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

# L1a. Appendix – Information about existing clinical samples in pathology and cytology biobanks

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| 1. Research study | |
| 1.1 Study title (as stated in in the application for ethical approval, clinical trial, or performance study): | |
| 1.2 Study working title and/or study-ID (if applicable): | 1.3 EU trial No. or EudraCT-no (in clinical trials of medicinal products): |
| 1.4 CIV-ID (for clinical investigations of medical devices): | 1.5 All registration numbers of the Swedish Ethical approval (not applicable for clinical trials or performance studies under the EU regulations 536/2014, 2017/745 and 2017/746): |
| 1.6 Summary of the research study (purpose, method, significance). A maximum of 300 words: | |

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| 1. Applicant | | |
| 2.1 Principal investigator (applicable for projects with an ethical approval registration number (section 1.5)) or,  Sponsor (applicable for projects with an EU trial No. (section 1.3) or CIV-ID (section 1.4)) | | |
| * + 1. Name: | 2.1.2 E-mail: | |
| 2.1.3 Work address: | 2.1.4 Postcode: | 2.1.5 City: |
| 2.2 Other contact persons (if other than specified in L1.1 or L1.2 (section 3.4) *or* T1.1 (section 4.2.6)) | | |
| 2.2.1 Name: | 2.2.2 Project role: | |
| 2.2.3 Phone: | 2.2.4 E-mail: | |
| 2.3 Pathologist participating in the study (if applicable\*)  *\*contact the region's biobank coordinator in the planning process for information if this is applicable in concerned region* | | |
| 2.3.1 Name: | 2.3.2 Extent of participation  Has participated in/reviewed the study design  Participates in the diagnostic work | |
| 2.3.3 Phone: | 2.3.4 E-mail: | |

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| 1. Invoice information | | |
| 3.1 Company/Organisation: | 3.2 Corporate identification no.: | |
| 3.3 Cost centre/Invoice ref. (if applicable): | 3.4 PO #: | 3.5 VAT reg. no: |
| 3.6 Invoice address: | 3.7 Postcode: | 3.8 City: |
| 3.9 Country: | 3.10 E-mail: | 3.11 Peppol-ID/GLN-code: |
| 3.12 Other information (e.g., preferred payment period): | | |

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| 1. Information about where samples are to be sent | |
| 4.1 Delivery address: | 4.2 Contact information to person receiving the samples (name, phone number, e-mail): |
| 4.3 Other information (for example preferred delivery date): | |

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| 1. Sample collection the application pertains (if applicable) | | |
| 5.1 Hospital/unit/laboratory etc.: | 5.2 Name/ID of sample collection: | 5.3 Other: |

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| 1. Information about the requested material | | | |
| The information below shall correspond to the material specified in L1.1/T1.1 or L1.3/T1.3.  Before submitting the application, please contact the biobank coordinator (biobankssamordnare) at the responsible biobank/region or concerned laboratory regarding questions about sample handling.  LAB-ID/list of personal identity numbers shall be forwarded after the biobank application has been approved, all in accordance with local routines for the retrieval of samples and the requirements of the General Data Protection Regulation (GDPR).  Sample preparation is normally executed by the biobank or a clinical laboratory (please note, not all facilities offer this service). Please observe that the material is a limited resource and representative material must always remain. | | | |
| 6.1 Individuals | | | |
| Total number of individuals, including screened individuals: | | | |
| 6.2 The requested material | | | |
| Provide a brief description of the requested material (type of tissue, quantity, and preparation) and what it will be used for (description of the analysis, e.g., optimization and test of three immune antibodies): | | | |
| 6.2.1 Diagnostic slides | | | |
| Are access to diagnostic slides requested (access to both slide and block are not given at the same time):  Yes  No | | | |
| 6.2.2 Quantity and preparation – paraffin embedded tissue blocks | | | |
| Specify the requested quantity and type of preparation of the paraffin blocks. | | | |
| No. of sections per block, on glass: | Section thickness (µm): | Type of glass: | No. of sections per glass: |
| No. of sections per block, in tube: | Section thickness (µm): |  | |
| TMA material; core diameter | No. of cores from tumor tissue: | No. of cores from normal tissue: | |
| The principal investigator wishes to perform the above stated preparation. | | | |

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| 6.2.3 Volume – liquid-based cytology samples |
| Specify requested aliquot/volume for liquid-based cytology samples.  Aliquot/volume (µl): |
| 6.2.4 Quantity and preparation – other material |
| For example, fresh frozen tissue or prepared DNA/RNA.  Brief description: |
| 6.2.5 Specify the minimum number of cuts/punches/amounts required to be able to include the individual in the study. If there is not enough material available to deliver what is desired. |
| Minimum no. of sections per block, on glass:  Minimum no. of sections per block, in tube:  Minimum no. of cores from tissue; from tumor tissue:       from normal tissue:  Minimum quantity/volume of liquid-based cytology samples:       µl |
| 6.2.6 Other preparation |
| Is staining or other preparations requested?  Yes, please specify:  No |
| 6.3 Coding of samples |
| Is coding of the samples required?  Yes, please specify:  No |

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| 1. Return of samples (To be completed by sample collection controller of existing samples, if applicable) |
| 7.1 Shall the samples be returned to the original sample collection?  Yes, sample type:  *Note: The time for return can be regulated in an MTA/equivalent*  No  Other: |

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| 1. General terms for access to samples and information |
| * Received samples may not, under any circumstances, be used for anything other than what has been approved by the responsible biobank in agreements about establishment and release for research (document L1.1 or L1.2) or regarding clinical trials or performance studies (document T1.1 or T1.2). * The rules stated in the Swedish Biobank Act and the General Data Protection Regulation (GDPR) are to be followed. Observe that also encoded data, in particular, are personal data as long as any individual can be identified using the code key and should be handled accordingly. * Samples and data shall be stored in such a way that no unauthorized person can access it. * When the research project has been finalized the samples shall be handled in accordance with the application of ethical approval or the decision for clinical trial or performance study, obtained consent and agreements about establishment and release of samples for research (document L1.1 or L1.2), or regarding clinical trials or performance studies (document T1.1 or T1.2). * The applicant may not transfer his/her rights or responsibilities in accordance with this agreement unless obtaining written approval from authorized representative for the responsible biobank. * In case the recipient prepares the material, it is never allowed to exhaust the material in the tissue blocks. Representative material of the tumour/normal tissue must always remain. * If clinical pathology samples made available for an action need to be withdrawn for the patient's care, the researcher/recipient must return the block/glass to the responsible biobank/laboratory unit within 72 hours. * Consent from all sample donors (or legal guardians) shall be obtained according to the study’s ethical approval from the Swedish Ethical Review Authority, Ethics Review Appeals Board, or decision from the Swedish Medical Products Agency. * The principal investigator shall keep all signed consent forms to be able to show them to the responsible biobank. The consent forms shall be kept until, whatever happens last of all samples in the study are used up or the study ends. |

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| 1. Signatures   (To be completed by the sample collection controller of existing samples) |
| 9.1 Endorsed or not endorsed |
| **The application is endorsed, with the following terms** for access to existing material (if applicable):        *alternatively*  **The application is not endorsed. Reason:** |
| 9.2 Additional notes (such as information relating to processing times, dates when the applicant can get access to samples and priorities): |
| 9.3 Sample collection controller of existing samples |
| 9.3.1 Signature: |
| 9.3.2 Name in print: |
| 9.3.3 Date: |