Application for ethical approval – *Annex 2*
Description of biological material

14. Description of biological material

14.1. Will new biological material from humans be collected for the project?

The issue relates to fresh collection of biological material (samples) from humans, i.e. material that is collected specifically for this research project.

☐ Yes
☐ No

14.1.1. [If yes to 14.1] **What type(s) of biological material is/are to be collected?**

State what type(s) of biological material is/are to be collected for this research project. If the option 'Other biological material' has been selected, this must be stated.

☐ Tissue
☐ Blood
☐ Other biological material, state which

[If other] – Max 100 characters

14.1.2. [If yes to 14.1] **Will the source of the biological material be traceable to a particular person, i.e. will it be possible to connect the biological material to the individual from whom the material has been collected?**

It is possible to connect the biological material to the individual in two ways: Either directly (the samples have been marked with identifying information such as initials, date of birth or similar) or by means of a code key (i.e. the material has been pseudonymised). If it is not possible to connect the biological material to the individual, the material has been de-identified.

☐ Yes
☐ No

14.1.2.1. [If yes to 14.1.2] **State how the biological material will be coded.**

When material has been coded, the individual's identity is replaced on the material by a code, and a code key is produced. The code key enables the identification of which individual the material comes from.

Max 2,000 characters

14.1.3. [If yes to 14.1] **How much biological material is planned to be collected?**

Provide the number of samples, the number of fragments and/or the volume that is to be collected on each individual occasion. Also provide the total number of samples, the number of fragments and/or the total volume for the study. If applicable, also provide the number of samples, fragments and/or the volume for each substudy.

Max 2,000 characters

14.1.4. [If yes to 14.1] **For how long is the project to have access to the biological material?**

State what period of time the research project will have access to the biological material.

From day month year – Until day month year

14.1.5. [If yes to 14.1] **Will the biological material be analysed and destroyed within six months of collection of the sample, i.e. is the exemption rule applicable?**

On 1 January 2019 a new exemption rule was introduced with regard to samples collected for research but which are not to be stored in biobanks. The exemption rule means that the biobank legislation is not applicable to samples that are intended for research, are to be analysed within six months of the samples having been collected and are to be destroyed immediately after they have been analysed. Both conditions must be fulfilled.

Even if the exemption rule applies to the current research project, all questions relating to biological material must be answered with the exception of questions concerning the name of the biobank and the entity responsible for it.

☐ Yes
☐ No

14.1.6. [If yes to 14.1] **Give reasons for the choice of period of time for which the project will have access to the biological material.**

Max 2,000 characters

14.1.7. [If yes to 14.1] **For how long is the biological material to be accessible after the project has been completed?**

State what period of time the applicant plans to have access to the biological material.

From day month year – Until day month year

14.1.8. [If yes to 14.1] **Give reasons for the choice of period of time for which the project will have access to the biological material after the project has been completed.**

Max 2,000 characters

14.1.9. [If yes to 14.1] **Provide the name of the biobank that will be responsible for storing the collection of samples.**

This refers to the biobank that is responsible for storing the collection of samples that is put together during the study, i.e. the collection for which the biological material is procured. If possible, provide the Swedish Health and Social Care Inspectorate (IVO) registration number.
***Biobank:** A collection of biological material from humans, stored for one or several purposes, and information about this material. A biobank may contain several collections of samples.*

Name of biobank

14.1.10. [If yes to 14.1] **State the entity responsible for the biobank**

State the entity responsible for the biobank that will be in charge of the collection of samples.

Entity responsible: the agency or organisation that has legal and financial responsibiity for an activity.

Entity responsible

14.1.11. [If yes to 14.1] **What analyses will be carried out on the biological material?**

Explain all analyses and processes that the biological material is to undergo.

Max 2,000 characters

14.1.12. [If yes to 14.1] **Where will the analyses be carried out?**

State where the analyses of the biological material will take place. If the analyses are to take place outside Sweden, the country/countries must be stated.
Various rules apply if the samples are to be sent off for analysis within Sweden, within the EU/EEA or outside the EU/EEA to what is known as a third country.

☐ As part of the organisation's own activities
☐ Within Sweden
☐ Outside Sweden, state country/countries

Max 200 characters

14.1.13. [If yes to 14.1] **How will the biological material be managed when the analyses have been carried out?**

Samples in a biobank that have been submitted for analysis within or outside the country must be returned to the biobank in Sweden or destroyed (disposed of) when they are no longer required for the purpose for which they were collected. Usually this should occur within a few years.

☐ The material will be destroyed.
☐ The material will be sent back to a biobank in Sweden.

14.2. Does the project plan to use biological material from humans from one or more existing collections of samples?

The issue is whether access to biological material or samples that have been collected in the past will be requested for this research project.

Ja/Nej

14.2.1. [If yes to 14.2] Which biological material is planned to be used?

State what type of biological material is to be used in this research project. If the option 'Other biological material' has been selected, this must be stated.

☐ Tissue
☐ Blood
☐ Other biological material, state which

[If other] – Max 100 characters

14.2.2. [If yes to 14.2] How much biological material is planned to be used?

Provide the number of samples, fragments and/or the volume of all biological material that is planned to be collected and used for this project.

Max 2,000 characters

14.2.3. [If yes to 14.2] Provide the name(s) of the biobanks from which the biological material will be collected and the entities responsible for them.

The name(s) of all the biobanks, and the entities responsible for them, from which the existing biological material will be collected or requested must be stated.

Biobank: A collection of biological material from humans, stored for one or several purposes, and information about this material. A biobank may contain several collections of samples.

Max 2,000 characters

14.2.4. [If yes to 14.2] Provide the name of the biobank that will be responsible for this collection of samples.

This refers to the biobank that will be responsible for the new collection of samples that is built up, i.e. the collection for which the biological material is procured. If possible, provide the Swedish Health and Social Care Inspectorate (IVO) registration number.

Biobank: A collection of biological material from humans, stored for one or several purposes, and information about this material. A biobank may contain several collections of samples.

Max 200 characters

14.2.5. [If yes to 14.2] State the entity responsible for the biobank

State the entity responsible for the biobank that will be in charge of the fresh collection of samples that is being procured.

Entity responsible: The agency or organisation that has legal and financial responsibiity for an activity.

Max 200 characters

14.2.6. [If yes to 14.2] State how the material is coded.

When material has been coded, the individual's identity is replaced on the material by a code, and a code key is produced. The code key enables the identification of which individual the material comes from.

Max 2,000 characters

14.2.7. [If yes to 14.2] What analyses will be carried out on the biological material?

Explain all analyses and processes that the biological material is to undergo.

Max 2,000 characters

14.2.8. [If yes to 14.2] **Where will the analyses be carried out?**

State where the analyses on the biological material will take place. If the analyses are to take place outside Sweden, the country/countries must be stated.

Various rules apply if the samples are to be sent off for analysis within Sweden, within the EU/EEA or outside the EU/EEA to what is known as a third country.

☐ As part of the organisation's own activities
☐ Within Sweden
☐ Outside Sweden, state country/countries
[State country/countries] – Max 500 characters

14.2.9. [If yes to 14.2] **For how long will the biological material be managed when the analyses have been carried out?**

Samples in a biobank that have been submitted for analysis within or outside the country must be returned to the biobank in Sweden or destroyed (disposed of) when they are no longer required for the purpose for which they were collected. Usually this should occur within a few years.

☐ The material will be destroyed.
☐ The material will be sent back to a biobank in Sweden.

14.2.10. [If yes to 14.2] **For how long is the biological material to be accessible to the project?**

State the length of time for which the biological material will be stored for this research project.

From day month year – Until day month year

14.2.11. [If yes to 14.2] **Give reasons for the choice of period of time for which the project will have access to the biological material.**
Max 2,000 characters

14.2.12. [If yes to 14.2] **How long is the biological material to be accessible after the project has been completed?**

State the period of time for which the applicant plans to have access to the biological material.

From day month year – Until day month year

14.2.13. [If yes to 14.2] **Give reasons for the choice of period of time for which the project will have access to the biological material after the project has been completed.**
Max 2,000 characters