

## DECLARATION ON THE USE OF HUMAN TISSUE FOR PURPOSES OF MEDICAL-SCIENTIFIC RESEARCH AT NONPROFIT INSTITUTIONS

### Information

1. The declaration is made by (name of institution or research facility):

\_\_\_\_\_  
represented by (title, name) as the official representative:

\_\_\_\_\_  
as well as the project director (title, name):

\_\_\_\_\_  
referred to hereafter as "tissue recipient" or "PD."

2. The application form containing the purposes and procedures of the research project for which the tissue shall be used, as well as information on the type of tissue, the amount required and further information was sent to HTCR.
3. Proof of non-profit status is enclosed with this declaration.<sup>i</sup>

### Limitations

4. The tissue recipient is using tissue only for the research project described in his/her application (see point 2) according to paragraph 2.
5. The tissue only serves research purposes, for *in vitro* use. **THE TISSUE OR TISSUE PRODUCTS WILL NOT BE USED IN HUMANS.**
6. The tissue recipient will not give the tissue or products derived from it to any third parties for further processing/use, with the exception of laboratory staff under the direct supervision of the PD. The PD ensures that the tissue cannot be accessed by unauthorized third parties.
7. The transport and necessary processing, if applicable (for example, preservation) of the tissue will be done independently only in accordance with the guidelines and procedures specified by HTCR or it will be contracted out accordingly to certified companies/service providers.
8. The tissue recipient guarantees that requests for, receipt of and nature of use of the tissue made available will be done in accordance with legal guidelines in effect locally.
9. The tissue recipient understands that HTCR cannot guarantee that the requested tissue will be available within a certain time period if it has not currently already been stored by HTCR.

### Guarantee and Liability

10. The tissue recipient is aware that the tissue made available is essentially experimental in nature and that HTCR cannot assume any guarantee for the suitability and composition of the material and in regard to third-party rights.
11. HTCR does not assume any responsibility with regard to possible health risks and other risks and hazards resulting from the tissue and its use for research. The tissue recipient assumes the responsibility for taking appropriate precautionary measures.
12. The tissue recipient understands that HTCR cannot provide any guarantees with regard to clinical data included.

13. In no case can anyone from HTCR, its representatives, employees, union representatives and agents be responsible and they are held harmless from all claims that may arise from the use, loss, claim to, damage or liability of any sort in the use, transport, receipt and storage at the tissue recipient's site.

### Obligations

14. The tissue recipient agrees to use human tissue only in an ethical and legally safeguarded manner and to support the HTCR foundation in this effort. To this end, the tissue recipient will mention HTCR in any publication which involves data from the use of the tissue provided.
15. The tissue recipient acknowledges that compensation is to be paid for costs which are incurred by the HTCR foundation in making available the tissue donated to them (patient information, organization, data collection and processing) – even though the foundation bears these costs within the scope of its capabilities.
16. The tissue recipient agrees to ensure the confidentiality of data given to him/her by HTCR and to guarantee its security. In addition, the tissue recipient confirms that the research performed with the tissue has the necessary local authorizations, if applicable.
17. After concluding the research project and in accordance with instructions from the HTCR foundation to be obtained in advance, the tissue recipient will either return remaining material, properly packed and via an appropriate means of transportation, or will destroy it accordingly.<sup>ii</sup>
18. In the case of a breach of this declaration, the HTCR foundation is authorized to return or destroy the material in accordance with para. 17. Additional claims remain reserved in this case.
19. The following signatures of an authorized person from the supervisory committee of the research institution, or the director of the research institution of the tissue recipient documents [sic] that the PD is authorized and able to use human tissue for medical-scientific research in accordance with all laws that affect this use.

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Signature of Official Representative

\_\_\_\_\_  
Signature of Project Director

<sup>i</sup> Academic institutions may be considered to be non-profit. In this case, it is sufficient to certify the signature of the official representative with the seal of the college/university

<sup>ii</sup> Use for subsequent projects can be approved in a new application