Q&A for the preparation of an ethics application

Ethics Commission of the Faculty of Human Sciences (latest version: 06/2025)

1. Formalia

1.1 Completeness: Have all questions marked in color in checklist H of the basic questionnaire been answered sufficiently? Are all required annexes attached (see checklist G)?

1.2 Scope: If several studies are mentioned in the application: Have all studies been explained or can the opinion of the ethics committee only include one/several sub-study(ies)?

1.3 Informed Consent: Are study information and a declaration of consent for participants attached? Are these documents separate from each other? *Note: At the time of consent to participate, all relevant information must already have been submitted.*

1.4 Comprehensibility: Is the application internally consistent and the study procedure logically comprehensible? Are *all* aspects and procedures (e.g. whether it is an online study or a face-to-face survey) clear?

1.5 Stigmatization: Is the use of stigmatizing adjective-based labels (e.g., 'depressive patients') avoided in favor of person-first language (e.g., 'patients with depression')?

2. Scientific nature

Comments on scientific nature should only be made with regard to ethical issues. These relate primarily to the treatment of the study participants, e.g. the extent to which the intended or expected gain in knowledge justifies the implementation and involvement of the research participants (effort and benefit). This differs explicitly from a scientific review (in the sense of a journal review). There is therefore no assessment of the scientific nature of the subject and research area.

2.1 Knowledge gain: Are the selected data collection and analysis methods suitable for adequately addressing the research objectives? Is the implementation methodologically sound and comprehensibly described? Is the potential knowledge contribution adequately substantiated? Can (empirical-quantitative) hypotheses be successfully tested statistically? Are possible methodological artifacts identified and addressed? Can the research objectives of a qualitative study be achieved with the selected study design, planned sample, and evaluation methods? (e.g. Is theoretical saturation realistically achievable within the planned sample size? Is the study population sufficiently diverse and relevant to the research question? Is the participant selection strategy (sampling approach) adequately justified?)

2.2 Cost-benefit aspect: Is the participant burden justified by the expected scientific contribution? When involving vulnerable groups (minors, etc.): Is it necessary to include these populations, or could the research question be answered through studies with less vulnerable participants?

2.3 Sample: Are participant recruitment and selection procedures clearly described (sampling method), and are they appropriate for the research objectives? Has the planned sample size been adequately justified according to disciplinary standards? Is the sample size appropriate - neither too small to compromise scientific validity nor too large to unnecessarily burden resources and participants? For studies where sample size cannot be estimated (e.g., qualitative research with theoretical saturation): What criteria or procedures will determine when data collection is complete?

2.4 Independence: How is the study funded? Who is the sponsor/funding organization? How is research independence ensured?

3. Information for participants

3.1 Voluntariness: Are participants informed about the voluntary nature of their participation, including their right to withdraw at any time and any consequences of withdrawal? Is this voluntariness not impaired by other aspects, e.g. critical wording, special benefits for participation or otherwise denied compensation? Will you recruite participants

through other institutions/gatekeepers? How do you clarify your relative independence from them, for example? For ex-ample, how do you ensure that participants are not treated differently by these institutions/gatekeepers than non-participants?

3.2 Compensation: Do participants receive compensation for their time and expenses? If so, is this clearly specified in terms of participant hours or monetary amount? Compensation should reflect the study demands (duration, workload, etc.). For prize drawings: Are participants adequately informed about the selection procedure and timing, probability of winning, how and when prizes are distributed, if any personal data collection is required (e.g., contact details, banking information). *Note: Compensation should be viewed as time and travel compensation, not as equivalent to minimum wage.*

3.3 Compensation in the event of termination: If the study is terminated prematurely, there should be corresponding partial compensation so that there is really no disadvantage. Is this and the specific implementation communicated transparently in the information for participants?

3.4 Comprehensibility: Are the documents formulated in such a way that they are understandable for the target group? For example, are incomprehensible technical terms avoided or adequately explained when used? Is the information for the participants written in the (foreign) language or, if applicable, in the (foreign) languages of the parents of underage participants? *Note: Special efforts to ensure adequate information are required if it can be assumed that the persons included in the study cannot understand the intentions and modalities of the research project without specific information, e.g. due to their social situation, their language skills or their cultural background.*

3.5 Publication: Are the participants informed about a possible publication of their data (in anonymized form)? Are the participants informed about the possible forms of such publications? Will they be made available to the participants? Does every participant have the opportunity to receive information about the study results? *Note: The Ethics Committee recommends that the study results be published on a project website so that no personal data (e.g. e-mail addresses) are collected for information purposes.*

3.6 Debriefing: Is there a (written/oral) debriefing after participation in the study, in which the participants are informed in more detail about the objectives and procedures of the study? Note: If (passive/active) deception is planned for the study and participants are not to receive all or incorrect information about the study in advance, a debriefing is mandatory afterwards. The time of this debriefing should not be too far away (e.g. several months) from the time of participation without substantive justification.

3.7 Walks as part of the data collection: Are participants informed about existing or missing insurance cover? Are they carefully informed about possible hazards or danger points on the route?

4. Safety

4.1 Inclusion of participants: Are there inclusion or exclusion criteria for study participation? Does a risk-benefit analysis justify the inclusion of vulnerable groups of people? Are the guidelines for inclusion formulated clearly enough and are they adequately reviewed?

4.2 Exclusion of participants: Is no group of people excluded without substantive justification and thus disadvantaged? Are the guidelines for exclusion formulated clearly enough and are they reviewed appropriately?

4.3 Burden: Is there an increased psychological or physical burden for participants or researchers as a result of conducting the study? Can an increased risk for the participants/researchers be assumed at all and are they informed about it? Is the risk sufficiently justified by the gain in knowledge of the research project and would the gain in knowledge not be achieved without this burden? Is the burden on the participants/researchers proportionate to the scientific knowledge gained? Is special care taken when assessing the burden for underage participants? What measures are planned by the researchers to minimize possible burdens or risks and are these sufficient?

4.4 Deception: Is certain information about aspects of the study withheld from the participants or are they given false information? If so, is this necessary and is the benefit/scientific knowledge gain proportionate to the potential burden of deception? Is sufficient information about the deception provided as soon as this is possible from a research perspective (see 3.6 Debriefing)?

4.5 Incidental findings: If information of personal relevance emerges during the study (e.g. results of a questionnaire to diagnose a mental illness, abnormalities in physiological measurements), the participants must have agreed to provide feedback in advance (DGPS, 2018). Is personally relevant information collected? Was appropriate consent

obtained as part of the consent to participate? Is sufficient support for participants guaranteed if such information (e.g. a serious diagnosis) is collected?

5. Data protection

5.1 Personal data: Should personal data be collected and to what extent is it needed to carry out the research project? Is there a clear concept for the appropriate handling of this data? Are participants informed of their rights under the GDPR? *Note 1: All data that can lead to the unique identification of a natural person is personal data (e.g. names, e-mail addresses, student numbers, account data, IP addresses, image or sound recordings). Various pieces of information that individually or collectively can lead to the identification of a specific person are also personal data. Note 2: Personal data must be adequate for the purpose and limited to what is necessary for processing ("principle of data minimization").*

5.2 Data protection officer (This only applies if personal data is collected.)
Does the study information for participants refer to the responsible data protection officers? Is their responsibility explained?

5.3 Storage: Are the participants informed about the storage of the collected data? What does this storage look like and does it jeopardize anonymization? *Note: The participants should also be informed whether the fully anonymized data will be stored for at least 10 years after the data evaluation in accordance with good scientific practice and/or whether it will be made available on a research platform within the framework of "Open Science", taking into account the data protection framework conditions.*

5.4 Anonymization/pseudonymization: Are the terms anonymization (changing personal data so that it can no longer be assigned to a person) and pseudonymization (name or another identification feature is replaced by a pseudonym, usually a multi-digit combination of letters or numbers) used correctly and consistently? Are the participants sufficiently informed about the underlying concepts? *Note 1: If a code generated by the participants themselves is used that is not known to the researchers, it is still pseudonymized data that falls within the scope of the General Data Protection Regulation. Note 2: Pseudonymized data should be anonymized as soon as possible (as soon as the research objective is achieved).*

5.5 Possible identification: In the case of small groups of participants with sometimes very specific information (e.g. nationality, level of education, etc.), it may be possible to identify individual participants. How is this handled and are the participants adequately informed about the handling of the data and the possible risk of identification?

5.6 Deletion of the data: Do participants have the option to have personal data deleted (during collection or retrospectively) and is sufficient information provided about this (e.g. that deletion is not possible after collection if data is collected anonymously)? If personal data is collected, are participants informed when it will be deleted or completely anonymized? *Note 1: A specific date must be given so that participants know by when they can assert their rights under the GDPR. Note 2: Personal data must be deleted or completely anonymized at the earliest possible date (as soon as the research objective has been achieved).*

5.7 Online tools: Are all programs and tools used for data collection and analysis accompanied by adequate data protection and do they comply with the GDPR? For example, are online tools or their data processing companies included in the EU-US Privacy Shield list?

5.8 External data storage: Is data collected by third parties, e.g. through the use of online questionnaire tools, and stored on external servers? Are participants informed about the collection of implicit data such as the IP address?

5.9 Image and sound recordings: Is a separate declaration of consent available for the production of image or sound recordings? Are the participants informed about the de-anonymization made possible by this? *Note: Image and sound recordings are, by their very nature, personal data that fall within the scope of the GDPR.*

5.10 Impact assessment: Are technologies used in the collection and processing of data that could entail a high risk of misuse? Is there a data protection impact assessment to mitigate the risks to the rights and freedoms of participants? Are remedial measures in place to ensure the protection of personal data and to demonstrate compliance with the regulation?

6. Minors

6.1 Ability to give consent: If no legal representative is present at the time of study participation: are minors capable of recognizing the consequences of the use of their data and expressing themselves accordingly (usually from about 14 years of age)? If the age of the participants is within this limit - is their ability to give consent recorded or ensured?

6.2 Legal representative: Will informed consent be obtained from a legal representative to participate in the study? How will informed consent be obtained? Is a legal representative present throughout the study (regardless of whether it is conducted off-site or at the participant's home)? Is the legal representative asked to conduct the study in private (e.g. to obtain uninfluenced responses) and what happens if they refuse? Is the minor willing to participate in the study? *Note: If the written consent of the legal representative has been obtained, the children should also be informed about the study in an age-appropriate manner and their consent obtained.*

6.3 Liabilty: Is the drop-off and pick-up of participants clarified and ensured? Is permission from the legal representative documented if the child is at least 11 years old and is to be exempt from being accompanied?

6.4 Prohibitions: Are the participants and their legal representatives sufficiently informed about the planned study in advance so that it can be ruled out that, for example, certain foods and stimulants fall under certain prohibitions of the legal representatives (e.g. for religious or medical reasons) or the legal distribution restrictions?

6.5 School: Is the approval of the school management obtained when studies are carried out at a school? Does this not interfere with the educational work? Are the legal provisions of the Education Act observed? If entire school classes are to take part: How is peer pressure on individual pupils to participate in the study avoided? *Note: In Germany, research studies in schools are generally subject to approval. There are differences between the federal states, which must be taken into account when planning the study (information on this can be found, for example, at: https://www.forschungsdaten-bildung.de/datenmanagement/recht-ethik/genehmigungen-schulerhebungen/).*

7. MTurk (Amazon Mechanical Turk, AMT) and similar platforms

The use of MTurk and similar platforms has been critically scrutinized for various reasons. In order to ensure that the use of such platforms is ethically justifiable and compliant with data protection regulations, the Ethics Committee considers it necessary to apply the following procedures when using MTurk:

7.1 Survey platform: The data may not be collected directly on MTurk, as Amazon would have access to it and is therefore not covered by the European GDPR. Participation via MTurk must therefore refer to an external platform (e.g. Qualtrics, Unipark, SoSci Survey, LimeSurvey etc.) on which the data is collected and which is used in such a way that it complies with the European GDPR.

7.2 Dealing with discontinuations: Participation vs. non-participation in a study (order acceptance vs. rejection) and full completion vs. premature termination of an order are stored in MTurk. This information is taken into account by MTurk for further orders. Here it is possibly questionable whether the ethical principle of voluntary participation (including the right to premature termination without personal consequences) could be jeopardized. The Ethics Committee therefore considers it necessary for the applicant to ensure that the successful completion of the task is communicated to MTurk despite the end of the study (e.g. by pressing a “Cancel” button or closing the window). A corresponding partial compensation should also be paid here so that there is really no disadvantage (e.g. 50% of the possible compensation if the survey is fully completed).

7.3 Anonymization/pseudonymization: It must be ensured that no link can be established between the data provided on the external platform and the MTurk Worker ID. If this is not possible, pseudonymized rather than anonymized data will be collected and the term “pseudonymization” must be added and explained in the participant information.

References

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Grundlegende Informationen zum Forschungsdatenschutz und der Datenschutz-Grundverordnung (DSGVO) finden sich auf der Website der Datenschutzbeauftragten der UzK: https://verwaltung.uni-koeln.de/stabsstelle02.3/content/forschungsdatenschutz/index_ger.html

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