



Research Ethics & Quality Committee (REQC) Policy & Procedure

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1.0 Scope

The Enable Ireland Research Ethics and Quality Committee (REQC) policy and procedure outlines specific procedures for undertaking research involving Enable Ireland service users/service owners, families and staff. Compliance with the ethical principles and practices outlined is essential. Production of quality research in line with Enable Ireland's core values and way of working is also required.

All research that involves gathering information about or from service users/service owners, their families or staff requires the formal written approval of the REQC. Any proposed changes subsequent to written approval, requires the consent of the REQC chairperson prior to implementation. Clinical, social and organisational research impacts directly and indirectly on service users/service owners, their families and staff at all levels within the organisation. The REQC requires all research to have clear aims and objectives that ultimately benefit service users/service owners, families or staff. All research must be aligned to Enable Ireland strategic objectives and be of benefit/added value to local and national service development.

1.2 Duty of Care

Enable Ireland has a duty of care to all service users/service owners who access services. At all times the interests, rights, privacy and welfare of service users/service owners are paramount. Enable Ireland is committed to the protection, well-being and safety of research participants and a duty to respect the rights, privacy and wishes of those participating in research.

Enable Ireland promotes the principles of non-maleficence and beneficence. The principle of non-maleficence places an obligation upon the researcher to do no harm and to safeguard service users/service owners; beneficence requires the promotion of good, and imposes a duty on the researcher to minimise harm and to maximise research benefits. (Enable Ireland, 2008: *Pathways of Service Delivery for Children and Families: Code of Practice*)

1.3 Research Governance

Research governance is the process by which the quality of research can be assured and the rights, dignity and safety of those involved can be protected. The responsibility of research governance is placed with the Enable Ireland REQC.

Research governance is required to:

- Safeguard participants in research.
- Protect researchers/investigators (by providing a clear framework to work within).
- Enhance ethical and scientific quality.
- Minimise all risks.
- Monitor practice and performance.
- Promote good practice and ensure lessons are learned¹.

The benefits of implementing research governance are summarised as follows:

- To protect those for whom Enable Ireland has a duty of care from any possible harm arising from participation in research.
- To enable accountability and transparency for any research undertaken through specific policy and procedures underlined by principles of best practice.

¹ Source: "What is Research Governance?" Imperial College London. Accessed 15 April, 2015

<http://www3.imperial.ac.uk/clinicalresearchgovernanceoffice/researchgovernance/whatisresearchgovernance>

1.4 Role of Enable Ireland

Enable Ireland's responsibilities include:

- Safeguarding service users/service owners, families and staff. The primary objective of Enable Ireland in regards to research is to safeguard and protect the rights of services users, their families and staff.
- Supporting service users/service owners to participate where appropriate and ensuring their inclusion in feedback upon completion of the research.
- Supporting research in accordance with Enable Irelands core values and StrategicPlan.

1.5 Role of the Enable Ireland REQC

The REQC is responsible for the review and approval of all research involving Enable Ireland service users/service owners and staff in accordance with this policy. The REQC is responsible for ensuring research governance and providing feedback and support in a timely and appropriate manner to all applicants.

The REQC complies with the EU General Data Protection Regulation (GDPR) 2016. All data protection risks will be directed to the Enable Ireland Data Protection Officer as required. The outcome of which will impact on the final decision made by the REQC.

The design of the research programme is the responsibility of the applicant. To obtain approval, the researcher must ensure that the research programme complies with the recognised standards and procedures contained within this policy.

All research studies must be developed, designed and implemented according to the compliance criteria, failure to do so will result in approval being declined. **(To ensure compliance, complete Criteria for Ethical Approval Checklist Appendix 2)**

2.0 Compliance Criteria for Ethical Approval

2.1 General Terms

- 2.1.1 Full compliance with the Enable Ireland REQC Policy and Procedure document.
- 2.1.2 Adherence to the 'Procedures for Applicants Submitting to the Enable Ireland REQC (Appendix 1).
- 2.1.3 Adherence to current safety practices, ethical standards, and legislation.
- 2.1.4 COVID-19 considerations - In accordance with Government Directives and National Public Health Guidance all REQC application must use remote data collection methods. Face to face data collection methods will not be considered until it is safe to do so.

2.2 Protection of Service users/service owners and Staff

- 2.2.1 Demonstrable evidence that the dignity, rights, safety and well-being of participants are protected at all times.
- 2.2.2 Research risks must be assessed by researchers with respect to their physical, social and psychological effects on service users/service owners, 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 must be outlined without causing any undue harm. (NDA, 2009: *Ethical Guidance for Research with People with Disabilities*).

- 2.2.3 Protocols must be 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 is essential. (NDA, 2009: Ethical Guidance for Research with People with Disabilities).
- 2.2.4 Follow up procedures and supports for participants in the event of any distress or questions must be outlined.
- 2.2.5 Presentation strategy of findings to service users/service owners/participants in an accessible manner (face to face preferred) must be outlined or in the event of remote data collection, strategy to ensure accessible dissemination of findings must be considered.
- 2.2.6 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.
- 2.2.7 Researchers must adhere to Public Health Guidance when making an application during the COVID-19 pandemic. The safety of service users/service owners and staff is paramount.

2.3 Gatekeepers

- 2.3.1 All proposed research studies within Enable Ireland are required to have an appointed gatekeeper who is an Enable Ireland staff member.
- 2.3.2 Researchers will not have access to service user contact information. The appointed gatekeeper will be tasked with inviting service users/service owners, families and staff to participate.
- 2.3.3 Researchers will have direct access to service users/service owners, their families and staff only when explicit consent is in place.
- 2.3.4 The appointed gatekeepers name must be stated on the Enable Ireland REQC Application Form (see **Appendix 3**)

2.4 Principal Investigators

- 2.4.1 Researchers are required to be honest and transparent in respect of their own actions in research and in their 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, adhering to data protection legislation as data controllers and acknowledging the direct and indirect contribution of colleagues, collaborators and others. Principal investigators must complete the Principal Investigators Declaration (see **Appendix 4**).
- 2.4.2 All data collection tools e.g. information sheet, questionnaire etc. must 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 only, store initials only and other specific personal identifiable information should be avoided unless there is a clear need. Data collection tools must be accompanied as an appendix to researchers overall application.
- 2.4.3 Researchers must declare any real or potential conflicts of interest to the Enable Ireland REQC coordinator and must abide by the guidance of the REQC in relation to managing same.
- 2.4.4 Researchers must consent to the processing of personal data for the purpose of obtaining REQC approval.
- 2.4.5 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.

2.4.6 Substantive changes to the research proposal must be submitted for a secondary ethical review. These amendments will be implemented only if/when approved.

2.4.7 Interim progress report (see **Appendix 7**) and final report of findings will be submitted to Enable Ireland as a stipulation of final approval.

2.5 Supervision

2.5.1 Nominated supervisors stated within the Enable Ireland REQC application form (see **Appendix 3**) are required to supervise during each stage of the research process. The appointed supervisor is required to comply and sign the 'Supervisor Declaration' (see **Appendix 6**).

2.6 Explicit Consent

2.6.1 Standard written protocols must be detailed within the REQC application form (see **Appendix 3**) detailing the process of obtaining explicit consent.

2.6.2 Obtaining explicit consent from participants: The consent form must be unambiguous, freely given, specific and informed. Consent must be provided in an appropriate accessible format and include: the nature and purpose of the research, what taking part involves, how the institution/principal investigator will process participants data and safeguards to ensure compliance with GDPR, the level of anonymity and confidentiality, voluntary participation and how the results will be disseminated.

2.7 Data Protection

2.7.1 Ensuring compliance with data protection legislation is a requirement of all research institutions. No use of any data, whether directly relating to service user, family or staff data will be sanctioned without the written permission of the REQC

2.7.2 Procedures to ensure the collection of high quality, accurate data including the integrity and confidentiality of data during processing and storage must be in place prior to commencement.

2.7.3 All researchers undertaking research for Enable Ireland must adhere to all Data Protection legislation this includes the EU General Data Protection Regulation (2016), and the Data Protection Act 2018. The Researcher and the researchers affiliated institution e.g. University/Organisation is the data controller and all data processing must abide by the institutions/organisations data protection policy and GDPR legislation. The individual researcher must have written confirmation from their affiliated institution that they accept they are the Data controller of the personal data processed by the researcher.

2.7.4 Explicit consent must be in place if personal data is required for data collection purposes e.g., interview, focus group

2.7.5 All data retrieved as a result of the field research must be anonymised and **personal data for access purposes be immediately destroyed**.

2.7.6 Removal of identifiers and the use of pseudonyms is mandatory to guarantee confidentiality and anonymity.

2.7.7 It is imperative that we can assure our participants that their data will be stored securely; this is of course particularly important where potentially sensitive personal details are involved. It is not adequate to simply say that the data will be stored safely.

2.7.8 Exact detail is required as to the use (and location) of locked cabinets, management of audio files, encryption of laptops, electronic storage and soon.

2.7.9 Where possible physical data such as survey forms etc. should be converted to electronic format as soon as possible and the originals shredded, however if required retention of physical data it should be safely stored in a locked cabinet/office.

2.7.10 If transcription is being outsourced the transcription service need to have signed a data

processing agreement that meets the requirements of [Article 28](#)².

2.7.11 Online Platforms: Enable Ireland will not sanction the use of Zoom, What's App video or chat or Survey Monkey as secure online data collection methods. When using online platforms for the purposes of data collection e.g. Microsoft teams, Google Forms, researchers must use the approved secure platform of their affiliated institution. The institution must have in place a data processing agreement with the specific platform being utilized. The Principal Investigator will need to confirm in writing that the provisions as required by [Article 28](#) of the GDPR are included in the data processor contract as noted by the Data Protection Commission see data protection commission website for further details in this regard).

2.8 Dissemination, Exploitation and Publication of Results

2.8.1 Where the research has been funded in whole or part by Enable Ireland, this contribution will be acknowledged in any publication.

2.8.2 Participants must be informed that the data may be subject to publication

2.8.3 Research findings with substantial implications for clinical practice or which are likely to attract strong public or media interest must be drawn to the attention of Enable Ireland through the REQC Coordinator before publication.

2.8.4 Written approval is required from the Enable Ireland REQC prior to any media engagement or if any dissemination involves media.

2.9 External Guidance from Professional Bodies

Formal written ethics approval from the researcher's own institution must be obtained and included as an appendix as part of the overall application to the Enable Ireland REQC. No research will commence without formal approval from Enable Ireland and the researcher's institutional REC. Findings must be open to critical review through the accepted scientific and professional channels.

Researchers must observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies (*Research Governance Framework for Health and Social Care, Second Edition 2005, Department of Health*).

² <https://www.dataprotection.ie/en/dpc-guidance/practical-guide-controller-processor-contracts>

Appendix 1

Procedures for Applicants Submitting to the Enable Ireland Research Ethics and Quality Committee (REQC)

Section A

Applicant Procedures

New applications will be reviewed four times per year. Specific dates will be published on the Enable Ireland website for each calendar year.

Step 1: Establish contact with relevant Enable Ireland service/department in order to assess what local supports would potentially be available for the study.

Step 2: Confirm and agree local Enable Ireland gatekeeper

Step 3: Upon application, complete and submit the following documents by email and post to the Enable Ireland REQC Coordinator:

1. Complete and adhere to the Criteria for Approval Checklist (**Appendix 2**).
2. Full completion of the 'Enable Ireland REQC Application Form' (**Appendix 3**).
3. Signed copy of the 'Principal Investigators Declaration' (**Appendix 4**).
4. Signed copy of the 'Principal Investigators Data Protection Consent' (**Appendix 5**).
5. Signed copy of the 'Supervisors Declaration' (**Appendix 6**).

Step 4: If approval is granted submit an Interim Progress Report (**Appendix 7**).

Step 5: Submit final report, dissertation or publications once study is complete.

A response from the REQC will be provided within 4 weeks of circulation to the committee following screening of applications subsequent to the relevant quarterly submission deadline which will be either:

1. **Approved**- the applicant may proceed with the research as outlined in the research proposal submitted to the REQC.

Or

2. **Provisionally approved**- subject to recommended provisions to the proposal or answers to questions posed to the applicant. The revisions and/or answers must be resubmitted to the REQC in a list format for further review. No research will be conducted prior to receiving written approval.

Or

3. **Approval declined**- Reasons will be provided to the applicant for declining approval. The applicant may re-submit to the REQC.

Section B

Enable Ireland REQC Procedures

Step 1: REQC Coordinator receives and screens completed application and requests basic amendments if required.

Step 2: Application form is sent to all panel members of the REQC by email for review only if it is fully completed or amendments as requested have been made.

Step 3: Discussion by REQC via email and teleconference as required.

Step 4: The REQC Coordinator consults with the DPO as required on specific data protection queries highlighted by the REQC.

Step 5: Decision made within 4 weeks of receipt of application by committee.

Step 6: Feedback provided by REQC Coordinator to the applicant as:

- (i) Approved,
- (ii) Provisionally Approved or
- (iii) Application Declined.

Step 7: Interim report provided by researcher on agreed date to REQC

Step 8: Final research report, along with a copy of associated dissertation/thesis submitted by researcher on agreed date to REQC.

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Cork.

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Appendix 2

Enable Ireland Criteria for Ethical Approval Checklist

Project Title: Principal Investigator: Date:

Enable Ireland Criteria for Ethical Approval Checklist <i>(Ensure all criteria are met prior to submission to the REQC to avoid extension of time periods)</i>		
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. Adherence to current safety practices, ethical standards, and legislation specifically in relation to data protection.		
4. COVID-19 considerations - In accordance with Government directives and National Public Health Guidance all REQC application must use approved remote data collection methods. Face to face data collection methods will not be considered until it is safe to do so.		
Protection of Service users/Service owners and Staff		
5. Demonstrable evidence that the dignity, rights, safety and well-being of participants are protected at all times exists.		
6. 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).		

7. 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, 2009: Ethical Guidance for Research with People with Disabilities)		
8. Follow up procedures and supports for participants in the event of any distress or questions are outlined.		
9. 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.		
10. 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.		
11. Researchers must adhere to Public Health Guidance when making an application during the COVID-19 pandemic.		
Gatekeeper		
12. The proposed research studies has an appointed gatekeeper who is an Enable Ireland staff member.		
13. The appointed gatekeeper will be tasked with inviting service users/service owners, families and staff to participate.		
14. 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.		
15. The appointed gatekeepers name is stated on the Enable Ireland REQC application form (see Appendix 3).		
Principal Investigator (PI)		
16. 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.		

17. The Data Protection Consent Form is completed.		
18. The 'Principal Investigators Declaration' is completed.		
19. 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.		
20. I/we declare no real or potential conflicts of interest.		
21. 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.		
22. Substantive changes to the research proposal will be submitted for a secondary ethical review. These amendments will be implemented only if/ when approved.		
23. PI will submit Interim progress report (see Appendix 7) and final report of findings to Enable Ireland as a stipulation of final approval.		
Supervision		
24. 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.		
25. The appointed supervisor has completed the 'Supervisor Declaration'.		
Explicit Consent		
26. Standard written protocols are detailed within the REQC application form (see Appendix 3) detailing the process of obtaining explicit consent.		
27. 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		
28. I/we will adhere to the following legislation: The EU General Data Protection Regulation (2016), 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.		
29. 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, outline how e.g. through an encrypted solution on laptop or encrypted USB.		
30. Removal of identifiers and the use of pseudonyms will be implemented to guarantee confidentiality and anonymity.		
31. 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.		
32. All hardcopies of personal data will be kept in a secure locked filing cabinet. Soft copies of personal data must will be kept on a locked, password protected computer. Once personal data collected has fulfilled its use, the data will be anonymised and the provisions of the Data Protection legislation must be adhered to at all times.		
33. 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.		
34. The Researcher and the researchers affiliated institution e.g. University/Organisation is the data controller and all data processing must abide by the institutions/organisations data protection policy and GDPR legislation Researchers must be aware of any further legal requirements that regulate their work. The individual researcher must have written confirmation from their affiliated institution that they accept they are the Data controller of the personal data processed by the researcher.		
35. Where possible physical data such as survey forms etc. should be converted to electronic format as soon as possible and the originals shredded, however if required retention of physical data it should be safely stored in a locked cabinet/office.		
36. Enable Ireland will not sanction the use of Zoom, What's App chat or video or Survey Monkey as secure online data collection methods.		

37. When using an online data collection method, researchers or their affiliated institution must have in place a data processing agreement with the platform. Researchers will need to confirm in writing that the provisions as required by Article 28 of the GDPR are included in the contract as noted by the Data Protection Commission		
38. If transcription is being outsourced the transcription service need to have signed a data processing agreement that meets the requirements of Article 28 ¹		
Dissemination, Exploitation and Publication of Results		
39. Where the research has been funded in whole or part by Enable Ireland, this contribution will be acknowledged in any publication.		
40. Participants must be informed that the data may be subject to publication and how they access results of the study.		
41. 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		
42. I/we will observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.		
43. Findings will be open to critical review through the accepted scientific and professional channels.		
44. 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.		
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.		

¹ <https://www.dataprotection.ie/sites/default/files/uploads/201906/190624%20Practical%20Guide%20to%20Controller-Processor%20Contracts.pdf>

Signed Principal Investigator:

Signed Co-Investigator (if applicable):

Date:

Appendix 3

Enable Ireland Research Ethics & Quality Committee Application Form

1. GENERAL INFORMATION		
Project Title		
Principal Investigator <i>(include principal investigators declaration form)</i>	Name	
	Qualification	
	Position	
	Organisation	<i>(include department and contact details)</i>
Co. Investigators/Student Researchers	Name	
	Position	
	Organisation	<i>(include department and contact details)</i>
	Role in project	
Supervisor Details <i>(include supervisor declaration form)</i>	Name	
	Position	
	Organisation	<i>(include department and contact details)</i>
Have you received permission from your university/institute's REC? (attach approval letter)	Y N	<i>If no, (i) explain why? (ii) outline source of approval</i>
Enable Ireland Details	Centre	
	Gatekeeper	<i>(insert name)</i>
	Local Service Manager	<i>(insert name)</i>
	Local Director of Services/National Manager	<i>(insert name)</i>

Duration of Project	Proposed Commencement Date:	Proposed Completion Date:
Use of External Sites		

2. SERVICE USER PARTICIPATION

Participant Initial Contact Describe how the appointed gatekeeper will contact participants	
Participant Involvement in Study Design & Implementation Will service users/service owners/staff be involved in the design/implementation? If yes, please describe.	<i>(if yes, please describe)</i>
Participants	Nature <i>(detail e.g. type of disability etc.):</i>
	Sample Number:
	Inclusion Criteria <i>(detail e.g. gender, age etc.):</i>
Voluntary Participation How will you assure service users/service owners or families that whether they agree to participate or not, will not in any way affect their present or future service? What is the potential benefit for research participants?	

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? (NOT TO BE COMPLETED DURING THE COVID-19 PANDEMIC)	
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Confidentiality How will you assure service users/service owners or families that their confidentiality will not be compromised in any way?	
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3. AIMS & OBJECTIVES

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

Specific Objectives	

Hypothesis	
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4. BENEFITS FOR SERVICE USERS/SERVICE OWNERS/FAMILIES/STAFF
--

Outline the benefits of the research for participants involved e.g. Service users/service owners, Families, Staff?	
---	--

5 .OUTCOMES/BENEFITS FOR ORGANISATION
--

How does this research align with our Strategic Objectives?	
--	--

How will this research inform local and/or national Service Development?	
Will Enable Ireland be identified in your study and if so, how?	
Specify submission date of the Enable Ireland Interim Report (see Enable Ireland Interim Report Template)	

6. METHODOLOGY	
Study Design Quantitative, Qualitative, Mixed Methods, etc.	
Describe Instruments/Measures (You must include a copy of any questionnaire, interview schedule, test, etc with your application)	
Time-frame Provide a detailed schedule of the tasks involved throughout the research project.	<i>(Note -No project can begin without approval from REQC)</i>
Statistical Methods Please provide detailed account	

<p>Procedures which may cause discomfort/distress</p> <p>Does your research include procedures that may cause discomfort or distress?</p> <p>How do you intend to eradicate potential risk to participants? What approach/follow up supports will be put in place?</p>		
7. EXPLICIT CONSENT & ASSENT		
<p>Participant Information</p> <p>Have you prepared an Invitation Letter and Information Sheet? Please include copies of the relevant materials as an Appendix.</p>	<p>Invitation Letter:</p>	
	<p>Information Sheet:</p>	
<p>Signed Explicit Consent</p>		
<p>Have you prepared a Consent Form? How will consent be obtained?</p>	<p>(Include copies of the relevant materials as an Appendix)</p>	
<p>Signed Informed Assent (if applicable)</p>		
<p>Have you prepared an Assent Form (agreement of young person) for participants under the age of 16</p> <p>NOTE: PARENTAL/GUARDIAN CONSENT IS ALSO REQUIRED FOR PERSONS UNDER THE AGE OF 16</p> <p>What is the time interval between giving information and seeking explicit consent?</p> <p>(It is recommended that a period of seven days be provided for reflection. If less than this, please justify).</p>	<p>(Include copies of the relevant materials as an Appendix)</p>	
<p>Information for participants under the age of 18</p>		
<p>Will each child receive information according to his/her capacity of understanding regarding the risks and benefits of the project?</p>	<p>(Include copies of the relevant materials as an Appendix)</p>	

8. DATA MANAGEMENT & DATA PROTECTION

Who will have access to the data? Please ensure those that have access have a need to know.	
What media of data will be collected? Will participants have an opportunity to review data collected? If audio taping 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.	Audio and Transcripts: Will the participant be given access to review a transcript of the audio tape interview? If, no explain, justify why? Photos and Videos:
Data Classification Please detail the data what will be collected e.g. email address, first name only of participants , IP address etc. considerable efforts to be made to collect minimal personal data	Anonymous:
	Pseudonymised:
	Coded:
	Personal Identifiable:
Data Protection Where will the data be stored? (encrypted laptop or USB) Who will have access to the stored data? Will the data be retained or destroyed after the project? Specify all personal data will be destroyed once anonymised. Outline how and by whom. Describe steps to ensure confidentiality of data? We require data is anonymised after it has been used.	Storage:
	Security:
	Confidentiality:
	Retention:
	Destruction:
Where will Data Analysis take place, and by whom? Please sign to confirm that you will not use or retain service user data for any reason other than that outlined in the research? Please confirm you undertake not to contact service user participants post completion of your research.	

<p>What online data collection platforms will you use?</p> <p>Specify if you have a data processing agreement in place which contain all the requirements of Article 28 of the GDPR as outlined in the Data Protection Commission website accessible at: https://www.dataprotection.ie/sites/default/files/uploads/2019-06/190624%20Practical%20Guide%20to%20Controller-Processor%20Contracts.pdf.</p> <p>(If you are applying as part of an undergrad or postgrad programme please utilise platforms where there is already a data processing agreement in place that meets the requirements of Article 28 of the GDPR) Use of personal counts is not permitted.</p>	
9. DISSEMINATION	
<p>Please comment on how the results will be conveyed back to individual participants.</p> <p>(Specify methods that will be used e.g. presentation to participants, workshop/conference, etc.....)</p> <p>How are you going to manage potential distress/upset, should this arise during dissemination?</p>	
<p>Please comment on how aggregated study results will be made available to Enable Ireland.</p>	
<p>Please describe your wider dissemination strategy.</p>	

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 and send a hard copy with signatures on declaration form to Helen Shave, Research Ethics and Quality Coordinator, Enable Ireland, HR & Corporate Affairs, Lavanagh Centre, Curraheen, Carrigrohane Co. Cork.

Appendix 4

Principal Investigator Declaration

	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 2016 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/ organization 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.	

10. I have named the appointed gatekeeper in the REQC application form and confirm that the gatekeeper is an Enable Ireland staff member.	
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 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.	

Name of Principal Investigator: _____

Signature of Principal Investigator: _____

Name of Co-Investigators: _____

Signature of Co-Investigators: _____

Date: _____

PLEASE NOTE THAT IF THERE IS MORE THEN ONE APPLICANT, ALL APPLICANTS MUST SIGN THE DECALARTION

Appendix 5

Principal Investigator Data Protection Consent Form

Enable Ireland processes personal data in compliance with the GDPR.

The categories of personal data we process include:

- Name
- Contact information
- Qualification
- Educational background
- 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 Data Protection Policy.

I have read and understood the information about Data Protection, and agree to my personal data being used in the way described above (YES /NO): _____

Name of Principal Investigator: _____
Signature of Principal Investigator: _____

Name of Co-Investigator(s): _____

Signature of Co-Investigators: _____

Date: _____

Appendix 6

Supervisor Declaration

SUPERVISOR DECLARATION
I have read and adhere to the Enable Ireland Research Ethics and Quality Committee (REQC) policy and procedure.
I pledge to supervise during each stage of the research process including drawing up proposals, preparing funding applications, data recording, data analysis and reporting.
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.
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.
I consent to the use of the below personal data in order to support the Principal Investigator application to the Enable Ireland REQC.

Name of Supervisor: _____

Occupation: _____

School/Department: _____

Organisation/Institution: _____

Signature of Supervisor: _____

Date: _____

Appendix 7

Enable Ireland (EI) –Research, Ethics and Quality Committee (REQC) Interim Progress Report

Ongoing approval of research projects by the EI REQC is conditional upon the provision of an interim progress report which must be submitted by the deadline date, as outlined in your approval feedback summary from EI REQC.

A brief summary of the project MUST be included on, or accompany, this interim progress report form.

Project Title: Principal Investigator: Date of Original Approval: What was the anticipated date of commencement at time of approval? What was the anticipated date of completion at time of approval?
--

<i>Please place an 'X' in the appropriate column</i>	Yes	No
1. Has the Project Commenced? Date of commencement: DD/MM/YYYY		
<i>(If project has been abandoned, please provide details)</i>		
2. If the approval was subject to certain conditions, have these conditions been met?		
<i>(If not, please give details)</i>		
Please indicate the stage of your data analysis: None / Proceeding / Complete		
3. Have problems been encountered in the following areas?		
Study Design & Implementation		
Ethics		
Recruitment of Subjects		
Finance		
Facilities, equipment		
Specify date all personal data was deleted and method used for same		
<i>(If yes, please give details)</i>		

4. Has the original research study been modified?		
5. Have all modifications been notified to the EI REQC?		
<i>(Please summarise any modifications to the protocol that have not been notified to the EI REQC)</i>		
6. Have participants withdrawn?		
<i>(If yes, please give details)</i>		
7. Are signed consent forms available for inspection?		
8. Has approval expired? If Yes, do you require an extension? Until when? DD/MM/YYYY		
<i>(Please give reasons)</i>		
9. Have there been any adverse events? (if yes, please provide details)		

Brief Summary

Write a brief statement on progress so far in attached word document. Please include:

- summary of findings to date
- details of any publications accepted or in press
- details of any presentations given (provide as attachment)
- whether participants involved in the study have been informed of the results

Please send your completed interim progress report and attachments to:

Helen Shave
Enable Ireland,
HR & Corporate Affairs,
Lavanagh Centre,
Curraheen, Carrigrohane, Co. Cork
hshave@enableireland.ie

Appendix 8

Further Resources

Cope Foundation [A Policy Document for Conducting Research in COPE Foundation](#)

Data Protection Commission: [A Practical Guide to Data Controller-Processor contracts](#).

Department of Health (2005) [Research Governance Framework for Health and Social Care](#)

Department of Health (2010) *Research Governance Framework: Resource Pack for Social Care, SSRG*. UK

European Science Foundation (2000), *Policy Briefing no. 10: Good scientific practice in research and scholarship*- [Science Policy Briefings: ESF Policy Briefing no 10 Good scientific practice in research and scholarship](#)

Health Research Board (HRB) [HRB Guidelines for Host Institutions on Good Practice](#)

Medical Research Council, Ethics Series (2005) [Medical Research Council - Good Research Practice \(2000\)](#)

National Disability Authority (NDA) (2002) [Guidelines for Including People with Disabilities in Research](#)

NDA (2002) [Ask Me Guidelines for Effective Consultation with People with Disabilities](#)

National Institute of Health Sciences [Guide to Good Research Practice](#)

Sociological Association of Ireland [Ethical guidelines. PDF](#)

Wellcome Trust (2005) [Guidelines on Good Research Practice | Wellcome Trust](#)

WHO Research for Health Strategy (2009) [WHO | WHO Research for Health Strategy approved by the 63rd World Health Assembly](#)