

# **Guidelines on ethical principles for human research outside Sweden**

Ref. no 1-429/2022

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**Karolinska  
Institutet**

# Guidelines on ethical principles for human research outside Sweden

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## Introduction

Since Karolinska Institutet (KI) is a collaborative and global university, a good deal of research is conducted outside Sweden. Such research is not always subject to the rules in Sweden concerning the protection of humans and the wider community.

Many countries have rules that correspond to those in force in Sweden, but others, if they have any at all, have rules that do not live up to what is considered an acceptable ethical standard in Sweden. KI's research must be ethically defensible.

*Researcher ethics* concern the researcher's responsibilities and relationship towards his/her research, the scientific community and society in general. The Act on responsibility for good research practice and the examination of research misconduct (SFS 2019:1150) stipulates that it is the responsibility of the researcher to comply with good research practice in his/her research and that the entity responsible for research has the overarching responsibility that the research is conducted in accordance with good research practice.

*Research ethics*, on the other hand, concerns respecting and protecting participants and others involved in a scientific study. A very important aspect of research ethics concerns the treatment of the individuals taking part in a study, whereby they shall be protected from injury or violation to the greatest extent possible.

KI's ethical rules for international collaboration<sup>1</sup>, both at departmental and individual level, require that an ethical review board or an equivalent local body approve the project before it is carried out.

The Act concerning the ethical review of research involving humans (SFS 2003:460), biological material from humans and sensitive personal data provides that such research may only be conducted if it has been ethically reviewed and subsequently approved. However, this law is only applicable to research conducted in Sweden.

As regards research on animals, ethical guidelines are in place for international collaborations involving animal research in a third country<sup>2</sup>.

## Purpose

These guidelines are for all employees and affiliated researchers engaged in research activities abroad.

The purpose of these guidelines is to ensure that research conducted abroad matches the ethical standards that apply to research conducted in Sweden as well as to protect individuals and safeguard respect for human dignity.

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<sup>1</sup> Ethical guidelines for international collaborations, ref. no 5-49/2014

<sup>2</sup> Karolinska Institutet's ethical guidelines for international collaborations – concerning animal-based research in a third country, ref. no 1-505/2020

## Principles of human research outside Sweden

When a researcher at KI takes part in an international research collaboration, he/she must comply with the rules and ethical guidelines in effect in Sweden and in the country where the research is being conducted. The part of the project to be conducted in Sweden shall be reviewed by the Swedish Ethical Review Authority; the part of the project conducted in the other country shall be reviewed there in accordance with the national rules. Valid approval must be obtained before the research may commence.

The researcher may not:

- participate in a project in another country without obtaining information of relevance to the ethical review of the research;
- participate in a project in another country that does not live up to the ethical principles that inform the rules governing research in Sweden. In the instances where foreign regulations or ethical guidelines allow anything that would be in breach of the rules and guidelines in effect in Sweden, an adequate level of protection for the participants must nonetheless be provided, preferably through the application of the Swedish standard also in the foreign country;
- participate in research that inherently contravenes KI's general values;
- locate research activities to another country in order to circumvent research ethical requirements of a Swedish standard.

### KI's ethics resource team

In the event of doubt as to whether a research project to be conducted outside Sweden is in compliance with these guidelines, researchers are asked to contact the KI ethics resource team. The team will then return an advisory statement on the basis of the information provided. Such a statement is merely a recommendation for the individual researcher's own judgement and does not constitute ethical approval.