K4. Instruction for completion of form L1: "*Access to sample collection and personal data for research*"

This is an instruction to the national form that shall be used when applying for access to samples from healthcare for research. Form L1 "Access to sample collection and personal data for research" is used for biobank services in County Council's/Region's in Sweden; such as to establish a new sample collection, make a withdrawal from an existing sample collection as well as release a sample collection. To get access to, and use samples within a County Council/Region in a research study, approval from a biobank custodian from the County Council/Region in question is required. Please contact the biobank coordinators regarding where the application should be sent in each County Council/Region (can be found under "Contact" at www.biobankssverige.se).

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The form comprises two parts:	
Part I. Application for establishment of and access to sample collection	Must be completed for biobank services (establishment, withdrawal and release) Please note, 5A is to be completed by those who wish that responsibility of the sample collection *remains* in the Healthcare Principal's biobank. Mark 5B if the sample collection will be *released*.
Part II. Agreement on release of samples and personal data	Must be completed if the sample collection will be *released* from the Healthcare Principal's biobank to another Principal (another County Council/region, university or company/department).

I. Application for establishment of and access to sample collection

New application or supplement to a previous application	Mark the box if the application relates to a new application *or* if it is a supplement to a previous application. The entire form does not have to be completed if the application relates to a supplement. Only complete the information that makes it possible to identify the previous approved application form, i.e.: • biobank's document-ID. See on top of page of approved application form. • study name • sample collection working title • study-ID • Ethical review board's registration number • as well as data that have been changed from the approved application form.

1. Study information	
Study name	Descriptive title without using classified information. Must accord with the title indicated in the application for ethical vetting and patient/research participant information.
Sample collection working title	If the project has a working title it shall be mentioned here. Must accord with the title indicated in the application for ethical vetting and patient/research participant information.

Study-ID	For Clinical Trials, the Study-ID shall be stated. If study-IDs for other types of research studies are available, they should be mentioned here as well. Must accord with the title indicated in the application for ethical vetting and patient/research participant information.

Decision from Ethics Review Board	To use samples in a research study, approval from the Ethical Review Board is required. • Specify the reference number from approved ethical vetting application. • Appendix: append the following with the application: ▪ Signed copy of the ethical vetting application together with any supplements ▪ patient/researcher information ▪ decision from Ethical Review Board, including any supplements It is important that the Biobank receive the latest version of the ethical vetting application, approved or submitted to the Ethical Review Board. If the complete ethical vetting application is not enclosed, a least following decisions and copies of the headings in the application for Ethical vetting must be submitted: • 1:1-1:6 Information on Research Principal, 2:4 Give an overview of procedures for examination, data collection and nature of data, 2:5 Indicate whether biological material will be stored in a biobank, 2:6 Documentation, data protection and filing/archiving, 4:1-4:2 Information and consent, 8 Signature and 9 Appendix 1 (if applicable).
The application regards	Mark the box if the application relates to newly collected samples or existing samples (see Definitions 1). If the application pertains to access to existing samples, please provide a brief description of the project.

Definitions: 1

Existing samples

- Healthcare Samples stored in a County Council's/Region's biobank for care, diagnostics and treatment. These samples belong to the healthcare's biobank and constitute a primary sample collection. To get access to these samples, a decision from the biobank Principal is required, who among other things review if enough material exists for the patient's own care, diagnostics and treatment. Newly collected samples handled by a local pathology lab within the healthcare are classified as existing samples.
- Samples from a previous completed research study where consent to continued saving exists, alternatively prospective collection of samples for research. Such samples can either be primary or secondary sample collections. To get access to these samples, decisions from the Biobank custodian and the sample collection controller is required.

Newly collected samples

Samples that are newly collected for a specific research project. Samples taken in the Healthcare Principal's operations and responsibility must always be established and registered in the Healthcare Principal's biobank in order to make tracing of samples in accordance with the Biobank Act. For information about which of the Healthcare Principal's biobanks the sample collection should be established/registered in, please contact the County Council's/Region's Biobank Coordinator. See www.biobankssverige.se.

2. Information concerning Applicant/Research Principal	
Specify the Principal for the research project	Research Principal is the organisation, authority or company/department with overall responsibility for the operation (legally and financially) where the Researcher in question works. The research principal in the

	biobank application must be the same as specified in the application for ethical vetting (e.g. County council/Region, Healthcare provider, Pharmaceutical company or Research Institution). Please note that the Research Principal specified here must be the same as stated in the application to the Ethical Review Board. A Research Principal can never be a person.
Principal investigator/researcher (Sample collection controller)	Specify the Principal investigator for the study, according to the application to the Ethical Review Board. In certain cases, it could be a local investigator, listed in the ethical vetting application 1.4, who will sign the agreement with a local biobank. In such cases, the national Principal Investigator shall be listed under other contacts.
Other contacts	Specify contact details for other collaborators, e.g. investigator, coordinator or research nurse.

3. Healthcare principal (the site of sample collection) **– Biobank/biobank department in question**	
Specify the principal at the biobank/biobank department	If samples that are going to be used for research are taken for healthcare within a County Council's/Region's operation, the County Council's/Region's Healthcare Principal is responsible for the samples. This applies regardless if the samples are being released directly after the sampling or not. More than one Healthcare Principal can be included in a study. In such events, a separate application must be sent to every County Council/Region in the study. For Information about which biobank/biobank department samples should be registered in (name of biobank and registration number according to the Health and Social Care Inspectorate), contact the Biobank Coordinator of the County Council/Region in question (can be found under "Contact" at www.biobanksverige.se).

4. Describe sample collection	
Sampling period	If applicable, specify date of planned sampling (from first to last sample).
Study period	Specify the dates when the study is scheduled to start and expected to finish.
The sample collection will be	Please select how the sample collection should be handled during and after the study (trial). Specify if the samples should be destroyed or saved. It is possible to select more than one option if parts of the sample collection are handled differently. If samples will be stored indefinitely after the study is completed, write "until further notice" instead of specifying numbers of years. If the application relates to "existing samples", mark whether samples will be returned to the original sample collection or not. If the sample collection will be sent for analysis, append document L2a "*Agreement on the transfer of human biological materials*" (MTA)
Samples in study	Describe content and volume of the sample collection and which samples are to be released. Information about which samples are to be released is needed to report the release of samples to IVO (the Swedish Health and Social Care Inspectorate). Describe type of tissue, blood, urine, cells, etc. Specify total number of individuals in the study. Specify *sample type* and *number of samples* (do

	not specify the method of analysis). The information filled in here must correspond to that indicated in the ethics application and the patient/researcher information. Please note, the same sample type can be listed on several lines. Please only make one mark per line to show how the sample should be handled (alt. 1–3). See **Example 1** below. If the application pertains to **"existing samples"** a more detailed description is needed. Use **Appendix L1a** for existing clinical pathology and cytology samples or **Appendix L1b** for existing liquid-based samples.

Example 1: 4 urine samples and 2+4 blood samples and 2 tissue samples from tumour, per patient in a study.

The sample collection will be

Instruction: the same sample type can be listed on several lines. Please only make one mark per line to show how the sample should be handled (alt. 1–3).

1. Analysed as soon as possible after sampling and destroyed after requested analysis.
2. Stored until the study is completed (*year*), after which the sample will be destroyed.
3. Saved after the study is completed up to and including (*year* or *until further notice*).

Study samples. Indicate with an X if the samples will be released**:**

Describe content and extent, i.e. type of tissue, cells/cell lines, blood, blood serum, blood plasma, cerebrospinal fluid, prepared DNA, urine, etc.	No. of individuals	No. of samples	Samples shall: 1 2 3 (one mark/box)	Samples shall be released
Urine	150	150x4=600 samples	☒ ☐ ☐	☐
Blood	150	150x2=300 samples	☐ ☒ ☐	☐
Tissue sample, tumour	150	150x2=300 samples	☐ ☐ ☒	☐
Blood	50	50x4=200 samples	☐ ☐ ☐	☒

5. Access to samples is requested by A: sample remains, B: samples are released	
A: Remains	**Mark A** if the sample collection remains in the healthcare principal's biobank. This applies even if the samples are being stored in the sample collection controller's operation. State **where the sample collection will be stored** and **if the sample collection will be sent for analysis.** If the sample collection will be sent for analysis, append document L2a "*Agreement on the transfer of human biological materials*" (MTA). **Access to sample collection during study period:** The Researcher usually has full right of disposal to the applied sample collection in approved application, during the research study. If that is not the case, or if specific terms exist, the **biobank** can specify these in an appendix to document L1 under "Application approved", "Terms to receive access to sample collection", "5. Other". **Access after completion of the applied study.** State if extended access to the sample collection is requested by marking Yes, and specifying special requests. Mark No if extended access not is requested.
B: Released	**Mark B** if the sample collection will be released. Release of samples means that biobank samples, together with biobank responsibility and right of disposal, physically are transmitted to the new biobank Principal. Recipient biobank must be registered in Sweden by a legal entity and be in the Health and Social Care Inspectorate biobank register. **Part II** of this form (last page of application) shall be completed
A and B	**Mark A and B** if a subset of the sample collection will remain and a subset will be released to another Principal. If the samples are to be

	released, **Part II** of the form regarding the released samples shall be completed as well. It must be clear in the form or the ethical vetting application which samples are going to remain and which samples that are going to be released.

Definitions: 2

A. Samples remain

When samples remain as a primary sample collection at the Healthcare Principal, the responsibility of the samples remains as the Healthcare principals, and existing routines in the Healthcare principal's biobank are used for storage, withdrawals, safety, confidentiality, etc. Researchers' access to samples and personal data for a specific project is controlled through an application.

B. Samples are released

Responsibility for and right of use to the samples in question is transferred from the Healthcare Principal to a new biobank Principal (often a Research Principal). Recipient biobank must be registered in Sweden by a legal entity and be in the Health and Social Care Inspectorate biobank register. The samples are then moved to a location outside the Healthcare Principal's operations and form a secondary sample collection. A secondary sample collection may not be released further. The Healthcare Principal continues to be responsible for saving documentation regarding samples and to whom samples are released to make tracing possible according to the Biobank Act. Samples that are sent for second opinion or analysis for healthcare purposes in or among Principals are not seen as released. Transfer of material between sample collections in the same Principal are not seen as released.

Send for analysis

Whether or not the samples are released or remain, samples may for some purposes be sent for analysis to another research department, within Pharmaceutical companies or to another third party within Sweden or abroad, without it being release of samples. The samples only are sent for a specific measure, and are not made available for the recipient operation's disposal. Terms:

1. Samples and personal data may not reveal a Donor's identity.
2. The Donor need to have given his/her consent to the fact that samples may be sent to another unit, within the country or abroad.
3. When samples no longer are needed they shall be returned, alternatively be destroyed.
4. If samples are sent abroad, a recipient Research Principal and Biobank custodian, who are Swedish, is required.

6. Other	
Access to personal data	State if you want access to personal data in addition to code/pseudonym. If Yes – specify what information. See Definitions 3 regarding personal data.
Special requirements	Specify any special requirements, for instance regarding storage, temperature, safety and integrity.
Other conditions	Specify if other conditions exist regarding handling of the sample collection. For instance, if there is a steering committee connected to the sample collection.

Definitions: 3

"**Personal data** is information that can be linked, directly or indirectly to a physically living person. This means that information linked to name or social security number are always personal data. Indirect information which don't link directly to a person, can also be personal data, if it can be used to trace a specific individual. Detailed information that indirectly points out where a person lives, such as property designation or geographical coordinates, are examples of personal data. Another example is when many and/or detailed information in combination makes it possible to link information to a person (individual). Also, coded or encrypted information are personal data as long as someone can use it to identify individuals, that is as long the code or encryption key is still valid. The researcher/principal investigator does not need to have direct access to the key code in

order for the information to be considered as personal data. Even if the key is stored at another authority and this authority have a non-disclosure agreement, the data are considered as personal data by the researcher." Every record of personal data shall be reported to the Personal Data Controller at the Principal.

Source: Personuppgifter i forskning, vilka regler gäller? Brochure can be found at www.datainspektionen.se

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

8. *Signatures*	
Principal Investigator/Researcher (sample collection controller)	Principal investigator/Primary investigator = researcher with primary responsibility for the research study in Sweden. Should be the same as in application to/decision from the Swedish Ethics Review Board. In certain cases, in studies that both have a local investigator and a national primary investigator, it could be the local investigator who will sign the agreement. Please note, in those cases, it must be the local investigator listed in the application for ethical vetting, item 1.4 Principal investigator/Primary investigator, alternatively local investigator, must sign the application before it is submitted to the biobank.
Biobank department custodian	Only applies to Southern Healthcare Region. The biobank department custodian must sign the application before it is submitted to the biobank.
Authorised representative of the healthcare principal's biobank	Often a biobank custodian. Mark the box if the application is approved or not. • If the application is approved, specific terms for approval can be specified under 3. "Other". • If the application is not approved, the reasons should be explained to the applicant in an appendix.

II. Agreement on release of samples and personal data

This part of the application should be completed if samples will be *released* to another Principal. Release of samples means that biobank samples physically are transmitted, together with biobank responsibility and right of disposal, to the new biobank Principal. The biobank custodian in the involved County Council/region must approve the release.

1. Recipient biobank	
Recipient biobank	The recipient biobank is responsible for the sample collection after release. The recipient biobank must be registered in Sweden by a legal entity and be in the Health and Social Care Inspectorate's biobank register. Specify the registration number from the Health and Social Care Inspectorate (IVO) and contact information to contact person and Biobank Custodian. The recipient biobank shall be specified the ethical vetting application.
Personal data (to be completed by the releasing biobank)	If personal data, except code/pseudonym, will be released. Describe how researchers will get access to the information. Personal data should be coded so that an individual sample donor cannot be identified. Coded data still is personal data as long as a code key exists, see Definitions 3.

2. Main agreement (for pharmaceutical trials)
Mark the box if this agreement constitutes a supplemental agreement to the "Main Agreement" met between the County Council/Region and the Company with regards to clinical pharmaceutical trials.

3. Terms	
Transport of samples	Specify who is responsible for transporting the samples, and the transport cost.
Special terms	Special conditions may be specified here, such as if the medical principal requires certain handling of excess samples, what happens to the samples after research is completed, the terms for the gathering of samples or if the project is discontinued prematurely.

Terms of release:

1. Approval of a regional Ethical Review Board.
2. Samples may not be used for research other than specified in the application for ethical vetting.
3. If samples, included in the sample collection are required for the care of the sample donor/patient, the samples shall primarily be used to meet these needs.
4. If samples included in the sample collection can advantageously be used in other research, which a regional Ethical Review Board has considered and approved, may the principal for the secondary sample collection issue approval for such procedure.
5. The biobank custodian upon the recipient biobank is responsible, after release, for the samples' quality being secured and that the patient's identity is protected.
6. Upon release of samples and personal data, there are requirements of how the samples' and personal data's identity designation ("Sample ID" and "Personal data ID", respectively) shall be formulated. The code key linking "Sample ID" and "Personal data ID" with the patient's identity shall be stored with the County Council/region.
7. Released samples may not be released to third part.
8. Terms of consent on research studies with associated part-studies. If a Research Participant withdraws his/her consent from the principal study, the Responsible investigator shall ensure that the Research Participant also is asked about withdrawal of consent of other associated studies that the Research Participant may be part of.
9. Other:

4. Signatures	
Healthcare principal **Authorised representative of the releasing biobank**	The agreement is signed by an authorized representative of the releasing biobank in the Healthcare Principal (usually a biobank custodian).
Research principal/equivalent **Authorised representative of the recipient biobank**	The agreement is signed by authorized representative of the recipient biobank in the Healthcare Principal (usually a biobank custodian). Recipient biobank is found at the Healthcare Principal (according to application for ethical vetting) or at another Principal with which the Research Principal has an agreement with.