When and where do I apply for an ethical review?

Instructions by the Helsinki Region Universities of Applied Sciences' Ethics Committee and the Helsinki and Uusimaa Hospital District Ethics Committee

Ethical review for research with human participants

Independent of the field of science and subject of interest, researchers are guided by general ethical principles which include, among other things, respect for the dignity, privacy, right to self-determination and other rights. Researchers shall always carry out their research in a manner to not cause significant risks, damage or harm to their subjects.

In addition to the general ethical principles that guide research, the methods of research that specifically target humans have been set in detail both in legislation and in the research community. Ethical reviews exist to support researchers in anticipating and avoiding possible harm and damage to the subject. Depending on the study design and the objective, the ethical review is carried out either by a statutory regional ethics committee (medical research under the Research Act) or by a human sciences ethics committee (other research targeting humans, later human sciences research).

The ethical review for each study is only carried out by one ethics committee. The following is a description of the division of labour between the Helsinki Region's Universities of Applies Sciences' human science ethics committee and the Helsinki and Uusimaa Hospital District (HUS)'s ethics committees. Included are also examples that can be used to select the correct ethics committee in so-called edge cases.

Regardless of the ethics committee, an ethics statement must always be sought for before the study may begin. **This statement is not a replacement for a research permit or the subject's consent to participate.** Organisations that often require a research permit for studying their staff, students, patients, members etc. already require a separate ethics statement from an ethics committee appended to a research permit application. After acquiring an assenting ethics review and a research permit, the researcher may approach their subjects and each of them may choose to consent or not consent to participating in the study.

1 Human science research

Human science research refers to all scientific research that targets humans or that uses human science methods. In addition to the humanities and social sciences, human science research includes natural science and technology research that targets humans, artistic research and non-invasive health research. Research in this context refers to research, development and innovation activities. Human science studies require an ethics assessment from a human sciences ethics committee in the cases specified in the National Board on Research Integrity (TENK)'s instructions. A study requires an ethics review **if any of the following conditions are met**:

- participation in the study deviates from the principle of informed consent,
- the study involves interfering with the physical integrity of research participants,
- the focus of the study is on minors under the age of 15, without separate consent from a parent or carer or without informing a parent or carer in a way that would enable them to prevent the child's participation in the research,
- the study exposes participants to exceptionally strong stimuli,
- the study involves a risk of causing mental harm that exceeds the limits of normal daily life to the research participants or people close to them,
- conducting the study could involve a threat to the safety of participants or researchers or people close to them.

Other types of study designs do not require an ethics review by a human science ethics committee.

Human science research requires an ethics review by the human science ethics committee of the researcher's location. The Human Sciences Ethics Committee for the Helsinki Region Universities of Applied Sciences issues ethics statements on request to the staff and students of its member organisations for postgraduate research (i.e. Master's thesis).

The member organisations of the Human Science Ethics Committee of the Helsinki region's Universities of Applied Sciences include Arcada University of Applied Sciences, Diakonia University of Applied Sciences (DIAK), HUMAK University of Applied Sciences, Laurea University of Applied Sciences, Häme University of Applied Sciences (HAMK), Metropolia University of Applied Sciences and Haaga-Helia University of Applied Sciences.

1.1 Examples of study designs that require an ethics statement from the human sciences ethics committee:

- the subjects are in a vulnerable position or in a dependent position to the research and/or the research organisation (e.g. conscripts, inmates, colleagues, subordinates and students), and it is questionable if their participation is truly voluntary,
- the study uses material that was collected for another purpose than the study itself, and the it is not possible to gain the subjects' consent to participate in the study,

- the study interfering with the physical integrity of research participants (e.g. measuring their physical condition), monitoring their physiological parameters (e.g. monitoring of sleep), taking physiological samples (e.g. saliva), consumption of food or other swallowable substance, and the study is not a medical research subject to the Medical Research Act,

- the subjects' physical freedom is limited in a manner that the subjects cannot interrupt their participation in the study within a reasonable time, and the study is not a medical study subject to the Medical Research Act,

- the research topic is one that subjects under 15 years of age are unlikely to let their guardians know about their participation. Such studies may have topics such as domestic violence, social issues, sexuality, substance abuse, or other similar studies,

- study designs, wherein the subjects are intentionally presented with ideas or material that are incompatible with the subjects' values (such as material containing violence or pornography),

- the study involves the subjects' or their families and friends' traumatic experiences,

- survey, interview and observation studies, where the study design or questions may cause an issue to the subjects' daily lives,

- studies in which the study design (e.g. studies on domestic violence, criminal activity or criminal organisations) or its implementation (e.g. studies in a crisis situation or area) may form a safety threat to the subjects, the researcher or people close to them. Data security risks may also pose a security threat if, for example, the subjects' personal data is collected and combined from several sources.

1.2 Example of a study design that does not require an ethics statement from the human sciences ethics committee:

- the study is solely based on publicly available information, archives, or document and register data, and does not involve a security risk due to data aggregation.

2 Studies subject to the Medical Research Act

An ethical review statement must be requested from the regional ethics committee for any medical study that targets humans. An ethical review must be carried out if the study involves medical research, as defined in the Medical Research Act, i.e. **all three conditions below are met**:

- the criteria for scientific research are met:
  - a research plan for a scientific study is in place,
  - the aim is to increase knowledge through the scientific method, and
  - the results of the study will be released to the general public in a publication channel approved by the scientific community.
- the study will increase knowledge regarding health, the causes, symptoms, diagnostics, treatment, prevention or the general nature of an illness, and
- the study interferes with the physical or psychological integrity of a human being (or that of a human embryo or foetus).

If the conditions above are met, studies subject to the Medical Research Act may include pharmaceutical, treatment, exercise, or nutritional studies that interfere with physical integrity of a human being. Medical studies include clinical pharmaceutical, device and equipment studies as well as clinical method studies, such as testing surgical procedures in an experimental setting. Theses for Bachelor's degree studies in Universities of Applied Sciences do not meet the criteria for scientific research, and they are therefore not reviewed by the HUS ethics committees.

Interference in physical integrity includes taking blood samples, examinations that include physical strain, and studies where food products are used with the aim to influence health, disease risk, or symptoms.

Interference in psychological integrity is when the study may pose a risk to the mental well-being of the subject. The Act is applied if a study may cause harm to the research subject's mental well-being beyond that of normal everyday life that they are unable to assess when considering their participation.

An ethical review statement is to be sought for a study subject to the Medical Research Act from the hospital district's ethics committee where the person responsible for the study operates (TVH) or in whose area the study is primarily carried out. In the Helsinki Region, ethical reviews are requested from the HUS ethics committees.

The types of medical research that are subject to the Medical Research Act and requires an ethics review statement from the HUS ethics committee include research on health, illness or healthcare wherein the subject is exposed to any kind of active intervention (treatment or rehabilitation measure). The submitter of the ethical review request is expected to justify and explain whether their study falls under the jurisdiction of the Medical Research Act.

2.1 Research that is subject to the Medical Research Act includes, among others:

- cross-sectional questionnaire or interview studies that interfere with the subject's psychological integrity and the study increases knowledge regarding e.g. health, causes of illness and treatments

- questionnaire, interview or observation studies that aim to discover the effects of the use of a treatment or rehabilitation method for a non-research purpose before and after treatment,
- studies that involve exercise for healthy people that provides knowledge on e.g. health, causes of illness, symptoms, or the general nature of illnesses,
- studies that involve exercise, when the study aims to increase knowledge on treatment or rehabilitation methods,
- nursing study wherein nurse work interventions (e.g. wound care, patient guidance) are used to influence health, risks of illness, symptoms, patient coping with an illness or quality of life,
- psychological research in cases where the subjects are patients or possibly people with an illness (depression, anxiety),
- psychological research that employ unusual research methods and the effects of which the subject is unable to assess when considering participation in a study,
- nutritional science research that, by ingesting a food product or other swallowable substance, aims to influence health or the risks or symptoms of an illness,
- clinical studies that are carried out to demonstrate the conformity of medical equipment (software may also be a piece of medical equipment when it is used to create or transform medical information in order to help healthcare professionals to use said information).

2.2 Research that is subject to the Medical Research Act may also include:

- questionnaire, interview or observation studies that collect health-related information from particular personal data groups and the study increases knowledge on e.g. the causes, symptoms, or treatment of illness.

2.3 Research that is not subject to the Medical Research Act is not, for example:

- register studies that are solely based on documents or statistics, wherein the subjects are not contacted,
- anonymous polls or opinion polls,
- one-time (cross-sectional) questionnaire and interview studies that do not interfere with a person's psychological integrity,
- exercise studies on healthy persons that produce data on the subjects' physical performance,
- behavioural studies that allow subjects to assess its effect on their own mental well-being on their own when considering their consent,
- studies that focus on psychological phenomena (i.e. motivation) rather than psychological issues or illnesses and that do not employ unusual research methods;

- service development and observation studies as well as quality and process projects in healthcare services that do not interfere with a person's physical integrity or involve scientific research.

Please note that the study designs noted above may require an ethics review by a human sciences ethics committee.