

GENERAL ETHICS PROTOCOL

For scientific research at the
Faculty of Psychology and
Educational Sciences of Ghent
University

FPPW Ethics Committee

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1 INTRODUCTION

1.1 Mission statement

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

The Ethics Committee thus also applies a **reflexive approach** to research ethics by enabling researchers to motivate, and reflect on, why they make certain choices during the research process. A reflexive approach is concerned with lived research ethics, with reference to an ethical awareness and ethical reflection in a wide diversity of research practices. With a representative from each faculty department serving in the committee, the Ethics Committee aims to act as a forum for open-minded reflection and debate when exceptions to the rules are legitimate or when ethical dilemmas and complexities arise in specific research projects.

1.2 Applicability

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

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

In addition, regardless of professional status of the person conducting the research (clinical psychologist or otherwise), advice from a medical ethics 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 the treatment or counselling of that person” (Wet Uitoefening Gezondheidszorgberoepen 2015, art. 68/1, § 3).

Also regardless of the professional status of the person conducting the research (clinical orthopedagogue or other), the advice of a medical ethics 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 ethics 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 (e.g. alcohol) 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 ethics 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).

1.3 Ethics Clinics

In order to improve communication and foster a reflexive approach, the EC will hold regular **Ethics Clinics**, in which some members of the Ethics committee will participate. Researchers applying for an SEP or seeking advice on ethical complexities can informally discuss the ethical aspects of the their research project with members of the Ethics Committee. This discussion can take place at any stages of the research, for instance:

- while designing the research project;
- after a decision has been made by the Ethics committee regarding an application for a Specific Ethics 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 Ethics Committee informally discuss a research project and try to find solutions to potential problems, the formal decisions are made by the Ethics Committee.

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

2 ETHICAL BASIC ASSUMPTIONS CONCERNING RESEARCH AT THE FPPW

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 integrity¹ and they follow good research practices. For general resources on good research practices, ethics and integrity, see the following webpage:

– <https://ugentbe.sharepoint.com/sites/intranet/SitePages/en/Themes.aspx?termId=19a9fe9d-d2b4-4c1f-aaec-540b75f74355>

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 Ethics committee for a formal advice.
4. Researchers are also responsible for deciding whether an application for ethical approval is required and whether the research complies with the General Ethics Protocol for all research under their supervision (i.e., PhD students, master students, volunteers, etc). Applications for approval of Master's theses are submitted by the supervisor. There are no separate ethical standards or procedures for Master's theses.

In case of doubt, supervisors can consult the Ethics 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 ensure 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 Ethics Committee, in whatever capacity taking part in an application, cannot be seated as a member of the review panel examining this very application. However, the member can be heard, like any other researcher, if the Ethics Committee judges it necessary to do so.

¹ See e.g. The European Code of Conduct for Research Integrity (2023) revised edition, ALLEA - All European Academies.

2.2 Research involving participants¹

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 intrude more deeply into their private lives 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 the risk of psychological and/or physical harm/injury is reduced to a minimum, taking into account the biological, psychological and social conditions of the participants, and that both the risk threshold and the level of pressure are specifically defined and regularly adjusted. When an intervention is applied, special attention must be paid to effects that could extend beyond the duration of the experiment or intervention.
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 try to correct any obvious misunderstandings 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 Ethics 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

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).

Ethics Committee with a specific ethical application (SEP) to motivate the deviation. Within the research context, it is 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 Ethics 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. In case of disagreement between adult siblings, the informed consent is considered not to have been given. Researchers who wish to deviate from this need to submit an application to the Ethics 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 offer inappropriate (financial or otherwise) rewards to attract participants. An inappropriate reward is for example a gift that exceeds the reimbursement of travel expenses and that does not stay in proportion to the time donated. Larger rewards 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 Ethics Committee should be asked to agree to it in advance, by use of the Specific Ethics 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, but no later than at the end of the research project.
24. After explaining the deception, the researcher again asks for the participant's informed consent. The researcher emphasises that refusal to consent will not affect the relationship between the participant and the researcher, nor will it affect any remuneration or compensation (if applicable). If the researcher deems it impossible or undesirable to ask for informed consent again, this should be motivated in the Specific Ethical Protocol
25. 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.
26. 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 Ethics committee. The committee will then discuss appropriate actions/improvements with the researcher.

2.3 Research using personal information¹

27. The legal framework for the processing of personal data and confidential information is determined by:
 - the General Data Protection Regulation (GDPR).
 - 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.
28. 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/en/ghentuniv/privacy/code-of-conduct-personal-data.htm>).
29. 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 : <https://www.ugent.be/en/facilities/ict/information-security/overview.htm>.
30. Only personal information relevant to the aims of the research project can be collected.
31. The preferred legal ground for processing personal information is 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.

In exceptional circumstances, however, one might consider basing the lawful processing of personal data on the legal ground of 'public interest'. However, a detailed justification as to why this is necessary must be provided. The procedure for using public interest as a legal ground is described [here](#).

Depending on the complexity of your file, the procedure to use public interest can significantly delay the processing of your application to the EC. It is therefore a good idea to contact the Ethics Committee before submitting your file.
32. 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.
33. Under the GDPR, all projects processing personal information are legally required to be registered into the Ghent University register of processing activities. Instructions on how to do this can be found at <https://onderzoektips.ugent.be/en/tips/00001795/>.
34. All relevant 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 the [Ghent University Policy Framework on Research Data Management](#).

¹ See Research Tip “What are personal data?” <https://onderzoektips.ugent.be/en/tips/00001781/>

35. As a matter of good practice, personal data is pseudonymised and, if possible, anonymised. This is done as soon as possible after the data are collected. Sensitive personal information that cannot be anonymised, is preferably deleted after the five-year retention period.
36. 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 Research with FPPW students as part of their education

2.4.1 Research involving the collection of data from students.

37. Participation in scientific studies as part of a course unit can be seen as an educational activity ("practicum") in which students acquire skills and competences necessary for their education.

Students cannot withdraw from necessary activities that are part of the programme of study, their training and its evaluation if they want to fulfil the conditions of that programme of study. Therefore, as a rule, permission from the students involved is not required for education-related activities. This is regulated in the OER

38. However, there is an exception to this rule. If the data collected from the student-participant are further processed in the context of scientific research, the status of the research is twofold: it is both an educational and research-related activity. In that case, the student must be asked for permission to participate in the research and for the (further) processing of his or her personal data in the context of scientific research. If this permission is not obtained, the lecturer has two options:
 - a) The educational activity takes place but without further processing of the data collected outside the educational context.
 - b) The student is given an alternative task (no participation in research) which allows him/her to earn the same course credits.

In the framework outlined above (37 and 38), the Faculty imposes the following additional conditions (39-46).

39. When students participate in research in the framework of a course unit, it must add value to the acquisition of one or more competences related to the programme. This implies that students are informed about the research questions, the theoretical framework(s), the method and, if possible, the results of the research in which they are participating.
40. If participation in research is part of a course unit, this is mentioned in the ECTS sheet.
41. Before the start of the study, students are informed about the nature of the study and about important factors that may influence their willingness to participate. They are given one of the following choices:
 - a) Between participation in the research or participation in the educational activity without further processing of the collected data;
 - b) Between participation in the study or an alternative task.

The responsible lecturer decides which choice applies. The students are informed clearly and timely about the relevant choice (e.g. during the explanation of experiment participation).

Care is taken that the student's choice is free. This means that they do not have to motivate this choice and it is made clear to them that this choice has no negative consequences for them. Permission to participate in the study is obtained using the standard ICF template of the FPPW Ethics Committee.

42. If an alternative task is offered, it must fit within the competences of the programme. The scope and content of the alternative task shall be proportionate to the participation in the study.
43. The responsible lecturer shall ensure that the student does not end up in an unacceptable position of dependence on the responsible lecturer and/or test leader.

44. When students participate in a study, all conditions for obtaining credit are clearly and explicitly stated in advance in the information letter (E.g. the student must answer at least 80% of the questions, or the student must participate in all three phases of the study, or the student must correctly identify the target in at least 60% of the trials, etc.).
45. The lecturer shall not attempt to discover the identity of students on the basis of the data collected, unless this is necessary for the purposes of the research. Preferably, the data collected shall be anonymised and at least pseudonymised as soon as possible. If the identification of the student concerned is unavoidable, this will in no way affect the assessment or supervision of the student.
46. When students have complaints, they can appeal to the Faculty Ombudsperson. If the Ombudsperson deems it necessary, the complaint is dealt with in consultation with the OC, the EC and the Faculty Board. The possibility to file a complaint and the procedure are clearly communicated to the students timely (e.g. in the information letter, on SONA, ...).

2.4.2 Research in which data are collected by students.

47. Within the framework of a course unit, students are sometimes required to carry out research themselves (e.g. the Master's thesis). In doing so, they are sometimes engaged for specific aspects of the research: recruitment, data collection or data analysis. The resulting data are sometimes (but sometimes not, e.g. assignment of practicals) used for ongoing research projects in the lecturer's department.

In such assignments, lecturers are expected to take the APA ethics code (2017) into account, as well as the document Ethics in Social Science and Humanities (EU, 2018) and our General Ethics Protocol. For example, the following situations may lead to problems:

- a) If a student asks her best friend or her grandmother to participate, they can hardly refuse. It is therefore difficult to guarantee 100% voluntary participation in the case of recruitment in one's own network.
 - b) Students receive personal (sometimes sensitive) information about family members or friends.
48. The Ethical Committee acknowledges these concerns but does not consider it necessary to impose specific rules to avoid them. However, the Ethical Committee encourages all faculty members to take the above concerns into account when engaging students in research. Below are some of the measures currently used by researchers at our faculty to avoid one or both of the above issues.
 - Students may not recruit from their own network but only via via (solution for a and b).
 - Students are encouraged but not required to recruit (partial solution to a).
 - No personal data are collected (b).
 - Student A processes data of a person recruited from student B's network by student B.

This list is not exhaustive and other measures are certainly possible.

49. Irrespective of the above concerns (a and b), it is necessary that the involvement of students offers added value for them to acquire one or more competences of the programme. This implies that students are briefed on the research questions, the theoretical framework(s), the method and, if possible, the results.

2.5 Reporting on research

50. 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.
51. 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.

52. 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.
53. 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
54. 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.
55. 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.
56. Researchers who have to assess publications of research proposals respect the confidentiality and the intellectual property of the person entitled.
57. 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 ETHICS COMMITTEE

Only research projects involving at least one researcher from AUGent will be evaluated by the Ethics Committee.

3.1 When is an application necessary?

Approval of a *medical ethics committee* or *veterinary ethics 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 Ethics committee* by means of the Specific Ethics Protocol.

- In case of deviation from the GEP;
- In case of deception (see 21);
- When the research concerns vulnerable populations (e.g., prisoners, children with a disability or persons in a dependent situation);
- When the research is likely to result in pain or more than mild discomfort;
- When incidental findings (relating to mental or physical health) are likely;
- When sensitive information¹ 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 (except when the external data processor is Qualtrics or Microsoft and the researcher uses a Ghent University account).

If none of the above applies, it is not necessary to ask the approval of the faculty's Ethics 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 Ethics Protocol" always applies and the application of all regulations of the general ethics protocol is the responsibility of the individual researcher/research team.

¹ Guidelines for the classification of information and data: <https://codex.ugent.be?regid=REG000272&lang=en>

If relevant, the application may be submitted to another ethics committee (e.g. if the research is a collaboration with another faculty, university, hospital or institution).

3.2 Application

All the details of the application procedure can be found on the following web page:

<https://www.ugent.be/pp/en/research/ec/overview.htm#Applyingforethicalapproval>

3.3 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 non-clinical populations (e.g., first only one sex then another or different age cohorts).

3.4 Amendments

If researchers want to conduct a closely-related follow-up study of a project that was already approved by the Ethics Committee, or want to make changes to their current protocol, they can submit an amendment insofar as the changes do not have ethical implications. 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. This list of examples is not exhaustive.

Details of how to submit amendments can be found here: <https://www.ugent.be/pp/en/research/ec/procedure#amendment>.

3.5 Statements about ethical concerns in publications

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

The research was approved by the Ethics committee of the Faculty of Psychology and Educational Sciences of Ghent University.

If a research has not been submitted to the Ethics committee but is complying with the *General Ethics 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 Ethics Protocol of the Faculty of Psychology and Educational Sciences of Ghent University.

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 Ethics Protocol, the Ethics Committee will deliver a waiver and the following sentence may be used:

The Ethics 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 Ethics Protocol.

If no waiver is given, the authors cannot say anything regarding approval of the Ethics Committee.

3.6 How long does an approval remain valid?

Data collection must start within two years from approval and be over within five years from approval. A new evaluation by the EC is necessary if data collection extends beyond five years. In this case, it is the responsibility of the researcher to request a new approval.