Governance of Access in the Telethon Network of Genetic Biobanks

Version: September 2022
The content of this document is extracted from Iacomussi et al., 2021. doi: ***10.1089/bio.2021.0057***

This document describes the governance of access adopted by the TNGB-Telethon Network of Genetic Biobanks.

The TNGB originated as a research project supported by Fondazione Telethon—an Italian charity fostering research on rare diseases—and is regulated by its own charter, which reflects the mission of the network and describes the governance (Table 1), the rules for decision-making processes for accessing the samples, and the ethical guidelines and policies.

The governance of access to biospecimens and data is a set of rules and functional norms set up by each biobank to provide ethical guidelines and practical procedures to handle the requests of external researchers to access the biobank's samples and data.

TNGB’s access arrangements implemented over the years:

1. A strong governance structure (Table 1) which constitutes an effective oversight and protective mechanism of access management, ensuring the objectivity of access review and the prevention of any conflict of interests in decision-making. The TNGB governance bodies composition is published on the website.

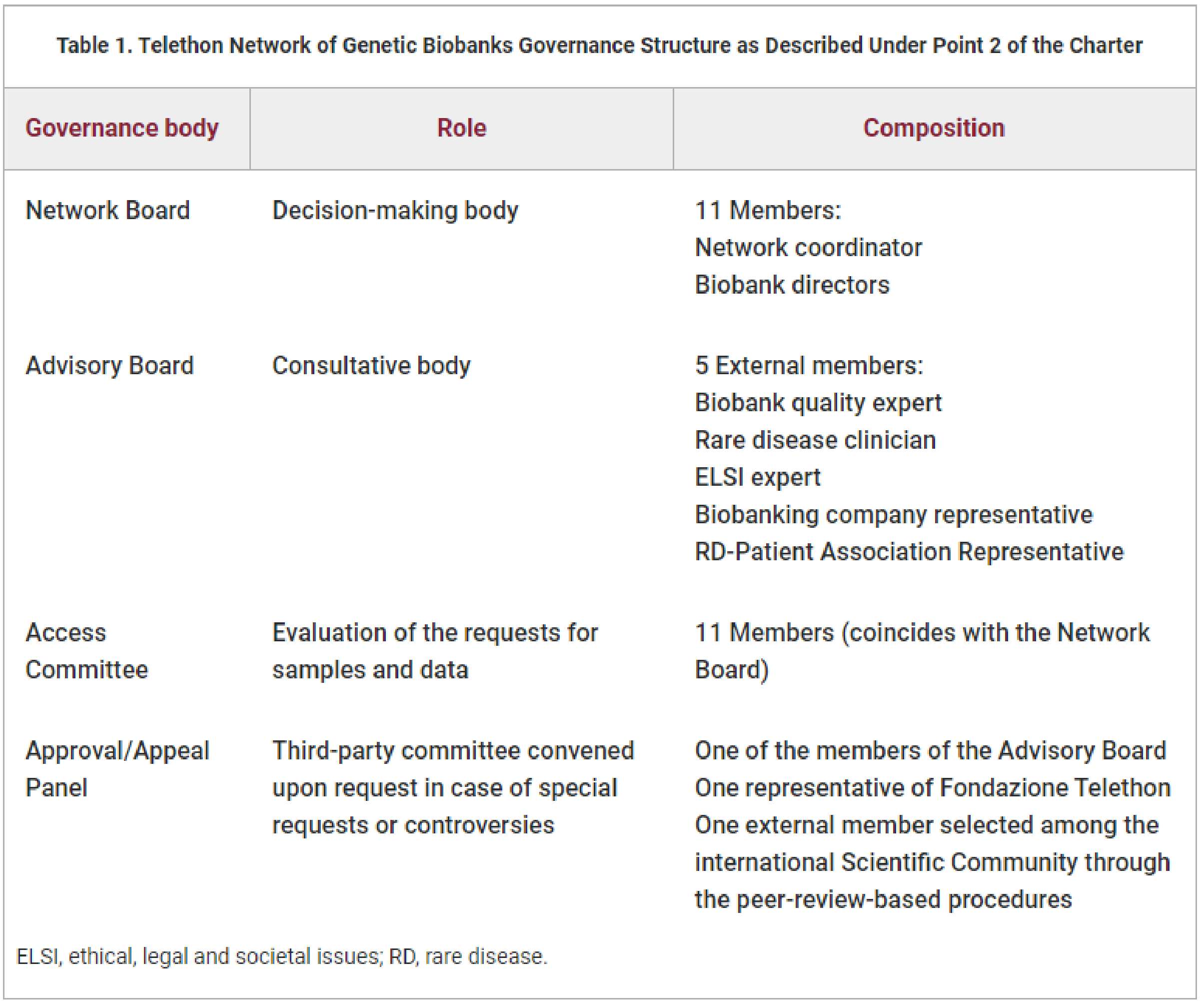

Table 1. Telethon Network of Genetic Biobanks Governance Structure as Described Under Point 2 of the Charter

Governance body	Role	Composition
Network Board	Decision-making body	11 Members: Network coordinator Biobank directors
Advisory Board	Consultative body	5 External members: Biobank quality expert Rare disease clinician ELSI expert Biobanking company representative RD-Patient Association Representative
Access Committee	Evaluation of the requests for samples and data	11 Members (coincides with the Network Board)
Approval/Appeal Panel	Third-party committee convened upon request in case of special requests or controversies	One of the members of the Advisory Board One representative of Fondazione Telethon One external member selected among the international Scientific Community through the peer-review-based procedures

ELSI, ethical, legal and societal issues; RD, rare disease.

2. A user-friendly sample online request form that contributes to promoting and facilitating access to the Network collection and guides researchers through the whole access process.

Version: September 2022
*The content of this document is extracted from Iacomussi et al., 2021. doi: **10.1089/bio.2021.0057***

3. Clear and publicly available rules of access (Table 2) that are equally applied to all researchers whether they work for for-profit or nonprofit organizations, including the Biobank's personnel within the Network (cfr. Charter 6.2, 6.5).

Table 2. Rules of Access by the Telethon Network of Genetic Biobanks

No.	Rule	Reference
1	Samples are made available for research purposes, provided that an adequate aliquot of those samples be safeguarded for the advantage of the patient/family, aimed at retrospective analysis	*Charter 6.2*
2	Samples are distributed only to qualified professionals who are associated with recognised research or medical organisations engaged in health-related research or in healthcare	*Charter 6.2*
3	Samples are made available upon request which must be adequately justified by the User by describing the research project, grant sponsor, planned experiments and expected results	*Charter 6.2*
4	After the request approval, the User's organisation is requested to sign the material transfer agreement	*Charter 6.2*
5	Respect of the Network's general mission by accepting the following general policies included in the MTA:	*Charter and MTA template*
	5a Samples supplied cannot be used for commercial purposes (e.g., sample re-sale);	*Charter 6.2*
	5b Samples cannot be distributed to other investigators without written permission of the Biobank Director	*Charter 6.2 and MTA template*
	5c Samples provided must be used only for the research project declared by the User in the request form	*Charter 6.2 and MTA template*
	5d Users are expected to feed back the analytic results from each single sample to the Biobank, in order to support further research and to give back the results potentially relevant for participant's health	*Charter 6.2 and MTA template*
	5e Any leftover samples must be destroyed once the project is completed or, in case of reuse, a new request has to be submitted	*MTA template*
	5f In the case of publication(s) of the results obtained using the sample(s), Users are expected to acknowledge the Biobank and the Network for having provided the service, and to send a copy of the relevant paper to the Biobank	*Charter 6.2 and MTA template*
	5g User's Institution is expected to pay for shipping and distribution services according to the service cost list	*Charter 6.3*

4. A transparent evaluation process (Figure 1) conveyed by the RCP which allows a shared visualization and management of the requests by all the members of the Network (cfr. Charter 6.1).

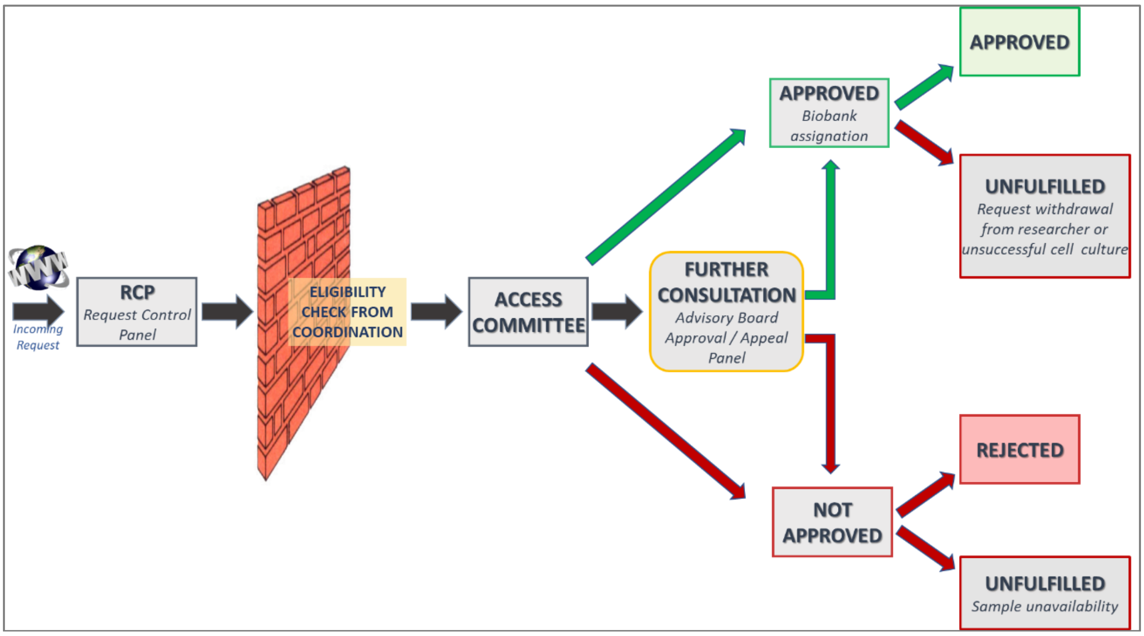

Figure 1: Request evaluation process by the Telethon Network of Genetic Biobanks

Briefly, for accessing the samples, researchers (from now on "users") can request through the online form any samples listed in the TNGB online catalog. The request must contain a description of the research project, the identification of the funding body, and the presence of the Ethics Committee approval.

Once the request has been submitted, the evaluation process begins (Figure 1). In brief, once the eligibility check is passed, the request is referred to the AC, which has 5 days to respond. In the case of a consensus, the request is assigned to the biobank(s); otherwise, in case of doubts about acceptance, a follow-up discussion among the AC is opened. The outcome of the discussion can result in two scenarios: the request is rejected following the TNGB's access rules or an external consultation is requested, that is, the Advisory Board or the Approval/Appeal Panel.

General info

- General questions can be addressed to the Network coordination Office at biobanknetwork@telethon.it
- Questions about the request status, the samples characteristics or the data associated to the samples should be addressed directly to the assigned biobank. Network contacts are managed by the Coordination office who does not have this type of information
- If any problem is met during any of the above described procedures, users can contact the Support Office at support@biobanknetwork.org
- Descriptions of the services provided by the Network, access rules and request approval procedure are available at http://biobanknetwork.telethon.it/Pages/View/Services
- A template of the Network documents (e.g., MTA and Informed consent) can be downloaded at http://biobanknetwork.telethon.it/Pages/View/Documents

Version: September 2022

The content of this document is extracted from Iacomussi et al., 2021. doi: ***10.1089/bio.2021.0057***