**Request form secondary non-commercial use of samples**

This document describes the arrangements between the researchers (Recipient) and the biobank (Provider) concerning the use, processing and distribution of biological samples for secondary use in accordance with the Royal Decree on Biobanks dd. January 9, 2018. The possibility of secondary use will in first instance be assessed by the biobank advisory council. If this secondary use falls outside the scope of the original informed consent, the patient must be asked for additional consent, unless the ethics committee consents to the use of the samples for this Project.

An electronically completed and signed version of this document will be archived at Biobank Antwerpen.

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| **Identification of the Project** |

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| Title of the project  ……………………………………………………………………………………………………………………………………………………………………………………………………………………………..…………..…... |
| Short name: ……………………... *(max 255 characters)* |
| Brief description of the project (max. 5 lines)  ……………………………………………………………………………………………………………………………………………………………………………………………………………………………..…………..…... |

Start date of the project: ……………………...

Anticipated end date of the project: ……………………...

Approval of the project by an ethical committee?  yes  No

Please attach the letter with the approval of the ethical committee and the submitted case.

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| **Description of the Project** |

For the information of the Biobank Advisory Council, please provide the following information

Background to the study

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Objective of the study

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Methodology of the study

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Endpoints of the study

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Scientific relevance of the study

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Please add the full study protocol  ok

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| **Involved researchers** | |
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| **Name lead investigator :** | …………………………………... |
| Work address: | …………………………………... |
| E-mail: | …………………………………... |
| Phone number : | …………………………………... |
| **Name of the researcher** who is practically responsible for the execution of the project : | …………………………………... |
| Work address: | …………………………………... |
| E-mail: | …………………………………... |
| Phone number: | …………………………………... |

Please add the CV of the researchers in the case of non UZA/UA researchers.

Names of the researchers who should have access to the study in BioSLIMS

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| --- | --- | --- | --- | --- |
| **Name** | **First name** | **User number** | **BIOSLIMS**  **Read-only access** | **BIOSLIMS**  **Registration rights** |
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*NOTE: The user number is the personnel number for those researchers working at UZA or UAntwerpen.*

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| **Origin of samples** |

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| * Samples from the collection of the central biobank ? | yes  No |
| * Samples from a collection within a decentralized hub ? | yes  No |
| * Samples from a local collection ? | yes  No |
| * Were you yourself, as a researcher, involved in the primary study in which these samples were collected ? | yes  No |
| * Is the research group that primarily collected the samples involved in the presented research? | yes  No |

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| **Identification of the required samples (*The Material*)** | | | |
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| Please mention in the description of the samples the maximum ischeamia times or other specifications if applicable.  Please indicate a preferred underlying diagnosis preferentially by means of ICD-11 coding if applicable. | | | |
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| Mother sample  (E.g. : plasma ) | Sample description  (E.g. of healthy control , minimum stored on -80°C) | Minimum quantity  (Volume,…) | Destination after analysis |
|  |  |  | a  b  c |
|  |  |  | a  b  c |
|  |  |  | a  b  c |
|  |  |  | a  b  c |
|  |  |  | a  b  c |
|  |  |  | a  b  c |
| a) Fully consumed by execution analysis | | | |
| b) Save after analysis by researcher till end of the study and then destroy | | | |
| c) Send back to the biobank after analysis | | | |

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| **Sample processing** | | |
| Please indicate below whether samples need any processing before shipment and specify if these processes should be performed by biobank staff | | |
| Mother sample  (copy from above ) | Sample processing  (E.g. : aliquoting, 6 tubes) | Processing performed by  (E.g. biobank/researcher) |
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| **Transport conditions and destination** | | | |
| Please indicate below which shipping conditions are required for each sample. Please make sure the destination is documented correctly and complete. | | | |
| Sample | Transport conditions  E.g. : dry ice | Destination | Remarks |
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| **Data** |

Samples in the biobank are by definition anonymised or pseudonymised. There is only limited data available for anonymised samples. For pseudonymised samples, the code table is in the possession of the researcher involved in the collection of the samples. The data included in the biobank's data management system are available on request. If more extensive data is required, this can be discussed at any time with the biobank manager so that the researcher involved in the primary collection of the samples can be contacted.

Additional personal or clinical data are required?  yes  No

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| Description of the desired data |
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| Restmateriaal bewaren: | | Ja: Kies tijdelijke bewaarconditie  Nee |
| **Terms and conditions** (as laid down in the UZA/UAntwerpen hMTA for non-commercial use: annex) | | |
|  |  | |
|  | The researchers declare they will abide to the destination and derivatives as determined in this agreement. | |
|  | The researchers agree to seek approval from the biobank (biobank advisory board) in the event of substantial changes to the study (additional samples, derivatives, protocols, etc.) | |
|  | The researchers guarantee that technical and organisational measures are taken to protect the personal data and guarantee the protection of the personal data in line with GDPR (EU) 2016/679, in particular the measures referred to in Article 32 GDPR and shall inform the biobank of any loss or unauthorised access or use of these data.  Consequently, the investigators will ensure that access to the personal data to be processed and processed is limited to staff members who need the data in order to carry out the tasks for the purposes of the research to be executed. All staff who have access to such personal data have been made aware of the importance of complying with the provisions of the GDPR and are bound by a signed confidentiality obligation.  The investigators commit to provide the following security measures:   * The pseudonymisation and encryption of personal data; * Ability to ensure the confidentiality, integrity, availability and resilience of processing systems and services on an ongoing basis; * Establish a procedure for regularly testing, assessing and evaluating the effectiveness of the technical and organisational measures to ensure the security of processing.   The researchers are looking forward to an update of the technical and organizational security measures that will undoubtedly follow in the composition of the new Data Protection Authority and meanwhile endorse the reference measures as prescribed by the previous privacy commission ("CBPL"). These reference measures can be found via the following link:  <https://www.gegevensbeschermingsautoriteit.be/sites/privacycommission/files/documents/referentiemaatregelen_voor_de_beveiliging_van_elke_verwerking_van_persoonsgegevens_0.pdf> | |
|  | The researchers guarantee that traceability, in accordance with Article 22 §4 of the Law of 19 December 2008, if applicable, remains guaranteed. This means, among other things, that the researchers guarantee that all samples and derivatives will be registered. | |
|  | The researchers will inform the biobank manager of any analysis that provides meaningful information on the donor's health condition, so that the administrator can possibly communicate this information to the donor or his treating physician. | |
|  | The researchers state that they will inform the biobank at the end of the study. | |
|  | The researchers guarantee to mention the biobank in every publication (article, poster, abstract, presentation) that uses the samples obtained and there will be send a pdf of this to the biobank within 60 days after publication.  (a) In the ‘methods’ section of the article: report the use of “Biobank Antwerpen”, Antwerp, Belgium; ID: BE 71030031000”. If relevant, specify the number of samples and type of biospecimens. Refer to the ‘references’ section of the article.  (b) In the ‘references’ section of the article cite as follows **in case of tumorbank material**: “BE 71030031000; Biobank Antwerpen, BBMR-ERIC, Belgian Virtual Tumourbank funded by the National Cancer Plan; No. Access: (specify number of accesses), Last: (specify date of last access in the format: Month, DD, YYYY). [BIORESOURCE]. As an example, the reference for Biobank Antwerpen would be: “BE 71030031000; Biobank Antweren, BBMR-ERIC, Belgian Virtual Tumourbank funded by the National Cancer Plan; No. Access: (1), Last: July, 01, 2016. [BIORESOURCE]” for a single access on July 1st 2016.  (c) In the ‘references’ section of the article cite as follows **in case of non-tumorbank material**: “BE 71030031000; Biobank Antwerpen@UZA, BBMR-ERIC, Belgian No. Access: (specify number of accesses), Last: (specify date of last access in the format: Month, DD, YYYY). [BIORESOURCE]. As an example, the reference for Biobank Antwerpen would be: “BE 71030031000; Biobank Antwerpen, BBMR-ERIC; No. Access: (1), Last: July, 01, 2016. [BIORESOURCE]” for a single access on July 1st 2016. | |
|  | The biobank will always be informed in case of complaints or deviations in connection with the samples . | |
|  | The biobank acknowledges that all information provided is strictly confidential and may only be used by the biobank to the extent legally required following the Biobank legislation . | |

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| **Funding** | |
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| There are costs associated with biobanks and the processing of samples. A cost is therefore agreed upon with the biobank. Some of these costs may go back to the researcher who was involved in the primary collection of the samples in order to partially compensate them for the expenses incurred. | |
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| Billing information : …………………………………...  Budget code: …………………………………...  For this project a cost is calculated of ……………………... euro.   |  |  | | --- | --- | | **Cost items** | **Budget** | | Biobank | | | * Study design |  | | * Recovery of storage cost |  | | * Recovery of registration cost |  | | Research group involved within  the primary collection of samples | | | * Intellectual property |  | | |
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| **Contract number** | | | |
|  | …………………………………... | | |
| **Signatures** | | | |
| **Principal Investigator** | |  | |
| Name: …………………………………...  Signatures:  Date: | | | |
| If this principal investigator is not affiliated with the UA or the UZA, the legal representative of the organisation must also sign.  Name: …………………………………...  Signatures:  Date: | | | |
| **Biobank Beheerder** | |  | |
| Name: MT Huizing  Signatures:  Date: | | | |
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| **Legal representative UZA** | | |
| Name: Johnny Van Der Straeten  Signatures:  Date: | | | |

Capitalized terms used but not defined herein will have the meaning ascribed to them in the Request form secundair gebruik van stalen to which this Human Material Transfer Agreement for Non-Commercial Use constitutes an exhibit.

1. **The Material.** Provider will make the Original Material available to Recipient for the performance of the Project. The Original Material is provided with a fee (excl. VAT) as set out on the Request Form solely to reimburse Provider for its collection, preparation, packaging and shipment costs. Provider retains ownership of the Material and its Confidential Information (as defined in Section 8 below). ”**Material**” means the Original Material and any and all modifications and derivatives thereof and progeny of any of the foregoing, and all data provided by Provider to Recipient (the “**Data**”).
2. **Restrictions on use.** Recipient agrees (i) to use the Material only for the Project, (ii) to restrict the analysis and/or modification of the Material solely to that needed to carry out the Project, and (iii) that the Material may not be used in humans or for any diagnostic or therapeutic purposes. Recipient will not use the Material (i) for any commercial purposes, including commercial screening, (ii) for sale or otherwise transferring Material to a third party, (iii) to generate scientific data or information that is directly or indirectly conveyed to any third party against compensation, or (iv) in research that is subject to consulting, licensing or similar obligations to commercial entities.
3. **Recipient’s research team.** Recipient will allow the use of the Material only by (i) Recipient Scientist and his/her properly qualified and trained research team members that are under his/her direct supervision and (ii) subcontractors that are properly identified in the Request Form in association with specific Project tasks; provided that any such persons need such access for the execution of the Project and only after they have been informed of and agreed to the provisions and restrictions at least as stringent as those stated herein. Without Provider’s prior written consent, Recipient and Recipient Scientist will not use the Material outside the premises of Recipient. Provider will properly and uniquely label each aliquot and derivative that it makes from Original Material provided under this agreement in traceable format as required under Belgian law.
4. **Approvals and licenses.** Provider warrants that (i) the explicit consent provided by the donors of the Original Material(or, in the absence of such explicit consent, a presumed consent or ethical approval)allows for the use of the Original Material for the Project, and (ii) if the Project implies a secondary use of the Original Material, a valid ethical approval covers such use. Recipient represents that it has obtained all other regulatory and ethical approvals and licenses that are needed for the use of the Material in the Project. Recipient will comply with all laws, regulations and guidelines applicable to the handling, use, storage and/or destruction of the Material.
5. **Reporting.** Recipient Scientist will report to Provider on the progress and results of the Project as required by the Request Form. By the earlier of 60 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. If analysis of Material would reveal meaningful information about the health condition of its donor and the Original 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 Original Material allowing Provider to re-identify the donor. Upon reasonable notice, Provider will have the right to audit Recipient’s compliance with the terms of this agreement and applicable law.
6. **Acknowledgment.** In all oral presentations, written publications or press releases relating to the use of the Material, Recipient and Recipient Scientist will acknowledge Provider’s contribution of the Material as required by the Request Form (unless requested otherwise in writing by Provider).
7. **Data protection.** The parties agree that the Material and Data constitute personal data that is subject to the General Data Protection Regulation (EU) 2016/679 and applicable complementing national laws (jointly “**Privacy Laws**”). The parties are independent controllers of the Material and Data and will fully comply with their respective obligations under the Privacy Laws. Recipient will maintain technical and organizational measures to protect personal data that are at least as stringent as those available on [*https://www.uza.be/privacy.html*](https://www.uza.be/privacy.html).. Recipient agrees to notify Provider within a period of 48 hours where Recipient becomes aware of or reasonably suspects that Material or Data has been or may have been lost, damaged or subject to unauthorized internal or external access or any other unlawful processing (a “**Security Incident**”) and to take reasonable steps to mitigate the impact of any such Security Incident. In the event that Recipient receives (i) any request from a data subject to exercise any of its rights under Privacy Laws in relation to the Material or Data (including its rights of access, correction, objection and erasure); and (ii) any other correspondence, inquiry or complaint received from a data subject, regulator or other third party in connection with the processing of the Material or Data (collectively, "**Correspondence**"), it shall promptly inform Provider and the parties shall cooperate in good faith as necessary to respond to such Correspondence and fulfill their respective obligations under Privacy Laws. Upon Provider’s request, Recipient shall restrict the processing of Material or Data identified by Provider. Recipient shall not transfer any Material or Data to a territory outside of the European Economic Area ("**EEA**") unless it has taken such measures as are necessary to ensure the transfer is in compliance with the Privacy Laws. Such measures may include transferring the Data to a recipient in a country that the European Commission has decided provides adequate protection for personal data; to a recipient that has achieved binding corporate rules authorization in accordance with Privacy Laws; to a recipient in the United States that has certified compliance with the EU-US Privacy Shield framework; or to a recipient that has executed standard contractual clauses adopted or approved by the European Commission. Recipient will not make any effort to identify individuals who are or may be the donors of the Original Material and may not combine data or results of the Project with other data which may result in identification of a donor.
8. **Confidential Information.** “**Confidential Information**” means any and all Data and information that is transferred from Provider to Recipient for the purpose of this Agreement. Confidential Information shall be maintained in confidence by Recipient and not be used for any purpose other than the Project. 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. 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.
9. **No warranties.** Any Material delivered pursuant to this agreement is understood to be experimental in nature and may have hazardous properties. Provider makes no warranties of any kind, either expressed or implied. There are no warranties of fitness for a particular purpose or that the use of the Material will not infringe any patent, copyright, or other proprietary rights. Recipient understands that while Provider attempts to avoid supplying Material contaminated with highly infectious agents such as for instance hepatitis and HIV, 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.
10. **Liability.** In no event shall Provider be liable for Recipient’s use, storage or disposal of Material. Recipient will indemnify, defend and hold Provider, its directors and employees and agents harmless from any third party claim arising from Recipient’s use, storage or disposal of Material or Data or breach of this agreement or applicable law, except to the extent caused by gross fault or willful misconduct of Provider.
11. **Termination.** Either party may terminate this agreement with 30 days written notice to the other party. Provider may terminate this agreement with 15 days written notice to Recipient in case of non-remedied breach of this agreement, bankruptcy of Recipient, or for causes such as an imminent health risk. This agreement shall terminate automatically at the earlier of (i) the completion date specified in the Request Form, or (ii) the completion of the Project. The provisions of this agreement that are intended to survive shall so survive after termination.
12. **Effect of termination.** When this agreement is terminated, Recipient will immediately cease using the Material and Data and any Data and unused and remaining Material (including any progeny, modifications and derivatives thereof) and all originals, reproductions, summaries and other tangible forms of Confidential Information will promptly either be destroyed in compliance with all applicable laws and regulations or will (at Recipient’s costs) be returned to Provider as required by the Request Form or as otherwise requested in writing by Provider.
13. **Miscellaneous.** This agreement shall be construed in accordance with the laws of Belgium, without giving effect to its conflict of law provisions. Any dispute relating to this agreement shall be submitted exclusively to the Commercial Courts of Antwerp, Belgium. This agreement together with the Request Form contains the entire understanding of the parties with respect to its subject matter, and supersedes all previous (oral and written) agreements, negotiations and discussions relating thereto. This agreement may not be modified, in whole or in part, except by the written consent of the authorized representatives of both parties. If any provision of this agreement is held to be unenforceable or void, the remaining provisions shall remain in full force and effect. This agreement and the rights and obligations contained herein may not be assigned, sublicensed or subcontracted by either party without the prior written and unambiguous consent of the other party.