

FAQ - FREQUENTLY ASKED QUESTIONS

In which cases do I need to apply for research ethics approval?

According to the <u>Dean's Instruction 1/2018 (XI.30.)</u>, research work involving the analysis of data from humans or human subjects can only be carried out with existing ethics approval. If the research is clearly psychological, educational, or other non-health-related, the Research Ethics Committee (REC) will issue the approval. In cases where the proposed research has medical and health implications (e.g. the target population is a person with a clinical diagnosis, or the research is carried out in a health institution, or the study involves an invasive procedure - e.g. blood sampling-, or the use of medical equipment - e.g., MR machine -, the application must be submitted to the Medical Research Council. If a research project involves only the processing of literature or a systematic summary study/meta-analysis, no research ethics approval is required. Likewise, no research ethics authorization is required for the analysis of publicly available material, e.g., website content, and public postings. However, if the analysis of documents (also) containing personal data (e.g., historical or archival documents containing names or other personal data) is involved, an ethics application must be submitted.

How far in advance of the start of the research should an ethics application be submitted?

Applications are assessed on a rolling basis, with a lead time of around 2-4 weeks. If additional information is required, the time required for approval may be extended. This should be taken into account in the timing of planned research. The REC will not issue a permit for studies that are already underway.

Applications should be submitted at least 1 month before the research is due to start (this allows time for review, including any requests for corrections). Data collection cannot start before the application has been formally approved. The REC meets on the last Friday of each

month to discuss, among other items on the agenda, ethics applications for which further questions have arisen during the primary review.

What constitutes personal data (when to fill in the 'Privacy Notice')?

Personal data is any information relating to an **identified or identifiable** natural person ("data subject"). An identifiable natural person can be identified, directly or indirectly, in particular by reference to an identifier such as a name, number, location data, or an online identifier; or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Therefore, gender, age (only the exact date of birth), type of residence (only the exact address), and type of employment/position (only if asked to name a specific position in a specific company, for example) are not personal data per se. If the subjects are contacted by e-mail or telephone, this is personal data, and image and sound recordings are also personal data per se.

If the researchers ask for any data from the participants by e-mail, they must also ensure that these data/sensitive correspondences are deleted at the end of the survey.

However, the use of publicly available and accessible data (e.g., official, publicly available email addresses, public posts on social media, and comments) is not considered personal data processing.

Can I collect personal data in a shared Qualtrics account with the research team?

Personal data cannot be collected in a shared (e.g., research group) Qualtrics account, only in the individual account of the supervisor(s) or the named data processor. Thus, personal data is collected in the Qualtrics system, but separately from research data, to which only the data controller/processor named in the privacy notice has access. Anonymous research data can still be collected in shared accounts.

What information is required in the 'Privacy Notice'?

In the section **'Which data do I consent to the processing of**?', you should **list in detail** all the data that will be processed during the research (e.g., name, email address, voice recording, etc.).

PLEASE NOTE, the content of this document has changed slightly. If the data are processed only within the Faculty of Education and Psychology of ELTE (FEP), it is sufficient to indicate the name and contact details of the contact person (typically the name of the leader of the research). At the data processor part, it is sufficient to indicate only the name of the software or platform used to collect/store the data, and whether the data are processed by an external entity, independent of the organization, who is solely acting on behalf of the data controller.

The "Privacy Notice" should also specify which platform, program, or application you use to collect and/or store personal data (e.g., Qualtrics, MsTeams, Zoom, etc...).

Why does the REC require both a Word transcript of the questionnaire and an online link to the questionnaire?

The Word transcript of the questionnaire is needed so that the reviewer can quickly and easily review each item of the questionnaire without having to click through the online link question by question, taking into account any conditions. Also, for archiving reasons, we ask for the Word transcript, as the link will become inactive after a while. In addition, the simultaneous inclusion of the link is necessary to ensure that the questionnaire sent to the target group is exactly the same as the one indicated in the request. Also, the REC has to check the questionnaire settings (e.g., conditional questions), and in case of any deception (debriefing), the REC has to check the resolving information, etc.

What is the recommended platform for the online questionnaire? Which platform can be used to conduct online interviews?

The REC recommends in particular the Qualtrics platform for editing questionnaires. The platform supported and recommended by the university for online communication and image/audio recording is MsTeams. However, the committee does not prohibit the use of other platforms.

What should I look out for when using credits/course points as an incentive in a research project?

The applicant needs to clarify whether, in the case of course dissemination, refusing to participate in research will not adversely affect the student (e.g., whether he/she can obtain a suitable grade without participating in the research; whether, in the case of a course involving participation in research, he/she can choose from other research to obtain a suitable grade).

Does the REC only grant research ethics approval to lecturers/researchers who are in the public servant or professor emeritus positions at ELTE FEP?

If a non-ELTE colleague submits an ethics application to us because he/she is the supervisor of a FEP student, the REC will consider the application. In this case, since the applicant is not an ELTE public servant, by filling in the application approval, he/she also consents to the processing of his/her personal data by the REC. Also in this case, the research supervisor must be a researcher with an academic qualification (DSc, PhD, CSc).

Can the REC review research carried out abroad? Can non-anonymous data collection be carried out in other countries?

Research conducted in person or online, where the recruitment of participants and the collection of data (e.g., MS Teams interview) takes place outside Hungary, is considered as data collection abroad. For research conducted abroad, the REC can fully review and approve online anonymous research targeting non-vulnerable groups over 18 years of age or on non-sensitive topics. Applications for studies with participants under 18 and/or vulnerable participants will be decided jointly by the members of the committee at the committee meeting.

It is not necessary to seek permission from the country of destination for data collection abroad, the REC can decide on its own authority on the granting of permission for data collection abroad. The application should explain the potential local risks of data collection abroad and the steps that the principal investigator or the researchers conducting the research will take to mitigate them.

Is it possible to deviate from the wording of the 'Informed Consent and Description of Research' in the ethics application form?

The Committee's view is that the text of the 'Informed Consent and Description of Research' in the application template should not be taken over verbatim, it is an aid. However, the following information should be included in the text: name and e-mail address of the research supervisor (e-mail address with FEP), the purpose of the research, name of the research organizer, type of study (e.g., questionnaire or evaluation of images according to specified criteria), length of the study, whether or not there is a fee for participating in the research, the mention of voluntary participation in the study, and the mention of the possibility of withdrawal/cancellation. The statement 'not treated for neurological or psychiatric disease' should be decided by the applicant in light of the purpose of the research and the population to be studied, and should be included/excluded from the consent form, depending on this decision.

What information should be included in the recruitment text in any case?

Recruitment letters should already mention the institution where the research is taking place, but in the case of questionnaire-based anonymous research, the e-mail address in the recruitment letter is not mandatory, as the link will lead to the 'Informed Consent and Description of Research, which will include the contact details of the researcher. For qualitative or offline research, it is, of course, important to provide the official contact email address(es) in the recruitment form, but this does not have to be personal, it can be a joint research group contact (with an elte ending).

What is an umbrella application and when is it appropriate to submit such an application?

An umbrella application is an application involving several research activities within the same research area.

If, for example, the institute/department/research group is investigating a larger topic over several years, with students changing in a given semester, and always researching a smaller slice of the larger topic, it is worth considering submitting an umbrella application. The main principles for umbrella proposals are:

- For all umbrella applications, additional, specific information should be provided (e.g., what specific tools are used in that particular study, who the participants are, etc.), as without this information, we cannot ethically consider the application.
- Include the end date (not several years) in the umbrella application.
- We request renewal of applications annually. If there are no changes, the principal investigator only needs to indicate in one sentence to the REC that he/she wishes to continue the research under the same conditions and requests an extension of the application (in this case, the application does not need to be resubmitted).

Is ethical approval from the Committee for Research in Psychology also acceptable for ELTE/FEP research?

Yes.

In which cases is it necessary to submit an extension and amendment application?

An extension is required if the current approval has not expired and the researchers do not plan to change anything other than the date of completion of the research. In this case, the normal review procedure is not necessary and the extension can be granted immediately. An application for an amendment can also only be submitted if the approval is still valid, in which case the amendment will go through the normal review process. If the research approval has already expired, only a new application can be submitted, as the validity of an expired approval cannot be extended.

Technical Information:

The starting date of the research must be no earlier than the date of submission of the application.

In all cases, please include the email address/contact details of the research supervisor in the text of the recruitment letter/research call in the information and consent form.

In the 'Informed Consent and Description of Research', subjects should be given a real choice if they agree to participate in the research, and therefore both 'yes' and 'no' options should be indicated.

A detailed list of the original and Hungarian language references of the questionnaires, tests, interviews, and other measurement tools to be used in the research (or used in the research) should be provided in the application, as well as information on the translation of the new measurement tool into a foreign language.

What information should be included in the application for (quantitative) research (What questions should be asked for quantitative research?)

- How and from where the participants will be recruited and what exactly is included in the recruitment text?
- What inclusion or exclusion criteria are used to select participants for the study?
- What method is used?
- Where is the data collected?
- Is the data collection anonymous or does it include the processing of personal data? In the latter case, data confidentiality must be ensured. (Anonymous and confidential data handling mean different things. If the participant is not identifiable at all, then anonymous data collection and processing will take place. If the person is identifiable, then confidentiality means that the researcher can identify the person, but the research data (e.g., questionnaire data, heart rate, reaction time data, etc.) collected during the research is stored without the personal data being associated with it, but instead, e.g., a code identifying the person, but the code-decode is stored separately from this data, in a secure place (e.g., locked or in a password protected file).
- In the case of personal data, a 'Privacy Notice' is also required, which should also specify how long the personal (!) data will be stored.

- It should be considered whether the person can be identified from the anonymous answers collected (e.g., if we know that the participant is the director of institution x, then even if the answers are anonymous, the person can be identified so the information and data protection should be handled accordingly, i.e., the data should be kept confidential).
- Are any incentives (e.g., money, credits) applied in the research? Are there any benefits to participating in the research?
- Is there any deception in the research? If so, how is this resolved after the data has been collected? If the study is conducted in an online setting, can it be ensured that debriefing is provided to those who drop out before the end of the study?
- How long is the study itself for each participant?
- In the case of an online questionnaire, please include the link, but a copy of the full online questionnaire is also required for archiving purposes (as links 'expire').
- For offline questionnaires, please also attach the questions/questionnaires.
- The links to the questionnaires used (both the original and the English version) should be included in the application. If it is your own translation, please indicate.
- Presentation of stimulus material (if relevant): attach videos, pictures, and audio material, in the case of cognitive paradigms, the stimulus material should be mentioned, if a new paradigm, the presentation of the stimulus material should be included.
- Tailor the content of the 'Informed Consent and Description of Research' form to the specific research (e.g., if the research is carried out in an institution (e.g., in a school), please include the informed consent for the head of the institution).
- Whether there are any risks for the participants to participate in the study. If so, how is this risk managed in the research?
- How and where will the data be stored?
- Who will be involved in the data collection? If relevant, taking into account the objectives and methodology of the study, what are the qualifications and skills of the researchers and data collectors?

- Are there any questions asked in the research activity that is worth providing information to the participant after the research (e.g., at the end of the questionnaire on gambling, the participant is given information on what problem gambling is and where to go for help)?
- If during the research activity, any data is generated that is relevant to the health of the subject and has medical or psychopathological significance (e.g., suicidal ideation, epileptiform patterns in EEG, etc.), care should be taken to ensure that it is brought to the attention of the subject with due care, indicating the need for targeted screening.

What information should we provide in qualitative research (What questions should we ask in qualitative research?)

- If relevant, what qualitative paradigm is used for the study (e.g., descriptive, postpositivist, interpretive, critical)?
- How and from where are participants recruited, and what exactly is included in the recruitment text?
- What inclusion or exclusion criteria are used to select participants for the study?
- What method is used? (e.g., interview, observation, questionnaire, focus group)
- In the case of interviews or questionnaires, exactly what questions are asked and how are they constructed (what theory, ideas, empirical work have you drawn on? Did you attach the set of questions to the application? In case of observation: what do you record, how do you code?)
- Where does the data collection take place?
- Is there an audio recording, or image recording? How, with what device, and software do you record them? Have you informed the participants about this in the 'Informed Consent and Description of Research'? Did you ask for their consent to record the audio/visual recordings? In the case of an online interview, how is consent to be interviewed given?
- Participants should be given a time limit for how long they can ask for the recorded material to be deleted and withdraw from the study (e.g., 1 week after the recording,

they can still delete the recorded audio material and withdraw from the study. After that, the audio recordings will be transcribed and personal data will be deleted from the transcripts.)

- Do you plan to quote verbatim from the transcripts? Has permission been sought from participants?
- How will you ensure that the anonymity of the subjects is preserved when communicating the results? How do you ensure that individuals are not identifiable when quoted verbatim?
- Who is involved in the data collection? If relevant, from the point of view of the objectives and methodology of the study, what qualifications and training do the researchers and interviewers have (e.g., in trauma interview research, do the interviewers have sufficient knowledge and training)?
- Is there any question that the researcher's position may influence the study (data collection or even analysis)?
- Is it considered that the relationship between the investigator and the subject may influence the outcome of the study?
- Are any incentives (e.g., money, credits) applied in the research? Do they benefit from participating in the study?
- How long is the study itself for each participant?
- Tailor the content of the 'Informed Consent and Description of Research' to the specific research (if the research is conducted through an institution (e.g., school), please include a prospectus for the head of the institution).
- Whether there is any risk for the participants to participate in the study. If so, how is this risk managed in the research?
- How and where will the data be stored?
- Are there any questions asked during the research activity that the participant should be given information on after the research (e.g., at the end of the interview on gambling, the participant will be given information on what problem gambling is and where to go if they need help)?

 If, during the research activity, any information is generated about the subject's health that has medical or psychopathological significance (e.g., suicidal ideation), care should be taken to ensure that it is brought to the attention of the subject with due care, concerning the need for targeted screening.