**BIOMATERIAL RELEASE PROTOCOL**

Request for the release and use of human biomaterial and corresponding data from the biobank

TITLE

for the purpose of scientific research

|  |  |
| --- | --- |
| Version |  |
| Date |  |

Please send completed forms to [toetsingscommissiebiobank@vumc.nl](mailto:toetsingscommissiebiobank@vumc.nl)

*only fully completed forms will be processed*

For questions, please contact the *Toetsingscommissie Biobank* (toetsingscommissiebiobank@vumc.nl)

or the *Centrale Loket Biobank* (biobankvumc@vumc.nl)

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| **1** | **GENERAL DETAILS** | | | |
| 1.1 | Applicant (responsible researcher) | Who is responsible for conducting the research? | | |
| 1.2 | Organisation and department |  | | |
| 1.3 | E-mail address | **@vumc.nl** | | |
| 1.4 | Telephone number / tracer |  |  | |
| 1.5 | Address of organisation |  | | |
| 1.6 | Contact person | Only if this is a person other than the applicant | | |
| 1.7 | Telephone number/ tracer |  | |  |
| 1.8 | E-mail address | **@vumc.nl** | | |
| 1.9 | Project cost account VUmc / Bank account number |  | | |
| 1.10 | Approver (Oracle) |  | | |

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| **2** | **DETAILS OF THE BIOBANK FROM WHICH A REQUEST IS BEING MADE** | | |
| 2.1 | TcB-number of the biobank | TcB-number of the biobank from which material is being requested | |
| 2.2 | What type of biobank is it? | Further use *(material left over after collection for regular care)*  De Novo *(collection for scientific purposes)*  Concerns post-mortem donation | |
| 2.3 | Is the Biobank linked to a (non) WMO-study? | Yes, WMO study with METC-number:  Yes, non-WMO study with METC-number:  No | |
| 2.4 | Head of Department responsible for the biobank | The Head of the Department at VUmc who initiated and is responsible for the biobank | |
| 2.5 | Organisation and department |  | |
| 2.6 | Telephone number/ tracer |  |  |
| 2.7 | E-mail address | **@vumc.nl** | |

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| **3** | **COLLABORATIONS** | |
| 3.1 | Are there any collaborations with parties other than the VUmc? | Yes  No, **proceed to question 4** |
| 3.2 | Type of collaboration | Non-commercial collaboration  (Please contact the IXA and attach a copy of the ‘Material Transfer Agreement’)  Commercial collaboration  (Please contact the IXA and attach a copy of the ‘Material Transfer Agreement’ or contract) |
| 3.3 | Name of the Institute / Company: |  |
| 3.4 | Name of contact person: |  |
| 3.5 | Postal address: |  |
| 3.6 | Postcode: |  |
| 3.7 | Town/city: |  |
| 3.8 | Country: |  |
| 3.9 | Telephone number: |  |
| 3.10 | E-mail address: |  |

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| **4** | **DETAILS OF THE RESEARCH PROPOSAL** | |
| 4.1 | Title of the research project |  |
| 4.2 | Research field | |
|  | Cardiac disorders  Congenital, familial and genetic disorders  Blood and lymphatic system disorders  Eye disorders  Ear disorders and labyrinthitis  Respiratory, thoracic and mediastinal disorders  Gastrointestinal disorders  Skin and subcutaneous tissue disorders  Nutritional or metabolic disorders  Infections and parasitic disorders  Neoplasms; benign, malignant and unspecified  Reproductive system and breast disorders | Endocrine disorders  Injuries, intoxication  Surgical and medical procedures  Vascular disorders  Pregnancy, perinatal period, puerperium  Social conditions  Immune system disorders  Liver and biliary disorders  Nervous system disorders  Psychiatric disorders  other: |
| 4.3 | Scientific relevance |  |
| 4.4 | Research question(s) |  |
| 4.5 | Methods | (Type of study population, primary and secondary outcome parameters, reason for amount of samples required) |
| 4.6 | Targetted start date |  |
| 4.7 | Laymen’s summary | What is the purpose of the research with these samples? Briefly explain why precisely these samples from this biobank should be used. Avoid using jargon. |

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| **5** | **MATERIAL RELEASE (TYPE AND AMOUNT REQUESTED)** | | | | | | |
| 5.1 | **Tissue** | | | | | | |
|  | **Material requested from the biobank** | | **Number of subjects** | **Total amount of samples** | | **Additional info** | |
|  | Paraffin blocks (FFPE) | |  |  | |  | |
|  | Frozen material | |  |  | |  | |
|  | Fresh material after excision | | *Please explain how much, the size and any other relevant additional information* | | | | |
|  | Irregular tissue (disease) | |  |  | | |  |
|  | Normal tissue | |  |  | | |  |
|  | ☐ Other: ………. | |  |  | | |  |
|  | **Requested processing of material from the biobank** | | **Number of subjects** | **Total amount of samples** | | | **Additional info** |
|  | FFPE processing of tissue (formalin-fixed; paraffin-embedded) | |  |  | | |  |
|  | Production of paraffin block | |  |  | | |  |
|  | Production of unstained ‘blank’ paraffin sections  *According to standard procedure, the sections will be cut in sequence and the first and final section will be given a HE-colour.* | |  | | | | |
|  | .. mounted to a coated slide | |  | |  | Desired thickness: | |
|  | .. mounted to an uncoated slide | |  | |  | Desired thickness: | |
|  | .. transferred to Eppendorf tube for DNA/RNA analysis | |  | |  | Desired thickness: | |
|  | Production of unstained ‘blank’ frozen sections  *According to standard procedure, the sections will be cut in sequence and the first and final section will be given a HE-colour* | | *When colouring is requested, please specify what type of colouring* | | | | |
|  | .. mounted to a coated slide | |  | |  | Desired thickness: | |
|  | .. mounted to an uncoated slide | |  | |  | Desired thickness: | |
|  | .. transferred to Eppendorf tube for DNA/RNA analysis | |  | |  |  | |
|  | Production of a TMA | |  | |  |  | |
|  | HE staining | |  | |  |  | |
|  | Histochemical staining | |  | |  |  | |
|  | Immunohistochemical staining | |  | |  |  | |
|  | In situ hybridisation (ISH) | |  | |  |  | |
|  | PCR | |  | |  |  | |
|  | Validation of immunohistochemiscal staining | |  | |  |  | |
| 5.2 | **CELLS** | | | | | | |
|  | **Material requested from the biobank** | | **Number of subjects** | | **Total amount of samples** | **Additional info** | |
|  | Vial with cell line | |  | |  |  | |
|  | Vial with PBMCs isolated from blood | |  | |  |  | |
|  | Vial with PMN isolated from blood | |  | |  |  | |
|  | Vial with blood platelets isolated from blood | |  | |  |  | |
|  | Vial with cells isolated from buffycoat | |  | |  |  | |
|  | Vial with cells isolated from bone marrow | |  | |  |  | |
|  | Ampoule with cells isolated from resection tissue (via dissociation) | |  | |  |  | |
|  | Cell pellets (mixture of red and white blood cells) | |  | |  |  | |
|  | **“**Snap-frozen cells” for DNA/RNA | |  | |  |  | |
| 5.3 | **BODILY MATERIALS/FLUIDS** | | | | | | |
|  | **Material requested from the biobank** | | **Number of subjects** | | **Total amount of samples** | **Additional info** | |
|  | Blood | |  | |  |  | |
| Serum | |  | |  |  | |
| Plasma (anticoagulant EDTA) | |  | |  |  | |
| Plasma (anticoagulant Citrate) | |  | |  |  | |
| Plasma (anticoagulant Heparin) | |  | |  |  | |
| Cerebrospinal fluid | |  | |  |  | |
| Urine | |  | |  |  | |
| Faeces | |  | |  |  | |
| Peritoneal dialysate | |  | |  |  | |
| Saliva | |  | |  |  | |
| Drainage fluid | |  | |  |  | |
| 5.4 | **DNA/RNA** | | | | | | |
|  | **Material requested from the biobank** | **Number of subjects** | | | **Total amount of samples** | **Additional info** | |
|  | DNA/RNA isolated from saliva |  | | |  |  | |
|  | DNA/RNA isolated from blood |  | | |  |  | |
|  | DNA/RNA isolated from bone marrow |  | | |  |  | |
|  | DNA/RNA isolated from cerebrospinal fluid |  | | |  |  | |
|  | DNA/RNA isolated from tissue |  | | |  |  | |
|  | **Requested processing of material from the biobank** |  | | |  |  | |
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| 5.5 | **DATA/CONSULTATION** | | | | | | |
|  | **Data requested from the data management system** | **Amount** | | | **Additional info** | | |
|  | Diagnostic reports (anonymyzed) |  | | | type | | |
|  | Consultation by a pathologist / hematologist / specialist |  | | | Hours and name of specialist | | |
|  | Sample overview from BIMS |  | | |  | | |

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| **6** | **PROCESSING OF HUMAN MATERIAL AND DATA** | |
|  | **Human Material** | |
| 6.1 | How will the human material be processed? | With personal data which could lead to the identification of the subject. *Please provide a reason:*  With coded data  With anonymous data (after linking the data to the material) |
| 6.2 | Who will be responsible for coding/anonymizing the material? | Human material is already coded  Biobank VUmc  other, namely:*name, job title, department and relation to the patient* |
| 6.3 | Is it possible to identify a participant based on the content of the material provided?  (e.g. DNA-research or due to a rare disease/condition). | No  Yes, in the following way:  *! This is only allowed with the explicit consent of the participant* |
|  | **Data** |  |
| 6.4 | Will medical data be used? | Yes  No, **proceed to question 7** |
| 6.5 | Which data sources would you like to use? | EPIC/EPD  Centrale Biobank VUmc  OpenClinica VUmc  Other, namely: |
| 6.6 | If data from EPIC/EPD will be required, please explain how access to the data will be granted. | Via a request for data extraction from EPIC/EPD  Researcher is patient’s treating physician  Other, namely: |
| 6.7 | How will data be collected and processed? | With personal data which could lead to the identification of the subject. *Please provide a reason:*  With coded data  With anonymous data (after linking the data to the material) |
| 6.8 | Who will be responsible for coding/anonymizing the data? | Biobank VUmc  other, namely:*name, job title, department and relation to the patient* |
| 6.9 | Is it possible to identify a participant based on the content of the data provided?  (e.g. by combining data and research results, or due to a rare disease/ condition, or a specific geographical location) | No  Yes, in the following way:  *! This is only allowed with the explicit consent of the participant* |

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| **7** | **CONSENT** | |
| 7.1 | In which way has the donor been informed about the use of human material for scientific purposes? | Via the ‘no objection’-principle of the VUmc (for further use of residual material)  Via a letter specifically for the biobank *(please provide as attachment)*  Via a letter for a WMO study with a biobank *(please provide as attachment)*  Concerns post-mortem donation, **proceed to** **8** |
| 7.2 | In which way has informed consent been provided for the use of human material? | ☐ Via the ‘no objection’-principle of the VUmc (for further use of residual material)  ☐ Via an informed consent form specifically for the biobank *(please provide as attachment)*  ☐ Via an informed consent form for a WMO study with a biobank *(please provide as attachment)* |
| 7.3 | In which way can the donor withdraw his/her informed consent? | By objecting to the further use of residual material (‘no objection’ principle of the VUmc)  By using a Consent Withdrawal form *(please provide as attachment)*  Not possible, because |
| 7.4 | How do the researchers plan to deal with donors who withdraw their consent or who object to the further use of their residual material | Biobank VUmc ensures that no human material or data of these subjects is provided  The research team ensures that no human material or data of these subjects is used  Not possible, because |

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| **8** | **SIGNATURE (of the responsible researcher/applicant)** | |
| 8.1 | The undersigned hereby declares that… | |
|  | * …he/she has truthfully completed this form * …he/she is aware of the *Reglement Toetsing Biobank VUmc*, and the procedures, conditions and guidelines with regard to the storage, release and use of human material and corresponding (clinical) data | |
| 8.2 | Name: |  |
|  | Job title: |  |
|  | Department: |  |
|  | Date: |  |
|  | Signature:  **NB: The form will not be processed if it has not been signed by the appropriate parties** | |

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| **9** | **SIGNATURE (of the head of the department responsible for the biobank)** | | |
| 9.1 | The undersigned hereby declares, on behalf of the biobank | | *title and TcB-number* |
|  | * …. that he/she agrees with the request for the release of material stated in this protocol and provides permission for the use of material by the above-mentioned applicant. * …. that the submitted request for the release of human material and/or corresponding (clinical) data adheres to the scientific requirements * …. that the above-mentioned research falls within the scientific scope of the division and the VUmc | | |
| 9.2 | Name: |  | |
|  | Department: |  | |
|  | Date: |  | |
|  | Signature:  **NB: The form will not be processed if it has not been signed by the appropriate parties** | | |

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| **10** | **APPENDICES (if applicable)** |
|  | Advice of the Local Scientific Committee |
|  | Original participant information letter, informed consent form and withdrawal form *(not necessary if material is collected according to the “no objection” principle)* |
|  | MTA  *(not necessary if the researcher will use material from his/her own biobank or if material will be used within VUmc)* |
|  | Contract(s) with collaborator(s) |
|  | Other, namely.: |