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, 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, 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, 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, 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 who access services. At all times the interests, rights and welfare of service users 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; 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 learned[1].

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, 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 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 Strategic Plan.

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 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. In accordance with the Enable Ireland Data Protection Policy all submissions received by the REQC will be subject to a Privacy Impact Assessment to identify and reduce the privacy risks of participants associated with the research. The outcome of the Privacy Impact Assessment 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.

2.2 Protection of Service Users 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, 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 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 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/participants in an accessible manner (face to face preferred) must be outlined.

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.

2.3 Gatekeepers

2.3.1 All proposed research studies within Enable Ireland are required to have an appointed gatekeeper who is an Enable Ireland employee.

2.3.2 Researchers will not have access to service user contact information. The appointed gatekeeper will be tasked with inviting service users, families and staff to participate.

2.3.3 Researchers will have direct access to service users, 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, 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. 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, the level of anonymity and confidentiality, voluntary participation and how the results will be disseminated.

2.7 Confidentiality

2.7.1 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.

2.7.2 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.

2.7.3 Removal of identifiers and the use of pseudonyms are required to guarantee confidentiality and anonymity.

2.7.4 All hardcopies of data must be kept in a secure locked filing cabinet. Soft copies of data must be kept on a locked, password protected computer. Appropriate measures must be taken to ensure the data is secure at all times e.g. encryption, password protection, data backups.

2.8 Data Protection

2.8.1 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.

2.8.2 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. Researchers must be aware of any further legal requirements that regulate their work.

2.9 Dissemination, Exploitation and Publication of Results

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

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

2.9.3 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.

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

2.10 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).*

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 7**).

Step 4: If approval is granted submit an Interim Progress Report (**Appendix 8**).

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:

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

Or

(b) **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

(c) **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: The REQC Coordinator receives and screens completed application and requests basic amendments if required.

Step 2: Privacy Impact Assessment (PIA is completed based on application submitted).

Step 3: The application form and PIA 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 4: Discussion by REQC via email and teleconference as required.

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 copy of associated dissertation/thesis submitted by researcher on agreed date to REQC.

For further information contact the Enable Ireland REQC Coordinator:
Mrs Kate McMahon, **Enable Ireland**, **HR & Corporate Affairs**, **8 Russet Court**, **Churchyard Lane**, **Ballintemple**, **Cork**. **Email: kmcmahon@enableireland.ie**. **Telephone: 0214290434**

APPENDIX 2

Enable Ireland Criteria for Ethical Approval Checklist

Project Title:
Principal Investigator:
Date:

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.		
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.		
Protection of Service Users and Staff		
4. Demonstrable evidence that the dignity, rights, safety and well-being of participants are protected at all times exists.		
5. 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).		
6. 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)		
7. Follow up procedures and supports for participants in the event of any distress or questions are outlined.		
8. Presentation strategy of findings to service users/participants in an accessible manner (face to face preferred) is outlined.		
9. 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		

Please place an 'X' in the appropriate column where 'No' is marked, supply explanatory notes	Yes	No
Gatekeeper		
10. The proposed research studies has an appointed gatekeeper who is an Enable Ireland employee.		
11. The appointed gatekeeper will be tasked with inviting service users, families and staff to participate.		
12. 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/.		
13. The appointed gatekeepers name is stated on the Enable Ireland REQC application form (see **Appendix 3**)		
Principal Investigator (PI)		
14. 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		
15. The Data Protection Consent Form is completed		
16. The 'Principal Investigators Declaration' is completed		
17. 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		
18. I/we declare no real or potential conflicts of interest.		
19. 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.		
20. Substantive changes to the research proposal will be submitted for a secondary ethical review. These amendments will be implemented only if/ when approved.		
21. PI will submit Interim progress report (see **Appendix 7**) and final report of findings to Enable Ireland as a stipulation of final approval		
Supervision		
22. 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.		
23. The appointed supervisor has completed the 'Supervisor Declaration'.		
Explicit Consent		
24. Standard written protocols are detailed within the REQC application form (see **Appendix 3**) detailing the process of obtaining explicit consent.		

Please place an 'X' in the appropriate column where 'No' is marked, supply explanatory notes		
25. 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		
26. 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.		
27. Removal of identifiers and the use of pseudonyms will be implemented to guarantee confidentiality and anonymity.		
28. 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.		
29. 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		
30. 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.		
31. 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		
32. Where the research has been funded in whole or part by Enable Ireland, this contribution will be acknowledged in any publication		
33. Participants must be informed that the data may be subject to publication and how they access results of the study.		
34. 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		
35. I/we will observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.		

36. Findings will be open to critical review through the accepted scientific and professional channels.		
37. 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.		

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 *(include principal investigators declaration form)*	**Name**		
	Qualification		
	Position		
	Organisation	*(include department and contact details)*	
Co. Investigators/Student Researchers	**Name**		
	Position		
	Organisation	*(include department and contact details)*	
	Role in project		
Supervisor Details *(include supervisor declaration form)*	**Name**		
	Position		
	Organisation	*(include department and contact details)*	
Have you received permission from your university/institute's REC? *(attach approval letter)*	**Y N**	*If no, (i) explain why? (ii) outline source of approval*	
Enable Ireland Details	**Centre**		
	Gatekeeper	*(insert name)*	
	Local Service Manager	*(insert name)*	
	Local Director of Services/National Manager	(insert name)	
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/staff be involved in the design/implementation? If yes, please describe.	*(if yes, please describe)*
Participants	**Nature** *(detail e.g. type of disability etc.):*
	Sample Number:
	Inclusion Criteria *(detail e.g. gender, age etc.):*
Voluntary Participation How will you assure service users 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?	
Confidentiality How will you assure service users or families that their confidentiality will not be compromised	

in any way?	
3. AIMS & OBJECTIVES	
Overall Aims The purpose of your research – what are you trying to discover/prove/achieve?	
Specific Objectives	
Hypothesis	
4. BENEFITS FOR SERVICE USERS/FAMILIES/STAFF	
Outline the benefits of the research for participants involved e.g. Service Users, 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.	*(Note -No project can begin without approval from REQC)*
Statistical Methods Please provide detailed account	
Procedures which may cause discomfort/distress Does your research include procedures that may cause discomfort or distress? How do you intend to eradicate potential risk to participants? What approach/follow up supports will be put in place?	

7. EXPLICIT CONSENT & ASSENT		
Participant Information Have you prepared an Invitation Letter and Information Sheet? Please include copies of the relevant materials as an Appendix.	**Invitation Letter:**	
	Information Sheet:	
Signed Explicit Consent Have you prepared a Consent Form? How will consent be obtained? (See Enable Ireland REQC Sample Consent Form)	(Include copies of the relevant materials as an Appendix)	
Signed Informed Assent (if applicable) Have you prepared an Assent Form (agreement of young person) for participants under the age of 16 NOTE: PARENTAL/GUARDIAN CONSENT IS ALSO REQUIRED FOR PERSONS UNDER THE AGE OF 16	(Include copies of the relevant materials as an Appendix)	

What is the time interval between giving information and seeking explicit consent? (It is recommended that a period of seven days be provided for reflection. If less than this, please justify).	
Information for participants under the age of 18 Will each child receive information according to his/her capacity of understanding regarding the risks and benefits of the project?	(Include copies of the relevant materials as an Appendix)
8. DATA MANAGEMENT & DATA PROTECTION	
Who will have access to the data?	
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	**Anonymous:**
	Pseudonymised:
	Coded:
	Identifiable:
Data Protection Where will the data be stored? Who will have access to the stored data? Will the data be retained or destroyed after the project? Describe steps to ensure confidentiality of data? (Secure retention of data for 5 years. If there is any reason to apply for variation from these guidelines, please give details and justify)	**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.**	
9. DISSEMINATION	
Please comment on how the results will be conveyed back to individual participants. (Specify methods that will be used e.g. presentation to participants, workshop/conference, etc.....) How are you going to manage potential distress/upset, should this arise during dissemination?	
Please comment on how aggregated study results will be made available to Enable Ireland.	
Please describe your wider dissemination strategy.	

Applicants must adhere to the Enable Ireland REQC Policy and Procedure. Please email a copy of your completed application including required appendices to kmcmahon@enableireland.ie and send a hard copy with signatures on declaration form to Kate McMahon, Research Ethics and Quality Coordinator, Enable Ireland, HR & Corporate Affairs, 8 Russet Court, Churchyard Lane, Ballintemple, Cork.

APPENDIX 4

PRINCIPAL INVESTIGATOR DECLARATION
I have read and will comply with the content of the Enable Ireland REQC Policy and Procedure document. **Initial:**
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. **Initial:**
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. **Initial:**
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. **Initial:**
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. **Initial:**
Participants will be informed that they may withdraw from the research without disadvantage to themselves and without being obliged to give any reason. **Initial:**
I have named the appointed gatekeeper in the REQC application form and confirm that the gatekeeper is an Enable Ireland employee. **Initial:**
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. **Initial:**
If the study receives approval, I agree to supply interim progress report and a final report/thesis etc. to the Enable Ireland REQC. **Initial:**
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. **Initial:**

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 employees 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 (Circle)	
Name of Principal Investigator:	_____
Signature of Principal Investigator:	_____
Name of Co-Investigator(s):	_____
Signature of Co-Investigators:	_____
Date:	_____

Appendix 6

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 REQC Consent Form

Insert Institution Address & Logo

Subject Information and Informed Consent Form

Date: _____ **Name:** _____

Project Title: _____ **Principle Investigator:** _____

Agreement to Consent

The research project and procedures associated with it have been fully explained to me. I have read the information letter and have had time to consider whether to take part in this study. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary. I am aware that my decision not to participate or withdraw will not restrict my access to Enable Ireland services normally available to me. Confidentially of records concerning my involvement in this project will be maintained in an appropriate manner. I agree that the data can be used in the publication of higher degrees, presentations and academic publications.

I, the undersigned, hereby consent to participate as a subject in the above described project conducted at insert location. I have received a copy of this consent form for my records. If I have any queries or about the study procedure or questions concerning my rights as a participant I can contact insert name and contact details

After reading the consent form, if you have no further questions about giving consent, please sign where indicated.

Signature of Subject: _____ Date: _____

Witness: _____ Date: _____

Appendix 8

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?

Please place an 'X' in the appropriate column	***Yes***	***No***
1. Has the Project Commenced? Date of commencement: **DD/MM/YYYY**		
(If project has been abandoned, please provide details)		
2. If the approval was subject to certain conditions, have these conditions been met?		
(If not, please give details)		
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		
(If yes, please give details)		
4. Has the original research study been modified?		
5. Have all modifications been notified to the EI REQC?		

(Please summarise any modifications to the protocol that have not been notified to the EI REQC)		
6. Have participants withdrawn?		
(If yes, please give details)		
7. Are signed consent forms available for inspection?		
8. Has approval expired? If Yes, do you require an extension? Until when? **DD/MM/YYYY**		
(Please give reasons)		
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:

Kate McMahon
Enable Ireland HR & Corporate Affairs
8 Russet Court Churchyard Lane
Ballintemple
Cork
kmcmahon@enableireland.ie
Tel: 0214290434

Appendix 9

Further Resources

Cope Foundation A Policy Document for Conducting Research in COPE Foundation

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 | Welcome Trust

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

POLICY REFERENCE

Title of Policy: Research Ethics and Quality Committee Policy & Procedure
Date Issued by HRCA: 02.07.2018
Last Review Date: 07.12.2017
Next Review Date: July 2020

Principal Reviewers:	Reviewers:	In Consultation with:
Kate McMahon Training, Quality & Research Officer Theresa Compagno, Director HR & Corporate Affairs	**Policy Group Members:** Annemarie Egan, HR Officer Clare Lenehan, Director Of Services Galway/Mayo Ed Meagher, IT Manager John O'Sullivan National Director of Services Maria. B Moran Administration Manager, Cork Mary Fox, Director of Services North East & Dublin Services Stephanie Cloonan Project Officer	Not Applicable

Reference Completed by
Print name: **Stephanie Cloonan**

Signed: Stephanie Cloonan

Job Title: **Project Officer**

Date: **02/07/2018**