# MATERIAL TRANSFER & SERVICE AGREEMENT [*for interventional studies where site contracts are put in place anyhow, terms and conditions of a MTA shall be integrated in the main contract no separate MTA shall be made; parts in red italic or highlighted in yellow need adaptation to each specific case; other sections may need to be altered to fit specific national legislation*]

**BETWEEN**

**«INSTITUTION\_NAME»**, with registered offices at «STREET\_NUM», «CODE\_POSTAL» «CITY» «POSTZIP» , «COUNTRY», represented by name of representative

(hereafter called the “LABORATORY”),

AND

**«INSTITUTION / ORGANISATION\_NAME»**, with registered offices at «STREET\_NUM», «CODE\_POSTAL» «CITY» «POSTZIP» , «COUNTRY», represented by name of representative

(hereafter called the “SPONSOR”)

## PURPOSE OF AGREEMENT

* The purpose of this Agreement is to determine the conditions covering both the release and transfer of the MATERIAL received from PROVIDER by the SPONSOR and their storage, access and use by LABORATORY for performing the RESEARCH (“the PURPOSE”).

## DEFINITIONS

* RESEARCH: The research to be performed as described in Schedule 1.
* FUTURE RESEARCH: any research run under the responsibility of the SPONSOR that was not specifically mentioned at the time of the Informed Consent by the patient because it was not known, limited to the ethically approved non-for profit cancer research performed within the scope of patient consent or in compliance with the article 32 of the declaration of Helsinki (version 2013).
* MATERIAL: The human biological material to be transferred in the framework of this agreement including any related information and data, collectively described in Schedule 2 of this agreement.
* DERIVATIVES: unmodified or modified descendants or functional sub-units from or expressed by the MATERIAL (including but not limited to proteins, DNA/RNA, viruses, cells and organisms).
* STUDY DATA: means the formatted data sets containing the patient data reported by Investigators on case report forms and data clarification forms or data obtained by the LABORATORY and/ or the SPONSOR and resulting from the analysis of the MATERIAL or DERIVATIVES.
* STUDY RESULTS: means the statistical analysis that includes the principal analysis of the primary end-point as defined in the RESEARCH.
* PROVIDER: The organization providing the MATERIAL.
* SPONSOR: the person, individual or group that takes responsibility for the initiation, management and financing (or arranging the financing) of the research.
* CUSTODIAN: legal entity responsible for safeguarding MATERIAL and oversight of its use. Formal responsibility for custodianship rests with organizations rather than individual persons. For the purpose of this MTSA CUSTODIAN is PROVIDER / SPONSOR / OTHER [*adapt as appropriate; it is not appropriate to speak about ownership in relation to material or derivatives; therefore the term of ownership shall not be used*]
* **CHAIN OF CUSTODY:** The flow of MATERIAL between the different parties involved in collecting, handling and using human biological material (e.g. the hospital/site, service providers, storage facilities and sites performing TR).
* **COORDINATOR OF THE CHAIN OF CUSTODY:** the entity responsible for ensuring all organizations participating in chain of custody act in compliance with the project, applicable legislation and existing contractual agreements. For the purpose of this MTSA the COORDINATOR OF THE CHAIN OF CUSTODY is SPONSOR
* THIRD PARTY: any person or organization not a signatory party of this agreement.
* LABORATORY: means validated infrastructure that is responsible for handling MATERIAL as instructed by the SPONSOR

 [insert address and contact details].

* BACKGROUND INTELLECTUAL PROPERTY (BACKGROUND IP) means any IP which pre-exists the RESEARCH OR FUTURE RESEARCH or is independently developed outside of the RESEARCH OR FUTURE RESEARCH that is owned or controlled by a party and which that party chooses at its sole discretion to make available for the purpose of carrying out the RESEARCH OR FUTURE RESEARCH
* INTELLECTUAL PROPERTY (IP) includes all copyright and neighboring rights, all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trademarks (including service marks), registered designs and circuit layouts, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields but excludes moral rights

## TERMS AND CONDITIONS

* 1. **THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.**
	2. For the PURPOSE, LABORATORY agrees to use MATERIAL and DERIVATIVES in accordance with all applicable laws, regulations, and policies.
	3. SPONSOR represents and warrants that all approvals, authorizations, and assurances necessary for receipt and use of MATERIAL and DERIVATIVES, including but not limited to approval of the relevant Ethical Committee have been obtained.
	4. LABORATORY shall maintain and manage MATERIAL and DERIVATIVES up to the high quality standard and any data shall be managed in compliance with the applicable data protection legislation. [*in case material from EU PROVIDER needs to be transferred to a third country, there may be a need to use a supplementary data protection clauses for transfer of data that can be found on http://ec.europa.eu/justice/data-protection/document/international-transfers/transfer/index\_en.htm*]
	5. LABORATORY will ensure MATERIAL and DERIVATIVES will be maintained in accordance with the requirements laid down by all applicable laws, regulations and guidelines, in particular in accordance with the Declaration of Helsinki and with the principles of good clinical practice as laid down by the ICH topic E6, Note for Guidance on Good Clinical Practice CPMP/ICH/135/95, the European directive EC/95/46 on the protection of personal data and the applicable SPONSOR’s policies.
	6. LABORATORY shall not perform any operations on the MATERIAL and DERIVATIVES, which are not in compliance with the PURPOSE or otherwise specifically required to be performed by the SPONSOR.
	7. LABORATORY will use the strict amount of MATERIAL and DERIVATIVES required for the RESEARCH and shall, at SPONSOR’s request:
		1. return the relevant MATERIAL to the PROVIDERor destroy the relevant MATERIAL
		2. destroy or fully anonymize DERIVATIVES.
		3. store the left-over MATERIAL and DERIVATIVES further for FUTURE RESEARCH as instructed by the SPONSOR.
	8. For the avoidance of doubt, all BACKGROUND IP used in connection with the RESEARCH or FUTURE RESEARCH shall remain the property of the party that makes it available for carrying out the RESEARCH or FUTURE RESEARCH. Each party grants to each other party a royalty-free, non-exclusive, non-transferrable license to use its BACKGROUND IP, with the right to sublicense the BACKGROUND IP to research collaborators to the extent necessary to carry out the RESEARCH or FUTURE RESEARCH.
	9. SPONSOR is owner of the STUDY DATA, STUDY RESULTS and IP arising from the conduct of RESEARCH or FUTURE RESEARCH.
	or
	SPONSOR and PROVIDER are co-owners of the STUDY DATA, STUDY RESULTS and IP arising from the conduct of RESEARCH or FUTURE RESEARCH.
	[*please, choose one of two options, second option is recommended when the contribution of PROVIDER is considerable*]
	10. SPONSOR acknowledges and agrees that nothing herein shall be deemed to grant to SPONSOR any intellectual property rights in any MATERIAL or in any results of research conducted by PROVIDER or any third-party using MATERIAL outside the scope of this Agreement.
	11. The MATERIAL shall not be sold.
	12. The MATERIAL shall not be destroyed or further distributed for any purpose other than processing of MATERIAL in the framework of RESEARCH or FUTURE RESEARCH without written consent of the SPONSOR.
	13. To the extent authorized by laws, the LABORATORY hereby agrees to defend, indemnify and hold harmless the SPONSOR and their respective trustees, officers, employees, trainees and appointees from and against any liability or claim arising from any non-authorized use of the MATERIAL or DERIVATIVES by the LABORATORY.
	14. Any information provided by the SPONSOR or by the LABORATORY that is not already in the public domain shall be treated at all times in strict confidence and shall be disclosed only to those persons who need to know such information for the purpose of this agreement, provided always that those persons are informed of the confidential nature of this information. The recipient of such information shall not have any obligation of confidentiality with respect to information that: (a) is or will be part of the public domain through no fault of the recipient; or (b) is already in the possession of the recipient prior to the communication of such information; or (c) is demonstrably developed independently by the recipient; or (d) is obtained from a THIRD PARTY not under a confidentiality obligation to the SPONSOR or the LABORATORY; or (e) is required by law to be disclosed to a competent judicial or administrative body.
	15. [*select as applicable*] SPONSOR shall compensate LABORATORY for the work performed in compliance with the schedule 3.

Or There is no financial compensation provided by SPONSOR for the release, transfer, storage and use of the MATERIAL in the framework of the current RESEARCH.

* 1. Publication shall be made according to the SPONSOR’s publication policy and in compliance with the protocol. Publication shall be in line with generally accepted principals of co-authorship
	2. This agreement shall start on the time of signature of this agreement until the end of all the RESEARCH related activities. Parties have the right to terminate this agreement at any time by giving thirty (30) days written notice to the other signatory parties. This agreement may only be extended or amended by a written agreement between the Parties.
	3. Both Parties may wish to terminate this agreement. Such termination shall be done through a written notice.
	4. In case of termination both Parties will ensure that appropriate measures are taken, within a maximum of 3 months from the decision (unless otherwise mutually agreed), to safely transfer MATERIAL or DERIVATIVES to the new place of storage or that MATERIAL is returned to PROVIDERS and DERIVATIVES are destroyed or appropriately anonymized. Costs of such a transfer or return shall be covered by the SPONSOR, unless the LABORATORY takes such a decision unilaterally in which case it shall solely assume all relevant costs.
	5. The agreement shall be construed in accordance with and governed by xxx law.
	6. The terms, provisions, representations, warranties and covenants contained in this Agreement that by their sense and context are intended to survive the performance thereof by the Parties hereunder shall so survive the completion of performance, expiration or termination of this Agreement.
	7. This agreement:
1. may be executed in counterparts which may be exchanged in facsimile, electronic or digital form and will together constitute the agreement (LABORATORY may receive the MATERIAL upon receipt of the SPONSOR’s facsimile, electronic or digital counterpart and may rely upon receipt as conclusive evidence that the SPONSOR agrees to be bound by this Agreement);
2. constitutes the entire agreement between the parties with respect to its subject matter;
3. may only be amended in writing signed by both parties;
4. may be enforced in any territory or country in the world where a breach of this Agreement occurs.

**IN WITNESS THEREOF**, this Agreement has been executed by the Parties through their duly authorized officers as of the date of.

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| Agreed and accepted for the **SPONSOR** on: | ....../....../............ |
| Name & title of authorized official: |  |
| Address: |  |
| Signature of authorized official: |  |

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|  |
| Agreed and accepted for the **PROVIDER** on: | ....../....../............ |
| Name & title of authorized official: | ……………………………………………………………… |
| Address: | ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| Signature of authorized official: |  |

Schedule 1 – RESEARCH

Insert relevant Research Plan here

Schedule 2 – MATERIAL

Insert relevant MATERIAL here

Schedule 3 – Payment

Insert payment schedule here