

# When is formal ethics review by an ethics committee required?

## Student educational exercises versus health research

### General guidelines

Research is defined as a systematic investigation designed to develop or contribute to generalisable knowledge. There is a grey area between health research projects and educational exercises regarding when such activities require formal ethics review. According to the Stellenbosch University (SU) Policy for Responsible Research Conduct,<sup>1</sup> “At SU, all research involving interaction with or observation of human subjects, or information linked to human subjects, or research involving groups of individuals, or organisations must go through a process of ethical screening and clearance.”

The following is intended as a general guideline when making such determinations. It is the supervisor’s and student’s responsibility to decide whether or not the exercise requires formal ethical clearance and to consult with HREC in this regard. Whether an exercise requires formal ethics review remains at the discretion of HREC, and HREC retains decision-making authority over each case. Regardless of whether an exercise is submitted for formal ethics review or not, all educational activities should be conducted with academic and scientific rigour. Supervisor/s and departments/divisions are responsible for ensuring that all educational activities undertaken at Stellenbosch University adhere to regulatory, institutional and faculty-related requirements, and are conducted in an ethical manner.

**Rule of thumb:** Get ethical clearance before starting the exercise. This has the advantage of being a learning experience for students, makes them aware of the ethics of conducting such exercises and, importantly, if an exercise produces interesting results, it can be disseminated – published, presented – as the exercise was conducted with ethical approval.

**Scenario 1: The exercise / activity does NOT fall under the definition of health research** (i.e. is legally exempt from review)

- As per the National Health Act (2003) and Department of Health (2015) ethics guidelines, educational exercises or research projects **that do not fall under the definition of health research** as outlined below, do not require formal ethics review by a Research Ethics Committee.
- Any exercise or project that could be **classified as health research** under the National Health Act definition **requires formal ethics review by a Research Ethics Committee:**  
“Health research” includes any research which contributes to knowledge of-
  - (a) the biological, clinical, psychological or social processes in human beings;
  - (b) improved methods for the provision of health services;
  - (c) human pathology;
  - (d) the causes of disease;
  - (e) the effects of the environment on the human body;
  - (f) the development or new application of pharmaceuticals, medicines and
  - (g) the development of new applications of health technology.
- If an exercise / project **does not** fall under this definition of health research, then it probably does not require formal ethics review by a Research Ethics Committee.
- Examples of such **exercises that are exempt from formal ethics review** include:
  - Systematic reviews using information that is available in the public domain;
  - Research involving the collection of study of existing data, documents, records and/or pathological specimens that are already in the public domain;
  - Research on commercial cell lines.
- If in doubt about whether the exercise falls under the definition of health research, it is **always advisable to consult with HREC** regarding whether the exercise should be submitted for review. There may be certain kinds of research – such as health-related ethics research – that would still require formal ethics review by HREC.
- Supervisors of such student exercises are nonetheless strongly advised to ensure that the activities involve minimal risk<sup>2</sup>, and that supervisors are providing on-site supervision during the exercise to ensure that it is being conducted ethically, and to mitigate risks.

<sup>1</sup> [http://www0.sun.ac.za/research/assets/files/Policy\\_Documents/POLICY%20FOR%20RESPONSIBLE%20RESEARCH%20CONDUCT%20AT%20STELLENBOSCH%20UNIVERSITY.pdf](http://www0.sun.ac.za/research/assets/files/Policy_Documents/POLICY%20FOR%20RESPONSIBLE%20RESEARCH%20CONDUCT%20AT%20STELLENBOSCH%20UNIVERSITY.pdf)

<sup>2</sup> **Minimal risk research:** the probability and magnitude of harm or discomfort anticipated in the research, is not greater, in and of itself, than that ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests. \*Be aware, too, of risks related to vulnerable populations, such as children or patients with mental disabilities.

**Scenario 2: The exercise / activity falls under the definition of health research BUT the findings will not be publicly presented or published outside of the classroom environment**

- As seen above, **health research is quite broadly defined** in the National Health Act, and quality assurance/improvement activities or related educational exercises that involve health facilities or systems, medical records and databases, and/or health-related diagnostic or interventional projects involving individuals or communities, may **qualify as health research** and therefore require formal ethics review.
- The Faculty of Medicine & Health Sciences at Stellenbosch University makes allowances for students to engage in *educational exercises* that **may qualify as health research** under the National Health Act (2003), as defined above.
- The *only* circumstances in which such exercises *may* be exempt from formal ethics review is when all three of the following conditions are met:
  1. The intention of the exercise is for educational purposes only **AND**
  2. There is no intention to present the findings of the research outside of the classroom environment **AND**
  3. There is no intention to publish the findings of the research.
  4. The burden placed on participants (data subjects) is low i.e the data collection activity is low risk and ethical principles of research such as informed consent, protection of privacy and confidentiality will be adhered to.
- Supervisors of such student exercises are nonetheless strongly advised to ensure that the activities involve minimal risk<sup>2</sup>, and that supervisors are providing on-site supervision during the exercise to ensure that it is being conducted ethically, and to mitigate risks.

**Scenario 3: The exercise / activity falls under the definition of health research AND there is an intention to publicly present or publish the findings outside of the classroom environment**

- Many undergraduate activities or exercises provide **interesting and valuable results** that may be worthy of publication. In some cases, it may in fact be unethical not to make valuable findings publicly known. Proof of ethical clearance will be required for publication or presentation and this cannot be given retrospectively.
- In these situations, where findings of exercises that fall under the definition of health research will be publicly presented or published beyond the classroom environment, **prospective ethics review** is required prior to commencement of the exercise.

**What are the fundamental ethical starting points or principals that need to be considered when deciding to class an activity as either 'research' or an 'educational exercise'?**

- It is only ethical to expect people to participate in research, during which they assume certain risks (including psychological or social risks such as stigmatisation) if the research is going to have either direct or indirect (future) benefits for patients or society in general.
  - In order to ensure an appropriate balance of risks versus benefits for participants, it is thus necessary for a Research Ethics Committee to formally review the research before it begins.
  - Research participants are used as 'a means to an end'. This can be justifiable if the research provides some value either to participants, similar persons in the future, or leads to improvement in health systems from which current or future participants stand to benefit.
  - When participating in an educational exercise participants are being used as a means to an end- that end involves training a new generation of health care workers and future researchers; this end is justifiable if the cost/risk/ burden to participants is kept to a minimal. If the results of educational exercises or research projects are not made public in any way, then there is no risk of exposure to potential risks such as identification and stigmatisation but there also no or limited opportunity for social benefit.
  - Hence it is essential that supervisors and their students think carefully before deciding that something that involves the systematic collection of data from humans is an 'educational exercise' and not research.
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