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| To be completed by the releasing biobank | | |
| Date of arrival: | Reg. no: | Sample collection ID: |

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| To be completed by the receiving biobank | | |
| Date of arrival: | Reg. no: | Sample collection ID: |

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

This form is used when applying for the release of samples for research. The agreement is drawn up between the releasing biobank and the receiving biobank. The principal investigator must sign the agreement and thereby confirm that the information is correct and complete. Upon release, samples cease to be part of the biobank from which they were released. Responsibility and the right to use samples are transferred to the biobank of the recipient. A sample may only be released to a recipient in Sweden and after the recipient has requested it. See document K4. Instructions for forms L1.1 and L1.2.

Released samples are established in the recipient's biobank. For applying to establish a sample collection form L1.1 is used.

Agreement on release should be supplemented with relevant appendices:

* Form L1a, L1b, L1c

*Please note that an approved biobank application (L1.2) does not mean that the research is approved if it is in conflicts with other legislation.*

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| 1. Research study | | |
| 1.1 Study title (as stated in in the application for ethical approval): | | |
| 1.2 Study working title and/or study-ID (if applicable): | | 1.3 EudraCT-no (in clinical trials of medicinal products): |
| 1.4 Application for ethical approval, including amendments  Handling of samples must fall under the ethical approval. | | |
| 1.4.1 All registration numbers of the Swedish Ethical approval: | Append the following:   * Application for ethical approval (signed). * Application for amendment of the ethical approval (if applicable). * Response to request for complementation of the application (if applicable). * Decisions regarding application for ethical approval (all). * Research participant information (if applicable). * Informed consent forms (if applicable). | |
| 1.5 Applicable appendices for access to existing samples shall be attached:  L1a. Appendix – Information about existing clinical samples in pathology and cytology biobanks.  L1b. Appendix – Information about existing biobank samples.  L1c. Appendix – Information about existing samples in the PKU biobank. (Swedish only) | | |

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| 1. Applicant/Research principal | | |
| 2.1 Responsible principal for research (research principal, as stated in in the application for ethical approval): | | |
| 2.2 Principal investigator  (the one who signed the application for ethical approval) | | |
| 2.2.1 Name: | | |
| 2.2.2 Phone: | 2.2.3 E-mail: | |
| 2.2.4 Work address: | 2.2.5 Postcode: | 2.2.6 City: |

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| 1. Releasing biobank | |
| 3.1 Principal of the biobank from where the sample collection is to be released: | |
| 3.2 Name of the biobank: | |
| 3.3 Biobank registration number (issued by the Health and Social Care Inspectorate | 3.4 Biobank department (if applicable): |
| 3.5 Contact person for the releasing biobank (to be completed by the biobank): | |
| 3.6 Phone: | 3.7 E-mail: |
| 3.8 Other information (to be completed by the releasing biobank, if applicable): | |

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| 1. Receiving biobank (where sample collection is to be established) | |
| 4.1 Principal of the biobank where the sample collection is to be established: | |
| 4.2 Name of the biobank: | |
| 4.3 Biobank registration number (issued by the Health and Social Care Inspectorate): | 4.4 Biobank department (if applicable): |
| 4.5 Contact person for the receiving biobank (to be completed by the receiving biobank, if applicable): | |
| 4.6 Phone: | 4.7 E-mail: |
| 4.8 Other information (to be completed by the receiving biobank, if applicable): | |

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| 1. Access to personal data |
| 5.1 Personal data. To be completed by the releasing biobank. Personal data (cf. Article 4 (1) GDPR) is any kind of information that can be directly or indirectly attributed to a living natural person. Personal data should normally be pseudonymised so that an individual sample donor cannot be identified. Note, however, that even coded data and the code itself are personal data as long as the code key remains. |
| 5.1.1 Do you want access to personal data in addition to a code or pseudonym (in accordance with the application for ethical approval)?  Yes, please specify:  No  *Please note that this agreement only regulates access to personal data directly related to the sample. The agreement does not regulate access to other personal data*  *Please note that in relation to personal data directly related to the sample, the parties also have to take the GDPR into account.* |
| 5.1.2 Specify where the code key, i.e. the link between a sample and the identity of the sample donor, is kept: |
| 5.1.3 The biobank’s/biobank department’s notes (if applicable):  Other personal data than sample code is desired, and a confidentiality assessment is necessary.  Notes: |

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| 1. Terms for release |
| 1. Approval for the study from the Swedish Ethical Review Authority or the Ethical Review Appeals Board.  2. Samples may not be used for research other than specified in the application for ethical approval.  3. If samples in the sample collection are required for the care, diagnosis and treatment of the donor/patient, samples should primarily be used to meet this need.  4. After release, the receiving biobank is responsible for ensuring that samples are handled in accordance with the requirements of the Biobank Act and approved application for ethical approval.  5. In the event of a breach of contract, during ongoing sample release, the agreement can be terminated by the releasing biobank.  6. In the event of a change in circumstances of significant importance for the documentation on which the agreement has been signed, a new application must be submitted. |
| 6.1 Special terms (if applicable): |

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| 1. Signatures |
| 7.1 Principal investigator  By signature, it is confirmed that the information provided is complete and that all terms stated in the biobank application and in all accompanying appendices are accepted. |
| 7.1.1 Signatures: |
| 7.1.2 Name in print: |
| 7.1.3 Date: |
| 7.2 For receiving biobank |
| 7.2.1 Signatures (authorised representative): |
| 7.2.2 Name in print: |
| 7.2.3 Date: |
| Decision (to be completed by authorised representative for releasing biobank):  **The application is approved with the following terms:**  **The application is denied with the following explanation:**  The decision can be reconsidered by the principal of the biobank. |
| 7.3 For releasing biobank |
| 7.3.1 Signatures (authorised representative): |
| 7.3.2 Name in print: |
| 7.3.3 Date: |