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| **To be completed by the releasing biobank** | | | | | |
| Date of arrival: |  | Reg. no: |  | Sample collection ID: |  |

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| **To be completed by the responsible/recipient biobank** | | | | | |
| Date of arrival: |  | Reg. no: |  | Sample collection ID: |  |

T1.3 Request for amendment of biobank agreement for clinical trials and performance studies

This form should be used by sponsors who wish to apply for an amendment of a biobank agreement established on forms T1/T1a, T1.1 and/or T1.2 Amendment of a biobank agreement according to the multicentre principle should be done on form N2.

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| 1. Clinical trial or performance study | | | | |
| 1.1 Reg. no/sample collection ID. (from former approved biobank application) | | | | |
| 1.2 Study working title (if applicable): | | | | 1.3 Protocol/CIP/PSP code: |
| 1.4 EU trial no/CIV-ID: | | | | *Documents from the clinical trial/performance study application do not need to be attached* |
| 1.5 Request for amendment refers to:  Note: Only sections with new or changed information with regards to the previous application, should be completed. | | | | |
| **New sponsor.** Complete section 2. | | | | |
| **Extended storage time and/or more samples (e.g. increased sample quantity, new sample types and/or more subjects).** Complete section 3.  The previous biobank application has been approved on form/s (several options are possible): | | | | |
| **T1/T1a/T1b/T1c** | **T1.1** | **T1.2** | **L1 (only applicable for clinical trials transferred to Clinical Trials Regulation, CTR)** | |
| **Addition of new sites/principals.** Complete section 4.  Attach form L1a/L1b if access to existing samples from a new principal (region) is desired. | | | | |
| **Cessation of continued release of newly collected samples via previous biobank agreement (T1, T1a, T1c and L1)**  L1 only applicable for clinical trials transferred to Clinical Trials Regulation, CTR.  Release of newly collected samples from a regions' biobanks to the specified receiving/responsible biobank is valid from the start of the sample collection and up to and including the date of the approved application for amendment (form T1.3). The releasing biobank (according to previous biobank agreement) continues to be responsible for saving documentation about the released samples and to whom the samples have been released to during this period, in order to enable the traceability of the samples.  After the date of the approved application for amendment (form T1.3), the following applies:  1. Samples are established directly into the sample collection at the specified recipient biobank, which is responsible for storing sample documentation to enable sample traceability.  2. The specified recipient biobank is responsible for ensuring that the information and documentation, concerning samples in the study, is correct and up to date. Any future changes to the study do not need to be notified to the principal where samples are collected.  3. Existing samples or newly collected samples that have a partial care purpose will continue to be established in the healthcare provider's biobank and released to the recipient in accordance with previous agreements. | | | | |
| **Other changes**  The application for amendment is only related to information included in the previous biobank application.  The previous biobank application has been approved on form/s (several options are possible): | | | | |
| **T1/T1a/T1b/T1c** | **T1.1** | **T1.2** | **L1 (only applicable for clinical trials transferred to Clinical Trials Regulation, CTR)** | |
| Describe the change: | | | | |

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| 1. New sponsor organisation | |
| * 1. Name of sponsor organisation: | |
| 2.2 Email address (organisation): | 2.3 Country: |

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| 1. Change in current sample collection |
| 3.1 Samples should be stored for use within the objective of the study, please specify new end date: |
| 3.2 Samples should be stored for future use, please specify new end date:        (*year or until further notice*) |

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| **3.3 Additional samples that will be included in the sample collection** | | | |
| **3.3.1 Existing archive samples** Append fully completed form L1a/L1b. | | | |
| A. Sample type | C. No. of subjects | D. No. of screen failures from whom samples will be saved | E. Quantity/PAD per subject |
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*Add more rows if needed.*

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| **3.3.2 Newly collected samples** | | | |
| B. Sample type | C. No. of subjects | D. No. of screen failures from whom samples will be saved | E. Quantity per subject |
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*Add more rows if needed.*

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| 1. Addition of concerned principals | | |
| Select the appropriate principal | | |
| **Principal** | **Newly collected samples from** | **Existing samples from** |
| Region Blekinge |  |  |
| Region Dalarna |  |  |
| Region Gotland *(Municipality without a region)* |  |  |
| Region Gävleborg |  |  |
| Region Halland |  |  |
| Region Jämtland Härjedalen |  |  |
| Region Jönköpings län |  |  |
| Region Kalmar län |  |  |
| Region Kronoberg |  |  |
| Region Norrbotten |  |  |
| Region Skåne |  |  |
| Region Stockholm |  |  |
| Region Sörmland |  |  |
| Region Uppsala |  |  |
| Region Värmland |  |  |
| Region Västerbotten |  |  |
| Region Västernorrland |  |  |
| Region Västmanland |  |  |
| Västra Götalandsregionen |  |  |
| Region Örebro län |  |  |
| Region Östergötland |  |  |

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*Add more rows if needed*

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| 5. Invoice address The invoice address will be used for the invoice of the biobank agreement. Please make sure that the information is correct for this purpose. The invoice will be sent to the most recently received information and an additional cost may be added if you need to adjust the information in an invoice that has already been sent.  The information has not been changed since the last application – leave section 5 empty. | | |
| 5.1 Company/Organisation: | 5.2 Corporate identification no. (if applicable): | |
| 5.3 Invoice reference: | 5.4 PO#: | 5.5 VAT reg. no. |
| 5.6 Invoice address: | 5.7 Postcode: | 5.8 City: |
| 5.9 Country: | 5.10 E-mail for invoice: | 5.11 Peppol-ID/GLN-code: |

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| 6. Signatures | |
| 6.1 For the sponsor  By signature, it is confirmed that the information provided is complete and that the terms and conditions in the biobank application and in all accompanying appendices are accepted. | |
| 6.1.1 Signature (authorised representative): | 6.1.2 Date: |
| 6.1.3 Print name: | 6.1.4 Email: |
| Decision by responsible biobank (completed by authorised representative)  The application is approved with the following terms:  The application is denied with the following explanation:  The decision can be reconsidered by the principal of the biobank. | |
| 6.2 For the responsible biobank | |
| 6.2.1 Signature (authorised representative): | 6.2.2 Date: |
| 6.2.3 Print name: | 6.2.4 Email: |

The principal of the biobank becomes the personal data controller for data in the biobank agreement. The data will be processed in accordance with the General Data Protection Regulation (GDPR). For more information regarding how personal data will be processed we refer to the principal.

## Amendment of agreement regarding release of samples

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| 7. Signatures applicable when samples are released | |
| 7.1 For the responsible/recipient biobank | |
| 7.1.1 Signature (authorised representative): | 7.1.2 Date: |
| 7.1.3 Print name: | 7.1.4 Email: |
| Decision by releasing biobank (completed by authorised representative)  The application is approved with the following terms:  The application is denied with the following explanation:  The decision can be reconsidered by the principal of the biobank. | |
| 7.2 For the releasing biobank | |
| 7.2.1 Signature (authorised representative): | 7.2.2 Date: |
| 7.2.3 Print name: | 7.2.4 Email: |

The principal of the biobank becomes the personal data controller for data in the biobank agreement. The data will be processed in accordance with the General Data Protection Regulation (GDPR). For more information regarding how personal data will be processed we refer to the principal.