



[*Biobank Name*]  
[*Biobank Address*]  
[*Biobank contacts and URL*]



[*Patient Organisation Name*]  
[*Patient Organisation Address*]  
[*Patient Organisation contacts and URL*]

## **Agreement for the management of the collection of biological materials from individuals affiliated to [*Patient Organisation Name*]**

### Preamble:

*[Description of the nature of the biobank (mission, policies, procedures and sustainability)]*

**[1-year preliminary agreement]** The [*Patient Organisation Name*] (hereinafter “Patient Organisation”) is interested in using [*Biobank Name*] (hereinafter “Biobank”) services.

**[Renewal]** The [*Patient Organisation Name*] (hereinafter “Patient Organisation”) and [*Biobank Name*] (hereinafter “Biobank”) signed an agreement on [*date of the signature*] for management of biological material samples from individual members.... The Patient Organisation wishes to continue using the Biobank’s services.

Both the Biobank’s and the Patient Organisation’s Charters are an integral part of this agreement and are mutually accepted.

### Parties:

1. [*Patient Organisation Name*], duly represented by [*Name*], President
2. [*Biobank Name*], duly represented by [*Name*], Biobank Director.

### Aims:

The aim of this agreement is to define the rules and tasks of the parties involved, for storage and distribution of biospecimens and related data from the individual members and families affected by [*Disease of interest of the Patient Organisation*].

### Tasks of the Parties

The Patient Organisation undertakes to:

- promote the biospecimen transfer to the Biobank, located in [*Biobank Address*];
- inform the referring clinicians responsible for taking samples as well as the laboratory responsible for the sample collection and preparation concerning documentation (informed consent and sample submission forms) needed for sample transfer and storage in the Biobank;
- select a representative of the Patient Organisation to liaise with the Biobank. The Patient Organisation can substitute its representative at any time;
- support the referring clinician / centre in organising sample taking and transfer to the Biobank;
- if applicable, inform the Biobank that a registry or clinical database containing data related to the stored samples is available;
- promote the Biobank among its associated families and partners and support its initiatives.

The Biobank undertakes to:

- provide a service of sample storage and distribution for the Patient Organisation in accordance with the procedures defined in its SOPs and Charter;
- include the sample collection into the Biobank sample catalogue;
- keep the Patient Organisation updated about the sample workflow;
- inform the Patient Organisation about any sample request rejection, explaining the reasons for rejection;
- inform the Patient Organisation at the earliest possible time about any possible closures/relocations of the Biobank or about any alterations to its Charter or organisational changes which may affect this agreement or modify its terms;
- inform the Patient Organisation about any modifications to annexes (informed consent, sample submission, sample request forms). Revised versions of these annexes will replace the ones previously approved;

- inform the researchers requesting the “[Name of the collection]” clinical data about the existence of a clinical database or of a registry (if any);
- ask researchers accessing the “[Name of the collection]” biospecimens to (i) cite the Patient Organisation in the “Acknowledgments” section of possible publications and (ii) send a copy of the publication to the Patient Organisation.

Duration:

**[1-year preliminary agreement]** This Agreement is valid for 12 months from the date of the signatures by the Parties. At the end of this period, if both parties are satisfied, this agreement can be renewed in writing for an agreed period.

**[Renewal]** This Agreement is valid until [Date]. At the end of this period, if both parties are satisfied, this agreement can be renewed in writing for an agreed period.

If they deem it necessary, either parties can at any time and for any reason withdraw from this agreement with 3 months written notice, which is to be sent by registered mail or by PEC (Certified Electronic Mail). In this case, biospecimens should be returned to the Patient Organisation who could decide to transfer them to another Biobank.

Express termination clause:

This agreement will terminate by rights under the [reference of the national Civil Code] in the following cases:

- i) proven non-fulfilment of the clauses of this agreement;
- ii) ceased activity of one of the parties;
- iii) amendment to Parties’ Charters that are considered in contrast with principals and procedures stated in this agreement and/or not agreed/communicated.

The following annexes, accepted by both Parties, form an integral part of this agreement:

- Informed consent to the storage of biological material (ANX. 1.A)
- Sample submission form (ANX. 1.B)
- Material transfer agreement form (ANX. 1.C)

Date

Seen and approved by

[Name]  
Director of the Biobank

[Name]  
President of the Patient Organisation