

DANMARKS NATIONALE BIOBANK

Guidelines on access to biological material and data from
The Danish National Biobank, Statens Serum Institut

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How do I gain access to material in The Danish National Biobank?

This guide describes how Danish and non-Danish researchers may gain access to biological material and data from The Danish National Biobank. The guide thoroughly describes the terms and criteria for retrieval, as well as the legal backdrop for the process. In short, the process has 4 steps:

1. Apply for approval from a research ethics committee

2. Submit an application to Scientific Services at the Danish Health Data Authority

3. The application is assessed by the DNB Scientific Board

4. Samples are handed out

1) In order to gain access to biological material, the project must be approved by a Research Ethics Committee (REC). It is a requirement of Danish law that all health science research projects that comprise human biological material have obtained such approval. Furthermore, the project must have been approved by the Danish Data Protection Agency or produce documentation that the project forms part of a local joint notification (umbrella notification).

2) Once the approval has been obtained, the project may apply via Scientific Services (Danish: Forskerservice); the joint Danish port of access to biological material and data under the Danish Health Data Authority. The application will then be forwarded to the Coordinating Centre at the Danish National Biobank, which will process the case. In addition to the approval of the REC and, where relevant, of the Danish Data Protection Agency, the project must submit a completed application form, a project description and a description of the data material needed.

3) All applications received are processed by the Scientific Board of the Danish National Biobank (DNB). The Board consists of the following members: Two persons appointed by SSI, including the Chair, one person appointed by the Council for Independent Research in Medical Science, one person appointed by Danish Regions, and one person nominated by the association Danish Patients. The Board assesses the applications in the order they are received and aims to answer the researcher within 30 days after receipt of a full application.

4) The terms of the hand-out are agreed upon, the samples are retrieved and handed out.

On the following pages, these procedures are described in further detail, but do also feel free to contact the Coordinating Centre directly for more information, advice and guidance at mail@nationalbiobank.dk or by phone +45 3268 9163.

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1. Purpose

The purpose of the collection of biological material in the Danish National Biobank (DNB) at Statens Serum Institut (SSI) is to strengthen the Danish research infrastructure and contribute to outstanding life science-based research and international research collaborations.

The fundamental principle is that biological material shall be available for research purposes on equal terms and without compromising the legal rights of any individual person.

The DNB contains biological material of three main types:

- a) Samples that fall under SSI's responsibility and decision-making competence (among others diagnostic samples submitted to SSI, including filter-paper blood samples from the screening of neonates for congenital conditions (PKU cards) or from research projects that donate samples to the DNB).
- b) Samples from other parts of public Danish healthcare that have been passed on/transferred to SSI's responsibility and decision-making competence.
- c) Other samples, i.e. samples that are stored at SSI on behalf of other stakeholders, including samples from large, specific research projects. It is a prerequisite for the storage of this type of samples in the DNB that samples be made widely available for research purposes.

In the case of samples covered by point (a) and (b) above, researchers may apply to the Coordinating Centre at the DNB to gain access.

With respect to samples covered by point c, the Coordinating Centre provides advice, upon agreement. The external biobanks that collaborate with the DNB include, e.g., the Danish Cancer Society (The cohort Diet Cancer and Health and the cohort Diet Cancer and Health - Next Generations), Copenhagen Studies on Asthma in Childhood (COPSAC), etc.

The DNB thus consists of a wide range of different types of biological material collected for different purposes; and for each collection, handing over of the material may be further regulated.

This guide initially describes the main principles that govern the work of the DNB and then the procedures relating to access to material via an application form.

2. The legal basis for access to biological material in the DNB

SSI is a public authority that is subject to a number of statutory provisions when handing over material from the DNB, including the Danish Health Act, the Danish Public Records Act, the Danish Public Administration Act and the Danish Act on Processing of Personal Data.

The basic public administration tenets of a *sound and proper administration*, *equality* and *proportionality* also apply to SSI's handing over of data when this occurs as part of its income-generating activities.

The Danish Public Administration Act's provisions on incompetence also apply to authorities' processing of cases about the establishment of contractual relations or similar private law dispositions, cf. the Act's Section 2, Subsection 2. SSI's processing of requests for the handing over of data from the DNB is thus also subjected to these provisions.

As SSI's supervising unit, the Danish Ministry of Health holds a non-statutory duty to supervise the handing over of data from the DNB. This duty is derived from the common principles of public and administrative law. The duty of supervision applies to general administrative issues in the area, but also to questions relating to the legality of SSI's administration in specific cases.

Even so, the assessment of a request for handing over of material from the DNB is not a decision in the sense described in the Danish Public Administration act, and applicants therefore do not have a right to lodge complaints. Nevertheless, it is assumed that the non-statutory duty of supervision of the Ministry of Health means that the Ministry has the right to make non-binding declarations ascertaining if general decisions and decisions made in specific cases abide by current law.

2.1 The Danish Act on Processing of Personal Data

The Danish Act on Processing of Personal Data is the main law governing how and when personal information may be processed. The Danish Act on Processing of Personal Data applies to private companies as well as public authorities.

As a main rule, the Danish Act on Processing of Personal Data applies to all electronic processing of personal information, and to any manual processing of personal information kept in a register.

It is the assessment of the Danish Data Protection Agency that not only the data part but also the physical part of a biobank are covered by The Danish Act on Processing of Personal Data, as collections of human biological material may be considered to fall under the Personal Data Processing Act's definition of a manual register, cf. Section 1, Subsection 2 of the Personal Data Processing Act.

The Danish Data Protection Agency supervises any processing comprised by the Act, cf. Section 55 of the Danish Personal Data Processing Act.

Section 5, Subsection 2 of the Danish Act on Processing of Personal Data establishes that collection of information shall be done for explicitly stated professional purposes, and that any subsequent processing shall be in line with the originally stated purposes. Subsequent processing of information for historical, statistical or scientific purposes exclusively is not considered incompatible with the purposes for which the information was originally collected.

The requirement that collection of information must be done for explicitly stated and professional purposes and that any subsequent processing may not be incompatible with the original purposes is known as *the principle of purpose* (or principle of finality). In accordance with this principle, the institution responsible for the data must always establish for which purpose(s) the data are collected.

The requirement that the data collection must be explicit means that the institution responsible for the data must state a data collection purpose that is adequately defined and delimited.

It follows from Section 5, Subsection 3 of the Danish Personal Data Processing Act that the information processed must be relevant and sufficient and may not include more detail than is required to fulfil the purposes for which the information is collected and the purposes for which the information is subsequently processed.

The terms “relevant” and “sufficient” ensure that the types of information collected match the purpose of the data processing. In addition, the requirement that data must be sufficient shall be understood in conjunction with the second part of the provision, which establishes that the processing of information by the institution responsible for the data must adhere to the principle of proportionality. The processing of the information may thus not exceed the authority vested in the institution responsible for the data concerning the purposes for which the data are used, cf. also the above described content of Subsection 2.

SSI’s registers contain sensitive personal information, e.g., about health-related conditions. It follows from Subsection 7, Subsection 1 that, as a rule, such sensitive personal information may not be processed.

According to Section 10, Subsection 1, sensitive personal information may, nevertheless, be processed if this occurs exclusively to perform statistical or scientific studies of considerable social importance, and if the processing is necessary for the completion of the studies.

Furthermore, it follows from Section 10, Subsection 2 of the Danish Personal data Processing Act that the information described in Subsection 1 may not subsequently be processed for other than statistical or scientific purposes. The same applies to other information that is collected for statistical or scientific purposes exclusively, cf. Section 6.

Additionally, it follows from Section 10, Subsection 3 that the information comprised by Subsection 1 and Subsection 2 may be passed on to third parties only following authorisation from the Danish Data Protection Agency or if documentation is present to show that the information forms part of a joint notification/umbrella notification. The Danish Data Protection Agency may define additional requirements for the passing on of information.

If the recipient wants to pass on the information, SSI shall be informed hereof. SSI can determine that the information may not be passed on by the recipient.

3. General terms

To ensure that current provisions in the field are met and to maintain the population’s support for the biobank, SSI has established the following practice and criteria that apply for access to data as well as to biological material in the DNB.

3.1 The DNB’s access to pass on information in pursuance of the Danish Act on Processing of Personal Data

As the institution that is responsible for the DNB (both the data part and the physical part, i.e. the biological material), SSI may grant access to the DNB for research purposes. As described above, it follows from the provisions of the Danish Personal Data Processing Act that access may be granted if this occurs exclusively to

perform statistical or scientific studies of considerable social importance, and if the processing is necessary for the completion of the studies, c.f. Section 10, Subsection 1 of the Danish Personal Data Processing Act.

Access to data/biological material is thus granted in accordance with the “need to know” principle, i.e. access is only given to the data/biological material required for the purpose in question. Any researcher applying for access to data/biological material shall therefore document that the requested data/biological material and the project description are proportionate.

3.2 Research Ethics Committee

When a project includes human biological material, an approval shall be obtained from a research ethics committee (cf. Section 13 of Act no 593 of 14 June 2011 on Scientific Ethical Processing of Health Science Research Projects).

As from 15 May 2012, private health science research projects that require notification to the research ethics committee system no longer need to be notified to the Danish Data Protection Agency¹. Regardless hereof, the Danish Act on Processing of Personal Data must still be observed.

Therefore, handling of sensitive personal information in health science research projects are exempt from the requirement of notification to and obtaining of approval from the Danish Data Protection Agency provided the project is covered by Act on Scientific Ethical Processing of Health Science Research Projects and has obtained an approval from a research ethics committee. Exemption from notification applies only to projects undertaken for a private unit responsible for data. Public projects must always be notified to the Danish Data Protection Agency.

3.3 Approval by the Danish Data Protection Agency

As described above, it is a prerequisite that the applicant obtains an approval from the Danish Data Protection Agency or presents documentation that the project forms part of a joint notification before SSI can pass on sensitive personal information to a public research project, cf. Section 10, Subsection 3 of the Danish Personal Data Processing Act.

The approval from the Danish Data Protection Agency or the joint notification specifies the conditions under which data may be processed. Only when the Danish Data Protection Agency and/or a research ethics committee has/have authorised the project may the DNB allow the researcher to receive the data/biological material.

3.4 Criteria for the assessment of applications

Section 5.1 of “Governance for the retrieval of biological material and data from the Danish National Biobank” specifies the following overall principles for the DNB Scientific Board’s assessment of handing over of data:

- The material shall only be handed over to researchers at a Danish public research institution responsible for data or to researchers at a Danish-established and non-commercial data responsible research and analysis setting that complies with current statutory provisions.

¹ Executive Order no. 410 of 9 May 2012 on the change of Executive Order on Exemption from the Duty of Notification of Certain Processes Performed for a Private Data Responsible Unit.

- The material in the DNB represents an unquestionable research value that should be exploited maximally to achieve social benefit.
- Researchers from abroad who collaborate with a Danish institution responsible for data, either as part of a public research institution or an established non-commercial research and analysis environment, may gain access to material from the DNB. Likewise, Danish and foreign companies that collaborate with a Danish institution responsible for data, i.e. a research institution of an established non-commercial research and analysis environment, may gain access to material from the DNB.
- Material from the DNB, including residual material that remains after a project has been concluded may not be used in new biobanks. The DNB lets the researcher receiving the material know if any residual material needs to be destroyed or returned to the Biobank.
- Research projects that are granted access to material from the DNB shall be of a high scientific quality. Due to the - in some cases - very limited material in the Biobank, the decision includes an assessment of whether the amount requested is necessary and if it may be reduced, or if the request should be denied completely due to scarcity of material. In the assessment hereof, the relevance of the research project is also considered (generation of new knowledge) and the overall social importance of the project.
- Some of the material in the DNB was collected with a specific objective in mind, and this needs to be kept in mind during the process leading to a recommendation with respect to access to the material. This includes, e.g., PKU cards that are collected for diagnostic purposes and to improve quality assurance and further development of neonatal screening. Therefore, handing over of PKU card material is possible only if sufficient material will remain for these purposes.
- A quarterly list will be published detailing the cases processed about handing out of health data from the DNB.
- The Strategic Alliance for Registry and Health Data (Danish abbreviation: STARS*) is included in the overall service provided by the DNB, including response times.

Furthermore, the DNB Scientific Board processes applications on the basis of the following criteria:

- The authorisation from a research ethics committee and from the Danish Data Protection Agency or a joint notification (if relevant) generally remains valid for two years from the request for biological material is received. This minimum duration serves to ensure that data/biological material can be processed and analysed.
- The authorisation from the research ethics committee and/or the Danish Data Protection Agency on the one hand, and the application submitted to the DNB on the other, shall concur with respect to the institution responsible for the data, data processors and institutions and addresses where data/biological material is stored and processed.
- There must be a meaningful correspondence between the project's title and purpose in the application that sent to a research scientific committee and/or the Danish Data Protection Agency and the submitted project description.
- The project description and the description of the data extraction shall be sufficient, i.e., it shall be possible to assess if the project meets the requirements of Section 10 of the Danish Personal Data Processing Act. Thus, there must be sufficient information available for the DNB to assess if the

project is conducted for scientific study of substantial social importance, and if the processing of biological material is necessary for the completion of the project.

- Applications for samples that would be used in research projects that may potentially compromise the Danish population's acceptance of the sample collection or SSI's diagnostic activity when the collection is established may either be rejected, or a request may be made that the application is modified.

The DNB may need to obtain additional information to establish if passing on of information is justified. Thus, the applicant may, for instance, be asked to submit a supplemental project description or a more detailed description of the reason why the project requests certain items of information.

3.5 Application for access to biological material

Applications for access to biological material are submitted electronically via Scientific Services at the Danish Health Data Authority. There is a direct link to Scientific Services (Forskertjeneste) at the DNB's web site. The application is then forwarded to the Coordinating Centre at the DNB. Applications are received at any time and are processed in the order they are received.

An application for biological material to the DNB must always include:

- A completed application form, which can be downloaded from the website of Scientific Services.
- A full project description, including:
 - A description of the planned analysis, information detailing at which laboratories the work will be done, a time schedule and details of project funding.
 - In case only very limited amounts of the material are available, a motivation explaining why it is necessary to use the requested sample material rather than alternative, more readily available samples/resources.
 - Documentation that the project group is capable of performing the planned analyses on the requested sample material (e.g. filter-paper blood samples) and argumentation to show that the analytical precision is sufficient to elucidate the biological question.
 - Information about where the analysis data will be stored during the entire project period.
- Application to and approval from a research ethics committee.
- Application to and approval from the Danish Data Protection Agency or a joint notification, if applicable.
- Description of the sample material. A report from the National Biobank Register may be included.

3.5.1 Requirements related to changes and amendments to the project

Researchers who wish to change or add something to their original protocol (e.g. add analyses or methods that do not change the original purpose of the study or request additional biological material) shall submit a supplementary application and update the project description and the description of the sample material needed to the Coordinating Centre and present a new approval from a research ethical committee. The DNB Scientific Board will then, cf. Section 3. *General terms*, assess whether the changes to the project may be implemented.

3.6 Terms related to the handing over of biological material

Researchers who apply for biological material with the DNB may be classified into five groups:

- a) External collaborators who request the handing over of own samples
- b) Researchers at a Danish public institution responsible for data or researchers at a Danish-established and non-commercial data responsible research and analysis setting (non-commercial)
- c) Researchers from abroad who cooperate with a Danish institution responsible for data, which is covered by the definition in point b. (non-commercial)
- d) Privately owned Danish companies who cooperate with a Danish institution responsible for data, which is covered by the definition in point b. (commercial)
- e) Privately owned foreign companies who cooperate with a Danish institution responsible for data, which is covered by the definition in point b. (commercial)

Biological material and associated data must not be shared with third parties unless this is stated in the application. Such passing on is subject to permission from SSI.

For a) Danish researchers who apply for the handing over of their own samples are defined as active biobank collaborators. For example, if the Danish Cancer Society requests access to its own samples, it would be an active biobank collaborator. This group does not need to apply via Scientific Services to obtain access to their own samples, and handing over also does not require processing in the DNB Scientific Board.

For b-e) The applying researcher may freely employ the biological material within the boundaries established by the approved research protocol. The definition in point b covers (among others) researchers at universities and hospitals, non-profit research institutions (e.g. the Danish Cancer Society), GPs and patient associations. In cases in which the biological material was derived from an external biobank, the researcher shall respect the original purposes for which the samples were collected and discuss any overlapping uses of the material with the principal investigator in advance. Furthermore, the researcher has a duty to acknowledge the work of the principal investigator in their work. The DNB encourages the establishment of collaborations between applicants and principal investigators to optimise the use of the resources as much as possible. The Coordinating Centre will gladly help establish contact between the two parties.

3.6.1. Requirements for comprehensive genome analyses and data

To ensure the safety of personally identifiable data and the Danish population's support to the Biobank, enhanced requirements apply to whole-genome analyses and data derived from such analyses.

The laboratory performing the analysis shall, to the extent possible, be located in Denmark or in a country with similar data safety standards (in accordance with the EU provisions on data processing).

Data must be transferred as quickly as possible to a secure server in Denmark with which SSI entered into a data processing agreement and shall then be deleted at the analysis laboratory. With respect to data from, e.g., the neonatal PKU sample collection (Danish Neonatal Screening Biobank), data may be hosted at Computerome with the Technical University of Denmark (DTU), in collaboration with SSI. Advanced remote access makes it possible for the project participants to perform all relevant data analyses.

3.6.2 Protection of anonymity

The receiving researcher must not attempt to identify individual persons from the data sets or from the submitted biological material. If the researcher has inadvertently identified an individual, this must not be recorded or shared with other persons, and the individual person in question must not be contacted.

If the researcher identifies a result of considerable importance for an individual's survival, disease course or quality of life, the DNB recommends that the researcher makes use of the Danish research ethics committee system to determine if the person should be contacted.

3.6.3 Protection of Intellectual Rights (IR)

SSI or external collaborators with copyright will always remain responsible for any databases and biological material, and primary data may not be patented without DNB approval. Beyond this, SSI will not claim any inventions/technologies that were developed on the basis of the resources of the Biobank.

SSI is the owner of the database and the biological material in the DNB (barring material from external partners), which will be updated and added throughout the life of the Biobank. Researchers are granted limited access to the Biobank's data and material - and not ownership rights. These rights allow them to use the material to conduct research in accordance with the approved protocol for a limited period of time. These rights may not be assigned, transferred, or passed on to any third party.

3.6.4 The return of surplus material

All surplus sample material and derived products, e.g. replicated DNA, must be returned to the DNB no later than 6 months after the end of analysis work. The returned samples must be identified unambiguously and be accompanied by a description detailing how the sample material was treated and stored. The DNB may also require that the material be destroyed. The receiving researchers must inform the Coordinating Centre in writing that all material has been either returned or destroyed.

3.6.5 The return of research results

As a prerequisite to the passing on of material from the DNB, it may be required that any data derived from the biological material are transferred (passed on) to the DNB upon the DNB's Scientific Board's recommendation. In such cases, the applicant must obtain an approval from the Danish Data Protection Agency or a joint notification to hand out the data in question, and said authorisation must be obtained and submitted to the Coordinating Centre before the biological material can be handed out. Depending on the type of character, the Coordinating Centre will draw up a contract with the applicant that establishes an exclusivity period, typically 1-2 years after the data have been produced, before the data may be made available to other research projects while meeting any other current provisions. Only in exceptional cases will exemptions be made that affect the length of the exclusivity period. Data derived from biological material from the Biobank may only be handed out if an authorisation for such purpose was given by the Danish Data Protection Agency.

3.6.6 Publications

The main applicant has a duty to inform the Coordinating Centre if a publication is expected to trigger controversy or in any other manner attract substantial public reactions. All publications must contain the following text under 'Acknowledgements': "This research has been conducted using the Danish National Biobank resource, supported by the Novo Nordisk Foundation, grant number 2010-11-12 and 2009-07-28" and a link to the article shall be shared with the DNB.

3.6.7 Communication

The titles of the project that have been completed are published on the DNB's communication platforms along with a summary of the protocol written in layman's language, a summary of the research results and

links to any related publications. It is the responsible researcher's task to provide this information. Contact information on the main applicant for each study made is provided by the Coordinating Centre as requested.

3.6.8 Withdrawal of approval to use biological material

In the event that the approval to use a single individual's biological material for research purposes is withdrawn, the receiving researchers are informed of this and asked to destroy any unused material and to verify in writing that this has been done. Researchers are not required to delete results from samples that have already been used. Withdrawn samples are not refunded.

3.6.9 Sanctions in case of breaches of the terms

Violation of the above terms will result in immediate exclusion from the use of the DNB.

Nevertheless, the DNB will make a specific assessment in each case of the severity of the breach. Thus, milder cases may trigger a written warning, as is also the case when the DNB assesses that a risk of a breach has been observed. In the case of repeated infringements which have been addressed by written warnings, the sanction is exclusion.

Furthermore, the researcher will be excluded from using the DNB in the future. In milder cases, however, following specific assessment, the researcher will be excluded from using the DNB temporarily for a period of no less than 3 years.

3.7 Terms of delivery and service

3.7.1 Prices

The DNB is partly funded by the Ministry of Higher Education and Science, the Novo Nordisk Foundation and the Lundbeck Foundation, partly by income-generating activities. The prices for passing on data and biological material from the DNB are established in pursuance of the Danish state's provisions on income-generating activities.

Thus, an amount is paid to the Coordinating Centre for the processing of the case and to the Biobank's laboratory, and the amount depends on the hours spent and the size and type of project.

3.7.2 Contract between the researcher and the DNB

Before any biological material is handed over, a project specification and a provisional quote will be prepared. The project specification details the price and also describes precisely how the samples will be made. The description is an interpretation of the sample description that the researcher has submitted, and frequently the preparation of the project specification will include dialogue with the researcher to determine any delimitation, etc.

The project specification and quote must be accepted in writing.

If the project specification and quote are not accepted, the researcher and the DNB may enter into a dialogue concerning possible changes and amendments to the samples extracted, and a new project specification and quote will then be issued. Next, an agreement will be prepared describing which biological material the access covers, based on the latest project specification that the researcher has received and observing the

provisions of the Danish Personal Data Processing Act as described above. The final price can be determined only once the sample hand-out has been completed.

3.7.3 Assessment period

The application will be assessed by the DNB, and the aim is to send out a decision per mail to the main applicant within 30 working days after the DNB receives the application from Scientific Services. In cases in which an application covers both register data and biological material, the application will follow two tracks; one with Scientific Services assessing the data application and another with the DNB assessing biological material. If the two elements are not mutually dependent, decisions will be sent out separately by the two institutions directly to the researcher. In cases in which handing over of biological material requires a prior data extraction from Scientific Services, the DNB awaits the description of the samples needed before initiating the case processing relating to the handing over. The processing time will therefore be min. 2 months. In case of very complex projects with multiple inter-dependencies, where multiple questions may require clarification, the processing time may be longer.

Working days are to be measured as the time DNB can actually work on the application. Weekends and holidays do not count as working days. This also applies to the time that passes while the DNB awaits documentation or responses from applicants for clarifying questions.

How long it takes to get permission to access biological material in each individual project depends on the following:

- If the application from the onset includes an approval from a research ethics committee, if relevant from the Danish Data Protection Agency, or if documentation is present to show that the project forms part of a joint notification, project description and description of the needed samples and if these are adequate.
- If the sample material requested is stored in an internal or an external sample collection. Approval for retrieval from external sample collections is passed on by the Coordinating Centre to the relevant collection's steering committee, which typically takes 1-2 months. The DNB, however, cannot guarantee a specific response time for external collections.

Once the DNB Scientific Board has approved the project, the main applicant will receive the following documents for signature:

- The DNB's contract for access to biological material (project specification and quote)
- The DNB's guidelines on access to biological material

Upon receipt of the signed documents, the Coordinating Centre will place an order for the project with the DNB's laboratory, which will then retrieve, process and ship the material as specified in the contract.

3.7.4 Shipping of biological material

Biological material can be cooled down and sent by freighter to the person stated in the contract. Any related data will be sent by encrypted email.