TFS-Info-03 Information on use and access procedure

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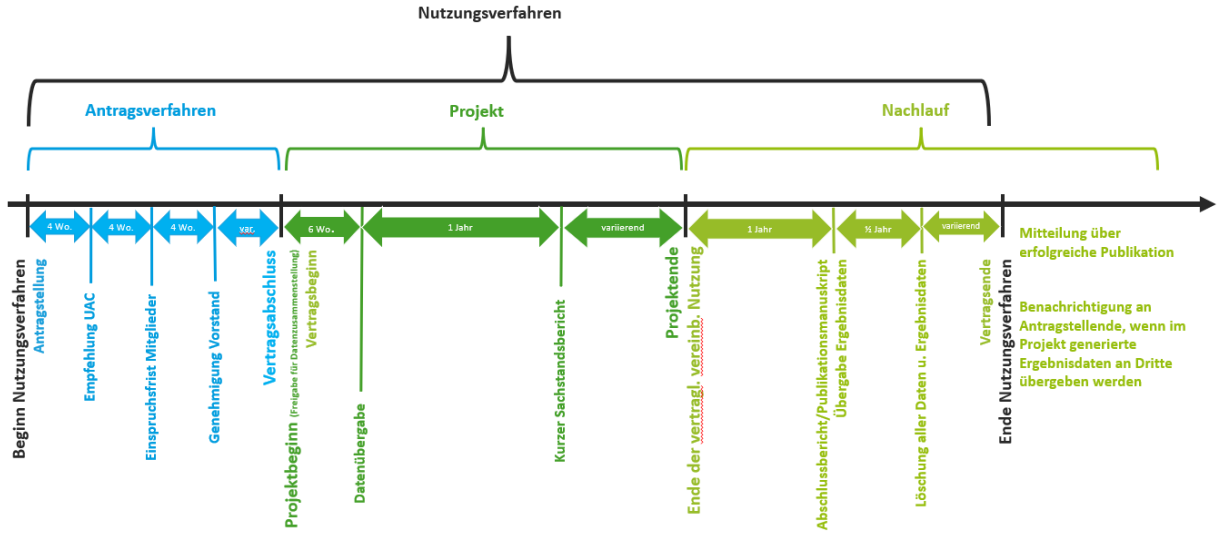
Introduction

This information sheet describes and explains the individual steps of the use and access procedure. The following figure shows the sequence of steps and marks the deadlines stipulated in the Use and Access Policy:



Use and access procedure

In order to be able to receive and use data and biosamples from the NAKO Health Study, the Transfer Unit implemented a use and access procedure based on the Use and Access Policy, which consists of an application procedure, a project phase and a follow-up period (see figure above).

1. Application procedure

1.1. Application

1.1.1. Submission

Applications and notifications of use can only be submitted via the NAKO web portal "TransferHub" at https://transfer.nako.de/.

1.1.2. Registration

Registration must be carried out once. All details must be filled in carefully, as they will later form the basis for generating the use/access agreement. **Changes to contact details, in particular the e-mail address, must be made in good time**, as otherwise correspondence will not be possible.

1.1.3. Main Applicant

The main applicant creates a new use and access application and only this person can submit the application. Co-applicants can be invited by this person and participate in the preparation of the application. There can only be one main applicant per application.

The application can be downloaded as a PDF/Word document. This is possible at any time via the application list, especially for draft applications prior to submission.

1.1.4. Co-applicants

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

1.1.5. Persons requiring access to the data

As persons requiring access to the data, **only enter the persons who should actually receive data**, as a use/access agreement must be concluded with **every** institution of the data recipients, which entails time and effort. Make sure to always enter persons requiring access to the data as co-applicants!

1.1.6. Follow-up applications

Follow-up applications must be submitted as new, separate applications; reference is made to the number of the previous application via the "Operation key of the old application" field. Variable sets and study populations defined in the course of the previous application can be reused and, if necessary, modified in copy.

1.1.7. Special case: Notifications of use

- The web portal “TransferHub” provides a simplified procedure for the use of data collected at the own study centre and decentralised biosamples via a notification of use. **Attention:** However, this does not apply to central units and facilities that are exclusively involved in the preparation, further processing or quality assurance of data.
- The Transfer Unit forwards **notifications directly to the Board of Directors**, which reviews them within a two-week period if possible and approves them if applicable.
- **Upon approval,** all persons involved in the notification receive an automated message that specifies any potential requirements.
- **Conclusion of a contract** is **not necessary** due to existing data processing agreements with the respective study centres. Therefore, only employees of a study centre may submit a notification of use.
- **Data is usually provided** within 2 weeks of approval. Necessary coordination for the transfer of replacement variables may delay this.
- If a **notification is rejected**, the notifying party must be informed, including a **statement of the reasons** drawn up by the Board of Directors.

1.1.8. Data selection

- **Selection of variables** in the "Data" tab: The data dictionary can be used to compile your own variable sets and save them under freely selectable names. These can then be reused at any time via the selection menu. **Only one set of variables** can 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.
- A predefined population can be selected as the **study population** in the selection menu. Alternatively, a new population can be defined. When defining a separate subpopulation, a set of variables must be created in advance, on the basis of which inclusion criteria can be formulated.

- At least one **examination wave** must be selected. If necessary, also explicitly select wave-independent data.
- For more information on applying for NAKO data, see (still pending: TFS-Info-02: Use and access applications and its fields or contents, roles as main and co-applicant as well as data user, variable selection, restrictions on the use of variables, determination of case numbers, justification of sensitive variables/accuracies, possible costs, possibly MRI sequences).

1.1.9. Biosample selection

- Biosamples are selected via the **"Biosample" tab**.
- Regulation of the **assumption of costs for the dispatch of** biosamples (still pending).
- For more information on applying for NAKO biosamples see TFS-Info-02b_Information_on applying for biosamples.

1.2. Application processing

1.2.1. Receipt of application

Receipt of application will be confirmed by automated e-mail.

1.2.2. Formal check

Formal check for completeness, appropriate time frame, availability of variables, biosamples, etc. by the Transfer Unit; request for revision if necessary.

1.2.3. Review by UAC

- **Forwarding of** application **to UAC**, which examines application within a four-week period in accordance with provisions of Use and Access Policy.
- When **applying for specific topics**: Involvement of other experts (e.g. persons responsible for the module of the MRI examination, representatives of the competence network for secondary and register data, biosample panel).
- When **applying for biosamples**: UAC reviews the research questions and study design and forwards the application to the biosample panel, consisting of a representative of the NAKO office or transfer office, a responsible board member or representative, 2 representatives of the PIs, head of the biorepository, representatives of the expert group (EG) OMICs, EG Biomaterial and Laboratory Analyses and/or work group (WG) Biosamples, a representative of the data infrastructures. (TFS-Info-02b: Information on applying for biosamples)
- If the UAC's review results in a **recommendation for revision**, an automated request for **resubmission** is sent to the applicant. Application is released for revision and forwarded to UAC again for review once it has been resubmitted.
- If the UAC's review results in a **recommendation for approval**, a corresponding automated notice with a four-week objection period is sent to the association members (stakeholders nominated by NAKO e. V., which are entitled to raise objections).
- If the UAC's review results in a **recommendation for rejection**, the applicant will be informed and given the opportunity to withdraw the application and submit a new one if necessary. If the application is not withdrawn, a corresponding automated notice with a four-week objection period is sent to the association members.

1.2.4. Objection period for association members

- After notice of the UAC recommendation, the association members have **four weeks to submit queries and express their interest and objections** to the application.
- The Board of Directors decides on **objections** :
  a) if the objection is admitted, it will be submitted together with the application to the general assembly, which will decide on it at its next meeting.
  b) if the objection is rejected, the objectors will be informed of the reasons for the rejection and asked to withdraw the objection if they can understand the reasons for the rejection. If they still wish to uphold the objection, the matter will be taken to the general assembly. If the objectors do not respond to the request to withdraw the objection within a period to be specified, the objection will not be considered further.
- If they **do not agree with the Board's decision**, objectors and applicants may submit the application to the general assembly for a decision.

1.2.5. Board of Directors' decision

- Upon expiry of the objection period, the **Board of Directors** usually **decides** on the application within a two-week period. Normally, the Board of Directors follows the recommendation of the UAC.
- If **approved**, the main applicant is automatically informed by e-mail and preparations are made to conclude the agreement.
- If a **biosample application is approved**, the biorepository will also be informed.
- If **a notification of use is rejected**, the applicant may submit the application to the NAKO e.V.'s general assembly for a final decision (see NO § 3.4.1 para. 11).

1.2.6. Application amendments/additions before conclusion of agreement

The following applies to amendments/additions prior to conclusion of the agreement:

- **Changes** with respect to the main applicant must be applied for informally by the main applicant via the Transfer Unit; if approved, the Transfer Unit will amend the application accordingly.
- **Changes** regarding the project management must be applied for informally by the main applicant via the Transfer Unit; if approved, the Transfer Unit will amend the application accordingly.
- **Inclusion of additional data/biosample recipients or co-applicants** must be applied for informally by the main applicant via the Transfer Unit; if approved, the Transfer Unit will amend the application accordingly.
- **Additional variables**, e.g. resulting from incorrect application, must be applied for informally by the main applicant via the Transfer Unit. If approved, the application is released for revision, the applicant revises the set of variables and resubmits the application. The application is then returned to the corresponding status.
- **Completely new additional variables** that are not directly related to the variables originally applied for and to the topic of the application require the submission of a new application.

1.3. Conclusion of agreement

- The **main agreement** is concluded with the institution (user) of the main applicant.

- If other data/biosample recipients are involved, a **subagreement** must be concluded with their institutions (co-users).
- In the future corresponding agreements will be generated in the application portal. Agreements are currently being sent to those concerned by hand.
- **Release for data compilation** can take place when the **main agreement** has been fully signed and received by the Transfer Unit. If other institutions are involved, data will only be provided to persons from the institutions with which an agreement has already been concluded. If applicable, data recipients must confirm that they will not pass on data to unauthorised co-applicants.

2. Project phase

2.1. Data transfer

- When the agreement is completed and data is available, data will be compiled, second-pseudonymised and encrypted by Integration Centre and Transfer Unit. In the NAKO Health Study, the free software VeraCrypt is used as standard for encryption. Data recipients should endeavour to have this software installed by their local IT department in good time.
- Smaller data volumes can be downloaded by all authorised data recipients via the TransferHub. Larger amounts of data will be sent on hard discs after consultation between the contractual partners. The user bears the costs for hard drives and shipping.
- **Interim transfer:** If not all data is available at the time of release for data compilation, an interim transfer can be made once. See TFS-Info-11: Information on applying for interim transfer.
- **Two-stage applications:** Special features for data and/or biosample transfer at different times. For example, only biosamples are analysed in the first step. The data required for evaluation is transferred in a second step once the analysis data has been returned. See (still pending: TFS-Info-0x: Information on two-stage applications).

2.2. Biosample transfer

Centralised biosample dispatch takes place in consultation with the biorepository. Compilation, "pick job", of the biosamples takes place in the biorepository. Shipment is made to the laboratory specified in the agreement. Project management will be invoiced in accordance with the fee schedule (still pending).

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

For more information on the transfer of biosamples, see (still pending: TFS-Info-05: Biosample selection, containers and volumes, transport/shipping, costs, rack and sample identifiers).

2.3. Use of data

For more information on the use of NAKO data, see (still pending: TFS-Info-04: Structure of the data, metadata/data dictionary, missings, data protection).

2.4. Use of biosamples

For more information on the use of NAKO biosamples, see (still pending: TFS-Info-06: Storage, pseudonymisation, analysis documentation/storage of context and metadata, whereabouts/reuse/destruction after use, return of racks if necessary).

2.5. Scientific evaluation

Scientific evaluation takes place within the contractually agreed project term.

2.6. Brief progress report

- 12 months after the transfer of data and biosamples (calculated from the date of the last transfer), a brief progress report must be sent to the NAKO e. V. office. For more information on the reporting obligations, see (still pending: TFS-Info-09: Structure, content and timing of reports).
- For specifications on progress reports, see (still pending: TFS-Info-09: Structure, content and timing of reports).

2.7. Agreement amendments/additions

- The transfer office must be notified of any **changes to (co-)project management** during the period of use; agreement amendment required.
- **Additionally required variables** resulting from incorrect applications or the **inclusion of additional data/biosample recipients or co-applicants from institutions already involved** require an informal application via the Transfer Unit and, if applicable, the Board of Directors, as well as registration of the new persons. If approved, changes are added manually to the application as an amendment, the application is updated and attached to the agreement documents.
- **Inclusion of data/biosample recipients from institutions not previously involved** requires an informal application via the Transfer Unit and, if applicable, the Board of Directors, as well as registration of the new persons. If approved, changes are added manually to the application as an amendment and a subagreement must be concluded with the institution concerned.
- **Completely new additional variables** that are not directly related to the variables originally applied for **and new research questions** require the submission of a new application.

3. Follow-up period

3.1. Reporting/publications

- Brief progress report 12 months after data and biosample transfer, see 2.6.
- 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, a publication manuscript may be submitted instead of a final report. For more information on the reporting obligations, see (still pending: TFS-Info-09: Structure, content and timing of reports).
- Always **report publications** on Use and Access Applications together with citation specifications **to transferstelle@nako.de**.

- These are fed into a central database for the planned external presentation.

3.2. Transmission of results data/return of biosamples

- Users and co-users must make **results data** available in full and in a suitable electronic form **no later than one year after the end of the project**. For more information on transmission of data and biosample results, see (still pending: TFS-Info-10: Content and formats for metadata, content and formats for results data, handling complex results data, data deletion).
- When transmitting the results data, care must be taken to ensure that the results data and the evaluation programmes used to generate these results are **self-explanatory and sufficiently documented**.
- The format of the results data to be transmitted electronically must be agreed with the Transfer Unit.
- A form that can be read with common and widespread software must be selected.
- In particular, the information must be categorised into the smallest meaningful units and thus be accessible. Metadata must be provided for these new variables.
- The user is responsible for archiving the evaluation programmes and algorithms.
- Transfer of the results data to the research database/study database by Integration Centre.
- Return of unused biosamples and generated biosamples must be clarified with the central biorepository.
- Fundamental clarification of the handling of residual samples is still pending.

3.3. Data erasure/sample destruction

- The user and co-user must **delete** all data and results data **no later than eighteen months after the end of the project** and inform the Transfer Unit of the deletion.
- Biosample recipients must offer unused biosamples to NAKO e. V. at the latest at the end of the project and make them available if necessary. If NAKO e. V. does not take them back, they must be destroyed in agreement with biorepository and the Transfer Unit must be informed.

List of abbreviations

IntZ	**Integration Centre**
TFS	**Transfer Unit**
NO	**Use and Access Policy**
UAC	**Use and Access Committee**