

# Terms of Use of the transfer provided by the Human Material Request Form for Non-Commercial, Scientific, Educational or Research Use.

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Please read these Terms and Conditions carefully as they specify the use of the Material provided by the Provider.

1. The following definitions apply:

- <b>Data:</b>	all data provided by Provider to Recipient for the performance of the Project.
- <b>Donor:</b>	the living or deceased human source of the Material.
- <b>Original Material:</b>	the description of the material being transferred as specified in the Human Material Request Form.
- <b>Material:</b>	Original Material and Modifications.
- <b>Modifications:</b>	substances created by the Recipient which contain/incorporate the Original Material.
- <b>Ethics Committee:</b>	fully recognized ethics committee of University Hospital Ghent.
- <b>Confidential Information:</b>	any and all Material, Data and information that is transferred between Provider and Recipient for the purpose of this Project.
- <b>Secondary Use:</b>	use of Original Material for purposes other than the original research project for which the Donor gave its informed consent.
- <b>Recipient Scientist:</b>	means the principal investigator/scientist and the individual scientists or researchers who is referenced on the applicable Human Material Request Form, employed or retained by Recipient, and using the Material and for whom the Material was requested and obtained by Recipient.
- <b>Recipient:</b>	the organisation, part of University Ghent, ordering and receiving the Material pursuant to submitting the Request Form.
- <b>Residual Material:</b>	Material that was collected for purposes of diagnosis or treatment that, after a sufficient part of the materials has been used, have become redundant and therefore could be destroyed.
- <b>Third Party:</b>	a person or entity that is not the Provider nor the Recipient.
- <b>Traceability:</b>	the ability to locate and identify the Material during any step from procurement, through processing, testing and storage, to distribution to the Recipient or disposal, which also implies the ability to identify the Donor; traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with this Material.
- <b>Project:</b>	the project with the project title as referred to in the Human Material Request Form.

- <b>Parties:</b>	Provider and Recipient collectively.
- <b>Provider:</b>	University Hospital Ghent

2. The Recipient is solely responsible that all Material and Data shall be used in compliance with all applicable laws, regulations and guidelines applicable to the handling, use, storage and/or destruction of the Material.
3. Recipient represents and warrants that it has obtained all regulatory and ethical approvals and licenses that are needed for the use of the Material and the Data in the Project.
4. Provider warrants that the consent provided by the donors of the Material (or, in the absence of such explicit consent, a presumed consent or ethical approval) allows for the use of the Material for the Project. When a Donor withdraws its consent to use the Material and Data in accordance with the applicable legislation, the Provider can request Recipient to promptly return such Material and/or Data.
5. Parties agree that the legal requirements for Secondary Use of Original Material and the use of Residual Material shall be assessed on a case-by-case basis, in full compliance with the applicable laws and as determined in the Project.
6. It is Provider's responsibility to make the Material and Data available for transfer without obligation thereto; Provider will motivate when Material cannot be made available for transfer.
7. Recipient and Recipient Scientist agree that the Material and Data can only be used for non – commercial, scientific, teaching or research use. The Material and Data can be used by the Recipient Scientist and/or his/her properly qualified and trained team members under his/her supervision, who have been properly informed by Recipient of these Terms and Conditions and the following restrictions:
  - a. The Material and Data shall be used only for the Project by Recipient Scientist or Recipient Scientist's team members involved with the performance of the Project.
  - b. The analysis and/or modification of the Material and Data must be restricted solely to that needed to carry out the Project.
  - c. The Material and Data shall not be used in humans or for any diagnostic or therapeutic purposes.
  - d. The Material and Data shall not be used outside the premises of the Recipient without the Provider's prior written consent.
  - e. The Material and Data shall in no event be sold or transferred to a Third Party.
  - g. The Material and Data shall not be subject to any subsequent transfer or made available to a person not participating to the Recipient Scientist's team or to any other entity within the Recipient.
  - h. The Material and Data shall not be used in research that is subject to consulting, licensing or similar obligations to commercial entities ("Commercial Use"). Such Commercial Use shall be subjected to a separate written agreement between Provider and Recipient.
  - i. The Material and Data shall not be directly or indirectly conveyed to any Third Party against compensation.

8. The Provider retains custodianship of the Material and Data, including any Material contained or incorporated in Modifications.
9. The Recipient Scientist shall identify any Modification and will notify the Provider immediately of any Modification.
10. Confidential Information shall be maintained in confidence by Recipient. Recipient shall disclose Confidential Information only to Recipient Scientist and Recipient Scientist's research team members who have a need to know for the performance of the Project. For the purposes of these Terms of Use, Confidential Information shall not include information that (a) has been published or was otherwise publicly available at the time of disclosure to Recipient; (b) was in the possession of or readily available to Recipient without being subject to a confidentiality obligation from a Third Party prior to the disclosure; (c) has become publicly known, by publication or otherwise, not due to any unauthorized act or omission of Recipient; (d) Recipient can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information; or (e) is required to be disclosed by law, regulation, or an order of court or a regulatory authority.
11. Unless prohibited by law or court order, The Recipient and the Recipient Scientist shall immediately inform the Provider of any inspection or audit and send to the Provider a copy of any such inspection report or results.
12. All Material processed, stored or distributed at the Recipient's premises must at all times be traceable. The Recipient shall have an effective and accurate traceability system which assigns a unique code to each Material and to each of the products associated with it. All data required for Traceability shall be kept for a minimum of 30 years after termination of the project.
13. Any Material is understood to be experimental in nature and may have hazardous properties. Provider makes no warranties of any kind, either expressed or implied. All Material should be handled as if potentially infectious. Recipient agrees to assume all responsibility for informing and training Recipient Scientist's research team members in the dangers and procedures for safe handling of human material.
14. All Material that is to be transferred shall be accompanied by written instructions by the Provider for transport, use and storage. All Material, Data and any technical information are provided as-is, without warranties of any kind, express or implied, including but not limited to any implied warranties, fitness for a particular purpose, typicality, safety, accuracy and / or non – infringement.
15. When Material and Data is transferred between Parties or within the premises of Recipient, consideration must be given to safety, and minimising the likelihood of theft, damage or loss during transport.
16. Provider is not responsible for any non-compliance by Recipient.
17. In no event, to the extent permitted by law, shall Provider be liable for any damages of any kind in connection with or arising out of the transfer, transport, use and storage of the Material and Data by Recipient, even if Provider has been advised of the possibility of such damages. In any event, Provider's liability towards Recipient shall never exceed the fees paid by the Recipient under these Terms of Use and the applicable Request Form.

18. The Provider shall make arrangements in order to make the Original Material ready for transfer. The Recipient is responsible to organise and to cover all transportation costs.
19. Recipient will indemnify, defend and hold harmless Provider, its directors, employees, students and agents from any Third Party claim arising from Recipient's use, storage or disposal of Material and Data or breach of these Terms of Use, except in case of gross fault or wilful misconduct by Provider.
20. Recipient shall secure and maintain in full force and effect insurance coverage to this Request Form and Terms of Use and in compliance with minimum amounts of insurance required by applicable laws or regulations. Upon request, Recipient shall provide Provider with certificates of insurance evidencing the required insurance coverage.
21. Recipient Scientist will report to Provider on the progress and results of the Project as required by the Request Form. By the earlier of sixty days after the publication of the results of the Project or completion of the Project, Recipient Scientist will provide Provider with a copy of the results of the Project, including a description of the effective use of the Material and Data for the Project and an opinion on their fitness for the purpose of the Project. Recipient Scientist will notify Provider in advance if any report on the results of the Project is reasonably likely to provoke controversy or otherwise attract significant public attention. In such circumstances, Provider reserves the right to make such recommendations, reservations or suggestions on the report as it sees fits (which it may make public) for consideration by Recipient.
22. In all oral presentations, written publications or press releases relating to the use of the Material and/or the Data, Recipient and Recipient Scientist will acknowledge Provider's contribution of the Material and/or the Data as required by the Request Form unless requested otherwise by Provider.
23. If analysis of Material would reveal meaningful information or other incidental findings about the health condition of its Donor, and the Material has been provided in traceable format, Recipient shall so inform Provider and provide the raw data and analysis revealing such information jointly with reference to the unique identifier of the Material allowing Provider to re-identify the Donor.
24. When the Project is terminated, Recipient will immediately cease using the Material and Data and any unused and remaining Material and Data (including any progeny, modifications and derivatives thereof and the Data) and all originals, reproductions, summaries and other tangible forms of Confidential Information will promptly either be destroyed or will (at Recipient's costs) be returned to Provider as required by the Request Form or as otherwise requested in writing by Provider, except for one copy of confidential information that may be retained solely for the purpose of determining Provider's continuing legal obligations hereunder. Provider shall provide Recipient with instructions within 15 days after termination of the Project. The Recipient shall act in compliance with these instructions within 15 days.
25. The Parties agree that the Material and Data can be considered as personal data that is subject to the General Data Protection Regulation (EU) 2016/679 and applicable complementing national legislation, including but not limited to the law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data (jointly "**Privacy Laws**"). The Parties shall be considered as independent data controllers and will fully comply with their respective obligations under the Privacy Laws. Recipient will not make any effort to identify individuals who are or may be the donors of the Material and may not combine the personal data or the results of the Project with

other data which may result in identification of a Donor. If Recipient becomes aware of any unauthorized use or disclosure of personal information, Recipient will promptly notify Provider.

26. Provider reserves the right to seek interest on payments that are unreasonably delayed by more than 30 days after receipt of an invoice.

27. These Terms of Use are part of the Request Form are binding and shall be governed by and construed in accordance with the laws of Belgium. In the event of a dispute arising, the Parties shall seek to resolve such dispute amicably. In case the Parties fail to settle the dispute amicably, the dispute shall be brought in the courts in Ghent, Belgium having exclusive jurisdiction.

For agreed and acknowledgement,

The Recipient