|  |
| --- |
| To be completed by the biobank  |
| Date of arrival:       | Reg. no:       | Sample collection ID:       |

# L1.1. Application for establishment of sample collection for research

All samples covered by the Biobank Act must be established in a biobank. This form is used when to apply for the establishment of a sample collection for research in a biobank. The form also handles the regulation of access to samples in the established sample collection. See document K4. Instructions for forms L1.1, L1.2 and L1.3.

If necessary, the agreement can be supplemented with, for example:

* Form L1a, L1b, L1c if existing samples are to be established as new sample collection.
* Operational service agreements/equivalent that regulate how established samples are to be handled.
* Form L2a1, L2a2 or L2a3 if established samples are to be sent for a specific action.

If samples are to be released, form L1.2 is used.

Request for amendment of previously approved biobank application is made on form L1.3.

*Please note that an approved biobank application (L1.1) does not mean that the research is approved if it is in conflicts with other legislation.*

|  |
| --- |
| 1. Research study
 |
| 1.1 Study title (as stated in in the application for ethical approval):      |
| 1.2 Study working title and/or study ID (if applicable):      | 1.3 EudraCT-no. (in clinical trials of medicinal products):      |
| 1.4 Application for ethical approval, including amendments Handling of samples must fall under the ethical approval. |
| 1.4.1 All registration numbers of the Swedish Ethical approval:      | Append the following:* Application for ethical approval (signed).
* Application for amendment of the ethical approval (if applicable).
* Response to request for complementation of the application (if applicable).
* Decisions regarding application for ethical approval (all).
* Research participant information (if applicable).
* Informed consent forms (if applicable).
 |

|  |
| --- |
| 1. Applicant/Research principal
 |
| 2.1 Responsible principal for research(research principal, as stated in the application for ethical approval)**:**      |
| 2.2 Principal investigator (the one who signed the application for ethical approval) |
| 2.2.1 Name:      |
| 2.2.2 Phone:      | 2.2.3 E-mail:      |
| 2.2.4 Work address:      | 2.2.5 Postcode:      | 2.2.6 City:      |
| 2.3 Local investigator (if applicable, in cases where there in collaboration are local researchers at the principal of the biobank)  |
| 2.3.1 Name:      | 2.3.2 E-mail:      |
| 2.4 Other contact persons. For example, study coordinator, research nurse (one or more can be stated if applicable) |
| 2.4.1 Name:      | 2.4.2 Project role:      |
| 2.4.3 Phone:      | 2.4.4 E-mail:      |

|  |
| --- |
| 1. Responsible biobank (where sample collection is to be established)
 |
| 3.1 Principal of the biobank where the sample collection is to be established:      |
| 3.2 Name of the biobank:      |
| 3.3 Biobank registration number (issued by the Health and Social Care Inspectorate):      | 3.4 Biobank department (if applicable):      |
| 3.5 Other information (to be completed by the biobank):      |

|  |
| --- |
| 1. The sample collection that is to be established
 |
| 4.1 The sample collection that is to be established contains (more than one alternative can be stated) |
| [ ]  **Newly collected samples** ***Please note*** *that newly collected samples that is handled in the same way as healthcare samples and is registered into a samples collection at a clinical laboratory (e.g. pathology) is to be specified as existing samples in this agreement.* [ ]  **Existing samples** – withdrawn from another sample collection at the responsible biobank. Relevant appendices shall be attached:[ ]  **L1a.** Appendix – Information about existing clinical samples in pathology and cytology biobanks.[ ]  **L1b**. Appendix – Information about existing biobank samples.[ ]  **L1c**. Appendix – Information about existing samples in the PKU biobank. (Swedish only)[ ]  **Existing samples** – that is released from another biobank. Agreement regarding release (form L1.2) shall be established.  |
| 4.2 Samples shall be accessible to the study |
| 4.2.1 From, date:      | 4.2.2 To, date:      |
| 4.3 Samples shall be kept after the study is completed |
| [ ]  Yes,       (*year or, until further notice*) | [ ]  No |

|  |
| --- |
| 4.4 Samples that will be included in the sample collection  |
| Instruction for completing the samples tables:1. Specify sample type (blood, urine, cerebrospinal fluid, type of tissue, faeces etc.) for newly collected samples.
2. Specify sample type (type of tissue, material from tumours, cells, blood, serum, plasma, DNA etc.) retrieved from or first registered in an existing sample collection.
3. Specify number of individuals, including screened individuals, from whom samples will be included in sample collection.
4. Specify number of samples per individual.
5. Specify what applies to respective sample type (one mark per row).
	1. Destroyed within nine months after sampling but not immediately (i.e. samples are stored longer than 1–2 days after completed analysis).
	2. Stored no longer than until the date stated in 4.2.2, after which samples are destroyed.
	3. Stored after study is completed (stated in 4.3).
 |

|  |
| --- |
| 4.4.1 Newly collected samples |
| A. Sample type (for guidance, see K4) | C. Number of individuals | D. Number of samples per individual | E. Samples shall:1 2 3(One mark/row) |
|       |       |       | [ ]  [ ]  [ ]  |
|       |       |       | [ ]  [ ]  [ ]  |
|       |       |       | [ ]  [ ]  [ ]  |
|       |       |       | [ ]  [ ]  [ ]  |

*Add more rows if needed*

|  |
| --- |
| 4.4.2 Existing samples |
| B. Sample type (for guidance, see K4) | C. Number of individuals | D. Number of samples per individual | E. Samples shall:1 2 3(One mark/row) |
|       |       |       | [ ]  [ ]  [ ]  |
|       |       |       | [ ]  [ ]  [ ]  |
|       |       |       | [ ]  [ ]  [ ]  |
|       |       |       | [ ]  [ ]  [ ]  |

*Add more rows if needed*

|  |
| --- |
| 1. Samples from the following principals are included in the sample collection that is being established
 |
| Principal | Newly collected samples from | Existing samples from |
| Region Blekinge | [ ]  | [ ]  |
| Region Dalarna | [ ]  | [ ]  |
| Region Gotland\* *(Municipality with no region, but responsible for health and medical care)* | [ ]  | [ ]  |
| Region Gävleborg | [ ]  | [ ]  |
| Region Halland | [ ]  | [ ]  |
| Region Jämtland Härjedalen | [ ]  | [ ]  |
| Region Jönköpings County | [ ]  | [ ]  |
| Region Kalmar County | [ ]  | [ ]  |
| Region Kronoberg | [ ]  | [ ]  |
| Region Norrbotten | [ ]  | [ ]  |
| Region Skåne | [ ]  | [ ]  |
| Region Stockholm | [ ]  | [ ]  |
| Region Sörmland | [ ]  | [ ]  |
| Region Uppsala | [ ]  | [ ]  |
| Region Värmland | [ ]  | [ ]  |
| Region Västerbotten | [ ]  | [ ]  |
| Region Västernorrland | [ ]  | [ ]  |
| Region Västmanland | [ ]  | [ ]  |
| Västra Götalandsregionen | [ ]  | [ ]  |
| Region Örebro County | [ ]  | [ ]  |
| Region Östergötland | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
|       | [ ]  | [ ]  |

*Add more rows if needed*

|  |
| --- |
| 1. Other information
 |
| * 1. Describe where (location/locations) samples will be physically stored:

      |
| * 1. Other information regarding the sample collection, for example if a decision from a steering committee is necessary for withdrawal/release (specify if applicable):

      |

|  |
| --- |
| 1. Invoice information (if applicable)
 |
| 7.1 Company/Organisation:      | 7.2 Corporate identification no. (if applicable):      |
| 7.3 Invoice reference:      | 7.4 PO #:      | 7.5 VAT reg. no:      |
| 7.6 Invoice address:      | 7.7 Postcode:      | 7.8 City:      |
| 7.9 Country:      | 7.10 E-mail:      | 7.11 Peppol-ID/GLN-code:      |

|  |
| --- |
| 1. Terms for establishment
 |
| 1. Approval for the study from the Swedish Ethical Review Authority.2. Samples may not be used for research other than specified in the application for ethical approval.3. Samples must be coded in accordance with the requirements of the Biobank Act and the application for ethical approval. The code key must be kept separate from coded samples and out of the reach of unauthorized persons. 4. Where applicable, there must be an agreement with the biobank/laboratory regarding the costs they have for providing access to the sample collection.5. If samples in the sample collection are required for the care, diagnosis and treatment of the donor/patient, samples should primarily be used to meet this need.6. The principal investigator’s responsibility for the research remains with the investigator. The biobank does not assume any responsibility, e.g. for documentation of signed consent, documentation of withdrawal of consent or ensuring the tracing of samples.7. Terms for consent for studies that have both a main study and sub-studies; If a research participant withdraws consent from the main study, the principal investigator must ensure that the research participant is also asked if they want to withdraw consent for sub-studies.8. The right of disposal of the sample collection, or consultation before other use of it, remains with the principal investigator for the duration of the biobank agreement.9. The principal of the biobank has the right to publish general information about established sample collections in the form of the purpose of the sample collection, the number of samples and sample types and, by agreement, the contact details of the principal investigator or other contact details.10. In the event of a breach of contract, the agreement can be terminated by the responsible biobank. In the event of a change in circumstances of significant importance for the documentation on which the agreement has been signed, the agreement shall be reviewed and, if necessary, revised.11. Samples may be sent for action to a recipient only after the one responsible for the biobank has drawn up an agreement (Material Transfer Agreement [MTA] or equivalent) with the recipient on the purpose of making the material available and what is to be done with samples after the action has been carried out. |

|  |
| --- |
| 1. Signatures
 |
| 9.1 Principal investigator By signature, it is confirmed that the information provided is complete and that all terms stated in the biobank application and in all accompanying appendices are accepted. |
| 9.1.1 Signature: |
| 9.1.2 Name in print:      |
| 9.1.3 Date:      |
| If applicable. In cases where the principal investigator is not at the principal of the biobank.  |
| 9.2 For the research principal By signature, it is confirmed that the information provided is complete and that all terms stated in the biobank application and in all accompanying appendices are accepted.  |
| 9.2.1 Signature (authorised representative): | 9.2.4 Signature (principal investigator/investigator) |
| 9.2.2 Name in print:      | 9.2.5 Name in print:      |
| 9.2.3 Date:      | 9.2.6 Date:      |
| Decision (to be completed by the biobank):[ ]  **The application is approved** and is valid thru the date specified in 4.2.2 or 4.3 (latest date applies) **with the following terms:**      [ ]  **The application is denied with the following explanation:**       |
| **Please note:** If there are changes in the study that require new ethical approval, these changes will not be covered by the existing biobank agreement. As a rule, existing biobank agreements must be altered if there are changes in the study that require new ethical approval.The decision can be reconsidered by the principal of the biobank.  |
| 9.3 For responsible biobank |
| 9.3.1 Signature (authorised representative): |
| 9.3.2 Name in print:      |
| 9.3.3 Date:      |

The principal of the biobank becomes the personal data controller for data in the biobank agreement when being received by the principal’s biobank. The data will be processed in accordance with the General Data Protection Regulation (GDPR). For more information regarding how personal data will be processed in your case we refer to the principal.