Karolinska Institutet

Clarification of rules regarding ethics permits

This document concerns research covered by the **Act on ethical review of research involving humans (2003:460)**[1], in which it was clarified on 1st January 2020 that all principal researchers involved must be stated in an ethical application. 'Principal researchers' means a government authority or a legal person who conducts the research. The role, assignment and responsibility of the respective principal researchers in the project must be described in detail in the ethics application.

When KI conducts research and processes human samples and/or sensitive personal data that require ethics approval in Sweden, KI must either have submitted and received approval as the applying research principal for the ethics application, or they must be listed as a principal research participant in an ethics application submitted by another research principal.

No action needs to be taken for ethical permits for ***completed projects*** for which KI was not mentioned as either a primary principal researcher applying or as a participating principal researcher principal. However, in those cases in which the research project is **still ongoing** and where KI is not, neither in the initial application nor in a supplementary application, listed as an applying or participating principal researcher, amendments to the existing ethics permit may be needed.

For ongoing studies, especially with ethics approval from before 1st January 2020, you usually need to check the specific study and the ethical considerations to determine if an amendment is necessary or not. In the case of an amendment, KI must be stated as a participating principal researcher, and KI's role and responsibilities must be clearly described. This also includes personal data and in some cases biobank data.

It is also important to ensure that KI is listed as the applying or participating principal researcher in all future projects for which ethical approval is required.

Contact the Research Support Office at compliance@ki.se or contact KI's lawyers at dataskyddsombud@ki.se for any help or questions.

A number of questions arose after the previous communication, and we hereafter try to address as many of them as possible, as well as clarifying some misunderstandings. In addition to this supplementary information, work has begun to review, and if necessary

[1] https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460/

to revise, the information on the website and the associated guidance texts. We ask for your patience with this as it will take some time to perfect. If something is unclear or if you do not find an answer, please contact us at compliance@ki.se.

Who assesses the research articles and ethics applications before the PhD defense?

This is done as before by the KI thesis defence committee.

An ethics application costs more if multiple principal researchers are included

This is not necessarily the case. If the research persons/study participants only have direct contact with one of the principal researchers, the same cost is paid as if there was only one principal researcher. This is regulated via the application form in *Ethix*.

I have an external employment (or a double employment at the hospital/a company and at KI) – that's enough for ethics

No, the employment has nothing to do with ethics, or even with the research conducted. It is what actually takes place within the framework of the various organizations (e.g. the hospital and the university) that is decisive. If you are employed at the hospital and research data is analyzed at KI, for example, KI must be included as a principal researcher in the application to EPM, as research is then conducted at KI. To exemplify this further, it sometimes happens that external consultants are hired to carry out part of a research project. The consultants then carry out the work/research within their business for the organization that hired the consultant (e.g. KI) and not for the company where the consultant is employed. When hiring a consultant, an agreement must be drawn up between the responsible organization and the consultant.

I have an external employment (or a dual employment at the hospital/a company and KI) - then I can move data as I want (between the organizations)

No, employment is not decisive. Healthcare data (data relating to patients) may **not** be moved in any way between different organizations and such data may not even be used for research at the hospital where the data was collected (which was done for the purpose of healthcare) without a request for access to the data for the purpose of research (addressed to the person who is responsible for the data, ultimately head of operations/equivalent). Regardless of whether a request for access to data is made internally within a healthcare provider or if the request is made by an external party (e.g. a university such as KI), any disclosure must be preceded by a confidentiality review. If sensitive personal data is to be disclosed for research purposes, an approved ethics permit is also required.

In addition, certain agreements may be needed depending on the setup of the study.

The doctoral student/supervisor is employed at the hospital

Where a person is employed is not decisive, but it is within which organization/which organizations' activities that the research is carried out that determines who/which organizations need to be listed as the principal researcher in an ethics application. For example. if the person plans the collection of data, processes the data, uses a KI computer or a KI program to analyze the data, is a doctoral student at KI and/or will

publish[2] in KI's name, then KI participates in the research. Another example is if you engage an external consultant within a project, then the research that the consultant carries out does not take place at the consulting agency, but at the organization that engages the consultant.

Research outside Sweden

If a research project is carried out outside of Sweden's borders, then as a rule no Swedish ethics permit is needed, but in most cases ethics approval is needed in the country/countries where the research is carried out. Note, however, that if data (sensitive personal data) and/or samples - which require ethics approval in Sweden - are transferred to Sweden, for example when a researcher at KI gets access to the data to review analyses, then a Swedish ethics approval is also needed that covers the analyzes carried out in Sweden. This also applies if the data and/or samples are pseudonymised, and the researchers in Sweden do not have access to the code key. A common example is when pseudonymised (coded) data from a database in e.g. the UK is used for research in Sweden, then a Swedish ethics approval is required. Similarly, when coded human samples collected abroad are analyzed in Sweden, provided they are traceable (i.e. there is a code key saved somewhere).Fully anonymized data and/or samples do not fall under the Ethics Review Act, but these are usually pseudonymized in the research conducted at KI.

Samples sent abroad - are both MTA and data agreement required?

A related question to ethics permits is which agreements might be needed in various collaborations. If human samples are to be sent abroad, usually both a *Material Transfer Agreement (MTA)* and a *data agreement* need to be drawn up. The type of data agreement can vary from case-to-case, but if you use a lab abroad, usually a data processing agreement (DPA) must be drawn up between the parties. However, if it is a research collaboration in which both parties jointly make decisions about the data, then instead a *Joint Controller Agreement (JCA*) may be relevant.

Why apply to have data released from a healthcare provider?

If sensitive personal data from healthcare is to be used for research at KI, you must request (apply) to have this data released from the healthcare provider to KI. In order for the data to be disclosed, it is required that KI is listed as a principal researcher in the ethics application (and of course that EPM has approved the research). If the data is released to KI, then KI is responsible for all further handling of the data, which significantly facilitates everything from compliance regarding access to data after completed projects as well as future research collaborations.

Clinical trials in new systems – automatic ethics application

Nowadays, applications for clinical trials are submitted via CTIS *(Clinical Trials Information System)* and no separate ethics application is made. Instead, the Medical Products Agency forwards parts of the application to the Ethics Review Authority for review and approval. In CTIS the sponsor is specified, rather than the principal researcher, which means that there is no possibility to list different participating principal researchers in the same way as when the ethics application is submitted to

[2] If you do not handle any sensitive personal data or carry out any other actions that, by law, require an ethics permit, but instead contribute method expertise, and that is why you are included amongst the paper authors, then KI does not need to be part of the ethics permit.

EPM via Ethix. In these cases it is especially important to clearly describe KI's role and responsibilities within the study so that, based on the text, it is understood that KI is a participating principal researcher.

It is another university that submitted the ethics application

In the same way as when it is another region, healthcare authority or a company that submits the ethics application, KI must be included as a participating principal researcher in research collaborations with other universities when the ethics application is submitted by the collaboration partner.