|  |
| --- |
| Filled in by responsible biobank |
| Date of arrival:       | Dnr:       |

# T1.2. Agreement regarding release of samples for clinical trials and performance studies

This agreement is used for application of release of samples for clinical trials and performance studies. The agreement will be established between the sponsor, the releasing biobank and the recipient biobank when existing samples are released from one biobank to another. Sponsor shall by signature confirm that the information provided is complete and correct. A sample may only be handed out to a recipient in Sweden and after the recipient has requested it.

The agreement shall be supplemented with relevant attachment:

* Form L1a and/or L1b

Released samples will be established in the recipient biobank. Form T1.1 can be used for establishment of sample collection.

*Please note that an approved biobank application (T1.2) does not mean that the study is approved if it is in conflict with other legislation.*

|  |
| --- |
| 1. General information
 |
| 1.1 Study working title (if applicable):      |
| 1.2 Full title:       |
| 1.3 EU trial number (if clinical trial of medicinal products):       | 1.4 CIV-ID (if study of medical device):      |
| 1.5 Applicable attachments for access to existing samples:[ ]  **L1a** for existing clinical pathology and cytology samples[ ]  **L1b** for other existing samples |
| 1.6 Name of sponsor organisation:      |

|  |
| --- |
| 1. Releasing biobank from which the samples will be released
 |
| 2.1 Principal of the biobank:       |
| 2.2 Name of the biobank:      | 2.3 Biobank registration number (issued by IVO, the Health and Social Care Inspectorate):      |

|  |
| --- |
| 1. Recipient biobank in which the sample collection will be established
 |
| 3.1 Principal of the biobank:      |
| 3.2 Name of the biobank:      | 3.3 Biobank department (if applicable):      |
| 3.4 Name of the biobank custodian:       | 3.5 Biobank registration number (issued by IVO, the Health and Social Care Inspectorate):      |
| 3.6 Postal address:      | 3.7 Name of contact person for the biobank:      |
| 3.8 Email to contact person:      | 3.9 Phone to contact person:      |
| 3.10 Additional information (completed by the biobank):      |

|  |
| --- |
| 1. Terms
 |
| 4.1 Transport of samples, if applicable |
| Specify who is responsible for transporting the samples and the transport costs:      |
| 4.2 Special terms, if applicable |
| Special conditions may be specified here, e.g. if the sponsor requires certain handling of excess samples, what happens to the samples after the research is completed, terms of sampling or if the project is discontinued prematurely:      |
| 4.3 Terms of release |
| 1. The application of clinical trial of medicinal products (regulation (EU) 536/2014), clinical investigation of medical devices (regulation (EU)2017/745) or performance study on in vitro diagnostic medical devices (regulation (EU)2017/746) must be approved. All specific terms in the approval that required a substantial modification before any investigation-related activity is performed on subjects, shall be fulfilled.
2. Samples can only be used in another study after new approval according to the Swedish Ethics Review Act or applicable regulation mentioned under point 1 and new approval of the biobank custodian.
3. If samples in the sample collection are required for the subject’s care, diagnostics or treatment, the samples shall be provided to meet these needs.
4. The recipient biobank is responsible for that samples are handled according to Swedish Biobank Act (SFS 2023:38) and approved clinical trial or performance study application.
5. Where applicable, an agreement shall be made concerning services and costs related to the sample release.
6. In the event of a breach of contract during ongoing sample release, the agreement may be terminated by the releasing biobank. In the event of a change in circumstances of significant importance for the documentation on which the agreement has been signed, a new application shall be submitted
 |

|  |
| --- |
| 1. Signatures
 |
| 5.1 For the sponsor  |
| By signature, it is confirmed that the information provided is complete and that the terms and conditions in the biobank application and in all accompanying appendices are accepted. |
| 5.1.1 Signature (authorised representative): |
| 5.1.2 Print name:      |
| 5.1.3 Email:      |
| 5.1.4 Date:      |
| Decision (to be completed by the biobank):[ ]  **The application is approved** [ ]  **The application is denied with the following explanation:**     The decision can be reconsidered by the principal of the biobank.  |
| 5.2 For the recipient biobank |
| 5.2.1 Signature (authorised representative): |
| 5.2.2 Print name:      |
| 5.2.3 Email:      |
| 5.2.4 Date:      |
| 5.3 For the releasing biobank |
| 5.3.1 Signature (authorised representative): |
| 5.3.2 Print name:      |
| 5.3.3 Email:      |
| 5.3.4 Date:      |
| The principal of the biobank becomes the personal data controller for data in the biobank agreement. The data will be processed in accordance with the General Data Protection Regulation (GDPR). For more information regarding how personal data will be processed we refer to the principal. |