K4.2 Instructions for completing form L1.2. for the release of samples for research

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.

L1.2 Agreement on the release of samples and personal data	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.
L1.1 Establishment of sample collection for research	See document K4.1
L1.3 Request for amendment of previously approved biobank application	Se document K4.3

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 application to the Ethical Review Authority is required if the study has been changed in a way that affects the safety of the research subjects, 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) are reviewed. In order to avoid delays in processing, it is important that the biobank receives the latest version (marked Avslutad or Beslutad in Ethix) 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). **Please note:** L1b only needs to be attached if all or parts of the existing sample collection from one research project is to be used in another project.

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 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 the sample collection is 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

Contact the responsible biobank regarding the signing method (electronic or wet-ink)

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.