

Routines for ethical review at the Department of Psychology

This document describes routines that concern considerations regarding ethical review of research conducted at the Department of Psychology. The routine is based on laws, regulations and policy documents that apply to research activities at Stockholm University. Even if the document is updated regularly, each individual researcher or supervisor has a responsibility to inform themselves about current legislation and which regulations apply.

Background

Since 2004, certain types of research involving humans have been subject to review in accordance with the Ethical Review Act (2003: 460) (in Swedish: **Lag (2003:460) om etikprövning av forskning som avser människor (EPL)**).

According to the Ethical Review Act, research is “scientific experimental or theoretical work or scientific studies through observation, if the work or studies are done to acquire new knowledge, and development work on a scientific basis, but not such work or studies performed only within the framework of higher education. or at the advanced level ¹”.

Examples of research that needs to be reviewed are:

- a. processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, data on a natural person's sexual life or sexual orientation, genetic and biometric data and data on a person's health.
- b. processing of personal data on offenses involving crimes, criminal convictions, coercive measures in criminal proceedings and administrative detentions
- c. physical interventions on a researcher or a deceased person
- d. methods that aim to affect a research person mentally or physically or that involve an obvious risk of harming a research person physically or mentally
- e. studies on biological material taken from a living or dead person and can be traced to that person

In accordance with SU's policy regarding ethics in research (www.su.se/ethicalreview and <https://www.su.se/staff/organisation-governance/governing-documents-rules-and-regulations/research/research-1.410257>), every researcher at the department has own responsibility to keep track of information regarding rules and guidelines regarding EPL. The head of department is responsible for giving employees good qualifications to take their individual responsibility so that no employee violates regulations that the researcher is aware of or should be aware of.

The Board of Appeal for Ethical Review (in Swedish: Överklagandenämnden för etikprövning, ÖNEP, <https://www.onep.se/>) is responsible for supervising the EPL and shall prevent researchers from being harmed physically, mentally or in terms of integrity. ÖNEP

¹ Student work that falls under the Act and where there is an intention for scientific publication in some form must undergo ethical review in advance.

initiates supervision every year for certain priority research areas, for example register research is one such area in 2022. The Board of Appeal is obliged to report charges if there is a reasonable suspicion of a punishable violation of EPL. In order to prevent research from taking place in violation of the EPL, the board has powers, e.g. to issue injunctions and prohibitions. The board may also issue injunctions when information or documents are not provided or when access is denied. An injunction or prohibition may be combined with a fine.

Before project start

When a new research project starts, the responsible researcher, together with other project staff, including any doctoral student / s, must identify and assess which ethical aspects and risks are relevant to the research. If the research project includes any of the points a-e mentioned in the section “background”, an application for ethics review must be sent to the Ethics Review Authority (Etikprövningsmyndigheten, EPM, <https://etikprovningmyndigheten.se/>). This applies to all research and development activities that fall under the Ethical Review Act, i.e. also research projects / research studies that lack external funding. Ongoing research projects, such as a secondary study, may also require a new basic application to be sent to EPM.

It can sometimes mean difficult demarcations to determine whether a project constitutes research according to the Ethical Review Act’s research definition in § 2 EPL. According to the practice of the definition developed by the appellate body, there is much to suggest that this is research if there is a scientific question and method, if the project is carried out by a person with scientific competence and if there is an intention to publish the results in a scientific journal.

Please note in particular that processing and analysis of foreign data carried out in Sweden may need to be ethically tested here according to the EPL, even if there is an ethics approval from the country of origin where the data material has been collected.

2. Researchers can receive support from the Office for Research, Engagement and Innovation Services (in Swedish: Forsknings- och samverkansstöd, FS) to make the assessment of whether a project or study needs to be examined by the Ethics Review Authority. The email address for FS is etik@fs.su.se. FS also has a digital ethics review tool that can be used to assess whether the project / study should be ethics reviewed or not. In the event of the slightest uncertainty as to whether ethical review is necessary, the ethics support function at FS should be contacted.

The form "Assessment regarding the need for ethical review of research" must be filled in and signed by the responsible researcher and submitted to the deputy head of department.

During the project

Responsible researchers receive a summary of their ongoing projects once a year and may answer questions about whether, for example, the project is ongoing or has ended and whether the project complies with EPM's decisions and conditions.

Application for ethical review

4. If you are applying for an ethics review to EPM, log in to the Ethix portal. In addition to submitting an application, it is also in this portal that you receive notifications, decisions and other matters concerning your application (<https://etikprovningmyndigheten.se/for-forskare/sa-gar-det-till/>). The application must be reviewed and signed by the head of department. In the event of a significant change relating to an already approved research project, an application for change must be made. If a change to an original project is extensive, a completely new application must be made.

It is important to carefully read and follow the EPM's instructions, see for example the section "frequently asked questions". Submitted application and decision from EPM must be sent to the registrar for record keeping.

5. Student work at undergraduate and advanced level should not normally be ethically tested by EPM. However, if the supervisor of the student work intends to publish the work in a scientific journal, or if the work is intended to form part of a dissertation at the doctoral education level, an ethical review is required². For further information about what applies to student work, please refer to the document "Declaration of ethics in connection with independent work" (decided by IS 2022-02-22).

The department's support

6. The department's working group on research ethics is part of the "collegial supervision" concerning research ethics issues and shall help to ensure that research subject to ethical review is not carried out without approval or in violation of conditions announced in connection with approval.

The working group will initiate open discussions with researchers at the department on relevant research ethics issues, such as current issues from ÖNEP. The working group can also address fundamentally important ethical issues and educational needs with FS. In accordance with the EPL, the working group cannot give any ethical approval for research projects and scientific studies.

If researchers wish to publish an article in a scientific journal, some journals may require that the study has been ethically tested. In cases where the research is not covered by the law and cannot be ethically tested, EPM can issue an advisory opinion. Another possibility is to briefly explain the EPL to the scientific journal in connection with the submission of the manuscript.

² When it comes to student work, even those that are carried out within the framework of research projects, it is important to consider whether the student whose thesis in question should be a co-author of a scientific publication. Students usually have copyright to their dissertations and if the scientific publication largely overlaps with the student work, it is most reasonable to include the student as a co-author.