### **Enable Ireland Criteria for Ethical Approval Checklist**

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| **Project Title:****Principal Investigator:****Date:** |

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| ***Enable Ireland Criteria for Ethical Approval Checklist******(Ensure all criteria are met prior to submission to the REQC to avoid extension of time periods)*** |  |  |
| ***Please place an ‘X’ in the appropriate column* *where ‘No’ is marked, supply explanatory notes.*** | ***Yes*** | ***No*** |
| 1. Full compliance with the Enable Ireland REQC Policy and Procedure requirements.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Adherence to the ‘Procedures for Applicants Submitting to the Enable Ireland REQC’ is in place.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Adherence to current safety practices, ethical standards, and legislation specifically in relation to data protection.
 | **\_\_\_\_** | **\_\_\_\_** |
| **Protection of Service Users and Staff**  |
| 1. Demonstrable evidence that the dignity, rights, safety and well-being of participants are protected at all times exists.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Research risks must be assessed by researchers with respect to their physical, social and psychological effects on service users, their families and staff and all research must conform to legal obligations. Risks will be commensurate with the expectation of benefit to participants or the importance of the area being explored. Benefits of the research for service users, their families and staff are outlined without causing any undue harm. (NDA, 2009: Ethical Guidance for Research with People with Disabilities).
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Protocols are comprehensively outlined to meet the needs of service users who have specific communication and cognitive difficulties e.g. easy-to read materials and illustrated information on the purpose and the scope of a research project. Full understanding of the research and its implications and guidance in making an informed decision about participation exists. (NDA, 2009: Ethical Guidance for Research with People with Disabilities)
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Follow up procedures and supports for participants in the event of any distress or questions are outlined.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Presentation strategy of findings to service users/participants in an accessible manner (face to face preferred) is outlined.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Participants must be informed of their right to raise any complaint in relation to the research undertaken under the Enable Ireland Complaints Policy, Dealing with Complaints from Members of the Public – Services
 | **\_\_\_\_** | **\_\_\_\_** |

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| ***Please place an ‘X’ in the appropriate column* *where ‘No’ is marked, supply explanatory notes*** | **Yes** | **No** |
| **Gatekeeper**  |
| 1. The proposed research studies has an appointed gatekeeper who is an Enable Ireland employee.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. The appointed gatekeeper will be tasked with inviting service users, families and staff to participate.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. I will not have direct access to service users, their families and staff until explicit consent is in place. Any personal data that is subsequently anonymised will be destroyed with immediate effect/.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. The appointed gatekeepers name is stated on the Enable Ireland REQC application form (see **Appendix 3**)
 | **\_\_\_\_** | **\_\_\_\_** |
| **Principal Investigator (PI)** |
| 1. We have been honest and transparent in respect of my/our actions in research and in all responses to the actions of other researchers. This applies to the whole range of research work, including experimental design, generating and analysing data, applying for funding, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. The Data Protection Consent Form is completed
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. The ‘Principal Investigators Declaration’ is completed
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. All data collection tools e.g. information sheet, questionnaire etc. will be accessible and developed using plain English. Data collection tools will be accompanied as an appendix to researchers overall application
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. I/we declare no real or potential conflicts of interest.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Regular review of progress will take place so that cognisance is taken of new findings: this will allow the project plan to be modified accordingly, where appropriate.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Substantive changes to the research proposal will be submitted for a secondary ethical review. These amendments will be implemented only if/ when approved.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. PI will submit Interim progress report (see **Appendix 7**) and final report of findings to Enable Ireland as a stipulation of final approval
 | **\_\_\_\_** | **\_\_\_\_** |
| **Supervision**  |
| 1. Nominated supervisors stated within the Enable Ireland REQC application form (see **Appendix 3**) will supervise during each stage of the research process including drawing up proposals, preparing funding applications, data recording, data analysis and reporting.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. The appointed supervisor has completed the ‘Supervisor Declaration’.
 | **\_\_\_\_** | **\_\_\_\_** |
| **Explicit Consent** |
| 1. Standard written protocols are detailed within the REQC application form (see **Appendix 3**) detailing the process of obtaining explicit consent.
 | **\_\_\_\_** | **\_\_\_\_** |

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| ***Please place an ‘X’ in the appropriate column* *where ‘No’ is marked, supply explanatory notes*** |
| 1. Obtaining explicit consent from participants; information will be provided in appropriate accessible formats and include the nature and purpose of the research, what taking part involves the level of anonymity and confidentiality, voluntary participation and how the results will be disseminated.
 | **\_\_\_\_** | **\_\_\_\_** |
| **Confidentiality**  |  |  |
| 1. Procedures to ensure the collection of high quality, accurate data including the integrity and confidentiality of data during processing and storage will be in place prior to commencement.
 | **\_\_\_\_** | \_\_\_\_ |
| 1. Removal of identifiers and the use of pseudonyms will be implemented to guarantee confidentiality and anonymity.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Explicit consent must be in place if personal data is required for data collection purposes e.g., interview, focus group. All data retrieved as a result of the field research must be anonymised and personal data for access purposes be immediately destroyed.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. All hardcopies of data will be kept in a secure locked filing cabinet. Soft copies of data must will be kept on a locked, password protected computer. Data will be retained for a maximum of 5 years and provisions of the Data Protection Act must be adhered to.
 | **\_\_\_\_** | **\_\_\_\_** |
| **Data Protection**  |  |  |
| 1. No further use of any data, whether directly relating to service user, family or staff data will take place without the written permission of the REQC.
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| 1. I/we will adhere to the following legislative acts: The EU General Data Protection Regulation (2016) ,The Data Protection Act (2003), The Freedom of Information Act (2003), and The Equal Status Act (2000). I/we are aware of any further legal requirements that regulate their work.
 | **\_\_\_\_** | **\_\_\_\_** |
| **Dissemination, Exploitation and Publication of Results** |  |  |
| 1. Where the research has been funded in whole or part by Enable Ireland, this contribution will be acknowledged in any publication.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Participants must be informed that the data may be subject to publication and how they access results of the study.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Research findings with substantial implications for clinical practice or which are likely to attract strong public or media interest will be drawn to the attention of Enable Ireland through the REQC Coordinator before publication. Written approval will be requested from the Enable Ireland REQC prior to any media engagement or if any dissemination involves media.
 | **\_\_\_\_** | **\_\_\_\_** |
| **External Guidance from Professional Bodies** |
| 1. I/we will observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Findings will be open to critical review through the accepted scientific and professional channels.
 | **\_\_\_\_** | **\_\_\_\_** |
| 1. Formal written ethics approval from the researchers own institution (if applicable) has been obtained and is included as an appendix as part of the overall application to the Enable Ireland REQC. This research will not commence without formal approval from Enable Ireland and the researcher’s institutional REC.
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| **Signed Principal Investigator:**  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Signed Co-Investigator (if applicable):**  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Date:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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