Attachment B

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 role of the Scientific Committee and the Research Framework are described in the protocol, amongst other topics.

The Collaborative Biobank is intended to be a resource to support research projects which should meet the following objectives: (1) 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 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.

1.3 Pre-conditions for Access

If a Principal Investigator (PI) is interested in CoBi samples, collaboration with one of the CoBi partners is required. Potential collaborative partners are the cooperating Transplantation-/Collection Centres or DKMS. Depending on which cooperation partner has been chosen by the PI, further application steps will be conducted:
A). Access applications submitted by DKMS or multiple Transplantation Centres must be submitted to the Scientific Committee for review followed by signing a Transfer Agreement.
B) As for access applications submitted by single Transplantation Centres no Scientific Committee review is necessary, a specific Transfer Agreement must be signed followed by an extensive review process.
Contact details of DKMS and relevant Centres are available on the website (www.cobi-biobank.com).

2 Factors Affecting Access

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 Biobank resources, the PI should make a request for a sample feasibility check (see section 2.5).

2.2 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, and the feasibility of the research project.

The level of scrutiny used to assess applications will be proportionate to the nature and scale of the research project.

The Collaborative Biobank wishes to encourage cooperation between future researchers, to make the most efficient use of the Collaborative Biobank.

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.

2.3 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.

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

2.4 Data available in the Collaborative Biobank

2.4.1 Sample-related Data

Sample-related data is produced at the time of sample collection, delivery at the Biobank, and DNA isolation. It also includes information about the quality, and quantity of the sample.

2.4.2 Medical Data

The Collaborative Biobank provides miscellaneous medical data of participants. For patients, data from different time points of medical treatment will be available. Donor data refers to the point of time at which the donor consented to participation in the Biobank.

2.4.3 Analysis data

The Biobank will collect analysis data which were generated during research projects. Depending on the contractual agreement with the PI, data from any research project which has previously been conducted using Collaborative Biobank resources may be available. This data could include sequencing data (e.g. from targeted gene sequencing).

2.5 Sample feasibility check

After a request via the website contact form, each PI or research group interested in resources of the Collaborative Biobank can access a link provided for the sample feasibility check. For the request the following information shall be completed in the contact form :

- Name,
- Email,
- Research institute/department,
- Address,
- Telephone number

After receiving the access data by the Collaborative Biobank support team., the PI will be able to see an overview of the available quantity of samples and/or data. 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 procedure, the PI can decide to apply for an access to samples and/or data.

2.6 Access Application Form

If the applicant has received a positive response from the feasibility check, he/she can complete a specific Access Application Form which is available via the website of the Collaborative Biobank. The 'Access Application Form' should be completed with the following information:

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. Objectives;

III. Names of all collaborators, including commercial/industrial;

IV. Name and address of the leading institute;

V. Curriculum vitae of the applicant Principal Investigator;

VI. Required data and/or quantity and type of samples with e.g., specification for gender selection and age range;

VII. Information about industrial and/or commercial partners;

VIII. Ethical approval by the competent Ethics Committee for the research project;

IX. Research project protocol;

X. Information addressing data security and privacy of the research project; and

XI. List of necessary data and samples including categorization (e.g. age, gender, diagnosis).

If necessary, Storage Protocols should be provided in the event that residual material is to be stored. Generally all residual material must be destroyed unless otherwise defined in the specific Transfer Agreement.

The completed form should be sent to the Collaborative Biobank Team. Once this has been done, the internal approval process starts.

2.7 Overview:Approval process

The approval process of export requests consists of four steps:

I. **Completeness check**: The completeness review will be performed on the basis of the application documents. This step shall be performed within two weeks after receipt of the application. If all necessary documents are provided, the application automatically advances to the second step.

II. **Ethico-legal review**: The export request will be assessed for compatibility with applicable legal and ethical requirements for research projects. This step also includes a participation request to all TCs necessary to provide the samples. This step shall be performed within two weeks after the completeness check.

III. Data access review

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

IV. **Scientific review (DKMS applications only)**: DKMS 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 eight weeks, or where clarification is requested, a maximum of 16 weeks after the ethico-legal review. In the event of open questions, the casting of votes for a decision can be put on hold.

V. **Transfer Agreement**: All approved research projects requested by Transplant Centres 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 contract (see section 2.10).

2.8 Response to the Access Application

The Collaborative Biobank Team will check the Access Application Form and seek any further information that is required.

When the main review (steps I-III) 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.

2.9 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 two months 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.

2.10 Transfer Agreement

As a condition of obtaining a generic approval for the use of both the samples and data, the Collaborative Biobank has made certain commitments. The Biobank therefore requires equivalent commitments from all TC related research by the signing of the Transfer Agreements. If the research project is approved, a Standard Transfer Agreement will be sent to the applicant 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. The Transfer Agreement must be signed by 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.

After the required samples and/or data have been supplied to the PI, the 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.

If a partner breaches the provisions of the Transfer Agreement then this could lead to immediate revocation of the licence to use resources of the Collaborative Biobank.

2.11 Provision of samples

In general, samples will be provided with a project-specific identification coding. 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;

II. The PI will then notify the Collaborative Biobank Team of convenient dates and location 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.

Applicant PIs are not entitled to transfer the samples to third party premises unless specifically stated in the Transfer Agreement.

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

2.12 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 with a project-specific identification coding. The PI will therefore receive double pseudonymised information only. This ensures data privacy and personal identification of data is most likely impossible.

2.13 Transparency and publication

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

To increase transparency, brief descriptions which have been released by the respective PI's will be made available for approved research projects. The PI will be required to submit status reports of the requested research project every two years and a final report at the end of the research project.

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.

Approval of such publications is not required from the Collaborative Biobank, but the PI must provide the report at least two weeks before the expected date of first public presentation or publication in any format.

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

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