|  |
| --- |
| To be completed by RBC |
| Date of arrival:       | RBC no:       |

N2. Request for amendment of agreement according to the multicentre principle

This form can be used by sponsors and investigators who want to apply for amendments to previously signed biobank agreements according to the multicentre principle in clinical trials and performance studies (forms T1 and T1a) and in other research studies (form N1a).

For clinical trials and performance studies: The request for amendment is to be sent to kliniskaprovningar@biobanksverige.se

For other research studies: The request for amendment is to be sent to the RBC (Regional Biobank Centre) where the original agreement (N1a) was signed.

|  |
| --- |
| 1. The clinical trial/performance study or other research study
 |
| 1.1 RBC no. (from former multicentre agreement)      |
| 1.2 Clinical trial or performance studyonly to be completed in case of clinical trial or performance study according to CTR, MDR or IVDR[[1]](#footnote-1) |
| 1.2.1 Study working title:      | 1.2.2 Protocol code:      |
| 1.2.3 EU trial no/CIV-ID:      | *Documents from the clinical trial/performance study application do not need to be attached* |

|  |
| --- |
| 1.3 The research studyonly to be completed in case of other research than clinical trial or performance study according to CTR, MDR or IVDR |
| 1.3.1 Study working title and/or study-ID (if applicable):      | 1.3.2 EudraCT no (in clinical trials of medicinal products, not according to CTR):      |
| 1.3.3 Application for ethical approval, including amendments (Handling of samples must fall under the ethical approval) |
| All registration numbers of the Swedish Ethical approval:      | Append the new versions of the following (if applicable):* Application for ethical approval (signed).
* Application for amendment of the ethical approval (if applicable).
* Response to request for complementation of the application (if applicable).
* Decisions regarding application for ethical approval (all).
* Research participant information (if applicable).
* Informed consent forms (if applicable).
 |

|  |
| --- |
| 1.4 Request for amendment refers to: |
| [ ]  **New samples** | Specify sample types:       | Specify expected number of individuals:       | Specify number of samples per individual:       |
| [ ]  **Extended study period** | State new expected date of final sampling:       | State new date for how long samples shall be…… accessible to for the study:      … saved after the study has been completed:       |
| [ ]  **New sponsor or principal investigator.** Enter name of new sponsor or new principal investigator further down (section 2).  |
| [ ]  **New research principal (applying principal of the research in the application for ethical approval):**       |
| [ ]  **Cessation of continued release of samples via previous agreement signed according to the multicentre principle.**Release of samples from the regions' e-biobanks to the specified receiving biobank is valid from the start of the sample collection and up to and including the date of the approved application for amendment (form N2). The releasing principal 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 N2), 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 RBC or the principal where samples are collected.3. If new sites are added after this approval date, the regions concerned will be notified by sending out forms T7a and L7 respectively. |
| [ ]  **Addition of new sites and participating investigators.** Please select additional new regions below (section 3) and specify new investigators (section 4). |
| [ ]  **Change of participating investigator.** Specify new investigators below (section 4). |
| [ ]  **Other changes,** specify what:       |
| *Please note that a new release of all or part of the sample collection to another receiving biobank is to be handled with form T1.2 or L1.2*  |

|  |
| --- |
| 1. New sponsor or principal investigator in the study
 |
| Sponsor or principal investigator for the study |
| * 1. Name of sponsor’s organisation or name of investigator:

      | 2.2 Clinic/Unit:      |
| 2.3 Address:      | 2.4 Region:      |
| 2.5 E-mail:      | 2.6 Phone:      |

|  |
| --- |
| 1. Addition of new sites
 |
| Select the appropriate Regions and expected number of individuals |
| **Region** | **Number of individuals** | **Region** | **Number of individuals** |
| [ ]  Region Blekinge |       | [ ]  Region Stockholm |       |
| [ ]  Region Dalarna |       | [ ]  Region Sörmland |       |
| [ ]  Region Gotland\* |       | [ ]  Region Uppsala |       |
| [ ]  Region Gävleborg |       | [ ]  Region Värmland |       |
| [ ]  Region Halland |       | [ ]  Region Västerbotten |       |
| [ ]  Region Jämtland Härjedalen |       | [ ]  Region Västernorrland |       |
| [ ]  Region Jönköping County |       | [ ]  Region Västmanland |       |
| [ ]  Region Kalmar County |       | [ ]  Västra Götalandsregionen |       |
| [ ]  Region Kronoberg |       | [ ]  Region Örebro County |       |
| [ ]  Region Norrbotten |       | [ ]  Region Östergötland |       |
| [ ]  Region Skåne |       | *\* Municipality without a region* |

|  |
| --- |
| 1. New participating investigators included in the study
 |
| * 1. New participating investigator at site
 |
| 4.1.1 Name:       | 4.1.2 Clinic/Unit:      | 4.1.3 Private care giver:[ ]  |
| 4.1.4 Address:      | 4.1.5 Region:      |
| 4.1.6 E-mail:      | 4.1.7 Phone:      |
| 4.1.8 Research nurse/Contact person:      | 4.1.9 E-mail:      |

|  |
| --- |
| * 1. New participating investigator at site
 |
| 4.2.1 Name:      | 4.2.2 Clinic/Unit:      | 4.2.3 Private care giver:[ ]  |
| 4.2.4 Address:      | 4.2.5 Phone:      |
| 4.2.6 E-mail:      | 4.2.7 Phone:      |
| 4.2.8 Research nurse/Contact person:      | 4.2.9 E-mail:      |

If there are more participating investigators involved in the study – copy the last box as many times as necessary.

|  |
| --- |
| 1. Cessation of continued release of samples via previous agreement signed according to the multicentre principle

only to be signed if this amendment is relevant |
| 5.1 Authorised representative of the receiving biobank |
| 5.1.1 Signature: |
| 5.1.2 Name in print:      |
| 5.1.3 Date:      |

|  |
| --- |
| 1. New invoice address
 |
| Please make sure that the invoice information is correct. An additional cost may be added if adjustments need to be done on an already sent invoice.  |
| 6.1 Company/organisation:      | 6.2 Corporate identification no. (if applicable):      |
| 6.3 Invoice reference:      | 6.4 PO#:      | 6.5 VAT reg. no.:      |
| 6.6 Invoice address:      | 6.7 Postcode:      | 6.8 City:      |
| 6.9 Country:      | 6.10 E-mail for invoice:      | 6.11 Peppol-ID/GLN-code:      |

|  |
| --- |
| 1. Signatures
 |
| This agreement shall be drawn up in two originals: One original will be filed by the deciding RBC, which is representative of the Healthcare principal. The other original will be sent to the principal investigator (sample collection controller) representing the research principal. A copy of the application will also be sent to the authorised representative of the recipient biobank. The sample collection controller and the authorised representative of the receiving biobank certifies that the samples shall be treated according to the earlier established agreement, ”Access to biobank samples and sample code in clinical trials and/or performance studies” (document T1) or “Access to newly collected samples and associated personal data in multi-centre studies” (document N1a).  |
| * 1. Sample collection controller

Sponsor (for studies with an EU trial number or CIV-ID according to section 1.2) alternatively,Principal investigator (for studies with an ethical approval number according to section 1.3)  |
| 7.1.1 Signature: |
| 7.1.2 Name in print:      |
| 7.1.3 Date:      |
| Decision (to be completed by authorised representative of the releasing biobank) [ ]  The request for amendment of agreement according to the multicentre principle is approved with the following terms:       [ ]  The request for amendment of agreement according to the multicentre principle is denied with the following explanation:       |
| 7.2 Authorised representative of the *releasing* biobank (RBC director or authorized person) |
| 7.2.1 Signature: |
| 7.2.2 Name in print:      |
| 7.2.3 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

1. Please note that there are exceptions where clinical trials and performance studies of a medical device do not fall within the scope of the MDR or IVDR and where the application is submitted to the Ethical Review Authority in accordance with the regular procedure. In this form, they must be listed as 'other research'. [↑](#footnote-ref-1)