Ethical considerations related to student work at NVS – a discussion paper

Karolinska Institutet

Target group: Supervisors and students
Version 20210128
Matters to consider **before, during** and **after**
student dissertations/degree projects, academic papers, etc.

The work of students is constantly subject to ethical considerations throughout the working process. Ethical evaluations are made and standpoints taken on a continuous basis and cannot simply be 'ticked off'. This document provides guidelines on ethical considerations that may be relevant before a student begins working on a project, while they are doing so and once the work is complete.

Document owner: Ethics Group for Student Work at the Department of Neurobiology, Care Sciences and Society (NVS).

BEFORE THE PROJECT: WHAT TO CONSIDER WHEN YOU PLAN STUDENT WORK

1. Ethical approval

One of the first issues to address is whether the planned project requires ethical approval. If the answer is yes and no existing ethical approval covers the work – choose another subject or method.
https://etikprovningsmyndigheten.se/
When conducting research, due consideration must be given to both the Swedish Act concerning the Ethical Review of Research Involving Humans (SFS 2003:460) and the Swedish Patient Data Act (SFS 2008:355), as well as the General Data Protection Regulation (GDPR) and Swedish Data Protection Act (SFS 2018:218). Ethical approval does not automatically grant access to medical records or permit data gathering in clinics or similar facilities. Even when ethical approval is granted, it is the head of the organisation/unit at the healthcare facility in question who authorises access to medical records or the collection of data.

The following information and guidance applies at KI in relation to ethics in student work:
https://ki.se/utbildning/etik
https://ki.se/medarbetare/etikprovning-av-examensarbeten

The following links may also be useful:
Swedish Research Council report on good research practice:
https://www.vr.se/english/analysis/reports/our-reports/2017-08-31-good-researchpractice.html

KI information on laws and guidelines regulating research documentation:
https://staff.ki.se/laws-and-guidelines-regulating-research-documentation-0

Swedish Ethical Review Authority: https://etikprovningsmyndigheten.se/

The Declaration of Helsinki contains ethical principles for doctors and others who participate in medical research. The declaration was adopted by the World Medical Association (WMA) in 1964:
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

We have compiled a number of cases that may offer guidance on what types of project have previously been deemed to require or not require ethical approval. The case can be found at the end of this document as Appendix 1.

2. Ethical considerations

Assess the value of the project:

- How will the project contribute to the development of knowledge?
- Is there already research being conducted in the field or existing studies?
- What ethical issues does the project raise? What ethical dilemmas are raised by the choice of subject, research questions/methods and any future publication?
- Are there any preconceptions/prejudices regarding groups of people that may affect the design of the study?

- Might any patient or societal group be stigmatised?
- Could the project damage confidence in research?

3. The research subject's perspective

- What reactions might the project provoke in individual or groups of research subjects?
- What reactions might the questions you ask provoke in respondents (if the chosen method involves interviews and/or a questionnaire)?
- What resources are available to deal with adverse reactions from research subjects?
- What commitments are required from research subjects in terms of time and attendance? Is there a risk that participation will cause stress, physical injury or any other discomfort?
- What reactions might be provoked by your presence in the observed situation (if the chosen method involves observation)?

4. GDPR (General Data Protection Regulation)

Learn more about GDPR: https://staff.ki.se/gdpr-at-ki

- How will research subjects taking part in the study receive information?
- How will you ensure that research subjects understand the implications of their participation in the study, that they are participating voluntarily and can withdraw their participation at any time?
- Ensure that written consent is obtained and documented. Information to research subjects in student work must be as rigorously designed as when participating in research projects. Examples of how to design information to research subjects is available [in Swedish] from the Swedish Ethical Review Authority website: https://etikprovningsmyndigheten.se/.

5. Information to the organisation

Regardless of whether or not the study requires ethical approval, always ensure that the head of organisation/unit has given their written approval to the study and that other affected individuals are informed according to the guidelines for the organisation in question.

6. Data processing

It is important to plan how data will be processed and stored. See under information on GDPR at https://staff.ki.se/gdpr-at-ki
The safest course of action is generally to enter into a data processing agreement. A template for data processing agreements for student work is included as Appendix 2 to this paper.
One alternative for work performed within the framework of an existing research project is to link the student and their project to the KI ELN electronic notebook.
If student work involves data collection in collaboration with foreign universities or other partners, please refer to KI's Ethical Guidelines for International Collaboration: https://ki.se/en/staff/ethical-guidelines-for-international-collaboration

WHAT TO CONSIDER WHILE CONDUCTING A PROJECT

1. Remain responsive to any changes in research subjects' consent during data collection.

2. If you make any changes during the working process, always check that the changes remain within the framework of the informed consent.

3. Keep a log of the working process itself in order to demonstrate compliance with ethical agreements and guidelines. Use your own document, a diary or KI ELN.
https://staff.ki.se/ki-eln-the-electronic-notebook

4. Plagiarism is unethical! Presenting someone else's texts as your own is considered plagiarism and is not compatible with good academic practice. KI uses the Urkund system to check fro plagiarism. Learn more at https://kib.ki.se/en/write-cite/academic-writing/using–sources.

5. Images. Keep in mind that photographs are often copyrighted and you will need permission to use them. The same applies to diagrams and tables from scientific articles. Permission may be requested from the publishers or you can use the available copyright functions when searching for images.

6. Consider how you communicate about the work in public forums such as social media or public spaces such as public transport. Be careful and respectful to ensure that individual research subjects or groups are not recognised or offended.

7. For supervisors: be sensitive to and prepared to deal with reactions that may arise in students when meeting research subjects or in relation to ethical dilemmas.

AFTERWARDS: WHAT TO CONSIDER ONCE YOUR PROJECT IS COMPLETE

1. How can your results be communicated? Consider the utility of your results from an ethical perspective, it is important that knowledge and results are made widely available so that the knowledge has benefits.
Student work is primarily intended to teach you not only the research process but also how to present your results, including in clinical activities.

2. What is publication? Defining what constitutes a publication has become more difficult now that so much material is published digitally. Most scientific journals do however require that the studies they publish have obtained ethical approval.

Appendix

Cases 1-3 that highlight dilemmas in student work and how these have been dealt with.

Case 1

Ethical considerations in a student project

Mira, a teacher on the Study Programme in Specialist Nursing, is assigned to supervise Ylva's master's dissertation. Ylva works as a middle manager at a clinic for children and youths and is interested in studying her own organisation. Naturally, it is important to evaluate the quality in the workplace and the head of the division, who manages several units, has a positive attitude to quality management. Prior to the first supervisory meeting, supervisor Mira gives a great deal of thought to how Ylva, as a student, can deal with the ethical considerations associated with her dissertation. One such consideration is that Ylva works as a middle manager on one of the units. Mira is concerned that prospective research subjects may feel pressured to participate if they are asked to do so by a manager in the unit. Mira also gives considerable thought to who might be asked to participate, given that children are a vulnerable group and research on children is avoided if less vulnerable alternative groups are available (CODEX rules and guidelines for research, https://codex.uu.se/forskning-pa-manniskor/forskning-pa-barn/).
During the supervisory meeting, Mira and Ylva also discuss how data should be processed and stored in relation to the new data protection regulation, GDPR.

DISCUSS:
Which ethical dilemmas does the case present?

Examples of ethical dilemmas presented by the case:

- Children are a vulnerable group and research on children is generally avoided.
- Ylva works as a manager and wishes to study her own organisation.
- Processing and storing data pursuant to GDPR.

Preconditions: Students have only a limited number of weeks set aside to complete their dissertation within the framework of the course.

Examples of alternative courses of action:

- Conduct a literature study instead of an empirical study. Continue with the planned empirical study as it constitutes a quality-assurance activity that follows the clinic's guidelines and has been approved by the head of division. Ethical review (doubtful given the timeframe).
- Ask children once ethical approval is obtained. Choose an alternative group that can answer the question.
- Ask someone else to collect data. Move data collection out of the unit in which the student works as a manager.
- Use personal data as the study constitutes a quality-assurance activity that follows the clinic's guidelines and has been approved by the head of operations. Pseudonymise the data so that personal data cannot be recovered and linked to specific individuals.

What action was taken in the case in question?

An empirical study was conducted as a quality-assurance measure, with consent obtained from the parents/guardians of research subjects. Data collection was moved to a different unit within the clinic, where the student did not have a management position. The student designed an anonymised qualitative questionnaire with open questions, making it more robust in the event of drop outs than a quantitative questionnaire. After receiving oral informed consent, the student distributed the questionnaire on a predetermined date and the participants posted their completed questionnaire in a sealed box.

Case 2

Direct access to medical records

Pia regularly supervises students' degree projects at her workplace, an orthopaedic surgery unit. There is no shortage of quality-assurance work required and the students can learn and provide great benefits at the same time: a win-win situation. A review was now required of the implementation of a new type of surgical method to treat hip fractures. The intention is to give the student access to patients' medical records in order extract certain data. Qualityassurance
activities of this type, when a healthcare provider reviews the quality of the care they provide, require no ethical approval; however, following a decision by the Swedish Data Protection Authority that Pia is unaware of, the head of organisation for Pia's unit is no longer willing to allow students to access medical journals.

DISCUSS:
Which ethical dilemmas does the case present?

- While quality-assurance activities do not normally require ethical approval and clearly benefit the organisation, in this case the student is not a member of staff employed at the unit and has had no direct contact with patients in terms of their care. The medical records contain a great deal of other sensitive data about the patients that the student should not have access to.

Examples of alternative courses of action:

- In this case, someone directly involved in the patients' care – such as the head of organisation or, by delegation, the supervisor – may review the patients' medical records and then provide the student with pseudonymised data.
- f the patients' data cannot be pseudonymised, then consent must be obtained from each patient who will be the subject of the quality-assurance work. The patient cannot however give the student consent to directly access the medical records system.
- Collect data from the Swedish Quality Registries.

What action was taken in the case in question?

According to the guidelines issued in late August 2018, students do not have the right to direct access to medical records. Data may be retrieved via, for example, their supervisor, as was the case here.

The decision by the Swedish Data Protection Authority related to two pharmacy students in Uppsala who had been reported by a patient at a local healthcare clinic for illegally accessing data in the patient's medical records. The decision can be read in its entirety [in Swedish] on the Authority's website:
https://www.datainspektionen.se/nyheter/2018/fel-lamna-ut-patientuppgifter-till-apoteksstuderande/
Lawyers at KI and Stockholm County Council subsequently established guidelines that were published in late August 2018:

Student access to medical records

Following the decision of the Swedish Data Protection Authority of 24 May 2018 concerning the disclosure of patient data via direct access to students at Uppsala University, the following information has been prepared by the Legal Office at Karolinska Institutet in consultation with lawyers at Stockholm County Council.

When is it permitted for students be granted direct access to medical record data?

According to the provisions of the Swedish Patient Data Act and the General Data Protection Regulation, students in healthcare may access medical records data using their own login in the medical records system (direct access). This is permitted when, in the course of their work placement, they participate in actual patient care and perform tasks that are comparable to those performed by other professional practitioners at a healthcare provider.

Students may also be granted access to the medical records system if they are performing systematic quality-assurance tasks on behalf of the healthcare provider in accordance with the healthcare provider's internal guidelines for such work.

When is it NOT permitted for students be granted direct access to medical record data?

Students who are not participating in providing care or in the healthcare provider's systematic quality-assurance work do not have the right to directly access patient data and shall not be authorised to access healthcare systems containing patient data. This applies even when the student is participating in a research project for which ethical approval has been granted.
That direct access is not permitted implies that the student shall not be issued with login information so that they can access the medical records system and search for data.

Access to medical records data through the disclosure of documents

Students may be given access to medical records data through the disclosure of paper or electronic records.

The process for retrieving this data consists of three steps: the extraction of data; obtaining the consent of patients or pseudonymisation; and the disclosure of the data.

- The task of extracting relevant data may be given to a designated individual employed by the healthcare provider; for example, a supervisor or teaching physician.
- The data must then be pseudonomised so that the patient's identity is not revealed. Alternatively, the patient's consent to disclosure may be obtained. (While patients may consent to the disclosure of personal data concerning them, they cannot consent to direct access.)
- Once confidentiality has been breached, the data may be disclosed in the form of paper or electronic records.

The provisions of the Swedish Public Access to Information and Secrecy Act (SFS 2009:400) shall be applied to any such disclosure.

Case 3

The use of social media to recruit participants

Felicia is in her final semester on the Occupational Therapy Programme and is about to begin her degree project, which she will be undertaking with Juan, a medical student. They are interested in finding out more about the experiences of those with a neuropsychiatric diagnosis regarding the prescription of aids. They plan to conduct an online survey but are unsure how to go about reaching prospective participants in the study. An acquaintance of Felicia is a member of an association for people with neuropsychiatric diagnoses and they have suggested reaching out via the organisation's Facebook group. Felicia and Juan present this proposal to their supervisor, Signe. While Signe thinks this is a good idea, she has a few questions about how they intend to proceed. She wonders whether they intend to post a link themselves or if an administrator from the association will do so. She also wonders whether they have considered that they will have no way of knowing how prospective participants understand and react to the information when they conduct an anonymous online survey, given that this may be particularly sensitive for their intended target group. Felicia and Juan agree with their supervisor, Signe, on this point and say they will give the matter some thought before the next supervisory meeting. Felicia is somewhat concerned about how they will manage to identify their research subjects and receive responses to the survey in the limited time available. There initial plan was to ask for access to the association's Facebook group the next day, but it will now be at least another week before they can get started.

DISCUSS:

Which ethical dilemmas does the case present?

Possible ethical dilemmas:

- The students have no way of knowing how participants take on board the information about the study and thus whether they have given informed consent.
- The questions may provoke reactions that the students are unable to respond to as they will not meet the participants.
- The participants can be viewed as a vulnerable group that, generally speaking, should not be subjected to student work.
- Facebook: how should they handle the possibility to comment, like, etc.

What action was taken in the case in question?

The students performed the degree project as planned having obtained approval from the chairperson of the association.

- As the questions were not considered to be sensitive, after consultation the supervisor and students assessed the risk of any misunderstanding on the part of participants in the study as small. While the questions might possibly provoke negative reactions concerning flaws in following up prescriptions for aids that failed to provide support in everyday life, this risk was deemed to be small.
- As the participants were recruited from among the membership of a patient association, they were not deemed to be a particularly vulnerable group.

Karolinska Institutet is one of the world's leading medical universities. Our vision is to advance knowledge about life and strive towards better health for all.
As a university, KI is Sweden's single largest centre of medical academic research and offers the country's widest range of medical courses and programmes.
Since 1901 the Nobel Assembly at Karolinska Institutet has selected the Nobel laureates in Physiology or Medicine.

Karolinska Institutet

Karolinska Institutet
171 77 Stockholm

Phone: 08-524 800 00
ki.se/en/nvs