Access Policy

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1 Overview of the access procedures

1.1 Collaborative Biobank Access Policy

The Collaborative Biobank (CoBi) adheres to ethical and quality standards at every stage, including its establishment, maintenance, and the use of its resources, as detailed in the protocol of the biobank.

The Collaborative Biobank is designed to provide long-term resources for future research projects with the following objectives (Research Framework): (1) to serve as a resource for studies that advance the prevention, diagnosis, and treatment of blood cancer; (2) to conduct research focused on improving the outcomes of hematopoietic stem cell transplantation; and (3) to refine donor selection for allogeneic transplantation. Medical investigators, or their designees, who apply to use samples and data from the Collaborative Biobank are required to submit written information detailing their research projects.

1.2 Objective of the Access Policy

The purpose of this Access Policy is to provide detailed and structured information on modalities and requirements for access to the samples and data (including medical data, sample information, and analysis results) in order to facilitate and maximize their utility for research. All decisions to grant access must consistently uphold the commitments made to participants (patients and stem cell donors) when they provided consent to participate in the Collaborative Biobank.

The procedures outlined in this Access Policy are designed to be clear and transparent. They are implemented with a focus on proportionality, accountability, and fairness, ensuring that all access requests are handled consistently and in alignment with ethical and legal standards.

2 Access to the Collaborative Biobank

2.1 Publicly available information

To ensure transparency, all necessary application documents (see paragraph 4.1) are accessible on the website of the Collaborative Biobank. Medical investigators, or their designees, are advised to apply for a Feasibility Check as an initial step to obtain detailed information about the available biobank resources (see paragraph 3).

Importantly, there will be no restrictions on the number of researchers granted access to the available samples and data from Collaborative Biobank. This open-access approach is intended to foster diverse analytical methods and interpretations of the samples and data.

2.2 Collaborative Biobank resources: Sample material

The Collaborative Biobank contains genomic DNA samples, plasma and viable cells from both, patients and stem cell donors. For genomic DNA, the following quantities can be provided: 100, 500 or 1000 ng. Routinely genomic DNA is provided in a total of 50 µl TE buffer (10 mM Tris, 1 mM EDTA pH8). If other buffers (e.g. ddH_2O) are preferred, this needs to be specified in advance on the access application form (AAF, see paragraph 4.1). Samples of viable cells from peripheral blood will be provided in quantities of about 5 x 10^6 mononuclear cells, or 2.5 x 10^7 mononuclear cells originating from PBSC collection, while plasma samples will be supplied in volumes of 200 µl.

2.3 Collaborative Biobank resources: Data

2.3.1 Medical data

The Collaborative Biobank provides medical data of patients treated with a hematopoietic stem cell transplant, including information on factors such as the indication, patient characteristics, treatment, donor type, and stem cell source.

2.3.2 Analysis data

Analysis data includes information generated from the analysis of samples, as well as data resulting from prior research projects. Depending on the contractual agreement with the medical investigator or their designee, data from any research project previously conducted using Collaborative Biobank resources may be accessible. This data could encompass various types of genetic and sequencing information, such as those obtained from targeted gene sequencing.

3 Feasibility Check

The Feasibility Check provides information on the availability of Collaborative Biobank resources. Currently, an informal research request should be sent via E-Mail to kontakt@cobi-biobank.de to obtain that information. Prospectively researchers may use a web-based open-access Availability Tool for the Feasibility Check. There will be possibilities to specify data or samples of interest by type and/or characteristics, e.g. age-range, gender, diagnosis, treatment, and type of transplant. Depending on the results of the Feasibility Check researchers may decide to formally apply for access to samples and/or data using the Access Application Form (see paragraph 4.1).

4 Access Application and Approval Process

All submitted applications are subject to a standardized approval process. This process includes a review to ensure compatibility with the Research Framework (see paragraph 1.1) and an assessment of the feasibility of the research project (see paragraph 3). Importantly, there is no preferential or exclusive access granted to any application, ensuring fairness and equal opportunity for all researchers.

The approval process of export requests consists of up to six steps.

4.1 Access Application Form

The formal export application starts with the submission of an Access Application Form (AAF) which is available via the website of the Collaborative Biobank. The Access Application Form should be completed, signed by the the medical investigator or their designee (hereafter named applicant) and all relevant documents (mentioned on the AAF) should be submitted together with the form. The applicant must justify the use of samples and data, specify which analysis will be performed, indicate statistical considerations, and must expand on the medical implications and scientific objectives of the proposed project.

The following information must be submitted with the Access Application Form:

I. A summary (200 words or less) of the research project, including an explanation of how it aligns with the Research Framework of the Collaborative Biobank (see section 1.1);

II. An Ethical approval letter of the responsible institutional review board (ethical review) for the research project or statement, why no ethical approval is required;

III. The research protocol; including the cohort of interest, specifications regarding samples or data to be requested, planned analyses and statistical considerations

IV. If applicable, Information addressing data security and privacy in the research project.

The completed form and all related documents should be sent to the Collaborative Biobank team via e-mail (kontakt@cobi-biobank.de). Once this is done, the internal approval process starts.

4.2 Completeness check

First, the submitted documents will be checked for completeness. This review will take place within a week and the applicant will be notified if any mandatory documents are missing. If all required documents are provided, the application will automatically move on to the next steps.

4.3 Ethico-legal review

The application will be reviewed and with respect to the following questions within two weeks. If any clarifications are needed, the Collaborative Biobank team will reach out to the applicant.

I. Does the project align with the Research Framework of the Collaborative Biobank?

II. Is an approval of the responsible institutional review board (ethical review) for the research project available?

III. How will data privacy issues be ensured?

IV. Is the research project commercially funded?

4.4 Data quality review

The data quality review will be conducted by the responsible Data Managers of the Collaborative Biobank team. Based on the applicant's search query, the Data Managers will extract information from the CoBi database. Additional variables will be derived from the extracted information, and analysis datasets will be created. The availability and data quality of the requested data will be assessed including the check for incomplete, inconsistent, incorrect and implausible data within the analysis datasets. This review will be shared with the applicant and included in the scientific review, if applicable.

This step will be completed within two weeks, running concurrently with the ethico-legal review (see paragraph 4.3).

4.5 Scientific review

In the fourth step, research applications will be evaluated by the Scientific Committee of the Collaborative Biobank in terms of medical and scientific merit. The committee shall review the application within four weeks, or up to eight weeks if further clarification is required. In the event of open questions, the casting of votes for a decision can be put on hold.

4.6 Response to the access application

Once the main review is completed, the Collaborative Biobank team will communicate one of the following outcomes to the applicant:

I. Approval, including the assignment of a CoBi project number;

II. Conditional approval, pending responses to outstanding questions. In this case, the Application process will be put on hold;

III. A preliminary rejection, accompanied by a summary of the reviewer's concerns, typically determined by the Scientific Committee. The applicant may then choose to:

   i. provide clarifications or amendments to the application;

   ii. withdraw the application; or

   iii. request reconsideration of the decision.

4.7 Transfer Agreement

All approved research projects require the conclusion of a Transfer Agreement. While specific details related to the research project may vary, all standard contractual terms are non-negotiable. Timelines for the provision of data and materials will be defined in the agreement.

As a condition for obtaining generic approval for the use of both samples and data, the Collaborative Biobank has made certain commitments, and in turn, requires equivalent commitments from all researchers through the signing of Transfer Agreements. If the application is approved, the draft of the Transfer Agreement will be sent to the applicant for review by their institution.

Collaborative Biobank samples and data may only be used for own non-commercial purposes, by all parties (including collaborating partners, DKMS and applying researchers). Applicants are not permitted to transfer the samples to third parties unless explicitly stated in the Transfer Agreement.

The Transfer Agreement must be signed by authorised representatives of both parties before the requested resources can be provided. Besides shipping costs, charges for the access to samples and data will only apply, if additional material processing steps are required.

4.8 Reconsideration of applications

If an applicant is advised that the Collaborative Biobank administrative team is minded to reject an application, they may request reconsideration.

The process for requesting reconsideration is as follows:

I. Within one month of the decision, the applicant should submit a written request outlining the reasons why the decision should be revised.

II. Within one month of receiving the request, the Scientific Committee will aim to review it alongside the original application. The Collaborative Biobank administrative team will then communicate the outcome to the applicant,

III. If the application is rejected following reconsideration, resubmission of the same proposal will not be accepted again.

5 Transfer of samples and/or data

5.1 Provision of samples

In general, samples are provided with a non-traceable code to ensure data privacy and prevent personal identification. Samples will be delivered to the applicant as follows:

I. The applicant will be notified when the requested samples are ready for shipment. They will also receive an invoice for shipping costs and any additional material processing fees, if applicable.

II. The applicant must inform the Collaborative Biobank team of the preferred delivery date and the destination address.

III. The shipment will be carried out by by an approved third-party courier;

IV. Upon receipt of the samples, the applicant must confirm delivery to the Collaborative Biobank team within one working day.

Residual samples must be destroyed at the end of the research project.

5.2 Provision of data

Data from the Collaborative Biobank can be provided in formats such as *.csv, MS Excel, or SPSS.

Similar to the samples, data will be delivered with a non-traceable code, ensuring that only double-pseudonymized information is shared. This ensures robust data privacy, making personal identification virtually impossible.

6 Transparency and publication

The Collaborative Biobank is committed to transparency and makes information widely accessible, including open-access publications and reports on its website.

After the completion of research, a summary of the research project (excluding confidential details) will be published on the Collaborative Biobank website. This summary will outline the purpose and use of the biobank resources, providing insights for collaborating partners and the public.

The applicant or their designee is strongly encouraged to publish findings derived from the Collaborative Biobank in academic journals or on open-access platforms within 24 months of project completion. Links to these publications will be featured on the biobank website.

All publications should include the following acknowledgement:

‘‘*This research has been facilitated by the Collaborative Biobank (www.cobi-biobank.com).*’’ The website link should be included and, if possible, tagged for search optimization.

While prior approval of publications by the Collaborative Biobank team is not required, the applicant or their designee is encouraged to share copies of publications for knowledge sharing.

Within six months of publication, the applicant must provide agreed-upon parts of the research results and analysis data in a suitable format for upload into the Collaborative Biobank.