Document: *K4. Instructions for completing form L1.1, L1.2 and L1.3*
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Established by: *Management team on behalf of the steering group for Biobank Sweden*

K4. Instructions for completing form L1.1 for the establishment of sample collection for research, L1.2. for the release of samples for research, and 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.

L1.1 Establishment of sample collection for research For instructions see page 2	Shall be used for the establishment of samples in a biobank • All samples that are to be used in research and that are covered by the Biobank Act must be established as a sample collection in a biobank in Sweden. • It is the biobank custodian who decides whether a sample collection is to be established in the biobank and for what purpose or purposes it may be used. • The application for establishment is made by the researcher applying via a so-called biobank application to the biobank custodian. • When the biobank application is approved and signed by the biobank custodian, it becomes an agreement/biobank agreement. • The purpose of the agreement on establishment is to meet legal requirements for research samples and regulate the researcher's (sample collection controller's) access to the sample collection for the purpose in question. The agreement may, if necessary, be supplemented with: • Form L1a, L1b, L1c if existing samples are to be established as a 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.
L1.2 Agreement on the release of samples and personal data For instructions see page 8	Shall be used if samples are to be released to another principal. One agreement per releasing biobank. A sample may only be released to another biobank in Sweden. Samples released cease to be part of the biobank from which they were released from. A sample that is preserved after the release must be established in a sample collection in a biobank at the recipient. • It is the biobank custodian who decides whether a sample collection shall be released. • If a biobank custodian rejects a request for the release of samples, the matter must be reviewed by the principal of the biobank at the request of the applicant. • The principal investigator applies for the release by sending the biobank application to the biobank custodian of the releasing biobank. The application is signed by the principal investigator as the person who has read and understood the same. • The applicable appendices regarding the samples that are to be released (existing samples) are signed by the sample collection controller of the concerned sample collection at the releasing biobank. • After signed approval by the biobank custodians at the releasing biobank and the receiving biobank, the biobank application becomes a biobank agreement between the releasing and the receiving biobank.

	• The purpose of the agreement is to regulate that the responsibility for and access to samples in the specific sample collection is transferred from the releasing to the receiving biobank.
L1.3 Request for amendment of previously approved biobank application For instructions see page 11	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

1. Research study

1.1 Study title	State the same name as stated in the application of ethical approval.
1.2 Study working title and/or study ID	If applicable, state the same working title as stated in the application of ethical approval
1.3 EudraCT-no.	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. For clinical trials and performance studies governed by any of the EU Regulations (536/2014, 2017/745 and 2017/746) and with an EU Trial Number or CIV ID, form T1.1 is used instead.
1.4 Application for ethical approval, including amendments	An approved application for ethical review for the study is required to use identifiable human samples in a research study. **Please note:** An ethical approval is valid until further notice provided that the research has begun within two years from the date on which the decision on approval gained legal force. An amendment of the application for ethical review is required if the study has been changed so that the safety of the research subjects is affected or if the change may otherwise affect the risk-benefit assessment made in the previous review of the application (e.g. if additional research subjects are to be included, if a larger amount of sample material is desired, or if new methods or new analyses are to be performed on already collected material). **1.4.1** All registration numbers of the Swedish Ethical approval. **Please note:** When processing the biobank application, the accordance between the biobank application, the application for ethical review, approval from the Swedish Ethical Review Authority (EPM) or the Ethics Review Appeals Board (ÖNEP) and research subject information (if available) is reviewed. In order to avoid delays in processing, it is important that the biobank receives the latest version approved by EPM/ÖNEP or the latest version sent to EPM for a decision on approval.

2. Applicant/Research principal

2.1 Responsible principal for research (research principal):	The research principal, the same as stated as the responsible research principal in the application for ethical approval. The research principal is the organisation, authority, or company in whose activities the research takes place. The research principal has the overall responsibility for activities (legal and financial) in which the researcher in question is active and as stated in the application for ethical review. In the biobank application, the research principal can never be a natural person. **Pleases note:** The premiss is that the responsible research principal also is the responsible principal for the biobank, but it is also possible to establish samples at another principal. In a research project with several participating research principals, there are several alternatives, such as: – *One* of the research principals may be appointed as the responsible biobank principal, for example the research principal named as the responsible research principal in the application of ethical approval, or – All participating research principals become biobank principals for the samples that are collected and stored in the biobank at each participating research principal.
2.2 Principal investigator	The principal investigator for the project (the research study) stated in the application for ethical approval. **Please note:** On their website, the Swedish Ethical Review Authority describes that the principal investigator has the overall responsibility for the research and is the contact person towards the Swedish Ethical Review Authority and should also be the contact person for the research participants. There is only one principal investigator for the entire study, even when several research principals participate. When applying for a sample collection to be established in a biobank at another principal: Normally, the principal investigator must submit the application for establishment to the research principal's biobank, but in some studies the study design means that the sample collection must be established at one of the participating research principals other than the one where the principal investigator is located: ○ If the principal investigator does not have the authority to sign an agreement with an external party, the one who have the authority of the responsible research principal also need to sign the agreement. In these cases, the application is signed by the principal investigator as the person who has read and understood the same. For this option, use section 9.2 for signature. ○ If there is a local investigator (other than the principal investigator) at a participating research principal (other than the responsible research principal) who will set up a sample collection and become the sample collection controller. See section 2.3.
2.3 Local investigator	The section is used in studies with several participating research principals with a study designed so that - samples must be stored and handled locally by the local investigator - the principal investigator is active at a research principal other than the participating research principal where the local investigator is active. If there is a local investigator at the participating research principal (other than the responsible research principal) who will establish a sample collection in the biobank of the participating research principal, this needs to be notified to the biobank where the sample collection is to be established by the principal investigator and verified by the participating research principal. Section 9.2 can be used for the signature of the participating research principal in this case.
2.4 Other contact persons	Provide contact information for additional persons, if applicable, e.g. contact persons for conducting the research study e.g. study coordinator or research nurse. Contact information for several people can be entered in the same box.

3. Responsible biobank (where sample collection is to be established)

3.1 Principal of the biobank where the sample collection is to be established	Provide the name of the principal of the biobank that is going to be responsible for the biobank samples. **Please note:** The responsible principal should primarily be the legal entity that decided on the collection of samples (the research principal). A sample taken both for patient care and for research must initially be registered in a biobank with the healthcare principal. Also, see note in 2.1
3.2 Name of the biobank	Provide the name of the biobank where samples are to be established.
3.3 Biobank registration number	**3.2 and 3.3** Contact the biobank custodian/coordinator for information regarding the name of the biobank and the registration number (according to the Health and Social Care Inspectorate, IVO), and if applicable, biobank department (for the South healthcare region).
3.4 Biobank department	
3.5 Other information	**To be completed by the biobank.**

4. The sample collection that is to be established

4.1 The sample collection that is to be established contains	Check applicable boxes to state if the application regards to newly collected and/or existing samples (see information box below). If access to existing samples from another sample collection is desired, check applicable boxes to state which appendices for existing samples are to be appended.
4.2 Samples shall be accessible to the study	**4.2.1** and **4.2.2** Specify the same time period as stated in the section "For how long is the project to have access to the biological samples" in the application for ethical review.
4.3 Samples shall be kept after the study is completed	State the same time period as stated in the section "For how long are the biological samples to be accessible after the project has been completed" in the application for ethical approval, i.e. for future research after the current study has been completed.
4.4 Samples that will be included in the sample collection	**4.4.1** Describe the content and number of newly collected samples. Specify the sample type collected from the sample donor (see example below). **4.4.2** Describe the content and number of existing samples. Specify the sample type that requires the approval of the sample collection controller (L1a, L1b or L1c) (see example below). A. Specify sample type (blood, urine, cerebrospinal fluid, type of tissue, faeces etc.) for newly collected samples. B. 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. C. Specify number of individuals, including screened individuals, from whom samples will be included in sample collection. D. Specify number of samples per individual. E. 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). **Please note:** Specified sample types must be covered by what is stated in the application for ethical review and the research participant information. Only one checked box per line on how to handle samples (alt 1-3). The same sample type shall appear in several rows if the number (columns C and D) and/or handling (column E) varies. More rows can be added by placing the cursor in the table, then hovering over the left edge of the table and pressing the + sign.

Example: In case of 1 urine samples and 3+4 blood samples per patient in one study.

4.4.1 Newly collected samples

A. Sample type	C. Number of individuals	D. Number of samples per individual	E. Samples shall: 1 2 3 (One mark/row)
Urine	150	1	☒ ☐ ☐
Blood	150	3	☐ ☒ ☐
Blood	50	4	☒ ☐ ☐

Example 1: In case of request for diagnostic slides from the primary diagnosis and from the recurrence occasion, fresh frozen tissue from both occasions. The study includes 150 individuals/patients.

4.4.2 Existing samples

B. Sample type	C. Number of individuals	D. Number of samples/PAD per individual	E. Samples shall: 1 2 3 (One mark/row)
Diagnostic slides	150	2	☐ ☐ ☒
Paraffin blocks	150	2	☐ ☐ ☒
Fresh frozen tissue (primary and recurrence occasion)	150	1–2	☐ ☒ ☐
Liquid-based cytology	150	1	☐ ☒ ☐

Example 2: In case of request for fluid-based cytology from the time of diagnosis. The study includes 350 individuals/patients.

4.4.2 Existing samples

B. Sample type	C. Number of individuals	D. Number of samples/PAD per individual	E. Samples shall: 1 2 3 (One mark/row)
Liquid-based cytology	350	1	☐ ☒ ☐

Information box:

Newly collected samples

- Samples that are taken for a specific research study must always be established in a biobank in accordance with the Biobank Act.

Existing samples

When deciding on access to existing samples for new research, consideration shall be given, among other things, to matters necessary for the person responsible for the purpose for which the sample was collected and preserved to be able to fulfil his or her responsibilities.

- Samples stored in regional biobanks taken within healthcare for the sample donor's treatment, diagnosis and treatment.

These samples belong to the healthcare system's biobank. In order to gain access to these samples, a decision is required from the biobank custodian, who among other things has the task of ensuring that the sample collection controller for the sample collection with healthcare samples assesses that enough material remains for possible future care, diagnostics and treatment. Existing samples also include newly taken samples that are handled according to healthcare routines by a clinical laboratory, such as the pathology unit, as an assessment of which

part/volume can be used for research without affecting diagnostics is required. Note: it is not permitted to request more material than the study requires.

or

- Samples taken during a now completed research study where consent to keeping them after study completion and future research exists.

Conditions for access to these samples are regulated in the existing biobank agreement between the sample collection controller and the biobank custodian. In order to gain access to these samples for a new research study, it should be taken into account that it does not interfere with ongoing research. It requires approval by the sample collection controller and then a formal decision by the biobank custodian and, if necessary, a new application for ethical review and a new biobank agreement.

5. Samples from the following principals are included in the sample collection that is being established

Specify the principal(s) from which new samples are collected and/or from whom existing samples are to be withdrawn from.

Please note: For traceability reasons, it is relevant for the biobank where samples are established to know if the sample collection to be established in the biobank has been collected/comes from other principals.

– Regarding newly collected samples: It is also relevant for the regions where samples are newly collected to be informed that they will not be the responsible principal, but that there is a biobank that has taken on the responsibility. Form L7 is used to notify the region where newly collected research samples are taken that they should not be the biobank responsible for these samples. The responsible researcher is responsible for ensuring that L7 is sent, but in cases where the responsible biobank is a region, the regions' biobanks have agreed (as a support to researchers) that they will send L7 to the regions where samples are newly collected. The information in paragraph 6 regarding the principals in which samples are newly collected is thus also a support for the responsible biobank and the responsible researcher to know which regions L7 should be sent to.

– Regarding existing samples: The information can also be used as a support to check that L1.2 has been signed for the release of samples.

More rows can be added by placing the cursor in the table, then hovering over the left edge of the table and pressing the + sign.

6. Other information

6.1 Describe where (location/locations) samples will be physically stored	Specify a plan for the physical storage of samples. This is important in order to know if additional agreements need to be drawn up. For example, if samples are to be stored physically in the responsible biobank (service agreements may need to be drawn up) or if samples are to be stored physically elsewhere within or outside the principal of the responsible biobank. If samples are to be stored outside the principal, a material transfer agreement (MTA) regarding the action of storage must be drawn up between the responsible biobank and the business where samples are stored physically.
6.2 Other information regarding the sample collection	Specify whether there are other conditions regarding the handling of the sample collection. This can be, for example, whether a steering group decision is required for withdrawal/retrieval.

7. Invoice information (if applicable)

For example, handling of application, taking out samples, registration, or deposit of samples in a biobank might generate a cost price from the Healthcare Principal. If applicable, specify invoice address.

8. Terms for establishment

The pre-printed terms are always in force when establishing a sample collection for research.

9. Signatures

9.1 Principal investigator *Please contact the responsible biobank concerning possible use of electronic signatures.*	*To be used when* • *the principal investigator applies for the establishment of a sample collection in a biobank at the research principal of the principal investigator.* • *the principal investigator applies for the establishment of a sample collection in a biobank at another principal and the principal investigator has the authority to sign an agreement with an external party.* The principal investigator (stated in 2.2) must sign the application. When the application is ready for signing on paper originals, the principal investigator must sign before the application is sent to the biobank. For further guidance on who shall sign, see document K4b (Swedish only).
9.2 For the research principal *Please contact the responsible biobank concerning possible use of electronic signatures.*	If applicable. In cases where the principal investigator is not at the principal of the biobank. *To be used when* • *the principal investigator applies for the establishment of a sample collection in a biobank at another principal and the principal investigator is not authorized to sign an agreement with an external party.* An authorised representative of the responsible research principal (the responsible research principal has been specified in 2.1) must sign the application (9.2.1–9.2.3). The principal investigator (specified in 2.2) must sign the application (9.2.4–9.2.6). When the application is ready for signing on paper originals, the principal investigator must sign before the application is sent to the biobank. • *local investigators at the participating research principal must be responsible for samples established in the biobank.* The principal investigator must notify (preferably via their work email) the biobank where samples are to be established (for current e-mail addresses, see biobanksverige.se) that a local investigator at the participating research principal will establish the sample collection. The participating research principal must be stated in the application of ethical approval. An authorised representative of the participating research principal where the local investigator is active must sign the application (9.2.1–9.2.3). The local investigator (specified in 2.3) must sign the application. When the application is ready for signing on paper originals, the principal investigator must sign before the application is sent to the biobank. For further guidance on who shall sign, see document K4b (Swedish only).
9.3 For responsible biobank	The biobank custodian or other authorised representative of the responsible biobank must sign the application. The biobank custodian (or other authorised representative) indicates by checking one of the boxes whether the application is approved or denied. • If the application is approved, specific conditions for the approving may be stated. • If the application is denied, this must be justified to the applicant. Reference to an appendix may be made.

L1.2. Agreement on the release of samples and personal data

1. Research study	
1.1 Study title	State the same name as stated in the application of ethical approval.
1.2 Study working title and/or study-ID	If applicable, state the same working title as stated in the application of ethical approval
1.3 EudraCT-no	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	An approved application for ethical review for the study is required to use identifiable human samples in a research study. **Please note:** An ethical approval is valid until further notice provided that the research has begun within two years from the date on which the decision on approval gained legal force. An amendment of the application for ethical review is required if the study has been changed so that the safety of the research subjects is affected or if the change may otherwise affect the risk-benefit assessment made in the previous review of the application (e.g. if additional research subjects are to be included, if a larger amount of sample material is desired, or if new methods or new analyses are to be performed on already collected material). **1.4.1** All registration numbers of the Swedish Ethical approval. **Please note:** When processing the biobank application, the accordance between the biobank application, the application for ethical review, approval from the Swedish Ethical Review Authority (EPM) or the Ethics Review Appeals Board (ÖNEP) and research subject information (if available) is reviewed. In order to avoid delays in processing, it is important that the biobank receives the latest version approved by EPM/ÖNEP or the latest version sent to EPM for a decision on approval.
1.5 Applicable appendices for access to existing samples shall be attached	The agreement must be supplemented by relevant appendices (several forms may be included) • Choose L1a for clinical samples in pathology and cytology biobanks. • Choose L1b for existing biobank samples. • Choose L1c for the PKU biobank. (Swedish only).

2. Applicant/Research principal	
2.1. Responsible principal for research	The research principal, the same as stated as the responsible research principal in the application for ethical review. The research principal is the organisation, authority, or company in whose activities the research takes place. The research principal has the overall responsibility for activities (legal and financial) in which the researcher in question is active and as stated in the application for ethical review. In the biobank application, the research principal can never be a natural person.
2.2 Principal investigator	The principal investigator for the project (the research study) stated in the application for ethical review.

3. Releasing biobank	
3.1 Principal of the biobank from where the sample collection is to be released	The legal entity (organisation, university, region, company, etc.) that holds the biobank where samples are stored.
3.2 Name of the biobank	State the biobank where samples are stored.
3.3 Biobank registration number	**3.2 and 3.3** Contact the biobank custodian/biobank coordinator for information regarding the name of the biobank and registration number (according to the Health and Social Care Inspectorate, IVO) and, if applicable, the biobank department.
3.4. Biobank department	
3.5–3.7 Contact person for the releasing biobank	**To be completed by the biobank**
3.8 Other information	**To be completed by the biobank**

4. Receiving biobank (where sample collection is to be established)	
4.1 Principal of the biobank where the sample collection is to be established	The legal entity (organisation, university, region, company, etc.) that holds the biobank where samples are to be established.
4.2 Name of the biobank:	State the biobank where samples are to be established.
4.3 Biobank registration number	**4.2 and 4.3** Contact the biobank custodian/biobank coordinator for information regarding the name of the biobank and registration number (according to the Health and Social Care Inspectorate, IVO) and, if applicable, the biobank department.
4.4. Biobank department	
4.5–4.7 Contact person for the receiving biobank	**To be completed by the releasing biobank**
4.8 Other information	**To be completed by the releasing biobank**

5. Access to personal data	
5.1 Personal data	To be completed by the releasing biobank. 5.1.1. To be completed by the releasing biobank. 5.1.2 To be completed by the releasing biobank. 5.1.3 To be completed by the releasing biobank. **Please note:** The biobank agreement only regulates access to personal data directly related to the sample. The agreement does not regulate access to other personal data from the patient's medical record, such as data on diagnosis, analysis results or treatment received. Before such information from the patient's medical record may be used for research, a decision on release of this data for the purpose of research must be made according to local routine for confidentiality assessment.

Information box:

Personal data is any information relating to an identified or identifiable natural person. An identifiable natural person is a person who can be identified, directly or indirectly, in particular by reference to an identifier such as name, national ID number, address, sample code (sample ID) if it is possible to link the sample code to an individual, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Information linked to name or national ID number is always personal data. Even information that does not directly identify an individual can be personal data if it is possible in some other way to link them to a specific individual. An example is when much and/or detailed information in combination can make it possible to link the data to a person. Encoded or encrypted data is also personal data as long as someone can make it readable and thus identify individuals, that is, as long as the code or encryption key remains. All personal data registers must be notified to the personal data controller of the principal.

6. Terms for release

Pre-printed	
6.1 Special terms (if applicable)	**To be completed by the releasing biobank, if applicable.**

7. Signatures

7.1 Principal investigator	The principal investigator (stated in 2.2) shall sign the application.
7.2 Authorised representative for *receiving* biobank	The biobank custodian or other authorised representative of the receiving biobank (stated in 4) must sign the application.
7.3 Authorised representative for *releasing* biobank	The biobank custodian or other authorised representative of the releasing biobank must sign the application. This person signs last. If a biobank custodian (or other authorised representative) rejects an application on the release of samples, the matter must be reviewed by the principal of the biobank at the request of the applicant. The applicant shall be informed of their right to request review.

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 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 (coloum 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)	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)	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)	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. Invoice address

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

6. Signatures

6.1 – 6.2 *Please contact the responsible biobank concerning possible use of electronic signatures.*	Fill in the name of the principal investigator (6.1.3) and e-mail (6.1.4) 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

7. Signatures applicable when samples are released

Completed by concerned biobanks

7.1 For the *responsible/receiving* biobank	The biobank custodian or other authorised representative of the responsible/receiving biobank must sign the application.
7.2 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.