**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

|  |  |
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| Version |  |
| Date |  |

Please send completed forms to 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** |  |  |  |
|  | [ ]  |  |  |  |
|  | [ ]   |  |  |  |
|  | [ ]  |  |  |  |
| 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.:  |