FACULTEIT PSYCHOLOGIE EN PEDAGOGISCHE WETENSCHAPPEN

GENERAL ETHICAL PROTOCOL FOR SCIENTIFIC RESEARCH AT THE FACULTY OF PSYCHOLOGY AND EDUCATIONAL SCIENCES OF GHENT UNIVERSITY

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Ethical Committee

Faculty of Psychology and Educational Sciences

UNIVERSITEIT GENT

CONTENTS

1 INTRODUCTION

Mission statement

The ethical committee (EC) of the Faculty of Psychology and Educational Sciences aims to promote ethical awareness and ethical reflection throughout the entire research process. The EC implements its mission in a combination of a procedural and reflexive approach.

The ethical committee applies a **procedural approach** to research ethics by providing a General Ethical Protocol. The General Ethical Protocol provides professional codes of conduct that serve as principles for researchers to adequately deal with, for example, informed consent, confidentiality, rights to privacy, and the protection of human subjects from harm. The General Ethical Protocol also describes in which instances the submission of a Specific Ethical Protocol is recommended. Rather than implementing a controlling institutional review procedure, the General Ethical Protocol aims to serve as a point of reference for researchers in the development of a more reflexive ethical awareness throughout their entire research project.

The ethical committee thus also applies a **reflexive approach** to research ethics by enabling researchers to motivate, and reflect upon, why they make certain choices during their research process. A reflexive approach deals with lived research ethics, with reference to an ethical awareness and ethical reflection in a wide diversity of research practices. Since one representative of each department of the faculty serves as a member in the committee, the ethical committee aims to function as a forum for open-minded reflection and debate when exceptions to the rules are legitimate or in the case ethical dilemmas and complexities emerge in specific research projects.

In order to improve communication and foster a reflexive approach, the EC will hold regular **Ethics Clinics**, which involves some members of the Ethical Committee. Researchers who apply for an SEP or want advice on ethical complexities can informally discuss the ethical aspects of the research project of the researcher(s) with members of the Ethical Committee. This discussion can take place at all stages of the research, for instance,

- while designing the research project;
- after a decision has been made by the Ethical Committee regarding an application for a Specific Ethical Protocol;
- during or after the execution of a research project, if problems or concerns arise.

While the Ethics Clinic is mostly a place where researchers and members of the Ethical Committee informally discuss a research project and try to find solutions to potential problems, the formal decisions are taken by the Ethical Committee.

The Ethics Clinic meets 2-3 times a year (the dates are announced on the website of the faculty) but can always be organized by appointment with members of the EC.

Applicability

This protocol concerns scientific research with human subjects in the field of psychology, educational sciences, social work and social pedagogy.

If the research project has a medical nature, the act of 7 May 2004 concerning experiments on human beings applies and the researcher has to present the project to a *medical ethical committee*, i.e. a committee complying with the regulations of subsection 4 of section 2 of this law.

In addition, regardless of professional standing of the person conducting the research (clinical psychologist or other), advice from a medical ethical committee must be sought if the research "has the goal or is suggested to have the goal to test, in a human participant and within a scientific setting of a clinical psychological framework, the prevention, the research, the detection or setting of a clinical psychological diagnosis of real or imagined psychological or psychosomatic suffering and treating or counselling of that person" (Wet Uitoefening Gezondheidszorgberoepen 2015, art. 68/1, § 3).

Also regardless of the professional standing of the person conducting the research (clinical orthopedagogue or other), advice from a medical ethical committee must be sought if the research is within the scientific framework of clinical orthopedagogy and is to perform autonomous actions that prevent, detect, and diagnose pedagogical diagnostics with special attention to contextual factors and the detection of problems related to education, behaviour, the development or learning of persons as well as the treatment and guidance of those persons *(Wet Uitoefening Gezondheidszorgberoepen 2015, art. 68/2, § 3).*

Applying to a medical ethical committee is also necessary in the following cases:

- When medical devices with potential health risks (e.g., MRI, TMS, TDCS) are used;
- When drugs, placebos, or other substances are administered to participants;
- When human body material is being sampled
- In case of recruiting or using client data of UZ Ghent patients, other hospitals, health insurance agencies.

In case of research with animals, advice must be sought from a veterinary ethical committee, i.e. a committee complying with the regulations of section 8, art. 21 of the law regarding the protection and well-being of animals (Wet betreffende de bescherming en het welzijn der dieren, 1986).

2 ETHICAL BASIC ASSUMPTIONS CONCERNING RESEARCH AT THE FACULTY OF PSYCHOLOGY AND EDUCATIONAL SCIENCES.

2.1 In general

1. Researchers design, conduct and report on research according to the accepted criteria of scientific and ethical behaviour. They adhere to the principles of research integrity[1] and they follow good research practices. For general resources on good research practices: www.ugent.be/intranet/en/research/organisation/research-integrity , www.equator-network.org/library/research-ethics-publication-ethics-and-good-practice-guidelines or archives.esf.org/fileadmin/Public_documents/Publications/ESPB10.pdf
2. Researchers design, conduct and report on research in a way that does not contravene (Belgian) law or EU law.
3. When preparing their research project, researchers examine the acceptability of the research with respect to these general basic ethical assumptions. In case of any doubt, they should contact the Ethics Clinic for a first informal advice or the faculty's Ethical Committee for a formal advice.
4. Researchers are also responsible for deciding whether an application for ethical approval is necessary and whether the research adheres to the general ethical protocol for all research under their supervision (i.e., PhD students, master students, volunteers, etc). In case of doubt, supervisors can consult the Ethical Committee. The supervisors, however, cannot be held accountable for ethical violations without their knowledge and committed by the student.
5. Researchers only carry out those tasks for which they have received a proper training and preparation.
6. As the occasion arises, researchers see to it that they have received the prior permission of any third party involved in the research project, such as host institutions or other relevant organizations, and, if necessary, that they provide additional information concerning their research project. They conduct their research according to the principles of this protocol and the research protocol approved by the host institution or organization.
7. A member of the Ethical Committee, in whatever capacity taking part in a protocol, cannot be seated as a member of the Committee examining this very protocol. However, he/she can be heard, like any other researcher, if the Committee judges it necessary to do so.

[1] See e.g. The European Code of Conduct for Research Integrity (2017) revised edition, ALLEA - All European Academies.

2.2 Research involving participants[1]

8. Researchers treat participants with respect and take measures to ensure that the rights and the wellbeing of the participants or anyone else involved in the research, are not violated or damaged. During their professional relationship they do not use methods that affect the dignity of the people involved, or that enter deeper into their private life than is strictly necessary for the research. Researchers see to it that they respect all that has been agreed upon with the participants.

9. If researchers want to involve participants with specific difficulties, or (potentially) provoking specific difficulties, they will acquaint themselves with these difficulties and will consult with competent experts if deemed necessary.

10. The research project is designed in such a way that risk on psychological and/or physical harm/injury are reduced to a minimum –bearing in mind the biological, psychological and social conditions of the participants– and that both risk threshold and the degree of pressure are specifically defined and regularly adjusted.

11. This also implies that if the mentioned risks are too high, the research project cannot be conducted if the effectiveness of alternative safer methods is comparable to obtain the same results.

12. Researchers inform participants in writing that their participation will take place on a voluntary basis and that they can refuse to participate or end their participation without a necessity to explain why. They inform, in writing, future participants in a way they comprehend the nature of the research project and determining factors that could have an impact on their willingness to participate (e.g. risks, inconveniences, adverse consequences or limitations to confidentiality). They explain all other aspects the future participant could ask for. Before the actual research project starts, researchers give all relevant information. The participants confirm that they have received that information ('informed consent'). In certain specific situations (e.g., research involving questionnaires, research with participants that cannot give their consent in writing or do not want to do so), one could deviate from this written confirmation and motivate one's decision in the SEP. Researchers will guarantee an adequate and timely debriefing after the study has ended and will also try to rectify obvious misconceptions of the participants.

13. If participants are in one way or another subordinate to them (students, clients, staff,...), researchers take all necessary precautions to protect the participants against potential adverse consequences of ending or refusing participation.

14. Minors can participate in research projects to obtain data that aim at or allow a better insight into a better education, well-being, therapy and/or social contact, or a better insight into the perspectives and experiences of these participants. This can happen on the condition that the burden on the participants is minimal. Minors aged 13 or more sign an active informed assent. Minors younger than 13, to the extent of their comprehension, are informed about the project, are involved in the decision on participating in an experiment, and sign an active informed assent.

15. For minors younger than 16, active informed consent is given by the parents (with parental authority) or the guardian. In conditions where active informed consent from the parents is not possible or desirable (e.g. if parents or a tutor are not available, if the relationship with the parents is broken, ...), the consent of the parents or the guardian can be restricted to a passive informed consent, provided this is well motivated by the researcher in the SEP application. However, researchers should ensure that the form does reach the guardians (e.g., via smartschool rather than flyers). For minors aged 16 or more, passive informed consent from the parents is acceptable and the minors give informed consent. Nevertheless, depending on the circumstances, active informed consent from the parents may be desirable.

16. If the research project is conducted in a host institution or school, a written informed consent is also necessary from the school. In this case, the host institution is also responsible for the participants and has the right and the duty to end any participation in the minor's interest when it considers this necessary.

17. The ethical committee provides standard informed consent forms for researchers on the faculty website, which researchers should use. Researchers who wish to deviate from the suggested informed consents need to submit an application to the ethical committee with a specific ethical application (SEP) to motivate the deviation. Within the research context, it is

[1] Participants in the meaning of human test subjects (e.g. behavioural sciences), respondents (e.g. in oral interviews, written questionnaires, etc.), as well as informants (e.g. in case studies).

sometimes necessary to rephrase some items (for children, non-native speakers, people with mental health problems, people with disabilities, etc.). However, if the meaning of the item stays the same and if no items are deleted, then there is no need to submit an application to the ethical committee.

18. For adults who are unable to provide informed consent for participation in research, it is necessary to obtain the consent of the legal representative. For those adults who fall under the statute for extended minor or who are declared unable, the parents or legal guardian will be able to provide consent for participation in research. With adult participants who do not fall within the previous section, the right to agree to participate in research is exercised by the cohabiting husband or wife, the legally cohabiting partner, or the actual cohabiting partner. Failing these, the right is exercised in the following order by: an adult child, a parent, an adult brother or sister of the future participant involved. If adult brothers or sisters become divided, the informed consent is considered not to be given. Researchers who wish to deviate from this need to submit an application to the ethical committee with a specific ethical application (SEP) to motivate the deviation. In any case, to the extent of their comprehension, adult participants have to be involved as much as possible in the decision on participating in research and they are informed about the risks and benefits thereof.

19. When, as to attract participants, professional services (e.g. therapy or education) are offered in return for participation in a research project, researchers should clearly explain the nature of these services, as well as the risks, the obligations and restrictions, and record it in writing together with either the participants or the host institution responsible, if the research project fits in with the assignment of the institution.

20. Researchers do not present inappropriate (be it financial or other) gifts to attract participants. An inappropriate gift is for example a gift that exceeds the reimbursement of travel expenses and that does not stay in proportion to the time donated. Larger gifts can be motivated, however, in the SEP. In general, the reimbursement scheme should follow three principles: transparency (the participant is fully informed about the payment scheme), uniformity (the same rule applies to all), and autonomy (the participant is free to quit at anytime and the payment scheme is not such that participants are encouraged to stay longer than they wish).

21. Researchers do not conduct research using deception unless they have determined that the use of deception is justifiable by the expected scientific, didactic or applied value of the study and when alternative procedures without deception that are as effective, are not considered to be available. When a research project is justifying deception, the Ethical Committee should be asked to agree to it in advance, by use of the Specific Ethical Protocol.

22. Researchers never mislead participants on important aspects that influence their willingness to participate, such as physical risks, inconveniences or negative emotional experiences, unless this can be justified by arguments regarding the future scientific, didactic or applied value of the study.

23. Any form of deception being a substantial characteristic of the design and the conduct of a research project needs to be explained to the participants as soon as possible, preferably before the end of their participation and at last at the end of the research project.

24. If scientific or human values justify withholding pieces of information or spreading them later, the researchers take all measures appropriate to restrict the resulting risks of damage as much as possible. Researchers inform participants about this previous to the start of the research project.

25. Should unexpected (adverse) effects occur that are ethically undesirable, during or as a consequence of the research project, these events will be immediately reported to the Ethical Committee. The committee will then discuss appropriate actions/improvements with the researcher.

2.3 Research using personal information[1]

26. The legal framework for the processing of personal data and confidential information is determined by:

- the General Data Protection Regulation (GDPR).

[1] Guidelines for the classification of information and data: https://www.ugent.be/en/facilities/ict/information-security/classification-data.pdf

- Belgian privacy legislation, in particular the Law of 30 July 2018 ("kaderwet") on the protection of privacy with regard to the processing of personal data, together with all amendments and implementing decrees.

27. All researchers who work with personal data or confidential information are expected to take note of and comply with the 'Generic code of conduct for the processing of personal data' (https://www.ugent.be/intranet/en/regulations/code_of_conduct/at_download/file).

28. Researchers respect the participant's privacy. All data (both digital and non-digital, e.g., photo, video, and audio recordings) containing personal information must be secured. If data are shared, the researchers take measures to protect the participants' privacy. For university guidelines see "working with personal data and confidential information in a secure manner" (https://www.ugent.be/en/facilities/ict/information-security/overview.htm).

29. Only personal information relevant to the aims of the research project can be collected.

30. The legal ground for processing personal information is obtained by informed consent. Consent to the processing of personal data about the participant should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the participant's agreement.

31. Participants have the right:

    - to be informed about which, how, why and when their personal data is processed
    - of access to their personal data; of rectification of their personal data; to demand a restricted processing of their personal data; to data portability of their personal data. However, if the exercise of the right is likely to render impossible or seriously impair the achievement of the research objectives, an exception can be motivated.
    - to erasure (the 'right to be forgotten'). However, If the exercise of the right is likely to render impossible or seriously impair the achievement of the research objectives, an exception can be motivated.
    - to object to (a part of) the processing of their personal data.
    - not to be subjected to automatic decision making / profiling.

32. Under the GDPR, all projects processing personal information are legally required to be registered into the UGent register of processing activities. Instructions on how to do this can be found at onderzoektips.ugent.be/en/tips/00001795 .

33. Data and accompanying documentation from research projects will be stored for a minimum of five years after 1) achieving the aims for which the data have been collected, 2) the project funding has ended and/or 3) the data have been published/reported (the latest of the three dates applies). See section 11.1 in https://www.ugent.be/nl/onderzoek/datamanagement/beleidskader-rdm.pdf . Sensitive personal data that cannot be anonymized must be deleted after 5 years.

34. In some cases, in compliance with all other sections of this protocol, 'informed consent' may not be necessary, e.g. for field observations without manipulation, interaction and collection of personal information.

2.4 Reporting on research

35. Researchers do not invent, modify, or delete relevant data or falsify results. 'Inventing' does not include simulation if it is presented as such. When results are made public researchers have the duty to account for the realization of the data set presented.

36. If researchers discover important mistakes in the data they have published, they take appropriate action to correct these mistakes by a rectification, a retraction, an erratum or another suitable publication.

37. Researchers do not present data that already have been published as original data. This does not exclude a new publication of data, e.g. for secondary analyses, as long as this is explicitly stated in this new publication.

38. Researchers can only be held responsible for the work that they have done or to which they have contributed. Only in that case they can be called the (co-)author and they can claim this work

39. First authorship and coauthorship reflect the scientific or professional contributions of the persons involved, no matter their relative status. The mere possession of an institutional title such as head of department does not justify any authorship. Small contributions to the research project or the publication should be acknowledged in a proper way, e.g., in a footnote or an introduction. For more details see, for example, American Psychological Association (APA) guidelines on authorship.

40. A PhD student is usually mentioned as the first author of every paper with multiple authors that is substantially based on the student's dissertation research.

41. Researchers who have to assess publications of research proposals respect the confidentiality and the intellectual property of the person entitled.

42. Researchers see to it that, if no other agreements with the persons involved have been made, any possible recognition of the participants in the report is excluded.

3 APPLYING TO THE ETHICAL COMMITTEE

3.1 Application for bundled studies

If researchers plan to conduct a line of closely-related studies, the authors may submit these in the SEP as "bundled studies". "Bundled studies" are studies in which the same task or procedure is used but is conducted with minor variations. Such minor variations can be for example changing the parameters or the type of stimuli in an experimental task, changing the modality, recruiting different nonclinical populations (e.g., first only one sex then another or different age cohorts).

3.2 Amendments

If researchers want to conduct a closely-related follow-up study of a project that was already approved by the ethical committee, or want to make changes to their current protocol, they can submit an amendment. Examples here can be recruitment of another group on the same task or procedure or a substitution of stimuli (e.g., happy faces for angry faces) or changes in researchers involved. In order to submit an amendment, please modify the original SEP, highlight all changes in color (or using track changes) and send the amended SEP to the Ethical Committee. Please mention the reference number of the original proposal.

3.3 When is an application necessary?

Approval of a *medical ethical committee* or *veterinary ethical committee* must be sought in any of the cases mentioned in the introduction.

In any of the following cases below, it is necessary to ask the approval of the *faculty's Ethical Committee* by means of the Specific Ethical Protocol.

- In case of deception (see 21);
- In case of research with minors (see 15);
- When the research concerns vulnerable populations (e.g., prisoners, children with a disability, schoolchildren or persons in a dependent situation);
- When the research is likely to result in pain or more than mild discomfort;

- When using psychophysiological measures as problems may arise out of these (e.g., incidental findings regarding potential health issues);
- When sensitive information[1] is being collected (such as for example race, political opinions, religious or philosophical beliefs, sexual life, trade union membership, medical information, information about suspicions, prosecutions, criminal or administrative convictions);
- When the researcher has doubts about the acceptability of his/her research.
- When 3rd parties are involved for collecting personal information.
- When external data processors are involved in the collection of personal information.

If none of the above applies, it is not necessary to ask the approval of the faculty's Ethical Committee. Nevertheless, dealing with ethical issues is always a very important part of each scientific research and it is good scientific practice to reflect on the ethical implications of one's research. The "General Ethical Protocol" always applies and the application of all regulations of the general ethical protocol is the responsibility of the individual researcher/research team.

3.4 Application

- Any application should be submitted by e-mail to the chairperson and the secretary of the EC. All necessary documents should be attached electronically.
- The application includes:
  1. the specific ethical protocol in its proper form (to be downloaded);
  2. all documents that will be presented to sign by the participants including the invitation/information letter.
  3. A copy of the data management plan (if the study requires one)
  4. A copy of the GDPR-record (when the study involves processing of personal information)
- One should take into account that there is a deadline for submission of ethical applications on the 15th of each month and that feedback can be obtained at the earliest the 15th of the following month. There is no deadline in July; all applications received between 16th of June and 15th of August will be assessed in September.
- Should the Ethical Committee have given a negative advice concerning a research proposal, a second advice can be applied for with the Ethical Committee of the Faculty of Psychology and Educational Sciences of KULeuven.

3.5 Statements about ethical concerns in publications

If a research is approved by the Ethical Committee, then the following sentence can be added to the publication reporting this research:

> *The research was approved by the Ethical Committee of the Faculty of Psychology and Educational Sciences of Ghent University.*

If a research has not been submitted to the Ethical Committee but is complying with the *General Ethical Protocol*, then the following sentence can be added to the publication reporting this research:

> *The research was conducted according to the ethical rules presented in the General Ethical Protocol of the Faculty of Psychology and Educational Sciences of Ghent University.*

In exceptional cases, if a researcher did not submit an SEP for a research project, they may ask for a waiver after the completion of the research. If the research complies with the ethical rules presented in the General Ethical Protocol, the ethical committee will deliver a waiver and the following sentence may be used:

> *The Ethical Committee of the Faculty of Psychology and Educational Sciences of Ghent University has confirmed that the research was conducted according to the ethical rules presented in its General Ethical Protocol.*

If no waiver is given, the authors cannot say anything regarding approval of the ethical committee.

[1] Guidelines for the classification of information and data: https://www.ugent.be/en/facilities/ict/information-security/classification-data.pdf