

## **Agreement for the management of the collection of biological materials from individuals associated to the RING 14 Associations affiliated to RING 14 International Onlus**

### Preamble:

Telethon Foundation (“FT”) is a non-profit organization supporting medical and scientific research on neuromuscular and other genetic diseases conducted by Organizations, Institutions and Associations with the same aim.

In 2008, FT established the Telethon Network of Genetic Biobanks (“TNGB”, <http://www.biobanknetwork.org/>) to coordinate by using an IT infrastructure, a number of Italian Genetic Biobanks, which are financially supported by FT and evaluated by the Telethon Biobank Committee through a peer-review selection. TNGB’s objective is to offer its services to Patient and Family Associations by centralising collections of rare genetic disease biospecimens and their related data, as well as to make them available to the Scientific Community and to families.

TNGB is the first Italian national network to share Standard Operating Procedures (SOPs) and guidelines on legal, ethical and quality related issues in compliance with national and international laws and recommendations. The *TNGB Charter* defines these issues as well as the relationships between TNGB partners.

The “Associazione Internazionale RING 14” and TNGB signed an agreement on the 10<sup>th</sup> December 2009 for management of biological material samples from individual members. RING 14 International Onlus (hereinafter “RING 14” or “Association”), a second level association to whom “Associazione Internazionale RING 14” is affiliated, wishes to continue using TNGB services by extending them to all its national affiliated chapters.

Both TNGB and the Association’s Charters are an integral part of this agreement and are mutually accepted.

### Parties:

1. Stefania Azzali, President of the RING 14 International Onlus
2. Chiara Baldo, Director of the Galliera Genetic Biobank, (hereinafter “GGB” or “Biobank”) and Mirella Filocamo, TNGB Coordinator, on behalf of FT (TNGB founding organization) having on 29<sup>th</sup> May 2012 received the authorisation from FT to sign this agreement.

### 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 rare genetic diseases associated with Chromosome 14.

### Tasks of the Parties

RING 14 undertakes to:

- promote the biospecimen transfer to GGB (a TNGB partner), located in Genoa, Italy, at the Galliera Hospital, Via Volta 6;
- 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) needed for sample transfer and storage in the Biobank;

- select a representative of the Association to liaise with the Biobank. RING 14 can substitute its representative at any time;
- pay for expenses of sample transfer to the Biobank;
- inform the Biobank that a database containing clinical data related to the stored samples is available. RING 14 will send all database updates to the Biobank;
- promote TNGB and FT among its associated families and partners and support their initiatives and organise seminars and/or scientific events.

TNGB undertakes to:

- provide a service of sample storage and distribution for the Association in accordance with the procedures defined in TNGB SOPs and Charter;
- appoint the GGB as entity hosting “Ring 14” collection by agreement with FT and the Association;
- include “Ring 14” samples in the TNGB catalogue;
- inform RING 14 about the distribution of its samples by compiling an annual report;
- inform RING 14 about any sample request rejection, explaining the reasons for rejection;
- inform RING 14 at the earliest possible time about any possible closures/relocations of GGB or about any alterations to the TNGB Charter or organisational changes which may affect this agreement or modify its terms;
- inform RING 14 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 “Ring 14” biospecimens about the existence of the clinical database managed by RING 14;
- ask researchers accessing the “Ring 14” biospecimens to (i) cite RING 14 in the “Acknowledgments” section of possible publications and (ii) send a copy of the publication to RING 14.

Duration:

This Agreement is valid until the end of the TNGB project financing termed as the 31<sup>st</sup> December 2017. At the end of this period, if both parties are satisfied, this agreement can be renewed in writing for an agreed period if TNGB project financing is renewed.

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 RING 14 who, in agreement with FT and TNGB, could decide to transfer them to another TNGB partner.

Express termination clause:

This agreement will terminate by rights under the Ex Article 1456 of the Italian 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, approved by all 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 19<sup>th</sup> May 2015

Seen and approved by

***Mirella Filocamo***  
TNGB Coordinator

***Chiara Baldo***  
Biobank Director

***Stefania Azzali***  
RING 14 President