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| **Filled in by Regional Biobank Centre (RBC)** | |
| Date of arrival: | RBC dnr: |

T1. Request for alteration of agreement for access to biobank samples and sample code in clinical trials and performance studies

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| This main application form is to be used by sponsors for access to biobank samples in clinical trials of medicinal products, clinical investigations of medical devices and performance studies of medical devices for in vitro diagnostics. For information regarding which samples that are covered by the Swedish Biobank Act (SFS 2023:38), see <https://biobanksverige.se/forskning/>.  See document Ti5. Instructions for completing form T1 and T1a. ([www.biobanksverige.se](http://www.biobanksverige.se)).  Note: The information regarding biological samples in the application for clinical trial of medical products, clinical investigation of medical devices or performance studies of medical devices for in vitro diagnostics will also be reviewed in parallel with the assessment of the application for access to biobank samples. | |
| ***1. General information*** | |
| * 1. Study working title (if applicable): | |
| * 1. Type of application:   ***This form is only used for requesting an alteration of existing biobank agreements established with form T1 and T1a. For initial applications and applications to amend existing biobank agreements drawn up with document T1.1, document T1.1 is used.***  ***Please see:***  [***https://biobanksverige.se/dokument/***](https://biobanksverige.se/dokument/)  [***https://biobanksverige.se/en/documents/***](https://biobanksverige.se/en/documents/)  **Alteration of previous biobank application**, RBC dnr:      .  Specify the *Study working title if applicable)*, *all information in section 2 or 3 as* well as the new information. | |
| 1.3. Type of study:  **Clinical trial of a medicinal product**, please fill in sections 2 and 4-8.  **Clinical investigation of a medical device**, please fill in section 3-8.  **Performance study of a medical device for in vitro diagnostics**, please fill in section 3-8. | |
| *2. 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: |
| *3. 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 (1.8 Clinical investigation title): | |
| 3.2 CIP code (1.7 Clinical investigation plan (CIP)): | 3.3 CIV-ID (1.4 Submission type): |

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

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| ***4. Sponsor*** | |
| **4.1 Sponsor organisation** | |
| 4.1.1 Name of sponsor organisation: | 4.1.2 Corporate identity number in Sweden (if applicable): |
| 4.1.3 Email address (organisation): | 4.1.4 Country: |
| **4.2 Contact point for biobank application** | |
| 4.2.1 Name of contact point (organisation): | |
| 4.2.2 Email address (organisation): | 4.2.3 Postal Address: |
| 4.2.4 Post Code: | 4.2.5 City: |
| 4.2.6 Country: | 4.2.7 Name of contact person (first and last name): |
| 4.2.8 Email address (contact person): | 4.2.9 Phone (contact person) |
| **4.3 The role of the contact point for the biobank application:**  **Sponsor** *according to General Data Protection Regulation ((EU) 2016/679), article 14*  **Legal representative** *according to General Data Protection Regulation ((EU) 2016/679), article 74*  **Principal Investigator/sample collection controller**  **Contract research organization (CRO)**  **Other:** | |

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| ***5. Recipient biobank***  ***Note:*** *Only applicable if samples will be released.*  *Samples can only be released to a Swedish biobank. Release entails that the responsibility and the right of disposal are transferred to the receiving biobank. Samples shall physically leave the releasing biobank.* | | | |
| 5.1 Name of biobank/biobank department: | | 5.2 Biobank registration number (issued by Health and Social Care Inspectorate) /biobank department ID (applies to the Southern Healthcare Region): | |
| 5.3 Biobank custodian (person responsible for the biobank): | | | |
| 5.4 Email to authorised representative of the biobank who will sign the agreement: | | | |
| 5.5 Contact person for recipient biobank: | | | |
| 5.6 Postal address: | | | 5.7 Email: |
| 5.8 Post Code: | 5.9 City: | | 5.10 Phone: |

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| ***6. Invoice address*** | | |
| 6.1 Company or Department/Institution: | 6.2 Corporate identity number in Sweden: | |
| 6.3 Cost centre/ref. invoice (if applicable): | 6.4 PO no. | 6.5 VAT reg. no. |
| 6.6 Postal address: | 6.7 Post code: | |
| 6.8 City: | 6.9 Country: | |

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| ***7. Attachments*** |
| ***7.1 Mandatory attachments:*** |
| * **T1a**. **Description of subjects, investigators, and regions included in a clinical trial or clinical investigation** *– must be submitted together with T1.* |
| ***7.2 Other documents:*** |
| **N4. Signing of power of attorney -** *Mandatory when study includes private healthcare provider.*  **Material Transfer Agreement (MTA)** - Mandatory if a *healthcare principals´ biobank is responsible for samples* that will be sent for analysis outside responsible entity. |
| ***7.3 Documents added to biobank agreement for review by sponsor (completed by RBC):*** |
| **Agreement T1b** - regarding samples that remain in the healthcare biobank  **Agreement T1c** - regarding release of samples according to the *multicenter principle*, signed with RBC  **Agreement T1c** - regarding release of samples with *separate agreements* signed with each region's biobank |

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| ***8. Signature***  ***Note:*** *The application must be signed by an authorised representative of the sponsor to certify that all information is correctly given.* | | |
| ***8.1 Authorised representative of the sponsor*** | |
| 8.1.1 Signature: | |
| 8.1.2 Print name: | |
| 8.1.3 Email: | |
| 8.1.4 Date: |