****

**LBG Pilot Research Ethics Committee**

**Application Form**

| **Project Lead:** | |
| --- | --- |
| **Supervisor (if student):** | |
| **List of all collaborators (with affiliated institutions in brackets):** | |
| **Student’s programme of study (if applicable):** | |
| **Project Title:** | |
| **Case Number (if known – assigned by Administrator at time of 1st submission):** | |
| **Proposed Project Start Date:** | **Proposed Project End Date:** |

**This is a:**

☐ New application for ethical review – first submission

☐ Resubmission with requested amendments

**The applicant is currently employed by the Ludwig Boltzmann Gesellschaft**

☐Yes ☐No

**The applicant confirms that their research does not fall within the remit of a legally mandated ethics committee for medical research**

**please see** [**https://www.bmbwf.gv.at/Themen/HS-Uni/Hochschulgremien/Ethikkommissionen.html**](https://www.bmbwf.gv.at/Themen/HS-Uni/Hochschulgremien/Ethikkommissionen.html)

☐Yes ☐No

**External projects: the applicant has sought the opinion of the ethics committee at their home institution and confirms that the project does not fall within that committee’s remit (please attach any paperwork confirming this to the application)**

☐Yes ☐No

**External projects: the applicant confirms that this project has not received a negative opinion by an ethics committee at any other institution, in Austria or abroad.**

☐Yes ☐No

**This study will:**

Collect or generate new data involving humans -> please fill in all sections of the form

Extract, re-code and analyse existing data that contains sensitive information (i.e. identifiable information) -> please fill in all sections of the form

Analyse secondary (archival) data that is routinely collected or is an existing anonymised dataset -> please only fill in Q1 and sign/date

**This application is complete with the following attachments (tick all that apply):**

| Advert/flyer ☐ | Consent Forms ☐ | Data collection tools (e.g. interview  questions) ☐ | | |
| --- | --- | --- | --- | --- |
| Participant  Information sheet ☐ | Confirmation of home institution EC (if applicable) ☐ | Other (please specify ☐ | | |

# **Contents**

# 

[**Section 1: Introduction**](#_9ksmtlpenpwk) **4**

[**Section 2: Good conduct in collaborative research**](#_lvxsfdk0e9vm) **8**

[**Section 3: Potential risks to participants and researchers**](#_q1guui7zuqwy) **9**

[**Section 4: Participants and data subjects**](#_ozlfn7s9yt9s) **12**

[**Section 5: Participant or data subject information and consent**](#_jdqxjt49d2e4) **15**

[**Section 6: Review, amendments and outcome**](#_a7she5ajo3je) **18**

# 

# 

# **Section 1: Introduction**

**External Research Ethics Approval:**

**Does your research project require the additional approval of any other institution and/or ethics committee, nationally or internationally (e.g. for a study involving conventional biomedical research and a patient involvement component).**

**In the case of international research, please note that even if your research does not require ethics approval in Austria, it may do so in the country of data collection.**

☐Yes ☐No

*If yes, please state the name of the review body and whether ethics approval has been sought/granted at the time of application and from whom:*

|  |
| --- |

IMPORTANT NOTICE: In the following sections, “participants” refers to any person involved in the research in addition to the applicant, i.e. conventional research subjects as well as PPIE participants/co-creators.

**Q1. Project summary**

**Please provide a brief summary of your proposed study. Do not exceed 1500 words. Our interest is in areas of your methodology where ethical issues may arise so please focus your detail on areas such as recruitment, consent, describing your participants and the nature of their involvement, and data handling.**

| **Background and rationale:**  **Aims and research questions:**  **Methodology:**  **Specific PPIE activities (if applicable):**  **Recruitment (inclusion/exclusion criteria, informed consent procedures, participant information modalities):**  **Data management:** |
| --- |

**Q2. What information about participants will you collect and/or use?**

|  |
| --- |

**Q3. Will the information include special categories of personal data (health data, data relating to race or ethnicity, to political opinions or religious beliefs, trade union membership, criminal convictions, sexual orientations, genetic data and biometric data) that is protected under DSGVO (GDPR)?**

☐ Yes ☐ No

*If “yes” – Explain what safeguards e.g. technical or organisational you have in place; including any detailed protocols if this requires special and/or external processing, storage, and analysis.*

|  |
| --- |

**Q3. Please identify and list any risks to the privacy of research participants, for example through data linkage, low participant numbers, geographical location…).**

**If there is no expectation of anonymity (e.g. PPIE participants are named co-researchers), please indicate this and specify how you will mitigate risk in this case. For example, if you are involving patients, have you discussed the potential consequences of making their medical status public with them?**

|  |
| --- |

**Q4. Will information containing personal, identifiable data be transferred to, shared with, supported by, or otherwise available to third parties outside of your organisation?**

☐ Yes ☐ No

*If “yes” - Please explain why this necessary and how the transfer of the information will be made secure. If the third party is based outside the European Economic Area please obtain guidance from the Data Protection Officer at your institution.*

|  |
| --- |

**Q5. Other than the use by third parties, how will the data be used, accessed or stored during and after the research?**

*Please describe the arrangements you have put in place to safeguard the data from accidental or deliberate access, amendment or deletion, including when it is in transit, and (where applicable) it is transferred outside the EEA.*

|  |
| --- |

**Q6. Will feedback on findings be given to your research project participants or data subjects?**

☐ Yes ☐ No

*If “yes” - How and when will this feedback be provided?*

|  |
| --- |

*If “no” - Please provide rationale .*

|  |
| --- |

**Q7. How do you intend to use/disseminate the results of your research project?**

|  |
| --- |

# **Section 2: Good conduct in collaborative research**

# 

**Q8. Does your project involve working collaboratively with other academic partners?**

☐ Yes ☐ No

*If “yes” please give details, including of any formal collaboration- or data sharing agreement*

|  |
| --- |

**Q9. Does your project involve working collaboratively with other non-academic partners ?**

☐ Yes ☐ No

*If “yes”, please give details, including any ethics and data protection training partners have/will receive*

|  |
| --- |

**Q10. Does your project involve employing local field assistants (including guides/translators)?**

☐ Yes ☐ No

*If “yes”, please give details, including any formal agreements/work contracts and remuneration and data protection arrangements*

|  |
| --- |

**Q11. PPIE only: will PPIE participants take part in data collection and analysis?**

☐ Yes ☐ No

*If “yes”, please give details, including any ethics and data protection training PPIE participants have/will receive*

|  |
| --- |

# **Section 3: Potential risks to participants and researchers**

**Q12. Is there a possibility for your research to induce any psychological distress or discomfort in the participants or others?**

☐ Yes ☐ No

*If “yes” state the types of risk and what measures will be taken to deal with such problems (e.g. liaising with mental health emergency services)*

|  |
| --- |

**Q13. Does your research project require any physically-invasive or potentially physically harmful procedures?**

☐ Yes ☐ No

*If “yes” give details and outline procedures to be put in place to deal with potential problems. Please also double-check that your research does not require legally mandated ethics review by a medical ethics committee.*

|  |
| --- |

**Q14. Does your research project require the use of privacy-invasive technology, such as CCTV, biometrics, facial recognition, vehicle tracking software?**

☐ Yes ☐ No

*If “yes” - Give details and outline procedures to be put in place to deal with potential problems.*

|  |
| --- |

**Q15. Does your research project involve the investigation of any illegal behaviour or activities (e.g. use of illegal drugs, abuse of vulnerable people such as children or adults in care…)?**

☐ Yes ☐ No

*If “yes” - Give details of any illegal behaviour or activities you may investigate and whether any legal duty to report to authorities may arise from this investigation.*

|  |
| --- |

**Q16. Is it possible/likely that dissemination of research findings or data could adversely affect participants or others indirectly associated with the research?**

☐ Yes ☐ No

*If “yes” - Describe the potential risk for participants/data subjects of this use of the data. Outline any steps that will be taken to protect participants.*

|  |
| --- |

**Q17. Could participation in this research adversely affect participants and others associated with the research in any other way?**

☐ Yes ☐ No

*If “yes” - Describe the possible adverse effects and the procedures to be put in place to protect against them.*

|  |
| --- |

**Q18. Is this research expected to benefit the participants, directly or indirectly?**

☐ Yes ☐ No

*If “yes” - Give details of how this research is expected to benefit the participants.*

|  |
| --- |

**Q19. Will the true purpose of the research be concealed from the participants/data subjects?**

☐ Yes ☐ No

*If “yes” - Explain what information will be concealed and why.*

|  |
| --- |

**Q20. Will the research involve covert data collection (e.g. covert participant observation)?**

☐ Yes ☐ No

*If “yes” - Please explain rationale and any measures taken to mitigate risk*

|  |
| --- |

**Q21. Will participants/data subjects be debriefed at the conclusion of the study?**

☐ Yes ☐ No

*Please elaborate:*

|  |
| --- |

**Q22. Could the researcher’s safety be compromised by the research or could the research induce emotional distress in the researchers?**

☐ Yes ☐ No

*If “yes” - Give details and outline procedures to be put in place to deal with potential problems.*

|  |
| --- |

# 

# **Section 4: Participants and data subjects**

**Q23. How many participants or data subjects are expected to be included in your research project?**

|  |
| --- |

**Q24. Are any of the participants or data subjects likely to be under 16 years of age?**

☐ Yes ☐ No

*If “yes” - Explain and describe how/from whom consent will be sought and the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q25. Are any of the participants or data subjects likely to be children in the care of state agencies (e.g. child protection/Jugendamt)?**

☐ Yes ☐ No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q26. Are any of the participants or data subjects likely to be known to have a disability or mental illness?**

☐ Yes ☐ No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q27. Are any of the participants or data subjects likely to be physically ill?**

☐ Yes ☐ No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q28. Are any of the participants or data subjects likely to be vulnerable or likely exposed to harm in other ways (e.g. people experiencing homelessness, people with harmful substance use, people engaging in sex work…)?**

☐ Yes ☐ No

*If “yes” - Explain and describe the nature of the vulnerability and the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q29. Are any of the participants or data subjects likely to be unable to communicate in the language in which the research is conducted?**

☐ Yes ☐ No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q30. Are any of the participants or data subjects likely to have reduced literacy that may affect their ability to give informed consent?**

☐ Yes ☐ No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q31. Are any of the participants or data subjects likely to be in a relationship (i.e., professional, student-teacher, other dependent relationship) with the researchers or other project staff?**

☐ Yes ☐ No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |

**Q32. Will participants receive any financial or other material benefits as a result of participation?**

☐ Yes ☐ No

*If “yes” - What benefits will be offered to participants and why?*

|  |
| --- |

# **Section 5: Participant or data subject information and consent**

**Q33. Will written or oral consent be obtained from all participants or data subjects?**

☐ Yes ☐ No

*If “yes” – attach participant information sheet and consent form and detail the process you will follow.*

*If “no” – explain why not and what process you will follow regarding consent, or if consent cannot or should not be sought for some reason, please provide a clear case and rationale for this (e.g. in international contexts where speaking to foreign researchers is prohibited, or where participants may feel intimidated by “official paperwork”).*

|  |
| --- |

**Q34. Have you made arrangements to tell participants what information you will hold about them and for how long?**

☐ Yes ☐ No

*If “yes” - what arrangements have been made?*

|  |
| --- |

*If “no” – why not?*

|  |
| --- |

**Q35. Have you made arrangements to tell participants whether you will disclose the information to other organisations?**

☐ Yes ☐ No ☐ N/A

*Please specify:*

|  |
| --- |

**Q36. In the case of children or adults unable to give consent participating in the research, will the consent or assent of a proxy/legal guardian be obtained?**

☐ Yes ☐ No ☐ N/A

*Please elaborate:*

|  |
| --- |

**Q37. Will the consent or assent of children participating in the research be obtained separate from parents/legal guardians?**

☐ Yes ☐ No ☐ N/A

*Please elaborate:*

|  |
| --- |

**Q43. In the case of participants who are not proficient in the language in which the research is conducted, will arrangements be made to ensure informed consent?**

☐ Yes ☐ No ☐ N/A

*Please elaborate:*

|  |
| --- |

I/we confirm that the information given in this application is truthful and complete. I/we acknowledge that intentionally making false claims or concealing information in this application may void any favourable opinion received.

—---------------------------

Signature and date

# **Section 6: Review, amendments and outcome**

| ***This section is to be completed after review only*** |
| --- |
| **ISSUES ARISING FROM THE PROPOSAL – to be completed by Ethics Committee** |
| Thank you for your application. The review process has generated the following queries regarding your application. Please address the following items, and provide a note underneath each comment letting us know how you have addressed them:  OR    Thank you for your application. We have completed the review process and can provide a favourable opinion.  OR  Thank you for your application. At this time, we cannot provide a favourable opinion due to the following fatal flaws::            **Signature:**    **Position:**    **Date:** |
| **APPLICANT’S SIGNATURE FOLLOWING REVISIONS – to be completed by applicant** |
| I confirm that I have addressed all of the queries generated during the ethical review process of my application. I have outlined in the box above underneath each comment how each request was addressed and/or provided further clarification.      **Supervisor/PI Signature:**    **Student signature:**    **Date:** |
| **CONCLUSION TO ETHICAL REVIEW – to be completed by Ethics Committee** |
| The applicant’s response to our request for further clarification or changes has now satisfied the requirements for ethical practice and the application has therefore been given a favourable opinion.    OR    Thank you for providing responses to our comments. Some outstanding questions remain:                  **Signature:**    **Position:**    **Date:** |