

## **Rules of Procedure of the Biobank and Data Access Committee Princess Máxima Center for Pediatric Oncology**

### **1. Definitions**

- 1.1 Biobank: the biobank of the Princess Máxima Center that contains Human biological material and Data for the purpose of research.
- 1.2 Data: pseudonymized clinical, medical and biological data related to patients and/or human biological material stored in the Princess Máxima Center biobank.
- 1.3 Human biological material: all components (e.g. tissue, cells, body fluids or DNA) originally derived from the human body.
- 1.4 Pseudonymization: the procedure by which the identifying fields within a data record are replaced by one or more artificial identifiers or pseudonyms. Pseudonymization occurs through a trusted third party (TTP) who maintains the key. Only a limited number of people with a patient - doctor relationship have access to the TTP for de- and re-identification purposes.
- 1.5 Biobank and Data Access Committee: the committee installed by the Board of Directors of the Princess Máxima Center that monitors the responsible management and grants approval of the release of Human biological material and Data (clinical, medical and/or biological) from the Biobank of the Princess Máxima Center.
- 1.6 Principal Investigator (PI): the person leading a research group of the Princess Máxima Center. The PI is responsible for the structure and execution of the scientific research for which the Request for Release is made. The PI is the point of contact for the Biobank and Data Access Committee in the context of the Request for Release.
- 1.7 Clinical Director: head of one of the four clinical program units in the Princess Máxima Center.
- 1.8 Request for Release: the PI's request for the release of Human biological material and/or Data for scientific research into pediatric cancer.
- 1.9 METC approval: the approval of the scientific research protocol by an accredited Medical Research Ethics Committee or similar foreign authority.
- 1.10 Internal Request for Release: a Request for Release of Human biological material and/or Data by a PI working at the Princess Máxima Center.
- 1.11 External Request for Release: a Request for Release of Human biological material and/or Data by a scientist who is not employed at the Princess Máxima Center. The scientist should submit the Request for Release in collaboration with a PI of the Princess Máxima Center.
- 1.12 DCOG: Dutch Childhood Oncology Group

### **2. Composition of Biobank and Data Access Committee**

- 2.1 The Board of Directors of the Princess Máxima Center appoints the members of the Biobank and Data Access Committee.  
The Biobank and Data Access Committee is composed as follows:
  - Preclinical scientist

- Pediatric oncologist/clinical scientist
  - Staff member of the diagnostic lab
  - Trial and Data Center representative
  - Clinical Director
  - Member of the Client Council
- 2.2 The Biobank and Data Access Committee will be assisted by a secretary and/or the Biobank coordinator and a legal counsel of the technology transfer office, who are not voting members of the committee.
- 2.3 The members of the Biobank and Data Access Committee appoint a chairman with an absolute majority of the votes cast.
- 2.4 The members are appointed for a period of three years and may be reappointed no more than twice.
- 2.5 Interim vacancies will be filled in consultation with the research management and the Biobank and Data Access Committee.
- 2.6 Members who are not employed at the Princess Máxima Center sign a confidentiality statement at the start of the membership.

### **3. Meeting and decision-making**

- 3.1 The Biobank and Data Access Committee itself determines the meeting frequency. In principle, the Biobank and Data Access Committee meets once every two weeks.
- 3.2 Meeting can take place physically or by conference call.
- 3.3 Members can also communicate their views to the Secretary by e-mail.
- 3.4 The Biobank and Data Access Committee makes decisions on the basis of consensus.
- 3.5 If no consensus is reached, the Biobank and Data Access Committee will decide by means of a vote. Decisions are made by a majority of votes cast, in the course of which at least three members must be present at the meeting or must have made their views known in advance.
- 3.6 If the Biobank and Data Access Committee fails to arrive at a decision, the Board of Directors of the Princess Máxima Center will decide.

### **4. Tasks and powers**

- 4.1 The Biobank and Data Access Committee monitors the responsible release of Human biological material and Data from the Biobank.
- 4.2 The Biobank and Data Access Committee keeps a Project Release Register.
- 4.3 The Biobank and Data Access Committee renders account for its activities each year by means of the annual report.

### **5. Procedure on requests for release**

- 5.1 The Biobank and Data Access Committee reviews Requests for Release according to the procedure as described in article 6 through 7.

- 5.2 Requests for Release are submitted to the Biobank and Data Access Committee by the PI, using the digital application form intended for this purpose. The appropriate Clinical Director is informed by the PI about the intended submission of the Request for Release.
- 5.3 In an External Request for Release, a scientist agrees to the conditions contained in a Material Transfer or Data Access Agreement. The compliance with the agreement(s) is monitored by the PI of the Princess Máxima Center.
- 5.4 The Biobank and Data Access Committee assesses Requests for Release that have been submitted at least one week before the meeting.
- 5.5 When reviewing Requests for Release, the Biobank and Data Access Committee may seek internal or external advice, for instance from a medical ethicist. In case of a request for advice to an external party, this party will sign a confidentiality statement.
- 5.6 For the purpose of the review of Requests for Release, the Biobank and Data Access Committee may ask the PI for further clarification or request the PI to change the research question.

## **6. Review criteria Requests for Release**

### 6.1 External Request for Release of Human biological material and Data

- 6.1.1 The Biobank and Data Access Committee agrees with an External Request for Release if all of the following criteria have been met:
  - a. The proposal fits within the mission statement of the Princess Máxima Center, that is to cure every child with cancer, and provide them optimum quality of life.
  - b. If applicable, the proposal has METC approval.
  - c. The question and methodology of the research have sufficient scientific value.
  - d. The use of the Human biological material and/or Data is necessary for conducting the research.
  - e. The proposal fits within the scope of the informed consent given by the patient or the proposed use of Human biological material and/or Data is possible on another legal basis.
  - f. The proposal does not overlap with (ongoing) research projects within the Princess Máxima Center or research projects part of international collaborations.
  - g. The requested material is sufficiently available in the Biobank.
  - h. The proposal requests Human biological material and/or Data that already has been used in previous publications or does not interfere with an ongoing research project (for instance, by influencing the endpoints of ongoing projects in the same population).
  - i. The proposal requests data that is not under embargo (e.g. data related to the outcome of an ongoing clinical trial).
  - j. The requesting research group already has a scientific collaboration with a research group within the Princess Máxima Center or is willing to setup a collaboration.

6.2 In addition to art. 6.1, the Biobank and Data access Committee only agrees with an External Request for Release from a commercial party, when clear agreements are made between the Princess Máxima Center and the requesting party about the distribution of revenue (in-)directly resulting from the research with the Human biological material and/or Data from the Biobank. On the basis of these agreements, at least a reasonable amount of that revenue will flow back to the Princess Máxima Center for the purpose of financing new scientific research. These agreements are included in a Material and Data Transfer Agreement.

6.3 Internal Request for Release of Human biological material and Data

6.3.1 The Biobank and Data Access Committee grants an approval for an Internal Request for Release if the criteria described in article 6.1.1 sub a through i have been met.

6.4 If the Request for Release concerns only the release of data, the Biobank and Data Access Committee agrees, if the following criteria have been met:

6.4.1 In the case of an External Request for Release of data, the criteria as described in article 6.1.1 sub a through f, h through j.

6.4.2 In the case of an Internal Request for Release of data, the criteria as described in article 6.1.1 sub d, e, f, h and i.

6.4.3 In case derivatives of the released materials and/or data are generated (e.g. DNA or DNA sequence data) the Biobank and Data Access Committee can request to return the remaining materials and/or data to the Biobank for future research purposes.

6.5 If another Request for Release of additional Human biological material and/or Data is submitted for a research for which Human biological material and/or Data was previously issued, this request is considered to be an amendment to the Request for Release, which will be subjected to a limited review by the Biobank and Data Access Committee. The Biobank and Data Access Committee reviews such a request in light of the criteria mentioned in article 6.1.1 sub f through i.

6.6 If a request concerns data and/or material that is part of a historical collection, collected by a different organisation such as the DCOG, then the material and data will be treated as stated in the rules for release as laid down by the original biobanking organisation. For this reason a representative of the DCOG will be a member of the committee and will have to approve release of the historical material and/or data on behalf of the DCOG.

## **7. Decision on Request for Release**

7.1 After discussing a Request for Release at the meeting, the Biobank and Data Access Committee will arrive at one, or a combination, of the following decisions:

- a. approval Request for Release,
- b. rejection Request for Release,
- c. request for additional information,
- d. seeking external advice.

- 7.2 If the Biobank and Data Access Committee requests the PI for additional information, it will place the Request for Release on the agenda for the next meetings again after receiving the additional information.
- 7.3 If the Biobank and Data Access Committee seeks external advice, it will place the Request for Release on the agenda for the next meeting again after receiving the advice.
- 7.4 The Secretary will send the PI the decisions on Requests for Release by e-mail. In case of a positive decision on an External Request for Release, a PI will also be offered a Material or Data Transfer Agreement for signing.
- 7.5 In all situations not provided for in these Rules of Procedure, the Biobank and Data Access Committee shall make a decision.

## **8. Costs for provisioning**

- 8.1 No costs for provisioning will be charged to internal PI's.
- 8.2 The actual costs for releasing and providing Human biological material and/or Data will be charged to external scientists if applicable. The Princess Máxima Center uses a list of fees for the cost of release and transportation.  
Pretreatment costs are determined on the basis of a quotation.  
A cost estimation section is part of the Material Transfer Agreement.

## **9. Safeguarding privacy and informed consent**

- 9.1 Human biological material and/or Data is made available to the PI's in pseudonymised (encrypted) or anonymized format depending on the decision of the Biobank and Data Access Committee regarding the content of the project.
- 9.2 Human biological material and/or Data is provided only in compliance with the consent given by the patient and/or the parents/guardian where applicable.