Faculty of Health Sciences/ Department of Community Medicine/ The woman and Cancer study
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Guidelines for granting access to research data and biological material from the Norwegian Women and Cancer Study (NOWAC)

Replaces the guidelines for NOWAC dated 28 April 2022.

1. Aim

1.1 Aim of NOWAC

NOWAC is a population-based health study that aims to study the factors which affect the risk of developing and surviving cancer in order to provide knowledge on the prevention of cancer, premature death, nationally and globally.

1.2 Aim of the guidelines

The aim of the guidelines are to ensure that data from NOWAC is used optimally to fulfil the aim of the study, protect the interests of participants, and ensure fair access to research data and human biological material. The guidelines do not include renewed contact with the participants.

2. Privacy and information security

It is a prerequisite for the disclosure of data and rights to analysis that the recipient complies with the applicable rules at all times to ensure participants' right to privacy. NOWAC processes its personal data to perform a task in the public interest, see GDPR Article 6(1)(e) and Article 9(2)(j), and the Regulation on Population-Based Health Surveys § 6-1. NOWAC may enter into agreements regarding rights to analysis, but the data material itself cannot be sold.

The research-responsible institution must independently assess whether a Data Protection Impact Assessment (DPIA) is necessary. If the project is based at UiT The Arctic University of Norway, it must obtain an assessment from SIKT, in accordance with UiT's guidelines, unless the project is applying for anonymous data. If the project is based at another institution, an assessment of how personal data is processed must be conducted in accordance with the institution's own guidelines.

Data from NOWAC is linked to the Cancer Registry of Norway and the Cause of Death Registy annually.

3. Applicant, application and agreement

3.1 Applicant

Projects leaders at institutions with research expertise can apply for access to research data or biological material from NOWAC. Master's and PhD students cannot apply themselves. A supervisor with research expertise, preferably the main supervisor, must apply on their behalf.

3.2 Application

The application must include a completed application form with an attached project description/protocol, including a publication plan and data management plan, a list of variables obtained from helsedata.no, and any description of the desired human biological material in order to receive data from NOWAC. The project description must demonstrate that the project is scientifically relevant and that data from NOWAC are necessary and/or suitable to address and/or answer the research question. The list of variables must reflect the research question of the project, and the use of the variables must be explained. Only the named individuals in the application is permitted access to the provided data material. The description of the desired human biological material must reflect the research question of the project, where human biological material is requested.

The publication plan should include the working titles of planned publications where the research question/focus for the publications are made evident.

The project must present approval from the Regional Ethics Committee (REK) and assessments from SIKT or the Data Protection Officer (PVO), where necessary. The application may also attach confirmation of the submitted application to REK or notification form sent to SIKT or PVO. NOWAC does not disclosure research data or human biological material without the necessary approval from REK and a positive assessment from SIKT or approval from PVO.

If project changes lead to the need for new research data, new biological material, other modifications, or access to research data or biological material for longer than agreed upon, the project must apply to NOWAC for this.

The project must use a new application form for project changes and attach documentation describing the changes. If necessary, documentation of any required change approvals from, for example, REK, must be included.

3.3 Agreement

An agreement on rights to the use of research data and/or human biological material will be entered into between NOWAC, Department of Community Medicine, UiT The Arctic University of Norway and the project's research-responsible institution.

If UiT is the research-responsible institution, both the project leader and representative for UiT, usually the head of the department, must sign the agreement on behalf of the project. If UiT is not the research-responsible institution, both the person with signing authority at the institution and the project leader must sign the agreement. The project leader acts as the contact person between UiT and the research-responsible institution.

If the project leader leaves the institution, the rights to analysis are retained by the original institution unless an agreement is made between UiT and the original institution. If it is wished that the rights to analysis are transferred to a new institution, a new agreement must be entered into between UiT and the new institution.

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

As a general rule, all projects using data from NOWAC should invite researchers who have in-depth knowledge of NOWAC as collaborators. Such collaborators should be offered co-authorship in

accordance with the guidelines established by the *International Committee of Medical Journal Editors* (latest revision 2008).

Evaluation criteria for granting access to data:

4.1 Academic relevance

The project must be academically justified and be of such a nature that is it best investigated within the framework of a population survey. Further the project must be in accordance with the objectives of NOWAC.

4.2 Consideration of on-going projects

The project description contained in the application should not be in conflict with other projects that are approved by NOWAC. This applies as long as these projects have access to data granted by NOWAC.

5. Rights

The participants in the study have control over their data and biological material whereby they can request that it be deleted and destroyed. UiT has the right of disposition and can enter into agreements regarding rights to analysis with researchers, but data or biological material cannot be sold as such. The right of disposition is limited by the participants' consents and by laws and regulations.

The recipient owns the results produced in the project. See guidelines, point 13 on the return of new data to NOWAC.

6. Payment and cost for data access

NOWAC charges fees to cover part of the costs associated with case processing, disclosure, and storage of data. The prices are set in accordance with the framework in the Health Register Act § 19 g *Payment for making data available*.

Information about prices for access to data and human biological material is available on the websites for NOWAC and the Administration Unit for Population Surveys at the Department of Community Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway.

7. Publication and dissemination

Access to research data is conditional on the results being made available to the public. This should preferably occur through the publication of a scientific article in a recognized academic journal, preferably in open access channels. Publication in the form of a report, monograph, or presentation of an abstract at research conferences may also be appropriate.

All articles (including reports and monographs) published from the data material provided by NOWAC must be sent to the Leader Group for NOWAC when the article is accepted for publication or published.

Public dissemination of results is also encouraged.

8. Time limitation

When entering into the agreement, a time limitation will be established, which entails that the project leader and any project collaborators have the first right to use the disclosed data during the agreement period. The rights to analysis will normally be limited to a scope that can be realized within the given timeframe. The time limitation is agreed upon separately based on the type and size of the project. Normally, rights are granted for 1-5 years, possibly in accordance with the period approved by the Regional Committees for Medical and Health Research Ethics (REK).

An extension for rights to analysis of the data can be applied for, see point 3.2 Application.

9. Coauthorship

If a project investigates research questions that are central to another project within NOWAC, the project leader of that project should be informed in order to consider possible collaboration between the groups in accordance with the Vancouver rules. The Vancouver rules are available from The International Committee of Medical Journal Editors. Projects that require in-depth knowledge of NOWAC and its variables should include at least one co-author from NOWAC.

10. Credit

It must be clearly stated in all publications that the data is sourced from NOWAC. If data from NOWAC is part of the material used in the publication, the authors should cite NOWAC as the source. This can be done in the title, abstract, and/or methods section. If the publication uses only data from NOWAC, the name, NOWAC, should be included in the title. In articles, NOWAC should be referred to as The Norwegian Women and Cancer Study (NOWAC) in English and *Kvinner og kreft-studien (KK)* in Norwegian.

11. Contacting participants

Researchers who have been granted access to research data from NOWAC are not permitted to contact the participants in the study unless they have applied for and received written permission from the Leader Group of NOWAC.

12. Human biological material

Researchers who wish to be granted access to human biological material must state this in the application to NOWAC, see NOWAC's website for more information.

13. After project completion

When the rights to analysis expire according to the agreement or at the end of the project, whichever occurs first, the disclosed data files must be deleted or returned.

Results from new analyses performed on human biological material from NOWAC should be returned for integration into the NOWAC database and for reuse in other project.

A written confirmation must be sent to NOWAC informing that data files have been deleted or returned. Confirmation must also be given that other copies of the data files do not exist, for example with collaborators.

NOWAC is required to inform its participants about research performed on the data. The project is therefore requested to send a short popular science summary of maximum 250 words to NOWAC at the end of the project.

14. Response to breach of agreement

In the event of a breach of the agreement, these guidelines, or relevant regulations, UiT, through the leader of NOWAC, will contact the project leader to clarify the actual circumstances. If UiT believes there is a breach of the agreement, the responsible research institution will be contacted. If it is still determined that a breach of agreement exists and the parties cannot reach an agreement, the analysis rights may be revoked with immediate effect.