

## **General Terms and Conditions for the Exchange of Materials – Provision by the BfR (Material Transfer-Terms and Conditions – Part A)**

Insofar as the Federal Institute for Risk Assessment (BfR - provider) makes material available to another party (recipient), the following General Terms and Conditions shall govern the legal relationship upon which the exchange of material is based, unless specifically agreed otherwise in writing. The recipient's General Terms and Conditions shall only be valid if the provider has explicitly agreed to them and they are not contrary to the provisions contained in the following. The provisions in particular with regard to ownership and usage rights are in the interest of the fulfilment of the tasks of the BfR within the framework of consumer health protection.

### 1. Definitions

*Derivatives* refers to biological material, which is an unaltered functional sub-unit or a product of the original material or its progeny (for example DNA and DNA-sequences of the original material or its progeny).

*Material* defines biological and chemical substances as well as reference materials, which typically, or within the scope of the respective exchange, are to be sampled or used in scientific experiments or studies. The term encompasses the original material as well as any progeny or derivatives.

*Original material* is the material in the biological and chemical condition that it had at the point of transfer.

*Progeny* refers to all biological materials, which are obtained by the recipient via the reproduction of the original material and which are identical to the original material.

*Third parties* are all legal or natural persons with the exception of the contract parties.

2. Unless specifically agreed otherwise in writing, the provider shall retain ownership of the material. This also includes the right of the provider to decide with regard to the further use of the material, including any unused material. The right of the recipient, to proceed with the material within the scope of the purpose related to the transfer, shall remain unaffected by this clause.
3. The recipient shall give the provider details of a contact person and responsible as principle investigator.
4. The parties undertake to preserve the confidentiality of any document, information or other material directly related to the subject of this Agreement that is duly classed as confidential in accordance with the General Data Protection Regulation (EU) 2016/79, if disclosure could cause prejudice to the other party, unless the recipient is required to disclose information in order to comply with applicable laws or regulations or with a court or administrative order.
5. The recipient may not use the material commercially and it is to be used solely for the purpose intended and agreed with the provider. The material may only be kept and used in the recipient's area of competence and under the scientific management and control of the responsible, Principle Investigator. It may neither be passed to persons within the recipient's organisation who do not work under the scientific management and control of the responsible, Principle Investigator, nor to third parties. The material may not be used in or on humans, in clinical studies or for diagnostic purposes relating to humans.

6. The recipient is aware that the material is, or may be, subject to property rights. The recipient will not claim or attempt to obtain patents, copyrights or any other industrial property rights for the material.
7. Should results that are obtained through the use of the material be published, it is to be stated in the publication that the material was provided by the BfR. Publications shall not require the provider's consent.
8. If results (discoveries) are obtained that are eligible for protection under copyright law, the recipient shall inform the provider of this in writing. The invention can be filed by both parties as equal applicants at the Patent Office in the form of an application for property rights. The parties shall agree by mutual consent with regard to the details of the registration and commercial exploitation.
9. When handling the material, the recipient shall exercise due care and attention and heed all laws, rules and regulations, guidelines/directives and other standards applicable with regard to the usage, storage and the transportation of the material. This applies particularly in view of the fact that the material may reveal hitherto unknown qualities. It shall be the recipient's own responsibility to inform himself with regard to the relevant legal regulations pertaining to the material, as well as the latest technological and scientific developments, including applicable technical standards (DIN, ISO etc.) and to observe the same.
10. Upon the written request of the provider (e.g. by letter, facsimile or e-mail) the recipient shall at his own cost and at his own discretion immediately destroy or return all unused material. In the case of the latter, the recipient shall provide written confirmation of this to the provider (e.g. by letter, facsimile or e-mail).
11. The provider is entitled to invoice the recipient with a fee for the transfer of the original material based on the German scale of fees for physicians (Gebührenordnung für Ärzte - GOÄ) or, if a fee cannot be derived from this, in accordance with the framework schedule of fees, each in its respective current version. The fee shall be waived, if the recipient is a Federal Authority. Regulations within the framework of joint projects remain unaffected.
12. The material is of experimental nature and may possess dangerous or risk-bearing qualities. The provider issues no guarantee - either explicitly or implicitly – with regard to the material, especially with regard to its suitability for any specific purpose or a certain operational capability or safety or harmlessness or innocuousness to health. Furthermore, the provider issues no guarantee that any patents or other third party rights will not be infringed by using the material.
13. Liability on the part of the provider is excluded with regard to damages in connection with the use, handling and storage of the material as well as for other damages in connection with the provision of the material subject to the provisions hereinafter. Liability for damages resulting from gross negligence or deliberate breach of duty on the part of the provider, its corporate bodies and vicarious agents, as well as for damages arising from injury to life, body or health resulting from a deliberate or negligent breach of duty on the part of the provider, its corporate bodies and vicarious agents remain unaffected.
14. The recipient hereby releases the provider, its corporate bodies and staff from all claims made by staff of the recipient or third parties due to or in connection with the usage, handling

January 21, 2021

or storage of the material or otherwise in connection with the provision of the material. The recipient shall reimburse the provider any costs incurred defending any such claims, especially court and legal fees.

15. German Law shall be exclusively applicable. Exclusive place of jurisdiction for all disputes arising from or in connection with this legal relationship shall be Berlin, Germany.