Checklist before signing an ethics application

Before signing an ethics application, the following general questions should be considered (other questions may also apply depending on the study):

- Which (if any) participating research principals are involved and what does the collaboration look like? (Could include other universities, regions, and/or companies.)
- Are there other partners, labs (for analysis), or similar that are not listed as participating research principals? If yes, why are they not listed?
- Will any data and/or samples be sent to other countries (e.g., countries outside the EU/EEA)? **Note:** This must be permitted according to the studies ethics approval and consent form (i.e. participants need to be informed).
- Will data and/or samples from another country be used for research in Sweden? **Note:** If such data/samples are pseudonymized[1] (coded) and a code key exists anywhere in the world (even if you yourself do not have access to the code key), Swedish ethics approval is required.
- Will the research use biobank samples? If yes, in which biobank are they registered? **Note:** Ensure relevant biobank agreements are in place or will be established *before* data collection begins.
- Which organization(s) will act as data controllers? **Note:** This should be clearly stated in the ethics application and may require data agreements. Only organizations listed as research principals can use "public interest" as a legal basis for being data controllers.

[1] Pseudonymized data are data that can be traced back to a living individual indirectly, usually via a code. Anonymized data cannot be traced back to a living individual either directly or indirectly

- Will data be released from, for example, a data registry or hospital, or are data agreements needed for transferring personal data between research principals (e.g., data processor agreements or joint controllership agreements)? Will data be pseudonymized (coded) or anonymized?
- Are there any risks associated with the research?

The answers should be included in the ethics application[2] and reflected in the participant information sheet and consent form. Each research principal's role and responsibility must be clearly described in these documents.

For clinical trials, the ethics application is part of the application to the Medical Products Agency for drug trials (CTIS), while applications for medical devices are still submitted to the Ethics Review Authority (changes to this are planned).

In addition to the above questions, you should consider funding arrangements and whether specific agreements are needed for those (e.g., collaboration agreements, project agreements, CTAs etc.).

Note that KI cannot provide insurance for research conducted outside of Sweden. In that case, researchers must ensure insurance is in place in the relevant country.

Approved and complete ethics applications must be registered at KI.

Contact: compliance@ki.se

[2] Guide to the application for ethics review | Staff Portal

Where to find this information in the ethics application

Type of information	Section in application	Comment
Participating research principal	1.4	
Data/samples that are sent abroad	3.4 4.1 6.1	Biological material, section 14
Data/samples from outside Sweden that are used for research in Sweden	6.4 12.2 14	Foreign data/samples, sections 3.4, 4.1, 6.1 and 14
Biobank samples	2.6	May also appear in other sections
Data controller	6.4	Several sections, mainly section 6.4
Risks associated with research	7.1	

[2]Guide to the application for ethics review | Staff Portal