# Guidelines for access to research data from the Hordaland Health Studies

*The Hordaland Homocysteine Study 1992-93 and HUSK 1997-99*

## 1. Background

The Hordaland Health Studies (HUSK) are led by researchers at the Department of Global Public Health and Primary Care, and the Department of Clinical Science, University of Bergen (UiB). Several scientists from other departments and institutions contributed to the planning, funding and baseline data collection. The purpose of these guidelines is to ensure that data collected will be utilized in the best possible way and that all interests are protected.

## 2. Requirements for applicants

Project leaders with research expertise and employed at institutions with research expertise can apply for access to research data from HUSK. The researcher must agree to the terms stated in these guidelines.

## 3. The application

The application shall contain a project description including the objectives/research questions that will form the basis of publications. Through the project description the project leader must demonstrate that the project is scientifically relevant and that research data from HUSK are suited to examine the posed questions.

## 4. Criteria for access to data and analysis rights

The following criteria apply:

### 4.1 Contributions to the Hordaland Health Studies

Professional, practical and financial contributions to the planning and / or implementation of the Hordaland Health Studies will be given significant weight.

### 4.2 Relevance

The project must be scientifically well-founded and appropriate to examine within the context of a population study.

### 4.3 Professional capacity

The applicant and his/her team must have the expertise and capacity to analyze and publish data, within a reasonable time.

### 4.4 Consideration of ongoing projects

The project must not be in conflict with other approved projects or publication plans.

## 5. Publication

It is a condition for access to research data that the results are made publicly available. This should preferably be done through publication of scientific articles, but publication in the

form of reports, monographs, or submission of abstracts to research conferences may also be relevant.

## 6. Time limit

The project leader has the right to use the allocated data in a predefined time period. Analysis rights should normally be limited to those that can be realized within the given time frame. This will normally be three years, but other periods can be agreed upon.

## 7. Co-authorship

The rules set by the International Committee of Medical Journal Editors (Uniform Requirements for Manuscripts Submitted two Biomedical Journals) must be adhered to. If a project uses key variables that come from another sub-project in HUSK, the project leader from the latter study should be offered co-authorship.

## 8. Review of manuscripts before publication submission

All manuscripts must be submitted to the HUSK' Publication Committee before being submitted for publication. The purpose is to ensure that all published results from HUSK are in accordance with assigned rights with respect to the use of variables and co-authorship, as well as to ensure that HUSK is described appropriately. This arrangement shall not delay the publication process unnecessarily.

## 9. Reference to the Hordaland Health Studies

It must be stated in all publications that the data come from the Hordaland Health Studies. This should be made visible in the method section and, if possible, should also be stated in the title of the publication. Consistent use of the term of the Hordaland Health Study should be used (The Hordaland Health Study (HUSK), or The Hordaland Homocysteine Study). It should be stated that the University of Bergen conducted the study, in cooperation with the Norwegian Institute of Public Health.

## 10. New data

Some projects generate new data. New data should in principle be transferred to the HUSK research database. Examples of new data are results of new blood sample analyses and collection of new endpoints.

## 11. Contact with participants

Researchers who have access to HUSK data are not permitted to contact study participants unless expressly granted permission from REK. No such application may be submitted to REK without written permission from the HUSK Steering Committee.

## 12. Breach of contract

In case of breach of contract the HUSK Steering Committee will contact the project manager for clarification of the actual facts. In case that an agreement is not reached, the case will be sent to the institution's manager responsible for the project.

## 13. Storage and use of HUSK data

HUSK data will be stored and analyzed on a secure server at the University of Bergen. This is a separate research server solution with two-factor authentication of users for projects which are mainly UiB internal and process sensitive personal data.

All publications must be in a form such that no individual participant can be recognized.

HUSK data shall only be used in accordance with the approved project description. If the project leader wishes to examine research questions beyond those included in the original project description, this must be approved by HUSK management.

By the end of the project, the data file must be deleted, and a confirmation must be sent to the HUSK Project Centre.

I have read and agree to these guidelines by checking the box on the application form.