# T1c. Agreement regarding release of samples in clinical trials and performance studies

This agreement is to be established between the healthcare principal and the sponsor/recipient biobank. When samples are released, the responsibility for and right to use the samples and associated sample codes are transferred from the healthcare principal to the recipient part.

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| 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 Is this agreement according to the multicentre principle?  Yes  No  If no, fill in section 2. | |

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| 1. Concerned biobank | |
| *Note: Only complete this section if the agreement is not according to the multicentre principle.* | |
| 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. Terms |
| 3.1 Transport of samples, if applicable |
| Specify who is responsible for transporting the samples and the transport costs: |
| 3.2 Special terms, if applicable |
| Special conditions may be specified here, e.g. if the healthcare principal 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: |
| 3.3 Terms of release |
| 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. After release, the biobank custodian at the recipient biobank is responsible for the quality of the samples being secured and that the patients´ identity is protected.  8. Upon release of samples, there are requirements of how the samples’ and personal datas´ identity designation (“Sample ID” and “Personal data ID”, respectively) shall be formulated. The code key linking "Sample ID" and "Personal data ID" with the patients´ identity shall be stored within the healthcare principal.  9. Released samples may not be released to third part.  10. Other: |
| 3.4 Terms of release according to multicentre principle |
| 1. The investigators shall **contact their Region’s e-biobank immediately** to hand over personal ID numbers for sample tracking and signing of a power of attorney in the event that private health care providers are included.  2. The sponsormust inform the deciding RBC if the conditions for the clinical trial are materially changed. |

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| 1. Signatures | | |
| 4.1 Sample collection controller other than sponsor (if applicable) |  | 4.2 Authorised representative of the sponsor  Also sample collection controller |
| 4.1.1 Signature: |  | 4.2.1 Signature: |
| 4.1.2 Print name: |  | 4.2.2 Print name: |
| 4.1.3 Email: |  | 4.2.3 Email: |
| 4.1.4 Date: |  | 4.2.4 Date: |
| 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. | | |
| 4.3 Authorised representative of the recipient biobank |  | 4.4 Authorised representative of the healthcare principal’s biobank |
| 4.3.1 Signature: |  | 5.4.1 Signature: |
| 4.3.2 Print name: |  | 4.4.2 Print name: |
| 4.3.3 Email: |  | 4.4.3 Email: |
| 4.3.4 Date: |  | 4.4.4 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.