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| To be completed by the recipient  |
| Date of arrival:       | Reg. no:       |

# L7. Responsible biobank for newly collected samples taken for research

Please note: Use form T7a for research that is a clinical trial or performance study according to CTR, MDR or IVDR.

Form L7 is used to notify a region, where newly collected research samples are taken, that said region will **not** be the responsible biobank for these samples. Samples are to be established in another biobank, which will be the responsible biobank.

**Background:** The main rule is that the principal that has decided on the collection is the responsible biobank. However, if the samples are collected in a region, it is assumed that the region will be the responsible biobank unless otherwise announced by the party that has decided on the collection. The principal that has decided on the collection should either:

* apply for the establishment of the sample collection in the biobank at the principal where samples are collected (form L1.1), or,
* notify the biobank custodian, in the region where samples are collected, that samples are to be established in another biobank (form L7 is used).

**Please note:** Form L7 must be signed by the responsible biobank and sent to the biobank in the region where collection takes place before it begins**.**

**Recommendation:** Establish a contact with assigned responsible biobank before an application is submitted to the Swedish Ethical Review Authority.

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| 1. Type of responsible biobank
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| 1.1 Mark one of the options below. Responsible biobank is: [ ]  **in a region**The form is not completed by the applicant, but is sent by the responsible biobank, as a cover page, together with approved L1.1 to the biobank coordinators in the regions where samples are newly collected.[ ]  ***not* in a region** The form is completed, signed by an authorised representative of the responsible biobank, and sent to biobank coordinators in the regions where samples are newly collected. Contact information can be found at [Kontakt - biobanksverige.se](https://biobanksverige.se/kontakt/) |

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| 1. The research study
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| 2.1 Responsible for the study |
| 2.1.1 Research principal:      |
| 2.2 Information about the study |
| 2.2.1 Study title specified in the application for ethical approval:       |
| 2.2.2. Study working title (if applicable):      | 2.2.3. Study ID (if applicable):      |
| 2.2.4 Registration number of the ethical approval:       | 2.2.5 Principal investigator:       |
| 2.2.6 Phone:      | 2.2.7 E-mail:      |

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| 1. Responsible biobank
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| The responsible biobank must be a Swedish biobank registered with the Health and Social Care Inspectorate  |
| 3.1 Principal of the biobank:       |
| 3.2 Name of the biobank/biobank department:       | 3.3 Biobank registration number (issued by the Health and Social Care Inspectorate):      |
| 3.4 Sample collection ID (if applicable):       | 3.5 Reg. no (if applicable):      |
| 3.6 Biobank custodian:      |
| 3.7 Contact person:      |
| 3.8 E-mail:      | 3.9 Phone:      |

**Terms:**

1. The research principal is responsible for ensuring that all samples are newly collected within the framework of research that is covered by an approved ethical application.
2. The research principal is responsible for ensuring that samples may only be used in another study after a new approval in accordance with the Ethical Review Act (2003:460).
3. The responsible biobank must have a Swedish corporate identification number and be registered with the Health and Social Care Inspectorate.
4. The responsible biobank is responsible for ensuring that samples are handled in accordance with the requirements of the Biobank Act (2023:38).
5. The responsible biobank is responsible for ensuring that samples are destroyed immediately if the sample donor or another person who has given consent for the storage and use of a sample withdraws the consent to the storage of samples.

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| 1. Signatures (if responsible biobank is not a region)
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| 4.1 For the responsible biobank |
| 4.1.1 Signature (authorised representative): |
| 4.1.2 Name in print:      |
| 4.1.3 Date:      |