Quality of Life and Management of Living Resources

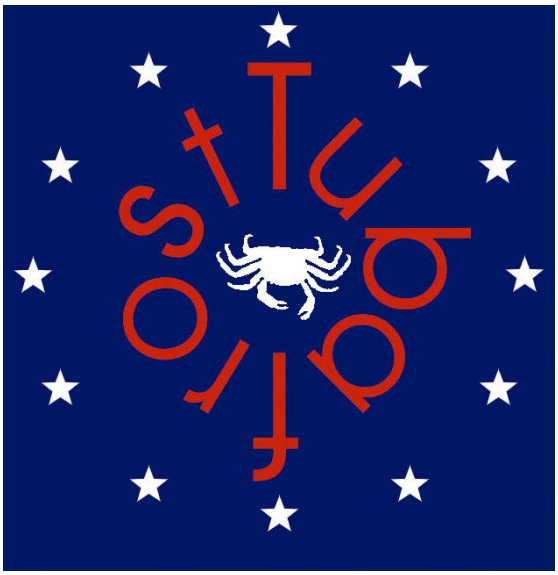
European Human Frozen Tumor Tissue Bank

TUBAFROST

QLRI-CT-2002-01551

Deliverable D 6.1

Assessment of policies and rules for a networked tissue bank



Introduction and purpose:

As a consequence of the rapid improvement of high throughput technologies for studying large and well-characterized series of tissues, the importance of tissue banking has risen tremendously over the last few years.
Large tissue banks and repositories exist in almost every sector of scientific and medical communities. These large tissue banks, bio-repositories, and core facilities are a major source of human tissue constituting a tool for fundamental and translational research. Integration of these bio-repositories in the TUBAFROST network will require the assessment of a series of incentives, policies and rules.

Tasks involved for Deliverable 6.1:

- Define the rights and responsibilities of all participants concerning the use of the European Human Frozen Tumor Tissue Bank Network.

- Develop incentives for the participating institutions and their contributing pathologists

It has been decided by the Tubafrost consortium that the authority on the decision to provide tissue after the receipt of a request through Tubafrost remains with the institute, which has collected the tissue. Tubafrost, however, will offer the possibility of bilateral communication amongst the local collectors involved in the request. Therefore task 6.3 (Develop a review system for proposed research) of Work package 6 has become redundant and will not be carried out. The tissue collecting institutes must carry out this task by their own insight.

Preliminary considerations

1. Participation in the European Human Frozen Tumor Tissue Bank Network will be only possible for those European institutions that can contribute tissues (collectors), such as *Hospitals* or *existing networks of tumor banks.* These institutions must, in addition, be able to meet the demands set by the Tubafrost consortium on minimum standards, protocols and quality control.

2. Access as a user or requestor to the European Human Frozen Tumor Tissue Bank Network will only be possible if the following conditions are met:

a. The requestor must be involved as a researcher at any tumor research group, hospital, university, existing network of tumor banks, national cancer association, research center, collaborative group, European commission, associated countries and international associations and involved in medical research only.
b. The requestor must be familiar with the European Code for Proper Secondary Use of Human Tissue, which will be developed in WP 7.
c. Requestor must be able to give an exact description of all planned research involving the tissue samples.
d. The requestor must have permission of the local Medical Ethics Commission to execute the planned research.
e. The planned research needs to be of sufficient quality to spend the valuable tissue samples on, to be judged by the individual collectors, which are involved in the application.
f. Requestor must have sufficient expertise at their disposal to perform the planned research.
g. Access should also be limited to those who are prepared to make a reference to the European Human Frozen Tumor Tissue Bank and the involved collectors of the tissue in future publications based on the results obtained on the received tissues (see also point 30).

3. In order to participate in the European Human Frozen Tumor Tissue Bank Network collector institutions will have to comply with criteria described in Annex I this deliverable in order to guarantee the network strategy.

Incentives for participating institutions

4. The available samples in the European Human Frozen Tumor Tissue Bank Network will stay at the collector institutes. As a consequence the authority and responsibility for the tissue falls on the collector.

5. Participant institutions will not be forced to issue their tissue to projects they do not feel worthwhile. Hence, the final decision as to the destination of the stored tissue will remain with the collector institutions.

6. The collector's institution approached by the requestors makes up the Tubafrost Tissue Transfer Agreement on their own authority (Annex II).

7. Collector institutions participating in the European Human Frozen Tumor Tissue Bank Network will open up their scientific perspectives by means of:
   a. Participation in large-scale studies.
   b. Access to larger homogeneous series of common and uncommon types of tumors.
   c. Improvement of multi-center connections.
   d. Possibility for all researchers to access and use cost-intensive technologies.
   e. Ethical and legal framework.
   f. Quality framework.
   g. Standardized framework for prospective collection of high quality samples linked to clinical data.

Incentives for Pathologists/Scientists to contribute tissue

8. As guardians of tissue and cell samples from patients and also experts in tumor biology, pathologists will take a leading role in the creation of tumor banks for research in the collector institutions. In this way, pathologists will be involved in the field of research of the samples they have diagnosed.

9. Although all Pathologists in a collector institution can participate in the creation of a tumor bank, the collector institutes will name a member of the institute responsible for the elaboration of the specific tasks of the European Human Frozen Tumor Tissue Bank Network.

10. Financial rules in the forthcoming business plan will result in additional incentives for the contributing institutions. (For instance a reduction in cost recovery price by significantly lowering the consortium contribution part and reduction in the annual membership contribution for access, which can be earned back by offering well documented and wanted samples.)

11. Participation in the creation of tumor banks will result in a number of incentives for the participating Scientist/Pathologists who could enhance their professional career. Among these incentives are:
   a. Opportunities to set-up co-operation between the requestor and tissue-issuing institute.
   b. Access to rare tumor entities and large collections.
   c. Rapid feedback on histology review (role played by the virtual tumor bank, WP5).
   d. Feedback on results of research.
   e. Co-authorship in the case of substantial contribution (see 30).
   f. Preferred access through for instance financial discount for collectors to the Tubafrost tissue collection (see 10).
   g. Free sections of tissue arrays they contribute to (always in agreement with the requestor).
   h. Access to new biotechnology.
   i. Pressure from patients who want their tissues preserved in order to benefit from future developments.
   j. Platform for exchange of material and research ideas.

Responsibilities of all participants concerning the use of the European Human Frozen Tumor Tissue Bank Network
As a consortium

12. The TUBAFROST consortium will set up a Steering Committee (or Steering Commission) once the TUBAFROST project has been completed. The steering committee will serve as the governing board of the European Human Frozen Tumor Tissue Bank Network and will continue the activities of the consortium as a yet to be determined legal entity.

13. The Tubafrost consortium participants will constitute the Steering Committee from the team leader, or from, a by the team leader indicated, volunteering person per Tubafrost consortium participant for this position.

14. One chairperson will be selected by the Steering Committee who will have coordinating functions. He/She will be responsible for coordinating the activities of the Steering Committee, for preparing meeting agendas and for scheduling and chairing meetings. The chairperson will prepare annual progress reports, which will include individual reports from each participant of the European Human Frozen Tumor Tissue Bank Network. The steering committee will decide after what time period re-election of the chairman takes place.

15. The Steering Committee will have primary responsibility for promoting the European Human Frozen Tumor Tissue Bank Network and for assuring the distribution of highly quality tumor samples for cancer research projects. This Committee will also promote and perform research activities related to tumor banking.

16. To protect the quality of the samples entered in the central database the Steering Committee will judge applications from tissue collecting institutes to join the Tubafrost network as a new tissue collector on the criteria set in Annex I.

17. The Steering Committee will provide technical advice and coordination to the new collector institutes.

18. The Steering Committee will contact collector institutes with requestors and to facilitate the agreement between the requestor and the collector institutes by offering standard consortium transfer agreements (Annex II).

19. The Steering Committee will inform the collector institution on which other requestors are approached for the same proposal. Hence, they can communicate with each other on the subject of the proposals.

20. Complaints regarding the issue of tissue, excesses and non-compliances of the signed Tubafrost Tissue Transfer Agreements will be handled by the Steering Committee.

21. The Steering Committee will update the European Human Frozen Tumor Tissue Bank Network strategy according to new knowledge.

For all participants

22. The routine diagnostic or prognostic use of the samples always has priority over the research use of the samples.

23. All participants will adopt the standardized work plan provided by the TUBAFROST consortium for ensuring the adequate management of the samples in terms of collection and storing as well as in the ethical and legal aspects of the clinical management of the samples.

24. Each member of the European Human Frozen Tumor Tissue Bank Network will prepare an annual progress report that will be submitted to the Steering Committee.

25. All collectors must communicate immediately the loss of availability to the central database if a sample is no longer available to Tubafrost the European Human Frozen Tumor Tissue Bank Network.

Rights of all participants concerning the use of the European Human Frozen Tumor Tissue Bank Network

26. The members of the European Human Frozen Tumor Tissue Bank Network will have priority for the use of the services/samples of the network.

27. The members of the European Human Frozen Tumor Tissue Bank Network will have the possibility of personnel exchanges between participating institutions as well as training courses in histopathology and related techniques.

28. The members of the TUBAFROST consortium will participate in the co-authorship of the European Human Frozen Tumor Tissue Bank Network related publications.

29. Allocating part of the research project budgets using stored tissue, to the concept of management of samples of Tubafrost the European Human Frozen Tumor Tissue Bank Network will be considered.

30. Acknowledgement policy. If results obtained with tumor tissues from European Human Frozen Tumor Tissue Bank Network result in a publication, the following statement should be included in the Acknowledgements or Material and Methods section of the manuscript: *"The tissue used in this publication was provided by Tubafrost the European Human Frozen Tumor Tissue Bank"*. In case facilities were used from the collecting institute(s), beyond the sole activity of issuing tissue, which in addition have contributed to a publication, the persons involved need to be treated as co-author of that publication.

References:

- *Oosterhuis JW, Coebergh JW, van Veen EB (2002). Nature Reviews 3:73-77.*
- *CNIO Meeting, Tumor Banks in Europe.*
- *Erasmus Medical Center, Rotterdam, Netherlands.*
- *Peter Riegman, personal communication.*
- *National Cancer Tissue Resource (NTRAC), Oxford, UK.*
- *The UK Children's Cancer Study Group (UKCCSG) Tumour Bank,UK.*
- *The Spanish Tumor Bank Network, CNIO, Madrid, Spain.*
- *CANCER RESEARCH CENTER AND UNIVERSITY of SALAMANCA (SPAIN).*
- *Human Brain Tissue Bank from the McKnight Brain Institute Florida, USA.*
- *Tissue and Biological fluids banks of HIV-related malignances. HIH Guide, Volume 23, Number 2, 1994.*
- *Kansas Cancer Institute: Tissue and Serum Repository, Kansas, USA.*
- *Alliance Against Cancer, Italy.*

Annex I:

Criteria for collector institutes in order to participate in Tubafrost the European Human Frozen Tumor Tissue Bank Network

1. All collector institutes must have availability and access to cancer patient specimens.

2. Collector institutes must have the availability of sufficient personnel (technicians, pathologists, etc) and infrastructure capacity for the development and/or maintenance of a tumor bank, which meets the minimal standards and can collect tissue according to the protocols and rules set by the European Human Frozen Tumor Tissue Bank Network.

3. In order to participate in the European Human Frozen Tumor Tissue Bank Network all or potential collector institutes will establish a tissue bank, collect specimens and corresponding clinical data according to the standardized collection methods and policies of the European Human Frozen Tumor Tissue Bank Network in order to assure quality control of specimens and data.

    a. The collector institutes will name a member of the institute, who is responsible for the scientific tasks of the tumor bank (macroscopic analysis, and selection and harvest of the surgery specimens). Those selected persons should demonstrate their interest in participating in the tumor bank and cancer research. He/she will be responsible of the functional aspects such as reception, processing and storing of the samples, quality controls, legal and ethical aspects, management of the information referring to each sample and the distribution of the samples.

    b. The collector institutes should have a technician responsible for the processing, storing and cryo-preservation of the samples.

    c. The collector institutes will indicate the existence of a budget, a physical space and equipment to perform the activities of the tumor bank.

4. The collector institutes are responsible for the association of samples with valid consent to ensure legal research use of TUBAFROST material by the requestor institutions.

5. The collector institutes will be required to accept and implement the common policies and procedures approved by the TUBAFROST consortium (or the Steering Committee).

6. The collector institutes will be required to accept cooperative action between the tumor banks of the European Human Frozen Tumor Tissue Bank Network.

Annex II:
Standard model for a consortium transfer agreement between collector and recipient

TUBAFROST TISSUE TRANSFER AGREEMENT

Comment [M1]: NB. In the original format it was not an agreement but am unilateral declaration by the recipient.

1. **Definitions:**
   a. Provider: A collecting member of TuBaFrost, the European Human Frozen Tissue Bank, which provides the tissue as specified in the TubaFrost request form.
   b. Recipient: An organization which has requested tissue from the TubaFrost repository.
   c. Collecting member: An organization, which is participating in TubaFrost by collecting tissue and making tissue available according to the procedures of TubaFrost.
   d. Tissue: Human biological material taken from patients in the course of a clinical procedure or specifically taken out in order to be used for research purposes.
   e. The tissue Tissue which is provided by provider to recipient following the request form and this Agreement
   f. Research: Scientific research on tissue and related data not involving the use of tissue in human subjects.
   g. Donor: The patient from which the tissue originates
   h. TubaFrost: The European Frozen Tissue Bank as defined (legal entity to be determined).

2. **Obligations of provider**
   a. Provider will provide the tissue and related data as described in the request form as far as possible
   b. Provider will notify recipient as soon as possible if providing the tissue and/or data meets obstacles, like (but not limited to) the tissue is needed for further diagnostic procedures for the donor, the tissue has become unavailable or has become unsuited for the requested use due to unforeseen circumstances, the tissue cannot be shipped or exported due to applicable regulations.
   c. Provider will only provide tissue and related data which may be used for the research as specified in the request form according to the regulatory and ethical standards applicable to provider

3. **Obligations of recipient**
   a. The tissue and data will only be used for research as specified in the request form
   b. Recipient will only use the tissue if so allowed by the regulatory and ethical standards applicable to recipient
   c. No attempts whatsoever will be made to find the identity of the donor or to derive other data form the tissue as follows from the research described in the request form.
   d. Tissue and their derivates shall not be sold, or distributed free of charge to third parties, and can only be used to produce commercial medical products (including the production of cells or cell products for sale) in collaboration and with written permission of the provider and proper consent of the patient.
   e. Recipient will bear the costs of preparing the tissue as requested in the request form and of handling and shipping the tissue to recipient
   f. After performing the agreed research the remaining tissue and their derivates will be returned to provider. The recipient agrees to assume all risks and responsibilities in connection with the receipt, handling, storage, use of the tissue and return shipment of the remaining tissue.
   g. The recipient will pay to the TubaFrost consortium the costs as set in its rules of procedure for its mediation between provider and recipient.

Comment [M2]: In the original text you said, not to drive data, but that is nonsense. The whole point of doing research with tissue is to derive data from it.

Comment [M3]: In fact, this clause is superfluous considering 3.a

Comment [M4]: To my opnion we should acquire a status for the consortium as a legal body

4. General clauses

a. Recipient understands that while provider attempts to avoid supplying tissue contaminated with highly infectious agents such as for instance hepatitis and HIV, all tissues should be handled as if potentially infectious. The recipient acknowledges that he is aware of and follows applicable regulations for handling human specimens and will instruct its staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

b. The tissue is provided as a service to the research community without warranty of merchantability or fitness for a particular purpose, including that which is described in the request form, or any other warranty, express or implied.
Provider nor the Tubafrost consortium can be held liable to recipient for any loss, claim or demand made by recipient, or made against recipient by any third party due to or arising from the use of the tissue by recipient, except to the extent permitted by law when caused by gross negligence or willful misconduct by provider.

c. The recipient hereby agrees to acknowledge the contributions of the European Human Frozen Tumor Tissue Bank (Tubafrost) in all publications resulting from the use of these tissues. Recommended wording to the Acknowledgment or Methods section is as follows: "*The tissue used in this publication was provided by Tubafrost, the European Human Frozen Tumor Tissue Bank Network*". In case facilities or services were used from the collecting institute(s), beyond the sole activity of issuing tissue, which in addition have contributed to a publication, the persons involved need to be treated as co-authors of that publication.

d. The undersigned warrant that they have authority to execute this agreement on behalf of respectively provider and recipient.

Comment [M5]: If it would just have been the recipient it should have been warrants.

Comment [M6]: We have dealt with this subject already.

Comment [M7]: Dealt with already

Name of Recipient _____

Division or Department _____

Institution _____ **Date** _____

Place _____

Function of Recipient _____

Signature of Recipient _____

Name of provider _____

Division or Department _____

Institution _____ **Date** _____

Place _____

Signature of Provider _____