

# Guidelines for access to research data from The Tromsø Study

Approved by Head of Department 06.02.2013. Replaces Guidelines approved by the Steering Committee for The Tromsø Study 24.01.2005

## 1. Background

The Tromsø Study was established and is led by researchers at the Department of Community Medicine at the University of Tromsø – The Arctic University of Norway (UiT). Researchers from other Departments and other institutions take part in planning and financing of the Study, as well as in the actual collection of data.

The purpose of these Guidelines is to ensure that the collected data are utilized optimally and in a way that secures all interests, and that conflicts concerning use of data are avoided.

## 2. Requirements for applicants

Principal Investigators (PIs) from institutions with bona fide research expertise are eligible to apply for access to research data from The Tromsø Study. The research institution, represented by the Principal Investigator, shall be the contractual partner in contracts regarding rights to analyse data. If the Principal Investigator leaves the research institution, the rights to analyse data will generally remain with the institution. If the rights to analyse data are to be transferred to another institution, a new contract must be signed.

## 3. Requirements for applications

The application must include a project description and a publication plan. Through the project description, the PI/research institution must demonstrate academic relevance, and that data from The Tromsø Study are necessary and/or suited to address the research question. The publication plan must contain working titles that indicate research questions for each planned paper.

## 4. Criteria for allocation of rights to data and analysis

The following criteria will form the basis for the decision:

### 4.1 Contribution to The Tromsø Study

Academic, practical and economic contributions to the planning and/or execution of The Tromsø Study will be substantially valued.

### 4.2 Academic relevance

The project and research questions must be academically well-founded and suited for examination within a population-based study. Priority is given to projects that correspond with the primary purpose of The Tromsø Study.

### 4.3 Academic capacity

The PI must substantiate that project associates have the competence and capacity to analyse and publish data in an academically satisfactory manner within reasonable time.

### 4.4 Conflicting projects

The project will not be granted access to data if the project description and publication plan are in conflict with other approved publication plans.

## 5. Cost of access to data and biological materials

Management of The Tromsø Study database and biobank, which includes development and quality assurance, necessitates a fee on data access. Prices for access to data sets and biological material are currently being reviewed. The principles for pricing will be described here when they are finalized.

## 6. Publication

A condition for access to data is that the results of the research project is made available to the public. Publication should preferably happen by means of a scientific paper published in a recognized academic journal, but publication in form of a report, monograph or presentation of abstract at a research conference may also be accepted.

## 7. Time limit

When a project is granted access to data, a part of the agreement will be a time limitation. This means that the PI and project associates will have first claim to utilize the allocated data to address the research question within this period. The amount of data a project is granted access to, will normally be limited to a volume that can be analysed in the agreed upon period. Such a period will usually be three years, but other durations may be agreed upon depending on the extent of the project.

## 8. Co-authorship

If a project uses variables which derive from another project under The Tromsø Study, the original PI shall be offered cooperation and co-authorship according to the recommendations established by The International Committee of Medical Journal Editors (latest revision 2017). The Vancouver Recommendations are available at <http://www.icmje.org/>.

## 9. Presentation of manuscripts

All papers (including reports and monographs) which are published based on distributed data material from The Tromsø Study, are to be sent to the Data Access and Publication Committee when the paper is accepted for publishing or published.

## 10. References

All publications must clearly state The Tromsø Study as the source of data. If data from The Tromsø Study is part of the material on which the publication is based, the authors must state The Tromsø Study as a source. This may be done in the title, abstract and/or methods section. If the publication is solely based on data from The Tromsø Study this should be stated in the title of the publication. The Tromsø Study Working Committee has produced standards for referencing The Tromsø Study as a source. The standards are published on The Tromsø Study web page.

## 11. New data

Some projects will generate new data. New data should be re-allocated to The Tromsø Study database, with regard to the PI and project associates' rights under paragraph 6 and 7. Examples of new data are new measurements, recording of clinical end-points, results from analysis of biological material and indexes based on other variables from The Tromsø Study. The PI must reach an agreement with The Tromsø Study Working Committee on how the re-allocation of data shall come to pass. Normally this should take place within two years of the conclusion of data collection.

## 12. Direct contact with participants

Researchers who are granted access to data from The Tromsø Study cannot contact Tromsø Study participants unless this has been specifically approved by The Tromsø Study Scientific Committee. Necessary project approval from the Regional Committee for Medical and Health Research Ethics

(REK) must be included in the application, and the participants' consent must be considered to cover proposed research questions, before such contact will be approved by The Tromsø Study.

### 13. Reactions in case of breach of contract

If a contract regarding access to data is breached, UiT/The Tromsø Study will contact the PI to clarify facts and circumstances related to the breach. If an agreement is not reached on this level, a written communication will be sent to the institution responsible for the project, and the institution will have the opportunity to intervene. If UiT and the responsible institution cannot reach an agreement, the following reactions may be considered:

*13.1 Rights to analyse data are revoked*

*13.2 A written approach will be made to the project's economic contributors with notification that the Principle Investigator has breached the agreement on rights to analyse data.*

*13.3. A written approach corresponding that of 13.1 will be made to relevant journal editors.*

In case of doubt concerning breach of contract, The Tromsø Study Working Committee will provide a legal consideration before implementing reactions according to 13.1-13.3.