**Contract Biobank Antwerpen**

This document describes the arrangements between the researchers (Recipient) and the biobank (Provider) concerning the registration of historical biological samples in accordance with the Royal Decree on Biobanks dd. January 9, 2018.

Definition: A historical collection is defined as a collection of samples collected before November 2018 (when the Royal Decree became applicable.

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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| --- | --- |
| Name of the collection |  |
| Short name  | *(max 255 characters)* |
| Original EC approval  | *(please include letter if available)* |
| Collection start date |  |
| Collection end date |  |
| Collection acquisition date |  |
| ICD-11 classification |  |
| Type of collection *(delete what does not fit)* | Academic/Industry/Public-private partnership/Governmental/Unknown |

NOTE: ICD-11 = International Statistical Classification of Diseases and Related Health Problems – Please use the latest version: https://icd.who.int/en

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| Brief description of the historical collection (max. 10 lines)……………………………………………………………………………………………………………………………………………………………………………………………………………………………..…………..…... |

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| **Identification of the custodian** |

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| **Name lead investigator** |  |
|  Work address |  |
|  E-mail |  |
|  Phone number |  |
| **Name contact person**  |  |
|  Work address |  |
|  E-mail |  |
|  Phone number |  |

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| **Identification of persons involved in the study** |

Please list below the researchers that require access to the data in the BIOSLIMS system. People that are required to edit the data should receive the appropriate training.

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| --- | --- | --- | --- | --- |
| **Name**  | **First name** | **User number**  | **BIOSLIMS****Read-only access** | **BIOSLIMS****Registration rights** |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |

NOTE: The user number is the personnel number for those researchers working at UZA or UAntwerpen.

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| **Identification of samples in the collection** |
|  |  |  |  |  |
| Description of the sample(Eg: 10 ml urine) | Estimated number of samples(Vb: 5 aliquots each of 2 ml) | Storage conditions(Eg: -80°C) | Current storage location(Eg: CDE, building S, room 4.36) | Transfer to central biobank preferred? |
|  |  |  |  | [ ]  yes [ ]  no |
|  |  |  |  | [ ]  yes [ ]  no |
|  |  |  |  | [ ]  yes [ ]  no |
|  |  |  |  | [ ]  yes [ ]  no |
|  |  |  |  | [ ]  yes [ ]  no |
|  |  |  |  | [ ]  yes [ ]  no |

NOTE: If stored decentral, it is the responsibility of the custodian to maintain and monitor the storage room and equipment to ensure continued sample quality. For every use of samples, a contract with the biobank is required in order to ensure registration in BIOSLIMS and reporting to the Ethical Committee in line with the Royal Decree of January 9, 2018 with regard to the biobanks.

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| Verantwoordelijkheid van de PI: | [ ]  Ja | [ ]  Nee |

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| **Informed consent (IC)** |

For every inclusion of samples and use thereof, the biobank is required to verify whether such use is acceptable and in line with applicable legislation. In practice, the biobank needs to verify whether a) an informed consent is present in which the patient approves the use of the samples for the given purpose, b) presumed consent applies or c) in the absence of consent, an ethics committee (EC) has approved the use of these samples for the given purpose. Please indicate below what is applicable for (parts of) the collection.

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| --- | --- | --- | --- |
| Description of the sample(Vb: 10 ml urine) | IC present?(\*) | Presumed consent?(\*\*) | Permission of an EC?(\*\*\*) |
|  | [ ]  yes [ ]  no | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
|  | [ ]  yes [ ]  no | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
|  | [ ]  yes [ ]  no | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
|  | [ ]  yes [ ]  no | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
|  | [ ]  yes [ ]  no | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
|  | [ ]  yes [ ]  no | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
| Verantwoordelijkheid van de PI: |

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|  \*: Please provide the template IC form. The decryption table remains with the principal investigator who assures the presence of the signed documents. \*\*: Please describe how presumed consent applies and provide evidence that such presumed consent is legally acceptable in the country of origin.\*\*\*: Please include the letter of the EC |
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| **Pseudonimization** |
| Samples are normally pseudominized. This means the patient identifiers are removed and can only be linked by use of a unique identifier (code). The decryption table remains with the principal investigator who ensures safekeeping in line with applicable legislation (most notably GDPR).Are the samples pseudominized? [ ]  Yes [ ]  NoDescribe the decryption key: ……………………...Are samples anonimized\*? [ ]  Yes [ ]  No\* Anonimization is only allowed with permission of the patient and in correspondence with the biobank physician manager. Samples registered in Biobank Antwerpen receive a unique code on top of any existing code. |
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| **Data** |
| The biobank works with a minimal data set based on MIABIS 2.0, with inclusion of SPREC coding and using the ICD-10 disease coding system. In most cases, additional clinical or research data often resides with the involved clinicians and/or researchers. Can you please indicate below whether such data is present and whether such data will be brought into (the ELN of) BIOSLIMS?

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| --- | --- |
| [ ]  Additional clinical data present? | [ ]  Yes [ ]  No |
| Kept where and in which format? |  |
| [ ]  Additional research data present?  | [ ]  Yes [ ]  No |
| Kept where and in which format? |  |
| [ ]  Data to be included in the ELN/BIOSLIMS?  | [ ]  Yes [ ]  No |

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| **Conditions for distribution of samples** |
| Samples can only be used for research upon signature of an agreement with the biobank in order to ensure registration in BIOSLIMS and reporting to the Ethical Committee in line with the Royal Decree of January 9, 2018 with regard to the biobanks. This also applies to such use by those researchers who are custodian of the collection. A request for use can be send to biobankantwerpen@uza.be after which such request will be evaluated by the biobank advisory council, a group of experts that will evaluate the scientific quality of the proposal and whether the use of the samples is in line with patient consent and applicable legal and ethical considerations. The custodian of the collection will be invited to participate in the council to ensure he or she is able to provide consent for the specific use. |

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| **Financing** |
| Biobanking comes with a cost. For each collection, the custodian and the biobank agree on the costs related to the uptake of a specific collection.

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|  | Amount (euro) |
| Project design |  |
| Storage cost |  |
| **Total** |  |

If the collection has been uploaded before 31/12/2019, no costs apply. If not, starting from 01/01/2020, a registration cost of 4 euro per sample applies. A deviation of this timeline can be requested at biobankantwerpen@uza.be In case part of the collection dates from after November 2018, the normal biobank fee of 4 euro per parent samples applies to those samples.

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| To the attention of: …………………………………...Billing information: …………………………………...Budget code or reference: …………………………………...For long-term storage, a one-time or periodic payment can be considered. Billing of this project will occur [ ]  once [ ]  periodically with …………………………………... month intervals |

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| **Bijlagen** |
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| Voeg overzicht bijlagen toe: | * …………………………………...
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* …………………………………...
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| **Contract number** |

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| **Signatures** |
| **Principal Investigator** |  |
| Name: …………………………………... | Signature: |
| Date:  |
|  |
| **Biobank Physician Manager** |  |
| Name: …………………………………... | Signature: |
| Date:  |