**BIOBANK PROTOCOL**

Request for the approval of

collecting human biomaterial

for the purpose of starting a biobank

Title

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

Completed forms may be sent 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 | Person responsible for the biobank  | Head of the department under which the biobank falls  |
| 1.2 | Organisation and department |  |
| 1.3 | E-mail address | **@vumc.nl** |
| 1.4 | Contact person biobank | Only if different to 1.1 |
| 1.5 | Job description | Click here to add text |
| 1.6 | Telephone number | Click here to add text |
| 1.7 | E-mail address | **@vumc.nl** |
| 1.8 | Sponsor  | Only if this is not VUmc |
| 1.9 | Funding body  | If applicable |

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| **2** | **BIOBANK DETAILS** |
| 2.1 | Title of biobank |  |
| 2.2 | Acronym of biobank | If applicable, or when the study should be registered in EPIC |
| 2.3 | Type of biobank | [ ] Further use (material left over after collection for regular care)[ ] De Novo (collection for scientific purposes) |
| 2.4 | Does the biobank already exist or has it not yet been initiated?  | [ ] Already exists[ ] Not yet initiated |
| 2.5 | Is the biobank linked to a (non)-WMO study? | [ ]  No[ ]  Yes, WMO study with METC-number: [ ]  Yes, non-WMO study with METC-number:  *If yes, what is the status of the study:* running/completed/not yet started |
| 2.6 | Is there a scientific committee involved in the biobank? | [ ]  Yes[ ]  NoIf yes, who is involved in the committee? |
| 2.7 | CMG-number | The number that is provided after registering with the Centraal Meldpunt Gegevensbescherming |
|  | Research field *(not applicable for ‘further use’ biobanks, more than one answer is possible)*: |
| 2.8 | [ ] Cardiac disorder[ ] 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/poisoning[ ] 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:  |
| 2.9 | Summary and aim of the project | Please provide a short summary of the project, including the main aims. What is the final objective of the biobank? Which general research questions do the researchers aim to investigate? |
| 2.10 | Please provide a short description of the type and amount of material that will be collected  | What type of material will be collected and how much?  |
| 2.11 | Please provide a motivation for the type and amount of material that will be collected | Why is this material in this amount required to be able to achieve the objectives?  |
| 2.12 | Biobank population | What type of people will provide material (e.g. healthy subjects, subjects with a particular disease)? |
| 2.13 | Amount of patients to be includedAmount of healthy subjects to be includedTotal | *per year, total.* |
| 2.14 | In which age group can the donors be classified? (more than one answer is possible) | [ ]  younger than 12 years[ ]  12 years or older, but younger than 16 years [ ]  16 years or older, **proceed to 2.16** |
| 2.15 | Reason for minors | Why is it necessary to collect material from donors under the age of 16 in order to be able to achieve the objectives?  |
| 2.16 | Are the donors capable (*wilsbekwaam*) of providing informed consent?  | [ ]  yes, **proceed to 2.18** [ ]  no |
| 2.17 | Reason for including donors who are not capable (*wilsonbekwaam)* of providing informed consent | Why is it necessary to collect human matieral from donors who are not capable of providing informed consent?  |
| 2.18 | Inclusion criteria | Are there specific inclusion criteria for the donors (e.g. medication use, illness, age, gender)?  |
| 2.19 | Exclusion criteria | Are there specific exclusion criteria for the donors (e.g. medication use, illness, age, gender)?  |
| 2.20 | Laymen’s summary | Explain why this biobank is being established. Why are these samples collected? What kind of questions are expected to be answered with the samples? Avoid using jargon. |

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| **3** | **TYPE AND AMOUNT OF MATERIAL (MORE THAN ONE ANSWER IS POSSIBLE)**What type and amount of material do you aim to store in the biobank?  |
| 3.1 | **TISSUE**  |
|  | **Desired material for the biobank** | **Number of samples** | **Amount per sample** **(e.g. ml., cm3, gram)** |
|  | [ ]  Tissue for freezing, collected by biopsy  |  |  |
| [ ]  Tissue for freezing, collected by resection |  |  |
| [ ]  Tissue for paraffin embedding, collected by biopsy  |  |  |
| [ ]  Tissue for paraffin embedding, collected by resection |  |  |
| 3.2 | **CELLS** |
|  | **Desired material for the biobank** | **Number of samples** | **Amount per sample****(e.g. ml., cm3, gram)** |
| [ ]  Cells isolated from blood |  |  |
| [ ]  Cells isolated from bone marrow |  |  |
| [ ]  Cells isolated from resection tissue (via dissociation) |  |  |
|  | [ ]  **“**Snap-frozen cells” for DNA/RNA |  |  |
| [ ] other, namely: … |  |  |
| 3.3 | **BODILY MATERIALS/FLUIDS**  |
|  | **Desired material for the biobank** | **Number of samples** | **Amount per sample****(e.g. ml., cm3, gram)** | **Method of collection** *(e.g. via existing line or additional venipuncture, invasive or collected by the donor)* |
|  | [ ]  Blood |  |  |  |
| [ ] Serum |  |  |  |
| [ ] Plasma (anticoagulant EDTA) |  |  |  |
| [ ] Plasma (anticoagulant Citrate)  |  |  |  |
| [ ] Plasma (anticoagulant Heparin) |  |  |  |
| [ ] Cerebrospinal fluid |  |  |  |
| [ ] Urine |  |  |  |
| [ ] Faeces |  |  |  |
| [ ] Peritoneal dialysate |  |  |  |
| [ ] Saliva |  |  |  |
| [ ] Drainage fluid  |  |  | plura, abdomen, other |
| [ ] Vaginal swab |  |  |  |
| [ ] Anal swab |  |  |  |
| [ ] Hair |  |  |  |
| [ ] Nails |  |  |  |
| 3.4 | **DNA/RNA** |
|  | **Desired material for the biobank** | **Number of samples** | **Amount per sample (e.g. ml., cm3, gram)** |
|  | [ ]  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 |  |  |

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| **4** | **BURDEN**What is the burden for the donors participating in the biobank (e.g. duration of visits, screenings).  |
| 4.1 | Duration: per visit |  |
| 4.2 | Amount of visits |  |
| 4.3 | Please describe the actions donors are required to undertake (e.g. questionnaires, interviews, physical/psychological examinations, diet).  | Please describe what actions are required, additional to the collection of human material.  |
| 4.4 | Will donors be tested for certain diseases/conditions (e.g. HIV, pregnancy)? | [ ]  yes (motivate) [ ]  no |
| 4.5 | Please describe the risks the donors may experience by taking part in the biobank |  |
| 4.6 | Why do you consider the risks to be minimal and the burden proportional to the objective of the biobank? |  |

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| **5** | **CONSENT AND WITHDRAWAL**Please describe the procedures for recruitment and how informed consent will be obtained. Please also provide the Participant Information Letter, Informed Consent Form and Withdrawal Form as attachments. For templates, please see the website of the TcB.  |
| 5.1 | Recruitment | Please briefly describe the method of recruitment: who approaches the potential donors, who provides information, who collects material?  |
| 5.2 | How much time do the donors/legal representatives get to consider their participation?  | Please provide a minimum and a maximum (e.g. minimum of 2 days, maximum of 2 weeks) |
| 5.3 | May the donors be approached again while they are participating in the biobank (e.g. for additional follow-up measurements)? | [ ]  yes (if yes, then the donors must provide explicit consent)[ ] no |
| 5.4 | Are there criteria the researcher will use to judge whether a donor should stop participating in the biobank?  | [ ]  yes, namely [ ]  no |

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| **6** | **STORAGE OF HUMAN MATERIAL, DATA AND PRIVACY**Procedures for the coding and storage of (personal) data and human material |
|  | **Human Material** |
| 6.1 | The Toetsingscommissie Biobank assumes that all material will be registered with the Biobank Central of the VUmc. If not, please provide a reason.  |  |
| 6.2 | Will all human material be coded before storage? | [ ]  yes[ ]  no, because  |
| 6.3 | Who is responsible for coding/anonymizing the material?  | [ ] Biobank VUmc, **proceed to 6.7**[ ] the department responsible for the biobank[ ]  other, namely:  |
| 6.4 | How will the material be coded? |  |
| 6.5 | Who has access to the coding key? |  |
| 6.6 | Where will the key be stored? |  |
| 6.7 | What is the maximum amount of time that the material will be stored for? |  years  |
| 6.8 | Why is it necessary to store the material for this length of time? | consider the objective, the type of material, the costs of storage  |
|  | **Data** |
| 6.9 | Will (personal) data be linked to the material stored in the biobank? | [ ] yes[ ]  no |
| 6.10 | Will all data be coded? | [ ] yes [ ]  no, because  |
| 6.11 | Who is responsible for coding/anonymizing the data? | [ ] Biobank VUmc, **proceed to 6.15**[ ]  the department responsible for the biobank[ ]  other, namely:  |
| 6.12 | How will the data be coded? |  |
| 6.13 | Who has access to the coding key? |  |
| 6.14 | Where will the key be stored? |  |
| 6.15 | What is the maximum amount of time that the data will be stored for? |  years  |
| 6.16 | Why is it necessary to store the data for this length of time? | consider the objective, the type of data  |

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| **7** | **IDEAS FOR FUTURE RESEARCH**If there are already ideas for possible future research, or for collaborations with commercial parties, please provide a short summary.  |
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| **8** | **SIGNATURE (responsible researcher)** |
| 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 submission, release and use of human material and corresponding (clinical) data
 |
| 8.2 | Name:  |  |
|  | Job description: |  |
|  | 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 (head of the department responsible for the biobank)**  |
| 9.1 | The undersigned hereby declares, on behalf of the biobank: | titel |
|  | * … that he/she agrees with the storage of the above-mentioned human material for the above-mentioned purposes
* … that he/she is responsible for the above-mentioned biobank
* …that the above-mentioned research falls within the scientific scope of the Division and of VUmc.
 |
| 9.2 | Name:  |  |
|  | Department: |  |
|  | Date: |  |
|  | Signature: **NB: The form will not be processed if it has not been signed by the appropriate parties**  |