K4.3 Instructions for completing form L1.3 request for amendment of previously approved biobank application

This is an instruction on how to complete form L1.3 to submit a request for amendment of a previously approved biobank application.

Form L1.3 shall be used when applying for an amendment to a previously approved biobank application submitted on form L1, L1.1, or L1.2.

L1.3 Request for amendment of previously approved biobank application

1. Research study	
1.1 Reg. no./Sample collection ID	State the same reg. no./sample collection ID as stated in the previously approved biobank application.
1.2 Study working title and/or study ID	If applicable, state the same working title and/or study ID as stated in previously approved biobank application.
1.3 EudraCT-no.	To be stated in clinical trials of medicinal products (according to Clinical Trials Directive (CTD)) with approval from the Swedish Medical Products Agency before 31ST January 2025. For clinical trials approved under the EU regulations for clinical trials (Clinical Trials Regulation (CTR), Medical Device Regulation (MDR), and In Vitro Diagnostic Regulation (IVDR)) and with an approved biobank application on form L1, T1, or T1.1, form T1.3 shall be used when applying for an amendment.
1.4 Application for ethical approval, including amendments	State all registration numbers of the Swedish Ethical approval relevant for the amendment application in question.
1.5 Previously approved biobank application is on form/s:	Mark the form(s) on which the previously approved biobank application was submitted. Multiple selections are possible. L1.3 can only be selected in combination with L1/L1.1/L1.2.
1.6 Application for amendment refers to	Mark which kind of amendments that the application is regarding. Multiple selections are possible. For the request of amendment concerning “Cessation of continued release of newly collected samples via previously signed biobank agreement (L1) where release (part II) is included” no further information is needed. The completed form is sent to the biobank that approved the release (the healthcare principal's biobank) according to previous agreements. In general, a request for amendment shall be made if the information specified in the previously approved biobank application has changed. For example, if the study title, details of the local researcher, or other contact persons need to be updated, select “Other amendment” and specify the change. If there is uncertainty regarding which "other changes" should be submitted, the biobank coordinator at the biobank concerned can be consulted

2. Change of Applying Research Principal and/or Principal Investigator

2.1 New Applying Research Principal for the research	State the new Applying Principal for the research (Research Principal); this must be the same as the Applying Research Principal specified in the approved amendment application submitted to the Swedish Ethical Review Authority.
2.2 New Principal Investigator	State the person who signed the application for ethical approval to the Swedish Ethical Review Authority and said person's contact information.

3. Change in current sample collection

3.1 Samples shall be accessible to the study, please specify new end date	Specify the new end date (YYYY-MM-DD) for how long the samples shall be accessible to the study.
3.2 Samples shall be stored for future use, please specify new end date	Specify the new end date (YYYY-MM-DD) or "until further notices" for how long the samples shall be kept for potential future research.
3.3 Additional samples that will be included in the sample collection	**3.3.1 Newly collected samples** Describe the content and number of newly collected samples the amendment concerns. For A, C and D see below. **3.3.2 Existing samples** Describe the content and number of existing samples the amendment concerns. For B, C and D see below. A. NEWLY COLLECTED SAMPLES: Specify sample type (e.g. blood, urine, cerebrospinal fluid, type of tissue, faeces) that the amendment concerns. The change may be the addition of a completely new sample type that was not included in the previously approved biobank application, more individuals or more samples per individual of the sample type(s) covered by the previously approved biobank application (see example below). *Add more rows if needed.* B. EXISTING SAMPLES: Specify sample type (e.g. type of tissue, material from tumours, cells, blood, serum, plasma, DNA) that the amendment concerns. The change may be the addition of a completely new sample type that was not included in the previously approved biobank application, more individuals or more samples per individual of the sample type(s) covered by the previously approved biobank application (see example below). *Add more rows if needed.* C. Specify number of individuals that the amendment concerns. The change may be the addition of more individuals than in the previously approved biobank application or a new sample type, more samples from the same number of individuals or more samples per individual (see example below). D. Specify number of samples per individual that the amendment concerns. The change may be mores samples per individual than the previously approved biobank application, or new sample type, or more individuals (se example below). Note: specified sample types must be covered by what has been stated in the application for amendment to the Swedish Ethical Review Authority and be included in the revised Research Subject Information. Same sample types can be stated on several rows if the number (column C and D) differs.

Examples of changes that entail more samples and how the information is entered in L1.3 when previously approved biobank application looks like below.

From the previously approved biobank application submitted on form L1.1:

4.4.1 Newly collected samples			
A. Provtyp	*C. Antal individer*	*D. Antal prov per individ*	*E. Prov ska: 1 2 3 (Ett kryss/rad)*
Blood	*150*	*1*	☐ ☒ ☐

Exemple 1: In case of completely new sample type that was not included in the previously approved biobank application. The amendment concerns the addition of the sample type urine (one sample per individual) but from the same number of subjects as in the previously approved biobank application.

3.3.1 Newly collected samples		
A. Sample type (for guidance, see K4.3)	C. Number of individuals	D. Number of samples per individual
Urine	150	1

Exemple 2: In case samples from more individuals than what was included in the previously approved biobank application. The change only concerns the addition of 50 test individuals, but otherwise the same sample types and number of samples per individual as in the previously approved biobank application.

3.3.1 Newly collected samples		
A. Sample type (for guidance, see K4.3)	C. Number of individuals	D. Number of samples per individual
Blood	50	1

Exempel 3: In case of more samples per individual than what was included in the previously approved biobank application. The amendment only concerns the addition of 20 samples per individual, but otherwise the same sample types and number of individuals as in the previously approved biobank application.

3.3.1 Newly collected samples		
A. Sample type (for guidance, see K4.3)	C. Number of individuals	D. Number of samples per individual
Blood	150	20

4. Addition of new principals

Mark the new principals from which new samples are to be collected and/or from which existing samples are to be collected. More rows can be added by placing the cursor in the table and then hovering over the left edge of the table and pressing the + sign. Applies only to amendments where the previous application has been approved on form L1, L1.1, or L1.3.

5. Other information

Specify other information regarding the sample collection that is to be added or amended.

6. Invoice address

Specify new invoice information if other than in the previously approved application.

8. Signatures applicable for the establishment of samples (for guidance see K4.3a)

8.1 Principal Investigator *Please contact the responsible biobank concerning possible use of digital signatures.*	Fill in the name of the principal investigator (8.1.3) and e-mail (8.1.4). Send the unsigned L1.3 by email to the biobank that approved the previous biobank application for review (contact details are available on the Biobank Sweden website).
or	
8.2 For the Research Principal	Fill in the name of authorised representative for the Research Principal (if other than the principal of the responsible biobank) (8.2.2) and e-mail (8.2.3). Fill in the name of the Principal Investigator (8.2.5) and e-mail (8.2.6). Send the unsigned L1.3 by email to the biobank that approved the previous biobank application for review (contact details are available on the Biobank Sweden website).

Amendment of agreement regarding release of samples

10. Signatures applicable when samples are released (for guidance see K4.3a)

10.1 Principal Investigator *Please contact the responsible biobank concerning possible use of digital signatures.*	Fill in the name of the principal investigator (10.1.3) and e-mail (10.1.4).
10.2 For the *responsible/receiving* biobank	Completed by the biobank. The biobank custodian or other authorised representative of the responsible/receiving biobank must sign the application.
10.3 For the *releasing* biobank	Completed by the biobank. The biobank custodian or other authorised representative of the releasing biobank must sign the application. The biobank custodian (or other authorised representative) marks relevant box to show if the application is approved or denied. • If the application is approved, specific terms for the approval may be specified. • If the application is denied, this must be justified to the applicant. Reference to the appendix may be made.