



UMEÅ UNIVERSITET

GUIDELINES FOR ETHICAL REVIEW AND PERSONAL DATA MANAGEMENT IN STUDENT PROJECTS AT THE FACULTY OF MEDICINE

Type of document:	<i>Guidelines¹</i>
Date of approval:	<i>16 March 2023</i>
Reg. no.:	<i>FS 1.1-140-23</i>
Approved by:	<i>Medical Faculty Board</i>
Validity:	<i>Until further notice</i>
Field:	<i>First- and second-cycle education</i>
Office in charge:	<i>Faculty Office of Medicine</i>
Replaces document:	<i>Guidelines for ethical review of student assignments at the Faculty of Medicine approved by the Faculty Board 14 June 2017, FS 1.1-1072-17</i>

¹ This document has been translated from Swedish into English. If the English version differs from the original, the Swedish version takes precedence.

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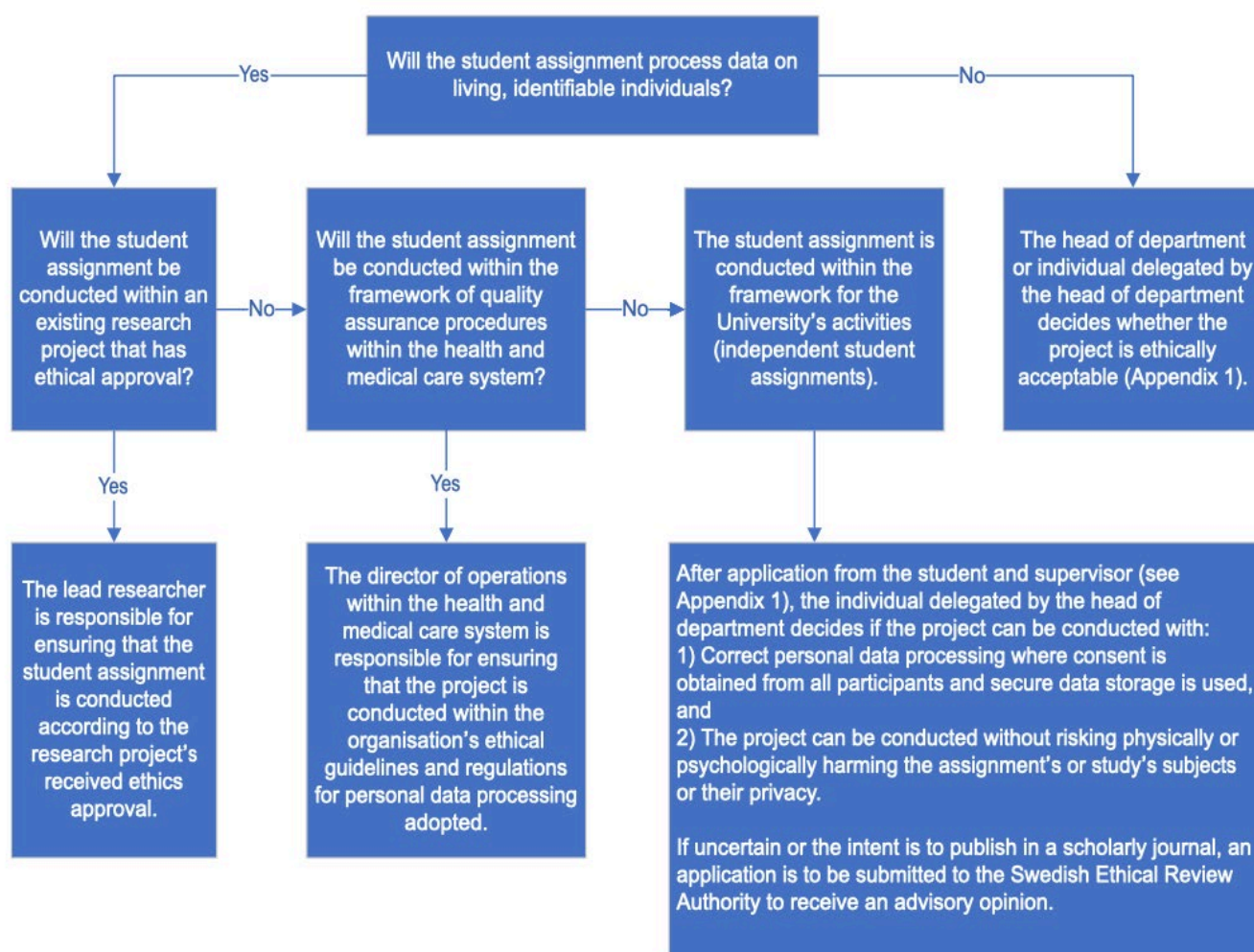
1. Summary

- A documented decision is to be taken for all student projects on how to conduct the project under ethically acceptable forms and, when necessary, how personal data will be processed. See Appendix 1.
- A student project that is part of a research project (see 2.2) is to adhere to the project's ethical guidelines and personal data processing.
- If a student project consists of quality assurance procedures for the health and medical care, the accountable medical care authority's rules and guidelines on ethics and personal data processing apply.
- A student project that is *not* included in an ethically reviewed research project or in a quality assurance procedure within the medical care system (in this document referred to as an *independent student project* (see 2.3)) can by definition not be given ethical approval. The project is to be conducted under ethically approved forms and follow the University's rules for processing personal data in student projects. If there are plans to publish the findings in a scholarly journal, the supervisor is responsible for applying for ethical approval before the project begins.
- When a planned student project (applies to both 2.2 and 2.3 below) is *not* part of a research project that has undergone ethical review and there is uncertainty to whether the project is legally required to have ethical approval in accordance with the Act Concerning the Ethical Review of Research Involving Humans (2003:460), the supervisor for the student project is to submit an application to the Swedish Ethical Review Authority with a request for what is known as an *advisory opinion*.
- To process personal data as part of an *independent student project* requires a separate consent from each person participating in the study whose personal data is processed. Note that the consent is not to include any sensitive personal data.
- The head of department is responsible for ensuring that procedures are in place to ensure that the student project is conducted under ethically acceptable forms and that processing of personal data follows Umeå University's Rules and procedures for processing personal data in student projects.² The procedures are to include the following:
 - How decisions on student projects can be conducted under ethically acceptable forms and, if personal data will be processed in independent student projects, how these data are documented and saved.
 - How consent is obtained, saved and disposed of after conclusion of independent student projects.
 - How the student is provided information on ethics and personal data processing rules and procedures.
- Each academic programme is to provide introductory training on research ethics and personal data processing, in addition to what is required on research methodology, theory of science and how academic papers are structured.
- Student projects and the project plan for student projects are to include the header "Ethical considerations". The supervisor is to ensure that the student is trained in describing and reflecting over ethical issues within student projects.
- Scientific secretaries at the Swedish Ethical Review Authority should be regularly invited to hold training for teacher groups/supervisors on issues related to ethical review.

² Rules and procedures for processing personal data in student projects, FS 1.1-322-22

Flow chart for how to manage personal data and consent in student projects

This determination is made by a person or group delegated to ensure student projects are conducted according to the acceptable ethical principles and that processing of personal data follows the central legal framework as noted in the flow chart below:



2. Managing different types of student projects

2.1 Underlying rules and principles

When planning and implementing student projects, consider both ethical aspects and rules for data processing. This includes assessment of risks and benefits, whether the student project requires ethical approval, general ethical principles on good data processing practices and consent to process personal data. The supervisor and the supervisor's department (head of department) are to ensure that this takes place. The Declaration of Helsinki and other ethical principles are good starting points (www.codex.vr.se) Relevant legislation includes the Act (2003:460) om ethical review of research on humans, the EU's data protection regulation (GDPR), regulations on patient journals in the Patient Data Act (2008:355) and the Swedish National Board of Health and Welfare's regulations on patient journals (SOSFS 2008:14). It is crucial that the faculty conduct training on ethical issues in all its programmes for both supervisors and students prior to degree projects. The scientific secretaries at the Swedish Ethical Review Authority are tasked with providing this type of training.

The student's personal data processing must comply both with GDPR (General Data Protection Regulation, 2016/679) and the University's regulations. See Umeå University's Rules and procedures for processing personal data in student projects. Umeå University is the ultimate personal data controller for student data processing within the framework of courses and programmes. If a student project involves quality assurance procedures within the medical care system, the accountable medical care authority's personal data processing applies. When journal data is used, it is assumed that the care giver conducts a personal data protection test (*menprövning* in Swedish – a test to see if personal data can be shared without harming the individual who's data is shared or close relations), normally delegated to the head of operations. If registry data containing sensitive personal data outside of the health and medical care system is used, the registry director makes the determination. Note that personal data covered by confidentiality is not intended for use in student projects.

A student project included in a research project is to follow the project's ethical guidelines and personal data processing. A student project not included in a research project, defined as an *independent student project*³, cannot be given ethical approval. In this context it is important to consider that, if there are plans to eventually publish findings in a scholarly journal, ethical approval is required, something that the supervisor is responsible for arranging and that this approval is to be granted prior to project start. This also applies to student projects conducted as quality assurance procedures for the medical care system. The project is to follow the University's rules for processing personal data in student projects.

The head of the supervisor's department is responsible for determining a procedure for assessing whether the student project is conducted according to acceptable ethical principles (applies both for student projects within research groups and independent student projects, see 2.2 and 2.3). The procedure is to specify how the decision was taken, documented, saved and disposed of. The procedure can be that the responsible supervisor makes an initial assessment and that the decision is made by the head of department or a delegated individual/group. For example, Teams can be used for documentation of decisions. All academic programmes and their hosting departments are to use Appendix 1 as a basis for these assessments.

Departments are also to have procedures for processing personal data for independent student projects. The procedures are to specify how consent was obtained, saved and disposed of after conclusion of independent student projects. Procedures are to follow Umeå University's Rules and procedures for processing personal data in student projects. The head of department is responsible for ensuring that only approved IT environments and tools at Umeå University are used for processing personal data in student projects.

There are different guidelines to follow for different types of student projects in terms of both ethical aspects and personal data processing. These are described in more detail in the

³ Rules and procedures for processing personal data in student projects, FS 1.1-322-22

following sections.

2.2 Student projects conducted as part of a research project with existing ethical approval

Student projects conducted **within** a research project fall under the Ethical Review Act and *are to be* covered by the research project's ethical approval. Umeå University is the research accountable authority when a student project is conducted within the framework of a research project at Umeå University. When a student project is conducted within another organisation, that research accountable authority has responsibility. In projects approved in accordance with the Ethical Review Act, the principal investigator is also responsible for ensuring that the student follows the research project's processing of data, including personal data.

Personal data processing for student projects within research projects falls under the legal category *general interest* in the General Data Protection Regulation and does not require consent from participants for personal data processing. Consent for participation in the study, on the other hand, is required. Student processing of personal data takes place under the conditions laid out in the research project and under the responsibility of the lead researcher. The student's personal data processing must also comply with the rules governing the research project and all the student's data processing must be done within secure storage places and the authorisation structure of the research project. The lead researcher should determine what types of data should be handled by students. Students included in a research project at Umeå University are equated with staff and thereby are covered by the confidentiality requirements that apply to staff. When a student project is conducted within another organisation, that research accountable authority has responsibility.

2.3 Independent student projects

Umeå University has responsibility for ensuring that student projects in first- and second-cycle courses and programmes are conducted under ethically acceptable forms. Student projects that process sensitive personal data and that are conducted **outside** of research projects (independent student projects) do not undergo ethical review since they are not defined by the Ethical Review Act as research. Quality assurance procedures within the medical care system are also not defined as research and therefore cannot obtain ethical approval. If uncertainty still exists on whether the student project needs to be ethically reviewed, an advisory opinion can be requested (see 2.4).

The background to the above is as follows: Preparations for the Ethical Review Act (Bill 2002/03:50) and the updated legislation from 2007 specify that first-cycle student projects normally do not require ethical reviews since they typically do not involve research. When the revision to the Ethical Review Act went into force in 2020, the exception from requiring ethical review for student projects was maintained but it was clarified that the exception applies to work or studies only performed within the framework of first- and second-cycle education. Work with amending the Ethical Review Act assumed that student projects do not include studies that could risk physically or psychologically harming research subjects or their privacy.

It is important to note that if the intention from the beginning is to publish the findings in a scholarly journal, ethical approval must be applied for when appropriate and before the student project begins. Because students are unable to apply for ethical approval, the supervisor is responsible for this.

For personal data in independent student projects, Umeå University has determined that GDPR only permits the University to support the processing of personal data through the legal category *consent*. In these cases, correct data processing (personal data processing) is to be ensured⁴. When personal data (all forms) is processed in student projects, the participants must have been informed and consent for this obtained. The student must

⁴ Rules and procedures for processing personal data in student projects, FS 1.1-322-22

therefore obtain a written consent from everyone who will be a part of the student project.

For independent projects, students may process personal data if consent has been obtained, if the student is judged to be capable of managing personal data and if the student project is judged relevant.

The head of the supervisor's department is responsible for ensuring procedures are in place for this appropriateness assessment, that the student is informed of applicable rules and of how consent and data are to be collected, saved and removed. Before allowing a student to process sensitive or personal data meriting special protection outside of a research project, the appropriateness assessment needs to give particular consideration to whether the student project is conducted under ethically acceptable forms (that the registered individuals' freedoms and rights are not jeopardised). The supervisor's department is responsible for ensuring an appropriateness assessment is conducted before a student project begins (Appendix 1).

All material containing personal data is to be stored and managed according to Umeå University's rules and regulations⁵. Only places provided by the University for collection, processing and storage of personal data may be used (see Section 8.3 in *FS 1.1-322-22*). Teams can be used for general personal data. For sensitive personal data or personal data meriting special protection, only places that Umeå University has explicitly approved for processing of this type of personal data may be used. Note that if complete pseudonymisation⁶ can be ensured, the data is no longer personal data and therefore does not fall under GDPR legislation.

2.4 Advisory opinion for student projects

When the planned student project (applies to both 2.2 and 2.3) *is not* a part of a previously ethically approved research project and it is uncertain whether the student project is appropriate to conduct from an ethical perspective, the supervisor is to submit an application to the Swedish Ethical Review Authority for an *advisory opinion*. The same application form is used as with regular approvals, in accordance with the Ethical Review Act (<https://etikprovningssmyndigheten.se>). Costs for this are covered by the supervisor and the supervisor's department. The Swedish Ethical Review Authority will assess the application according to its normal principles. If the student project is not judged as research (see 2.3), it falls outside the Ethical Review Act's purview and only an advisory opinion can be received. For example, the opinion could be that "The Authority sees no ethical issues with the student project" or changes could be suggested. An advisory opinion has the same fee as a regular approval process and, as a rule, the same processing time and can only be conducted if the research has not yet begun, i.e., the decision must be made prior to collecting data.

An advisory opinion cannot be appealed.

3. Ethical review cannot be performed after the research has begun

The Swedish Ethical Review Authority cannot assess projects after the research has begun. The same applies to advisory opinions. For this reason, in cases of uncertainty, it is recommended that ethical review be conducted well in advance. In practice, this means that a student project conducted without ethical approval cannot be included in potential future doctoral education or published for scholarly purposes, if an ethical permit is required for the study.

⁵ Rules and procedures for processing personal data in student projects, *FS 1.1-322-22*

⁶ Note that

- Anonymisation is to be irrevocable.
- It is not sufficient to remove names and/or personal identity numbers for the data to be anonymised.
- Anonymisation and pseudonymisation are different things and should not be confused.

4. Rules and regulations for ethical reviews

4.1 Ethical review of research on humans

Ethical review for research on humans is regulated in the Ethical Review Act (SFS 2003:460). The act applies to research involving physical intervention on a research subject or research conducted with a method intended to affect the research subject physically or psychologically. This act also applies to research involving a physical intervention on a deceased individual or intended for studies of biological material taken from a living or deceased individual and that can be traced back to this individual. The act also states that all research involving processing of personal data as specified in Article 9.1 of the EU's data protection regulation (sensitive personal data and data on health, sex life, genetic or biometric data, etc.) is to be ethically reviewed, regardless of whether the research subjects have submitted their explicit consent or not. For a project to be assessed in an ethical review, it must be defined as research.

Ethical review of research on humans, human tissue or sensitive personal data is conducted by the Ethical Review Authority (<https://etikprovningssmyndigheten.se>). Applications are national and new applications are assessed by one of the Authority's regional offices, though not the regional office where the application is submitted. For applications that do not fall within the Ethical Review Act's purview, the Authority can issue what is known as an *advisory opinion* based on an ethical review of the proposed student project. Applications processed by the Swedish Ethical Review Authority are charged a fee, even if it only results in an advisory opinion. See also <https://etikprovningssmyndigheten.se>.

4.2 Ethical review of research on animals

The Animal Protection Act (1988:534) requires that the use of animals in animal research receive ethical approval by a regional animal research ethics committee before use begins. No exceptions are made for the use of research animals for educational purposes. When reviewing cases, the committee is to weigh the research's importance against the suffering of the animal. All vertebrates are covered by the regulations.



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Appendix 1. Appropriateness assessment of first- and second-cycle student projects

1. Student project title:
2. Student name:
3. The project is intended as a basis for the following degree: <input type="checkbox"/> Bachelor's <input type="checkbox"/> Master's (60 credits) <input type="checkbox"/> Master's (120 credits) <input type="checkbox"/> Professional qualification On the following programme:
4. The project will be conducted together with another student: <input type="checkbox"/> No <input type="checkbox"/> Yes, name: _____
5. Will the student project include processing of data on living, identifiable individuals? <input type="checkbox"/> Yes (go to Question 6) <input type="checkbox"/> No (go to Question 9)
6. What form does the personal data processing take? <input type="checkbox"/> The student project included in a research project (legal category <i>general interest</i> , go to Question 7). <input type="checkbox"/> Independent student project within the framework for the University (legal category <i>consent</i> , go to Question 9). <input type="checkbox"/> The processing of personal data occurs within the framework for another personal data controller, e.g., systematic quality assurance procedures within the health and medical care system (go to Question 8). <input type="checkbox"/> Other (go to Question 9 and clearly describe how processing will take place).
7. Does the research project require ethical approval? <input type="checkbox"/> Yes, and ethical approval has been obtained. Specify the Ethics Review Authority's registration number and accountable authority for the application: _____ (go to Signature). <input type="checkbox"/> Yes, but ethical approval has not yet been received. This form is to be supplemented with information on approval from the Ethics Review Authority before the degree project begins (go to Question 9). <input type="checkbox"/> No, ethical approval is not required (go to Question 9).

<p>8. Is there a decision from an accountable medical care system authority that the quality assurance work is to be conducted?</p> <p><input type="checkbox"/> Yes. Attach a copy of the decision (go to Signature).</p> <p><input type="checkbox"/> No. This form is to be supplemented with information on approval from the accountable medical care system authority before the degree project begins (go to Question 9).</p>
<p>9. What risk/risks for ethical problems can arise?</p>
<p>10. What measures are planned for eliminating or reducing these ethical risks?</p>
<p>11. What is the expected relevance/benefit of the degree project?</p>
<p>12. How will the findings be made public?</p>
<p>13. Is the student project intended to be published in a scholarly journal?</p> <p><input type="checkbox"/> Yes. This leads to the project likely being considered as research, see Question 7.</p> <p><input type="checkbox"/> No</p>
<p>14. Describe how and when information about personal data processing is provided when the volunteer is recruited?</p>
<p>15. Describe who asks about participation, when this occurs and how the informed consent is documented.</p>
<p>16. Start of data collection:</p>
<p>17. Describe where and how long the material will be stored and who will have access to the collected data.</p>

Appendixes		
Submitted with	Appendix no.	Description
<input type="checkbox"/>	1	Information letter for participants
<input type="checkbox"/>	2	The form <i>Consent to processing of personal data and information to registered parties</i> .*
<input type="checkbox"/>	3	Survey, questionnaire, interview guide or similar
<input type="checkbox"/>	4	Information letter to head of operations or equivalent
<input type="checkbox"/>		Other Appendixes
<input type="checkbox"/>		Other Appendixes

* The individuals who will respond to questions, be observed or in other way studied within the framework of the degree project are to be provided easy-to-understand information about the purpose of the work and methodology used so that they understand the consequences of participating in the study. This information is intended to provide a basis for the individual actively deciding whether they want to give consent for participation, known as informed consent. The individual is to be informed also that they can withdraw their consent at any time without consequences, even if the consent was given at an earlier stage. A template can be downloaded from Umeå University's website for personal data processing in student projects.

The student's or students' signature(s), place, and date

The student project is judged to be appropriate for implementation based on the above description.

☐ Yes

☐ No

Name (authorised decision-maker appointed by the head of department):

Phone:

Email:

Signature:

Date: