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

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

L1.3. Request for amendment of previously approved biobank application

This form is to be used by researchers who wish to apply for an amendment to an approved biobank application prepared on forms L1, L1.1 and/or L1.2.

Please note that if the amendment concerns an approved biobank application according to the multicentre principle (form N1a or T1c), form N2 must be used for the request for amendment. For clinical trials that have been transferred to the Clinical Trials Regulation (CTR) and have an approved biobank application on form L1, form T1.3 must be used for the request for amendment.

The amendment application is sent to the biobank that approved the previous biobank application.

|  |
| --- |
| 1. Research study
 |
| 1.1 Reg. no./Sample collection ID (from previously approved biobank application)       |
| 1.2 Study working title and/or study ID (if applicable):      | 1.3 EudraCT-no. (in clinical trials of medicinal products according to CTR):      |
| 1.4 Application for ethical approval, including amendments. (Handling of samples must fall under the ethical approval.) |
| All registration numbers of the Swedish Ethical approval:      | New versions of the following documents are to be appended:* 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).
 |

|  |
| --- |
| 1.5 Application for amendment refers to:Specify the information added and/or change from the previous application |
| [ ]  **New principal investigator and/or new research principal.** Complete section 2. |
| [ ]  **Extended storage time and/or mores samples (e.g. increased sample quantity, new sample types and/or more individuals).** Complete section 3.The previously approved biobank application is on form (more than one can be marked): |
| [ ]  **L1** | [ ]  **L1.1** | [ ]  **L1.2** |  |  |  |
| [ ]  **Addition of new principals.** Complete section 4. Append form L1a/L1b/L1c to every new principal (region) if access to existing samples is desired.  |
| [ ]  **Cessation of continued release of newly collected samples via previously signed biobank agreement (L1) where release (part II) is included.** Release of newly collected samples from a region’s biobank to the specified receiving biobank is valid from the start of the sample collection and up to and including the date of the approved application for amendment (form L1.3). The releasing principal, according to previous biobank agreement, continues to be responsible for saving documentation about the released samples and to whom the samples have been released to during this period, in order to enable the traceability of the samples.By date of approved amendment (form L1.3), the following applies:1. Samples are established directly into the sample collection at the specified recipient biobank, which is responsible for storing sample documentation to enable sample traceability.
2. The specified recipient biobank is responsible for ensuring that the information and documentation, concerning samples in the study, is correct and up to date. Any future changes to the study do not need to be notified to the region’s biobank or the principal where samples are collected.
3. Existing samples or newly collected samples that have a partial care purpose will continue to be established in the healthcare provider's biobank and be released to the recipient in accordance with previous agreement.
 |
| [ ]  **Other changes**The application for amendment is only related to information included in the previous biobank application. The previous biobank application has been approved on form/s (several options are possible): |
| [ ]  **L1** | [ ]  **L1.1** | [ ]  **L1.2** |  |  |  |
| Describe the change:       |

|  |
| --- |
| 1. New research principal and/or new principal investigator
 |
| 2.1New responsible principal for the research (research principal, as stated in the application for ethical approval to the Swedish Ethical Review Authority):       |
|  2.2 New principal investigator(the one who signed the application for ethical approval to the Swedish Ethical Review Authority.)  |
| * + 1. Name:

      | 2.2.2 Clinic/Unit:      |
| 2.2.3 Work address:      | 2.2.4 Region:      |
| 2.2.5 E-mail:      | 2.2.6 Phone:      |

|  |
| --- |
| 1. Change in current sample collection
 |
| * 1. Samples shall be accessible to the study, please specify new end date:

      |
| * 1. Samples shall be stored for future use, please specify new end date:

      (*year or until further notice*) |

|  |
| --- |
| **3.3 Additional samples that will be included in the sample collection** |

|  |
| --- |
| **3.3.1 Newly collected samples** |
| A. Sample type (for guidance, see K4)  | C. Number of individuals | D. Number of samples per individual |
|       |       |       |
|       |       |       |

*Add more rows if needed.*

|  |
| --- |
| **3.3.2 Existing samples** Append fully completed form L1a/L1b/L1c |
| B. Sample type (for guidance, see K4) | C. Number of individuals | D. Number of samples/PAD per individual |
|       |       |       |
|       |       |       |

*Add more rows if needed.*

|  |
| --- |
| 1. Addition of new principals
 |
| Select the appropriate principal |
| **Principal** | **Newly collected samples from** | **Existing samples from** |
| Region Blekinge | [ ]  | [ ]  |
| Region Dalarna | [ ]  | [ ]  |
| Region Gotland *(Municipality without a region)* | [ ]  | [ ]  |
| Region Gävleborg | [ ]  | [ ]  |
| Region Halland | [ ]  | [ ]  |
| Region Jämtland Härjedalen | [ ]  | [ ]  |
| Region Jönköpings län | [ ]  | [ ]  |
| Region Kalmar län | [ ]  | [ ]  |
| Region Kronoberg | [ ]  | [ ]  |
| Region Norrbotten | [ ]  | [ ]  |
| Region Skåne | [ ]  | [ ]  |
| Region Stockholm | [ ]  | [ ]  |
| Region Sörmland | [ ]  | [ ]  |
| Region Uppsala | [ ]  | [ ]  |
| Region Värmland | [ ]  | [ ]  |
| Region Västerbotten | [ ]  | [ ]  |
| Region Västernorrland | [ ]  | [ ]  |
| Region Västmanland | [ ]  | [ ]  |
| Västra Götalandsregionen | [ ]  | [ ]  |
| Region Örebro län | [ ]  | [ ]  |
| Region Östergötland | [ ]  | [ ]  |

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

*Add more rows if needed.*

|  |
| --- |
| 5. Other information  |
| 5.1 Other information regarding the sample collection, for example if a decision from a steering committee is necessary for withdrawal/release (specify if applicable):      |

|  |
| --- |
| 6. Invoice addressPlease make sure that the invoice information is correct. An additional cost may be added if adjustments need to be done on an already sent invoice.  [ ]  The information has not been changed since the last application – leave section 6 empty.  |
| 6.1 Company/organisation:      | 6.2 Corporate identification no. (if applicable):      |
| 6.3 Invoice reference:      | 6.4 PO#:      | 6.5 VAT reg. no.:      |
| 6.6 Invoice address:      | 6.7 Postcode:      | 6.8 City:      |
| 6.9 Country:      | 6.10 E-mail for invoice:      | 6.11 Peppol-ID/GLN-code:      |

|  |
| --- |
| 7. Signatures |
| 7.1 Principal investigatorBy signature, it is confirmed that the information provided is complete and that the terms and conditions in the biobank application and in all accompanying appendices are accepted. |
| 7.1.1 Signature: | 7.1.2 Date:      |
| 7.1.3 Print name:       | 7.1.4 E-mail:      |
| Decision by responsible biobank (completed by authorised representative) [ ]  The request for amendment is approved with the following terms:       [ ]  The request for amendment is denied with the following explanation:      The decision can be reconsidered by the principal of the biobank. |
| 7.2 For the responsible biobank |
| 7.2.1 Signature (authorised representative): | 7.2.2 Date:      |
| 7.2.3 Print name:      | 7.2.4 E-mail:       |

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

## Amendment of agreement regarding release of samples

|  |
| --- |
| 8. Signatures applicable when samples are released |
| 8.1 For the *responsible/receiving* biobank |
| 8.1.1 Signature (authorised representative): | 8.1.2 Date:      |
| 8.1.3 Print name:      | 8.1.4 E-mail:      |
| Decision by releasing biobank (completed by authorised representative)[ ]  The request for amendment is approved with the following terms:      [ ]  The request for amendment is denied with the following explanation:      The decision can be reconsidered by the principal of the biobank. |
| 8.2 For the *releasing* biobank |
| 8.2.1 Signature (authorised representative):  | 8.2.2 Date:      |
| 8.2.3 Print name:      | 8.2.4 E-mail:      |

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