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

# T1.1. Establishment of sample collection for clinical trials and performance studies

All samples that are covered by the Swedish Biobank Act (SFS 2023:38) shall be established in a biobank (for more information, see <https://biobanksverige.se//>). Form T1.1 is used when requesting the establishment of a sample collection in a biobank for the purpose of clinical trials of medicinal products (according to Clinical Trials Regulation, CTR), clinical investigations of medical devices (according to Medical Devices Regulation, MDR) and performance studies of medical devices for in vitro diagnostics (according to the In Vitro Diagnostic Medical Devices Regulation, IVDR). Form T1.1 regulates access to newly collected samples and access to samples in an established sample collection. For support see [**Ti5.1. Instructions for completing form T1**](https://biobanksverige.se/wp-content/uploads/Ti5.-Instructions-for-completing-form-T1-and-T1a.pdf)**.1**

*Note:* T1.1 should not be used for establishment of a sample collection for performance studies where IVDR is not applicable and an ethical application is submitted directly to the [Ethics Review Authority](https://etikprovningsmyndigheten.se/medicintekniska-produkter/) according to the Swedish Ethics Review Act. For these cases, form L1.1, or equivalent can be used to establish a sample collection.

If applicable, the agreement can be supplemented with, for example:

* Form L1a and/or L1b if existing samples will be established as a new sample collection.
* Operational service agreements/equivalent that regulate how established samples are to be handled.
* Material Transfer Agreement (Form L2a2 or L2a3 or equivalent) if established samples will be sent outside the responsible biobank’s entity for an action.

The information regarding biological samples in the application for clinical trial of medical product, clinical investigation of medical device or performance study of medical device for in vitro diagnostics to the Swedish Medical Products Agency will be reviewed in parallel with the assessment of the application for access to biobank samples, if submitted at the same time.

*Please note that an approved biobank application (T1.1) 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 Type of study:  **Clinical trial of a medicinal product**, fill in sections 2 and 4-11.  **Clinical investigation of a medical device**, fill in section 3-11.  **Performance study of a medical device for in vitro diagnostics**, fill in section 3-11. | |
| 1. Identifiers for clinical trials of medicinal products   Note: The information must be consistent with the information in the EU-portal Clinical Trials Information system, CTIS | |
| 2.1 Full title (English): | |
| 2.2 Protocol code: | 2.3 EU trial number: |

|  |  |
| --- | --- |
| 1. Identifiers for clinical investigations of medical devices or performance studies of medical devices for in vitro diagnostics   Note: The information must be consistent with the application of clinical investigations of medical devices or performance studies of medical devices for in vitro diagnostics | |
| 3.1 Full title (English): | |
| 3.2 CIP code/PSP code: | 3.3 CIV-ID: |

Sections below cover both clinical trials of medicinal products, clinical investigations of medical devices and performance studies of medical devices for in vitro diagnostics.

|  |  |
| --- | --- |
| 1. Sponsor | |
| 4.1 Sponsor organisation | |
| 4.1.1 Name of sponsor organisation: | |
| 4.1.2 Email address (organisation): | 4.1.3 Country: |
| 4.2 Contact point for biobank application | |
| 4.2.1 Name of contact point (organisation): | |
| 4.2.2 Postal address: | |
| 4.2.3 Post code: | 4.2.4 City: |
| 4.2.5 Country: | 4.2.6 Name of contact person (Swedish contact person for sponsor that is not Swedish): |
| 4.2.7 Email address (contact person): | 4.2.8 Phone (contact person) |
| **4.3 The role of the contact point for the biobank application:**  **Sponsor** *according to regulation (EU) 536/2014, article 71*  **Legal representative** *according to regulation (EU) 536/2014, article 74*  **Principal Investigator**  **Contract research organization (CRO)**  **Other:** | |

|  |  |
| --- | --- |
| 1. Responsible biobank  (where the sample collection is to be established)Only a biobank registered at the Swedish Health and Social Care Inspectorate (IVO) can be the responsible biobank. | |
| 5.1 Principal of the biobank: | |
| 5.2 Name of biobank: | |
| 5.3 Biobank registration number (issued by IVO): | 5.4 Biobank department (if applicable): |
| 5.5 Name of biobank custodian: | 5.6 Name of contact person for the biobank: |
| 5.7 Email to contact person: | 5.8 Phone to contact person: |
| 5.9 Additional information (completed by the biobank): | |

| 6. Sample collection that is to be established  *This information must be covered by the information regarding biological samples in the application of clinical trials of medicinal products, clinical investigations of medical devices or performance study of medical devices for in vitro diagnostics.* |
| --- |
| **6.1 Sample collection that is to be established includes:**  **Existing archive samples**  **L1a** for existing clinical pathology and cytology samples  **L1b** for other existing samples  **Newly collected samples**  ***Newly collected******tissue*** *which is assessed or stored for a diagnostic purpose at the local pathology laboratory is regarded as existing samples in this agreement. Only tissue that is collected exclusively for a study-specific purpose with no diagnostic requirement can be regarded as newly collected samples.* |
| **6.2 Agreement regarding release of samples from another biobank (completed by responsible biobank)**  **T1.2** Agreement regarding release should be signed with each releasing biobank custodian. |

| 6.3 Samples that is to be included in the sample collection |
| --- |
| **Description of samples**  *Fill in information and mark appropriate alternatives. The information must be covered by the application for clinical trial/performance study.*   1. Specify sample type (type of tissue, material from tumours, cells, blood, serum, plasma, DNA etc.) registered in an existing sample collection from which the samples shall be retrieved. Specify extent if possible. 2. Specify sample type retrieved from subjects (blood, urine, cerebrospinal fluid, type of tissue, faeces etc.). Specify extent if possible. 3. Specify the number of subjects. 4. Specify the number of screen failures from whom samples will be saved, if applicable. 5. Specify number of samples per subject for each sample type. 6. Specify year if samples are stored for use within the objective of the study. 7. Specify year if samples are stored for future use, i.e. other use than described in the protocol. |

| 6.3.1 Existing archive samples | | | | | |
| --- | --- | --- | --- | --- | --- |
| A. Sample type | C. No. of subjects | D. No. of screen failures from whom samples will be saved | E. Quantity per subject | Samples are stored for  (both F and G can apply): | |
| F. Use within the objective of the study until year: | G. Future use until year: |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*Add more rows if needed.*

| 6.3.2 Newly collected samples | | | | | |
| --- | --- | --- | --- | --- | --- |
| B. Sample type | C. No. of subjects | D. No. of screen failures from whom samples will be saved | E. Quantity per subject | Samples are stored for  (both F and G can apply): | |
| F. Use within the objective of the study until year | G.Future use until year |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*Add more rows if needed.*

|  |  |  |
| --- | --- | --- |
| 7.Concerned principals | | |
| Principals from whom samples will be established in the sample collection for the current clinical trial/performance study. Mark if samples will be newly collected and/or if existing samples will be released from the principal’s biobank. | | |
| Additional information (if applicable): | | |
| 7.1 Regional principals | **Newly collected samples from** | **Existing samples from** |
| Region Blekinge |  |  |
| Region Dalarna |  |  |
| Region Gotland (*municipality with no region, but responsible for health and medical care*) |  |  |
| Region Gävleborg |  |  |
| Region Halland |  |  |
| Region Jämtland Härjedalen |  |  |
| Region Jönköping County |  |  |
| Region Kalmar County |  |  |
| Region Kronoberg |  |  |
| Region Norrbotten |  |  |
| Region Skåne |  |  |
| Region Stockholm |  |  |
| Region Sörmland |  |  |
| Region Uppsala |  |  |
| Region Värmland |  |  |
| Region Västerbotten |  |  |
| Region Västernorrland |  |  |
| Region Västmanland |  |  |
| Västra Götalandsregionen |  |  |
| Region Örebro County |  |  |
| Region Östergötland |  |  |

|  |  |  |
| --- | --- | --- |
| 7.2 Principals that is not a region | **Newly collected samples from** | **Existing samples from** |
|  |  |  |
|  |  |  |

*Add more rows if needed*

|  |  |  |
| --- | --- | --- |
| 8. Invoice address  Please make sure that the invoice information is correct. An additional cost may be added if adjustments need to be done on an already sent invoice. | | |
| 8.1 Company/Organisation: | 8.2 Corporate identification no. (if applicable): | |
| 8.3 Invoice reference: | 8.4 PO #. | 8.5 VAT reg. no. |
| 8.6 Invoice address: | 8.7 Postcode: | 8.8 City: |
| 8.9 Country: | 8.10 E-mail for invoice: | 8.11 Peppol-ID/GLN-code: |

|  |
| --- |
| 1. Terms of establishment |
| 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. Samples must be handled and coded according to Swedish Biobank Act (SFS 2023:38) and approved clinical trial or performance study application. The sample code key must be stored separated from coded samples and inaccessible to unauthorised persons. 5. The sponsor’s responsibility regarding the clinical trial/performances study remains with the sponsor. The biobank does not assume any responsibility regarding the documentation of consent, documentation of withdrawal of consent, and tracking of samples. 6. In case of withdrawal of consent in the clinical trial, the sponsor is to ensure that the subject is asked about withdrawal of consent for all other associated part studies that the subject may be part of, if applicable. 7. Where applicable, an agreement shall be made concerning services and costs related to the sample collection. 8. Samples can be sent for action to a recipient outside the responsible biobank’s entity only after the responsible for the biobank has established an agreement (Material Transfer Agreement, MTA or equivalent) with the recipient that regulates the purpose of access and how the samples are to be handled after performed action. 9. In the event of a breach of contract, the agreement may be terminated by the responsible biobank. In the event of a change in circumstances of significant importance for the documentation on which the agreement has been signed, a review and, if necessary, a revision of the agreement shall take place. |

|  |
| --- |
| 1. Signatures |
| 10.1 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. |
| 10.1.1 Signature (authorised representative): |
| 10.1.2 Print name: |
| 10.1.3 Email: |
| 10.1.4 Date: |
| Decision (to be completed by the biobank):  **The application is approved** and is valid thru the date specified in 6.3 with the following terms:  **The application is denied with the following explanation:**    The decision can be reconsidered by the principal of the biobank. |
| 10.2 For the responsible biobank |
| 10.2.1 Signature (authorised representative): |
| 10.2.2 Print name: |
| 10.2.3 Email: |
| 10.2.4 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.