

Guidelines for governance and use of HUNT data and biological material – valid from 01.08.2019

The purpose of The HUNT Study is to be a provider of material to be used in research on antecedents and consequences of health and disease from a public health perspective. The research material should be utilized to its best potential. HUNT research material is available for qualified researchers affiliated with a Norwegian research institute. Access can be granted to researchers located outside of Norway in collaboration with a Norwegian research institute.

HUNT was initiated in the 1980s in a collaboration between Norwegian Institute of Public Health, National Health Surveys and Nord-Trøndelag County Council, with help from the Ministry of Health. HUNT is a national project recruiting participants from the Northern part of Trøndelag County. HUNT is governed by the Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology (NTNU).

All research involving HUNT material must be carried out responsibly and follow ethical norms and applicable law and guidelines.

These guidelines will be revised when needed.

1. Purpose of guidelines

The purpose of these guidelines is to promote the best use of HUNT material, fair access to the material, protection of participants' interests, and to motivate interdisciplinary collaboration.

2. Privacy protection and ethics

All research based on HUNT material must safeguard participants' privacy and abide by established norms for research ethics. All applicable laws and guidelines must be followed at all phases in the research project.

All research projects must be approved of by an ethical committee, in most cases this will be a Regional Committee for Medical and Health Research Ethics (REC).

- If REK cannot process a request for an ethical assessment of a project, it shall be assessed by a Data Protection Officer.
- The use of HUNT material in a table format (not data file) does not require REC approval.
- When merging HUNT data with registers the Health Research Act does not apply to, approval from the registers must be obtained by the Principal Investigator in addition to HUNT approval.

3. Right to decide over and dispose of HUNT material and Data Controller Responsibility.

HUNT participants, meaning those who have donated data and biological material, have the right to decide over their own research material. They have the right to be informed on what kind of data is registered about them and how their material is used. They can demand their data and

biological material deleted or destroyed. NTNU, through the Faculty of Medicine and Health Sciences has the right of use, restricted by participants' consent and Norwegian law. The Faculty of Medicine and Health Sciences can enter into agreements granting the right to analyze HUNT material with researchers affiliated with public research institutes or with commercial interests. HUNT material itself cannot be subject to sale. NTNU through HUNT Research Centre is Data Controller and Data Processor for HUNTs data material.

4. Procedure for processing of applications for the use of HUNT material

An internal procedure for processing of applications for the rights to analyse HUNT material describes how applications are taken in and processed by the HUNT Data Access Committee (DAC), and is available in Norwegian.

5. Criteria for assessing applications for the use of HUNT material

All applications for the use of HUNT material are considered by HUNTs Data Access Committee, who will assess whether the intended use is consistent with the purpose of The HUNT Study.

The following aspects are a part of this assessment:

- Potential utility of the project: Is the project likely to lead to new knowledge about health and disease? Projects considering health issues that are relevant for many or that shed light on more serious health issues will be prioritized above those who do not.
- Quality of the project's protocol and research team.
- Feasibility: practical and financial.
- Applications for the use of biological material are subject to stricter assessment than for data use only, because the biological material is finite. DAC will strive for a minimal and optimal use of such resources. If a project applies for scarce material, projects studying health issues relevant for the participant will be prioritized over use of the material for other research questions. For example will research on cancer allow the use of scarce samples from participants who have experienced cancer, but not from controls with little sample material left, and other controls will be chosen for inclusion in the project
- Overall assessment of the project:
 - Will the project contribute to a good use of the HUNT material?
 - Is the project in line with participants' consent and expectations?
 - Is it expected that the project will contribute positively to HUNTs reputation?

6. Partners for agreements

HUNT enters into agreements with research institutions, not individual researchers. The Principal Investigator's research institute will have the final professional, administrative and economic responsibility for compliance with the agreement, and co-signs the agreement with HUNT.

7. Basis for agreement

An agreement for the right to analyze HUNT material will be based on research questions as described in the application to HUNT with protocol and publication plan.

- An application for the use of HUNT data must include a protocol describing background, methods and research questions for the project. A publication plan including working titles and a short description for planned publications shall be part of the protocol.
- An agreement on the use of HUNT data will be based on and limited to the research questions described in the protocol.
- Access to HUNT research material for a project is restricted to persons listed in the application for this project. Data files are not to be merged with files from other projects or from registers.
- In the case of a change in publication plans, an application for such change shall be sent to HUNT Research Centre and will be assessed by HUNT DAC.
- All applications for the use of HUNT material will be treated confidentially. However, HUNT is obliged to inform research participants on projects using HUNT material. Therefore, all applications must include an abstract in Norwegian, which will be published on HUNT's website and may be used for public information.
- If a project wishes to merge HUNT data with register data from hospitals or national registries, it is the Principal Investigator's responsibility to obtain the necessary approval(s) from such registries.
- HUNT Research Centre will provide a data file with unique participant IDs for each project. These will not match IDs from other projects, and merging with other files from other projects is regarded as a breach of agreement.

HUNT Research Centre encourages collaboration between research teams and is positive to contact between research groups. HUNT Research Centre cannot guarantee exclusivity for research questions studied, but will try to put research teams into contact who have common interests.

8. Duration of agreement

Agreements will usually last between 2 and 4 years, depending on the amount of publications planned. There is a possibility for extension of an agreement by sending an application to HUNT Research Centre before the agreement expires. A valid ethical approval is a requirement for an extension.

9. Delivery of research material

HUNT databank provides a data file according to the project's variable order and the project's research questions.

When applied for and upon approval from the register, HUNT databank also provides the necessary information to registers to merge register data. The Principal Investigator needs to inform HUNT about registers' approval.

The delivery of biological material will conform to the necessary quantity and quality for the analyses the material will be used for, such that the least possible amount is given out, and that all material will be used in analyses. Any potential rest material should be destroyed after analyses unless agreed otherwise with HUNT Research Centre.

10. Presentation of manuscript to HUNT Publication Committee

To safeguard the interests of HUNT and its participants, manuscripts shall be sent in to HUNT's Publication Committee before submission to a scientific journal. HUNT will check whether the material is used according to the agreement.

In the case of a breach of agreement and after legal consultation, HUNT Research Centre may undertake such steps as:

- Send a warning to the PI's institute
- Contact journal editor in the case of unauthorized publication
- Withdraw the rights of analysis

11. Collaboration and co-authorship

The Principle Investigator has responsibility on who to include as a co-author. Vancouver recommendations for co-authorship shall be followed.

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

The use of some variables may entail a duty to contact the researcher(s) responsible for collecting the data and offer a collaboration on the project. This may result in co-authorship according to Vancouver recommendations. It is the Principal Investigator's responsibility that this be done when informed so by HUNT Research Centre.

12. Management of The HUNT Study

The Faculty of Medicine and Health Sciences is the responsible Data Controller for The HUNT Study on behalf of NTNU. Executive management is delegated to the CEO at HUNT Research Centre.

- Processing of applications for the use of HUNT data shall be in accordance with the Act relating to procedure in cases concerning the public administration (Public Administration Act). Only complete and correct applications can be taken in for assessment by DAC.
- DAC is the advisory body for HUNT Research Center's CEO, and DAC shall ensure that research material from The HUNT Study is governed by these guidelines.
- DAC's leader is HUNT's CEO. Other members include a researcher employed at HUNT Research Centre, CEO or other person employed for HUNT Databank, CEO or other person employed for HUNT Biobank, HUNT advisors for governance of HUNT material and projects.
- In some instances, HUNT DAC will invite other researchers to review an application under the conditions of confidentiality and respect for intellectual property right of the applicant researcher.
- In the case of disqualification of DAC members, the CEO with the Department of Public Health and Nursing or the Dean for the Faculty of Medicine and Health Sciences will take the role of DAC leader for the project in case.

13. All HUNT material is governed by HUNT Research Centre

All HUNT material, stemming from waves of data gathering in HUNT Studies through questionnaires, clinical examinations, sample gathering and other means of gathering material, including all material stemming from additional projects, is governed by these guidelines.

14. Research material shall be returned, deleted or destroyed when projects end

Results from analyses of HUNT shall be returned to HUNT Databank. When the project ends, data files shall be deleted and leftover biological material shall be destroyed unless otherwise agreed.

- Returned results will be integrated in HUNT Databank and can be used by other researchers.
- When the project ends, all data files shall be deleted and a confirmation of deletion shall be sent to HUNT Research Centre.

15. Priority for researchers contributing with additional projects.

Data gathered through additional projects or new variables generated through the analysis of HUNT material are incorporated in HUNT Databank and managed by the Faculty of Medicine and Health Sciences, and these guidelines apply to such data. Researchers responsible for additional projects / generated variables may agree on a right of exclusive use of the gathered material for up to 5 years. The usual application procedure applies when data from additional projects are used in combination with other HUNT data.

16. Commercial interests

The use of HUNT may result in financial profit by the development of products or services originating in information from HUNT material.

- The right to analyze HUNT material is aimed at academic research and entails an obligation to make public the results of the research in academic journals. Publication of research results from HUNT may be postponed if immediate publication would harm the financial interests of the Principal Investigator's organization. The delay should be as short as possible but can for instance be used to file an application for a patent. HUNT Research Centre wishes to be informed of such results of commercial interest or that lead to a patent application.

17. Costs for the use of HUNT material

The costs for the use of HUNT data are published on HUNT's website:

<http://www.ntnu.no/hunt/priser>.

Costs for selection, processing, analyzing or delivery of samples must be added.

18. Final remarks

These guidelines are a translation of the Norwegian "Retningslinjer for forvaltning og bruk av data og biologisk materiale fra Helseundersøkelsen i Nord-Trøndelag". No rights can be derived from this translation. In case of doubt, the Norwegian guidelines are to be referred to.