Access Policy

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1 Overview of the access procedures

1.1 Collaborative Biobank Access Policy

The Collaborative Biobank will operate under ethical and quality standards during its creation, maintenance and use of resources, as outlined in the protocol of the Collaborative Biobank.

The Collaborative Biobank is intended to be a resource to support research projects which should meet the following objectives: (1) to serve as a resource for research projects intended to improve prevention, diagnosis and treatment of blood cancer; (2) to conduct research aimed at improving the outcome of haematopoietic stem cell transplantation, and; (3) to improve donor selection for allogenic transplantation. The Principal Investigator (PI), who applies for samples and data use from the Collaborative Biobank, will be asked to provide written information on the research project.

1.2 Objective of the Access Policy

The intention of this Access Policy is to facilitate access to the samples and data (such as medical data, sample data, and analysis data) to permit the widest possible usage.

At all times, decisions to grant access must fulfil the commitments made to participants (patients and donors) when they gave consent to take part in the Collaborative Biobank.

It is intended that the procedures of this Access Policy are clear and transparent, and are implemented in a manner which is proportionate, accountable and fair.

2 Accessibility to the Collaborative Biobank

2.1 Publicly available information

To guarantee transparency, all necessary documents for application will be available on the Collaborative Biobank website. To receive detailed information about the Biobank resources, the PI should make a sample feasibility check first (see paragraph 3).

The level of scrutiny used to assess applications will be proportionate to the nature and scale of the research project. There will be no restrictions on the number of researchers who can be provided with samples and data that are available in the Collaborative Biobank. This approach of the Biobank is intended to encourage rapid reporting of findings and different approaches to the analysis and interpretation of samples and data.

2.2 Samples available in the Collaborative Biobank

The Collaborative Biobank contains (genomic) DNA samples. For (genomic) DNA, the following quantities can be provided: 100, 500 or 1000 ng in a total of 50 µl TE buffer (10 mM Tris, 1 mM EDTA pH8). Other preferred buffers (e.g. ddH_2O) need to be stated in advance with the access application form.

As the Collaborative Biobank has been established as a prospective resource, samples from participants are expected to be used responsibly.

2.3 Data available for export in the Collaborative Biobank

2.3.1 Sample data

Sample data is created at the time of sample collection, delivery at the Biobank, and DNA isolation. It also includes information about the quality, quantity, correct storage and handling of samples.

2.3.2 Medical data

The Collaborative Biobank provides medical data of the patients treated with a haematopoietic stem cell transplant including data on e.g. indication, patient characteristics, treatment, donor type and stem cell source.

2.3.3 Analysis data

Analysis data contains information generated by analysing samples and which were provided after conducting future research. Depending on the contractual agreement with the PI, data from any research project which has previously been conducted using the Collaborative Biobank resources may be available. This data could include different types of genetic and sequencing information (e.g. from targeted gene sequencing).

2.4 No preferential or exclusive access

The Collaborative Biobank has standardised approval process steps (subject to ongoing review and amendment) for the assessment of all applications, including the compatibility of the research project with the Research Framework of the Collaborative Biobank (see paragraph 1.1), and the feasibility of the research project (see paragraph 3).

3 Sample feasibility check

Using the Collaborative Biobank website, the PI can use the freely web-based Availability Tool for a sample feasibility check. As part of the check the PI has the option to select specific data or samples by type or characteristics, e.g. requested age-range, gender, diagnosis, treatment, and type of transplant. Following this feasibility check and with regard to the available resources for his research project, the PI can decide to apply for an access to samples and/or data.

4 Approval Process

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

4.1 Access Application Form

If a positive response could be obtained from the feasibility check, the PI, acting now as applicant, can complete a specific Access Application Form which is available via the website of the Collaborative Biobank. The Access Application Form and other relevant documents should be completed and submitted. The PI must justify the use of samples and data, specify which analysis will be performed, 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. Lay summary (200 words or less) of the research project, including an explanation of how the proposed project meets the Research Framework of the Collaborative Biobank (see section 1.1);
II. Ethical approval by the competent Ethics Committee for the research project or state, why no ethical approval is required;
III. Research project protocol; and
IV. If applicable, Information addressing data security and privacy of the research project.

The completed form and all documents should be sent to the Collaborative Biobank Team by e-mail. Once this has been done, the internal approval process starts.

4.2 Completeness check

First of all, the documents submitted are checked for completeness. This will be performed within one week and the PIs will be notified if mandatory documents are missing. If all necessary documents are provided the application automatically passes to the second and third step.

4.3 Ethico-legal review

The application will be checked with respect to the following questions. If clarifications are necessary, the Collaborative Biobank Team will contact the PI.

I. Is the project covered by the Research Framework of the Collaborative Biobank?
II. Is the approval of the competent Ethics Committee for the research project available?
III. How will data privacy issues be ensured?
IV. Is the research project commercially funded?

The ethico-legal review shall be performed within two weeks.

4.4 Data quality review

Parallel to the ethico-legal review, the data quality review will be conducted by the responsible Data Managers of the Collaborative Biobank Team. Based on the search query of the PI, the Data Managers will extract information from the central database and the analysis database. Additional variables will be derived from the information extracted and analysis datasets will be created. The data quality will be assessed by checking incomplete, inconsistent, incorrect and implausible data in the analysis datasets. This data quality review will be passed on the PI and it will be included in the scientific review.

This step shall be performed within two weeks parallel to the ethico-legal review.

4.5 Scientific review

In the fourth step, research applications will be evaluated by the Scientific Committee of the Collaborative Biobank with regard to medical and scientific merit. The committee shall act upon the application within four weeks, or where clarification is requested, a maximum of 8 weeks. In the event of open questions, the casting of votes for a decision can be put on hold.

4.6 Transfer Agreement

All approved research projects require a Transfer Agreement. Apart from specific details regarding the research project, all standard contractual terms are not negotiable. Timelines for the provision of data and material will defined in the agreement.

As a condition of obtaining a generic approval for the use of both, samples and data, the Collaborative Biobank has made certain commitments. The Biobank therefore requires equivalent commitments from all research by the signing of the Transfer Agreements. If the research project is approved, the draft of the Transfer Agreement will be sent to the PI for review by their institution.

All collaborating partners, including DKMS and future researchers, may only use samples and data from the Collaborative Biobank for their own non-commercial purposes. Applicant PIs are not entitled to transfer the samples to third party premises unless specifically stated in the Transfer Agreement.

The Transfer Agreement must be signed by authorised representatives of both parties before the resources requested can be provided. Beside the shipping costs, charges for the access of samples and data charges will only be incurred in case of additional material processing steps.

4.7 Response to the access application

When the main review has been completed, the Biobank Team will communicate one of the following responses to the applicant PI:

I. Approval;

II. Approval conditional on responses to outstanding questions. In this case, the Application process will be put on hold;

III. A statement that the reviewers tend to reject the application (with summary reasons given), which will typically be determined by the Scientific Committee. The applicant PI can then elect to (i) clarify or amend the application; (ii) withdraw the application; (iii) request that the decision be reconsidered.

4.8 Reconsideration of applications

If an applicant PI is advised that the Biobank is minded to reject an Application, they may request that the application be reconsidered.

The process for having an Application reconsidered is as follows:

I. Within one month of the decision, the applicant should submit a written request, giving their reasons why they consider that the decision should be revised;

II. Within one month of receipt of such a request, the Scientific Committee will aim to consider it along with the original application and the Collaborative Biobank will then respond to the applicant PI;

III. If, following reconsideration, the application is rejected, the PI will not be able to submit the same proposal again.

5 Transfer of samples and/or data

5.1 Provision of samples

In general, samples will be provided with a non-traceable code. This ensures sample privacy and prevents personal identification of samples. Samples will be provided to the applicant PI in the following manner:

I. The PI will be notified when the requested samples have been retrieved and are ready for shipment. The PI will be invoiced for the shipment costs and any additional material processing costs, if applicable;

II. The PI will then notify the Collaborative Biobank Team of convenient dates and location/address for the sample delivery;

III. The delivery will be arranged through an approved third party;

IV. Within one working day of receipt, the applicant PI must notify the Collaborative Biobank Team that the samples have been received.

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 the following formats: .csv, MS Excel, or SPSS format.

Data to be exported will be provided as well with a non-traceable code. The PI will therefore receive double pseudonymised information only. This ensures data privacy and personal identification of data is most likely impossible.

6 Transparency and publication

The Collaborative Biobank aims to make as much information as possible publicly available. This includes open access publications and reports on our website.

After the research has been completely conducted, a lay summary of the research project will be put on the Collaborative Biobank website (with confidential information removed) in such form that other partners and the wider public can see the purpose for which the resource is being used.

The PI is required to use their best endeavours to publish the findings of any research derived from the Collaborative Biobank, in an academic journal or on an open source publication site within 24 months after completion of the project. Corresponding links to any related publications will be provided on the website of the Biobank.

All publications should include the acknowledgements '*This research has been facilitated by the Collaborative Biobank (www.cobi-biobank.com)'*. The link to the website should be provided. If possible this information should be tagged for search tools.

Approval of such publications is not required from the Collaborative Biobank Team, but the PI is encouraged to provide the publication for knowledge.

Within six months after publication, the applicant PI is required to provide parts of the research results and the analysis data upon agreed on, for upload into the Collaborative Biobank in a reasonable format.