# T1b. Agreement regarding samples in clinical trials and performance studies that remain in the healthcare biobank

This agreement shall be used by sponsors who desire access to samples and associated sample code from healthcare for clinical trials and performance studies when samples remain in the healthcare principal’s biobank.

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| 1. General information
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| 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):      |

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| 1. Concerned biobank
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| 2.1 Entity responsible for the biobank/biobank department in which the sample collection is registered or planned to be registered:      |
| 2.2 Name of biobank/biobank department:      | 2.3 Biobank registration number (issued by the Health and Social Care Inspectorate) / biobank department ID (only applies to Southern Healthcare Region):      |

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| 1. Storage of samples
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| The sample collection (or part of it) shall legally remain in the biobank of the healthcare principal. |
| 3.1 State where the samples shall physically be stored: |
| **Unit**:      **Hospital** (if applicable)**:**       **City:**       |
| 3.2 Access to sample code |
| Information regarding responsibility for and handling of the sample code is stated in the document “Compliance with use of biological samples” (Följsamhet med regler för hantering av biologiska prov).  |

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| 1. Terms of access
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| 1. Approval of the clinical trial according to Regulations (EU) 536/2014 on clinical trials, 2017/745 on medical devices and/or 2017/746 on in vitro diagnostic medical devices and that all specific terms in the approval of the clinical trial or performance study, which require the approval of a substantial modification before any investigation-related activity is performed on subjects, shall be fulfilled.2. If samples included in the sample collection are required for the care of the sample donor/patient, the samples shall primarily be used to meet these needs.3. Samples may not be used for other purpose than specified in the application of the clinical trial.4. If samples included in the sample collection are stored for future research, a new approval from the Swedish ethical committee must be obtained before samples can be used for a new purpose.5. The sponsor or investigator, as applicable, is responsible for the documentation of consent and collected samples, documenting the withdrawal of consent, and taking care of tracking samples and other measures resulting from withdrawal of consent.6. In case of withdrawal of consent in the clinical trial, the sponsor or investigator, as applicable, should ensure that the research participant is asked about withdrawal of consent for all other associated part studies that the research participant may be part of, if applicable.7. Where applicable, an agreement shall be made with the healthcare principal/laboratory concerning their costs to prepare access to the sample collection.8. If samples in the sample collection will be sent for analysis to a laboratory sited outside the healthcare principal, a Material Transfer Agreement (MTA) (document L2a2 or L2a3) is needed before samples are sent.9. Other:       |

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| 1. Signatures
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| 5.1 Sample collection controller other than sponsor (if applicable)  |  | 5.2 Authorised representative of the sponsor  [ ]  Also sample collection controller |
| 5.1.1 Signature: |  | 5.2.1 Signature: |
| 5.1.2 Print name:       |  | 5.2.2 Print name:      |
| 5.1.3 Email:      |  | 5.2.3 Email:      |
| 5.1.4 Date:      |  | 5.2.4 Date:      |

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| Decision (to be completed by the biobank or RBC):[ ]  **The application is** approved and is valid thru the date specified in T1a; 2.2, 2.3 or 2.4 (latest date applies) with the following terms:[ ]  **The application is denied with the following explanation:**The decision can be reconsidered by the healthcare principal. The healthcare principal’s decision can be turned over to the Health and Social Care Inspectorate for review/verdict. |
| 5.3 Biobank department custodian (please note, only applies to the Southern Healthcare Region) |  | 5.4 Authorised representative of the healthcare principal’s biobank |
| 5.3.1 Signature: |  | 5.4.1 Signature: |
| 5.3.2 Print name:      |  | 5.4.2 Print name:      |
| 5.3.3 Email:      |  | 5.4.3 Email:      |
| 5.3.4 Date:      |  | 5.4.4 Date:      |

The healthcare principal of the biobank becomes the personal data controller for data in the biobank agreement when being received by the healthcare principal’s biobank. The data will be processed in accordance with the General Data Protection Regulation (GDPR). For more information regarding how personal data will be processed in your case we refer to the healthcare principal.