of the 'KISO Survey Cohort' consistently adheres to the following requirements:

- approving which collaborations can get access to and use data from the 'KISO Survey Cohort' and Dataset - including ensuring that Guest Researcher Agreement and Data Processing Agreement is drawn up in accordance with these Terms of Use.
- permissions and agreements with the Data Protection Agency including register the data access in the records of research projects involving personal data – Project Like Mine (PLM).
- Optimal scientific quality and originality according to common standards
- Available and sufficient resources in terms of research competence, facilities, and funding.

- Research plans are, if necessary, approved by ethical committees and relevant data protection authorities and comply with the conditions set by these authorities
- The sub-project involves the least possible burden on the 'KISO Survey Cohort' participants.
- Does not harm the reputation of 'KISO Survey Cohort', with particular regard to ethical and moral considerations
- Commits to being available for advice and guidance for sub-project participants
- Holds regular meetings, at least every 6 months.

The steering committee is committed to working towards the goal: *The purpose of the research project, Women in Healthy Transition (KISO), is to uncover the challenges and opportunities women in Denmark experience before, during, and after menopause.* The steering committee strives for consensus in its decisions. Finally, the Chairman and the Head of Department at IFSV must approve the steering committee's decisions.

Research Use of the 'KISO Survey Cohort' and Dataset

Collaboration partners seeking access to data from the 'KISO Survey Cohort' are encouraged to initiate a dialogue with the Principal Investigator, Maria Hybholt (maria.hybholt@sund.ku.dk) or Project Manager, Terese Høj Jørgensen (tshj@sund.ku.dk). Subsequently, a written application must be submitted to the Steering Committee via the electronic application form on the website (<http://kiso.ku.dk/survey-application>). The application should include a project description, objectives, timeline, and budget, as well as a CV. Approved research collaborations are required to enter into a Data Processing Agreement with UCPH and for external researchers a Guest Researcher Agreement as well. Sub-projects must have a sub-project leader who is responsible to the steering committee for the practical implementation of the sub-project. Such sub-projects will generally consist of a collaboration between several researchers, whose mutual rights to data and authorship must be specified in 1) a project description and 2) a written Guest Researcher Agreement and Data Processing Agreement between the sub-project leader and the Head of Department at IFSV.

New sub-projects are pre-reviewed by the Chairman and the Vice-chairman and presented to the steering committee for evaluation.

A formal collaboration agreement must be signed by the Head of Department at IFSV, defining the sub-project's scientific content and planned publications. The collaboration agreement also specifies a number of conditions that the sub-project leader is obliged to comply with:

1. The sub-project leader must in a collaboration with the Chairman and the Vice-chairman agree about publications, media coverage, and other relevant external activities related to the 'KISO Survey Cohort'.
2. The sub-project leader must in a collaboration with UCPH ensure that all publications from the sub-project include the necessary scientific acknowledgments (see below) and must also obtain approval of the manuscripts' descriptions of the 'KISO Survey Cohort' before they submit for publication.
3. Dialogue on relevant collaboration with selected members from the steering committee in the sub-project is initiated with the Chairman and Vice-chairman.
4. The sub-project leader has full responsibility for ensuring that the sub-project complies with its own institutional guidelines, the data protection agency's conditions and applicable GDPR. In principle, researchers with approved collaboration agreements can access selected data variables through the 'KISO Survey Cohort' dataset.
5. The sub-project leader pays for the time spent on data administration and any access to data.
6. The sub-project leader must ensure that data is only used for the purpose described in the project description, that data is not copied or transferred to others without prior written agreement with the KISO Survey Steering Committee and the Head of Department at IFSV, and that data is deleted 5 years after the planned sub-projects are published, or secondarily after the collaboration with the steering committee is terminated unless another agreement is made.
7. The sub-project leader must ensure that other involved researchers are made aware of the content of the agreement and the rules for collaboration between the sub-project and the 'KISO Survey Cohort'.

If a sub-project does not proceed satisfactorily scientifically, within the agreed timeframe, or if there is a breach of the applicable conditions for collaboration, the steering committee may choose to terminate the collaboration. If the collaboration is terminated, access to data will be deleted.

Publication, Authorship, and Acknowledgment

All publications are made according to the principles of good scientific practice. In epidemiological research, the specific principles of good epidemiological practice, as written by the International Epidemiological Association, January 2007, and in full accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Journals, from February 2006 (Vancouver rules) (www.icmje.org), are used.

All planned publications using data from the 'KISO Survey Cohort' must be jointly agreed upon by the collaboration partners.

It is recommended to forward initial manuscripts drafts to the PI and project manager to ensure compliance with the terms of the agreement regarding the use of data from the 'KISO Survey Cohort' before they are submitted to a scientific journal. The project manager will provide feedback on any significant deficiencies related to the description of the 'KISO Survey Cohort' within an agreed timeframe, usually two weeks. A copy of published articles (including abstracts) based on results from a sub-project must be sent to the project manager.

Acknowledgement of KISO Survey in Publications:

- For publications that exclusively or primarily use data from the 'KISO Survey Cohort', "KISO Survey Cohort" is indicated in the title, if the journal allows it.
- For publications that use data from the 'KISO Survey Cohort' together with other data sources, "KISO Survey Cohort" is indicated in the title if meaningful. If not indicated in the title, "KISO Survey Cohort" must be mentioned in the abstract.
- "KISO" must be indicated as a keyword where possible.
- The following text is included in the "Acknowledgements" or equivalent place where it makes sense in the respective journal, if the researchers are not part of the author list:
 - English: Authors thank M Hybholt, SN Biener, and TSH Jørgensen at the University of Copenhagen, Denmark, who established and are responsible for the data collection.
 - Danish: Artiklens forfattere takker M Hybholt, SN Biener, og TSH Jørgensen fra Københavns Universitet, som initierede projektet og er ansvarlige for dataindsamlingen.

Changes to Terms of Use

Proposals for changes to these Terms of Use may be adopted at a steering committee meeting when the issue has been submitted to the steering committee and included on the agenda no later than 7 days before the meeting and at least 3/4 of the members present vote in favor. Members who are absent may vote for changes to the terms of use prior to the meeting by email to the chairman.

Dispute

Any dispute that may arise in connection with the understanding and compliance with these Terms of Use will be decided by the Head of Department at IFSV.