BIOBANK SVERIGE

Document: *K4.3 Instructions for completing form L1.3*
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Established by*: Management team on behalf of the steering group for Biobank Sweden*

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

This is an instruction on how to complete the form to apply for the establishment of samples in a biobank and for the release of samples from a biobank.

L1.3 Request for amendment of previously approved biobank application	Shall be used when requesting amendment of previously approved application on form L1, L1.1 and/or L1.2.
L1.1 Establishment of sample collection for research	See document K4.1.
L1.2 Agreement on the release of samples and personal data	See document K4.2.

L1.3 Request for amendment of previously approved biobank application

1. Research study	
1.1 Reg. no./Sample collection ID (from previously approved biobank application)	State the same reg. no./sample collection ID as stated in the biobank application the amendment regards.
1.2 Study working title and/or study ID (if applicable)	If applicable, state the same working title and/or study ID as stated in previously approved biobank application.
1.3 EudraCT-no. (in clinical trials of medicinal products according to CTR)	To be stated in clinical trials of medicinal products with approval from the Swedish Medical Products Agency. In order to identify clinical trials of medicinal products in Europe, each trial has a unique EudraCT number. For more information about EudraCT numbers, go to the Medical Products Agency's website.
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 Application for amendment refers to	Mark which kind of amendments that the application is regarding and specify the changes made compared to the previous application. Note! If the application for amendment concerns the cessation of continued release of newly collected samples according to a previously signed biobank agreement (L1) where release (Part II) is in progress, 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. If there is uncertainty regarding which "other changes" should be submitted, the biobank coordinator at the biobank concerned can be consulted. In general, an amendment

	application must be made if the information specified in the previously approved biobank application has changed. For example, if the study period specified in the previously approved biobank application needs to be extended, select "Other change" and describe the change.

2. New research principal and/or new principal investigator

2.1 New responsible principal	State the new responsible principal for the research (research principal), same as stated in the application for ethical approval to the Swedish Ethical Review Authority
2.2 New principal investigator	State the name of 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 (YY-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 (year or until further notice)	Specify the new end date (YY-MM-DD) for how long the samples shall be kept for 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. **3.3.2 Existing samples** Describe the content and number of existing samples the amendment concerns. A. NEWLY COLLECTED SAMPLES: Specify sample type (blood, urine, cerebrospinal fluid, type of tissue, faeces etc) 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 (type of tissue, material from tumours, cells, blood, serum, plasma, DNA etc.) 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 the example below.

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

Specify 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.

5. Other information

Specify other information regarding the sample collection, for example if a decision from a steering committee is necessary.

6. Invoice address

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

7. Signatures

7.1 – 7.2 *Please contact the responsible biobank concerning possible use of electronic signatures.*	Fill in the name of the principal investigator (7.1.3) and e-mail (7.1.4) and e-mail the unsigned L1.3 to the biobank that approved the previous biobank application for preview (contact information can be found at biobanksverige.se).

Amendment of agreement regarding release of samples

8. Signatures applicable when samples are released

Completed by concerned biobanks

8.1 For the *responsible/receiving* biobank	The biobank custodian or other authorised representative of the responsible/receiving biobank must sign the application.
8.2 For the *releasing* 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.