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| To be completed by the recipient | | |
| Date of arrival: | Case ID: |

# T7a. Responsible biobank

#### when newly collected samples are to be collected for clinical trials or performance studies regulated by CTR, MDR or IVDR

This form is used to notify the region, where newly collected samples for the clinical trial/performance study are collected, that they should **not** be the responsible biobank for these samples. Samples are to be established in another biobank, which is then the responsible biobank.

**Background:** The main rule should be that the Sponsor is the responsible biobank. However, if samples are collected in a region, the starting point is that the region where samples are taken is the responsible principal for the samples unless otherwise notified by the Sponsor. This means that the Sponsor either:

* apply for the establishment of the sample collection in the biobank to the biobank custodian where the sample is collected (form T1.1), or,
* notifies the biobank custodian, where samples are collected, that samples are to be established in another biobank (this form)

**Please note:** The form must be signed by the responsible biobank and sent to the region's biobank before collection of samples begins.

**Recommendation:** That the issue of which is the responsible biobank is established before the application for a clinical trial or performance study is submitted to the authority that authorises the clinical trial or performance study.

This document can be used as an attachment to the clinic agreement or financial agreement.

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| 1. Clinical trial/performance study[[1]](#footnote-2) | |
| 1.1 Responsible for the study | |
| 1.1.1 Sponsor | |
| 1.2 Information about the study | |
| 1.2.1 Study title specified in the application for clinical trial/performance study: | |
| 1.2.2 Study working title (if applicable): | 1.2.3 Protocol code (if applicable): |
| 1.2.4 EU-trial no./CIV-ID: | 1.2.5 Contact person at the Sponsor (name): |
| 1.2.6 Phone: | 1.2.7 E-mail: |

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| 1. Responsible biobank | |
| The responsible biobank must be a Swedish biobank registered with the Health and Social Care Inspectorate. | |
| 2.1 Principal of the biobank: | |
| 2.2 Name of the biobank/biobank department: | 2.3 Biobank registration number (issued by the Health and Social Care Inspectorate): |
| 2.4 Sample collection ID (if applicable): | 2.5 Case ID (if applicable): |
| 2.6 Biobank custodian: | |
| 2.7 Contact person: | |
| 2.8 Phone: | 2.9 E-mail: |

**Villkor:**

1. The Sponsor is responsible for ensuring that all samples are newly collected within the framework of a clinical trial or performance study authorised in accordance with the applicable EU Regulation: Clinical trial of medicinal products for human use (EU Regulation No 536/2014), clinical trial of medical device (EU Regulation No 2017/745) or performance study of in vitro diagnostic medical devices (EU Regulation No 2017/746)
2. The Sponsor is responsible for ensuring that samples may only be used in another study after a new approval in accordance with the Ethical Review Act (2003:460) or permission in accordance with the applicable EU regulation mentioned under 1.
3. The responsible biobank at the Sponsor must have a Swedish organization number and be registered with the Health and Social Care Inspectorate.
4. The responsible biobank at the Sponsor is responsible for ensuring that samples are handled in accordance with the requirements of the Biobank Act (2023:38).
5. The responsible biobank at the sponsor is responsible for ensuring that samples are destroyed immediately if the sample donor or another person who has given consent for the preservation and use of a sample withdraws their consent to the preservation of samples.

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| 1. Signatures |
| 3.1 For responsible biobank |
| 3.1.1 Signature (authorised representative): |
| 3.1.2 Name in print: |
| 3.1.3 Date: |

1. [↑](#footnote-ref-2)