Interim procedure for the Reference Research Ethics Committee Midlands Area and Corporate (Regional Health Area B)

Is this document a:

Policy ☐ Procedure x Protocol ☐ Guideline ☐

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1. Statement

The HSE Reference Research Ethics Committee (RREC) Midlands Area and Corporate (Regional Health Area B) will follow the procedures outlined in this document with regard to all requests for research ethics review from HSE staff, including in Section 38 and 39 services, academic students and researchers who wish to access the facilities, staff, patients or clients, or information pertaining to the staff, patients or clients in its area.

This RREC recognises the value of high quality, ethical research and will endeavour to support researchers to achieve this while recognising that research involving human subjects is a privilege grounded in trust. Therefore, members will endeavour to ensure that all parties involved in the research process are protected by ensuring research abides to high quality ethical standards and will be committed to creating a positive environment for all its members, whereby all RREC volunteers are respected and valued.

In all dealings this RREC will operate with fairness, respect, honesty, transparency, consistency and integrity. The Committee undertakes to engage in timely, clear and respectful communications with applicants and with each other. It will operate in an environment where all RREC members are afforded opportunity to contribute to the review process. To this end, members will make all reasonable efforts to give of their time to review applications and to atend meetings.

2. Purpose

The purpose of this document is to:

2.1 Provide guidance to people who request ethics review for a research study.

2.2 Describe the requirements and documentation involved in submitting an application.

2.3 Set out the procedure to be followed by the RREC in reviewing a research proposal from an ethics perspective.

3. Scope

3.1 Coverage of HSE RREC Midlands Area and Corporate (Regional Health Area B)

3.1.1 HSE services and funded services (Section 38 and 39 services), which do not have access to their own REC, in Regional Health Area B (CHO7 and part of CHO8):

- Co. Laois
- Co. Offaly
- Co. Longford
- Co. Westmeath
- Co. Kildare

- Dublin South City
- Dublin South West
- Dublin West
- West Wicklow

3.1.2 Hospitals in the geographic region which do not have a hospital ethics committee, namely (as of March 2022) Midland Regional Hospital (Mullingar, Tullamore and Portlaoise).

3.1.3 HSE Corporate Services nationally.

3.2 People for whom this guidance has relevance

3.2.1 All members of the RREC Midlands Area and Corporate (Regional Health Area B).

3.2.2 All HSE staff (including staff in Section 38 and 39 services) who wish to carry out research which needs access to facilities, staff, patients or clients, or information pertaining to staff or patients or clients of the HSE Midlands Area and Corporate, including S38 and S39 services which do not have access to their own REC (Regional Health Area B).

3.2.3 All students, employed by the HSE or external to the HSE, who wish to carry out research which needs access to facilities, staff, patients or clients, or information pertaining to staff or patients or clients of the HSE Midlands Area and Corporate, including S38 and S39 services which do not have access to their own REC (Regional Health Area B).

3.2.4 All investigators, external to the HSE, who wish to have access to staff, patients or clients, facilities or information pertaining to patients, clients or staff of the HSE Midlands Area and Corporate (Regional Health Area B), including Section 38 and 39 Services which do not have access to their own REC, for the purposes of research.

3.2.5 Managers of facilities and sites where research is being conducted.

3.3 Research covered by this document

3.3.1 This document is concerned with all research involving clients, patients, employees and facilities of the HSE Regional Health Area B and Corporate Services, excluding clinical trials of medicinal products and devices. It should be noted that The HSE RREC Midlands Area and Corporate (Regional Health Area B) is not recognised by the Department of Health under regulation 7 of the European Communities Regulations (Clinical Trials on Medicinal Products for Human Use (S.I. 190 of 2004)). This RREC therefore does not consider clinical trials of medicinal products and devices.

3.3.2 Research taking place in the organisations listed above, that involves the participation of health service users, their personal data and/or their biological samples, health and social care staff, or the use of HSE healthcare services, premises or infrastructure, either directly or indirectly, must be reviewed by a HSE Reference REC, with the exception of those research studies under the remit of the National Research Ethics Committees (NRECs).

3.3.3 NRECs are responsible for the ethical review of Clinical Trials of Investigational Medicinal Products (CTIMPs) and the clinical investigations of Medical Devices (MD) – see https://www.nrecoffice.ie/ for information.

3.3.4 This RREC is not a Clinical Ethics Committee and does not deal with or give an opinion on ethics issues in clinical practice and health service provision.

4. Legislation and other related policies

4.1 HSE National Framework for the Governance, Management and Support of Research

4.2 HSE Consent for Research Policy 2021 (publication awaited, in the interim please visit https://hseresearch.ie/patient-consent for information).

4.3 General Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

4.4 Data Protection Act 2018 gives further effect to the GDPR in the State in areas where the GDPR gives limited flexibility to Member States. The Health Research Regulations 2018-2020 were made under that Act and are collectively referred to as Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 S.I. No. S.I. No. 314 of 2018 and subsequent amendments.

4.5 State Claims: Clinical Indemnity Scheme.

4.6 A range of national and international guidelines on the conduct of ethical research also underpin the ethical review carried out by the HSE RRECs. These include:

- The Nuremberg Code
- The Declaration of Helsinki
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- ICH-Good Clinical Practice Guideline E6 (R2).
- Ethical conduct in research professional guidance from the Nursing and Midwifery Board of Ireland

- Guide to professional conduct and ethics for registered medical practitioners from the Irish Medical Council.
- Using international guidelines, Emanuel et al (2000), proposed an ethical framework of seven principles, which provide coherent guidance to all clinical research stakeholders in all research settings. Reviewing research studies using these seven principles, (Value, Validity, Fair subject selection, Favourable risk–benefit ratio, independent review, Respect for persons, and Informed consent) is the core business of the RREC.

5. Glossary of definitions and abbreviations

5.1 Definitions

- ***Clinical audit***: 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. *(National Review of Clinical Audit, 2019).* Clinical audits do not require RREC review, but ethical considerations should still be considered.

- ***Ethics*****:** The moral fitness of a decision or course of action *(Collins English Dictionary 2000)*

- ***Registry:*** A system which collects a defined minimum dataset from patients with a particular disease, undergoing a particular procedure or therapy, or using a healthcare resource. *(National Review of Clinical Audit, 2019*). If the registry is to be used for research purposes, RREC approval is needed.
- ***Research***: A study designed and conducted to generate new generalizable or transferrable knowledge. It includes quantitative, qualitative, mixed methods and action research studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses. See Section 7.2 for information on **health research** specifically.

- ***Service evaluation:*** A study seeking to assess how well a service is achieving its intended 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. *(National Review of Clinical Audit, 2019).* Service evaluations do not require RREC review, but ethical considerations should still be considered.

- ***Valid ethical approval application*:** An application that has been submitted by an appropriately qualified investigator, is complete, with all the necessary documents attached and has been signed and dated.

5.2 Abbreviations:

- ***DPIA*** Data Protection Impact Assessment
- ***ERMS*** Electronic Research Management System
- ***GDPR*** General Data Protection Regulation
- ***HPRA*** Health Products Regulatory Authority
- ***HSE*** Health Service Executive
- ***HSE RREC SCO*** HSE Reference Research Ethics Committee Support and Co-ordination Office
- ***NREC*** National Research Ethics Committee
- ***PPG*** Policy, Procedure, Guideline
- ***REC*** Research Ethics Committee
- ***RGMS*** Research Governance Management and Support
- ***RREC*** Reference Research Ethics Committee
- ***SOP*** Standard Operating Procedure
- ***S38*** Section 38 are organisations that provide a defined service on behalf of the HSE, and the funding is provided annually, under a formal service level agreement framework *(Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees).*
- ***S39*** Section 39 organisations are usually, independent not-for-profit agencies accountable to the State through compliance and regulatory structures and are recognised under legislation as providing services that enable people who require supports to live the best quality of life they can. *(Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees).*

6. Roles and responsibilities

6.1 Role of the HSE RREC Midlands Area and Corporate (Regional Health Area B)

6.1.1 This RREC will protect the safety, welfare and the rights of participants in health research, in accordance with recognised ethical principles and standards, relevant EU Directives, ICH-GCP E6 (R2) guideline, national legislation, in alignment with the HSE National Framework for the Governance, Management and Support of Research, the Standard

Code of Governance and Management Required for HSE Reference Research Ethics Committees and other relevant policies (see section 4 above).

6.1.2 This RREC will help to protect host institutions and researchers by ensuring research abides to high quality ethical standards and will be committed to creating a positive environment for all its members, whereby all RREC volunteers are respected and valued.

6.1.3 This RREC will uphold the principle that the goals of research and researchers are always secondary to the dignity, rights, safety and well-being of the research participant.

6.1.4 This RREC will encourage ethical research in the services and regions within its scope (see Section 3).

6.2 Responsibility of HSE RREC Midlands Area and Corporate (Regional Health Area B)

It is the responsibility of this RREC and its members to:

6.2.1 Decide, independently, whether the research proposal under review will protect participants.

6.2.2 Know and understand the provisions of the Data Protection Acts 1988 and (amendment) 2003 and their obligations as set out in those Acts - data collected from clients or patients of the HSE must comply with the Data Protection Acts (several helpful guidance documents are listed in section 4 above). The RREC will seek external opinion if needed.

6.2.3 Adhere to the guidance in this document and to operate in line with the principles outlined in Section 7 below and in the Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees .

6.3 Responsibility of line managers and heads of departments

It is the responsibility of line managers and heads of departments to:

6.3.1 Ensure staff are made aware of this document.

6.3.2 Maintain this document in the Policies, Procedures and Guidelines (PPGs) manual on their particular ward, unit or department.

6.4 Responsibility of the principal investigator

It is the responsibility of the principal investigator of the study:

6.4.1 To be aware of and adhere to the procedures outlined in this document.

6.4.2 To obtain approval to carry out the study from the relevant HSE service. This approval extends beyond line management approval – it requires institutional approval and registration of research as per the HSE's Research Governance Framework. While it is

acknowledged that not all organisations have this registration process in place, it would be anticipated that they would have some way of registering research in the interim.

6.4.3 To obtain agreement from their line manager to carry out the research – it should be noted that a favourable ethics review from the RREC is not the same as approval from the relevant institution or service to proceed with the study. Authorisation from HSE management must be sought separately and evidence submitted with the application to this RREC.

6.4.4 To ensure that they have adequate clinical indemnity for their research activity before embarking on it. For employees of the HSE, they are **likely** to be covered by the State Clinical Indemnity Scheme (CIS) (see section 4), but it is the responsibility of the principal investigator to ensure this is the case. Where research is sponsored by external organisations such as pharmaceutical companies, the CIS cover extends to treatment only and does not cover product liability or claims arising from trial design or protocol. Researchers must *be clear on their own liability, the liabilities of the HSE and the liabilities of external organisations and must make sure there is adequate indemnity for all liabilities*.

6.4.5 To know and understand the provisions of the Data Protection Acts 1988 and (amendment) 2003 and their obligations as set out in those Acts. Data collected from clients or patients of the HSE must comply with the Data Protection Acts. Several helpful guidance documents are listed in section 4 above.

7. Overarching principles

7.1 Principles of research

7.1.1 A range of national and international guidelines on the conduct of ethical research studies have been published (as referenced in section 4 here), including The Nuremberg Code, the Declaration of Helsinki and The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Using international guidelines, Emanuel et al. proposed an ethical framework of seven principles, which provide coherent guidance to all clinical research stakeholders in all research settings. The principles are outlined as follows in the HSE National Framework for the Governance, Management and Support of Research:

7.1.1.1 ***Value:*** The research study should have social, scientific or clinical value. The research study should be important, generalisable, and should include a plan for sharing results so that society can benefit. Resources should not be wasted on studies without integral value and human beings should not be exposed to risk without some scientific or social value.

7.1.1.2 **Validity:** The research study should be scientifically and methodologically robust and valid. The study, as designed and proposed, should be able to answer the research question. The Council for International Organisations of Medical Sciences guidelines explicitly state, "*scientifically unsound research on human subjects is ipso facto unethical in that it may expose subjects to risks or inconvenience to no purpose.*" The research study should also be practically feasible and possible to execute.

7.1.1.3 **Fair subject selection:** The scientific goals of the study should determine who the participants or subjects are, as opposed to including a group of participants because they are either vulnerable or privileged. Likewise, exclusion of a group should not depend on convenience but on scientific objectives and efforts should be made to include a representative sample. Subjects should be selected in a manner that minimises risks and enhances benefits. Those who bear the risk of the research study should enjoy its benefits and those who benefit should share the risk.

7.1.1.4 **Favourable risk-benefit ratio:** Research is ethical if the potential risks to individual subjects are minimised, the potential benefits to individual subjects are enhanced, and the potential benefits to individual subjects and society are proportionate to or outweigh the risks. The requirement for a favourable risk–benefit ratio embodies the principles of non-maleficence and beneficence, long recognised as fundamental values of clinical research.

7.1.1.5 **Independent review:** Independent review by a committee not associated with the research study helps to minimise the impact of potential conflicts of interest. Independent review also reassures the public and potential participants of the validity of the research.

7.1.1.6 **Respect for persons:** Individuals must be treated with respect from the time they are approached, throughout their participation, and when their participation ends. Respect involves having regard for the welfare, rights, beliefs, perceptions, and customs, both individual and collective, of individuals involved in research studies. Participants' information should be managed in accordance with confidentiality and privacy rules. Participants should be permitted to change their minds and withdraw from the study without penalty. They should be informed of any relevant new information that the study generates. Their welfare should be monitored throughout their participation. If subjects experience adverse reactions, they should be provided with appropriate treatment and removed from the study if necessary. Once the research study is over, there should be a mechanism to inform participants of what was learned from the research.

7.1.1.7 **Informed consent:** Participants should be accurately informed of the purpose, methods, risks, benefits and alternatives to the research study. They must understand this information, and have the capacity to understand it and its bearing on their own clinical situation. They must make a voluntary and un-coerced autonomous decision to participate.

7.2 What health research is

7.2.1 Health research requires ethical review and is defined in the Health Research Regulations 2018 as:

- research with the goal of understanding normal and abnormal functioning, at the 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 population 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

7.2.2 It is a broad definition and includes (as outlined by the Health Research Board):

- experimental, translational and clinical research
- public health and social care research
- population health research
- basic and translational health research
- research into treatment strategies, medical device or product development
- any actions taken to establish whether an individual may be suitable for inclusion in the research

7.3 Activities not requiring RREC review

7.3.1 Specific activities do not require RREC review. These include:

- Research utilising existing publicly available documents or data
- Observational studies in public places in which the identity of the participant remains anonymous
- Case study of one patient with the proviso that written informed consent has been obtained from the relevant study subject/participant
- Quality assurance studies
- Clinical Audits
- Service Evaluations

7.4 Differentiating research from other activities

7.4.1 It can be difficult to differentiate research, audit and evaluation. The HSE National Review of Clinical Audit (November 2019) distinguishes between clinical audit, service evaluation and research and indicates when research ethics committee review is required (Appendix 1). While the Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees outlines additional activities that generally do not require ethical approval (Appendix 2).

7.4.2 The NHS's Health Research Authority, in conjunction with the UK's Medical Research Council, has developed a useful decision making tool to help you decide if your activity is a research project, clinical audit, evaluation study or usual practice. It is available at http://www.hra-decisiontools.org.uk/research/index.html (**please note** that this a UK tool and therefore refers to UK structures, however, it remains a useful tool to determine if your activity is research).

7.4.2 For further information please see HSE's Research & Development page "What is Research" at https://hseresearch.ie/.

7.4.3 If this RREC is consulted about whether or not RREC review is required because of uncertainty as to whether the work is research, audit or service evaluation, you will be asked to consult the guidance above.

7.4.4 If, having considered the guidance above, you are still in doubt about the need for a RREC review, you will likely be advised to submit a full RREC application as this is the only way that the RREC will have all relevant information to hand in order to make a decision. This is because a review of a study by the Chair and/or the Vice-Chair to decide whether it should go to the RREC for ethics review is quite an involved process, particularly if additional information is required. Requests like these are often made before the project is fully worked up. These sort of requests often become more delayed than straightforward submission and review. If you ask this RREC whether review is required and the information is unclear or there is great uncertainty, you will most likely be advised to submit the project for full ethics review. **Ultimately, it is a decision for the principal investigator to decide whether to submit a project for ethics review**.

7.4.5 To undertake retrospective ethical reviews is not good practice and, as such, it should be noted that the RREC will not undertake a retrospective review of projects that have commenced or have been completed.

7.4.6 The RREC does not provide 'waivers' for ethics review of projects. It is the responsibility of the principal investigator to decide whether ethics review is required.

7.4.7 For staff wishing to publish the results of an activity that is not research and does not require RREC review, this RREC does not provide a letter stating that approval is not needed. This RREC reviews only research projects. It is suggested that staff link in, as appropriate, with their Quality and Patient Safety lead or clinical audit department for guidance. For further information about clinic audit, please visit https://www.hse.ie/eng/about/who/nqpsd/ncca/

7.4.8 In accordance with the Health Research Regulations, RECs can no longer conduct Expedited Reviews by Chair approval. However, it is recommended that HSE RRECs conduct the reviews in a manner that is proportionate to the level of risk of the study. In order to assess the level of ethical risk, HSE RRECs can use the "Screening Questions for Proportionate REC Review" (see Appendix 3).

8. Guideline

8.1 RREC constitution and membership

8.1.1 The RREC is constituted to ensure competent, independent and just ethical review of research proposals submitted to the committee.

8.1.2 Recruitment of members and the composition of RRECs is guided by Section 5 of the Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees.

8.1.3 Members are appointed for a term of 3 years. Appointments can be renewed.

8.1.4 Updates to membership will be communicated to the HSE REC SCO on an annual basis via proforma reports.

8.1.5 Each member will receive a letter of appointment signed by the RREC Chair or the HSE REC SCO.

8.1.6 Members must agree to take part in education and on-going training appropriate to their roles as HSE RREC members. The minimum required is 8 hours in any calendar year.

8.1.7 Members are expected to treat as confidential all applications, meeting deliberations, information on research participants and volunteers and related matters.

8.1.8 Each member of the RREC is expected to attend a minimum of 6 meetings annually.

8.1.9 The RREC chair must attend all meetings – if unavailable, the Chair must ensure that a Deputy Chair is available to fulfil the role of Chair for the meeting.

8.1.10 The RREC is constituted so that it can function with a quorum for the duration of its scheduled meetings. A quorate meeting is one attended by no fewer than 7 members, including:

- The chair or deputy chair
- Three expert members (2 of whom should have relevant clinical expertise)
- A member with relevant methodological expertise. This person may provide their opinion in advance of meeting if they are unable to attend

8.1.11 The Patient Representative, Lay Member or PPI Contributor should be consulted as part of the RREC review process. While it is preferable that they are present at each meeting, their attendance is not currently necessary to achieve a quorum, but when they are in attendance, they do contribute to the quorum. If the member is unable to attend, they should provide their opinion in advance of the meeting.

8.1.12 The RREC may seek advice from specialist referees on any aspects of a research proposal that fall beyond the members' expertise. Such expertise will be acquired locally in the first instance, however, the HSE REC SCO may assist where there is difficulty acquiring such expertise locally or where the expert is needed from another area due to possible conflict of interest. The terms of reference for such referees will be established and will be available on the RREC webpage once finalised.

8.1.13 A HSE RREC may appoint a sub-committee comprising committee members to review amended applications (i.e. applications that have already been reviewed at a full RREC at which request for further information, clarifications or amendments were made) without the need for the application to be reviewed by the full committee. This is dependent on the availability of members of the HSE RREC to form a sub-committee that meets in addition to the standard 10-12 HSE RREC meetings per year. A terms of reference for such a sub-committee would first be developed.

8.2 Application processes and documentation – information for the applicant

8.2.1 The meeting dates are available on the local RREC webpage. Meeting frequency will normally be 10-12 per year. The throughput will be monitored by the RREC Manager.

8.2.2 The deadline for the receipt of applications will be **at least 20 working days** before the RREC meeting. This is to allow sufficient time for applications to be screened by the RREC Manager and/or Chair, and provided to RREC members in advance of the meetings.

8.2.3 So that the RREC can monitor the number of applications, to ensure the meeting limit is not exceeded, the applicant must email REC.B.CorporateMidlands@hse.ie:

- to inform the RREC of their intention to submit an application
- indicating the meeting date for which they are applying
- indicating the number of applications being submitted

8.2.4 If an applicant submits an application within the deadline but there are no available slots for that meeting, their application will be reviewed at the next meeting.

8.2.5 The application form and the associated documents are available at www.hse.ie/rrecmidlands/

8.2.6 The standardised application form is available here and in-depth instructions on how to complete each question are available here.

8.2.7 Each application must be accompanied by a fully completed checklist (each item must be ticked – yes, no or n/a as appropriate) and appropriate documentation. **It is recommended that the applicant familiarises themselves with the checklist so that they know what they are expected to submit** with their application form and have time to compile same for submission.

8.2.8 The DPIA, if same is needed, must be completed and sent to the relevant HSE or service specific DPO for review - see the DPIA section on the RREC webpage for further information. The applicant should allow themselves sufficient time to complete the DPIA and to have it reviewed by the DPO so that it can be submitted to the RREC by the application deadline.

8.2.9 Applications and documentation should be submitted by email only to REC.B.CorporateMidlands@hse.ie. This process will be in place pending the introduction of an Electronic Research Management System.

8.2.10 Keep the attachment sizes as small as possible so that the email is not quarantined by HSE email content filter.

8.2.11 All attachments or appendices included with the application form should have a clear file name.

8.2.12 Applications will be returned, without review, if they are not complete and not accompanied by all relevant documentation upon submission.

8.2.13 Please note:

- if participant consent is needed for the research project, all consent related documentation (i.e. participant information leaflet, informed consent form) must be submitted with the application form
- if the research study involves children aged under 18 years, age appropriate patient information leaflets and assent forms for each paediatric age grouping in your study must be submitted with the application form
- it is the responsibility of the Principal Investigator to ensure all documentation is completed honestly and truthfully

- if the RREC approves the research study the approval letter will include information indicating that the Principal Investigator, or the person they have nominated, will be required to:
    - report serious adverse reactions related to study drug/ intervention/ procedures to the RREC
    - submit an annual update, end of study notification, and a final report to the RREC

8.2.14 Applicants can expect to receive a formal decision letter **within 10 working days** of the RREC meeting.

8.3 Meetings, submission and review timelines – information for RREC members

8.3.1 The **meeting dates** for the following year will be agreed by the committee before the final RREC meeting within a calendar year. The meeting dates will be available on the local RREC webpage, and will also be forwarded to the HSE Reference REC Support and Co-ordination office for inclusion on their website.

8.3.1 **Meeting frequency** would normally be 10-12 per year. The throughput will be monitored by the RREC Manager.

8.3.2 The **deadline for the receipt** of applications will be at least **20 working days** before the RREC meeting. This is to allow sufficient time for applications to be screened by the RREC Manager and/or Chair, and provided to RREC members in advance of the meetings.

8.3.3 **The number of applications** reviewed per meeting will **initially** be capped at 15 to allow sufficient time to review all applications on the agenda. A limit on applications per meeting may be applied to enable this. As the RREC becomes more established this will be reviewed. If an applicant submits an application within the dealdline but there are no available slots for that meeting, their application witll be reviewed at the next meeting.

8.3.4 Once received, applications will be screened by the RREC manager to ensure the **documentation is complete and clear** and the applicant will be contacted if any documents are missing and to seek any clarifications. Such clarifications will be recorded in writing (via email pending introduction of ERMS) and provided for review to the RREC members together with the application.

8.3.5 Applicants can't submit additional documentation after their study has been put forward to the RREC members for the RREC meeting.

8.3.6 Once screened by the RREC manager and Chair, applications will be **provided to RREC members for review 10 working days before** the RREC meeting.

8.3.7 Should an application be submitted for a neonatal or paediatric study the application cannot be considered unless at least one person with the relevant experience and knowledge in neonatal/ paediatric health is part of the review. If this person(s) with the relevant

experience and knowledge is not already a member of the RREC or they have a conflict of interest with the study, then the RREC will need to request external advice.

8.3.8 **Sharing of documents** with RREC members will be done by Sharefile (pending introduction of the ERMS). Sharefile is a highly secure file sharing platform where files are encrypted both during transfers and storage in the servers. All members will have read access to the RREC folder in Sharefile which will be co-ordinated by the RREC manager and RREC administrative support. Documents will be deleted from the Sharefile after each meeting.

8.3.9 The master copy of each application and supporting documentation will be saved on HSE shared drive (see Section 8.14.1 for retention periods) – this is encrypted and access is limited to the RREC Chair, manager and administrative support. This system is in place pending the introduction of the ERMS.

8.3.10 Time requirement is estimated at approximately 3 – 3 ½ hours for meetings and appropriate time to allow for the preparation process to be conducted in such a way as to ensure an effective and efficient consideration of the application at hand.

8.3.11 The RREC meetings may be **conducted in person, remotely (virtually) or using a combination** of both. While it is acknowledged that engagement between the members can be facilitated by being present in person, remote virtual meetings provide the advantages of including a broader membership to the committee, overcomes issues associated with lack of consistent access to suitable meeting space and provides safety to members during periods of Covid-19 infection surges.

8.4 Remote conduct of meetings

8.4.1 Cisco WebEx will be used by the RREC for remote conduct of meetings. It offers end to end encryption and allows screen sharing and is permitted for use by HSE for remote meetings.

8.4.1 Microsoft Teams is also permitted for use, although has proven somewhat problematic for HSE staff not on HealthIrl server. If necessary, the use of WebEx –v- MS Teams will be assessed during the first months of the RREC.

8.4.2 Zoom is not permitted for use by the HSE.

8.4.3 The initial meetings will take place remotely. However, as the RREC is established and depending on the Covid-19 infection rates and public health guidance, the RREC manager will endeavour to make a meeting room available for those who wish to attend in person.

8.4.4 Participants should remain on mute unless speaking.

8.4.5 Participants should use “raise hand” function.

8.4.6 Meetings will be minuted but under no circumstances are to be recorded.

8.5 RREC pre–meeting procedures

8.5.1 The manager or administrative support will communicate, in a timely way, with applicants, respond to all enquiries regarding submission procedures and committee meeting dates, and forward/direct applicants to the documentation needed:

- The standard application form
- The guidance notes on completing the standard application form
- A checklist for completion
- A list of closing dates and meeting dates for the current year
- A copy of this guideline document

8.5.2 The manager will advise, if necessary, that attendance of applicants at RREC meetings to discuss their applications is not required. However, the RREC has discretion to invite an applicant to attend the RREC meeting to answer any questions the committee may have if the complexity of the study requires so. If this is the preferred approach, it is important that any and all required amendments and queries that were discussed with the applicant are documented in a formal letter using the same procedure for those who have not attended a HSE RREC to discuss their application.

8.5.3 Upon receipt of the application the RREC manager, working with the administrative support:

- assigns a reference ID number to each application (this will be automated once ERMS is introduced)
- screens the applications to ensure all fields are completed sufficiently and all of the necessary information is provided
- enters all details onto the RREC database which is maintained on the HSE shared drive with access limited to RREC chair, manager and administrative support

8.5.4 The RREC manager / administration support will share with committee members, via Sharefile, the agenda, minutes from the previous meeting, and all application forms and associated documents. This will include any amendments, proportional review opinions, adverse events or other notification from previous research applications received on the agenda for discussion by the RREC.

8.5.5 The RREC manager / administration support will set up the meeting (virtual meeting link and room booking, as necessary, with videoconference equipment) and ensure meeting link and details are circulated in a timely manner.

8.5.6 Apologies, where known, by members should be submitted as soon as the yearly schedule is circulated, however, it is fully accepted that this is not always possible – where a member cannot attend a meeting, apologies should be sent as soon as practical.

8.5.7 If a principal investigator or researcher is required to attend the RREC, the RREC manager will inform them of their appointed time.

8.5.8 The RREC manager and Chair will ensure that the required balance of skill sets are among the RREC members invited to the meeting, and monitor planned attendance to ensure a quorum.

8.5.9 The RREC manager / administration support will maintain copies (on HSE shared drive with access limited to RREC Chair, manager and administrative support) of all correspondence with applicants.

8.5.10 The RREC manager / administration support will maintain the application log in such a way that a list of Chairperson's Actions can be readily obtained.

8.5.11 The manager, with the Chair's input as necessary, will allocate proposals for review to HSE RREC members in line with members' areas of skill and special interests.

8.5.12 All HSE RREC members are encouraged to familiarise themselves with all of the applications and associated documents on the agenda in advance of meetings.

8.5.13 Two in-depth reviewers will be assigned to each study and each will carry out an in-depth review of their allocated studies and report on same at the RREC meeting for discussion and decision. The in-depth reviewers need to attend the meeting. An aide memoir/template will be provided.

8.5.14 The reviewers will be recorded on the RREC database by the RREC manager or administrator.

8.5.15 The electronic research management system will be able to automate some of these processes (i.e. automatically acknowledge receipt of applications etc.), however, at present this will be a manual process.

8.6 Proportionate REC Review:

8.6.1 In accordance with the Health Research Regulations, research ethics committees can no longer conduct Expedited Reviews of health research by Chair approval.

8.6.2 However, it is recommended that HSE RREC conduct the reviews in a manner that is proportionate to the level of risk of the study.

8.6.3 In order to assess the level of ethical risk, RRECs can use the "Screening Questions for Proportionate REC Review" (see Appendix 3).

8.6.4 Using this tool, the risk assessment will be done by the RREC Manager, the Chair or the Deputy Chair.

8.6.5 Applications deemed of low risk will be pre-assessed by specific RREC members – these members will rotate to ensure appropriate spread of applications across committee members and across the year.

8.6.6 The assumption is that 6-7 applications per meeting will be low risk and will be suitable for proportionate review. This assumption is based on the experience of the Chairperson in her work with the Midlands REC.

8.6.7 Those individuals responsible for reviewing the low risk applications will present them in an expedited manner at the RREC meeting for approval by the full committee.

8.6.8 It would be anticipated that the presentation would take 5 minutes per application.

8.6.9 If the volume of low risk applications is very large, a subcommittee meeting chaired by the Chair or the Deputy Chair could be set up in advance of the main meeting to pre-review and pre-approve the applications.

8.7 RRECs meeting procedures

8.7.1 A **quorate meeting** comprises no fewer than seven members, including:

- The chair or deputy chair
- Three expert members (two of which should have relevant clinical expertise)
- A member with relevant methodological expertise. This person may provide their opinion in advance of meeting if they are unable to attend

8.7.2 The aim is to **have at least 10 to 13 members per meeting**, out of a panel of 27 members.

8.7.3 At the meeting and under the direction of the Chair, the **minutes** of the previous meeting and any matters arising are discussed.

8.7.4 RREC members are asked to **declare any conflict of interest** with regard to the specific applications tabled. If a member declares a conflict of interest, they will leave the meeting while the other RREC members discuss the application. This will be documented in the minutes of the meeting. The member will return once the application has been discussed and a decision reached.

8.7.5 Should a RREC member feel that an applicant has attempted to influence their decision or apply pressure in advance of the meeting, that member may declare a conflict of interest and proceed as per 8.7.4 above.

8.7.6 If applicants are provided with a time period to address the RREC on their application, they will be introduced to the RREC by the Chair and will be in the meeting during their assigned period only and cannot remain in the room while the RREC discuss their application or when another applicant is discussing their application. The Chair will take the lead asking questions.

8.7.7 **Sufficient time** should be allowed to review all applications on the agenda. Currently this RREC is working on the premise that the **number of applications** reviewed per meeting will **initially** be capped at 15 to allow sufficient time to review all applications on the agenda. This number will be reviewed by the Chair and RREC manager following the initial meetings.

8.7.8 Drawing on the seven requirements for determining whether a research trial is ethical from "What makes clinical research ethical?", elements of the lead reviewer form from the Health Research Authority (NHS) and checklist for ethics reviewers from the University of Sheffield, when reviewing proposals this RREC will consider the following:

8.7.8.1 Social or scientific value

Evaluation of a treatment, intervention, or theory that will improve health and wellbeing, or increase knowledge. Consideration will be given to the following:

- What is the rationale for this study?
- Is it a good idea – important and necessary?
- Does it add scientific value that will impact on people's health and wellbeing?

8.7.8.2 Scientific validity

Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data. Consideration will be given to the following:

- Is there a clear aim?
- Does the study do what it says it's going to do?
- Will executing the study as described, have the potential to find what it sets out to find / show?
- Is the study design / methodology appropriate to successfully address the aims and objectives of the study?
- Is there involvement of patients, service users and the public in the design of the study?
- Have bias, confounding and chance been eliminated or reduced, as much as possible?
- Is there a valid sample size calculation?

8.7.8.3 Fair subject selection

Selection of subjects so that stigmatised and vulnerable individuals are not targeted for risky research and the rich and socially powerful are not favoured for potentially

beneficial research. The benefits and risks of research should be distributed fairly among all social groups and classes, taking particular account of age, disability, gender, race, religion or belief and sexual orientation, as well as economic status and culture. Involvement of patients, service users and the public in the design may provide assurances that recruitment is likely to be equitable. Description and justification of the sample population; the sampling procedure and sample selection with inclusion and exclusion criteria of research participants:

- Are those who will benefit from the study results (new knowledge) included as study participants?
- Will those who share the risk and burden of the research, benefit from the research?
- Will those who participate in the study (as a described cohort and not the specific individuals), benefit from the findings of the study?
- Is everybody, to whom the researcher wishes to generalise their research, included?
- Are exclusions scientifically justified?
- Consider the population which is likely to be included in the research and what the needs of this group might be.
- Will it be feasible for provisions to be made available for potential participants who might have difficulty understanding English?
- How are research participants recruited?
- How are the potential participants initially approached?
- How does participation impact on their clinical care?
- Are the gatekeepers involved identified and on board?

8.7.8.4 Favourable risk benefit ratio

Minimisation of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and to society. Involvement of patients, service users and the public in the design may provide assurances that the risk-benefit ratio is likely to be favourable. Consideration will be given to the following:

- Are the potential benefits to individuals and society well described?
- Are those who are at higher risk of harm excluded from the study, presuming that those studied generate generalisable knowledge?
- Are all risks identified?
- Are identified risks minimised – steps that have been taken to minimise or eliminate the risk, hazards, discomfort, and distress and enhancement of potential benefits
- Do the benefits outweigh the risks for this study?

8.7.8.5 Independent review

Review of the design of the research trial, its proposed population, and risk-benefit ratio by individuals unaffiliated with the research

8.7.8.6 Informed consent and the quality of research participant information

Provision of information to subjects about purpose of research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate. Involvement of patients, service users and the public in the design may provide assurances that the consent process is robust, taking the needs of participants into account. Consideration will be given to the following:

- How will informed consent be obtained? Is the method appropriate? Is the wording clear?
- Who obtains the consent?
- As part of the consent process, do research participants have adequate time to consider the information, and the opportunity to ask questions?
- Is there any inducement?
- Is consent obtained to allow GPs to be informed?
- Can the researcher be sure that participants can give informed consent that is free from coercion?
- Will participants understand what is being asked of them and what they are contributing to?
- Are all of the relevant supporting documents included? (e.g. information sheets, consent forms, GP letter, interview schedules, questionnaires)
- Are materials for participants clear and free from technical terms, jargon and abbreviations as far as possible?
- Are the materials appropriate for the intended audience (e.g. children)?
- Where consent requires additional facilitating resources, such as may be required in disability research, has attention been given to varied and appropriate methods of communication, employment of advocates and interpreters and continued consent negotiation throughout the research process?
- Has language and culture been acknowledged?
- Have translation issues been considered?

8.7.8.7 Respect for potential and enrolled participants

Respect for subjects by permitting withdrawal from the research; protecting privacy through confidentiality; informing participants of newly discovered risks or benefits; informing participants of results of research; maintaining welfare of participants. Involvement of patients, service users and the public in the design may provide

assurances that that respect for participants is present. Consideration will be given to the following:

- Impact and relevance of the research on the local community
- Description of community consultation
- The extent to which the research contributes to the enhancement of local healthcare
- Description of the availability and affordability of any successful study product to the relevant communities following the research
- The manner in which the results of the research will be made available to participants and the study communities
- Do the researchers demonstrate an awareness of research transparency? (For example, study registration, sharing of results, plans for publication)
- Is it clear to the participants who is leading the research and how to contact them?
- Safeguarding:
  - Is there an appropriate Designated Safeguarding Contact(s) named?
  - Is it clear to the participant how they can report any safeguarding concerns or incidents and how these will be dealt with (taking account local context)?
  - Is there an appropriate process for the handling and escalation of safeguarding concerns and incidents?
  - If the research is collaborative, is there an agreement between parties regarding how this will be managed?
- Withdrawal:
  - Can participants change their mind/withdraw from the research?
  - Is the withdrawal process clearly explained?
  - At what stage would it be no longer possible for participants to withdraw?
- Is participant's privacy respected?
- Are the dignity, rights, safety and wellbeing of the participants considered?
- Are participants informed of newly discovered risks or benefits? How is this done?
- Are participants informed of results of research? How is this done
- How is the welfare of participants maintained?
- Arrangements and feedback at the end of the study?
- Has the researcher provided evidence of appropriate indemnity and insurance?

8.7.8.8 Confidentiality and privacy

It is important that adequate measures have been taken to ensure anonymity, confidentiality and security of personal information concerning research participants.

These must be appropriate to the research project and they must be realistic. Consideration will be given to the following:

- Is it clear to the participants how the data will be managed and which organisation will be the Data Controller, including a description of provisions to ensure the confidentiality and security of personal information concerning participants?
- Is it clear to participants what the data will be used for, and the legal basis that is being relied upon for this (under GDPR)?
- Are data or samples being sent outside of Ireland? How are they protected? Are participants made aware?
- Is it clear to the participants who will have access to their data and in what form for example, aggregated, anonymised or pseudonymised (note that pseudonymised data can be restored to its original state with the addition of information which then allows individuals to be re-identified). This also includes biological samples and medical records.
- Does this take account of any intended future use?
- Are research participants, informed that access to their medical notes may be required?
- How are biological samples obtained (if applicable), what is the purpose for which they will be used and for how long with they be stored?
- Is it clear to participants how long the data (written, recorded, video, etc) or samples will be held?
- Will personal data be permanently deleted / destroyed when they are no longer required?
- Are arrangements made to deal with incidental disclosure?
- Is it clear to participants how to complain about how their personal data is being handled, should they wish to do so?

8.7.8.9 **Suitability of the researcher, investigator and supporting staff**

Medical research must be conducted only by people with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

- Is the researcher suitable for this project?
- Do they have the necessary qualifications and skills?
- Are there are conflicts of interest?
- If they have supporting staff, do they have the skills necessary to support the research?

8.7.8.10 **Other questions for consideration may include:**

- Is there enough detail in the application?
- Are there any obvious gaps, ambiguities or uncertainties in how the research will be carried out?

- Are facilities being used suitable?
- Has the safety of the research team been considered?
- Is there a process in place to manage risks to the researcher/team?
- Does the research have any implications for the reputation of the HSE?
- Is there missing information, typographical errors, or application errors?

8.7.9 The decision to approve a research application by the RREC will usually be arrived at by **consensus**. However, if agreement cannot be reached in this manner a **majority vote** of more than two thirds is required. If a majority vote cannot be achieved, further information will be sought from the applicant.

8.7.10 **Decisions are recorded** by the HSE RREC manager and circulated to all members of the committee.

8.7.11 **Minutes of the meetings** are also recorded by the RREC administration support person and circulated to all members of the committee in advance of the following meeting.

8.8 Outcomes from RREC review

8.8.1 There are 5 possible outcomes from the RREC review. They are:

A. Favourable opinion:

- This allows a Principal Investigator to conduct the research as outlined in the research protocol.

B. Provisional favourable opinion:

- The applicant is asked for further information or minor changes to be made.
- The Chair reviews the further information and then issues full approval and this is noted at the next RREC meeting.

It should be noted that all requests for new information and changes must be communicated to the applicant at the one time, following the outcome of the meeting. The only further changes or updates that can be requested will relate to the new information provided by the applicant.

C. No opinion with a request for significant further information, changes to be made, or a resubmission. The responses will be assessed by the full RREC at the next scheduled meeting.

D. No opinion pending a consultation(s) with an external referee(s) or expert(s).

E. Unfavourable opinion:

- The research may not go ahead, but the decision can be appealed (see "Section 8.13 Process for appealing the decision of a HSE Reference REC")

8.8.2 Decisions and feedback is provided to applicants within **10 working days** of the meeting. For applications that are deemed to have been complete when received by the submission deadline, this forms the standard reliable turn-around review time, linked with the meeting schedule.

8.8.3 The Chair or vice-chair will sign all communications, or the RREC Manager may sign on their behalf. The communication shall include, but is not limited to:

- project identification and reference number
- exact title of proposal reviewed
- name and address of applicant
- date and place of the decision
- clear statement of the decision taken, A to E above
- details of further information required and /or specified conditions to be met
- reasons for an unfavourable opinion

A template linked to the RREC database will be available to assist this process.

8.8.4 The applicant should reply to the RREC manager by email with a description of the changes and additional information. Replies should be submitted within **60 days** from the date of the first RREC response.

8.8.5 Responses received under **category B** will be assessed by the Chair and responded to. Replies from the Chair will be sent within **15 working days**.

8.8.6 Responses received under **category C** will be assessed by the full RREC at the **next scheduled meeting**. A response from the RREC will be sent **within 10 working days** of the meeting.

8.8.7 If the initial response from the RREC is in **category D**, a **proposed timescale** for a response will be included in the initial response letter.

8.8.8 No research should start until a final letter of approval has been sent by the RREC Chair and relevant institutional approval has been obtained.

8.8.9 Copies of all correspondence will be maintained by the RREC manager.

8.9 RREC process for amendments

8.9.1 As per the NREC's Operational Framework (September 2021) an amendment is any modification made to the study protocol or any other material information coming to pass **after the study has started**, which may have an impact on the conduct of the study.

8.9.2 An amendment can be categorised as substantial or non-substantial:

8.9.2.1 A **substantial amendment** or substantial 'modification' is a change to the research study that is likely to have a significant effect on the:

- safety, health, rights, physical or mental integrity of the subjects of the study;
- scientific value of the study, or the robustness or reliability of the data; generated by the study;
- conduct or management of the study; or
- quality or safety of any investigational medicinal product or device used in the study

8.9.2.2 A **non-substantial amendment** is any change to the research study in terms of the RREC application, the protocol, study team, or any other supporting documentation that does not meet the definition of a substantial amendment.

8.9.3 Researchers who wish to submit an amendment to a RREC should track changes to their original application, along with a summary cover letter, which should also stipulate if and how re-consent will be sought (this process will change with the introduction of the ERMS).

8.9.4 Amendments should be submitted in line with deadlines for receipt of full applications.

8.9.5 Amendments will be reviewed by 2 committee members, preferably the 2 members who were the initial reviewers. The reviewers will present their recommendation at the full RREC meeting. The same procedure as stated in Section 8.8: Outcomes from HSE Reference REC review will apply when reviewing amendments.

8.10 Process for Safety Reporting

8.10.1 As per the HSE's Incident Management Framework "… patient safety incidents require disclosure in accordance with the requirements of the HSE Open Disclosure Policy... It is the responsibility of the staff member identifying the incident to report the incident either by completion of the appropriate National Incident Report Form (NIRF) or direct entry to NIMS if available."

8.10.2 It is recommended that the HSE Integrated Risk Management Policy: Incorporating an overview of the Risk Management process is adhered to and all investigators should comply with the HSE Incident Management Framework 2020.

8.10.3 For any research study the **Principal Investigator** must report, using the template in Appendix 4, serious adverse reactions related to study drug/ intervention/ procedures, including Suspected Unexpected Serious Adverse Reactions (SUSARs) or unforeseen events that might affect the risk/benefits profile of the study to the RREC that issued ethical approval. These are reviewed by the Chair who may escalate them for full RREC review.

8.10.4 The RREC or Study Protocol may require additional safety reporting. The management of this process will be decided at the application stage or when an amendment is under review (whichever is applicable).

8.11 Process for notifying the HSE RREC of the termination of research

8.11.1 The RREC will require final reports for all research projects and it is the responsibility of the researcher to notify the RREC when a study is completed or terminated using the template in Appendix 5.

8.11.2 If the study was terminated, the reasons for this should be specified.

8.11.3 Failure to provide necessary updates may result in refusal by the RREC to review any future applications until due final reports are submitted.

8.11.4 Reminders for final report submission can be generated automatically via the ERMS (once set-up). In the interim, a reminder will be sent by this RREC's manager / administrative support and same will be logged on the database.

8.12 Process for appealing the decision of a RREC

8.12.1 In the case of an appeal of a RREC decision, the application is sent to 3 other HSE RRECs for review. A decision of at least 2 out of the 3 RRECs dealing with the appeal will be final.

8.12.2 The HSE Reference REC Support and Co-ordination Office will co-ordinate the appeals process, including the selection of the three other HSE RRECs. The timeline for this will be provided to the applicant once determined. Issues that determine the timeline will include the process to identify the RRECs to review, their capacity to review and the frequency of their meetings.

8.13 Process for handling complaints

8.13.1 Research sites and locations may receive complaints about researchers or the ethical conduct of research. Complaints may be made to RREC by patients (or their family members or next of kin), research participants (or their family members or next of kin), researchers, staff of institutions, or others. To this end, the applicant should include the RREC contact details on their participant information leaflets. All complaints will be handled promptly and sensitively by the RREC:

- Complaints should be submitted in writing to RREC.
- The RREC Manager will acknowledge the complaint, and also inform the HSE Reference REC Support and Co-ordination Office, within 5 working days of its submission and outline the course of action in response to the complaint.
- The RREC manager will keep the HSE Reference REC Support and Co-ordination Office informed of any actions and decisions made in relation to the complaint. If the HSE Reference REC Support and Co-ordination Office needs any additional information it will be supplied by the RREC.

8.13.2 Support in managing the complaint is available from the HSE Reference REC Support and Co-ordination Office.

8.13.3 Information related to the management of complaints should be visible on the RREC website and HSE's Research & Development website.

8.13.4 Should any patients, research participants, researchers, staff of institutions, or others be dissatisfied with the response of the RREC to their complaint they can approach the HSE Reference REC Support and Co-ordination Office. The RREC manager will provide the necessary contact details/pathway.

8.14 Record keeping and archiving

8.14.1 The **application form and additional documentation** submitted by the applicant should be kept for **5 years after completion** of the study. They will be stored on the HSE server with folder access restricted to RREC chairperson, manager and administrative support. Date for destruction for each application will be recorded on the RREC database. The RREC manager will take responsibility for destruction.

8.14.2 **Minutes and correspondence** will be stored on the HSE server with folder access restricted to RREC chairperson, manager and administrative support. These documents can be archived for the time that is necessary once a minimum of **7 years** has passed. As a general rule, minutes and correspondence should be kept for a minimum of 7 years to accommodate any potential audits or other activities that will involve a review of the RREC's minutes and correspondence. The RREC manager will take responsibility for destruction.

8.14.3 The duration for which records are kept and archived when the ERMS comes into use is currently unknown as the process is ongoing.

8.14.4 Approved research may be subject to ongoing ethics review. The frequency of such review will reflect the degree of risk to participants in the research project. As a minimum the RREC requires an annual report from investigators. This should include;

- progress to date
- a description of measures taken to maintain and secure personal information and records pertaining to the research
- a statement of compliance with the approved proposal and/or amendments to the proposal
- final report in the case of a completed project

8.14.5 The RREC will produce an annual report during Quarter 1 of each year for the preceding year.

8.15 Training for HSE RREC members

8.15.1 Training will be facilitated by the HSE Reference REC Coordination and Support Office and may take place in collaboration with the National Office for Research Ethics Committees.

8.15.2 RREC members should **complete 8 hours** of learning each year. To meet the minimum requirement for training, learning must be **linked to the work of the RREC** and relate to either issues of ethical principles or legislation relevant to ethical review.

8.15.3 RREC members are encouraged to partake in relevant training either by attending a face-to-face training, completing e-learning or undertaking independent self-directed learning.

8.15.4 Members can obtain continued professional development (CPD) points from their professional body by submitting certificates of attendance to training events and also attendance at RREC meetings:

- Such certificates of attendance to meetings can be obtained from the RREC Manager upon request (Appendix 6 – template certificate of attendance at RREC meeting)
- Certificates of attendance to training events will be automatically provided by the National HSE Coordination and support office.
- The RREC manager will keep meeting attendance records that can be used to verify attendance.

8.15.5 All HSE RREC members will need to complete Standard REC training (including experienced members who have not completed it). Training includes:

- Induction training which includes understanding the role and responsibilities of Research Ethics Committee members, introduction to the standard code of management and practice required for HSE RRECs and understanding the overall HSE research governance process
- Introduction to the basics of Research Ethics Committee review
- Ethical principles of research
- HSE Consent Policy
- Data protection

8.15.6 Other recommended training includes, but is not limited to, Equality, Diversity and Human Rights training, Research Integrity training and Principles of Good Clinical Practice.

8.15.7 The Chair should complete operational training to facilitate adherence to the Standard Code of Governance and Management Required for HSE Reference REC.

8.15.8 Training records will be kept by each the RREC office and supplied upon request to the National HSE REC SCO during the process of quality assurance.

9. Implementation Plan

9.1 This guideline will be available on this RREC's website and on the HSE Research and Development website

9.2 This guideline will be made available to investigators when an inquiry is made to the manager of the RREC.

9.3 This guideline should be read by the applicant before submitting an application to the RREC.

9.4 It is not anticipated that there will be any training requirements for researchers in relation to this guideline. Guidance notes on the completion of the HSE common application form will be provided for the researcher.

10. Revision and Audit

10.1 As this RREC is newly established, this document is likely to be revised in quarter 2, 2022.

10.2 Further feedback will be sought after 1 year from RREC members and research applicants as to their opinions on the guideline and the research ethics process.

10.3 Thereafter the review cycle will be every 3 years (and sooner if indicated).

11. References and further information

- *Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 S.I. No. S.I. No. 314 of 2018 and subsequent amendments* accessed from https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
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- The Medical Research Council (MRC) Regulatory Support Centre and the Health Research Authority (HRA) (2020). *Is my study research?* Accessed from http://www.hra-decisiontools.org.uk/research/index.html (**please note** that this a **UK** tool and therefore refers to UK structures, however, it remains a useful tool to determine if your activity is research).
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12. Appendices

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Appendix 1 Distinguishing between clinical audit, service evaluation and research

	Research	Clinical Audit	Registry	Service Evaluation
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.	Registries are systems which collect a defined minimum dataset from patients with a particular disease, undergoing a particular procedure or therapy, or using a healthcare resource.	Service evaluation seeks to assess how well a service is achieving its intended 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.
Answers Questions	Research demonstrates what should be done.	Clinical audit demonstrates whether a predetermined standard is being met.	Registries show the details of certain patient groups. They can be used to answer both clinical audit and research questions.	Service evaluation tells how well a service is working.
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 practised for quality assurance and improvement purposes	To monitor a patient population or healthcare process. A registry may have an improvement aim, a cost focus or form an epidemiological database used for research	To evaluate current practices for information purposes. The information can inform management decisions.
Context	Local or national level	Local or national level	National level only	Local level only
Methods	Has a systematic, quantitative or qualitative approach to investigation	Measures practice against evidence-based clinical standards	Carries out data collection and analysis	Measures current service without comparison against standards
Requirement for REC Review	Yes	No, but ethical considerations should still be considered	Yes, if for the purposes of research	No, but ethical considerations should still be considered

From the National Review of Clinical Audit (2019)

Appendix 2 Other activities that generally do not need ethical approval

Activity	Explanation
Research utilising existing anonymised publicly available data* **(*when the publically available data has already been anonymised)**	"Data can be considered 'anonymised' when individuals are no longer identifiable. It is important to note that a person does not have to be named in order to be identifiable. If there is other information enabling an individual to be connected to data about them, which could not be about someone else in the group, they may still 'be identified'. In this context, it is important to consider what 'identifiers' (pieces of information which are closely connected with a particular individual, which could be used to single them out) are contained in the information held. Where data has been anonymised, the original information should be securely deleted to prevent any reversing of the 'anonymisation' process. In most cases, if this deletion does not take place then the data is classified as 'pseudonymised' rather than 'anonymised', and is still considered personal data."[1]
Case study of one patient with the proviso that the written informed consent has been obtained from the relevant subject and according to the HSE Consent for Research Policy	Case study is a type of academic publication that shares a particular medical/ healthcare case, which is unusual or haven't been described before, to readers who may encounter a similar case. A case study is informative and useful part of healthcare education. It is important to note that case studies cannot provide specific guidance on the management of subsequent patients who present in a similar fashion to what was reported in the case study.
Advanced health analytics carried out by employees of the HSE and its funded organisations for the purpose of discharging their legal obligations for the planning and delivery of health and social care services using routinely collected data.	Advance analytics work carried out by employees of the HSE and its funded organisations for the purpose of public health, service planning, etc. is not considered to be under the remit of the HSE National framework for the governance, management and support of research and therefore does not require research ethical approval. When in doubt, the advice of the relevant Data Protection Officer should be sought. The GDPR article 9 condition for this work is 9:2(h); member state law the Health Act 2004
Public Health Practice	Public Health infectious disease practice can share some of the features of research such as systematic methods, epidemiological investigation design, the collection and assessment of personally identifiable and protected health information. It may involve selection of participants, statistical analysis of data and publication. However, the purpose, essential characteristics and legal basis of public health practice are different to research[2] When in doubt, the advice of the relevant Data Protection Officer should be sought. Also, should the activity raise any ethical considerations or issues, the advice of a Research Ethics Committee can be sought.
Infectious disease investigation and control practice	HSE Departments of Public Health Departments investigate and control infectious disease under the Infectious Diseases Regulations 1981, part of the Medical Officer of Health legislation. A Medical Officer of Health (MOH) is obliged under these Regulations to investigate the nature of notifiable infectious diseases. An MOH "shall make such enquiries and take such steps as are necessary or desirable, for investigating the nature and source of such infection, for preventing the spread of such infection, and for removing conditions favourable to such infection" (Regulation 11). In addition, under article 19 of these

	Regulations, others are obliged to provide requested information to the MOH. The GDPR article 9 condition for this work is 9:2(i); Member State law is the Infectious Disease Regulations 1981 (as amended).
Other statutory Public Health Practice	The Health (Duties of Officers) Order 1949 obliges Medical Officers of Health to: 1. Examine human epidemiology. The Medical Officer of Health shall inform themselves ".....as respects the causes, origin and distribution of diseases in the county". (Health (Duties of Officers) Order, 1949 Schedule) 2. Carry out Public health risk assessment (PHRA). The Medical Officer of Health shall inform themselves "as respects all influences affecting or threatening to affect injuriously the public health in the county". (Health (Duties of Officers) Order, 1949, Schedule) The GDPR article 9 condition for this work is 9:2(i); Member State law is the Health (Duties of Officers) Order 1949 and Health Act 2004.
Quality Assurance and Quality Improvement Activities	Quality assurance (QA) measures compliance against certain necessary standards/ process, whereas Quality improvement (QI) is a continuous improvement process focused on processes and systems. The HSE uses The Kings Fund (2019)[3] definition of quality improvement as "the systematic use of methods and tools to try to continuously improve the quality of care and outcomes for patients". The National Quality Improvement (QI) Team supports services to lead sustainable improvements for safer better health care: https://www.hse.ie/eng/about/who/qid/ Quality Assurance and improvement activities may, on occasions, involve research activities, and in those cases, REC approval is necessary.

From: Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees

[1] https://www.dataprotection.ie/en/dpc-guidance/anonymisation-pseudonymisation

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4025700/

[3] https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/national-qi-tool-an-introduction-sept-2019.pdf

Appendix 3 Proportionate REC review screener questions

If the Chair, or any member of the RREC, answers 'No' to any question from 1 to 3 and/or answers 'Yes' to any question from 4-13 then the research study is not for proportionate review as it is not an ethically low risk study

1	Research which only surveys the safety or efficacy of established non-drug treatments, involving limited intervention and/or no change to the participants'' treatment	Yes/No
2	Research using data that is fully publicly available anonymous data to the researcher	Yes/No
3	The study using existing data already collected and which will be used in accordance with the broad consent for research already in place (i.e. no additional samples data being collected)[1].	Yes/No
4	Potential conflict of interest issues identified?	Yes/No
5	Study includes vulnerable groups, other than children aged 18 years or younger (paediatric studies), such as staff who may feel under pressure to take part, due to their connection with the researcher? (e. g. unequal relationship) Children aged 18 years or younger (paediatric studies) are listed as a vulnerable group however if all other answers on the form qualify the study for proportionate REC Review then it may proceed as an ethically low risk study.	Yes/No
6	The study offers incentives which may unduly influence participants' decision to participate? (e. g. involves financial payment other than covering expenses that may occur)	Yes/No
7	The study involves activities where the safety/wellbeing of the researcher may be in question? (e. g. potential risk of physical threats, compromising situation, etc.)	Yes/No
8	The study involves sensitive topics that may make participants feel uncomfortable i.e. sexual behaviour, illegal activities, racial biases, etc. or where accidental disclosure would not have serious consequence?	Yes/No
9	The study involves physical stress/distress, discomfort except for minimally invasive basic science studies involving healthy volunteer studies or participants (e.g. which involve the taking of a single blood sample or other similarly invasive intervention).	Yes/No
10	The study involves behavioural/physiological intervention or further analysis of samples that could incidentally lead to discovery of ill health or concerns about wellbeing in a participant.	Yes/No
11	The study requires participants to take part in the study without their knowledge and/or consent at the time? (e. g. covert observation of people, emergency research).	Yes/No
12	The study involves deception or withholding information from subjects other than withholding information about the aims of the research until the debriefing.	Yes/No
13	Study has a 'Material Ethics Issue' that does not fit the above categories. Please expand	Yes/No

[1] Health Research Regulations 2018 3(1)(e) provides that explicit consent from the individual may be obtained "*for the purpose of the specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof*".
Broad consent is about giving people consent choices at each stage of the research process and an individual may give their consent to: (1) the specific and immediate processing planned; (2) the next level of research that might be envisaged or (3) use of their data for a more general research questions/topics in the specified area of research or in a related area of health research, that cannot be envisaged right now.

From: Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees

Appendix 4 Safety reporting template

Full title of study:
Study Reference number:
Date of this report (dd/mm/yyyy):
NIMS Record Number (if applicable)**:**

Please select reason for completing this report:

☐ Serious Adverse Reaction (i.e. Event at least possibly related to the study drug/ intervention/procedures
☐ Suspected Unexpected Serious Adverse Reactions (SUSARs)
☐ Unforeseen event(s) that may have affected the risk/benefits profile of the study (i.e. new and emerging evidence that relates to the safety profile of the study such as a recent publication or safety signal etc.)

Is this the

☐ Initial Report ☐ Follow-up to the report dated:

Why is this event Serious? Please tick the appropriate option:

Death	☐
Life Threatening	☐
Hospitalisation or prolongation of existing hospitalisation	☐
Persistent or significant disability or incapacity	☐
Congenital anomaly or birth defect	☐
Medically significant (requires interventions to prevent permanent impairment or damage	☐

Description of the Event:

Information about the Event:

Start Date (and if known time):

☐ Ongoing ☐ Stop date (and if known time):

In the opinion of the Principal Investigator the relationship to study:

☐ Possible ☐ Probable ☐ Definite

Reporter Information	**Principal Investigator**
Name:	Name:
Title:	Title:
Email:	Email:
Date (dd/mm/yyyy):	Date (dd/mm/yyyy):
	Signature:

Appendix 5 Final Progress Report (completed by researcher)

When you initially applied to the HSE Reference Research Ethics Committee, you agreed to a Final Progress Report. Please complete the FINAL PROGRESS REPORT below and return it to HSE Reference Research Ethics Committee for Area X at [insert email address].

Study Reference number:

1.) Final Number of participants recruited to this study:

2.) Total number of subjects who completed the project:

3.) Has the study ended because it is
Completed: Yes ☐ No ☐ If yes, please state date (dd/mm/yyyy):
Terminated: Yes ☐ No ☐ If yes, please state date (dd/mm/yyyy):

3.b) If the study has been terminated, please state why.

4.) During the study period did any serious adverse events at least possibly related to the research study drug/ intervention/procedures, including Suspected Unexpected Serious Adverse Reactions (SUSARs) or unforeseen events that could have/did affect the risk/benefits profile of the study occur? Yes ☐ No ☐

4.b) If yes. When they were reviewed by the Chair was it escalated for full HSE Reference REC review? Yes ☐ No ☐

5.) Has the research been published? Please include publication references

6.) Has the research resulted in a change in (clinical) practice? Please elaborate

Submitted by (Name is Block Capitals): Date:

On behalf of (Name is Block Capitals): Date:

Appendix 6 Certificate of attendance at RREC meeting

Continuing Professional Development (CPD) Confirmation of Attendance as a member of the HSE Reference Research Ethics Committee	
This is to certify that:	**<Delegate Name>**
Attended a meeting entitled:	**<Title of Activity>**
At the venue:	**<Venue>** **<Venue Address>**
On the following date(s)*:	**<Date of Activity>**
CPD Credit:	**This activity attracts: <No of Credits>** **in the Internal (Practice and Evaluation) Category**
Organised by:	**<Organiser Name>**
Contact:	**<Organising Institution>** **<Address, Phone, Email>**

Appendix 7 Data Protection Officers – CHO

CHO	CHO Areas	Email
CHO 1	Donegal	ddpo.west@hse.ie
CHO 1	Sligo/Leitrim/West Cavan	ddpo.west@hse.ie
CHO 1	Cavan/Monaghan	ddpo.west@hse.ie
CHO 2	Galway	ddpo.west@hse.ie
CHO 2	Roscommon	ddpo.west@hse.ie
CHO 2	Mayo	ddpo.west@hse.ie
CHO 3	Clare	ddpo.west@hse.ie
CHO 3	Limerick	ddpo.west@hse.ie
CHO 3	North Tipperary/East Limerick	ddpo.west@hse.ie
CHO 4	Kerry	ddpo.south@hse.ie
CHO 4	Cork	ddpo.south@hse.ie
CHO 5	South Tipperary	ddpo.south@hse.ie
CHO 5	Carlow/Kilkenny	ddpo.south@hse.ie
CHO 5	Waterford	ddpo.south@hse.ie
CHO 5	Wexford	ddpo.south@hse.ie
CHO 6	Wicklow	ddpo.dne@hse.ie
CHO 6	Dun Laoghaire	ddpo.dne@hse.ie
CHO 6	Dublin South East	ddpo.dne@hse.ie
CHO 7	Kildare/West Wicklow	ddpo.dml@hse.ie
CHO 7	Dublin West	ddpo.dml@hse.ie
CHO 7	Dublin South City	ddpo.dml@hse.ie
CHO 7	Dublin South West	ddpo.dml@hse.ie
CHO 8	Laois/Offaly	ddpo.dne@hse.ie
CHO 8	Longford/Westmeath	ddpo.dne@hse.ie
CHO 8	Louth/Meath	ddpo.dne@hse.ie
CHO 9	Dublin North	ddpo.dne@hse.ie
CHO 9	Dublin North Central	ddpo.dne@hse.ie
CHO 9	Dublin North West	ddpo.dne@hse.ie

Accessed from https://hseresearch.ie/data-protection-and-research/#contacts on 10.03.2022

For further information on data protection and research, visit https://hseresearch.ie/data-protection-and-research/

Appendix 8 Data Protection Officers – hospitals

Hospital	DPO Email
Bantry General Hospital	ddpo.south@hse.ie
Beaumont Hospital Dublin	dpo@beaumont.ie
Cappagh National Orthopaedic Hospital	dataprotection@nohc.ie; dpo@nohc.ie
Cavan General Hospital	ddpo.dne@hse.ie
Children's Health Ireland at Connolly in Blanchardstown	CHIDPO@NCHG.IE
Children's Health Ireland at Crumlin	dataprotection@OLCHC.ie; dpo@olchc.ie
Children's Health Ireland at Tallaght	CHIDPO@NCHG.IE
Children's Health Ireland at Temple Street	dpo@cuh.ie
Connolly Hospital	ddpo.dne@hse.ie
Cork University Hospital/CUMH	ddpo.south@hse.ie
Croom Orthopaedic Hospital	ddpo.south@hse.ie
Ennis Hospital	ddpo.south@hse.ie
Kerry General Hospital	ddpo.south@hse.ie
Letterkenny University Hospital	ddpo.west@hse.ie
Lourdes Orthopaedic Hospital, Kilcreene	ddpo.south@hse.ie
Louth County Hospital	ddpo.dne@hse.ie
Mallow General Hospital	ddpo.south@hse.ie
Mater Misericordiae University Hospital	dataprotection@mater.ie -subject access requests, dpo@mater.ie - general data protection related enquiries
Mayo University Hospital	ddpo.west@hse.ie
Mercy University Hospital	gdpr@muh.ie
Midland Regional Hospital Mullingar	ddpo.dml@hse.ie
Midlands Regional Hospital Portlaoise	ddpo.dmlUH@hse.ie
Midlands Regional Hospital, Tullamore	ddpo.dml@hse.ie
Monaghan Hospital	ddpo.dne@hse.ie
Naas General Hospital	ddpo.dml@hse.ie
National Maternity Hospital	dpo@nmh.ie
Nenagh Hospital	ddpo.south@hse.ie
Our Lady of Lourdes Hospital, Drogheda	ddpo.dne@hse.ie
Our Lady's Hospital, Navan	ddpo.dml@hse.ie
Portiuncula University Hospital	ddpo.west@hse.ie
Roscommon University Hospital	ddpo.west@hse.ie
Rotunda Hospital	dpo@rotunda.ie
Royal Victoria Eye and Ear Hospital	dpo@rveeh.ie
Sligo University Hospital	ddpo.west@hse.ie
South Infirmary Victoria University Hospital	dpo@sivuh.ie
South Tipperary General Hospital	ddpo.south@hse.ie
St Columcille's Hospital	ddpo.dml@hse.ie
St Luke's General Hospital, Kilkenny	ddpo.dml@hse.ie
St Michael's Hospital, Dun Laoghaire	stmhfoi@stmichaels.ie

Hospital	DPO Email
St Vincent's University Hospital	dataprotection@st-vincents.ie; dataprotection@svhg.ie
St. James's Hospital	dataprotection@stjames.ie
St. John's Hospital	igo@stjohnshospital.ie
St. Luke's Radiation Oncology Network	ddpo.dml@hse.ie
Tallaght University Hospital	roi@tuh.ie
The Coombe Women & Infants University Hospital	dataprotection@coombe.ie
UH Galway and Merlin Park University Hospital	ddpo.west@hse.ie
University Hospital Limerick	ddpo.south@hse.ie
University Hospital Waterford	ddpo.south@hse.ie
University Maternity Hospital Limerick	ddpo.south@hse.ie
Wexford General Hospital	ddpo.dml@hse.ie

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