**Ethical support – Frequently Asked Questions (FAQs)**

# FAQs about the ethical review in Sweden

When is ethical approval needed?

Ethical approval from the Swedish Ethical Review Authority is needed if you are conducting research on humans, human tissue, or sensitive personal data.

When does ethical approval need to be in place?

Ethical approval must be in place before the work/research begins. This applies to all types of approval that may be required for a study.

Does the KI Ethics Council approve ethical applications?

No, the Ethics Council at KI does NOT provide ethical approval. Only the Swedish Ethical Review Authority can grant ethical approval.

Can you use existing ethical approval for another research project?

As long as the new project does not deviate from the research described in the ethical application, and the consent given by the patients/subjects, an existing approval can often be used in several different externally funded projects.

Are there annual reviews or renewals of ethical approvals in Sweden?

No, this is not done in Sweden.

# Analysis of samples

Is ethical approval required for analyzing blood samples?

Yes! Swedish legislation requires ethical approval for human samples, and blood is included in “human samples”.

Handling of blood does not require a special permit from The Swedish Work Environment Authority (Arbetsmiljöverket). Do I still need ethical approval?

Handling blood is something other than analyzing human samples. Ethical approval is required for human samples, including blood, and is regulated by specific legislation.

# Some examples

To do research on aborted fetuses (a research ethics question).

In EU projects, costs in connection with the production of, for example, tissues or cells from aborted fetuses are not a permitted cost. However, if other funding is used to obtain stem cells from aborted fetuses, for example, then the stem cells can be used within the EU project. Cost associated with the stem cells (e.g., analysis of cells) would also be permitted.

Biopsy samples taken from a deceased person (after consent from relatives) in another EU country, which are anonymized and sent to Sweden to be part of a research project. The procedure is not subject to an ethical review in the other EU country. Will the project be subject to ethical review in Sweden according to the Ethics Review Act (etikprövningslagen)?

The biopsy itself is not subject to ethical review, because it is not performed in Sweden. Handling of the material can be subject to ethical review, however, this depends on if the biopsy is taken for medical purposes, and the biological material can be traced back to the person. This is why it is important to understand the distinction between “anonymized” and “pseudonymized” data <https://staff.ki.se/personal-data-in-research>). If the material is only pseudonymized, then an ethical review may be required for the part of the research that is to be carried out in Sweden, but this may not always be the case. Therefore, it is a good idea to apply for an ethical approval for precautionary measures. Most journals require ethical approval for studies to be published, which suggest that it would be good to also apply for ethical approval in Sweden.

Human cells are obtained from international companies or from a collaborating partner within Europe that already has an ethical approval in its country (i.e., applicable to isolation, culture, and usage of the cells). The company or collaborating partner has access to personal data about the donors, but the researchers in Sweden will not have access to any personal data. Is the project subject to ethical review in Sweden according to the Ethics Review Act?

Since the cells are not obtained in Sweden, the research is not subject to ethical review. Similar to the example of “biopsy from a deceased person”, it may be a good idea to apply for ethical approval, as it can be difficult to give a definitive answer when you do not have access to a complete application. Since most journals require ethical approval of a study to be published, then it would be advisable to apply for ethical approval in Sweden as well.

# EU-related questions

How does ethical review differ within EU countries compared to Sweden?

In research projects that collaborate with countries within the EU, one must be aware that ethical laws and regulations may differ between the different countries. Many reviewers lack knowledge about Swedish legislation and the differences that exists within the EU. It is, therefore, the responsibility of the researcher/PI to explain the Swedish legislation and its system to, for example, ERC’s reviewers.

Below are some common concerns posed by reviewers.

To apply for an ethical approval.

In many countries within the EU, ethical reviews are done locally at the hospital, university, or institution where the research and/or data collection will be carried out. In Sweden, there is a National Ethical Review Board, which processes all applications, regardless of where in Sweden the research is conducted.

Annual reviews and renewals of ethical approvals.

In many countries, annual reviews or renewal of ethical approvals are often required. In Sweden, this is not required.

Data that will be used in an ongoing project has received ethical approval in Sweden, but according to comments from ERC’s reviewers, it was not enough since another researcher’s/PI’s name appears on the ethical approval for that study.

The researcher/PI must explain for the reviewer that in Sweden, existing ethical approvals can also be used for new projects and new PIs, even if that approval is not specific to the new project or that particular PI. An important note here, however, is that the research must still be conducted within the framework of the original ethical approval, in which case there is no need to apply for a new approval.

Data Protection Officer (DPO): Do most EU external research funders require that the host institution appoints a DPO?

Yes, all EU research funders require DPOs at the host institution. At KI, the DPO is Mats Gustavsson (appointed by the president), who works in the legal department.

# Specific requirements for the Swedish Research Council (Vetenskapsrådet)

Basic ethical requirements.

The researcher needs to have all ethical permits and ethical approvals in place before the research starts. However, the permits should not be submitted to the Swedish Research Council, unless they explicitly request it.

More info: <https://www.vr.se/english/applying-for-funding/requirements-terms-and-conditions/conducting-ethical-research.html>

# Specific requirements for Horizon2020

Basic ethical requirements.

Horizon2020 conducts an ethical review of all projects and adheres to the ethical principles for human subject research. One step in this process is the researcher is required to complete an “ethics self-assessment”, which addresses ethical issues within the research project, and is submitted together with the application. If any information is missing or there is an insufficient description, Horizon2020 will ask the researcher for more details.

More info about ethics self-assessment: <https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf>

More info about the ethical review: <https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/from-evaluation-to-grant-signature/grant-preparation/ethics_review_en.htm>

# Specific requirements for Horizon Europe

Basic ethical requirements.

The process to assess and address the ethical dimension of activities funded under Horizon Europe is called the Ethics Appraisal Procedure. This includes ethical reviews, checks, and audits from the start to the end of the project. Researchers must begin by completing an “ethics self-assessment” and submit it together with their application. If any information is missing or unclear, the researcher will be asked to provide more details and resubmit the assessment.

More info about ethics self-assessment:

<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf>

More info about the ethical review:

<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf>

# Specific requirements for MSCA (Marie Skłodowska-Curie actions)

MSCA follows the same ethical principles and requirements as Horizon2020/Horizon Europe. MSCA often requires more detailed information from the very start of the process.

# Specific requirements for ERC-grants (European Research Council Grants)

Basic ethical requirements.

The researcher must complete an “ethics self-assessment”, which addresses ethical issues within the research project. It must be submitted together with the application.

More info: <https://erc.europa.eu/>

More info on Medarbetarportalen: <https://staff.ki.se/erc-application-guidelines>

Ethics advisor or an ethics advisory board.

For ERC projects, the EU-commission can sometimes request an ethics advisor or an ethics advisory board.

Research Support Office (RSO) can provide support for certain issues, for example, finding an ethics advisor. Contact RSO at compliance@ki.se if you need help.

It is common for questions to arise when writing the ethics report, however, it is not strictly regulated. There is a fair amount of leeway when writing the ethics report. Here <https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf> you can read more about the roles and functions for ethics advisors, especially in Appendix II, where there are suggestions for headings that can be used in a report.

This is usually managed by the PI and the ethics advisor directly.

*“The applicant must check if special derogation pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place. A declaration of compliance with the applicable national legal framework(s) must be provided*.*”* What to answer?

A common answer often used for this question is: “All relevant national legislation is followed, and there are no special derogation(s).”

*“The applicant must confirm that the Host Institution has appointed a Data Protection Officer (DPO). The contact details of the DPO must be made available to all data subjects involved in the project. For Host Institutions not required to appoint a DPO under the General Data Protection Regulation, a detailed data protection policy for the project must be provided.”*

From the researcher: ”KI is the host for my ERC project, but both of our ethical approvals relating to the study have Region Stockholm as the Sponsor (huvudman). If I understand correctly, we are expected to include contact information for the DPO in the patient information – but should we refer to the DPO at KI, or the DPO at Region Stockholm/KS?”

It is more complicated when there is more than one Sponsor, but a common answer often used for this question is: *“Both KI and Region Stockholm, the legal entity for the ethical approvals, each have appointed a DPO. Depending on what part of the study the information concerns, the relevant contact information will be provided.”* For example, if the researcher has data and/or samples from Region, then it is Region’s DPO that is referred to. For data that already exists at KI, i.e., if the researcher will transfer data/samples from Region to KI, then you refer to KI’s DPO.

*“A justification for the processing of "special categories of data", as listed in art.9 of the General Data Protection Regulation 2016/679, must be provided.”* What is needed here?

In these cases, the researcher must provide a justification and a grouping of what kind of data is needed. It can be, for example, that personal data is needed for the consent and to allow for tracing for subsequent data analysis. The researcher can stipulate that only necessary personal data will be saved (although you may not collect/save data that may *potentially* be needed, there can always be a reason why data is collected/saved).

*“The applicant must evaluate the ethical risks related to the data processing activities of the project. This must include an opinion on whether a* *Data Protection Impact Assessment (DPIA) should be conducted under art.35 of the General Data Protection Regulation 2016/679. The opinion, the risk assessment and, if applicable, the Data Protection Impact Assessment, must be provided.”* What needs to be delivered here? Are there any models to look at?

It depends on whether you can justify that no DPIA is needed or not. More information and templates are available at: <https://gdpr.eu/data-protection-impact-assessment-template/>.

# US-related questions

How are ethical reviews different in the US compared to Sweden?

In research projects that collaborate with the US, the researcher must be aware that ethical laws and regulations may differ between the countries. It is often the responsibility of the researcher/PI to explain the Swedish legislation and the system for American ethical reviewers if any questions arise.

Below are common issues and differences that exist between the US and Sweden.

To apply for ethical approval.

In the US, ethical approval is done locally at the hospital, university, or institution, where the research/data collection is to be carried out. In Sweden, there is a National Ethical Review Board, which processes all applications, regardless of where in Sweden the research is conducted.

Annual reviews and renewal of ethical approvals.

In the US, annual reviews or renewal of ethical approvals are conducted. In Sweden, this is not required.

Living/deceased people and ethical approval.

In the US, ethical approval is only required to conduct research on living people, not for the deceased. In Sweden however, ethical approval is required for material from both living and deceased people.

# Other questions

Questions/conflicts regarding authorship.

For questions regarding this, you can turn to KI’s scientific representative <https://staff.ki.se/scientific-representative>

Send/process data between different parties/countries *within* the EU/EEA, what applies?

As part of the ethical approval, it must be included that data is to be sent from KI to another party/country within the EU/EEA, or if another party must process the data on behalf of KI.

If data is to be processed by another party on behalf of KI, a **data processor agreement** (personuppgiftsbiträdesavtal) must be drawn up between the parties. Templates for data processing agreements can be obtained from the legal department; avtal@ki.se

If KI processes personal data for which someone else is the controller for the processing of personal data (personuppgiftsansvarig), then KI is the processor (personuppgiftsbiträde). This means that the Head of Department, or equivalent, signed this agreement.

Send/process data between different parties/countries *outside* of the EU/EEA, what applies?

As part of the ethical approval, it must be included that data is to be sent from KI to another party/country outside the EU/EEA and the data must be pseudonymized (coded).

If data is to be processed outside the EU/EEA on behalf of KI, a **data processor agreement** (personuppgiftsbiträdesavtal) must be drawn up between the parties. Agreements may also be required if KI will process data on behalf of someone else. Templates can be obtained from the legal department; avtal@ki.se

Read more about GDPR here: <https://staff.ki.se/faq-on-the-gdpr>

Read more about transferring of personal data to outside the EU/EEA here: <https://staff.ki.se/transfer-of-personal-data-to-third-country-or-international-organizations>

Read more about data processor agreements here: <https://staff.ki.se/data-processor-agreement>