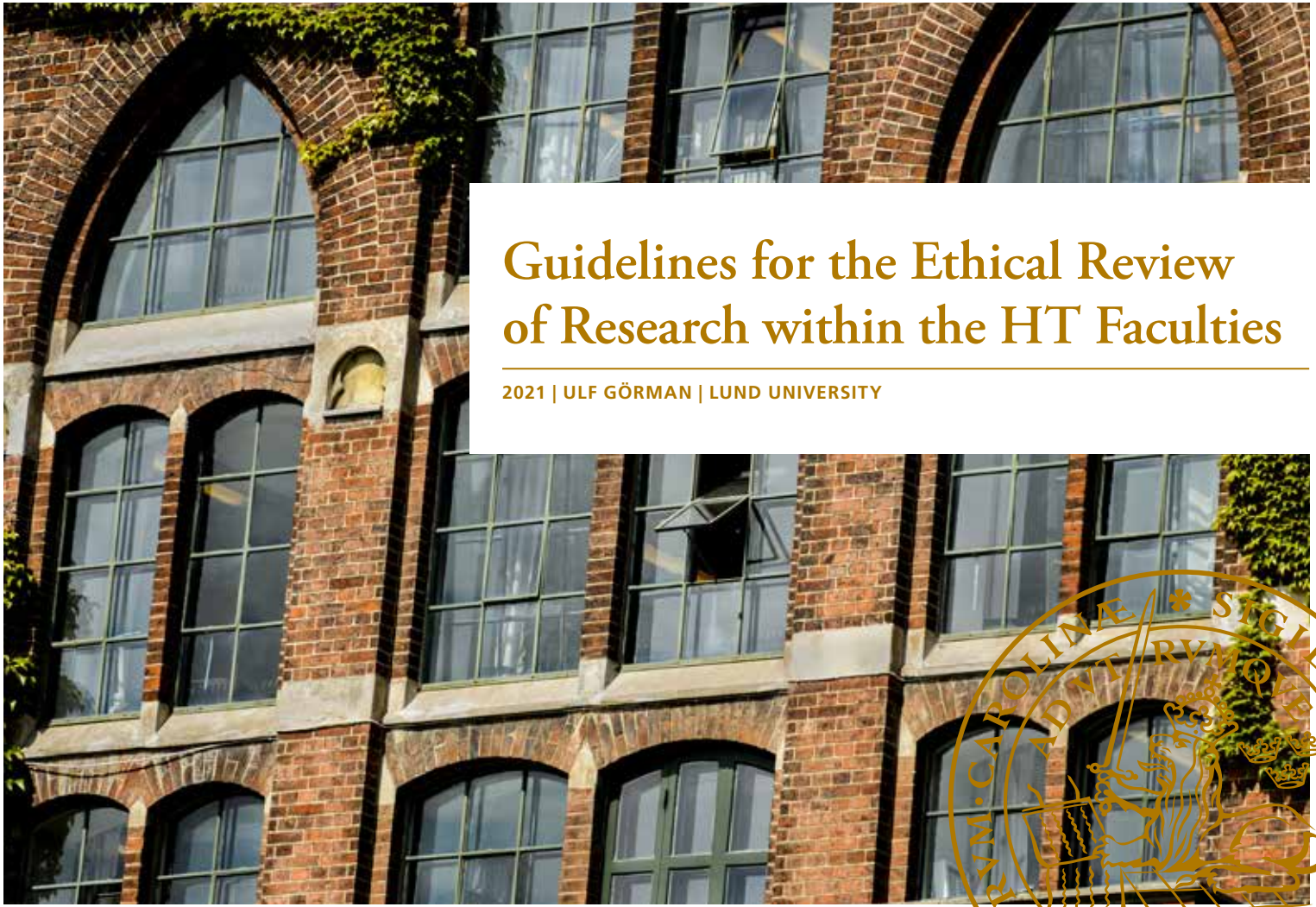

Guidelines for the Ethical Review of Research within the HT Faculties

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Preface

Ethical considerations and guidelines are necessary if research is to be used in a responsible manner for the development of science in our society, today and in future.

Doctoral students, researchers, and teachers at the Joint Faculties of Humanities and Theology must be well versed in the legislation on research ethics and capable of insightfully applying ethical principles in their work. The aim of the present guidelines is to contribute to this.

This text is primarily intended for research staff, but also contains a special section on student projects based on the recommendations issued in 2018 by the Ethics Council of the Joint Faculties of Humanities and Theology.

These guidelines are a thoroughly updated and expanded version of a previous text from 2017, *Lathund för etikprövning*, and take into account the changes made to the relevant legislation since then. The revision has been made by the author of the original text, Professor Ulf Görman, who for a long time was Scientific Secretary of the Regional Ethical Review Board in Lund. Björn Petersson, a member of the Ethics Council at Lund University and Docent in Philosophy, contributed information and advice during the revision process. The Board of the Joint Faculties of Humanities and Theology has approved this document for distribution and dissemination within the faculties.

Guidelines of this kind cannot predict future changes in legislation, nor can they take all eventualities into account. Thus they are no substitute for the responsibility of continuously keeping abreast of current legislation regarding research ethics in general or ethical review in particular. The links that are provided here and there in the text and the collection of links at the end of the text aim to make it easy for the reader to find current and supplementary information.

1 October 2021
Stephan Borgehammar and Barbara Törnquist-Plewa
Deputy Deans

INTRODUCTION

The objective of these guidelines is to describe what researchers within the humanities and theology need to know and take into account when planning research involving humans or information about humans. This includes what to keep in mind when considering whether an ethical review is necessary and, when this is the case, how an application should be drawn up. The guidelines contain information on practice and provide advice that is addressed especially to researchers within the Joint Faculties of Humanities and Theology ('the HT Faculties'). [1]

This information is also relevant to the education offered at these faculties. Independent projects carried out by students, in particular degree projects and research-preparatory papers, should, among other things, involve training in taking into account and demonstrating an ethical approach. One section of the text is dedicated to issues brought to the fore when students at the basic and advanced levels of education work with questions and materials involving humans or information about humans. The special issues foregrounded in this context have to do with the fact that this education is at the threshold of research, and that it constitutes training for future research or the consumption of research.

I have extensive experience of the ethical review of research as a member of a Swedish ethical review board, as well as of the ethical review of research financed by the European Commission. The information about practice and the advice presented in this publication are based on this experience, and should be understood as precisely that – experience-based advice, not an official interpretation of the regulations in force. In this document, 'the Ethical Review Board' refers to the board on which I worked. The examples provided are non-specific descriptions of reviews carried out by this board.

Since 2017, when an earlier version of this document, *Lathund för etikprövning*, was published, several important changes have occurred that warrant a revision. The new *European Union General Data Protection Regulation* (GDPR) has entered into force. In Sweden ethical review was reorganised in 2019, and the legislation relevant for ethical review has been revised. Lund University has drawn up routines and guidelines.

[1] My thanks to Björn Petersson, Linus Broström, Kristin Asgermyr, Mikael Falk, Annakim Eltén, and Andrea Mervik for valuable input on the drafts of this text. Naturally, I take full responsibility for any errors or ambiguities in the final text.

Issues regarding ethical review are a separate part of research ethics. An ethically acceptable approach in research also demands, among other things, avoiding research misconduct. Paragraph 2 of the Act on Responsibility for Good Research Practice and the Examination of Research Misconduct (2019:504) defines 'research misconduct' as

> a serious deviation from good research practice in the form of fabrication, falsification or plagiarism that is committed intentionally or through gross negligence when planning, conducting or reporting research.

The research ethical concept of 'good research practice' is, in its turn, broader and includes ethical considerations that are not necessarily prescribed by law. Guidelines for dealing with suspicions of research misconduct and other deviations from good research practice can be found at staff.lu.se/research-and-education/research-support/research-ethics-and-animal-testing-ethics/deviations-good-research-practice.

The Lund University webpages on research ethics contain information about ethical guidelines and laws relevant to the research process. At the centre is the Swedish regulatory framework and the provisions of Lund University. These webpages also provide the contact details of people, departments, and authorities with a special responsibility for answering questions about the research ethical framework. forskningsetik.lu.se

The present document deals only with ethical review issues concerning research on humans. At the HT Faculties at Lund University research that includes experiments on animals is also conducted. For questions about animal testing ethics and the approval of research on animals, see staff.lu.se/research-and-education/research-support/research-ethics-and-animal-testing-ethics/animal-testing-ethics.

RESEARCH INVOLVING HUMANS

With respect to the protection of humans, the most important documents relevant for research in the humanities and theology are the EU *General Data Protection Regulation* (GDPR) and the Swedish *Act Concerning the Ethical Review of Research Involving Humans* ('the Ethical Review Act'; in Swedish *Etikprövningslagen*). All researchers planning to work with information about humans have to be familiar with and observe the GDPR. This is true not only when the researcher collects information directly from the research

participants themselves, but also when he or she makes secondary use of previously collected information.

All researchers planning to work with
- sensitive personal data or data regarding violations of law;
- experiments aiming to have an effect on humans; or
- experiments exposing their participants to risks

are also required to be familiar with and observe the Ethical Review Act, to apply for ethical review of the research, and not initiate the research until ethical approval has been granted.

THE GENERAL DATA PROTECTION REGULATION (GDPR)

Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), better known as the GDPR, entered into force on 25 May 2018 and is the directly applicable legislation regarding personal data processing in the EU member states. The GDPR is a law common to all EU member states that prescribes rules and limits for all processing of personal data, not only for research. The GDPR defines specific areas where national legislation may add supplementary provisions to or exceptions from certain provisions in the Regulation. The Ethical Review Act was revised in 2020, and the revision contains such supplementary provisions with respect to research. No exceptions have been made in Swedish legislation from provisions on the rights of data subjects with regard to the processing of personal data for research purposes.[2]

Lund University is the personal data controller for all personal data processing conducted within the framework of the University's activities. The Staff Pages contain detailed information about the GDPR and its general application at the University.
staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr

A *Data Protection Officer* is available to provide support for anyone intending to process personal data. The tasks of the Data Protection Officer include providing information and advice to those who process personal data and

[2] Government bill 2017/18:298 'Processing of personal data for research purposes' (Prop. 2017/18:298 *Behandling av personuppgifter för forskningsändamål*), pp. 103–30..

supervising their compliance with the GDPR. The University Data Protection Officer can be contacted for help with any questions not answered via the link provided above.

All research projects at Lund University where personal data (i.e. not only sensitive personal data) are processed must be registered in *Personal Data Lund University* (*PULU*). Guidelines and more information regarding personal data processing in research can be found at
staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr/area-specific-information/research.

The Swedish Authority for Privacy Protection (*Integritetsskyddsmyndigheten* (IMY); formerly the Swedish Data Protection Authority) is the authority given the task of supervising the processing of personal data to make sure that it does not lead to an undue breach of personal integrity. IMY regularly carries out inspections and can impose fines. Information about provisions and practices can be found at IMY.se.

What are personal data?

Personal data are any kind of information that directly or indirectly relates to a living natural person. The GDPR defines personal data as

> any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (Article 4(1)).

Name or personal identity number are the most obvious examples of data that make it possible to directly link information to a particular person. In addition, research data may constitute personal data for many other reasons. *Indirect* identification means that someone who gains access to the information can find out to whom the information refers, even when the information does not contain direct identifiers. Some oft-mentioned examples of indirectly identifiable data are
- information that by simple means can be linked to a particular person, such as a mobile telephone number, email address, or IP address;

- information that together with one or more additional pieces of information can be uniquely linked to a particular person, such as a residential address or GPS data for a person's domicile.
- Indirect identification is also possible if the person who gains access to the material can identify to whom the information refers by using specific pieces of information that each on its own cannot be used to identify a person. A number of studies have investigated how much information is needed in order to make such an indirect identification. It was estimated that three to five specific pieces of information were sufficient to identify to whom the information referred, even in the case of a large amount of data.

The GDPR requires that a person processing personal data must 'implement appropriate technical and organisational measures [...] to [...] protect the rights of data subjects' (Article 25). It is common that researchers 'anonymise' in various ways materials that contain data on individuals, i.e. take measures that impede the identification of these individuals. This is correct and appropriate, but the data will nevertheless often be considered personal data.

The GDPR mentions in particular *pseudonymisation* as an appropriate safeguard that impedes identification of personal data in connection with research (Article 89(1)). Pseudonymisation involves replacing the names of the people concerned with a code number and drawing up a special code list, a so-called code key, and keeping this in a separate location. Pseudonymised data are to be considered identifiable, and the safeguards mentioned in the GDPR are applicable.[3] When someone other than the researcher him- or herself has the code key, the data are usually described as linked. Linked data are also identifiable personal data. The same applies if a researcher instead, or as well, chooses to encrypt the data.

Information on deceased persons does not constitute personal data and is not protected by the GDPR. Consequently, it may be used in research without an ethical review. Information on deceased persons is however protected in other Swedish legislation that needs to be observed. The researcher must also consider the fact that data regarding a deceased person may indirectly reveal information about still living relatives. Then such data also constitute personal

[3] See the GDPR, Recital 26 and Article 4(5).

Photo: Charlotte Carlberg Bärg

data about these relatives, and are therefore protected by the GDPR. When these data are used for research, ethical approval is required if the information in question is considered sensitive personal data.

The decisive criterion for whether the work of a researcher constitutes processing of personal data is not simply how the results are presented, because all work done in a research project must be taken into account. If the researchers in the project have access to, and in one way or another process data at the level of the individual, then the project should be considered to include personal data processing.

What does personal data processing involve?

The processing of personal data is:

> any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (GDPR, Article 4(2))

In other words, when a researcher acquires access to information that directly or indirectly can be linked to a living natural person, all processing of this material is considered personal data processing. The rules and limitations of the GDPR apply to all working methods included in the description above, not just computerised data processing.[4]

According to the GDPR, all personal data processing must rest on a particular *legal basis*. The permitted legal bases are listed in Article 6(1). When research is conducted by a Swedish public authority, the legal basis may be that the processing is necessary in order to perform a task that is in the public interest (Article 6(1)(e)). Lund University is such an authority.

Note that researchers should not claim *consent* as a legal basis for personal data processing when there is 'a clear imbalance between the data subject and the controller, in particular where the controller is a public authority' (GDPR, Recital 43). Consent is often needed or required for other reasons, but in most cases is not sufficient as a legal basis for personal data processing in connection with research.

For processing of *sensitive personal data* (in the GDPR referred to as 'special categories of personal data') more restrictive rules apply. It is worth pointing out that the main rule in the GDPR is that processing of special categories of personal data is prohibited, with a number of exceptions (Article 9(1)). The processing of such personal data is permitted if the processing is, among other things, necessary for 'scientific or historical research purposes' (Article 9(2)(j)). This processing shall be subject to appropriate safeguards (Article 89(1)). In Sweden ethical review and approval by the Swedish Ethical Review Authority are mandatory safeguards.[5]

[4] According to Article 2(1), the GDPR applies to 'the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system'. By filing system is meant 'any structured set' of data (Article 4(6)). The Central Ethical Review Board has in a number of decisions made the general assessment that personal data collected in order to be used in research are structured in order to facilitate searching or compiling.

[5] Government bill 2017/18:298 'Processing of personal data for research purposes' *(Prop. 2017/18:298 Behandling av personuppgifter för forskningsändamål*), pp. 84–90.

THE ETHICAL REVIEW

Bad experiences from earlier research involving humans have led to legislators around the world imposing both rules and control mechanisms for such research. In Sweden, these rules are expressed in the Ethical Review Act, and the primary control mechanism is the ethical review, which means that all research activities falling within the scope of the Act must be ethically reviewed before they are allowed to begin.

The major tasks of the ethical review system are to protect the integrity and safety of research participants, to examine the value of the research, and to balance this against the risks it involves for the research participants. Some of the principal rules are:

- A person's welfare should always be given precedence over the needs of society and science (Section 8).
- Research may only be approved if the risks to which the participant in the research is exposed are counterbalanced by its scientific value (Section 9).

The Swedish Ethical Review Authority, which was established in 2019, is based in Uppsala, but its work is conducted in six regions by a total of eighteen departments. Each department consists of ten representatives with scientific

backgrounds and five representatives from the general public. The chairperson of a department must be or must have been a judge.

The government has determined that ethical review shall, in principle, be financed by the research. For this reason a fee is imposed, which in 2021 is either 5,000 Swedish crowns or 16,000 Swedish crowns for an application, and 2,000 Swedish crowns for an amendment. The current fees can be found at the website of the Ethical Review Authority. The fees are transferred directly to a government account. The work of the Ethical Review Authority is financed via the state budget.

An ethical review is a relatively detailed procedure. A significant amount of material must be produced and collated, and an application pursuant to the Ethical Review Act shall be submitted. The structure of the project must be presented in detail. This means, among other things, a description of the recruitment process, the data that will be collected, the variables used in the analysis, the origin of the data collected, etc. Security measures for data processing must be specified.

The final version of the information communicated to the research participants must be enclosed with the application. This applies primarily to research participant information, consent forms, questionnaires, interview guides, and similar materials. The application form must be completed in Swedish, in consideration of the representatives for the general public. A research protocol must also be enclosed. This cannot simply be a copy of the application, but should function as reference material when the scholarly representatives look for in-depth information about how the investigations are to be conducted.

The procedure takes at least one month. It is not uncommon for the Ethical Review Authority to pose questions if the application is not completely clear. The applicant is then offered an 'opportunity to complete' the application. In such cases the processing time is also extended. Such a request for additional information usually means that the Authority wants to know more about the details of the project and its implementation. But the Authority can also suggest a revision of various aspects of the project design.

The Ethical Review Authority has a limited number of options in making a decision: an application can be approved, conditionally approved, rejected, or dismissed. When the Authority has imposed conditions, the researcher is bound to comply with these. An application is dismissed if it does not fall within the purview of the Ethical Review Act, i.e. if it does not require authorisation. The application is then not considered on its merits. The Authority can also issue an advisory opinion. See the section below, *Requirement for an ethical review at publication*, for information about, and a discussion of, this option.

An application for ethical review is submitted electronically. Forms and detailed instructions on how to write an application for ethical review and the enclosures required can be found at the website of the Ethical Review Authority.
etikprovningsmyndigheten.se

Those who are not satisfied with a decision of the Ethical Review Authority can appeal to the Ethics Review Appeals Board (*Överklagandenämnden för etikprövning*, formerly the Central Ethical Review Board). Decisions from both the Ethics Review Appeals Board and the Central Ethical Review Board are published on the website of the Ethics Review Appeals Board.
onep.se

Ever since ethical review began in 2004, each department makes its own independent decisions concerning the applications submitted to it. The departments are in regular contact with each other and hold national meetings, in order to, among other things, arrive at similar practices. The new Ethical Review Authority also works in several other ways to reach consensus. The decisions of the Central Ethical Review Board as well as those of the Ethics Review Appeals Board are considered precedential.

The following description primarily raises questions that can be of interest to researchers within the disciplines of the humanities and theology.

WHAT RESEARCH REQUIRES ETHICAL REVIEW?

Research falling within the scope of the Ethical Review Act may only be undertaken if it has been approved in an ethical review. Research that requires authorisation is described in Sections 3–4 of the Act. With respect to research within the disciplines of the humanities and theology, this applies to all investigations involving

- the processing of sensitive personal data;
- the processing of personal data regarding violations of law;

Photo: Johan Persson

- experiments
  - performed according to a method the purpose of which is to affect a research participant physically or mentally;
  - that include an apparent risk of injuring the research participant either physically or mentally.[6]

Sensitive personal data are personal data revealing a person's

- racial or ethnic origin;
- political opinions;
- religious or philosophical beliefs;
- trade union membership;

and involving the processing of

- genetic data;
- biometric data for the purpose of uniquely identifying a natural person;
- data concerning health;
- data concerning a natural person's sex life or sexual orientation (GDPR, Article 9(1)).

[6] Section 4 of the Ethical Review Act also mentions research involving a physical intervention or concerning studies of biological material. Because such research is hardly ever done within the humanities and theology it will not be discussed further in this document.

When are these criteria applicable?

In an ethical review the question of when any of these criteria is applicable often comes up. The practice that has evolved means, among other things, that the researcher is considered to have collected sensitive personal data if one of the following applies:

- any one of the sensitive factors is one of the criteria for recruitment to the study, e.g. if the researcher recruits people with certain particular religious convictions or a specific health problem;
- the researcher poses direct questions linked to any of the sensitive factors;
- the researcher poses open questions, where it is not unlikely that the answers may reveal information regarding any of the sensitive factors;
- other circumstances in the investigation make it not unlikely that information about any of the sensitive factors will be revealed.

'Not unlikely' as used here means that it is possible to detect a risk. This risk does not, however, necessarily have to be significant.

Racial or ethnic origin
The current practice is that this provision is applied to personal data regarding ethnicity or ethnic origin without presupposing that specific human races can be identified.

So what type of information might this be? The purpose of this provision is to protect people who may risk being discriminated against. It has therefore primarily been applied with respect to minority groups. Some examples of factors that are considered to reveal ethnicity are skin colour, mother tongue – particularly when it comes to minority languages – or several pieces of information taken together, such as name and linguistic competence, or citizenship together with some other specific piece of information.

Political opinions
This provision has been used primarily with respect to membership of or sympathies for a political party, or a particular idea of how society is or should be organised. Actions such as taking part in animal rights activism have been considered to be an indication of a political opinion. The stipulation has not been applied to mere membership in a non-political interest group.

Religious or philosophical beliefs
The provision refers to a conviction and is usually applied to religious beliefs of a certain substance. Such a belief can also be one of pronounced atheism. 'Philosophical belief' is applied primarily to philosophical beliefs regarding a view of life.

Trade union membership
The concept is applied to membership of an organisation intended to safeguard the interests of employees.

Genetic data
Because this is a new criterion in the GDPR, it has not yet been possible to identify a specific practice.

Biometric data for the purpose of uniquely identifying a natural person
Because this is a new criterion in the GDPR, it has not yet been possible to identify a specific practice.

Data concerning health
This provision is primarily applied to information about ill health. It has also been invoked with regard to information about addiction. Specific pieces of information that individually or together convey information about the state of a person's health must be considered sensitive personal data.

Data concerning a natural person's sex life or sexual orientation
This concept has not only been applied to sexual activities, but also to information about specific sexual inclinations or preferences, and, in addition, to information about gender reassignment. The concept is not applied to information that refers exclusively to gender or civil status.

Data regarding violations of law
The right to process 'personal data regarding violations of law that include crimes, judgments in criminal cases, penal law sanctions, or administrative deprivation of liberty' is limited because such information can violate the integrity of the data subject and lead to discrimination. The provision is usually also applied to the *suspicion* of violations of law.

Purpose of affecting
This provision is applied when a researcher aims to bring about a change in a research participant. This change does not have to be permanent. For instance, experiments that aim to investigate how people act under stress and that begin with stress induction have been considered subject to authorisation on the basis of this provision. According to decisions by the Central Ethical Review Board, the provision shall not be applied when there is no intention to cause a change.

Risk of injuring a person
This provision is given wide application and is considered to include, among other things, studies that are physically or psychologically stressful to research participants, for instance where participation may lead to discomfort.

The question of whether there is an obvious risk of injuring a person must be assessed *before* any protective and safety measures are taken. When an investigation can entail risks for research participants, these risks shall be identified and a plan to minimise them shall be drawn up. If the risks are obvious, an application for ethical review shall be submitted. Such research requires authorisation even when the researchers are used to handling the risks that may arise, or when there are established safety routines for a particular research activity.

A risk of injuring a person may arise in connection with laboratory experiments conducted within the HT Faculties. The Ethical Review Board has on a number of occasions determined that studies involving eye tracking require approval following ethical review. The Board has also determined that studies using, for example, EEG equipment attached to a person's head require authorisation. Some investigations can also involve obvious stress or discomfort for research participants, something which is considered a risk.

PROCESSING OF PERSONAL DATA THAT HAVE ALREADY BEEN MADE PUBLIC

Sometimes researchers wish to study personal data that have already been made public. Can such data even be considered personal data, and if so, will the data need to be protected in some way? Is an ethical review necessary?

The fact that personal data have already been made public orally or in writing does not mean that these data may be freely used in research. The data may be incorrect or may have been made public without consent. Continued processing may be incompatible with the consent of a data subject. Even if there is a legal basis for research using the data, a researcher must determine whether the persons involved shall be informed. An approval following an ethical review is required when the research includes continued processing of sensitive personal data. Regulations regarding defamation must also be taken into account.

Legal judgments in criminal cases raise special issues. These issues have been the subject of discussion within the area of ethical review, and several clear precedents from the Central Ethical Review Board are relevant. The fact that everyone has a right to access public documents does not mean that such information can be freely used in research. Judgments in criminal cases contain identifiable personal data, and case numbers or detailed information about the crime in question can lead to the indirect identification of the persons involved. Further processing in research will then include the processing of personal data regarding violations of law, which requires authorisation according to the Ethical Review Act.

REQUIREMENTS ON THE CONTENT OF RESEARCH

The planned activities must also fulfil requirements regarding the content of research. The Ethical Review Act defines research as

> scientifically experimental or theoretical work or scientific studies conducted through observation, when the

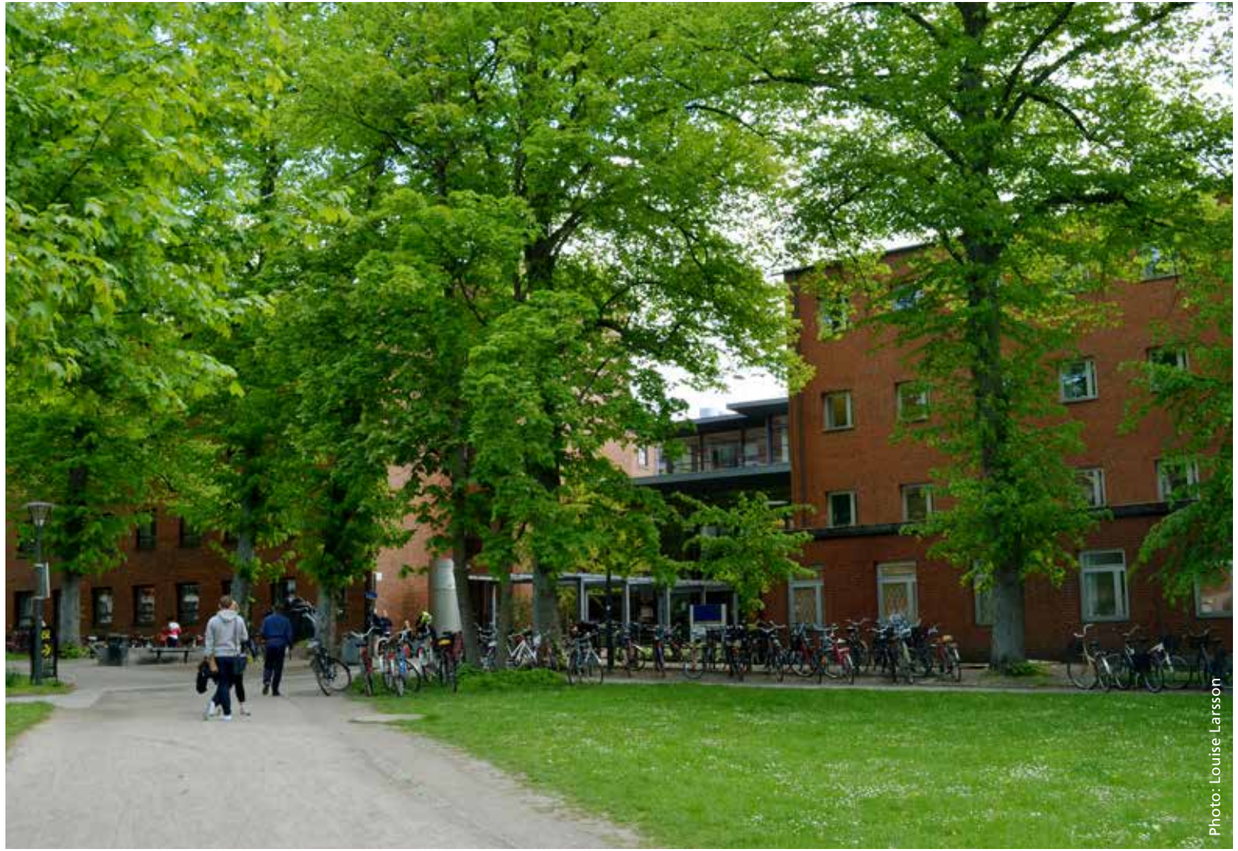

Photo: Louise Larsson

work or studies are done to acquire new knowledge, and developmental work on a scientific basis, with the exception of work that is performed solely within the framework of higher education at the basic or advanced levels.

A project can also be dismissed on the grounds that it does not constitute research. This will be the case if there are no scientific questions asked, if it is obvious that the project will not be carried out using scholarly methods, or if it appears to be a part of a marketing process.

Researchers often disagree with each other about the quality of other scholars' research. Ethical review must take a position regarding such scholarly disagreements. The resolution to this situation is that when a research method is accepted within at least a portion of the academic community, then it can also be considered research for the purpose of an ethical review. Projects that are intended to be the foundation of a doctoral degree or that have been awarded grants by established research funding bodies shall, in principle, always be considered research.

The number of participants

Another factor to be assessed is whether a sufficient number of people will be involved in an investigation in order for the results to be statistically significant. Nor shall an unnecessarily large number of research participants be recruited, because participation in a research project can be a burden on the participants. This factor applies primarily to quantitative investigations, while in the humanities and theology qualitative studies are more common. For qualitative studies it is often not considered relevant to make exact calculations of how many participants are required in order to attain significant results, but it is nevertheless reasonable for a researcher to point out that the study in question is a qualitative one and explain the reasons for choosing a particular number of participants.

Pilot projects

Pilot projects do not always satisfy the normal requirements for being scientific. It is common for such a project to simply be a survey or involve a limited number of participants. Such projects can nevertheless be approved if it is clear that they generate hypotheses and are part of a long-term research plan, even if this plan has not yet been determined in its entirety. In such cases a researcher should make it clear that the work is part of such a context. Researchers should be aware that they do not have a right to begin a project in practice without an ethical review by claiming that the initial stage was 'only a pilot'.

Register compilation versus research

Approval following an ethical review can only be granted for research, and the approval must be linked to a particular research project. This approval may then include the compilation of a register or the use of an existing register required for the project in question. However, approval cannot be granted for simply compiling information for use in a future, but not yet planned, research project. Register compilation not connected to a particular research project does not in itself constitute research, and for this reason it cannot be approved.

SOME SPECIFIC KINDS OF RESEARCH

Field research, ethnographic studies, and observational studies

Qualitative investigations of human phenomena in their natural social settings are common in several research areas in the humanities and theology. These often involve sensitive personal data, such as political or religious ideas or sexual issues.

With respect to such research it can be difficult to set clear limits for what the research shall include. A few examples:

- Persons recruited as research participants can easily end up revealing more information about themselves and their circumstances than they intended.
- It can be difficult to know in advance which persons will participate in the social environment that is to be studied. For this reason, the research may affect other persons than those the researcher had originally intended to recruit.
- The research participants may have expectations regarding the researcher that come into conflict with his or her role as a researcher.

Such risks must be identified and appropriate measures must be taken in order to overcome them.

Within the framework of their employment at Lund University, many doctoral students and postdoctoral researchers conduct field research in countries other than Sweden. In such cases a researcher will, in addition to the GDPR, have to observe the regulations in force in each country where part of the project takes place. Today most countries have regulations regarding the recruitment of research

participants and the processing of personal data. When a researcher wishes to do interviews or observations in another country, he or she will have to find out what rules apply in that country. There may be limitations with respect to the processing of personal data, and there may be requirements for the ethical approval of the recruitment of research participants. How this is to be handled must be assessed on a case-by-case basis.

When fieldwork is conducted within the framework of a researcher's employment in Sweden, it is taken for granted that part of the work will also be also carried out in Sweden, for example the analyses, the writing of reports, and the preparations for publication. Research data will also be imported to Sweden. If the research data contain sensitive personal data, an ethical review is required also in Sweden.

An example can illustrate this. A researcher in Lund was to interview prisoners in South Africa about their views of life. The decision reached at the ethics review in Sweden was that the project required authorisation. The South African authorities required an ethical approval in South Africa, and they also wanted a copy of the Swedish approval.

For more information about international conditions, see *International projects*.

Vulnerable persons

The concept of 'vulnerable person' is often used in connection with research ethics, but it lacks a consistent definition. During an ethical review the following groups, among others, may be considered vulnerable depending on the circumstances: children, pregnant women, prisoners, refugees, the aged, persons with mental or physical impairments, persons who are vulnerable because of a deficiency in, for instance, economy or education, and persons who may risk being exposed to discrimination. This is true especially of research that takes place in low- and middle-income countries or that involves research participants who are illiterate or have language difficulties. In such cases both the information and the consent, as well as the implementation of the investigation itself, must be handled with particular care. Research may only be carried out on vulnerable groups if it can be expected to provide knowledge that is impossible to obtain in some other way.

Photography and filming

For the purposes of an ethical review, video recordings and photographs are considered personal data because it is easy to recognise a person in an image. When a researcher wishes to photograph or film his or her research participants, information must always be provided and consent acquired. The information must be clear and include what is to be photographed and how, during which time, for what purpose, and how the images are intended to be used. There must be a clear commitment that the images will not be used for any other purpose than that which is stated in the information, including how the images will be stored and if or when they are to be destroyed. If there is a risk that the photographs or the video recordings will reveal sensitive personal data, an application for ethical review is required.

In research projects where a researcher wishes to use recordings at a later date to show images at lectures or in publications, it is usually required that the person depicted must be informed in each particular case about the intended use and be allowed to see the material, and that the material may only be used if the person in question has given his or her written consent.

Camera surveillance in locations to which the general public has access falls within the scope of the Camera Surveillance Act. For camera surveillance or surveillance using a microphone in locations to which the general public has access, a permit is required from the Swedish Authority for Privacy Protection (IMY). When a researcher wishes to use this type of equipment, an approval from IMY should be enclosed with the application for ethical review.
imy.se/verksamhet/utfora-arenden/ansok-om-tillstand-for-kamerabevakning/

Case studies

Case studies, involving detailed information about, and an analysis of, the circumstances of a particular individual, must be handled with special care. The researcher must count on the person described in such a research report being recognisable. Careful information needs to be provided and consent acquired that explicitly addresses the publication of the data.

Focus group interviews

Focus group interviews have become a common instrument in qualitative research. This research method gives rise to special problems insofar as the conversations in a

focus group may deal with, or may touch upon, sensitive personal data. In their planning, researchers should be restrictive with processing sensitive personal data in this way. If focus groups are nevertheless considered an appropriate method, measures must be taken in order to make the participants aware of the fact that they may not disseminate sensitive information outside the group or following the discussion. If sensitive personal data are nevertheless processed, measures must be taken so that these are minimised and protected or anonymised during any continued data processing. Any risks of this kind that may arise must be identified and clearly described in the application for ethical review, and the measures taken to minimise the risks must be presented.

An unauthorised revelation of sensitive personal data may constitute a personal data breach, i.e. a security incident that involves personal data. Such data breaches require special measures according to the GDPR. For instructions on the prevention and handling of personal data breaches, see staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr/general-information-and-support/security-measures-personal-data-and-how-manage-security-breach.

Research on social media

Research using information from the internet, not least from social media, has become common. Such studies also raise a number of questions, not least regarding the integrity of the participants. One aspect that needs to be considered is that many people who participate in conversations on social media may perceive the social group as a closed environment, where information is often provided in confidence. The participants often underestimate the degree of publicity that may result from this. If researchers collect information that is already available on a forum of some kind, the researchers should therefore respect the integrity of the participants by making them aware of the fact that information supplied by them may be processed. Whenever possible, participants should be given an opportunity to say no to participation or have the opportunity to see what has been collected and then say no to the use of certain data. This is also true if over time a researcher passively observes a certain chain of events in such a forum or in any way interacts with the forum's participants. On several occasions researchers studying social media have posted information about the research being undertaken and what it involves, so that this information can be read by the participants, after consultation with, and approval of, the website organiser.

Especially with respect to persons who in one way or another are vulnerable, an awareness of being observed may stimulate undesirable behaviour. For example, in connection with such observational studies it has happened that instances of self-harm have been triggered in persons prone to self-harming behaviour. Undesirable dependency relationships can also develop, for instance a desire to have a more personal relationship with a researcher than a professional approach allows for. In an application for ethical review, risks of this and similar types must be identified and appropriate measures need to be planned.

Research planned successively

Applications for ethical review of research projects that are not planned in their entirety from the beginning, but instead develop gradually, have become more common. Among other things, this is true of action research, where the idea is often that the work is meant to develop through interaction between a researcher and the practice that is being studied. With respect to such research, the Ethical Review Board has demanded that the research methods used must be described with such clarity and attention to detail that each investigation can be assessed from an ethical perspective. If a project consists of several investigations included in various partial studies, and detailed planning of these is to be done successively while taking into consideration experience acquired during previous studies, then the researchers must apply for independent approval of each of the various sub-studies as and when they are finally planned.

Asking professional actors about their work

Information provided by professional actors about their work is normally not considered personal data at all. After all, they are talking not about themselves but about their work. There are, however, obvious exceptions. If the questions or answers touch on a person's view of life, their attitude towards their work, or how they have been personally affected by that work, then that person is no longer speaking about their work but about themselves. The same applies if other people are mentioned in the questions or answers. When a researcher is using questionnaires it is easy to control the answers, but this is more difficult when it comes to interviews. The assessment of the Ethical Review Board has been that if it is not unlikely that the answers during an interview will contain sensitive personal data, the study requires authorisation.

Information about a third party

Sometimes researchers plan interviews or questionnaires in which a research participant is asked to talk about other people, for instance a sick relative. It is then considered that the interviews will collect personal data about this third party. In such cases the relative in question should be informed about the planned investigation and be given an opportunity to consent to (or decline permission for) the research participant being interviewed providing such information.

In connection with interviews with professional actors, an interview can easily lead to the research participant wishing to use examples from their professional activities, and that information may then end up revealing sensitive personal data about a third party. If the circumstances are such that this is not unlikely, even if such personal data are not needed for the research, the researcher should already in the letter of information ask the research participant not to discuss examples that by their nature make it possible to recognise the third party to whom the case refers.

HOW TO DETERMINE WHETHER AN ETHICAL REVIEW IS REQUIRED

A researcher him- or herself is responsible for determining whether a research project may or may not process sensitive personal data, and thereby also for deciding whether an application for ethical review must be submitted. In unclear situations it is recommended that an application for ethical review be submitted. The researcher is criminally liable if he or she intentionally disregards a requirement for ethical review.

It may sometimes be unclear whether the research will actually process sensitive personal data. An example can illustrate this. There are questionnaires in which pupils are asked about their views on sex education. What then determines whether a project using such questionnaires processes sensitive personal data? As long as the pupils answer questions about, for example, sex education being relevant and instructive, then everything is about the education and not about the pupils themselves. But if the questionnaire or an interview instead touches on a pupil's own sexual activities or preferences, this information constitutes sensitive personal data about that pupil. The same applies if they speak about other people. When planning questions for questionnaires and interviews it is important to consider this issue. Questionnaire forms and interview guides must always be enclosed in their final versions with an application for ethical review, so that the Ethical Review Authority can make its own assessment.

Some examples of assessments made by the Ethical Review Board

Sound recordings, for instance of an interview or during observations, are considered personal data even if no names are mentioned, because it is easy for someone who knows a person to recognise that person by their voice.

A researcher might wish to interview people who are involved in prohibited activities, for instance vandalism or the purchase of sexual services. The Ethical Review Board has, in a number of such cases, determined that these interviews will touch on sensitive personal data or data regarding violations of law, and that for this reason the investigations require authorisation.

Investigations about the quality of life for people who have previously had some form of disease are also considered to require authorisation.

Historical research does not fall within the purview of the GDPR or the Ethical Review Act if it *exclusively* processes information about people who are deceased and the information cannot indirectly reveal information about their living relatives. But twentieth-century history and contemporary history often deal with information about living individuals, and when sensitive personal data are involved, such investigations require authorisation.

The concept of *register-based research* can refer to many different kinds of projects. The decisive factor for whether such a project needs to be ethically reviewed is whether it will involve the processing of sensitive personal data or data regarding violations of law. If the processed data consist exclusively of information at a group level, such as correlations and statistics, the research does not warrant an ethical review. However, if the project includes the processing of data at an individual level an ethical review is required, provided that these data include sensitive personal data or data regarding violations of law. Here are two examples to further illustrate these issues.

A researcher wanted Statistics Sweden (SCB) to release material containing posts about individuals. Each post was

identified by a serial number, and no names or personal identity numbers would be released. Statistics Sweden would not retain a code key. In the context of the assessment made by the Central Ethical Review Board in similar cases, it was considered that the processing of the data by Statistics Sweden was occasioned by the research project and would involve processing of sensitive personal data, and that the study for this reason required authorisation. In addition, the information to be released about each individual was so detailed that indirect identification was considered possible. For this reason, demands were also imposed on the researcher to provide data protection in order to protect the research participants' rights to confidentiality.

Another researcher wished to have access to data material from Statistics Sweden via *MONA, Microdata ONline Access*. Getting data material from MONA means that a researcher can order aggregated data, i.e. statistical frequencies and correlations. The researcher can prepare for making an order by getting an overview of the data on his or her computer screen, but must sign an agreement not to copy any raw data. In the case in question, the Ethical Review Board judged the processing of the information done by Statistics Sweden to have been occasioned by the research project and that it would involve processing of sensitive personal data. For this reason, the study required authorisation. The material released by Statistics Sweden to the researcher, and which the researcher could then process would, on the other hand, be exclusively statistics and not personal data. For this reason, no requirements for data protection were made with respect to the researcher's processing of the released data.

If the nature of a research project is such that it can be unclear whether it requires authorisation, then it is the Ethical Review Authority that should make the final assessment, and for this reason it is recommended that a researcher always apply for ethical review in such cases. Not until after one or several decisions that in similar cases make clear when an ethical review is necessary, can a researcher draw firm conclusions about the need for an ethical review of future projects.

THE SIGNIFICANCE OF PUBLICATION

If a planned research project is carried out by qualified researchers and is intended to lead to scholarly publication of the results, then the presumption, in the context of an

Photo: Charlotte Carlberg Bärg

ethical review, is that the project in question constitutes research. If the results are only intended to be disseminated internally within the researchers' own organisation, the presumption is that the project does not constitute research. This illustrates the clear connection between scholarly work and publication. The aim of scholarly work must be its publication. The publication shall be scholarly, i.e. it must be included in a context where it is clear that the work constitutes a contribution to science.

In connection with ethical review, publication refers primarily to peer-reviewed scholarly journals. Within the humanities this type of scientific publication has not had the same dominant position as has been the case in many other disciplines. Scholarly publications include, for instance, doctoral dissertations, scholarly monographs, and chapters in anthologies that claim to present scholarly results, but do not, on the other hand, include textbooks and other teaching materials. Popular science literature consists primarily of compilations of previous research.

The regular publication of student papers, for instance in *LUP Student Papers*, does not count as publication in a scholarly context.

If there is no plan for scholarly publication, the project cannot gain approval in an ethical review. For this reason a researcher must already in the application present a plan for publication, which does not, however, have to be specified. In general, a declaration of intent is accepted with the understanding that it is the researcher's intention to publish the results in a scholarly context.

Approval in an ethical review must refer to research that has not yet been carried out. A project that has already been carried out and that was not originally considered to be research cannot be redefined after the fact as research, and it cannot be approved in an ethical review.

REQUIREMENT FOR AN ETHICAL REVIEW AT PUBLICATION

It is not uncommon for journals to require ethical approval before publishing an article, even if the authors may not consider this necessary according to the Ethical Review Act. Certain journals may have this as a general requirement, while others may require it after reviewing a manuscript. It is reasonable that journals that publish human research use such strategies in order to protect their own and the research participants' interests. Researchers working with research involving humans therefore have reason to investigate in advance whether this requirement may be imposed by the journals in which they are interested in being published. Because it is impossible to obtain approval retrospectively, the researcher or researchers must consider this possibility already before a project is initiated.

In cases where the research does not fall within the purview of the Ethical Review Act, the Ethical Review Authority can issue an *advisory opinion.* This means that the Authority states that it does not consider a project to be subject to the Act, but that it does not see any ethical impediments to the implementation of the project. Alternatively, it may provide comments which a researcher should take into consideration. If a researcher wishes the Authority to issue an advisory opinion, he or she must submit an application for ethical review and tick the box indicating that an advisory opinion is being requested.

An advisory opinion is understood as a positive ethical opinion according to international practice, which researchers can refer to in connection with publication. If a researcher applies for ethical review and states that he or she does not wish to have an advisory opinion, and the Authority determines that the project is not subject to the Act, then the researcher should expect the Authority to *dismiss* the application. The meaning of this may be difficult to understand in a journal's editorial office. Keeping, among other things, these circumstances in mind, it may be appropriate to always state when applying for an ethical review that an advisory opinion is being requested.

When publishing research that requires authorisation according to the Ethical Review Act, the authors must indicate, at an appropriate place in the text, that the project has been given approval in an ethical review and specify which authority has approved the project, as well as the date and registration number of this approval. An advisory opinion for research that does not require authorisation can be described as a 'positive opinion'.

THE RECRUITMENT PROCESS

The process for recruiting research participants to a research project must be carefully planned. In an ethical review, the following factors in particular are taken into account.

In most cases a researcher wishes to recruit healthy adults who are fully capable of deciding for themselves whether or

not to participate in the research. In the event that this is not the case, an explanation is required for why deviating from the norm is necessary to successfully carry out the research.

Those asked to participate in a research project must not be in a state of dependency towards the person doing the recruitment. Clear examples of relationships that constitute states of dependency are those between teachers and students/pupils, and between managers and employees. Furthermore, a person who is asked to participate must be given time for consideration before deciding whether to participate. It must also always be clear that it is completely voluntary to participate in a research project.

The assessment of the Ethical Review Board has been that recruitment should often be done in several stages. The first contact may be seen as a call for expressions of interest, where brief information is provided regarding what a project is about. In the following stage, those who have expressed an interest are provided with the complete research participant information and given an opportunity to ask questions. Persons who have expressed an interest must then be given time for consideration before deciding whether to participate in the project.

Often a researcher finds it helpful when a mediator who already knows the intended research participants establishes an initial contact with them. On many occasions the Board has considered it acceptable for such a person to make the call for expressions of interest, but the continued recruitment process should then be taken over by a researcher towards whom the intended research participant is not in a state of dependency.

RESEARCH PARTICIPANT INFORMATION

Those who are recruited to participate in a research project shall be given information about the research in which they are expected to participate. An information leaflet shall contain a description of anything that the potential respondent needs to know in order to determine whether they wish to participate in the project. The leaflet must be drawn up with care and describe the project in an objective manner. It must not contain any exaggerations or persuasive elements.

A new, clear, and detailed support template for research participant information is available at the website of the Ethical Review Authority and can be downloaded from there. etikprovningsmyndigheten.se

This new support template takes into consideration the requirements for information about the processing of personal data according to Article 13 of the GDPR. Do not use older templates that do not contain this information.

If possible, information should be provided both orally and in writing. The potential respondent shall be given an opportunity to ask questions.

INFORMATION TO RESEARCH PARTICIPANTS IN SPECIAL CASES

Oral and written information must always be provided in a language that the recipient understands well. The content must be adapted to the intellectual and linguistic ability of the recipient.

Special requirements apply regarding form and content when dealing with children. For research participants under the age of fifteen, a guardian (both guardians in the case of joint custody of a child) must always be provided with the information and must make the decision concerning participation. The child shall also be given age-appropriate information and an opportunity to object to participation. Young people between the ages of fifteen and eighteen who understand what the research involves for them shall themselves be informed and decide whether to participate.

Regarding adults with a limited ability to make decisions, for example because of illness, a weakened state of health, or mental disorder, a researcher needs to assess in connection with the recruitment whether the person in question is capable of making up his or her own mind about participating. If they are, the information must be adapted in an appropriate manner. For persons who lack the capacity to make decisions, it is in the first place the nearest relative who shall be consulted or the limited guardian when there is one and it is a part of his or her duties to make such decisions on behalf of the person in question. The research participant shall always be given an opportunity to him- or herself decline to participate. In an application for ethical review the routines that will be used in order to determine a potential respondent's ability to make decisions must always be described, as well as how the recruitment will be accomplished in a manner that protects the integrity of the potential respondents.

With respect to field research, not least in low- and middle-income countries, several other factors that limit a participant's ability to assimilate information are brought to the fore. A researcher should identify such factors and describe how they will be dealt with in order to protect the rights of the intended research participants.

CONSENT

Obtaining informed consent is considered one of the most important procedures in order to protect the rights and interests of the research participants. It is important for researchers to see informed consent not simply as a formality, but as a way to ensure that every participant in an investigation has been provided with sufficient information and that their participation is voluntary. Sometimes this needs to be accomplished in various ways due to different circumstances.

Consent must be acquired before an investigation begins. Consent acquired only after an investigation has been concluded will not be accepted.

Consent to participate in a research project must always be a voluntary, specific, and informed expression of a person's will. The consent must be explicit and refer to specific research. The consent must be documented. Normally this is done in writing by having a research participant sign a consent form.

Consent form

A consent form must be brief and not contain any new information. All information required for a decision on whether to participate must be included in the information leaflet. Information and consent forms shall be drawn up in two copies, and the research participant must always be able to keep one copy of each of these. The researcher's copy of these forms must be preserved. A support template for the consent form is available at the website of the Ethical Review Authority.

Other forms of consent

Consent can also be given in other ways. In certain research projects it can be appropriate to make a sound or video recording of the consent. This is, for instance, the case when a recording of an interview or a chain of events is already being made. But this method can also be used when a research participant has reading and writing difficulties because of illness or a lack of education. When research participants for special reasons do not want to reveal their identity or are illiterate, the Board has also accepted the use of a personal mark or symbol in the form of a cross, or the like.

When web questionnaires are used, it is common that the person logging in lands on a page with complete research participant information and is thereafter asked whether he or she is prepared to participate in the study. Only when the person in question clicks on YES is he or she transferred to the questionnaire.

When a researcher is in direct contact with a research participant it is often unproblematic to provide oral and written information. At interviews a research participant shall be given oral and written information in advance and then be given time for consideration before an interview begins. In connection with interviews it is also common that an active decision to participate in an interview is considered sufficient instead of consent, and this is often accepted at an ethical review, unless special circumstances exist that make the research particularly sensitive. The same is true of postal surveys.

INFORMATION AND CONSENT WHEN INFORMATION IS OBTAINED FROM ANOTHER SOURCE THAN THE RESEARCH PARTICIPANT HIM- OR HERSELF

When the personal data that are to be used in a research project are not collected from a research participant him- or herself, the issue concerning information needs to be dealt with in a different way. The GDPR requires that a data subject in such cases shall be informed in accordance with Article 14, with the exceptions stated in Article 14(5). Regarding sensitive personal data, the Ethical Review Authority must approve the procedure. The requirements to be imposed on how information is to be provided depend to a large extent on the particular circumstances. Based on previous experience, a few typical cases can nevertheless be discerned.

If a researcher wishes to collect and process sensitive personal data from one or more existing registers of some kind, a research participant must in the first place be informed via letter, possibly one preceded by personal contact. The research participant information shall then be provided according to the directions in the previous sections. Depending on the degree of intrusion of integrity, i.e.

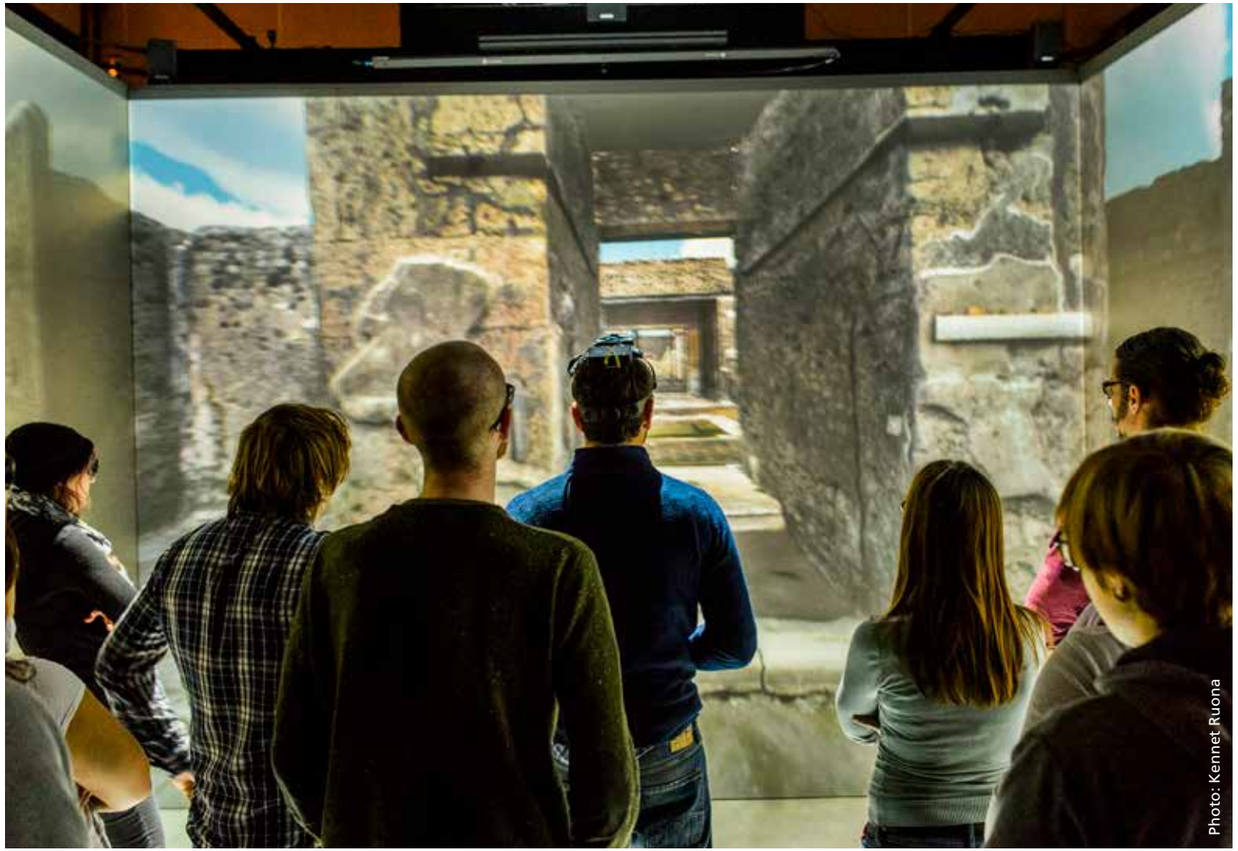

Photo: Kennet Ruona

how sensitive and intimate the information is, the Ethical Review Authority can decide that written consent shall be required, or that it is sufficient that those who have been approached are offered an opportunity to decline to participate. This so-called opt-out procedure means that contact information is provided along with information about how to proceed if a potential respondent does not want his or her data to be used in the investigation.

If the number of research participants is so large that providing individual information would involve a disproportionate effort, such information does not have to be provided. Instead, information can then be offered in such a way that it can, as far as possible, reach the persons concerned. In such cases it is often considered appropriate to have an opt-out option as well. This procedure is usually only considered applicable when the number of concerned individuals is in excess of a few hundred people, but not if a researcher has access to some type of easily available information channel, such as email addresses.

For this purpose advertisements have often been placed in daily newspapers. Because an advertisement is only available at a particular time and to readers of a particular newspaper, it is important to find other channels of information as well. Recently it has become more common that information is (instead or also) provided on the website of the organisation responsible for the research and is kept available there throughout the duration the project.

If a researcher wishes to reuse information that has previously been collected for another research project, an assessment must first be made as to whether the new purpose is covered by the information given to the research participants and the consent they provided in connection with the previous project. If the new purpose is covered by the previous informed consent, new information does not have to be provided. If not, new information must be provided in one of the ways stated above. In order to determine this issue in the event of uncertainty, an assessment is often made as to whether there is reason to believe that a research participant would be surprised to find that their information is being used in a new context.

CONSENT FOR THE USE OF PERSONAL DATA FOR FUTURE RESEARCH

The principle of purpose limitation is central in the GDPR. It is described in Article 5(1)(b) as follows:

> [Personal data shall be] collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation').

The question of the purpose of scientific research is further explained in Recital 33:

> It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research.

When researchers wish to create an opportunity to reuse personal data collected for a specific research project, this principle has been applied as follows:

When potential research participants are asked to give their informed consent for participation in a research project, they shall be informed about the purpose of the project and told what their participation involves. They shall also be informed about and asked to give their consent to the processing of personal data within the project. It is also possible to ask the research participants to consent to future processing of the collected personal data for continued research. The research that is referred to must, however, be limited to similar research within a limited and related area of research. Researchers may not ask for consent for unspecified future research. A researcher must retain all signed consent forms and, if necessary, create a register in order to keep track of which kind of consent each of the participants has given.[7]

For example: If a researcher recruits people for an interview study about political opinions among people living in the Rosengård district in the city of Malmö, it may be possible to ask the research participants for consent to use the collected personal data for further research on political opinions, or for further research on the circumstances of people living in Rosengård.

[7] For further explanations of the acquisition of consent, see the GDPR, Recitals 32, 42, and 43.

The kind of consent planned and the procedure used for acquiring it must be described in an application for ethical review.

OPEN ACCESS TO RESEARCH DATA

For some years work has been ongoing to create open access to data that have been collected or generated in connection with research. The purpose of this work is often described in terms of the so-called FAIR principles (Findable, Accessible, Interoperable, and Reusable). This work refers to many types of research data and also includes data derived from research involving humans. In Sweden it is the Swedish Research Council that coordinates this work. vr.se/english/mandates/open-science/open-access-to-research-data.html

The aim of the Open Data Directive (EU) 2019/1024 is to ensure that, among other things, research data can be reused by being made available in accordance with the principle of open by default. The Directive does not affect the legal protection of individuals with regard to the processing of personal data, and the reuse of personal data is only permitted if the principle of purpose limitation is met. As these guidelines are being prepared in September 2021, adaptation of the Swedish legislation to this Directive is still ongoing.

A number of research funding bodies are already requiring researchers to draw up a data management plan (DMP), which, among other things, describes how the FAIR principles are realised and how the protection of personal data is taken into account. This is, for example, true for the European Commission and the Swedish Research Council.

Such data may include information that refers to living individuals. For researchers involved in work with open access to research data, it is therefore important to investigate to what extent the availability of the information about humans that will be collected or generated within the framework of a project is in line with the principles of the GDPR, with respect to, among other things, purpose limitation, information, and consent. When it comes to personal data, a researcher must consider whether it is at all appropriate and legally possible to make such data openly accessible. In particular, this applies to sensitive personal data. If making certain data from a research project available proves to be incompatible with these principles,

then the data management plan must exclude these data from the open access.

If researchers intend to make data derived from living individuals openly accessible, all relevant circumstances shall be presented in an application for ethical review and the data management plan should be enclosed with the application.

SECURITY DURING DATA PROCESSING

The Ethical Review Authority shall make a *de facto* review of the protection of the research participants' safety and integrity. For this reason it is not sufficient for a researcher to simply refer to the fact that one or the other regulation will be complied with. Instead, the procedures for data security that the researcher plans to use shall be presented. It is then the task of the Ethical Review Authority to examine and assess whether these procedures meet the relevant requirements.

According to the GDPR, the controller and the processor of personal data shall take appropriate technical and organisational measures to ensure a level of security that is appropriate for the risks in question, in particular protection from 'accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed' (Article 32).

Security measures as well as methods of unauthorised access are continually being developed. The personal data used in different research projects also have varying degrees of sensitivity. A reasonable security level for each individual project therefore needs to be adapted to the particular circumstances. It is appropriate for a researcher to consult experts on security issues in order to plan the security level and the necessary measures.

At Lund University researchers are offered the use of the platform LUSEC, which is an environment for storing, handling, and analysing data in a highly secure manner in accordance with the GDPR. This service is subject to a fee. LUSEC should be considered as a suitable security environment for sensitive research data. If a lower security level is considered sufficient, the security measures in LUSEC can serve as a model. For more information, see med.lu.se/english/intramed/teaching_research/research/research_data_management/lusec.

ARCHIVING AND DISPOSAL OF RESEARCH DATA

Researchers sometimes plan to destroy the collected material immediately after the completion of a project. This is in violation of the Swedish Archives Act, and it is, in addition, a serious deviation from good research practice.[8] The reason for this is that access to research data is necessary in order to enable renewed scientific review, as well as a review of any suspicion of research misconduct.

Each public authority must have a document management plan based on the Swedish Archives Act and the instructions of the Swedish National Archives. According to the Lund University plan the following applies, among other things: certain primary material may be disposed of ten years after the completion of a project – fifteen years in the case of medical research – i.e. ten (fifteen) years after the presentation of the results, publication, and final statement of accounts. Decisions are made by the concerned head of department or equivalent in consultation with the Records Management Division and the researcher/research manager in question. For more information, see staff.lu.se/support-and-tools/legal-records-management-and-data-protection/records-management.

The material must not be disposed of if it is considered to have:

- continued value for the scientific area in question;
- value for another area of research;
- value with respect to the history of science;
- value with respect to cultural history;
- value with respect to the history of individual persons;
- significant public interest

There is a plan for the disposal and preservation of research documents within the HT Faculties, drawn up by the Records Management Division: staff.lu.se/sites/staff.lu.se/files/gallrings-_och_bevarandeplan_ht.pdf.

and guidelines for the archiving or storage of research data at the HT Faculties, drawn up by the Working Committee of the Faculty Board: internt.ht.lu.se/fileadmin/user_upload/HT-intra/HT-fakulteterna/Forskningsdata/Riktlinjer_forskningsdatalagring_beslut.pdf.

[8] See medarbetarwebben.lu.se/sites/medarbetarwebben.lu.se/files/2022-01/Riktlinjer-avvikelse-god-forskningssed-uppdatering%202021_tillg.pdf

The Libraries of the Joint Faculties of Humanities and Theology ('the HT Libraries') provide support throughout the entire research process, and the research support group is the first instance for questions regarding publication and data management. Many questions are dealt with directly, others are referred to or answered by experts, primarily within Lund University. Information and contact information can be found at htbibl.lu.se/en/researcher/research-data-management/.

RISKS AND INSURANCE

The organisation responsible for the research is considered accountable for the risks to which research participants are exposed. If a research participant is injured and it can be confirmed that the injury was a result of his or her participation in the project, the responsible organisation may be liable for damages. The organisation cannot absolve itself of this liability by referring research participants to private insurance.

How this liability is apportioned, for instance within Lund University, is an internal issue. Public authorities do not normally take out insurance, apart from in special cases. For such purposes the Legal, Financial and Administrative Services Agency (*Kammarkollegiet*) provides an insurance service that offers insurance covering special protection for personal injury, corresponding to the protection for accidents in the occupational injury insurance. In connection with research projects that involve particular risks, universities sometimes take out such an insurance. When the risks to which research participants may be exposed are not negligible, researchers should consider whether special insurance is justified.

There are cases where researchers within the HT Faculties are in contact with research participants who are patients within the health and medical care services. In particular, this applies when a research project is carried out in collaboration with researchers in the medical sciences. Healthcare providers have, according to the Patient Injury Act, an obligation to have insurance that covers injuries within the health and medical care services. Regions with responsibility for healthcare have their own insurance, the patient insurance (*Patientförsäkringen*) with the regions' mutual insurance company, LÖF (*Landstingens Ömsesidiga Försäkringsbolag*). This insurance also covers harm that may be caused in connection with research on persons who are patients in the health and medical care services.

Photo: Johan Bävman

In such cases, Region Skåne or some other relevant healthcare provider should be listed as the organisation responsible for the research in order to make sure that the patient injury insurance applies. On the other hand, when Lund University is the recipient of a grant for a research project, the University shall be listed as the organisation responsible for the research. The Ethical Review Act has foreseen and allows for multiple organisations responsible for the research participating in the same research project (Section 23). The Ethical Review Board has recommended that the option of having joint responsibility for the research shall be used whenever this is appropriate. Joint responsibility for the research must be clearly stated in an application for ethical review.

APPLICATION FOR AMENDMENT

It is possible to apply for an amendment of a previously approved research project. This sometimes causes researchers concern. When is an application for amendment necessary? Is it in certain cases possible to apply for an amendment instead of submitting a completely new application?

The possibility of applying for amendments originally developed in connection with pharmaceutical trials. In this area it is compulsory to make an amendment if the project needs to be re-evaluated because of scientific developments, events that have occurred and that may affect the safety of the research participants, or other significant circumstances.

The concept of an amendment has also been given a broader application, when researchers, for other reasons than the ones mentioned above, find that they need to make revisions to a project. It is not uncommon that researchers want to revise the recruitment process because it has proven difficult to attract a sufficient number of research participants. Another example is when the researchers have found that in order to handle the research issues in the project, they need to add an additional question to the research topics or another measuring instrument.

More significant changes are involved when researchers wish to add a completely new dimension to a project, or when they wish to study similar questions on the basis of experiences gained from an already completed project. The Ethical Review Authority has the following to say about such cases:

> If the revision of an original project is extensive, for example if a new design of the study or a new study hypothesis is suggested, or new groups of research participants with other characteristics than the original ones are to be studied, a completely new application must be submitted.

The Ethics Review Appeals Board has also, in a number of decisions, expressed the view that clearly modified research questions compared to those in the original application cannot be accommodated within the framework of an application for an amendment.

An application for an amendment shall be submitted to the Ethical Review Authority along with the required enclosures, and shall contain a clear presentation of how research issues, investigation procedures, data management, and publication plans will be affected. A form and instructions can be found at the website of the Ethical Review Authority.
etikprovningsmyndigheten.se/for-forskare/andringsansokan

INTERNATIONAL PROJECTS

Participation in international research projects

Many scholars are involved in international projects, where researchers from multiple countries participate, investigations are carried out in several countries, and data are transmitted between countries. In such cases researchers have to ensure that the work is carried out in accordance with the regulations in force in each country where any of the activities take place. Questions regarding recruitment of research participants and their participation, personal data processing, and ethical review are discussed in the *Field research* section above.

For research carried out at Lund University, the personal data processing must meet the requirements in the GDPR regardless of where in the world the research is carried out or whose personal data are processed.[9] In addition, all research conducted by scholars at Lund University shall, as a minimum, meet the ethical requirements imposed by Swedish law. According to a decision by the Vice Chancellor on 25 March 2021, employees at Lund University shall

- not participate in research projects abroad without gaining access to information of importance for an ethical review of the research;
- not participate in research projects abroad that do not live up to the ethical standards applicable to research in Sweden;

[9] Cf. GDPR, Article 3(1).

- not locate activities in countries abroad for the purpose of avoiding publicity, review, or criticism regarding the content or implementation of the research.

Data exchange with other countries
Rules for the processing and protection of personal data are different from one country to another. For this reason, the European Union monitors the protection of personal data and issues directions for the transfer of personal data between countries. There is free movement for personal data among the EU Member States and the EEA countries (Norway, Lichtenstein, and Iceland). The responsibility for data security then rests on the authorities in each country where a portion of the data is handled. However, research participants have the right to know that data are being transferred to another country, and the research participant information shall include information about the transfer of data and where the data are processed. For projects that take place in part in countries outside the EU and the EEA, two conditions shall be taken into account:

Export of data
Personal data may only be transferred to a country outside the EU/EEA, a so-called *third country*, under certain limited circumstances. These are described in detail at staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr/general-information-and-support/transfer-personal-data-outside-eu-and-eea.

Import of data
It is not uncommon that researchers want to import information containing personal data from a third country. The researcher him- or herself or another person may plan to collect data in connection with field research or research collaborations, or have sometimes already collected such data. It also happens that researchers want to reuse information archived in a third country from a previous research project. This may only be done if the research participants to whom the data refer have enjoyed protection corresponding to the EU level of protection for their safety and integrity, in connection with the collection and continued processing of the information.

In the application for ethics approval, the researcher shall inform the Ethical Review Authority of the countries that participate in a research project, describe the data flow, present and document the circumstances regarding the collection of the data to be imported, and describe the safeguards that have been or will be implemented.

STUDENT PROJECTS

According to the Ethical Review Act, projects carried out by university students at a basic or advanced level do not constitute research. Tasks labelled as research at this level of education should rather be considered training for potential future research.

The government states that students should not be given the responsibility for carrying out activities in which people participate and where there is a risk of harming those people physically, psychologically, or with respect to their integrity.[10] This should be understood as follows: students at the basic and advanced levels shall not normally carry out projects that would require authorisation according to the Ethical Review Act if they were carried out by a trained researcher.

The university is the controller when students process data within the framework of their studies. If a person within the framework of an educational course or programme deals with data about individuals, it is the organisation responsible for the education, and in practice the students' supervisor, who is responsible for making sure that the integrity and safety of the persons affected are taken into account and that the regulations in force are complied with.

When students carry out projects that involve humans or in which personal data are processed, this must be done with great care, and the safety and integrity of the persons concerned shall be protected. It is primarily the responsibility of the supervisor to make an assessment of how this shall be done in practice. The supervisor allocates the assignments meant to be carried out in the educational programme or course to the students. This is often done by the student suggesting an assignment which, not seldom following revision, is approved by the supervisor. This is also true of subjects for degree projects and other academic paper projects.

According to the 2018 recommendations of the Ethics Council of the HT Faculties, the point of departure for student projects must be to avoid ethically problematic methods or objects of research. The same ethical ap-

[10] Government bill 2007/08:44 'Certain ethical review issues etc.', *(Prop. 2007/08:44 Vissa etikprövningsfrågor m.m.)*, p. 20..

proach as that applied by researchers should be applied by students, under the supervision of and in consultation with a scientifically competent supervisor. Suggestions for student projects that are potentially problematic in this respect should be examined beforehand by the board of supervisors or a corresponding senior group in the discipline, for the purpose of identifying potentially ethically questionable elements or circumstances. The reviewing group should take as its point of departure the guidelines that can be found, for instance, at forskningsetik.lu.se and publikationer.vr.se/produkt/god-forskningssed.

In most cases this will probably mean that when planning studies involving humans or personal data that are carried out by students, it is advisable to avoid investigations that aim to influence people, that can expose the persons concerned to risks, or which include the processing of sensitive personal data or personal data regarding violations of law. However, there are other opportunities for students to practise the recruitment of persons for studies that include interviews, focus groups, or experiments, as long as these studies do not require authorisation according to the Ethical Review Act or are in some other way ethically problematic or controversial. There are also opportunities for students to process personal data that do not consist of sensitive personal data, after providing information to, and potentially acquiring consent from, the persons concerned. The rules of the GDPR shall be followed.

It is not possible to have sensitive personal data released for a student project from the national registers managed by, for instance, the National Board of Health and Welfare (*Socialstyrelsen*) or Statistics Sweden (SCB). Such registers are regulated by the Public Access to Information and Secrecy Act. According to this Act, information may be released for a limited number of purposes, of which research is one. On the other hand, there is not considered to be any scope within the framework of this Act for releasing data for use in an educational programme or course.

It is, however, not uncommon that students in the final stages of an educational programme wish to carry out investigations that affect humans and which in various ways include risks or breaches of integrity, and which go beyond the opportunities described above. Under such circumstances a scientifically competent supervisor shall assume the main responsibility for the investigation and engage the student as an assistant. The supervisor shall apply for

ethical review for an investigation that requires authorisation according to the Ethical Review Act. The application for ethical review must be submitted and approved before the project begins. Approval cannot be given for work that has already been carried out.

Master's theses and other research-preparatory projects

Students following a master's programme in many cases see this education as the first step on their way to a doctoral education. It is also common to have a plan for including the degree project from a Master's programme in a future doctoral programme. This imposes special demands for conscientiousness when it comes to projects that include the processing of sensitive personal data or experiments involving humans.

Each investigation intended to be presented within the framework of a licentiate or doctoral degree shall be managed according to the rules that apply to scientific projects. The requirements for ethical review shall be observed, and in the event of research that involves humans or the processing of personal data it is the researcher's responsibility to, at the publication stage, provide an account of whether the research has been ethically reviewed and how. This means that such projects shall be ethically reviewed if they fall within the scope of the rules for research that requires authorisation according to the Ethical Review Act. This assessment must be made before the work begins.

Regarding questions that need to be taken into account before publication, see the sections *The significance of publication* and *Requirement for an ethical review at publication*.

The Central Ethical Review Board has, on a number of occasions, concluded that when a student wishes to carry out a project intended to be included within the framework of a future doctoral programme, this shall be considered research and may be approved in an ethical review, even if the student has not yet been enrolled as a doctoral student. If this is the case, the circumstances should be clearly described in the application for ethical review.

Projects carried out by those who have been admitted to a doctoral programme shall be considered research, but this research shall be conducted under the supervision of a researcher with sufficient competence. He or she shall

have the scholarly competence required to conduct such research, normally at least a doctoral degree and recent experience of research with a relevant specialisation. The supervisor should assume an active responsibility during the planning and implementation of the investigation. In such cases the comprehensive responsibility of the supervisor shall be clearly described in an application for ethical review, and it is the supervisor who should submit the application for ethical review.

LINKS TO LAWS AND OTHER DOCUMENTS

Information about the *Act Concerning the Ethical Review of Research Involving Humans* and a link to the current version of the Act can be found at the website of the Swedish Ethical Review Authority.
etikprovningsmyndigheten.se/for-forskare/vad-sager-lagen

The General Data Protection Regulation, *GDPR*, is an extensive document eighty-eight pages in length, of which the thirty-one initial pages explain the reasons for the legislation. These recitals contain explanations and place the provisions in context. Next follow the provisions, arranged into ninety-nine articles. The text is available in the official language of each EU Member State. The full text of the GDPR as well as detailed descriptions and explanations of the areas covered by the Regulation can be found at the website of the Swedish Authority for Privacy Protection.
imy.se/en/organisations/data-protection/this-applies-accordning-to-gdpr/

The European Commission has published a guidance document, *Ethics and Data Protection*, containing advice on data protection issues regarding research planning along with a number of links to other documents with detailed information about the GDPR, its interpretation, and its application.
ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

The European Commission has also published a guidance document, *Ethics in Social Science and Humanities*, providing information and detailed advice for researchers within the social sciences and humanities who intend to work with research involving humans or personal data.
ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf

In their booklet *The European Code of Conduct for Research Integrity*, All European Academies (ALLEA) describes a number of foundational principles on which good research practice is based. This can be downloaded from the website of ALLEA.
allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf

In their booklet on good research practice, *God forskningssed*, the Swedish Research Council provides an overview of the most important issues of scholarly research ethics and how these should be dealt with. The latest revised edition has only been published online, and can be downloaded from
vr.se/uppdrag/etik.html.

Uppsala University runs the website *CODEX*, which contains a collection of rules and guidelines for research. Here a large number of national and international documents describing ethical guidelines for the research process are collected and regularly updated. CODEX contains both comprehensive materials and directions for many different specific research specialisations.
codex.uu.se/?languageId=1

LINK COLLECTION AND CONTACT INFORMATION

Below is an overview of the links provided in the running text and contact information to people who can provide individual guidance.

1. Websites with general information

Introductory information about handling sensitive research data can be found at the website of the Libraries of the Joint Faculties of Humanities and Theology:
htbibl.lu.se/en (Researcher > Research Data Management > Data Management > Personal Data and Confidentiality). A librarian can be contacted for guidance.

More detailed information with links to both internal policy documents at Lund University and external websites can be found on the Lund University Staff Pages:
forskningsetik.lu.se

The Staff Pages also include dedicated pages concerning data protection and records management:
staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr

staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr/general-information-and-support/security-measures-personal-data-and-how-manage-security-breach

staff.lu.se/support-and-tools/legal-records-management-and-data-protection/personal-data-and-data-protection-gdpr/area-specific-information/research

staff.lu.se/support-and-tools/legal-records-management-and-data-protection/records-management

The Joint Faculties of Humanities and Theology have issued guidelines for storing research data and a disposal and preservation plan (in Swedish):
internt.ht.lu.se/fileadmin/user_upload/HT-intra/HT-fakulteterna/Forskningsdata/Riktlinjer_forskningsdata-lagring_beslut.pdf

staff.lu.se/sites/staff.lu.se/files/gallrings-_och_bevarande-plan_ht.pdf

2. Links to public authorities and special resources

The Swedish Ethical Review Authority:
etikprovningsmyndigheten.se

The Ethics Review Appeals Board:
onep.se

The Swedish Authority for Privacy Protection (formerly the Swedish Data Protection Authority):
IMY.se

The Swedish Research Council webpage on open access to research data:
vr.se/english/mandates/open-science/open-access-to-research-data.html

LUSEC, the Lund University platform for high-secure handling of research data:
med.lu.se/english/intramed/teaching_research/research/research_data_management/lusec

3. Contact information of resource persons

Questions regarding the ethical regulatory framework for research can be addressed to:
Senior Lecturer Mats Johansson, forskningsetik@lu.se
Senior Lecturer Björn Petersson, bjorn.petersson@fil.lu.se

Questions regarding the correct handling of personal data can be addressed to:
Lund University Data Protection Officer Kristin Asgermyr, dataskyddsombud@lu.se

Questions about storing sensitive research data can be addressed to:
Archivist Mikael Falk, mikael.falk@htbibl.lu.se

Ethical considerations and guidelines are necessary if research is to be used in a responsible manner for the development of science and our society, today and in the future.

The aim of the present guidelines is to familiarise doctoral students, researchers, and teachers at the Joint Faculties of Humanities and Theology with the legislation on research ethics and to enable them to insightfully apply ethical principles in their work.

LUND UNIVERSITY

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