



HUMAN TISSUE AND CELL RESEARCH

Nonprofit Foundation under German Civil Law

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FB-Nr. 7.1.1_VFD_FB_4

Revision 2

Inkraftsetzung: 04.05.2012

Stand 05/2012

DECLARATION ON THE USE OF HUMAN TISSUE FOR PURPOSES OF MEDICAL-SCIENTIFIC RESEARCH

Information

1. Declaration is given by (company name/name of involved institution/ research institution):

legal representative of company (title, name), subsequently referred to as "user":

Person responsible for the project (title, name), subsequently referred to as „PR“:

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 charitable status is given.ⁱ

Limitations

4. The user/PR uses the tissue only for the research project described in the application form (see Paragraph 2).
5. The tissue only serves research purposes, for use *in vitro*. **THE TISSUE OR TISSUE PRODUCTS WILL NOT BE USED IN HUMANS.**
6. The user/PR 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 PR. The PR ensures that the tissue cannot be accessed by unauthorized third parties.
7. Transport and necessary processing, if applicable (for example, preservation) of the tissue, will be commissioned to companies/service providers associated with HTCR.
8. The user/PR 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 user/PR understands that as a basic principle, there can be no obligation for HTCR to the supply of tissue. Particularly HTCR cannot guarantee that the requested tissue will be available within a certain time period if it has not currently already been stored by a tissue bank on behalf of HTCR.

Guarantee and Liability

10. The user/PR 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 user/PR assumes the responsibility for taking appropriate precautionary measures.
12. The user/PR 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 user's/PR's site.

Obligations

14. The user/PR supports the HTCR foundation in paying heed to the use of human tissue/clinical data only in an ethical and legally safeguarded manner. To this end, the user/PR agrees to ensure the confidentiality of data given to him/her by HTCR and to guarantee its security. In addition, the user confirms that the research performed with the tissue has the necessary local authorizations, if applicable. He/she will also meet the obligation to **consult his/her research ethics committee** as referred to in the Medical Association's professional code of conduct/WMA declaration of Helsinki.
15. If research results based on data from the use of the tissue provided are published, the user will **mention HTCR in any publication** which involves data from the use of the tissue provided.
16. The user/PR 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). An agreement is to be made with the foundation **regarding reimbursement of costs**, depending on how the tissue is supplied, as well as on the duration and scope (number of donors, indications) of tissue supply. In case of academic/non-profit-use HTCR will bear these costs in terms of a research funding, all or part within the scope of its capabilities.
17. After conclusion of the research project and in accordance with instructions from the HTCR foundation to be obtained in advance, the user/PR will either return remaining material, properly packed and via an appropriate means of transportation, or will destroy it accordingly.ⁱⁱ
18. In the case of a breach of this declaration, the HTCR foundation is authorized to return or destroy the material in accordance with paragraph 17. Additional claims remain reserved in this case.
19. With the following signatures of user/PR the signatories comply with all mentioned paragraphs (1-19) of this declaration.

Place, date

Signature of legal representative (companies only)

Signature of person responsible for project (PR)

ⁱ 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.

ⁱⁱ Use for subsequent projects can be approved in a new application.

Erstellung:

RT
26.02.2011/04.05.2012

Prüfung:

Geschäftsführender Vorstand
28.02.2011/04.05.2012

Freigabe:

Vorsitzender Stiftungsrat
28.02.2011/04.05.2012