Ethical Reviews and Student Project Work

# Research v. Education

Research is important for the progress of individuals and society. And so, society and its members are entitled to (a) research, (b) that research addresses important matters, and (c) research is of high quality. Society sets these requirements for research so available knowledge will be developed and deepened, and methods will improve.

In turn, individuals must be kept safe and so the *criterion of protection of the individual* exists. This involves society’s desire to protect against unwarranted observation of living conditions, and that individuals will not be subjected to psychological or physical harm, humiliation or a violation of the personal integrity.

Much of research ethics can be described as a balance between the need for research, and the need to protect the individual. Neither the demand for research nor the criterion of protection of the individual are “absolute”, they must always be weighed against each other. Consequently, the responsible researcher must always consider the expected contribution to existing knowledge against any potential negative consequences for the participants and information providers, and where appropriate, any third party. Therefore, both short and long-term consequences must be considered. Sweden has several ethical review boards, who determine whether research may be conducted or not. Research may only be conducted if the scientific value outweighs any risks to the participants’ health, safety or personal integrity. If the expected results can be achieved in an alternative manner with fewer risks to participants’ health, safety and personal integrity, this method must be chosen.

A different process applies to student projects. The purpose of a student's independent work is to develop the student’s skills related to the learning outcomes of the programme or course being studied. This means that when the scientific value of research is evaluated, the interests for the students to receive good education is included.

The interests in students receiving a good education are less important than any potential risks to an individual’s health, safety and personal integrity. Especially as it is often possible to provide good education without risk to an individual in any way. If a student will conduct a project that, had it been conducted by a researcher would have been subject to an ethical review, particular caution must be exercised. If the project involves any risks to individuals, an alternative method for the project should be considered.

# Ethical review of research

The Ethical Review of Research Involving Humans Act provides a valuable starting point for student projects, as it highlights areas where specific vigilance is called for. The Act states that research must be evaluated and approved by an Ethical Review Board, if it includes processing of sensitive personal information in accordance with the Swedish Personal Data Act.

“Personal data” is any piece of information that can be traced back to a living physical person. Hence, information that can be linked to names or personal identity numbers is always classed as personal data. Personal data can also include information that does not directly single out an individual,

if it is possible to connect the data to a specific person in any other way. Detailed information that directly indicates where a person lives, such as a land registry number or geographical coordinates are examples of personal data. Another example includes substantial and/or detailed information, which when combined can be traced to a person. Coded or encrypted information is also personal data, if it can be read and individuals identified; i.e., for as long as a code or encryption key is still available.

Sensitive personal data refers to personal information that reveals: race or ethnic origin, political opinions, religious or philosophical convictions, or membership in trade union organisations, health details and information about a person's sex life or sexuality, in addition to genetic information, and biometric data that can be used to clearly identify a physical person.

Sensitive personal data also includes information about criminal convictions, transgressions of the law, or coercive measures.

Furthermore, the Ethical Review Act must be applied to research involving physical interventions on research participants, being conducted to physically or mentally affect the participant, or that involves a clear risk of physical or psychological harm to the participant. The Act must also be applied to studies using biological materials taken from a living person, and that can be traced back to this person, or if research involves a physical intervention on a deceased person, or will study biological materials taken from a deceased person for medical purposes and that can be traced to this person.

The term “health” has a broad interpretation regarding sensitive personal data and ethical review of research. The concept comprises information that touches upon all aspects – physical and psychological – of a person’s health. For example, it might include information about substance misuse, sickness absence, experiencing of bullying, pregnancy, and doctor’s appointments. The WHO defines health as a state of complete physical, mental and social well-being. Such information that affects an individual’s physical, psychological and social well-being should therefore be treated as sensitive personal data.

# Ethical Review of student work

Work being conducted as part of first and second-cycle university studies is not classed as research. Legislators believe that students should not be subject to the same responsibility that comes with conducting work with human participants, and where there is a risk that these people could face physical or psychological harm, or damage their integrity. It is the responsibility of the education provider to ensure that student projects conducted at first and second-cycle levels follow ethically guaranteed and safe forms.

The board of the Faculty of Health and Society has decided that student projects with ethically sensitive content must be vetted by a specific Ethics Council, tasked by the Faculty to ensure that first and second-cycle student projects are performed in an ethically safe and correct manner. Here, the responsibility lies with all of those who have influence upon the course or programme content, i.e., supervisors, course coordinators, examiners etc. However, in practice, it is often the supervisor who in consultation with the student ensures that project work with ethically sensitive content is vetted by the Ethics Council. It is the task of the review board to recommend or dissuade students from conducting the project work in a certain manner. The verdict of the Ethics Council is only a guideline and is valid as long as the legislation hasn´t changed. You, as a student, must be informed about any changes of the legislation.

# Which student projects must be vetted by the Ethics Council?

Student projects of all levels conducted at the Faculty of Health and Society must be vetted if the content is ethically sensitive. The description of the ethical vetting of research (see above) can be used as guidance. To summarise, this means that all student projects that contain sensitive personal information must be examined by the Ethics Council, in addition to all student projects that entail a physical procedure, or physical or psychological impact on participants, and all student projects that involve studies of biological materials.

# Application form

For the Ethics Council to be able to assess any student projects, the student(s) must submit an application. The forms created by the Ethics Council for processing student projects are described as follows:

The name and contact details of both student and supervisor will be requested, the course or programme being studied by the student(s), and the title of the project.

From the Ethics Council’s perspective, the education cycle is important, as first-cycle student projects face more restrictive evaluations than second-cycle projects. This is because students at second-cycle level are expected to have obtained greater knowledge, experience and preparedness for processing the ethical issues that may arise from various projects.

This information must then be followed by a summary of the project, max. 150 words. Essentially, this is an abstract that describes the project background and purpose, and the materials and methods that will be used for data collection and analysis. The purpose of this section is to provide a brief outline of the project, and will then be followed by a section in which the student

will be asked to include a more detailed and concise description. The form will ask for the primary question the study intends to answer. The student will then be asked to describe the investigation procedure, the type of data that will be collected, and how this data will be processed. As regards the latter, it is recommended that all relevant stages of the process are included, in addition to which variables/questions will be used. Listing these in bullet points is suggested. If interviews or questionnaires will be used, these should be included in the application.

If the material contains sensitive personal information, see above, it is important that unauthorised persons are prevented from accessing this data throughout the process, and once the project has been completed. The Ethics Council wants to see that there is a method in place to protect questionnaires collected, that personal data is not recorded on a mobile telephone with internet access, that personal data is not stored or processed on a computer with access to the internet, and that all data collected is destroyed once the academic paper has been examined. Strictly speaking, all processing of personal data infringes on privacy, hence the Ethics Council wishes to receive a brief description of how the integrity of the participants will be guaranteed when data is collected, stored, processed/analysed, and presented.

The Ethics Council then wishes to see a presentation of the data collection context, e.g., if interviews will be conducted at a school, or if confidential information from social services or the healthcare sector will be used. The necessary permits must be accounted for, and the person in charge of the activities must provide their approval.

The Ethics Council requires a statement that the materials collected and results will only be used, presented and published as a student project. The primary purpose of all student projects is to evaluate what a student has learnt through examination. After the examination, the collected data must be destroyed. In certain cases, the collected data might be used in other contexts, e.g., collecting samples from a healthcare clinic. The Ethics Council has full understanding for this, but it must be reported and described in the information to the participants. However, if the purpose of the data collection is to use the material in a different research publication – not simply the student project – the Ethics Council believes that the Regional Ethical Review Board is the body in charge of vetting the project's ethical aspects. The Ethics Council only assesses student projects.

Therefore, the Ethics Council requests information about the study population, and the way in which students intend to contact the intended participants. The requested information includes the group of individuals in mind, how contact will be established, and the selection criteria. The Ethics Council requests separate, more detailed reasoning regarding minors or individuals with reduced cognitive function. As the risk of harm is greater in projects involving such groups, there is cause to assess whether the learning outcome can be achieved in an alternative manner, for example by choosing participants will full autonomy.

In certain cases, relationships may influence an individual’s decision to participate or abstain from a project. This is the case if the student or supervisor works at the clinic where the study is being conducted, and the patient would like to stay on good terms with the student/supervisor to receive the best treatment possible. It might also be the case that the supervisor is, or could be, the student’s manager, or that the supervisor will be the examiner. These types of complicated relationships should be avoided entirely. Therefore, the Ethics Council requests a brief statement of whether such relationships exist that could affect the student project.

Often, we can all view questions from various research institutions as inconvenient or an infringement. It is always worth considering just how many individuals need to be contacted to achieve the necessary response frequency to answer the questions, so neither too few or too many individuals are disturbed unnecessarily. Research projects generally require comprehensive power calculations, i.e., how many people need to be disturbed so the questions can be answered. However, in order to assess the student project, the Ethics Council only requires a brief, well-considered account of how comprehensive the material will be.

In all studies, from student work to research projects, it is of utmost importance that participants are informed about the purpose of the study, and that they have the right to decide if they will participate – in other words, that they are able to provide well-informed consent. The Ethics Council requests details of the information that will be presented to participants, and how the participants will receive this information. The application must include the information that will be presented to the participants, see below.

The information letter must provide a basis for informed consent from the participants. Suitable methods for obtaining written consent include a signed consent form. If this method is used, the form that will be used must be submitted with the application, see below. In other cases, it might be more suitable to state in the information letter that by answering and returning the questionnaire, the person accepts participating in the study. The Ethics Council requests information about how, and in what form, the consent will be collected.

Therefore, the Ethics Council wishes that the student evaluates any risks the student project may entail for participants, and how these risks will be managed. In certain cases, data collection may involve direct risks, for example when as part of their studies to become a biomedical analyst, the student must collect blood samples. However, the most obvious risk is the infringement on privacy that a questionnaire might entail, and is collected through informed consent, and that collected material is only processed confidentially and used for the academic paper alone. The student should be able to guarantee that participation in the project does not involve any known long or short-term risks.

As initially stated, much of research ethics can be described as a balance between the need for research, and the need to protect the individual. The Ethics Council subsequently requests that the student highlights any benefits or advantages the participant may attain through participation, for example finding out blood sugar levels from blood tests taken by students who will become biomedical analysts, or students on nursing programmes as part of a student project. However, questionnaires seldom have concrete benefits for participants in student projects. This must be stated.

In certain cases, participants may belong to a vulnerable population, for example unaccompanied refugee minors, or individuals applying for assistance or healthcare and treatment. These individuals may falsely be of the impression that participation in a study might positively influence decisions for social interventions or other decisions from government agencies. The Ethics Council strongly requests that the student highlights these conditions or similar, and clarifies how these problems will be addressed.

The application form concludes with questions regarding how results from the academic paper will be made public. All student projects will be published on DiVA, Malmö University Electronic Publishing, and this must be stated. In certain cases, feedback may be provided to various interested parties/receivers, for example the treatment centre where data collection was conducted. In such cases, this must be stated in the application form and the information letter.

Feedback and dissemination of results are important. However, it is also important that everyone participating in the study is offered the greatest possible confidentiality. Therefore, the Ethics Council requests a brief account of how participants’ integrity will be assured, for example only group analyses will be conducted, or all information provided during interviews will be anonymised. In order to guarantee the participants’ integrity in the long term, for example so printed interviews cannot later be found in a collection of papers, all material collected must be destroyed once the student project has been examined. This is to be stated in the application and the information letter to participants. This also applies to recordings and possible email / SMS correspondence. It may be appropriate to create an email address only for the project in order to then be able to delete and close the account. If the collected materials will be saved, the student must state the reasons for this, and subsequently how the participants’ integrity will be guaranteed in the long-term.

# Appendices

Several appendices are to be submitted with the application form.

## Written information for participants

A template is available from the Ethics Council website, and should be used so it is clear that the work is a student project for Malmö University. The upper section of the document is to include the project title, date, name and contact details for the students responsible for the study. The course or study programme must also be provided in connection with Malmö University’s contact information.

The information letter must contain everything a person can reasonably expect to be made aware of to be able to consent or abstain from participation in a student project, but nothing more. The written information is a supplement to the verbal information provided. The opportunity to ask questions must always be provided. The information letter is kept by the participant.

It is important that information is provided using simple and clear language, and does not contain words that may be interpreted as creating pressure or an exaggeration of the potential value of the study. In principle, the student’s individual learning is the sole value of a student project. Information should be adapted to a person’s age and other circumstances, or any other reason for reduced decision-making ability. For student projects that include children, the information must be directed to both the child (if they can read) and their guardian.

The information should not be too long, a maximum of 1-2 pages. It must be adapted to the intended population, so participants fully understand what the project entails. The relevant sections can include the following points with headings to facilitate readability:

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| **No.** | **Heading** | **Comment** |
| 1 | Background and purpose | Provide brief information about who will conduct the student project: name, student on XX programme at Malmö University, and XX level of the academic paper. Also give a short but concise description  of the background and overall purpose. |
| 2 | Enquiry on participation | State why the person is being asked, and how their details were obtained  beforehand. |
| 3 | How will the study be performed? | From the perspective of the person being asked, provide a brief description of what will be required from them, including what personal details and other data will be processed. Where appropriate, information must be clear about how the investigation procedures differ from routine treatment, and if there are any objective and foreseeable  risks or advantages as a result of participation. |
| 4 | Processing data and confidentiality | This must state how personal information and collected data will be processed, and how the results will be presented, i.e., in an academic paper published on DiVA. It must also state that personal details and collected data will be processed to prevent unauthorised persons from gaining access, that personal details and  collected data will be destroyed after the paper is examined, and that Malmö University is responsible for processing  personal data. |
| 5 | Voluntary participation | It must be clear that participation is voluntary and may be withdrawn at any time without explanation, and that all personal information and collected data will then be destroyed. It must clearly state who to contact in order to withdraw consent from participation. If the participant is a patient or client, it must be clear that the results of participation will not influence  the regular treatment or care. |
| 6 | Persons responsible | For the person being asked to participate to receive further information, the students’ names and contact details (email and  telephone) must be stated. The supervisor’s name and title should be submitted. |
| 7 | Confirmation of consent | This must clearly state that the person being asked has been informed, had the opportunity to ask questions and have them answered, and provided consent to participate in the study. The way consent will be documented must  also be clearly stated. |

## Written consent form

If signed consent will be obtained, the consent form that will be used must also be included in the application. The Ethics Council requests that the template available from the Ethics Council website is used, and that it is clear that the work is a student project for Malmö University.

## Authorisation from the supervisor

The student can face difficult ethical problems in their work. In order to give the student the advice and guidance they might need, it is important that the application is complete. The Ethics Council therefore requires that each application that will be submitted to the Council for evaluation before conducting a student project has been seen by the responsible supervisor before its submission. This means that the supervisor must also read and check that the application is complete and can be understood, so the Ethics Council has the possibility to provide a statement. Authorisation from the supervisor is best provided on the applicable form.

## Signed permission from the Head of organisation/equivalent

In cases where data collection will be conducted at any form of organisation, such as a school, health clinic, social services office or workplace, the authorised organisational representative must approve the student project. This is to guarantee that the head of organisation has evaluated the suitability of the project being conducted, and that the project does not obstruct activities or entail any risks for the participants. It is important to maintain a credible collaboration with the organisations involved, taking future student projects into consideration. Should the student project involve confidential materials, such as patient records, investigations from social services or extracts from data registries, permission to access this data from the authorised representative is expected. It is the duty of the student and their supervisor to investigate if any other permits might be necessary.

In such cases, the Ethics Council requests that there is signed permission from the head of the organisation and/or other documents are appended to the application.

## Interview guide and/or questionnaire

If interviews or questionnaires will be used, these should be included.

# Where can information from the Ethics Council be found?

Information about the Ethics Council, forms and meetings can be found from the following sites:

The Ethics Council page, with information about its activities and composition can be found on the staff pages: <http://mah.se/medarbetare/For-HS-medarbetare/Rad-vid-Halsa-och-samhalle/Etikradet/>

Ethical reviews for Swedish-speaking students can be found via the following address: [http://www.mah.se/fakulteter-och-omraden/Halsa-och-samhalle-startsida/Student-pa-](http://www.mah.se/fakulteter-och-omraden/Halsa-och-samhalle-startsida/Student-pa-HS/Etikprovning-/) [HS/Etikprovning-/.](http://www.mah.se/fakulteter-och-omraden/Halsa-och-samhalle-startsida/Student-pa-HS/Etikprovning-/) Use the following simple address if you want to refer to the page: [http://www.mah.se/etikprovning.](http://www.mah.se/etikprovning)

Ethical reviews for English-speaking students can be found via the following address: [https://www.mah.se/english/faculties/Health-and-Society/Education/Ethical-review/.](https://www.mah.se/english/faculties/Health-and-Society/Education/Ethical-review/) Use the following simple address if you want to refer to the page: [https://www.mah.se/Ethical-](https://www.mah.se/Ethical-review) [review.](https://www.mah.se/Ethical-review)

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