**Research Ethics & Quality Committee (REQC)**

**Application Documentation Pack**

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| **Project Overview Information** |
| **Project Title:** |  |
| **Principal Investigator:** |  |
| **Date:** |  |
| **Purpose of Research (e.g. Research Project for Masters/PHD etc.):** |  |

**IMPORTANT NOTES FOR COMPLETING THE DOCUMENTATION PACK:**

* This documentation pack contains the following:

Part 1 Enable Ireland Criteria for Ethical Approval Checklist Part 2 Principal Investigator Declaration

Part 3 Enable Ireland Research Ethics & Quality Committee Application Form Part 4 Principal Investigator Data Protection Consent Form

Part 5 Supervisor Declaration Part 6 Overall Signature Page

* Applicants are required to complete all areas of the documentation, attach relevant appendices (e.g. copy of consent forms/institute approval (if applicable)/other supporting appendices) and submit to Enable Ireland’s REQC for review and a decision.
* Where any changes occur to any of the information provided in the initial application from the applicant must contact Enable Ireland’s REQC Co-coordinator to liaise with Enable Ireland’s REQC Chair for approval to proposed changes to the application in advance of applying same.

# **Part 1 Enable Ireland Criteria for Ethical Approval Checklist**

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| ***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. |  |  |
| 2. Adherence to the ‘Procedures for Applicants Submitting to the Enable Ireland REQC’ is in place. |  |  |
| 3. All relevant managers named on the Application Form have read and have a full understanding of the research proposed. |  |  |
| 4. Where multiple sites/locations across CHO areas are involved, the National Directorate of Services is in support of the application in principle subject to REQC Approval. |  |  |
| 5. Adherence to current safety practices, ethical standards, and legislation specifically in relation to data protection. |  |  |
| 6. Public Health considerations reviewed. |  |  |
| **Protection of Service users/Service owners and Staff** |
| 7. Demonstrable evidence that the dignity, rights, safety and wellbeing of participants are protected at all times exists. |  |  |
| 8. 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/service owners, their families and staff are outlined without causing any undue harm. (NDA, 2009: Ethical Guidance for Research with People with Disabilities). |  |  |

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| 9. Protocols are comprehensively outlined to meet the needs of service users/service owners 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: Ethical Guidance for Research with People with Disabilities) |  |  |
| 10. Follow up procedures and supports for participants in the event of any distress or questions are outlined. |  |  |
| 11. Presentation strategy of findings to service users/service owners/participants in an accessible manner (face to face preferred) is outlined or in the event of remote data collection, strategy to ensure accessible dissemination of findings must be considered. |  |  |
| 12. 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. |  |  |
| 13. Researchers must adhere to Public Health Guidance when making an application. |  |  |
| **Gatekeeper** |
| 14. The proposed research studies has an appointed gatekeeper who is an Enable Ireland staff member. |  |  |
| 15.The appointed gatekeeper will be tasked with inviting service users/service owners, families and staff to participate. |  |  |
| 16. I will not have direct access to service users/service owners, their families and staff until explicit consent is in place. Any personal data that is collected will be subsequently anonymised and will be destroyed with immediate effect once its use has been exhausted. |  |  |
| 17. The appointed gatekeepers name is stated on the Enable Ireland REQC application form. |  |  |
| 18. The gatekeeper has received approval from the relevant Service Manager and National Services Forum Manager to participant in the research as gatekeeper. |  |  |
| 19. The Gatekeeper has a full understanding of the project requirements and has signed the application submitted to REQC. |  |  |

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| **Principal Investigator (PI)** |
| 20. 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, adhering to data protection legislation as data controllers generating and analysing data, applying for funding, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others. |  |  |
| 21. The Data Protection Consent Form is completed. |  |  |
| 22. The ‘Principal Investigators Declaration’ is completed. |  |  |
| 23. All data collection tools e.g. information sheet, questionnaire etc. will be accessible and developed using plain English. Researchers must seek the minimum personal data from our service users/service owners and if possible collect first names, store initials only and other specific personal identifiable information should be avoided unless there is a clear need. Data collection tools will be accompanied as an appendix to researchers overall application. |  |  |
| 24. I/we declare no real or potential conflicts of interest. |  |  |
| 25. 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. |  |  |
| 26. Substantive changes to the research proposal will be submitted for a secondary ethical review. These amendments will be implemented only if/ when approved. |  |  |
| 27. PI will submit Interim progress report (see Policy **Appendix 2**) and final report of findings to Enable Ireland as a stipulation of final approval. |  |  |
| **Supervision** |
| 28.Nominated supervisors stated within the Enable Ireland REQC application form will supervise during each stage of the research process including drawing up proposals, preparing funding applications, data recording, and data analysis andreporting. |  |  |
| 29.The appointed supervisor has completed the ‘Supervisor Declaration’. |  |  |
| **Explicit Consent** |
| 30. Standard written protocols are detailed within the REQC application form detailing the process of obtaining explicit consent. |  |  |

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| 31. Explicit consent must be in place if personal data is required for data collection purposes e.g., interview, focus group. |  |  |
| 32. 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, how the institution/principal investigator will process participants’ data and safeguards to ensure compliance with GDPR voluntary participation and how the results will be disseminated. |  |  |
| **Data Protection** |
| 33. I/we will adhere to the following legislation: The EU General Data Protection Regulation (2018), The Data Protection Act (2018), The Freedom of Information Act (2003-2014), and The Equal Status Act (2000) and any amendments to these pieces of legislation. I/we are aware of any further legal requirements that regulate their work. |  |  |
| 34. I /we will clearly document who the data controller is and explain all processes proposed for the research. |  |  |
| 35. I/we agree to comply with all requirements set out in Section 2.7 of Enable Ireland REQC Policy & Procedure. |  |  |
| 36. Prior to submitting the application to Enable Ireland’s REQC, I/we understand we must be clear on who the data controller is and how best all obligations in relation to data protection can be met. |  |  |
| 37. 1/we will provide a copy of the completed DPIA and decision from the relevant DPO. Where DPIA is not completed detailed explanation for same will be provided in Enable Ireland’s REQC application for consideration. |  |  |
| **Dissemination, Exploitation and Publication of Results** |
| 38. Where the research has been funded in whole or part by Enable Ireland, this contribution will be acknowledged in any publication. |  |  |
| 39. Participants must be informed that the data may be subject to publication and how they access results of the study. |  |  |
| 40. 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. |  |  |

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| **External Guidance from Professional Bodies** |
| 41. I/we will observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies. |  |  |
| 42. I /we understand findings will be open to critical review through the accepted scientific and professional channels. |  |  |
| 43. 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. |  |  |
| 44. I/we understand, where it is not possible to obtain ethical approval prior to submission to the REQC full approval will not be provided. Where appropriate, applicants may receive ‘Provisional Approval’ which will be subject to receiving the Institute’s Ethical Approval. |  |  |
| 45. By signing below, the person signing hereby warrants that they have the authority to sign on behalf of their Institution and bind the Institution to the terms hereof. |  |  |
| 46. I/we understand applicants that are not required to submit an application to a REQC (or similar) in their respective institute. For such scenarios, the applicant must provide a detailed explanation in the space provided in the application. |  |  |

**Part 2 Principal Investigator Declaration**

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|  | **Initial** |
| 1. I have read and will comply with the content of the Enable Ireland REQC Policy and Procedure document. |  |
| 2. I certify the information in this form is accurate to the best of my knowledge and belief and I understand my ethical and legal responsibilities as Principal Investigator of this study. |  |
| 3. I confirm that all named co-investigators have signed below, have read and complied with the Enable Ireland REQC Policy and Procedure document and received the final version of the study protocol and of this application form and are in agreement with their role. |  |
| 4. I understand the obligations to and the rights of participants particularly concerning their safety and welfare, the obligation to provide information sufficient to give explicit consent, the obligation to respect confidentiality and all the obligations as set out in the EU General Data Protection Regulation 2018 and Data Protection Act 2018. |  |
| 5. I understand my affiliated university/organisation is the data controller and any platforms for data collection purposes, storage and processing must be used in line with my institutions data protection policy. |  |
| 6. I will utilise data collection platforms that have a data processing agreement with my institution/ organisation I understand under no circumstances will individual personal accounts be used. |  |
| 7. I confirm that all named co-investigators are aware that all data must be immediately anonymised and all personal data to be destroyed with immediate effect. Confirmation of deletion will be made to the Enable Ireland REQC. |  |
| 8. Participants will be informed that they are in no way obliged to volunteer if there is any personal reason (which they are under no obligation to divulge) or if they simply do not want to participate in the research. |  |
| 9. Participants will be informed that they may withdraw from the research without disadvantage to themselves and without being obliged to give any reason. |  |

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| 10. I have named the appointed gatekeeper in the REQC application form and confirm that the gatekeeper is an Enable Ireland staff member who has approval from the relevant NSF Manager and Service Manager for project participation. |  |
| 11. All relevant information about serious adverse reactions and new events likely to affect the safety of the subjects will be reported to the Enable Ireland REQC in writing. |  |
| 12. If the study receives approval, I agree to supply interim progress report and a final report/thesis etc. to the Enable Ireland REQC. |  |
| 13. In the event of premature termination, suspension or deferral of this project, I agree to provide a report to the Enable Ireland REQC outlining the circumstances for such termination, suspension or deferral. |  |
| 14. By signing part 7 of this document, the person signing hereby warrants that they have the authority to sign on behalf of their Institution and bind the Institution to the terms hereof. |  |

# **Part 3 Enable Ireland Research Ethics & Quality Committee Application Form**

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| **1.GENERAL INFORMATION** |
| 1. **Project Title**
 |  |
| 1. **Principal Investigator**

*(include principal**Investigators**declaration form)* | **Name** |  |
| **Qualification** |  |
| **Position** |  |
|  | **Organisation** *(include department and contact details)* |  |
| 1. **Co- Investigators/Student Researchers**
 | **Name** |  |
| **Position** |  |
| **Organisation** *(include department and contact details)* |  |
| **Role in project** |  |
| 1. **Supervisor Details**

*(include Supervisor**declaration form)* | **Name** |  |
| **Position** |  |
| **Organisation** *(include department and contact details)* |  |
| **5. Have you received** | *If no, (i) explain why? And (ii) outline source of approval.* |  |
| **permission from your** |
| **university/****institute’s** |
| **REC?** *(attach a copy of the submitted REC with a copy of the**approval/provisional approval* |
| *letter).* |

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| 1. **Enable Ireland Details**
 | ***Centre(s)*** |  |
| ***Gatekeeper (s) (insert name)*** |  |
| ***Local Service Manager(s) (insert name(s))*** |  |
| ***Local Director of Services/National Services Forum Manager (s) (insert name)*** |  |
| ***National Directorate Support Received (where multiple******CHO areas involved)*** |  |
| 1. **Proposed Commencement Date:**
 |  |
| 1. **Specify submission date of the Enable Ireland Interim Report** (see Enable Ireland Interim Report Template)
 |  |
| 1. **Proposed Project Completion Date:**
 |  |
| 1. **Proposed Date Researcher will submit final report to Enable Ireland.**
 |  |
| 1. **Use of External Sites**
 |  |
| **2. AIMS & OBJECTIVES** |
| 1. **Overall Aims**

The purpose of your research – what are you trying to discover/prove/ achieve? |  |

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| **2. Specific Objectives** |  |
| **3. Hypothesis** |  |
| **3. PARTICIPANT SAMPLE, CRITERIA & INCLUSION** |
| 1. **Participant Nature** *(i.e. detail e.g. type of disability/staff role/others relevant etc.):*
 |  |
| **2. Sample Number** |  |
| 1. **Justification for sample number.**
 |  |
| 1. **Inclusion Criteria** *(be specific in relation to the required research detail e.g. gender, age etc.):*
 |  |
| 1. **Describe participant involvement in Study Design & Implementation (if any).**

i.e. Will the service users/ service owners/staff be involved in the design/ implementation? If yes, please describe. |  |
| **4. BENEFITS FOR SERVICE USERS/SERVICE OWNERS/FAMILIES/STAFF** |
| 1. **Outline the benefits of the research for participants involved e.g. Service users/service owners, Families, Staff?**
 |  |
| **5. OUTCOMES/BENEFITS FOR ORGANISATION** |
| **1. How does this research align with Enable Ireland’s Strategic Plan?** |  |
| **2. How will this research inform local and/or national Service Development?** |  |
| **3. Will Enable Ireland be identified in your study and if so, how?** |  |
| **6. Voluntary Participation, Meeting Participants and Confidentiality** |
| **1. Voluntary Participation**How will you assure service users/service owners or families that their participation is purely voluntary and that whether they agree to participate or not, will not in any way affect their present or future service? |  |
| **2. Meeting with Participants**If your research involves meeting with the service user or family, where and when will this happen? Detail which investigator will carry this out? |  |
| **3. Confidentiality**How will you assure service users/service owners or families that their confidentiality will not be compromised in any way? (Referencerelevant Application Appendix) |  |
| **7. Role of Gatekeeper** |
| 1. **Participant Initial Contact**

Describe how the appointed gatekeeper (s) will contact participants. |  |
| 1. **Provide details for all of the tasks assigned to the gatekeeper.**
 |  |
| 1. **Provide details on expected timeline/time required from the gatekeeper to fulfil proposed tasks.**
 |  |
| **8. METHODOLOGY** |
| **1. Study Design**(mark with x) | Quantitative |  |
| Qualitative |  |
| Mixed Methods |  |
| Action Research |  |
| Other, please describe |  |
| **2. Describe in detail the study design include reference to the specific instruments/measures used.** |  |
| 3**. List the titles of all supporting documents being submitted with this application i.e. questionnaires, interview schedule, test assessment/consent.** |  |
| **4. Time-frame** *(Note -No project can begin without full approval from REQC*)Provide a detailed schedule of the tasks & timeline involved throughout the research project. |  |
| **5. Statistical Methods** Please provide detailed account |  |
| **6. Research Risks****Please provide project risks and mitigation measures in place i.e.** how do you intend to eradicate potential risk to participants? |  |
| 1. **Procedures which may cause discomfort/distress.**
	1. Does your research include procedures that may cause discomfort or distress?
 |  |
| ii. Has this been outlined to the service manager/national manager |  |
| iii. What approach/follow up supports will be put in place? |  |
| **iv.** Details whatresources are required to facilitate the supports required. |  |
| **9. INFORMATION LETTER, INVITATOIN LETER, EXPLICIT CONSENT & ASSENT** |
| 1. Have you prepared an Invitation Letter and attached a copy to the application. *(State Yes/No and Appendix Number and Title)* |  |
| 2. Have you prepared an Information Sheet and attached a copy to the application. *(State Yes/No and Appendix Number and Title)* |  |
| 3. How will consent be obtained, provide details e.g. hardcopy letter/included at the beginning of the survey? |  |
| 4. Have you prepared a Consent form? Copy required. *(State Yes/No and Appendix Number and Title)* |  |
| 5. Have you prepared an Assent form (agreement of young person) for participants under the age of 16 (if applicable)?Copy required. *(State Yes/No and Appendix Number and Title)* |  |
| 6. Have you prepared a Parental/Guardian Consent form for participants under the age of 16? Copy required. *(State Yes/No and**Appendix Number and Title).* |  |
| 1. **What is the time interval between giving information notice and seeking explicit consent? (*Note, it*** *is recommended that a period of seven days be provided for reflection. If less than this, please justify).*
 |  |
| 1. Will each participant receive information according to his/her capacity of understanding regarding the risks and benefits of the project? Provide detail and attach copies of relevant material.
 |  |
| **10.DATA MANAGEMENT & DATA PROTECTION** |
| **Governance & Procedure: Data Controller Status, DPO Consultation & DPIAs** |
| 1. Please specify which arrangements are in place to ensure that personal data will be processed as is necessary
	1. to achieve the objective of the health research and
	2. to ensure that it shall not be processed in such a way that damage or distress to the data subject
 |  |
| 2. Explicitly state who the data controller of the project is?*Seek verification from your institute if you are unsure in advance of submission to Enable Ireland REQC.* |  |
| 3. Are there any other processors/joint controller relationship/other individual data controllers etc? Provide detail. |  |
| 4. Please specify any person other than the named data controller, joint controllers or processors with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing. |  |
| Please specify any person or organisation who provides funding for, or otherwise supports, the project. |  |
| 5. Have you consulted with your institutes DPO prior to submitting this REQC application?*If yes, what was the outcome?**If not, why not?* |  |
| 6. Does you projectrequire Enable Ireland to sign any agreementse.g. Data Sharing Agreement / Data Processing Agreements/ joint Controller Agreement etc. *Provide explicit detail and attach a copy of the requested documentation for**consideration by Enable Ireland.* |  |
| 7. Has a risk assessment and/or data protection impact assessment beencarried out, taking in to account local policy and/or legal requirements?*If yes, please attach copy and provide detail in relation to current status.**If not, please provide justification for same. .**Note: Where a type of processing is likely to result in a high risk to the rights and freedoms of individuals, the controller must, prior to the processing, carry out a data protection impact assessment.’ General Data Protection Regulation (GDPR) Article 35(1).* |  |
| 8. The provision of training in data protection law and practice to anyone involved in carrying out the health research is a mandatory legalrequirement. Please specify the provision of training you have completed.See definition of health research: [https://www.hrb.ie/fun](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [din g/gdpr guidance](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [for](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [researchers/gdpr](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [and](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [health](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [research/what is](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [research/ : :text What](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [2](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels)[0is 20health 20resear](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [ch](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) [3 ,system 20and 20w hol e 20body 20levels](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/#%3A%7E%3Atext%3DWhat%20is%20health%20research%3F%2Csystem%20and%20whole%20body%20levels) |  |
| 9. Please specify the measures in place that demonstrate compliance with the data minimisation principle (Is itadequate, relevant and limited to what is necessary?) |  |
| 10. Please specify the controls in place to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data. |  |
| 11. Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased. |  |
| 12.Please specify measures to protect the security of the personal data concerned. |  |
| 13.Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed. |  |
| 14.Please specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures. |  |
| 15.Please specify which arrangements are in place to ensure that personal data is processed in a transparent manner. |  |
| **11.Data Processing – Classification and Processing** |
| 1. What data is being collected (be as specific as possible e.g. name, age, details regarding hip surveillance/IP Address/Email etc.)? |  |
| 2. What is the legal basis for processing the data? |  |
| 3. How is the data being collected (i.e. be specific in relation to any online platforms/software being utilised)? |  |
| 4. or online platforms/software being used, are they approved institute systems with therequired DPA in place. |  |
| 5. Would you class the data collected in this study as anonymous, pseudonymised, or identifiable data? |  |
| 6. If PSEUDON ISED’, please confirm who will retain the key’ to re identify the data? |  |
| 7. Where will data which is collected be stored (e.g. (encryptedlaptop/USB/OneDrive etc.)? |  |
| *8.* Who will have access to the data *(i.e. access to those on a need to know basis)?* How will they haveaccess, provide detail? |  |
| 9. Will data collected be at any stage leaving the site(s) of origin? If yes, please elaborate. |  |
| 10.Where will data analysis take place, who will perform data analysis (if known) and how will it be carried out? |  |
| 11.After data analysis has taken place, will data be retained? |  |
| 12.If yes, for how long, for what purpose, and where will it be retained? |  |
| 13.How will data destruction take place when the retention period has concluded? |  |
| 14.Please comment on the confidentiality of collected data. |  |
| 15. Will any of the interview data collected consist of audio recordings / video recordings? ( /N) *If yes, please elaborate.* |  |
| 16.Will any of the study data collected consist of photographs/ video recordings? ( /N)*If yes, please elaborate.* |  |
| 1. If audio taping/videos/photos forms part of the study design you must allow the participant access to the transcript, if they so wish. This must be included in the Explicit Consent form and Information Leaflet.

Has it been included? |  |
| 18.Will participants have an opportunity to review data collected? |  |
| **12.0 Access to Healthcare Records (Mark N/A if not applicable to your project)** |
| 1. Does the study involve access to healthcare records (hard copy / electronic)?If yes, please elaborate. |  |
| 2. Who will access these healthcare records and how will they get access? |  |
| 3. Will consent be sought from patients for research team members to access their healthcare records? *Note, Consent is required from the patient to access healthcare records for research purposes unless a ‘consent declaration’ has been**granted or are the records are anonymous.* |  |
| 4. Who or what legal entity is the data controller in respect of the healthcare records? |  |
| 5. What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?*A ‘consent declaration’ or anonymised records are the only options here.* |  |
| 1. Who will document the access on an access log and provide to the data controller of the records?
 |  |
| **13.0 DISSEMINATION** |
| 1. Please describe how the results will be conveyed back to individual participants.(Specify methods that will be used e.g. presentation to participants, Workshop/conference/ online/in person/ prerecorded session etc ..) |  |
| 2. How are you going to manage potential distress/upset, should this arise during dissemination? |  |
| 3. Please comment on how aggregated study results will be made available to Enable Ireland. |  |
| 4. Please describe your wider dissemination strategy and include relevant timeline. |  |
| 5. Please confirm you undertake not to directly contact participants post completion of your research. |  |

**Applicants must adhere to the Enable Ireland REQC Policy and Procedure. Please email a copy of your completed application including required appendices to** **hshave@enableireland.ie**

# **Part 4 Principal Investigator Data Protection Consent Form**

Enable Ireland processes personal data in compliance with the GDPR. The categories of personal data we process include:

1. Name
2. Contact information
3. Qualification
4. Educational background
5. Employer details

The personal data outlined above forms part of the REQC application process and is looked for in the REQC application form.

The purpose of this data is to process the REQC submission by consenting to the use of this data it will be shared and accessed by REQC members.

REQC members are suitably qualified Enable Ireland staff and two third party volunteers from third level institutions.

There is no strict statutory or contractual requirement for you to provide data to us but if you do not provide at least that data that is necessary for us to assess suitability for engagement by us then it will not practically be possible for us to process your REQC submission

Your personal data will be kept in a secure manner and accessible to designated Enable Ireland staff members only.

You have the right to access your personal data upon request. Your files will be retained in line with Enable Ireland’s Retention Schedule. For more information see Enable Ireland [Privacy Policy | Enable Ireland](https://enableireland.ie/privacy-policy#%3A%7E%3Atext%3DWe%20obtain%20personal%20data%20about%2Cways%20described%20in%20this%20Notice).

**By signing Part 6 of this document you agree you have read and understood the information about Data Protection, and agree to my personal data being used in the way described above.**

# **Part 5 Supervisor Declaration**

|  |  |
| --- | --- |
| **Name of Supervisor:** |  |
| **Occupation:** |  |
| **School/Department:** |  |
| **Organisation/Institution:** |  |

|  |
| --- |
| **As research supervisor:** |
| 1. I have read and adhere to the Enable Ireland Research Ethics and Quality Committee (REQC) policy and procedure. |
| 2. I pledge to supervise during each stage of the research process including drawing up proposals, preparing funding applications, data recording, and data analysis and reporting. |
| 3. I am fully aware of the details of this project, having read the application in full and I agree for it to proceed as outlined. |
| 4. I can confirm that the application is an appropriately high standard and of educational value and all the necessary facilities and resources are available to the researcher. |
| 5. I consent to the use of the below personal data in order to support the Principal Investigator application to the Enable Ireland REQC. |

**Part 6: Overall Signature Page**

When all required REQC documentation has been completed in full (i.e. all parts) listed on summary table at the beginning of this document) this signature page must be completed.

We undersigned, acknowledge any substantive changes to the research proposal must be submitted for a secondary ethical review. These amendments will be implemented only if/when approved.

|  |  |
| --- | --- |
| **Principal Investigator Name:** |  |
| **Principal Investigator Signature:** |  |
| **Date:** |  |

|  |  |
| --- | --- |
| **Co-Investigator****Name:** |  |
| **Co-Investigator****Signature:** |  |
| **Date:** |  |

|  |  |
| --- | --- |
| **Supervisor Name:** |  |
| **Supervisor Signature:** |  |
| **Date:** |  |

|  |  |
| --- | --- |
| **Gatekeeper Name:** |  |
| **Supervisor Signature:** |  |
| **Date:** |  |

By signing this overall signature page, the signatories confirm that they have read & understood all the contents of Enable Ireland’s REQC Policy & Procedure and the mandatory documentation for same, also agreeing to abide by all the requirements contained therein.