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Preamble

The aim of this Use and Access Policy is to promote the scientific use of the Data collected by the NAKO e. V. and the Biosamples obtained. This requires a broad availability of Data and Biosamples for scientists from the institutions in the German National Cohort and for external scientists. In this respect, the German National Cohort is guided by the principles of 'Data Sharing', 'Open Science' and 'Fair'. Due to the special requirements for protecting the rights of the participants and the high scientific value of the existing Data and Biosamples, planned access to them must be carefully reviewed with regard to the objectives and the benefits that can be achieved.
§ 1 Definitions

In the list of definitions below, specific concepts and matters are listed first. They are followed by the role concepts, which are characterised by the fact that they can be filled by different individuals in the respective use procedure.

For the purposes of this Use and Access Policy for the exchange of Data and, where applicable, Biosamples within the framework of the NAKO Health Study, the following terms have the following meanings:

1. **Data**
   the personal Data from the various parts of the NAKO Health Study (e.g. interviews, examinations, measurement results of Biosamples, images, secondary data and register data, Results Data from previous Projects). The Level 3 rules always apply to Data from Level 3 Projects, unless it is stated there that the Use and Access Policy applies.

2. **Results Data**
   all personal Data obtained in the course of Use of Data and from the analysis of Biosamples. These are in particular variables derived from the transferred Data (e.g. categories, scores and indices).

3. **Metadata**
   non-personal Data describing processes, variables, categories and the like.

4. **Work Results**
   all results of non-personal evaluations (e.g. publications, software, methods and procedures developed in the Project) that arise from carrying out Projects on the basis of the Data and, if applicable, Biosamples provided for use, irrespective of their legal protectability, including in particular Data, knowledge (e.g. about substances and organisms), know-how and inventions. The use and exploitation of Work Results is regulated in the Exploitation Policy (Verwertungsordnung).

5. **Biosamples**
   all biological samples obtained from participants in the NAKO Health Study or provided by participants and stored in the NAKO Health Study (central and decentral) Biosample Repositories. This includes, for example, serum, plasma, urine, saliva and tissue samples as well as Biosamples obtained from them, such as blood components and DNA. The Level 3 rules
always apply to Biosamples from Level 3 Projects, unless it is stated there that the Use and Access Policy applies.

6. Use of Data
any inspection or processing, in particular the statistical evaluation, of personal Data of the NAKO Health Study for scientific projects, publications, lectures or for preparation of further statistical evaluations in accordance with an Agreement for Use/Access.

7. Use of Biosamples
the transfer, storage, processing, pooling and scientific analysis of Biosamples in accordance with the Agreement for Use/Access.

8. Use and Access Application
the document requesting use of cross-centre Data and Biosamples from the NAKO e. V. in the form of a Project. It contains, among other things, the scientific justification for use of the Data and Biosamples and the description of the criteria and configurations according to which the use will be carried out. A Use and Access Application must be submitted via the "NAKO TransferHub" web portal and becomes part of the Agreement for Use/Access after it has been approved.

9. Notification of Use
the document reporting use of the Data and, if applicable, Biosamples from the notifying party's own study centre in a Project. It contains, among other things, the scientific justification for the use of the Data and, if applicable, Biosamples and the description of the criteria and configurations according to which the use will be carried out. Notification of Use must be submitted via the "NAKO TransferHub" web portal; after it has been approved use without an Agreement for Use/Access is possible.

10. Agreement for Use/Access
the document regulating all essential points of Use of Data and, if applicable, Use of Biosamples. It is necessary to enter into an Agreement for Use/Access in order to start a Project which uses Data that is not only local Data.

11. Contractual Partner
the legal persons who enter into an Agreement for Use/Access with the NAKO e. V. Each Contractual Partner must provide the Transfer Unit with the name of one or more authorised signatories to sign the agreement.

12. Amendment
the subsequent change to the Use and Access Application with retroactive effect to the time when it was submitted, by which the Contractual Partner may be granted additions or
deviations within the scope of the requested purpose of use after the agreement has been entered into, in particular as follows:

a) the subsequent provision of variables where it is recognised that they have to be included after the Agreement for Use/Access has been entered into, (i) by type (qualitative amendment), in particular the parameters for variable selection, or (ii) to an appropriate extent (quantitative amendment), in particular the number of cases or participants,

b) an extension of the agreed Project Term (time amendment),

c) any Use of Data by third parties beyond the scope of the Agreement for Use/Access, in particular for external analyses (transfer amendment).

13. Project
the Project which is in line with the objectives of the NAKO Health Study for which NAKO Data and, if applicable, Biosamples are to be used and which is described in the Use and Access Application or the Notification of Use. The Project is limited in time and is financially supported by the applicant's funds.

14. Level 3 Project
a project that goes beyond the regular NAKO Health Study examination programme, which usefully supplements and expands the NAKO Health Study's scientific programme with additional examination aspects, questionnaires or Biosample collections. Only the study centres can apply for Level 3 Projects.

15. Project Term
the period of contractually agreed use beginning upon transfer of the Data and, if applicable, Biosamples and ending at the end of the term specified in months by the User when submitting the application.

16. Study Database
NAKO's central database for primary data collection. The Data are initially raw data that are quality-assured and transferred to the Research Database by NAKO before being used. The Study Database is operated by NAKO’s Integration Centre.

17. Research Database
NAKO's central database for long-term data storage of all generally quality-assured data and files (e.g. medical device files, MRI images). The Research Database is operated by the Integration Centre and accessed by TransferHub for compilation of Data.

18. NAKO TransferHub
the web portal of the Transfer Unit at https://transfer.nako.de/. The TransferHub provides information for potential applicants and allows to submit Use and Access Applications and
Notifications of Use through personal access accounts and for all of the parties involved to track the entire application and use procedure.

19. **Use and Access Committee (UAC) (role in the use procedure)**
a committee established in accordance with the Articles of Association to assist the Board of Directors in reviewing applications for the transfer of Data and Biosamples (for details see § 3).

20. **Independent Trust Centre (ITC) (role in the use procedure)**
the responsible body that stores and processes the NAKO's Data that identifies a person in a central location and separately from medical data. The ITC stores pseudonyms assigned to participants for data collection purposes and manages consent forms, including documentation of changes to consent in the event of revocations.

21. **Integration Centre (role in the use procedure)**
the body responsible for storing and processing the medical data of NAKO participants. The Integration Centre manages the Metadata (data dictionary) of all data elements/variables and integrates the Results Data into the Research Database.

22. **Transfer Unit (role in the use procedure)**
the responsible body in the NAKO that handles and coordinates the entire process of providing Data and Biosamples for scientific evaluation. Its tasks also include monitoring deadlines for progress reports and final reports, for deletion of transferred Data and for publications. The Transfer Unit operates the application management system NAKO TransferHub (see above). The contact address for scientists and general enquiries is: transfer@nako.de.

23. **Central Biorepository (role in the use procedure)**
the NAKO Health Study’s Central Biorepository for Biosamples is at Helmholtz Munich. The Central Biorepository operates NAKO's laboratory information management system and is involved in selecting participants for Projects with regard to checking the availability of the required Biosamples. Once it has been instructed by the Transfer Unit, the Central Biorepository is responsible for transferring centrally stored Biosamples to the recipients named in the Use and Access Application based on the information on the participants in the study.

24. **Decentral Biosample Repository (role in the use procedure)**
the Biosample Repositories where a part of the Biosamples collected are stored decentrally under the responsibility of the respective study centre that collects them. Biosamples and their storage temperature are documented in NAKO's laboratory information management system. Removals, relocations and withdrawals of decentrally stored samples are promptly
documented by the decentral Biosample Repository/Repositories in the NAKO laboratory information management system.

25. **Tumour Tissue Bank (role in the use procedure)**
NAKO’s tissue bank, which is affiliated with the National Centre for Tumour Diseases (NCT) in Heidelberg. It offers central and quality-assured storage and processing of tissue samples of relevant tumour diseases from participants, which are transferred from the pathologies in the federal territory to NAKO’s Tumour Tissue Bank in Heidelberg and stored there centrally.

26. **User (role in the use procedure)**
a natural person or legal person who is involved in the Project and becomes a Contractual Partner of the NAKO e. V. by legally entering into the Agreement for Use/Access (e.g. a university institution as a body with legal capacity for a legally dependent institution or another dependent scientific institution).

27. **Project Management (role in the use procedure)**
a natural person working for the User who performs central coordinating tasks in relation to the NAKO e. V. in connection with preparing and implementing the Agreement for Use/Access and the Project.

28. **Project Participants (role in the use procedure)**
all persons involved in a project as Main Applicants, Co-applicants, Data Recipients and, if applicable, Biosample Recipients, and their staff.

29. **Main Applicant (role in the use procedure)**
the person who prepares and submits the Use and Access Application and normally handles Project Management.

30. **Co-applicant (role in the use procedure)**
all persons additionally named in a Use and Access Application. These persons can contribute to the application but cannot submit it. Co-applicants only receive Data if they are named as Data Recipients in the Use and Access Application and an Agreement for Use/Access has been entered into with their institution.
§ 2 Basis and purpose of use

2.1 Purpose of the policy

(1) Within the framework of the constitutionally protected freedom of research, this Use and Access Policy aims to achieve transparent and fruitful use of the Data and Biosamples in accordance with the Articles of Association, while at the same time safeguarding data protection and the legitimate interests of the participants in the protection of their personal rights and the interests of the institutions involved in the implementation of NAKO, while ensuring compliance with scientific standards.

(2) In addition to this Use and Access Policy, the respective applicable data protection regulations (at state, federal and EU level), laws on patents and copyrights, other legal and ethical framework conditions, if applicable, and Good Research Practice (GRP), Good Epidemiological Practice (GEP) and Good Practice of Secondary Data Analysis (GPS) must be observed.

The Articles of Association, the Data Privacy and IT Security policies, the Code of Ethics (Ethik-Kodex), the Publication Policy (Publikationsordnung) and the Exploitation Policy (Verwertungsordnung) of the NAKO e. V., must also be taken into account, as amended from time to time.

2.2 Legal basis of use

(1) The informed consent of the participants concerned in accordance with the signed consent form is the basis of any collection, processing and use of Data and any taking, further processing, analysis and evaluation of Biosamples.

(2) If participants revoke their consent, their Data and, if applicable, Biosamples will no longer be made available for Projects. See the Code of Ethics (Ethik-Kodex) and the NAKO's Data Privacy and IT Security Policy (Datenschutz- und IT-Sicherheitskonzept) for further details.

(3) The Use of Data and Biosamples requires a Use and Access Application or, under certain conditions (see § 3.3 (1)), Notification of Use.

(4) Use and Access Applications must go through an approval procedure of the NAKO e. V., which is completed when an Agreement for Use/Access is entered into.

(5) A Notification of Use only requires the approval of the NAKO e. V. Board of Directors.

2.3 Rights of use

(1) The rights of use in the Data and the property rights in the Biosamples were transferred to the NAKO e. V. by the participants by declaration of consent. This applies irrespective of the rights of use granted in each case or the transfer to the Users named in the Agreement for Use/Access.

(2) If the Agreement for Use/Access is entered into, the User is granted in accordance with this Use and Access Policy a simple, revocable, non-exclusive, non-transferable, right of use in the Data and, if applicable, Biosamples which is limited in time and territory, limited to the duration and purposes of the Agreement for Use/Access and which can only be sublicensed
with the consent of the NAKO e. V., provided that the Data and Biosamples are only used for purposes in line with the objectives of the NAKO e. V. and the interests of the NAKO e. V. are not impaired.

(3) With regard to registering and using patents and other industrial property rights relating to or established by the Data or Biosamples, reference is made to the Exploitation Policy (Verwertungsordnung) of the NAKO e. V.

2.4 General principles for the Use of Data and Biosamples

(1) Appropriate security measures will be taken to ensure the personal rights of participants and the confidentiality of their Data and Biosamples when these are transferred for Projects. Data that identifies a person (names, addresses) always remain with the Independent Trust Centre and are not passed on to third parties.

(2) The User and its employees involved in the Project undertake not to attempt to re-identify persons whose Data and, if applicable, Biosamples they have received, and not to publish or pass on to third parties any Data that could enable third parties to re-identify individual persons.

(3) The User may not pass on Data, Biosamples or any Data derived from these to third parties in any form beyond the agreements in the Agreement for Use/Access or to make them accessible or known to third parties, unless the User is obliged to do so by law, court order or official order. The User must inform the Transfer Unit without undue delay of any transfer or access given on the basis of a legal obligation, court order or official order within the meaning of sentence 1. The Transfer Unit will inform the Board of Directors, which will decide on further steps.

(4) If Data, Biosamples or derived Data are passed on to third parties (e.g. external laboratory facilities) as required by the User and permitted under the Agreement for Use/Access, the User is required to contractually oblige the respective Recipient to comply with the data protection provisions of the Agreement for Use/Access and the associated General Contractual Terms and Conditions of Use (ANVB).

2.5 Use only permissible within the scope of the application and approval

(1) Transferred Data and, if applicable, Biosamples may only be used for the requested and approved use and only until the end of the Project. Any requirements and conditions set out in the permit must be complied with. Any further (intended) use of the Data or Biosamples must be requested separately; this also applies to any necessary use beyond the period originally applied for (see § 4.1).

(2) In the event of an authorised transfer to third parties (see § 4.4), such transfer of Data will be made exclusively by the Transfer Unit (see § 4.1); centrally stored Biosamples will be transferred exclusively by the Central Biorepository or the Tumour Tissue Bank (see § 4.2).

(3) In cases pursuant to § 3.3 (2) j) and (3) g), aggregated Work Results may be provided to the respective external sponsor in accordance with the respective cooperation agreement and, if applicable, the conditions associated with the approved use. Data and Biosamples may not be transferred.
2.6 No derivation of further funding

No claim to financial support or other funding or support from the NAKO e. V. may be derived from access to or the transfer of Data and Biosamples.

2.7 Reporting and the duty to inform

The User must submit a progress report to NAKO’s Transfer Unit 12 months after the transfer of Data or Biosamples. Within one year after the end of the Project, a final report must also be submitted to the Transfer Unit in electronic form. In the case of Use of Data for preparation of a scientific publication, the submission of the publication manuscript (electronically as a PDF) will suffice as the final report. The User must inform the NAKO e. V. about publications resulting from the Project.

2.8 Transmission and management of Results Data

(1) Results Data must be made available to the Transfer Unit by the User in full and in suitable electronic form after the evaluations and processing of the Data are completed, but no later than one year after the Project ends. The Metadata must also be provided to describe the Results Data.

(2) The Results Data must be documented sufficiently and in a self-explanatory manner. The format of the Results Data must be agreed with the Transfer Unit. It is important that common software is used in a form that can be read. The evaluation programmes are to be archived by the User.

(3) The Results Data are integrated into the Research Database. If the Results Data are used by other researchers, the respective User from whose Project the Results Data originate will be informed of this at the time of the data transfer. The Transfer Unit passes on contact details for this purpose. The researcher who has requested and is using the Results Data of other researchers will be advised to proceed in accordance with Good Research Practice and Good Epidemiological Practice with regard to involving the other researchers from whose Project the Results Data originated. Further details are set out in § 2.9.

(4) The Transfer Unit will comply with the obligation to retain all Data provided for use and the Results Data with respect to publications in accordance with Good Research Practice. The Transfer Unit ensures that the Data for the Project can be made available for subsequent Use of Data for the purposes specified in Good Research Practice (see Recommendation 6.1 of the Guidelines for Good Epidemiological Practice of the DGEpi).

2.9 Publication and use of the Work Results

(1) The rules of Good Research Practice apply to all publications in which Data or Biosamples are used.

(2) In publications based in whole or in part on Data or Biosamples, a note must be included stating that they were provided by the NAKO e. V. The Publication Policy (Publikationsordnung) is binding for all Project Participants and governs the type and extent to which the parties associated with NAKO and involved in data generation or data processing are to be taken into account in publications. Reference should be made to the funding bodies
with the wording "funded by the German Federal Government, the Federal States and the Helmholtz Association" (see Publication Policy).

(3) Details regarding the rights of use and exploitation rights of the NAKO e. V. in the Work Results after the end of the Project are governed by the Exploitation Policy (Verwertungsordnung).

2.10 Deletion of Data and, if applicable, return of unused Biosamples

(1) The User is required to delete all Data (Data provided and Results Data) eighteen months after the end of the Project Term. This does not apply to the Work Results. The Transfer Unit must be informed of the deletion without undue delay.

(2) The Biosamples not used in the context of the Project must be offered and, if necessary, provided to the NAKO e. V. at the latest at the end of the Project. The decision on whether to destroy or return remaining samples is made by the NAKO e. V. Board of Directors. If the NAKO e. V. does not take back the remaining unused Biosamples, then they are to be destroyed in consultation with the Central Biorepository or the Tumour Tissue Bank. If the remaining unused Biosamples are returned, the procedure must be clarified with the Central Biorepository or the Tumour Tissue Bank. The Transfer Unit must be informed in writing without undue delay if remaining Biosamples are returned or destroyed.
§ 3 Application procedure

3.1 Basic principles for the application procedure

The use of Data and Biosamples can be granted to scientists for all types of health-related research in the public interest. An application procedure has been established for this purpose. The transfer of Data or Biosamples for commercial use is excluded. Please contact the Transfer Unit for all questions about the application procedure (transfer@nako.de).

3.2 Use and Access Committee (UAC)

(1) The Use and Access Committee is a committee established in accordance with § 9 (4) no. 5 of the NAKO e. V. Articles of Association to support the Board of Directors in reviewing Use and Access Applications. It assesses the Use and Access Applications received according to organisational aspects (feasibility), (data protection) legal and scientific aspects and then makes a recommendation (approval/revision/rejection) for the Use and Access Application. (For procedure see § 3.4.1 (1) to (6)) The UAC members are elected by the General Assembly on the proposal of the Board of Directors. Their term of office is four years. Members may be re-elected.

(2) The UAC shall hold regular consultations in accordance with the tasks assigned to it under this Use and Access Policy. Representatives of the Transfer Unit and the Central Executive Office can take part in the consultations. When applying for the use of Biosamples, a representative of the Biorepository or the Tumour Tissue Bank must be consulted. Other experts can be consulted for specific topics (e.g. persons responsible for the module of the MRI examination, representatives of the Competence Network for Secondary Data and Registry Data). The UAC will decide by a simple majority of its members. Each member of the UAC has the right to submit a resolution for revision to the General Assembly of the NAKO e. V..

3.3 Form and content of the Use and Access Application and the Notification of Use

(1) The Use of Data and the Use of Biosamples always require the approval of the NAKO e. V. and that a corresponding Agreement for Use/Access is entered into. There is a simplified Notification of Use procedure for using Data and/or Biosamples collected in the notifying party’s own study centre or from decentral Biosamples, (see § 3.4.2). 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 Use and Access Application and the Notification of Use must be submitted to the NAKO e. V. on the web portal of the Transfer Unit (https://transfer.nako.de/). In this context, the information relevant for granting approval pursuant to subsection 2 must be entered for Use and Access Applications. For Notifications of Use, the information relevant to granting approval pursuant to subsection 3 must be completed.

(2) The Use and Access Application must contain at least the following information:

a) title of the Project,
b) Project Participants,
c) function of the Project Participants,
(d) summary description of the Project,
(e) intended period of use,
f) objectives of the Project,
(g) scientific background,
(h) justification of feasibility,
(i) resources (material and human) available for implementation,
j) details on the Data and Biosamples (type/quantity of Data/Biosamples, if applicable, information on parameters to be determined from Biosamples, selection of participants and Biosamples, required amount of Biosamples and justification, method of analysis and information on whether the use is carried out in cooperation with external sponsors, e.g. from the private sector, or financed by an external cooperation partner),
k) generally comprehensible presentation of the Project and the objectives pursued for publication on the NAKO e. V. website.

(3) The Notification of Use must contain at least the following information:
a) title of the Project,
b) Project Participants,
c) function of the Project Participants,
(d) summary description of the Project,
(e) intended period of use,
f) objectives of the Project,
g) details on the Data and Biosamples (type/quantity of Data/Biosamples, if applicable, information on parameters to be determined from Biosamples, selection of participants and Biosamples, required amount of Biosamples and justification, method of analysis and information on whether the use is carried out in cooperation with external sponsors, e.g. from the private sector, or financed by an external cooperation partner),
h) generally comprehensible presentation of the Project and the objectives pursued for publication on the NAKO e. V. website.

(4) The basis for a Notification of Use is the existing Data Processing Agreement, which the NAKO e. V. has entered into with the respective study centre and in which the study centre concerned and its data processing bodies are specified.
(5) During the ongoing application process, certain changes to the application may be approved without resubmitting the application. For this matter, the applicant(s) must send a written request to the Transfer Unit. The Board of Directors or the Transfer Unit will decide on the request, if necessary, after consultation with the UAC. This concerns in particular the following points:

- including additional applicants from other institutions

- including additional variables if it is clearly evident that it was erroneous when the application was submitted or if more suitable variables have become available in the meantime

- change of Project Management to another institution

- assumption of the function of Project Management by another institution

This provision explicitly applies only to changes during the application phase; a contract amendment is required after the agreement has been entered into, even for minor changes (see § 4.4).

3.4 Application review

3.4.1 Use and Access Applications

(1) The Transfer Unit will forward the Use and Access Applications that are received to the Use and Access Committee.

(2) The Use and Access Committee will review the applications based on the following criteria:

a) identity and scientific reputation of the applicants,
b) conclusiveness of the scientific justification for the Project described (scientific concept including case number justification and analysis strategy),
c) coherence of the application with the scientific questions of the German National Cohort,
d) compliance with legal and ethical standards and the provisions of this Use and Access Policy,
e) whether the objectives of the application correspond to the participants' consent forms,
f) availability of a sufficient Data and Biosample pool,
g) whether the Data and Biosamples requested in the Use and Access Application correspond to the planned evaluations or analyses,
h) achievability of the objective of the evaluations or analyses with the resources described in the application,
i) whether the application is in line with the collaborative nature of the German National Cohort (preferential use of Data and Biosamples from participants from all participating study centres),
j) applicants who are association members, module experts and members of expert groups are given priority over external applicants,
k) if it is necessary to re-contact participants in order to implement the Project it may be appropriate and necessary to delay the project until the next scheduled wave of follow-up observations/examinations or to cooperate with other Projects where it is necessary to re-contact participants,
l) overlap with other Use and Access Applications (applied for, approved and completed) - the aim here is joint processing / mediating cooperation if several parties are interested in the same issue,
m) applicants have culpably and significantly violated this Use and Access Policy in a previous case.

(3) If use of Biosamples is requested, the following criteria will also be taken into account when assessing the request in order to optimally utilise the limited pool of Biosamples:

a) conclusiveness of the scientific justification for the use of the requested Biosamples, the choice of biomarkers to be analysed and the type of measurement method (including information on accuracy and precision of the measurement and validity and reliability of the biomarkers, if available),
b) relationship between the Biosamples to be provided and the scientific importance of the objective of the Use of Biosamples and the total amount of Biosamples available,
c) obligation of applicants to use Biosamples sparingly,
d) consideration of similar biomarker determinations that already exist and
e) minimisation of thawing and freezing cycles of the Biosamples.

(4) The Use and Access Committee will meet for consultation every four weeks to expedite processing of Use and Access Applications.

(5) After reviewing the application, the Use and Access Committee will electronically transmit one of the following recommendations to the Transfer Unit:

a) The application should be approved.
b) The application should be rejected.
c) Revision and resubmission.

If a basically positive recommendation requires modification, the Transfer Unit will request that the applicants revise and resubmit. After resubmission, the UAC will reassess and, where applicable, give a positive recommendation without restriction.

(6) The recommendation must be justified in each case, and any conditions or modifications that are required must be specified. The applicants have the right to be heard.

If the Use of Biosamples is approved, the UAC may ask applicants to collaborate with another Project or carry out the Project at a later date if more efficient Use of Biosamples can be achieved by doing so.

(7) The Transfer Unit will inform the Board of Directors, members of the NAKO e. V., coordinators of infrastructure units and competence units, module experts and spokespersons from the expert groups and their deputies electronically about a positive recommendation by the UAC without restrictions and, if applicable, about a negative recommendation (see subsection 11). For each application, this information is limited to the names and institutions of all applicants, title of the Project, Project Term and a summary of the Project.

(8) After sending the positive or, if applicable, negative recommendation from the UAC, any member of the NAKO e. V. can file an objection within a period of four weeks and request that the Use and Access Application is presented to the NAKO e. V. General Assembly for a decision.
The objection must be submitted in writing to the Transfer Unit in due time and must be substantiated. The Board of Directors will review the objection:

a) if the objection is admitted by the Board of Directors, 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. 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.

(9) The NAKO e. V. Board of Directors usually makes its decision on the Use and Access Application within two weeks after the deadline for objections has expired, if an objection is not received. In particular, the Board of Directors may request that several applicants working on the same or very similar issues cooperate on the issues and harmonise the methods used. If the Use and Access Application can only be approved subject to conditions or after certain modifications, the applicants will be asked to revise their Use and Access Application accordingly and resubmit it. The Board of Directors may invite external experts to the meetings.

(10) If an application is approved, the Transfer Unit will be instructed to handle further procedures. To increase the transparency of the approval process, approved Projects with Use of Data/Biosamples are published on the NAKO e. V. website with their current status (approved / expired / published) after Data/Biosamples have been transferred.

(11) The UAC will inform the applicants in the event of a negative recommendation, and they will be given the opportunity to withdraw the application. If the application is not withdrawn, the application procedure continues with a recommendation for rejection, as described under (7). If a Use and Access Application is then rejected by the Board of Directors of the NAKO e. V., the applicants may submit the application to the General Assembly of the NAKO e. V. for a final decision.

3.4.2 Notification of Use

(1) Notifications of use are submitted on the Transfer Unit web portal but, unlike applications, they are not reviewed by the UAC. The Transfer Unit forwards the notifications directly to the Board of Directors for review, which usually examines them, and where applicable, confirms them within a two-week period.

In the event of a confirmation, the notifying party will be informed accordingly, and any relevant conditions will be specified. The Data are then compiled by the data management of the Transfer Unit.

The notifying party will also be informed if a notification is rejected with a statement of the reasons for the rejection from the Board of Directors.

(2) The Board of Directors has the right to stop the transfer of Data for a Notification of Use for an indefinite period, e.g. if the majority of the board members are of the opinion that the matter should only be evaluated and published using the complete data set of all participants.
(3) Members of the NAKO e. V. are able to view all Notifications of Use. This access is limited to the names and institutions of all applicants, the title of the Project, the period of use and a summary of the Project for each notification.

### 3.5 Refusal to approve use

(1) Approval of use may be refused irrespective of the Project’s eligibility for approval if the Project Management or other Project Participants have culpably breached this Use and Access Policy to a significant degree in a previous case.

(2) A significant breach is deemed to exist in particular if

- a) the rights of use under § 2.3 have been disregarded,
- b) prior use exceeded the scope permitted under § 2.5,
- c) the reporting obligations under § 2.7 have not been fulfilled,
- d) the project results were not made available in accordance with § 2.8 or
- e) the Publication Policy was violated.

### 3.6 Agreement for Use/Access

(1) After the Use and Access Application has been approved, it is necessary to enter into an Agreement for Use/Access in order for Data and, if applicable, Biosamples to be transferred. In the Agreement for Use/Access, the Contractual Partners and the applicants undertake in writing to comply with the Use and Access Policy and the conditions.

(2) The Agreement for Use/Access includes the Use and Access Application as an annex and also specifies:

- a) the Contractual Partners,
- b) the duration of the Project (start and end are determined by the time of Data/Biosample transfer),
- c) the obligation to report and inform according to § 2.7 and to provide the Results Data according to § 2.8,
- d) the latest time for returning any unused Biosamples (is based on the time of the Biosample transfer)
- e) the latest time for deleting the transfer data (is based on the time of the Data transfer) and
- f) other requirements and conditions.

(3) The sample agreement to be used is available on the "NAKO TransferHub" web portal.
§ 4 Transfer of Data and Biosamples

4.1 Compilation and transfer of Data

(1) The set of variables in an application will not be finalised until after the application has been approved for data compilation to take into account any changed availabilities, etc. An updated application will be reviewed, approved and documented by the Transfer Unit, involving the Board of Directors and/or the UAC as appropriate, and will not require an amendment, if this has been agreed in the agreement.

(2) After the Agreement for Use/Access has been entered into the Transfer Unit will compile the data from the Research Database into one or more data sets in cooperation with the Integration Centre in accordance with subsections 2 to 5 below.

(3) After the current consent of the participants to the Use of Data has been verified, the Data is compiled in compliance with the Data Privacy Policy and § 2.2 (1+2) and § 2.4 (1).

(4) Data that identifies a person (e.g. names, addresses) will not be made available. All identifiers needed to link the Data are consistently replaced by project-specific pseudonyms. The link between the original identifiers and project-specific pseudonyms is stored in the Independent Trust Centre. The Users only receive pseudonymised data and do not receive allocation lists for the pseudonyms.

(5) The NAKO e. V. Board of Directors may decide on a two-stage data transfer for categories of Use and Access Applications or Notifications of Use in general, or in individual cases. The categories may be Use and Access Applications for e.g. image data (MRI, 3D echo), for Biosample analyses or geo-coordinates. During the first data transfer, the complex Data (DICOM images, geo-coordinates) or Biosamples are then transferred with a basic set of a few variables necessary for the evaluation. After the evaluation of these Data or analysis of the Biosamples by the Users, the Results Data must be transferred to the Transfer Unit and integrated into the Research Database. During the second data transfer, the Results Data are then transferred for use together with the requested study variables in a newly pseudonymised form.

(6) The technical details for the data transfer will be agreed upon by the Transfer Unit in consultation with Project Management. Every transfer of Data and Biosamples is logged.

(7) The provision of Data by the Transfer Unit will in most cases occur within 6 weeks after the agreement has been entered into, provided that the Data are available. For Notifications of Use, Data should be provided within 2 weeks.

4.2 Transfer of Biosamples

(1) In addition to the provisions under § 4.1, the following provisions apply to the transfer of Biosamples:

   a) The Transfer Unit will draw up a selection of the participants and the Biosamples to be removed from storage on the basis of the Agreement for Use/Access. The selection of participants/Biosamples is sent to the biorepository to ensure the availability of the Biosamples before the baseline dataset is finalised.
b) The Central Biorepository and the Tumour Tissue Bank will be instructed to carry out the transfer/dispatch of the Biosamples. The Biosamples will only be transferred/sent to the Biosample recipients (laboratories) specified in the Agreement for Use/Access.

4.3 Costs and fees

(1) Fees for costs incurred for the provision of Data and Biosamples may be charged based on a decision by the General Assembly.

(2) The Users will bear all shipping costs for items sent by post (e.g. on data carriers) or for transport of centrally stored Biosamples and all other costs incurred in connection with the transfer.

(3) Additional costs may be incurred for material or personnel at the participating institutions in connection with preparing and transferring the Data and Biosamples. Such additional costs are generally covered from resources from the Project requesting them. Further details will be regulated in the Agreement for Use/Access as necessary.

4.4 Subsequent changes to the Use and Access Application

If there are requests for changes to the application after the Agreement for Use/Access is entered into, the User can be granted an Amendment (see § 1 no. 12) on request. Such a request for Amendment must be addressed to the Transfer Unit. The decision will be made by the Transfer Unit or the Board of Directors, if necessary with the involvement of the UAC, as a rule within 4 weeks in the form of an approval or a rejection. If it is rejected, the reasons will be provided together with the decision. The result will be documented and communicated to the User by the Transfer Unit. Each approved Amendment becomes part of the Agreement for Use/Access as an addendum. This does not apply to revised sets of variables in accordance with § 4.1 (1).
§ 5 Contacting participants; identifying data

(1) The User and its staff, employees and representatives involved in the Project undertake to refrain from any attempt to contact the participants concerned whose Data and, if applicable, Biosamples they have received.

(2) It may be necessary to re-contact participants for the Projects, e.g. to collect additional data or obtain additional Biosamples. In order not to overburden the participants' willingness to participate, such Projects will be reviewed paying particular attention to the significance of the expected outcome of the research and the related effort for participants. As a rule, such Projects are classified by the association as Level 3 Projects and treated accordingly.

(3) Re-identification of the participants concerned (e.g. to enable re-contacting) may only be carried out by the Independent Trust Centre after this has been approved by the Board of Directors.

(4) Re-contacting the participants concerned will be carried out exclusively by the relevant study centre. However, this step can be combined with a request to participants for consent to sharing contact details with the User and being contacted by the User for the sole purpose of carrying out the approved Project.
§ 6 Liability

6.1 Liability of the NAKO e. V.

(1) Data and Biosamples may have inherent errors or damage. Biosamples can be infectious.

(2) The NAKO e. V. does not guarantee the accuracy of the Data or the suitability of the Data and Biosamples for the approved purpose.

(3) The NAKO e. V. is not liable for damage of any kind caused by working with the Data and Biosamples.

(4) The above limitations of liability do not apply to intent or gross negligence on the part of the NAKO e. V. Apart from intentional breaches of duty, the NAKO e. V. is not liable for indirect damage. The above limitations of liability also apply to the legal liability of the NAKO e. V. and the personal liability of its legal representatives, employees and vicarious agents.

6.2 Responsibility and liability of the data/Biosample users

(1) The Users are responsible for the Data and Biosamples provided. The Data and Biosamples must be saved and/or stored in such a way that third parties do not have unauthorised access to them.

(2) The User can transfer responsibility for the Project to one of the other Project Participants by mutual agreement.

(3) In addition, the User is required to immediately appoint a successor if the Project Management leaves their institution. The NAKO e. V. must be informed in writing without undue delay of any change in Project Management. The respective User is responsible for communicating this.

(4) The User is liable for all damage of any kind incurred by the NAKO e. V. caused by its members, employees or third parties during the use of the Data and Biosamples provided. Damage to the NAKO e. V. may arise in particular from unauthorised use or disclosure of Data and Biosamples and from violations of (data protection) legal regulations.

(5) The User must indemnify the NAKO e. V. against all claims of third parties which are raised against the NAKO e. V. or its members in connection with the use of the Data and Biosamples provided. This does not apply if the User is not at fault for the occurrence of the claim.

(6) The User must ensure that the persons working with the Data and Biosamples comply with this Use and Access Policy.
§ 7 Legal consequences of breaches

Withdrawal or restriction of the rights of use

(1) In the event of breaches of this Use and Access Policy or of the provisions of the Agreement for Use/Access or of conditions imposed on the Use of Data, the NAKO e. V. may revoke the permission to use granted to the User in whole or in part.

(2) This applies in particular, if (this list is not exclusive)
   a) the rights of use of the NAKO e. V. under § 2.3 are disregarded,
   b) use has exceeded the scope permitted under § 2.5,
   c) the reporting and information obligations under § 2.7 are not fulfilled despite a reminder to this effect,
   d) the Work Results are not made available in accordance with § 2.8 or
   e) the Publication Policy is breached.

(3) If permission to use is revoked, the use of the Data and/or Biosamples provided must be discontinued without undue delay or the Data must be deleted without undue delay and unused Biosamples must be returned in accordance with § 2.10 (2). Results Data must be sent to the Transfer Unit. Restrictions on the rights of use will be agreed by means of an addendum to the Agreement for Use/Access, which the user is required to enter into.

(4) Further claims of the NAKO e. V., namely in case of culpable violations by the Project Participant, remain unaffected.

(5) The decision on the restriction or revocation of the permission to use will be made by the General Assembly on recommendation of the Use and Access Committee.
§ 8. Final provisions

Entry into force and transitional arrangements

The Use and Access Policy was adopted by the General Assembly of the NAKO e. V. on 16 September 2022 and entered into force upon approval by the Joint Science Conference’s Expert Committee on 14 December 2022.

Disclaimer: This English translation of the NAKO Use and Access Policy is provided for informational purposes. The English text was translated and reviewed for accuracy. In the event that the English and German carefully versions permit different interpretations, the German text shall prevail.