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

# T1a. Appendix – Description of samples, subjects and sites included in clinical trials and performance studies

Specify the investigators responsible for the sample collection at each site in the clinical trial. In multicentre study agreements, the responsible investigator on each site is obliged to contact the e-biobank in his/her region regarding how samples shall be traced if needed. The purpose of this procedure is that the Biobanks in Medical Care Act entitles a donor to change a previously granted consent at any time. It is the e-biobank custodians´ responsibility to be able to track samples in a secure manner.

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| ***1. General information***  |
| 1.1 EU trial number (if clinical trial of medicinal products):       | 1.2 CIV-ID (if studies of medical devices):      |
| 1.3 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/en/documents/>***[ ]  **Alteration of previous biobank application**, RBC dnr:      . Specify *all information in section 1* as well as the new information.  |

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| ***2. Description of the samples******Note:*** *The information in this section 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.* |
| **2.1 Sample type** |
| [ ]  Newly collected samples – fill in **section 2.3** [ ]  Tissue samples[[1]](#footnote-1) [ ]  Other samples [ ]  Existing archive samples – fill in **section 2.4**[ ]  Tissue samples, Clinical Pathology/Cytology – Attach **L1a** “Information about existing clinical samples in pathology and cytology biobanks”[ ]  Other samples – Attach **L1b** “Information about existing samples in biobanks” **Additional information, if applicable:**       |

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| **2.2 Clinical trial/performance study duration in Sweden** |
| 2.2.1 Estimated recruitment start date in Sweden (month/year):       | 2.2.2 Estimated end of trial date in Sweden (month/year):      |
| **Description of samples***Fill in information and mark appropriate alternatives.The information must be covered by the application for clinical trial/performance study.*A. Specify sample type retrieved from subjects (blood, urine, cerebrospinal fluid, type of tissue, faeces etc.). Specify extent if possible.B. Specify sample type (type of tissue, material from tumours, cells, blood, serum, plasma, DNA etc.) registered in an existing sample collection and retrieve from here. Specify extent if possible.C. Specify the number of subjects. If samples will be saved from screen failures, these individuals must be included in the number of subjects.D. Specify number of samples per subject for each sample type.E. Mark the box if samples shall be released. Secure information in T1, section 5, and where additional information is provided. F. Specify year if samples are stored for use within the objective of the study. Must be consistent with the form “Compliance with applicable rules for biological samples”, section 3.G. Specify year if samples are stored for future use, i.e. other use than described in the protocol. Must be consistent with the form “Compliance with applicable rules for biological samples”, section 4. |
| **2.3 Newly collected samples**  |
| A. Sample type and extent | C. No. of subjects | D. No. of samples per subject | E. Samples shall be released | 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: |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
|       |       |       |[ ]        |       |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
| **2.4 Existing archive samples**  |
| B. Sample type and extent | C. No. of subjects | D. No. of samples per subject | E. Samples shall be released | 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 |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |
|       |       |       |[ ]        |       |
|       |       |       | [ ]  |       |       |
|       |       |       | [ ]  |       |       |

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| ***3. Involved regions and number of subjects per site***  |
| Additional information regarding regions and subjects per site (if applicable):       |
| **Mark involved regions and specify expected numbers of subjects** | **To be completed by RBC:**  |
| **3.1 Region** | **3.2 Estimated number of subjects** | **3.3 Samples will:***If multicenter principle is applicable, samples will be released from the e-biobank of each region* |
| [ ]  Region Blekinge |       | [ ]  be released from, or [ ]  remain in, Region Blekinges biobank 462[ ]  be released from e-biobank 839[ ]  other alternative:       |
| [ ]  Region Dalarna |       | [ ]  be released from, or [ ]  remain in, Biobank Dalarna, Diagnostic pathology samples 874. [ ]  be released from [ ]  remain in Biobank Dalarna, Research and newly collected samples 873. [ ]  be released from e-biobank 857[ ]  other alternative:        |
| [ ]  Region Gotland\* |       | [ ]  be released from, or [ ]  remain in Region Gotlands biobank 575[ ]  be released from e-biobank 853[ ]  other alternative:        |
| [ ]  Region Gävleborg |       | [ ]  be released from, or [ ]  remain in, Region Gävleborgs biobank 984[ ]  be released from e-biobank 814[ ]  other alternative:       |
| [ ]  Region Halland |       | [ ]  be released from, or [ ]  remain in, Region Hallands biobank (Klinisk Patologi & Cytologi) 325..[ ]  be released from e-biobank 841[ ]  other alternative:       |
| [ ]  Region Jämtland Härjedalen |       | [ ]  be released from [ ]  remain in Biobanken Region Jämtland Härjedalen 398.[ ]  be released from e-biobank 782[ ]  other alternative:       |
| [ ]  Region Jönköping County |       | [ ]  be released from [ ]  remain in Laboratoriemedicins kombinationsbiobank 868.[ ]  be released from e-biobank 767[ ]  other alternative:       |
| [ ]  Region Kalmar County |       | [ ]  be released from, or [ ]  remain in Pathology/Cytology biobank 488[ ]  be released from, or [ ]  remain in Clinical chemistry biobank 491[ ]  be released from, or [ ]  remain in Clinical microbiology biobank 490 [ ]  be released from e-biobank 768[ ]  other alternative:       |
| [ ]  Region Kronoberg |       | [ ]  be released from, or [ ]  remain in Biobank Kronoberg 340[ ]  be released from e-biobank 838[ ]  other alternative:       |
| [ ]  Region Norrbotten |       | [ ]  be released from, or [ ]  remain in Region Norrbotten biobank 3[ ]  be released from e-biobank 869[ ]  other alternative:       |
| [ ]  Region Skåne |       | [ ]  be released from, or [ ]  remain in Region Skånes biobank 136[ ]  be released from e-biobank 803[ ]  other alternative:       |
| [ ]  Region Stockholm |       | [ ]  be released from, or [ ]  remain in Stockholms Medicinska Biobank 914[ ]  be released from e-biobank 772[ ]  other alternative:       |
| [ ]  Region Sörmland |       | [ ]  be released from, or [ ]  remain in Biobank Sörmland 872[ ]  be released from e-biobank 761[ ]  other alternative:       |
| [ ]  Region Uppsala |       | [ ]  be released from, or[ ]  remain in Uppsala Biobank 827[ ]  be released from e-biobank 779,[ ]  other alternative:       |
| [ ]  Region Värmland |       | [ ]  be released from, or [ ]  remain in Region Värmlands biobank 924[ ]  be released from e-biobank 794[ ]  other alternative:       |
| [ ]  Region Västerbotten |       | [ ]  be released from, or [ ]  remain in Biobanken Norr 472[ ]  be released from e-biobank 818[ ]  other alternative:       |
| [ ]  Region Västernorrland |       | [ ]  be released from, or [ ]  remain in Pathology/Cytology 437[ ]  be released from, or [ ]  remain in Laboratory medicin Västernorrland 438 [ ]  be released from e-biobank 826[ ]  other alternative:       |
| [ ]  Region Västmanland |       | [ ]  be released from, or [ ]  remain in Pathology/Cytology biobank 554 [ ]  be released from, or [ ]  remain in Clinical microbiology biobank 84 [ ]  be released from, or [ ]  remain in Clinical chemistry biobank 442.[ ]  be released from e-biobank 748[ ]  other alternative:       |
| [ ]  Västra Götalandsregionen |       | [ ]  be released from, or [ ]  remain in Biobank Väst 890.[ ]  be released from e-biobank 773[ ]  other alternative:       |
| [ ]  Region Örebro County |       | [ ]  be released from, or [ ]  remain in Region Örebro County biobank 454[ ]  be released from e-biobank 763[ ]  other alternative:       |
| [ ]  Region Östergötland |       | [ ]  be released from, or [ ]  remain in Biobank Östergötland, 1[ ]  be released from e-biobank 769[ ]  other alternative:       |
| *\* Municipality with no region, but responsible for health and medical care* |

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| **4. Principal investigators and trial sites** |
| Instructions: The investigators contact details and site address from the application for clinical trial of medical products, clinical investigation of medical devices or performance studies of medical devices for in vitro diagnostics will be compiled in an appendix of the biobank application and does not need to be filled in again. If an investigator should be sample collection controller instead of sponsor, tick the box 4.1.2. The indicated investigator should also sign the agreement T1b and/or T1c. Applicable if the sponsor only is active outside Sweden.If there are more principal investigators involved – copy the last box as many times as necessary. |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 The trial site is a private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 The trial site is a private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 The trial site is a private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 The trial site is a private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 The trial site is a private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 The trial site is a private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

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| 4.1 Trial site  |
| 4.1.1 Name of investigator:      | 4.1.2 The investigator is sample collection controller instead of sponsor (if applicable) [ ]   |
| 4.1.3 Region:      | 4.1.4 Private clinic [ ]  |
| 4.1.5 Name of local contact person in addition to the investigator:      | 4.1.6 Email address (local contact person):      |

1. *Note that 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.* [↑](#footnote-ref-1)