# TFS-Info-03 Information on the use and access procedure

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## Content

# Introduction

This fact sheet describes and explains the individual steps of the use and access procedure.

# Use and access procedure

To facilitate the receipt and use of data and biosamples from the German National Cohort (NAKO), the Transfer Unit has established a use and access procedure, based on the Use and Access Policy, comprising an **application procedure**, a **project phase**, and a subsequent **follow-up period**.

# 1. Application procedure

## 1.1. Application

### 1.1.1. Submission

Applications and notifications of use may only be submitted via the NAKO web portal 'TransferHub' at **TransferHub-EN**.

### 1.1.2. Registration

Registration must be completed once only. All information must be provided with due care, as it will subsequently form the basis for generating the use/access agreement. **Any changes to contact details, particularly the e-mail address, must be made in good time**; otherwise, correspondence cannot be ensured.

### 1.1.3. Main applicant

The main applicant shall initiate a new use and access application, and only this individual is authorised to submit it. Co-applicants may be invited by the main applicant and may contribute to the preparation of the application. Each application may have only one main applicant.
The application may be downloaded as a PDF or Word document. This is possible at any time via the application list, including for draft applications prior to submission.

### 1.1.4. Co-applicants

All individuals who wish to participate in the project in any form can be entered as co-applicants without necessarily receiving any data. Co-applicants must also be registered.

### 1.1.5. Persons requiring access to the data

As individuals who require access to the data, **only enter persons who should actually receive the data**, as a use/access agreement must be concluded with **each** of the institutions of all data recipients, which involves a considerable effort. Always enter persons who require access to data as co-applicants!

### 1.1.6. Follow-up applications

Follow-up applications must be submitted as new, separate applications. The field 'Issue key of the old application' shall be used to reference the number of the preceding application. Variable sets and study populations defined during the previous application may be reused and, where necessary, modified in their copied form.

### 1.1.7. Data selection

- Selection of variables using the 'Data' tab: The data directory can be used to compile your own variable sets and store them under freely selectable designations. These can be reused at any time through the selection menu. **Only one set of variables** may be selected **per application**.
- When selecting the variables, first **look for derived variables**. These variables should be prioritised for analysis over the source variables from the survey.
- In the selection menu, a predefined population can be selected as the **study population**. Alternatively, a new population can be defined. When defining an individual subpopulation, a set of variables must be created in advance, on whose foundation inclusion criteria can be formulated.

### 1.1.8. Biosample selection

- The biosamples are selected via the **'Biosamples' tab.**
- Regulation on the **coverage of costs for the dispatch of biosamples** (still pending).
- For further information on applying for NAKO biosamples, please refer to **Biosample applications**.

## 1.2. Application processing

### 1.2.1. Receipt of application

The **receipt of application** will be confirmed by automated e-mail.

### 1.2.2. Formal review

**Formal review** by the Transfer Unit to verify completeness, an appropriate timeline, availability of variables, and other relevant criteria; where necessary, a request for revision will be issued.

### 1.2.3. Review by UAC

- **Forwarding** of the application **to the Use and Access Committee (UAC)**, which examines the application within a four-week period in accordance with the conditions of the use and access policy.
- When **applying for specialised topics**: involvement of subject-specific expert groups.
- When **applying for biosamples from the central biorepository**: the Biosample Panel shall review the application and issue a statement. Subsequently, the UAC shall assess the scientific question and study design, taking into account the statement provided by the Biosample Panel.
- If a review by the UAC results in a **recommendation for revision**, an automated request for **resubmission** is sent to the applicant. The application will be released for revision and forwarded to the UAC for review after resubmission.
- If the UAC review results in a **recommendation for revision**, an automated request for **resubmission** will be sent to the applicant. The application will be released for revision and once resubmitted, forwarded to the UAC for renewed review.
- If the UAC review results in a **recommendation for approval or rejection**, the application shall be submitted to the Board of Directors for a final decision.

### 1.2.4. Decision of the Board of Directors

- Upon receipt of the UAC's recommendation, the **Executive Board shall decide** on the application, preferably within one to two days. As a rule, the Board of Directors follows the UAC's recommendation.
- In the event of a **rejection**, the applicant will be informed by automated e-mail, including the reasons for the decision.
- In the event of an **approval**, the main applicant will be notified automatically by e-mail and the process to conclude the agreement will be initiated.
- If **a biosample application is approved**, the biorepository will also be notified.
- For all approved applications, an **automated notification will be sent to the NAKO partners**.

### 1.2.5. Application alterations/amendments before conclusion of agreement

The following applies to alterations/amendments prior to the conclusion of the contract:

- A **change of the main applicant** must be requested informally via the Transfer Unit; the corresponding alteration to the application will be made by the Transfer Unit.
- The **addition of further data or biosample recipients or additional co-applicants** must be requested informally by the main applicant via the Transfer Unit; the corresponding amendment to the application will be carried out by the Transfer Unit.
- **Additional variables** arising, for example, from an erroneous application must be requested by the main applicant via the Transfer Unit using an application form. In the event of approval, the application will be released for revision, the applicant will revise the set of variables and resubmit the application. The application will then be returned to the corresponding status.
- **Completely new additional variables** that bear no direct relation to the variables originally requested or to the subject of the application require renewed review by the UAC and, where applicable, by the Board of Directors.

## 1.3. Conclusion of contract

- The **main agreement** is concluded with the institution (user) of the main applicant.
- Where additional data or biosample recipients are involved, a **sub-agreement** must be concluded with each of their respective institutions (co-users).
- The conclusion of agreements is carried out by the Transfer Unit.
- **Authorisation for data compilation** may be granted once the fully signed **main agreement** has been received by the Transfer Unit. If additional institutions are involved, data provision will be made only to persons affiliated with institutions with which an agreement has been concluded. Data recipients may, where applicable, be required to confirm that they will not pass data on to unauthorised co-applicants.

# 2. Project phase

## 2.1. Data transfer

- Once the agreement has been fully executed and the data is available, the data will be compiled, secondarily pseudonymised and encrypted by Integration Centre and Transfer Unit.

Within the German National Cohort, the open-source software VeraCrypt is used as the standard tool for encryption. Data recipients should ensure in good time that this software is installed by their local IT services.

- Smaller data volumes will be made available to all authorised data recipients via the TransferHub. Larger data volumes will be shipped on hard drives, following coordination between the contracting parties. The costs for hard drives and shipping shall be borne by the user.
- **Two-stage applications**: NAKO e. V. may require a two-stage data handover. In such cases, for example, only the analysis of biosamples will be carried out in the first stage. Only after the analytical results have been returned will the complementary data required for further evaluation be provided in the second stage.

## 2.2. Biosample transfer

Centralised biosample dispatch will be carried out in consultation with the biorepository. The compilation of biosamples is performed in the biorepository, and shipment is made to the laboratory specified in the agreement. The invoice will be issued to the project management in accordance with the applicable schedule of fees (pending).

The decentralised dispatch of biosamples is handled locally but is subject to the same regulations.

## 2.3. Scientific evaluation

The scientific evaluation shall be conducted within the project term stipulated in the agreement.

## 2.4. Interim report

- Twelve months after the transfer of data and biosamples (calculated from the date of the final transfer), the Transfer Unit may, in individual cases, request a brief interim report. A corresponding form will be provided for this purpose.
- In the case of contract extensions, an interim report must generally be submitted.

## 2.5. Contract alterations/amendments

- Any **changes concerning the (co-)project management** during the period of use must be communicated to the Transfer Unit in writing.
- After data provision has taken place, **additional variables** and/or **additional data/biosample recipients or co-applicants belonging to already participating institutions** may be requested via an amendment in the TransferHub. Upon approval of the amendment, the additional variables and/or additional persons will be incorporated into the application, the application will be updated accordingly, and both the amended application and the amendment will be added to the contract documentation.
- The **inclusion of data or biosample recipients from institutions not previously involved** requires an amendment submitted via the TransferHub. Upon approval, the persons will be incorporated into the application, and a sub-agreement must be concluded with the respective institution.
- **Completely new additional variables** that bear no direct relation to the variables originally requested, **as well as new research questions**, require the submission of a new application or follow-up application.

# 3. Follow-up period

## 3.1. Reporting/Publications

- Where applicable, a brief interim report may be required twelve months after the transfer of data and biosamples; see Section 2.4.
- A final report on the research project must be submitted electronically in written form no later than **one year after the end of the project**. In the case of scientific publications, the manuscript may be submitted in lieu of a final report.
- **Publications** arising from use and access applications, together with the required citation specifications, must always be **reported to** **publications@nako.de**.
- For planned external communication, these publications will be entered into a central database.

## 3.2. Transmission of results data/return of biosamples

- The user and co-users shall transmit the **results data, analysis programmes and metadata no later than twelve months after the end of the project**. NAKO e. V. shall decide on their use within the research database and may, at its discretion, waive the requirement for submission.
- The format of the results data to be transmitted electronically must be agreed with the Transfer Unit.
- A format must be selected that can be read using commonly used and widely available software.
- The user shall archive the analysis programmes and algorithms.
- The transfer of the results data into the research database/study database shall be carried out by the Integration Centre.
- The return of unused or generated biosamples must be clarified with the biorepository.
- The fundamental procedure for handling residual samples is still pending clarification.

## 3.3. Data deletion/destruction of biosamples

- The user and co-users must **delete all data and results data no later than eighteen months after the end of the project** and must inform the Transfer Unit of the deletion.
- Biosample recipients must **offer any unused biosamples** to NAKO e. V. at the latest upon completion of the project and, where applicable, make them available. If NAKO e. V. does not reclaim these samples, they must be **destroyed in coordination with the biorepository**, and the Transfer Unit must be notified accordingly.