Research Ethics & Quality Committee (REQC)

Policy & Procedure

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1.0 Policy Statement

Enable Ireland is committed to actively promoting and developing responsible and ethical research, based on the key principles of honesty, transparency, openness and accountability. We achieve this through nurturing a culture of research integrity, and ensuring that all research is carried out in an ethical and responsible manner.

Enable Ireland has a duty to ensure that the research we support is carried out to the highest standards, and this policy clearly defines the requirements that applicants must adhere in order to comply with good research practice.

1.1 Scope

The Enable Ireland Research Ethics and Quality Committee (REQC) policy and procedure outlines specific procedures for undertaking research involving any Enable Ireland stakeholder e.g. 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.

The REQC is made up of internal and external members with varying relevant knowledge and experience in current research practices within their nominated field of expertise (e.g. Services/Research/Data Protection/Social Work/Speech & Language Therapy).

Each member has demonstrable commitment to safeguarding participant's rights in the research process and is committed to the furtherance of ethical research practice and excellence.

1.2 What is Research?

The definition of research adopted in the HSE Action Plan for Health Research 2019–2029, is that of "the attempt to derive generalizable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods". This definition is underpinning this policy[1].

[1] https://hseresearch.ie/what-is-research-2/

1.3 Health and Social Care Research

Health and social care research is defined in the Health Research Regulations 2018 as follows:

- Research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels;
- Research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;
- Research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;
- Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;
- Research with the goal of improving the health of the populations as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.
- Health research may also include action taken to establish whether an individual may be suitable for inclusion in the research.

1.4 Differentiating Research from Other Activities

Research is often confused with other activities requiring a rigorous approach to methodology in terms of design, procedure, analysis and interpretation of data. Research is a separate activity, however, from clinical audits, standard service evaluations/quality improvement pieces, or public health or advanced health analytics work carried out by Enable Ireland for the purpose of carrying out its legal obligations for the planning and delivery of health and social care services.

See Table 1 Differentiating Research from Other Processes.

1.5 Table 1 – Differentiating Research from Other Processes:

Theme	Research	Clinical Audit	Service Evaluation / Quality Improvement Pieces of Work
1 **Definition**	Research is designed and conducted to generate new generalizable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses.	Clinical audit is a clinically led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and acting to improve care when standards are not met.	Service evaluation seeks to access how well a service is achieving its attended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service.
2 **Answers Questions**	Research demonstrates what should be done.	Clinical audit demonstrates whether a predetermined standard is being met.	Service evaluation tells how well a service is working.
3 **Purpose**	To generate new knowledge and find out what treatments, interventions or practices are the most effective.	To find out if best practice is being practiced for quality assurance and improvement purposes.	To evaluate current practices for information purposes. The information can inform management decisions.
4 **Context**	Local or national level.	Local or national level.	Local level only.
5 **Method**	Has a systematic, quantitative or qualitative approach to investigation.	Measures practice against evidence-based clinical standards.	Measures current service without comparison against standards.
6 **Requirement for REC Review**	Yes.	No, but ethical considerations should be considered.	No, but ethical considerations should be considered.

When in doubt, contact Enable Ireland's REC Coordinator:
https://enableireland.ie/services/research

1.6 Is my project research, evaluation or audit?

The NHS's Health Research Authority in conjunction with the UK's Medical Research Council have developed a useful decision making tool to help you decide if your activity is a research project, clinical audit, evaluation study or usual practice.

You can find this decision-making tool on their webpages by clicking on the following web link: **http://www.hra-decisiontools.org.uk/research/index.html**

If your activity **is a form of research**, and depending on the nature of it, it will most likely require compliance with the Health Research Regulations 2018 and amendments, including Research Ethics Committee approval and explicit consent from participants.

If your activity is **not research** the general GDPR legislation still applies. It is the responsibility of the researcher to ensure they are compliant with the legislation that applies.

1.7 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 has 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: *Pathways of Service Delivery for Children and Families: Code of Practice*).

1.8 Research Governance

Research governance[2] 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[1].:-

- 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.

[2] https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/what-is-research-governance/

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.

1.9 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 Ireland's core values and Strategic Plan.

1.10 Role of the Enable Ireland's 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) and the Data Protection Act (2018). All data protection risks will be directed to the Enable Ireland Data Protection Officer as required for review. 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 see Appendix 1)**

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 All relevant managers must be named on the Application Form. It is the responsibility of the named manager to ensure they have read and have a full understanding of the research proposed.
2.1.4 Where multiple sites/locations across CHO areas are involved, the National Directorate of Services must support the application in principle subject to REQC approval.
2.1.5 Adherence to current safety practices, ethical standards, andlegislation.
2.1.6 Public Health considerations for current re uirements must always be adhered to

2.2 Protection of Service users/Service owners and Staff

i. Demonstrable evidence that the dignity, rights, safety and well-being of participants are protected at all times.

ii. 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. (NDA, 2009: Ethical Guidance for Research with People with Disabilities).

iii. 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. Service Users/Owners must be supported to enable them to understand the research and its implications and to make an informed decision about participation. (NDA, 2009: Ethical Guidance for Research with People with Disabilities p36).

iv. Follow up procedures and supports for participants in the event of any distress or questions must be outlined.

v. 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.

vi. Participants must be informed of their right to raise any complaint in relation to the research undertaken under the Enable Ireland Complaints Policy.

vii. Researchers must adhere to all relevant current Public Health Guidance when making an application. The safety of service users/service owners and staff is paramount.

2.3 Gatekeepers

i. All proposed research studies within Enable Ireland are required to have an appointed gatekeeper who is an EnableIreland staff member.

ii. 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.

iii. Researchers will have direct access to service users/service owners, their families and staff only when explicit consent is in place.

iv. The appointed gatekeeper's name must be stated on the Enable Ireland REQC Application Form and provide their signature to the final aspect of the documentation (see**Appendix1)**

v. The relevant Service Manager and National Services Forum Manager of the Gatekeeper must approve fulfilling the role of Gatekeeper for the project in advance of the application being submitted to REQC.

vi. It is the responsibility of the Gatekeeper to ensure they have a full understanding of the project requirements in advance of the application being submitted to REQC.

2.4 Principal Investigators

i. 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 1**).

ii. 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.

iii. 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.

iv. Researchers must consent to the processing of personal data for the purpose of obtaining REQC approval.

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

vi. An Interim progress report (see **Appendix 1**) and final report of findings will be submitted to Enable Ireland as a stipulation of finalapproval.

2.5 Supervision

i. Nominated supervisors stated within the Enable Ireland REQC application form are required to supervise during each stage of the research process. The appointed supervisor is required to comply and sign the 'Supervisor Declaration'.

ii. See Appendix for details.

2.6 Explicit Consent

i. Standard written protocols must be detailed within the REQC application form detailing the process of obtaining explicit consent.

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

iii. 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 (include a link to the relevant data controller Privacy Policy), the level of anonymity and confidentiality, voluntary participation and how the results will be disseminated.

2.7 Data Protection

i. Ensuring compliance with data protection legislation is a requirement of all researchers.

ii. No use of any data, whether directly relating to service user/service owner, family or staff data will be sanctioned without the written permission of the REQC.

iii. 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.

iv. All researchers undertaking research for Enable Ireland must adhere to all Data Protection legislation (i.e. GDPR and DP Act 2018).

v. Prior to submitting an application to the Enable Ireland's REQC, the researcher must ensure they have clarified who the Data Controller of the project is as this will dictate the compliance obligations for the researcher. This must be documented in the submitted REQC application.

vi. **See key definitions re controller/processor etc via Data Protection Commission:**
Definition of Key Terms | Data Protection Commission
https://www.dataprotection.ie/en/individuals/data-protection-basics/definition-key-terms

vii. **Data controller status will dictate for example (non-exhaustive list):**

- The Policies & Procedures the data controller must adhered to e.g. where Enable Ireland is data controller 1) the suite of policies & procedures must be followed, 2) Enable Ireland GDPR Awareness Training must be completed and 3) Enable Ireland retention schedule and destruction type will be dictated by its retention schedule.

- **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', see General Data Protection Regulation (GDPR) Article 35(1). In advance of submitting the application to REQC, the researcher is responsible for identifying the risk associated with the data processing for the project and must supply a completed DPIA where required/requested to do so by Enable Ireland.

- **Note, for projects where Enable Ireland is data controller it is the responsibility of the researcher to ensure:**
  - they are aware of the approved online platforms (e.g. Teams). Enable Ireland will not sanction the use of Zoom, WhatsApp video or chat or Survey Monkey as secure online data collection methods. In limited cases, Microsoft Forms may be used in line with national directive available via the Forms Page (e.g. anonymous information, no health information/sensitive information).

  - they only engage with Enable Ireland approved software and currently have a DPA in place. Where a new software system is required, ensure you allow sufficient time to verify via dpo@enableireland.ie if the software is a possibility.

- Any third party processors being used e.g. transcription service, have a DPA in place. The DPA contract template is available via Inform. See Data Protection Policy regarding process of signing.

- **Note, for all other data controllers, it is the responsibility of the researcher to ensure:**
  - Engagement with third party processors/software must have a Data Processing Agreement in place that meetings the requirements of GDPR Article 28. It is the responsibility of the researcher to confirm the required DPA is in place for all processors related to the project for example:

    - If transcription is being outsourced the researcher must ensure there is the required Data Processing Agreement in place.
    - Only approved online platforms/software of the institute are being used. Note, the researcher may be asked to provide a copy of the DPA in place.
    - See DPC Guidance: https://www.dataprotection.ie/en/dpc-guidance/practical- guide-controller-processor-contracts

- The researcher is responsible for ensuring they identify any other relevant data controller/processor/joint controller relationships relevant to the project.

- It is the responsibility of the researcher to demonstrate they understand their role in relation to ensuring compliance with GDPR for the project. If unsure of any aspect of the data protection elements of the research application, to avoid delays, Enable Ireland require you to raise queries with the relevant data controller's DPO in advance of submitting the RECQ application.

- All researchers must note the title of the GDPR training they have completed.

x. Data minimisation is key for research projects and compliance with GDPR. Where possible, all data retrieved as a result of the field research, should be anonymised and **personal data for access purposes be immediately destroyed (i.e. when completely anonymised GDPR no longer applies)** to the data gathered but will still apply to for example consent forms processed.

xi. Prior to submitting an application to the REQC, the researcher is responsible for ensuring they understand the difference between anonymisation and pseudonymisation of data. See DPC Guidance: https://www.dataprotection.ie/en/dpc-guidance/anonymisation-pseudonymisation.

2.8 Dissemination, Exploitation and Publication of Results

i. Where the research has been funded in whole or part by Enable Ireland, this contribution will be acknowledged in any publication.
ii. Participants must be informed that the data may be subject to publication.
iii. 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.
iv. 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

2.9.1 Institution REQC Requirements

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, where relevant. 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. No research will commence without formal full 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 be aware of and observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies (*RCSI 'Good Research Practice').*

2.10 Applicants without Linked Institute REQCs

Occasionally, applicants 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.

Occasionally, a researcher may not have a linked supervisor, where that is the case a detailed explanation must be provided to Enable Ireland for consideration.

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

3.1 Applicant Procedures

New applications will be reviewed four three 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 (see Appendix 1) by email and post to the Enable Ireland REQC Coordinator:

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

Step 4: If approval is granted submit an Interim Progress Report (**Appendix 2**).

Step 5: Submit final report, dissertation or publications once study is complete. A response made byte REQC will be provided within 6working weeks from date of submission deadline. The decision made will be one of the following:

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

   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 with changes tracked.
   - For efficiency, it is the responsibility of the researcher to provide a reply without a delay within the timeframe provided.
   - **No research will be conducted prior to receiving written approval.**

   Or

3. **Application Declined** - Reasons will be provided to the applicant for declining approval. The applicant may re-submit to theREQC.

3.2 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 6 working weeks of submission deadline date.

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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Appendix 1

Research Ethics & Quality Committee (REQC)

Application Documentation Pack

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-ordinator 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

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).		

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 (see **Appendix 1**).		
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.		

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 **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 (see **Appendix 1**) will supervise during each stage of the research process including drawing up proposals, preparing funding applications, data recording, and data analysis and reporting.		
29. The appointed supervisor has completed the 'Supervisor Declaration'.		
Explicit Consent		
30. Standard written protocols are detailed within the REQC application form (see **Appendix 1**) detailing the process of obtaining explicit consent.		

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.		

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

	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.	

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

1.GENERAL INFORMATION		
1. Project Title		
2. Principal Investigator *(include principal investigators declaration form)*	**Name**	
	Qualification	
	Position	
	Organisation *(include department and contact details)*	
3. Co-Investigators/Student Researchers	**Name**	
	Position	
	Organisation *(include department and contact details)*	
	Role in project	
4. Supervisor Details *(include supervisor declaration form)*	**Name**	
	Position	
	Organisation *(include department and contact details)*	
5. Have you received permission from your university/ institute's REC? *(attach a copy of the submitted REC with a copy of the approval/provisional approval letter).*	*If no, (i) explain why? And (ii) outline source of approval.*	

6. 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)	
7. Proposed Commencement Date:		
8. Specify submission date of the Enable Ireland Interim Report (see Enable Ireland Interim Report Template)		
9. Proposed Project Completion Date:		
10. Proposed Date Researcher will submit final report to Enable Ireland.		
11. Use of External Sites		

2. AIMS & OBJECTIVES	
1. Overall Aims The purpose of your research – what are you trying to discover/prove/ achieve?	

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	
3. Justification for sample number:	
4. **Inclusion Criteria** *(be specific in relation to the required research detail e.g. gender, age etc.):*	
5. 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? (Reference relevant Application Appendix)	

7. Role of Gatekeeper		
1. Participant Initial Contact Describe how the appointed gatekeeper (s) will contact participants.		
2. Provide details for all of the tasks assigned to the gatekeeper.		
3. 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?	
7. Procedures which may cause discomfort/distress. i. 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 what resources 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 orm? Copy re uired. *(State Yes/No and Appendix Number and Title)*	
5. Have you prepared an Assent orm (agreement of young person) for participants under the age of 16 (if applicable)? Copy re uired. *(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 re uired. *(State Yes/No and Appendix Number and Title)*	

7. 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)*	
8. 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 a. to achieve the objective of the health research and b. 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 project re uire Enable Ireland to sign any agreements e.g. Data Sharing Agreement / Data Processing Agreements / oint 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 been carried out, taking in to account local policy and/or legal re uirements? *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 legal re uirement. Please specify the provision of training you have completed. See definition of health research: https://www.hrb.ie/fundin g/gdpr guidance for researchers/gdpr and health research/what is research/ : :text What 20is 20health 20research 3 ,system 20and 20whol e 20body 20levels	
9. Please specify the measures in place that demonstrate compliance with the data minimisation principle (Is it ade uate, 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 the re uired 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. (encrypted laptop/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 have access, 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?	

12.12.If yes, for how long, for what purpose, and where will it be retained?	
13.13.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.*	
17.If audio a. taping/videos/photos forms part of the study design you must allow the participant access to the transcript, if they b. so wish. This must be included in the Explicit Consent orm 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.*	
6. 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:

a. Name
b. Contact information
c. Qualification
d. Educational background
e. 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.

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.

Appendix 2
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		
Specify date all personal data was deleted and method used for same		
(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:

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

Email: hshave@enableireland.ie

Appendix 3 Further Resources

Data Protection Commission: A Practical Guide to Data Controller-Processor contracts.

Department of Health (2005) Statement of Priorities – Health & Social Care Research 2023 – 2025

European Science Foundation 'Science Policy Briefings'

Health Research Board (HRB) 'Publications'

HSE Research & Development: - HSE | Research & Development (hseresearch.ie)

https://www.who.int/our-work/science-division/research-for-health

Key Roles in the Governance and Management of Health Research - HSE | Research & Development (hseresearch.ie)

Medical Research Council, Ethics Series (2005) 'Better Research, Better Methods' Guidance Portal

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

National Institute of Health Sciences National Institute of Health Sciences & Regional Medical Library

NDA (2002) 92023) Conducting Collaborative Research with People with Disabilities'

Wellcome Trust (2005) 'Research Guidelines & Documents'

https://wellcome.org/search?search=research

What is Research? - HSE | Research & Development (hseresearch.ie)

WHO Research for Health Strategy (2009) Research for Health