**Ethikkommission der Humanwissenschaftliche Fakultät, Universität zu Köln**

**Application Form (Version: 05/2024)**

**Application form for the evaluation of a research project**

**A. Title/name of the research project**

**B. Name and address of the principal investigator (supervisor)**

Surname, first name:

Address:

Telephone number:

E-mail:

**C. Short summary of the research project (*max.* 500 words)**

(Objectives, participant sample or target group, methodical approach, scientific knowledge gain etc.)

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**D. Are other researchers involved in the research project?**

Name/Faculty/Place:

**E. External funding?**   Yes  No (self-financed)

Funding organization:

**F.1 Is an ethics statement required from the funding organization?**   Yes  No

**F.2 Is this a proposal for the alternative two-step procedure for DFG proposals?
(see explanation of the application procedure)?**   Yes  No

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| **G. The application is accompanied by ... *Please tick if applicable*** |  |
| Informed consent form for the participants **(compulsory)** |  |
| Declaration of consent for study participation **(mandatory/**please argue carefully, should you opt to not ask participants for informed consent**)** |  |
| Separate declaration of consent for image and/or sound recordings (**mandatory**, if image or sound recordings are planned) |  |
| Statement as to whether the application has been submitted to another ethics committee **(mandatory)**. If yes, attach statement of the other ethics committee (**mandatory**, if any) |  |
| All steps of the research process in tabular form including (if applicable) description of the sample, its recruitment, instructions, tasks, questionnaires (naming only), as well as all other methods used in the study **(mandatory)** |  |
| Research proposal used for funding organization (**obligatory** if study is financed by funding organization) |  |
| Debriefing for studies with active or passive deception (**mandatory**, if applicable) |  |

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| **H. Checklist for the study (please tick "yes" or "no"; if not applicable mark with "n/a" in the white field)** |  |  |
|  | Yes | No |
| **1. Voluntarism:**Is the voluntariness of participation ensured? (Please also check whether special incentives or dependent relationships might affect voluntariness – see the document “comments on checklist”) |  |  |
| **2. Legal Capacity:**Will people participate in the study who are unable to give consent to participate themselves because they are underage, have a limited ability to judge participation, or are incapable of judgement (e.g. babies, small children, persons under 18 years of age, persons who are incapable of consent in a legal sense)? |  |  |
| **3. Vulnerable and/or marginalized groups:**Will the study involve people who belong to a particularly vulnerable group (e.g. people with disabilities, people in inpatient or outpatient treatment facilities, prisoners, people with dementia, people in retirement homes, or discriminated against or marginalized groups of people)? |  |  |
| **4. Explicit statement regarding the right to terminate participation at any time:**Are the participants assured that they can terminate their participation at any time without having to give a reason and with no negative consequences? |  |  |
| **5. Inclusion and exclusion criteria:**Are there inclusion and/or exclusion criteria for participation? |  |  |
| **6. Informed consent:**Are participants fully informed about the objectives and purposes of the study in a language accessible to them? |  |  |
| **7. Informed consent:**Is informed consent obtained in written form? (compare comments to checklist) |  |  |
| **8. Deception about participation:**Is it necessary for people to participate in the study without having been informed of their participation at that time, without having given their consent (e.g. in the case of experimental field studies, covert observation), or while not having been sufficiently informed about the purpose and content of the study (this does not entail full disclosure of hypotheses)? |  |  |
| **9. Active deception about content, purpose, method or setting:**Are people actively and deliberately deceived about the content, purpose, method and/or setting of the study (e.g. by presenting a fake research purpose, giving false information, concealing important information etc.)? |  |  |
| **Potential Dangers** |
| **10. Intimacy/Stigmatization:**Are there any questions regarding topics that could transgress individual intimacy boundaries of interviewees (e.g. stressful personal experiences or sexuality), or for which the answers could be perceived as stigmatising (e.g. illegal or deviant behaviour such as drug use, addictions or the abuse of stimulants, but also political convictions)? |  |  |
| **11. Psychological stress for participants:**Can participants be expected to suffer psychological stress, fear, exhaustion, or other negative effects as a result of the study? |  |  |
| **12. Physical risks for participants:**Will any invasive measurements be conducted on the participants of the study? Will they be subjected to potentially stressful (e.g. blood, saliva) or harmful procedures? Will physical pain be inflicted? Can any side effects be expected? |  |  |
| **13. Psychological or physical risks for researchers:**Is there any potential danger for the researchers (e.g. psychological stress due to problematic interview topics and situations)? |  |  |
| **14. Substance allocation:**Will the participants in the study be given drugs, placebos or other substances? |  |  |
| **15. Dealing with relevant findings:**Are important findings relevant to participants likely to be identified (e.g. diagnoses, suicide risk, or abnormal laboratory findings)? |  |  |
| **16. Conflicts of interest:**Are there possible conflicts of interest (e.g. cooperation partners, participants)? |  |  |
| **Data Protection** |
| **17. Anonymization or pseudonymization:**Are the data either completely anonymized (so that it is not possible to assign the data to individuals) or pseudonymized (storage of the data with a personal code; associated data and names are stored in separate files); and are the applicable data protection regulations considered in each case? |  |  |
| **18. Data access:**Is it certain that only people who are committed to confidentiality have access to the personal data (e.g. storage in locked cabinet, password-protected computer file)? |  |  |
| **19. Deletion of personal data at the request of the participants**Can participants request the deletion of their data at any time, for example by means of a personal code, and are they informed about this option? Alternatively, if no personal code is generated, can the deletion of data be requested immediately after their participation and are participants notified of this fact? (see comments on checklist) |  |  |
| **20. Deletion of the data after a specified legal retention period.**Is the deletion of personal data guaranteed after a specified legal retention period and will the participants be informed about this? |  |  |
| **21. Non-disclosure of other participants without obligation of confidentiality:**When in a group setting, are participants explicitly asked to maintain confidentiality with regard to personal information disclosed by other participants? |  |  |
| **22. Publication Strategy:**Both the publication of research data and the publication of research results require ethical considerations. Is the chosen form of anonymization or data aggregation guaranteeing the anonymity of the participants in your project? |  |  |
| **23. Information rights**Do the participants have the opportunity to be informed about the research results after completion of the study? |  |  |
|  | Yes | No |

If you have marked one or more questions in the checklist of the basic questionnaire with a cross in a coloured field, please also submit a detailed explanation of the response to the respective item (in each case under the header "Statement on H.XX", e.g. "Statement on H.13"). Please also consider cost-benefit aspects of the study and, in the case of data protection, the relevant legal framework conditions.

**Declaration of the responsible scientist**

Advice from the ethics committee can only be provided in a meaningful way if data collection has not yet begun and possible comments and advice from the ethics committee can be taken into account. I therefore confirm that the research project has not yet been started and will not be started until the consultation has been fully completed.

I confirm that all information provided in this application is correct and in accordance with the professional ethical guidelines relevant to me.

I also confirm that the information provided does not deviate from any information possibly provided in the application to the relevant funding institution.

I am aware that the ultimate responsibility for compliance with the guidelines lies with me.

Place, Date Signature (responsible project leader)

**Appendix**

Please also provide the further relevant information in the following order:

1. The research process in a tabular format (see template below) and the informed consent, declarations of consent, etc. used in the study.
2. If applicable, comments on indexed points under H.
3. If applicable, statements of other ethics committees
4. If applicable, the research proposal (if research is financed by a funding organization)
5. Research Process

The following table provides an overview of the essential aspects of research projects relevant for ethical evaluation. It can serve as a guide and a possible template and you are welcome to use it for your applications. Should you consider additional aspects as ethically relevant for your research project, please supplement the table accordingly.

**(if not applicable answer with "n/a")**

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| **1. Method of data collection** How do you want to collect data? (e.g. field study, guided interview, standardized interview). Mode of data collection (e.g., online, face-to-face/oral, written, ...)?  |
| e.g..Study 1: Guided interview, online, secure communication platform (name).Study 2: Experiment: personal visit of the laboratory necessaryStudy 3: Written questionnaire, online via survey platform (name)Further explanations, if necessary |
| **2. Description of the target group**Who should participate in your research project? Marginalized groups? Age (groups)? Capacity to give consent? |
| e.g. Study 1: Experts from the mentioned fieldsStudy 2: Individuals with major depression, 18-65 years Study 3: Children/adolescents, age group(s), (parental consent will be obtained)Further explanations, if necessary |
| **3. Sampling/Selection of participants**a) Sample size? How was it determined? Provide an explanation of methodological considerations and parameters for determining group and sample sizes.b) Briefly explain the intended sampling procedure (e.g. random sampling) or describe according to which criteria you will select participants. |
| e.g.Study 1: approx. 20 persons, explanatory notesStudy 2: approx. 90 persons in total, 45 persons each in experimental and control group, explanatory notesStudy 3: approx. 165 persons, determined via a-priori power analysis with the following parameters…Further explanations, if necessary |
| **3. Recruitment of participants**Please describe how you will contact participants. How will participants receive information about the study and how will informed consent be obtained? |
| e.g.Study 1: Newsletters and advocacy websites; written informed consent in advance via email.Study 2: Outpatients through attending physicians; via email via platform (naming); written informed consent in person at site prior to study start.Study 3: Via information flyer/project homepage; informed consent via online survey platform Further explanations, if necessary |
| **4. Incentives/Compensation** Please explain whether compensation/incentives are provided for participants and what it looks like. If compensation is provided, what happens if participation is cancelled? Plan for partial compensation. |
| e.g.Study 1: No compensation for expenses / incentives providedStudy 2: 8 euros after completion of participation; in case of discontinuation, compensation according to actual time spent.Study 3: Sweepstakes, explanation of the procedureFurther explanations, if necessary  |
| **5. Instructions/tasks for study participants**Briefly describe the instructions and tasks participants will receive and the expected duration of participation (reference to the attached study information may be sufficient). |
| e.g.Study 1: See detailed description in the attached study information.Study 2: Detailed description of the procedure for experimental and control group, duration approx. 1 hourStudy 3: Answering a standardized online questionnaire, duration approx. 20 min.Further explanations, if necessary |
| **6. Questionnaires and instruments**Please briefly describe the contents of the questionnaires (topics, items and scales). |
| e.g.Study 1: Guided interview on the following content / research questions… (further explanations).Study 2: n/a Study 3: naming of items/scales Further explanations, if necessary |
| **7. Anonymization or pseudonymization**a) Are personal data (which?) required in your research project (e.g. names, contact details, videos and voice recordings, etc.)? (Note: Video and voice recordings always require a separate declaration of consent).b) Please explain your strategies for anonymization or pseudonymization of personal data. |
| e.g.Study 1: Names and e-mail addresses are collected and stored for written contact/appointments; research data are collected and analyzed anonymouslyStudy 2: Research data are pseudonymized; explanation of personal data collectedStudy 3: Anonymized collection of research data; no reference to persons possibleFurther explanations, if necessary |
| **8. Programs/tools**a) Which programs/tools are used for data collection and analysis and do they comply with the GDPR?b) If applicable, is implicit data collected (e.g. IP address)? How is this data shielded? |
| e.g.Study 1: DFNconf (Konferenzdienst im Deutschen Forschungsnetz), data protection explanations.Study 2: n/aStudy 3: LimeSurvey, complies with DSGVO, implicit data is not collectedFurther explanations, if necessary |
| **9. Data storage and backup**Please explain where, how, and for how long the data (identifiers, if applicable) will be stored and transmitted. Will external servers be used? Will transmission be encrypted?How is access to personal data protected (technically and organizationally)? |
| e.g.Study 1: separate storage of research and contact data; only project management has password-protected access to personal data (voice recordings, names, contact data; voice recordings are transcribed after the collection and deleted immediately after transcription (at the latest xy); encrypted transmission of voice recordings to the transcription company is ensured (explanation); anonymized research data are stored for 10 yearsStudy 2: Coding list is kept in paper form locked in a cabinet; only data trustee (name) has access/key; coding list is destroyed at time xy; anonymized research data are stored for 10 yearsStudy 3: only project management has access to separately stored contact data; contact data is destroyed at time xy; anonymized research data is stored for 10 yearsFurther explanations, if necessary |