Research & Development
Taighde & Forbairt

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

July 2022

Contents

Glossary of key terms

Abbreviations

CHI	Children's Health Ireland (Children's Hospital Group)
COVID-19	Coronavirus Disease 2019
CHOs	Community Healthcare Organisations
CI	Chief Investigator
CTIMPs	Clinical Trials of Investigational Medicinal Products
CTR	Clinical Trials Regulation
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
ERMS	Electronic Research Management System
GDPR	General Data Protection Regulation
HPRA	Health Products Regulatory Authority
HRCDC	Health Research Consent Declaration Committee
HRCS	Health Research Classification System
HRR	Health Research Regulations
HSE	Health Service Executive
MD	Medical Devices
MDR	Medical Device Regulation
NREC	National Research Ethics Committee
PPI	Public and Patient Involvement
PI	Principal Investigator
REC	Research Ethics Committee
RGMS	Research Governance Management and Support
RHA	Regional Health Area
R&D	Research and Development
R&E	Research and Evidence
SCO	Support and Coordination Office
SOP	Standard Operating Procedure
S38	Section 38
S39	Section 39
ToR	Terms of Reference

SECTION A. Context

1. Introduction

The HSE National Framework for the Governance, Management and Support of Health Research[1] was launched in 2021. The framework articulates how both ethical and institutional oversight are necessary for the appropriate governance of health research in the HSE and its funded organisations. While the Research Ethics Committees (RECs) in the HSE and Section 38 (S38) organisations have fulfilled a very important role in research governance to date, the current system faces significant challenges. Hence, the full implementation of this framework will require both the reform of the HSE Research Ethics Committees and the development of capability for research governance, management, and support within the services hosting research activity.

The reform of the HSE Research Ethics Committee system will be coordinated by HSE National Research and Development (R&D) in collaboration with the HSE REC Reform working group (Appendix 1) and it will follow an agreed roadmap. The "Roadmap for the Reform of Health and Social Care Research Ethics Committees"[2] outlines the creation of several HSE Reference RECs. Six of the Reference RECs will be aligned to the future Regional Health Areas, as proposed in the Sláintecare Action Plan, and there is the possibility to develop one aligned to Children's Health Ireland. They will work to the operational and transparency principles articulated in this "Standard Code of Governance and Management for the HSE Reference RECs", while supported by a central national coordinating office. In order to achieve full national integration, the HSE Reference RECs will seek to establish working partnerships with existing RECs in S38 organisations and will coordinate, as far as possible, with the statutory National Research Ethics Committees (NRECs).

This reform aims to address the challenges of an existing system which is fragmented, uncoordinated, and under-supported, with a view to creating an efficient and effective system that supports and encourages high quality health research activity.

1 https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf
2 https://hseresearch.ie/wp-content/uploads/2021/12/HSE-Roadmap-for-the-Reform-of-Health-and-Social-Care-Research-Ethics-Committees-Draft-V0.6.1.pdf

2. Difference of Remit between RECs reviewing Health Research

While all the Health RECs have different remits, it is important that all and each of these works with each other to create an integrated national mixed model system. The effectiveness of the mixed-model system relies on appropriate communication channels between all RECs to ensure that the entirety of Irish health research is grounded in the highest standards of ethics, governance, and research practice.

2.1 The HSE Reference Research Ethics Committees

HSE Reference Research Ethics Committees (HSE Reference RECs) are Research Ethics Committees which have been appointed by the relevant HSE Appointing Authority (see section 4.3 HSE Reference RECs Appointing Authority) to provide a service to HSE and HSE funded organisations. The primary role of the HSE Reference RECs is to protect the safety, welfare, and rights of participants in health research, in accordance with recognised ethical principles and standards, relevant EU Directives, Good Clinical Practice Guideline ICH-GCP E6 (R2), national legislation, in alignment with the HSE National Framework for the Governance, Management, and Support of Research and other relevant policies (see section 4.1 Relevant Policy / Legislation for HSE Reference RECs). HSE Reference RECs also help to protect host institutions and researchers by ensuring research adheres to high quality ethical standards and will be committed to creating a positive environment for all its members, where all REC volunteers are respected and valued[1,2.]

HSE Reference RECs have regional cover and provide a REC service to

- HSE acute and community services located within a Sláintecare Regional Health Area.
- HSE funded services (i.e. S38[3] and S39[4]) located within a Sláintecare Regional Health Area who do not have access to their own REC.
- HSE National Services and Corporate Divisions within their Sláintecare Regional Health area.

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 NRECs. For studies involving multiple

3 S38 are organisations that provide a defined service on behalf of the HSE. The funding is provided annually under a formal service level agreement framework

4 S39 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 support to live the best quality of life they can.

sites at least one of the sites should be within the geographical area covered by the chosen HSE Reference REC. The HSE Reference RECs will provide a single opinion for studies under their remit that involve multiple HSE, S38 or S39 sites or have national scope. The HSE Reference REC selected for the review of these studies should have under their geographical remit at least one of the sites involved in the study.

Note: HSE Reference RECs will be enabled to provide a single opinion for national studies or studies involving multiple sites in a phased manner, as outlined in the 'HSE Roadmap for the Reform of the Health and Social Care Research Ethics Committee'.

It should be noted that as the reform of the HSE RECs system progresses beyond Phase One this document will need to be updated to reflect the agreed approach for each of the tasks, within the phases of reform. This version of the 'Standard Code of Governance and Management required for the HSE Reference Research Ethics Committee' enables Phase One and partially supports Phases Two to Four

2.2 The National Research Ethics Committees

National Research Ethics Committees (NRECs), operational from May 2021, are responsible for the ethical review of Clinical Trials of Investigational Medicinal Products (CTIMPs) and the clinical investigations of Medical Devices (MD). They are operationalised through the National Office for Research Ethics Committees, which is an independent statutory office, hosted by the Health Research Board, and answerable to the Minister for Health. The scope of the Terms of Reference of the NREC-CT and NREC-MD is informed by Regulation EU No 536/2014 (IMP) and Regulation EU No 2017/745 (Devices), respectively. These committees will operate on a statutory basis by amendments (secondary legislation) made by the Minister for Health to existing Statutory Instruments. This will enable Ireland to meet its obligations as a Member State to implement EU Regulations for clinical trials of medicinal products (Regulation EU No 536/2014) (IMP) and Regulation EU No 2017/745 and for clinical investigations of medical devices (Regulation EU No 2017/745). A further element of reform is the National Research Ethics Committee Bill.

The NRECs[5] provide a single national opinion on applications received by their National Office (both for IMPs and MDs). This enables the NREC review process to run in coordination (where necessary) with the Health Products Regulatory Authority (HPRA) to ensure Ireland meets its Member State obligations to return a 'single national opinion' in relation to pending EU Regulations, including for CTIMPs (EU No 536/2014) and clinical investigations of medical devices (EU No 2017/745).

5 NRECs will be operating pre-legislatively for approximately 6 months until the activation of the Europe-wide legislation (EU Clinical Trial Regulation No. 536/2014) in December 2021. The National Office for Research Ethics Committees will work in a mixed-model system to support research ethics across the spectrum of health research in Ireland, with clarity of committee remits a key aspect of its effective working. Following a defined period of transition, local RECs will no longer be authorised to review research studies that fall within the remit of the NRECs.

Current responsibilities of the NRECs[6]:

- The remit of the NREC-CTs is to review the submission of ethics applications related to Clinical Trials of Investigational Medicinal Products (CTIMP). This includes interventional trials with medicinal products for human use, and low-interventional trials (trials with authorised medicinal products, used in accordance with the marketing authorisation, and additional diagnostic and monitoring procedures not posing additional risk or burden to patients' safety compared to normal practice).
- The remit of the NREC-MD is to review the submission of ethics applications related to Clinical Investigations of Medical Devices. This includes Non-CE marked medical devices being used in a clinical investigation for one or more of the purposes outlined in Article 62 of the Medical Devices Regulation (EU) 2017/745; CE-marked medical devices being used in a clinical investigation outside the scope of its intended purpose; CE-marked devices being further assessed in a clinical investigation (PMCF) within the scope of its intended purpose, which involves submitting participants to additional procedures deemed invasive and/ or burdensome and Clinical investigations of medical devices which do not fall under Article 62 of Medical Devices Regulation (EU) 2017/745.

While additional NRECs may be established in a variety of health research areas over time, clinical trials or medicinal products for human use and clinical investigations of medical devices are the initial priorities[7].

2.3 Hospital RECs

Hospital RECs are responsible for the review of research studies that are hosted by the hospital.

Appendix 2 outlines the process that a researcher should follow to determine if the study requires NREC or HSE Reference REC/Hospital REC approval. If in doubt, researchers should seek advice from the regulatory affairs professional in their local Clinical Research Facility/ Centre if possible, or from the Health Products Regulatory Authority (HPRA) to seek their opinion.

> **Note:** Currently, studies involving multiple hospitals require multiple hospital REC approvals. The REC Reform Roadmap anticipates the establishment of bilateral agreements between hospital based RECs and the HSE Reference RECs to enable the appropriate operationalisation of single review for studies involving multiple sites.

6 Note: During the pandemic the COVID-19 NREC reviewed both the site specific assessment forms and data protection aspects of projects. However, future NRECs will focus exclusively on ethical aspects of projects, with the responsibility for governance remaining exclusively with the institution.

7 Studies involving ionising radiation represent a regulated remit for health research and as such, will be encompassed in the national system of research ethics review. The National Office is working with the Department of Health and local REC stakeholders to find an appropriate mechanism for review of studies involving ionising radiation, recognising the expertise required. It is expected that a national route for ethics review of studies involving ionising radiation for medical purposes will be developed by Q1 2022. In the meantime, such applications should continue to be directed to existing 'recognised RECs' under this remit.

2.4 Academic RECs

Academic RECs are part of the governance structures of third level institutions. Those academic studies that involve HSE patients or staff (or their data and/or samples), HSE premises or infrastructure require both academic and HSE/Hospital REC approval (as per November 2021).

Note: The REC Reform Roadmap anticipates the establishment of bilateral agreements between the HSE and the academic RECs to reduce the need for duplicate ethical review while maintaining appropriate level of research governance.

3. Integration of the HSE Reference REC review with other local and national governance and regulatory functions

3.1 Integration with HSE Research Governance Management and Support (RGMS) functions

The HSE Framework for the Governance, Management, and Support (RGMS) of Research introduces the concept of the RGMS function to provide organisational oversight to ensure that healthcare services manage the organisational risks, as appropriate, and comply with their regulatory, legal, and financial obligations. This function plays a complementary governance role to that of research committees, while also having a role in the management of research and the provision of support for the research community.

While the RGMS functions and the HSE Reference RECs are independent from each other, it is important that their work is coordinated to ensure effective process.

3.1.1 HSE Research Governance processes

Research governance encompasses a wide range of activities which include risk assessment from an institutional perspective (i.e. data protection, reputational risk), site approval, evaluation of insurance and indemnity requirements, legal, financial, regulatory, and contractual issues. The coordination of institutional governance with REC approval will be essential to enable an effective and efficient overall approval and authorisation system for research in healthcare settings. Such coordination will be facilitated by the implementation of a National Research Information Management System and the use of a national standard application form.

RGMS and ethical approval processes should occur in parallel. Final authorisation for the study will remain with the host site.

Until the introduction of a national electronic research management system (ERMS), to enable appropriate governance of projects approved by a REC outside of the host institution (i.e. a HSE Reference REC or the NREC):

- Researchers must log all proposal submissions to the NREC or HSE Reference REC, and decisions, with the relevant RGMS function for their institution. Until

such a time that Research Offices are developed as per the RGMS framework, this function may be represented by their local REC, research coordinator, head of service, etc.

- Appropriate information campaigns need to ensure Principal Investigators[8] are aware of their responsibilities in this regard.
- The research site should wait for NREC and RGMS approval before authorising the project.

3.1.2 Clarity of responsibilities with regards to Data Protection

- The right to personal data protection, and associated protection measures in research, provided for in the General Data Protection Regulation 2016/679 (GDPR) are given further effect under the Irish Data Protection Act 2018 and further and more specific implementation through the Health Research Regulations 2018-21 (HRR) (together referred to as Data Protection Law). It is important to underline the distinction between the role of a REC (which focuses on any aspects of data protection that might have ethical implications9) and a Data Protection Officer (DPO). The DPO advises and informs organisations and staff on data protection compliance, including data protection implications, identification and mitigation of risks associated with a study and risk assessment and monitoring requirements.
- DPOs have protection against personal liability for their activities and against criminal liability in extreme cases. These protections do not extend to RECs.
- The GDPR considers health data as personal sensitive data which belong to 'special categories' of personal data. Under Data Protection Law, one of the responsibilities of the data controller (i.e. the organisation) is to ensure that risks to data subjects (i.e. individuals whose data are processed) associated with the research project, and their mitigation, are identified, assessed, and recorded, and that participants in the research are appropriately informed and can exercise their rights.
- All researchers must complete the data controller's risk assessment to determine the level of risk associated with their research study.
- Where the risk assessment shows that there is a high risk to the rights and freedom of the data subjects and no exceptions apply, then the Controller needs to complete a 'Data Protection Impact Assessment' (DPIA).
- Specific GDPR and statutory (e.g. optional and mandatory Data Protection Commission lists, Public Body) requirements may apply and mandate that a DPIA is automatically required. It is advised that the researcher(s) contact their organisation's DPO for support and guidance.

8 The HSE National Framework for the Governance Management and Support of Health Research defines principal investigator responsibilities as: "The principal investigator (PI) is responsible for the day-to-day management of the research study at the research site. The PI retains ultimate responsibility for the management of the research study, even if tasks are delegated to other research staff… In the case of multisite studies, the lead researcher who takes overall responsibility for the research study is referred to as the Chief Investigator, and the lead researcher within each site is referred to as the PI. If there is more than one PI at one site, they are referred to as co-PIs. All co-PIs have the same PI responsibilities, as described above. Other investigators involved in the research study, but who do not share the PI responsibilities, may be referred to as collaborators"

9 https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-021-00616-4

- The risk assessment may involve the use of a structured matrix to assess the likelihood and severity of risk. Indicators could include the:
    - type of data e.g. personal, special category
    - data subjects and level of vulnerability
    - processing involved and the purpose i.e. complexity, multiplicity, scale
    - data flow required i.e. intra or inter organisation or sharing within and outside the EEA
    - associated safeguards and mitigating factors i.e. pseudonymisation, organisational mechanisms, data security.
- At minimum it shall be compliant with Article 29 Working Party Guidelines (WP29) on determining whether processing is "likely to result in a high risk" for the purposes of the GDPR[10].
- The Reference REC must be satisfied with the data protection assessment and consider the assessment in the context of any ethical implications for the research study. If the Reference REC has any concerns or queries concerning the data protection, they must liaise with the DPO before approving the study.
- Table 1, from the European Commission, outlines indicators of data processing that are likely to entail higher ethical risks. Please note that this is not an exhaustive list.

The Principal Investigator is responsible for communicating the outcome of applications to the Health Research Consent Declaration Committee (HRCDC) to the relevant REC, and the RGMS function (this will be enabled via the ERMS when in place). When in doubt, decisions as to whether a HRCDC Consent Declaration is needed will be taken by the HSE Reference REC.

For more information on 'Data Protection and Research', please see the National HSE R&D website[11].

10 https://ec.europa.eu/newsroom/article29/items/611236
11 https://hseresearch.ie/data-protection-and-research/

Table 1: Example indicators of data processing that may entail higher ethical risk

Types of Personal Data	• Racial or ethnic origin • Political opinions, religious or philosophical beliefs • Genetic, biometric or health data • Sex life or sexual orientation • Trade union membership
Data Subjects	• Children • Vulnerable people • People who have not given their explicit consent to participate in the project
Scale or complexity of data processing	• Large-scale processing of personal data • Systematic monitoring of a publicly accessible area on a large scale • Involvement of multiple datasets and/or service providers, or the combination and analysis of different datasets (i.e. big data)
Data-collection or processing techniques	• Privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals) • Using camera systems to monitor behaviour or record sensitive information • Data mining (including data collection from social media networks), 'web crawling' or social network analysis • Profiling individuals or groups (particularly behavioural or psychological profiling) • Using artificial intelligence to analyse personal data • Using automated decision-making that has a significant impact on the data subject(s)
Involvement of non-EEA countries	• Transfer of personal data outside the EEA • Collection of personal data outside the EEA

https://ec.europa.eu/newsroom/article29/items/611236

3.1.3 Integration of REC and governance processes via the Electronic Research Management System (ERMS)

The national roll out of an ERMS will be essential for the integration of research governance and ethical approval processes. The ERMS will facilitate the submission of a single research registration form, which will be reviewed by the Research Ethics Committee and the relevant RGMS function.

The system will facilitate the various approval and review workflows, linking the different stakeholders, including the DPO, that need to be involved in the review process in a risk proportionate manner, reducing timelines for study approval. It will facilitate the standardisation of approval processes at national level. The system will ensure that the decision of a HSE Reference REC or REC, with responsibility for

community and/or hospital based research for a multicentre study, is available to all HSE Reference RECs to enable a single review. The HSE National Office for Research and Development are coordinating the procurement of the ERMS system, which will be introduced in a phased manner appropriate to the level of readiness of the sites RGMS functions and of the HSE Reference RECs.

The system will enable investigators to log approvals from NREC, HRCDC and HPRA for their projects, hence facilitating communication between the different entities involved in the research governance life cycle.

The system will use a national standard application form, that will include the content for evaluation by both the RGMS function and the REC. The ERMS forms will be based on the HSE Reference REC Standard Application Form.

3.2 Health Research Consent Declaration Committee

The HRCDC was established as part of the Health Research Regulations made under the Data Protection Act, 2018. The Regulations make explicit consent the default position for processing personal data for health research. However, it is recognised that sometimes, in specific situations, obtaining consent is not possible but the public interest of doing the research significantly outweighs the need for explicit consent. In these cases HRCDC has a decision making role. The Health Research Regulations 2018 enable a data controller, undertaking health research using personal data, to apply for a consent declaration. This means that the consent of the individual is not required for the obtaining and use of their personal information for the health research concerned. In order that such applications are carefully considered from a range of perspectives, the Health Research Regulations 2018 provides for an independent committee, the HRCDC, to make decisions on those applications.

3.3 Health Products Regulatory Authority (HPRA)

The HPRA is the state agency responsible for regulating medicines, medical devices, and other health products in order to protect public and animal health. They also have a role in monitoring the safety of cosmetics. Medical devices must be classified by the HPRA before they are placed on the market. General medical devices have four risk categories:

Class I (lowest risk)

- Class IIa
- Class IIb
- Class III (highest risk)

Multiple factors determine the classification of a device, such as the part of the body affected, the level of invasiveness of the product, the duration of use and whether or not the device is active. The rules governing device classification are listed in Annex IX

of Directive 93/42/EEC and Schedule 9 of the related Irish regulation and are elaborated on in the MEDDEV guidance 'MEDDEV 2.4/1 Guidelines for the Classification of Medical Devices'.

The HPRA should be contacted if there is a lack of clarity about the category of medical device, so that the correct REC (NREC or Reference REC) can be identified. Clarification on a classification may be submitted using the HPRA documents listed below, available from the HPRA website www.hpra.ie:

- ADV-F0006 'Request for Classification of a Medical Device'.
- FIN-G0002 'Guide to Fees'.
- FIN-F0018 'Fee Application Form'.

SECTION B. Governance and Management of HSE Reference RECs

4. Governance and Management

4.1 Relevant Policy / Legislation for HSE Reference RECs

The following legislation and HSE policies apply to the HSE Reference RECs:

- HSE National Framework for the Governance, Management and Support of Research[1].
- HSE Consent for Research Policy 2021.[12]
- 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 repealed Directive 95/46/EC (General Data Protection Regulation).
- Data Protection Act 2018 which gives further effect to the General Data Protection Regulation 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 the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 S.I. No. S.I. No. 314 of 2018 and subsequent amendments.

A range of national and international guidelines on the conduct of ethical research also underpin the ethical review carried out by the HSE Reference RECs. These include The Nuremberg Code,[13] The Declaration of Helsinki,[14] The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research[15] and ICH-Good Clinical Practice Guideline E6 (R2)[16]. Using international guidelines, Emanuel et al (2000)[17], proposed an ethical framework of seven principles, which provide 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 REC.

12 HSE National Policy for Consent in Research, In preparation – expected publication date Q1 2022.
13 The Nuremberg Code (1947). In: Mitscherlich A, Mielke F. Doctors of Infamy: The Story of the Nazi Medical Crimes. New York: Schuman; 1949: xxiii–xxv
14 World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects [Internet]. 2018 [cited Day Month Year]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
15 The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979. Available from: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
16 Guideline for Good Clinical Practice E6 (R2) 2017: www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf
17 https://jamanetwork.com/journals/jama/fullarticle/vol/283/pg/2701

4.2 Structures for the HSE Reference REC system

The HSE Reference REC system will introduce the following structures to provide appropriate governance, leadership, support, and guidance to the HSE Reference RECs. These include:

- HSE Reference REC appointing authority (HSE National Committee for the Governance, Management and Support of Research)
- HSE Reference REC Support and Coordination Office (HSE REC SCO)
- HSE Reference REC Chairs and Managers Group

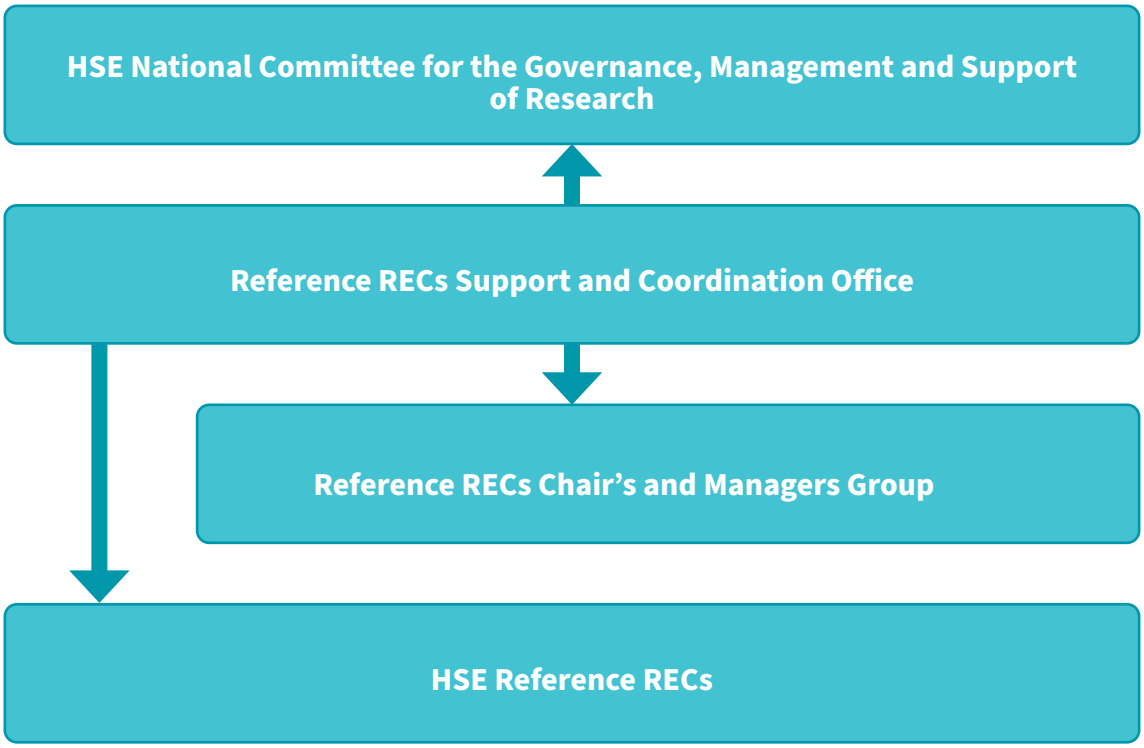

Figure 1. Structure Relationships – lines indicate the support offered by the HSE REC SCO in its relationship with the other structures

4.3 HSE Reference RECs Appointing Authority

The HSE National Committee for the Governance, Management, and Support of Research will appoint, and oversee each of the HSE Reference RECs. Overall, the Committee will have responsibility for overseeing research governance, management, and support at national level (Appendix 3).

The HSE National Committee for the Governance, Management, and Support of Research in its role as appointing authority should:

- Have no role in the deliberation and provision of ethical opinion
- Be independent of local health delivery structures where research is performed

- Be of senior stature with decision-making power.

The HSE National Committee for the Governance, Management, and Support of Research will be responsible for:

- Granting the nomination of HSE Reference RECs to existing or newly created RECs.
- Considering the nomination, by the HSE's REC SCO, of the Chair for each HSE Reference REC
- Providing strategic advice to HSE Reference RECs on potential remedial actions should problems arise.
- Reviewing the HSE Reference RECs annual reports.
- Advocating for a sustainable operational model, that is resilient to organisational change.
- Providing advice on the best approach to interact with the National REC, S38 and S39 organisations and other RECs.
- Ensuring transparency about REC activity with the public e.g. through the publication of annual reports.
- Evaluation of compliance with the HSE Code of Governance and Management Required for HSE Reference Research Ethics Committees as indicated by the quality assurance programme coordinated by the HSE Reference REC Support and Coordination Office. This could include auditing activities if deemed necessary.
- Suspending the operations of a HSE Reference REC for major infringements of the HSE Code of Management and Governance.
- Determining the need for additional HSE Reference RECs if necessary.

4.4 HSE Reference REC Support and Coordination Office

This is a national office, set up as an integral part of HSE Research & Development, and will have a Grade VII Manager. The Manager for the HSE REC SCO will report to the Senior Research and Development Manager (Community Services) or other nominated manager within the National Office for Research & Development.

The HSE REC SCO will have a number of functions:

a) Provide the administrative link between the HSE Reference RECs and the HSE National Committee for the Governance, Management, and Support of Research and implement all relevant operational protocols to enable appropriate oversight, including:
   - Submitting information regarding the composition and local arrangements for each HSE Reference REC prior to the formal establishment of the committee for approval.

- Communicating to the committee any changes of HSE Reference REC Chair.
- Developing a quality assurance programme to encourage a consistently high level of service to applicants, based on regular monitoring and audit of their operation and performance, and an appraisal scheme to support committee officers in performing their duties.
- Managing the request and submission of annual reports.
- Implementation of transparency measures and public communication.

b) Provide support to the HSE Reference RECs by:

- Providing support in the recruitment of their members, officers, and administrative staff.
- Advocating for recurring funding for HSE Reference RECs in order to facilitate the performance of their function in a sustainable manner.
- Linking with HSE Reference RECs to ensure that a rotation system (e.g. staggered tenure) is in place for REC members to achieve business continuity, and the development and maintenance of expertise within each HSE Reference REC.
- Working with the National Office for Research Ethics Committees to support the development of a national training programme for REC members and administrative staff.
- Assisting with operational advice to the HSE Reference RECs.

c) Provide secretarial support to the HSE Reference RECs Chairs and Managers Group through:

- Meeting management and administration.
- Working with the Chair to develop an annual programme of work.
- Liaising with the National Office for Research Ethics Committees on behalf of the group.

4.5 HSE Reference RECs Chairs and Managers Group

This group will be composed of one Chair or Deputy Chair per committee and managers of all the HSE Reference RECs. The group will have a rotating chair for a maximum period of one year.

The functions of this group are to:

- Establish agreed standards for Ethical Review and to provide a consensus view to support the work of individual HSE Reference RECs, in line with ethical standards and legislative requirements.
- Advise the HSE REC SCO on training needs and other requirements.
- Propose amendments to the HSE Code of Management and Governance, to the

HSE Reference RECs appointing authority, to ensure alignment with international codes of best practice and respond to future developments.

- Strengthen communication and collaboration between the HSE Reference RECs, the S38 RECs, and the National Office for Research Ethics Committees and contribute to developing an integrated REC system for Health Research. This may include expanding the membership of this group to encompass representatives from Hospital RECs when appropriate.

4.6 Reporting and Accountability of the HSE Reference RECs

The HSE Reference RECs will be required to report annually to the HSE National Committee for the Governance, Management, and Support of Research (via the National HSE Reference REC SCO). The ERMS will facilitate the reporting requirements. This annual report may contain information relevant to its procedure including, but not limited to:

- Membership and changes in membership
- Number and dates of meetings held
- Attendance of members; confirmation of participation by expert and lay members
- Substantive changes to the standard operating procedures
- List of training undertaken by members
- Number of submissions considered, and the decision reached
- The types and number of submissions listed according to the UK Health Research Classification System[18]
- Time taken from acceptance of application to final decision for each submission
- List of projects completed or terminated during the year.

The HSE Reference RECs will be accountable to the HSE National Committee for the Governance, Management, and Support of Research via the HSE REC SCO.

The purpose of the HSE Reference RECs is to ensure that appropriate steps are taken to protect the rights and welfare of humans participating in a research study. To mitigate against any potential conflict of interest, it is crucial the HSE Reference RECs remain independent of the researchers, the organisations funding the research, and the organisations where the research will take place. Overall, HSE Reference RECs ethical decisions must be free from the pressure of:

- Political influence
- Institutional affiliation
- Trades union or profession-related interests
- Direct or indirect financial inducement or any impression thereof

18 The Health Research Classification System (HRCS) is a bespoke system for classifying the full spectrum of biomedical and health research, from basic to applied, across all areas of health and disease. Please see https://hrcsonline.net/ for more information

- Coercion
- Strategic concerns
- Market forces
- Agency, discipline, or topic-related bias.

HSE Reference RECs will also be accountable for operational performance, to the HSE National Committee for the Governance, Management, and Support of Research and, if required, to the governing authority of the legal entity hosting the committee (i.e. when the HSE Reference REC is part of a university or a S38 hospital structure)

A reporting mechanism (regular reports) will be put in place to ensure sufficient oversight of the HSE Reference REC system. The HSE Reference RECs should provide sufficient information, through the HSE REC SCO, to the HSE National Committee for the Governance, Management, and Support of Research.

4.7 HSE Reference RECs Management Team

The management team for the HSE Reference REC will include the:

- HSE Reference REC Chair,
- HSE Reference REC Deputy Chair,
- HSE Reference REC Manager.

The person responsible for the operational management of the HSE Reference REC is the REC Manager. They will be supported by an administrative support officer if required. A suitably qualified REC manager may be involved in the ethics review of research proposals.

4.7.1 Role of the Reference REC Chair and Deputy Chair

The main purpose of the role of Chair is to lead the Reference REC to ensure that all study applications seen by the committee receive ethical review within relevant guidelines, legislation, and Standard Operating Procedures (SOPs).

The Chair, as leader of the committee, is responsible for the committee function, ensuring that all ethical issues are explored, and clear decisions made and recorded.

Responsibilities include:

- Chairing the regular HSE Reference REC meetings and sub-committee meetings ensuring that ethical issues are explored, debated, and recorded.
- Ensuring that all study applications seen by the committee receive ethical review within relevant guidelines, legislation, and SOPs, and within the Terms of Reference of the REC.

- Being available to the Reference REC Manager on a planned or ad hoc/daily basis as necessary (i.e. to check and approve the minutes, to ensure decision letters are sent within timelines etc).
- Offering support and mentorship as required to the Deputy Chair and committee members.
- In collaboration with the Reference REC Manager, ensuring the membership of the committee meets the defined criteria.
- Assisting with recruitment and selection of new members.
- In collaboration with the Reference REC Manager, ensuring that their own, and members training is up to date.
- Reviewing the REC Annual Report.
- Feeding back to the HSE REC SCO on any administrative issues or concerns that affect the efficient running of the REC.
- Responsibility for implementing any recommendations of the HSE National Committee for the Governance, Management and Support of Research.

The Reference REC Deputy Chair is responsible for:

- Deputising for the chair where necessary. This includes, but is not limited to, undertaking some or all of the responsibilities of the Chair as listed above.
- Supporting the chair in providing proportionate review of low risk studies.

4.7.2 Role of the Reference REC Manager

The REC Manager role may be carried out on a part time basis but the contribution to the role must be recognised by the employing service, with protected time, and the duties included as part of their overall role.

The Reference REC Manager is responsible for:

- Reviewing applications as they are received to ensure they are complete, presented clearly, and ready for REC review, in order to improve the efficiency of the committee.
- Management of the HSE Reference REC office and line management of the REC administrative support officer.
- Ensuring compliance of operations with the HSE Reference REC Code of Management and Governance.
- Ensuring effective recruitment strategies are put in place to maintain appropriate HSE Reference REC membership as per agreed guidelines.
- Supporting the Chair and Deputy Chair as appropriate.
- Ensuring appropriate communication with relevant parties (i.e. local Research Office, HSE REC SCO).

- Providing secretarial support to the HSE Reference REC and the work of any sub-committees.
- Ensuring appropriate protocols are followed for identifying and selecting officer roles such as the Chair and the Deputy Chair or Chairs of the subcommittees, etc.
- Co-ordinating training for the HSE Reference REC members and liaison with the HSE REC SCO.
- Ensuring appropriate reports are submitted to the HSE REC SCO for the HSE National Committee for the Governance, Management and Support of Research

The Reference REC Manager will report to their line manager for HR matters, leave etc. and to the HSE Reference RECs HSE National Committee for the Governance, Management and Support of Research via the HSE REC SCO.

4.7.3 Role of the Reference REC Administrative Support Officer

The Administrative Support Officer supports the work of the REC Manager. The requirement for this post will depend on volume of work and work practices. Workload will be reduced by the introduction of the ERMS.

The REC Administrative Support Officer is responsible for:

- Providing administrative support to the Chair and Deputy Chair, and managing the administrative tasks associated with the REC office.
- Providing administrative support to the REC office.
- Providing support to HSE Reference REC members and Principal Investigators in using the REC information systems.
- Providing administrative support for the compilation of the annual report, recruitment processes, appeals, etc.
- The administrative support officer could be a member of the research office and, if workload allowed, have shared administrative support responsibilities (Research Office and REC).
- Managing the electronic research information management system and providing support to system users.

4.7.4 Eligibility and length of service of HSE Reference REC Officers

The eligibility criteria for the REC officers are as follows:

The HSE Reference REC Chair:

- Ideally, the Chair will have either at least two years' experience as a REC member or have relevant experience in research and/or ethics before they can be elected. If the Chair does not have previous experience as a REC member or Chair of a REC, they should be mentored for six months by an experienced REC Chair appointed by the HSE REC SCO.

- Should serve at least one term (three years), which can be renewed either to remain in the role of Chair or become a Deputy Chair, if a vacancy is present, or committee member. Shorter terms can be acceptable provided that a succession plan is in place.
- While the Chair for the HSE Reference RECs, usually a clinician, may be selected locally, such an appointment must be approved by the HSE Reference REC appointing authority.
- It is not necessary for the Chair to be a medical doctor; however, it can be beneficial if the chair is medically qualified.

The HSE Reference REC Deputy Chair:

- Will have either at least two years' experience as a REC member or have relevant experience in research and/or ethics before they can be elected. If the Deputy Chair does not have previous experience as a REC member or Deputy Chair of a REC, they will be mentored for six months by the Chair.
- Should serve at least one term (three years), which can be renewed either to remain in the role of Deputy Chair or become Chair, if a vacancy is present, or committee member.
- Will be selected locally.

There may be more than one Deputy Chair. It is not necessary for the Deputy Chair to be medically qualified, however, if the Chair is not medically qualified, it would be beneficial for the Deputy Chair to be so.

The HSE Reference REC Manager:

- Must have appropriate administrative and management experience and be a member of HSE staff and employed by the HSE.
- May have a relevant qualification or training in research methodology and/or ethics in order to screen applications. If the HSE Reference REC Manager does not have a relevant qualification or training in research methodology and/or ethics, it will be provided by HSE REC SCO.

The time spent in the role of HSE Reference REC manager must be part of the total allocation of work rather than additional to a full-time workload.

5 Membership and Recruitment of Members for HSE Reference RECs

5.1 HSE Reference REC Membership

A HSE Reference REC should ensure competent, independent, and just ethical review of research proposals that are submitted to the committee. The committee's composition will include both officers and committee members.

The guiding principle for appointing members to a HSE Reference REC is to ensure that the committee has the appropriate expertise, skills, knowledge, and perspectives to ensure thorough ethics review:

- HSE Reference RECs should be multidisciplinary and multi-sectoral in composition.
- Two thirds of the total membership should be "expert members", meaning any of the following:
  - A practising or retired health practitioner.
  - Have qualifications or experience relating to the conduct of health research (outside being a member of a Research Ethics Committee).
  - Have qualifications or experience in the area of ethics.
  - Have qualifications or experience in research methodology/ epidemiology/ statistics.
- Membership needs to include Patient Representatives and/or lay members and the committee should strive to have at least one present in every meeting. Overall membership should include a minimum of two Patient Representatives or lay members and a maximum of four. The Patient Representative or lay member should be consulted as part of the review process (this consultation can take place remotely before the meeting), and, while it is preferable that they are present at every meeting, their attendance is not necessary to achieve a quorum. If they are present however, they can contribute to the quorum. It is important to note that Patient Representatives or lay members are not required to meet the same criteria as expert members. Patient Representatives and lay members bring their personal lived experience as patients or members of the public, which is important in the context of research that better meets the needs of patients.
- The committee must have a Chair and a Deputy Chair.

It is advisable for a committee's expert members to include:

- A member with knowledge of and current experience in the areas of research that are regularly considered by the HSE Reference REC (i.e. relevant scientific expertise).
- A member with knowledge of, and current experience in, the professional care, counselling, or treatment of people (e.g., nurse, medical practitioner, clinical psychologist).
- Member(s) with training in ethics (e.g., ethicist, philosopher, theologian)
- A member with a qualification in law and/ or expertise in data protection matters. Note: this person is not required to provide legal advice or represent the committee, but to give their opinion as part of the committee consensus.
- A member with training in statistics.
- A member with knowledge in research methodology

A high-level international scoping exercise on the membership, constitution, and recruitment of REC members was conducted. Based on this review, recommendations are as follows:

- HSE Reference RECs should typically consist of 15 members (can be between10-21). HSE Reference RECs can have more than 21 members, if they have a high throughput, to facilitate timely reviews.
- Each HSE Reference REC member is asked to attend a minimum of six meetings (out of 10 to 12) annually.
- The HSE Reference REC Chair must attend all meetings. If the Chair is unavailable to attend (e.g. will be on annual leave) then the Chair must ensure that a Deputy Chair is available to fulfil the role of Chair for the meetings that they cannot attend.
- Each HSE Reference REC should be formed 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 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 the meeting if they are unable to attend.
- HSE Reference RECs may seek advice from specialist referees on any aspects of a research proposal that fall beyond the members' expertise. The terms of reference for such referees should be established.
- A HSE Reference REC may appoint a sub-committee comprised of committee members to review amended applications, without the need for the application

to be reviewed by the full committee. This is dependent on the availability of members of the HSE Reference REC to form a sub-committee.

5.2 Recruitment of HSE Reference REC members

Recruitment of members can be supported by the HSE REC SCO in liaison with local management structures. Organisations availing of the service provided by a REC must support the recruitment of members for the committee.

A wide range of recruitment strategies to attract suitable HSE Reference REC members should be used, including seeking candidates through hospitals, health and social care community services, GP surgeries, voluntary and advocacy agencies and charities, newsletters, workplaces, universities, trade union offices, healthcare and statistical journals and conferences.

The recruitment process will involve all applicants completing an Expression of Interest Form (Appendix 4), including basic information about themselves as well as their reasons for wanting to become a member of the Committee. They will also be asked to submit a short curriculum vitae (CV) with their application. It should be noted that references requested as part of the form do not necessarily need to be employment related and can be from a person (although not a relative) who can attest to the character of the applicant. Recruitment must follow other HSE policies, e.g., Equal Opportunities, Diversity etc.

The following recruitment procedures should be standard for all HSE Reference RECs:

a) Procedures for selecting candidates

- The selection process can be coordinated and supported by the National HSE REC SCO or can be done directly by the HSE Reference REC management team as appropriate.
- The evaluation of expression of Interests should be carried out by the HSE Reference REC management team and relevant Directors of Research or Chief Academic Officers and can be supported by the HSE REC SCO.
- Expressions of Interest will be evaluated for demonstration of the skills and attributes necessary for effective HSE Reference REC participation. This will include an ability to work as part of a team, to understand complex issues to the extent required to form and voice an opinion, and to be objective in considering issues and weighing-up conflicting opinions. Additionally, applicants interested in the roles of Chair or Deputy Chair should evidence relevant experience, at an appropriately senior level, and knowledge of the Irish health research environment as it relates to the remit of the HSE Reference RECs (see section 4.7.4 Eligibility and length of service of HSE Reference REC Officers).
- Member selection will be proposed based on the diversity of skills, qualifications, interests, and backgrounds required to make decisions on REC applications received by the HSE Reference RECs.

b) Procedures for appointing members

Once appointed, candidates will receive a written letter of offer, indicating the terms and conditions of the appointment, and duties and responsibilities. This may include:

- Duration of appointment
- Renewal policy
- Disqualification procedures
- Resignation procedures
- Policy concerning declaration of conflict of interests
- Details of allowable expenses
- Expected commitments:
  - To protect and safeguard the rights and interests of human participants taking part in research, while promoting and facilitating research excellence.
  - Preparedness to have their name, profession and affiliation published.
  - Treating as confidential all applications, meeting deliberations, information on research participants/volunteers and related matters.
  - Attendance at a minimum of six HSE Reference REC meetings a year. Should a member fail to do so, the Chair should address this with the member concerned.
  - Taking part in education and on-going training appropriate to their role as a HSE Reference REC member.

The offer letter should be signed by the relevant HSE Reference REC Chair of relevant HSE Reference REC or HSE REC SCO.

Proforma letters of appointment can be obtained from the HSE REC SCO.

c) Duration of an appointment

Members are appointed for a term of three years. Appointments can be renewed. If a committee member has completed their term of three years and does not wish to serve another term the HSE Reference REC the Manager should write a letter to thank the person for their service, detailing their role and dates of service. (See Section 4.7.4 Eligibility and length of service of HSE Reference REC Officers).

d) Renewal of an appointment

The HSE Reference REC Manager will write to a member of the committee six months prior to the end of their three-year term and notify them of the date their term ends. The REC Manager will request that the committee members notify them within a month of receiving the correspondence, their intention to either stay for an additional term (and, if applicable, they would want to be considered for the role of Chair of Deputy Chair) or if they will not be seeking to renew their membership.

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

Should the committee have any concerns about offering a second term to an existing Chair, such concerns should be brought to the attention of the HSE REC SCO. The HSE REC SCO will evaluate the matter and bring it to the attention of the REC appointing authority if necessary.

e) Procedure for replacing members or seeking new members

Advertisement campaigns can be run by the individual HSE Reference REC or managed by the National HSE REC SCO. Such recruitment campaigns should be supported by the management of relevant hospital and community services. Staff who volunteer to become members of these RECs should be able to do so within their allocated working hours and be remunerated for relevant expenses.

f). Procedure for resignation of a member

It is hoped that all members will complete their term of three years. However, should a member wish to leave the HSE Reference REC prior to the end of their term, they are requested to inform the REC Manager with at least one month's written notice and, if possible, the reasons why they are resigning.

Should the Chair or Deputy Chair wish to leave their role, but not the HSE Reference REC, prior to the end of their term (three years) they are requested to inform the REC Manager. They should give at least one month's written notice and the reasons why they are resigning from their Chair role.

In all cases, the REC Manager must acknowledge, in writing, the resignation and inform both Chair (or when relevant, the Deputy Chair) and the HSE National Committee for the Governance, Management, and Support of Research via the HSE REC SCO.

The HSE Reference REC Manager should write a letter thanking the person for their service, detailing their role and dates of service.

g) Procedure for the disqualification of a member

Should a REC member not adhere to the Standard Code of Governance and Management, or local policies that impact on the appropriate operations of the HSE Reference REC, then the HSE Reference REC Manager should alert the Chair or Deputy Chair (when the Chair is not available, or the member concerned is the Chair). The HSE Reference REC Manager, Chair or Deputy will discuss the matter with the person and agree a resolution. The resolution may involve additional training or further supports for the member. The REC Manager will need to inform the Chair, or where relevant the Deputy Chair, of the outcome of the meeting.

If no resolution is reached or the behaviour continues, the HSE Reference REC manager, with the Chair and Deputy Chair, will be entitled to disqualify the member from attending any future committee meetings. This process must be appropriately documented. Should the REC member wish to appeal the disqualification, they may do so by contacting the HSE Reference REC Appointing Authority via the HSE REC SCO.

When the Chair is the person who may be subject to disqualification, it falls to the Deputy Chair to find a suitable resolution and put the support in place as appropriate. The Deputy Chair needs to notify the HSE REC SCO so that support and guidance can be provided throughout. If a solution cannot be found, or the problem persists, a report will be filed by the HSE REC SCO for escalation to the HSE Reference REC Appointing Authority.

Valid reasons for disqualification include:

- Lack of attendance at the minimum number of meetings required per year,
- Information supplied in the Expression of Interest (EoI) form is incorrect,
- Not declaring a conflict of interest

h) Training of members

(See Section 8.13Training for HSE Reference REC members)

6 Financial considerations for HSE Reference RECs

6.1 Remuneration of HSE Reference REC members

This section is in the process of being developed.

6.2 HSE Reference REC operations budget

It is intended that a working budget will be made available to the HSE Reference RECs to cover running costs.

6.3 HSE Reference REC charges

It is intended that the following charges will apply for studies submitted to HSE Reference RECs:

- Review of unfunded studies will be provided free of charge
- Review of studies funded by national or international funding agencies (i.e. HRB, SFI, EU) will incur a fee of €200 per new application; €100 for Substantial amendments and free service for non-substantial amendments.
- Review for commercially funded studies will incur a fee of €400 per new application; €200 for substantial amendments and free service for non-substantial amendments

- Administration of Payments will be processed via the National REC SCO and facilitated by the national electronic research management system.
- The roll-out of the payment system will start one year after the establishment of the last HSE Reference RECs in order to provide applicants with the opportunity to include REC charges as part of their grant applications.

This charging system will become effective once Stage 1 of the HSE REC reform roadmap is completed.

7 What requires REC review

For the purpose of this code and in alignment with the HSE RGMS Framework, research is defined in line with the Health Research Regulations 2018. Determining whether a project needs ethical approval is often dependent on whether it is a form or research, clinical audit, or service evaluation.

It is important to distinguish between the different activities as research is bound by specific governance requirements.

The HSE National Review of Clinical Audit (November 2019)[19] distinguishes between clinical audit, service evaluation and research and indicates when REC review is required (Table 2).

Table 2 - Differentiating research from other processes (as per the National Review of Clinical Audit (2019)

	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.

19 https://www.hse.ie/eng/services/publications/national-review-of-clinical-audit-report-2019.pdf

	Research	Clinical Audit	Registry	Service Evaluation
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

In addition, other activities that generally do not require ethical approval are included in Table 3.

Table 3 - Other activities that may not require REC review

Activity	Explanation
Research utilising existing anonymised publicly available data* **(*when the publicly 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."[20]

20 https://www.dataprotection.ie/en/dpc-guidance/anonymisation-pseudonymisation

Activity	Explanation
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 an 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 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[21] 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 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).

21 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4025700/

Activity	Explanation
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) 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".[22] 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.

When in doubt, individuals may contact the Audit Office, the Research Office, or the REC Manager for advice. For further information please see HSE's Research & Development page "What is Research" at https://hseresearch.ie/.

Any project involving research activity may require the approval of a REC before the activity commences, as **retrospective REC approval is not permitted**.

On occasions, and for a variety of reasons (e.g. publisher requirements in advance of publication), staff undertaking projects that are not research (i.e. clinical audit) may require a letter stating that their activity does not require research ethical approval. The automatic generation of a generic letter to this effect will be facilitated through the ERMS, but it will require staff to log the project details within the system, which will be designed to facilitate this.

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

SECTION C. Standard Operating Procedures

8 Standard Operating Procedure (SOP) for HSE Reference REC

The operations of the HSE Reference RECs should be guided by the Standard Operating Procedures (SOPs) below. The Reference RECs are ultimately accountable to the HSE National Committee for the Governance, Management, and Support of Research.

The SOP should be reviewed every three years unless an earlier review is indicated. The HSE REC SCO will co-ordinate the review.

The SOP is relevant to the following people:

- All members of the HSE Reference RECs.
- All HSE staff, who wish to carry out research using facilities, staff, patients, or information pertaining to staff or patients of the HSE.
- All students, employed by the HSE or external to the HSE who wish to carry out research using facilities, staff, patients, or information pertaining to staff or patients of the HSE.
- All investigators, external to the HSE who wish to have access to staff, patients, facilities, or information pertaining to patients or staff of the HSE, for the purposes of research.

The SOP applies to HSE Reference RECs, but the adoption by S38 and 39 Hospital RECs will facilitate the intended REC reform and integration. Please see the HSE's "Roadmap for the Reform of Health and Social Care Research Ethics Committees" for further information.

8.1 Application processes and documentation

- The REC application process will be online via the ERMS. Prior to the implementation of the electronic system, completed applications will be submitted via email to the REC manager using the REC Standard Application Form (SAF).

- With the completed REC SAF, applicants will be required to submit additional documents. It is important to note that the list provided is a guide – documentation required will depend on the study, whether it is a first submission or an amendment.
  - Completed Data Protection Risk assessment and decision/opinion of the DPO.
  - Proof of Insurance
  - Application Form
  - HSE Reference REC Checklist for Researchers
  - Evidence of Fee Payment (if applicable)
  - Study Protocol
  - Summary CV for Principal Investigator (two pages only)
  - Research Participant Information Leaflet
  - Research Participant Consent Form
  - Research Participant Assent Form
  - Letter of Invitation for participant
  - Cover letter on headed paper
  - Case Report Form
  - Validated Questionnaire
  - Non-validated Questionnaire
  - Interview schedule
  - Any other written materials provided to the participant e.g. participant diary
  - Copies of recruitment material for research participants, e.g. posters, newspaper adverts, website where appropriate, a printed script for video or audio recordings.
- If the HSE Reference REC approves the research study, the approval letter will inform the Principal Investigator, or the person they have nominated, that they will be required to report serious adverse reactions related to study drug/ intervention/ procedures to the HSE Reference REC. The approval letter will also state that the Principal Investigator, or the person they have nominated, will need to submit an annual update and a final report to the HSE Reference REC.

8.2 HSE Reference REC: meetings, submission, and review timelines

- The time requirement is estimated at approximately two-three hours for meetings and time for the preparation process to be conducted in such a way as to ensure an effective and efficient consideration of the application. If necessary, additional meetings can be arranged.
- 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

the HSE Reference REC does not have the relevant expertise, or there is a conflict of interest, then the HSE Reference REC will need to request external advice.

- All HSE Reference RECs should have a standard turn-around time for a submission that is deemed to be complete.
- The meeting dates for the following year should be agreed by the committee before the final Reference REC meeting within a calendar year.
- The meeting dates should be available on the local Reference REC webpage and should also be forwarded to the HSE Reference REC SCO for inclusion on their website.
- Meeting frequency would normally be 10-12 per year. The frequency of the meetings should be based on the demand for the service. The demand for the service should be monitored by the Reference REC manager and the number of meetings may be increased if required.
- The deadline for the receipt of applications should be approximately 20 working days before the HSE Reference REC meeting. Researcher submission deadlines and Reference REC meeting dates should allow sufficient time for applications to be screened by the REC Manager and/or Chair and provided to Reference REC members in advance of the meetings.
- Once received, applications will be screened by the REC manager to ensure the documentation is complete and clear, and to contact the applicant if any documents are missing and to seek any clarifications. Such clarifications will be recorded in writing, (via the ERMS or by email) and provided for review to the REC members together with the application.
- Once screened by the HSE Reference REC manager and Chair, applications should be provided to Reference REC members for review 10 working days before the Reference REC meeting.
- Applicants cannot submit additional documentation after their study has been sent to the HSE Reference REC members for the Reference REC meeting.
- The number of applications reviewed per HSE Reference REC meeting will depend on the number received for that period and on the complexity of the proposals. Sufficient time should be allowed to review all applications on the agenda. A limit on applications per meeting may be applied to enable this. If necessary, more meetings may be added to the calendar year.
- The HSE Reference REC 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, as Reference REC members from more distant locations can be also recruited. A combination of “in person” and a virtual approach may be preferable.
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- Sharing of documents should be done via the ERMS. While ERMS is rolled out, documents should be shared with members via Sharefile or another secure HSE approved system. This is a highly secure file sharing platform where files are encrypted both during transfers and storage in the servers. This tool is advisable when sharing files with REC members outside of the HSE.

8.3 Remote conduct of meetings

The HSE Reference REC manager should assess the preferences of the HSE Reference REC members and make a meeting room available for those who wish to attend in person.

The following platforms are currently recommended for the hosting of HSE Reference REC remote/virtual meetings:

- Cisco WebEx meetings
- Microsoft Teams

Both offer end-to-end encryption and allow screen sharing.

The use of Zoom for the conduct of the HSE Reference REC meetings is not supported by the HSE.

8.4 HSE Reference REC Pre–Meeting Procedures

Prior to the REC meeting, the HSE Reference REC manager will:

- Communicate with applicants, respond to all enquiries regarding submission procedures and committee meeting dates, and forward documentation to applicants if required.
- Screen all applications to ensure all fields are completed sufficiently and all of the necessary information is provided.
- Assign a reference ID number to each application[23]
- Share the agenda, minutes from the previous meeting, and all applications forms and associated documents to committee members via Sharefile.
- Include on the agenda any amendments, proportionate review opinions, adverse events or other notifications from previous research applications reviewed.
- Set up the meeting (virtual meeting link and room booking with videoconference equipment).
- Ensure that the REC members invited to the meeting have the required balance of skill sets.
- Monitor planned attendance to ensure a quorum.

23 This will become an automated process when the ERMS is introduced.

- Maintain copies of all correspondence with applicants.
- Create an application log in such a way that a list of Chair's Actions can be readily obtained.
- Allocate proposals for review to HSE Reference REC members. While HSE Reference REC members in attendance at a meeting are invited to review all of the applications, and associated documents, in advance of meetings there should be one primary/lead reviewer and one secondary reviewer assigned to each study.
- The ERMS will be able to automate some of these processes (e.g. acknowledge receipt of applications).

Attendance of applicants at REC meetings to discuss their applications is not required. However, it is at the discretion of the HSE Reference REC if they wish to invite an applicant to attend the REC meeting to answer any questions the committee may have if the complexity of the study requires it. If this is the preferred approach, it is important that 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 Reference REC to discuss their application.

Proportionate REC Review: In accordance with the Health Research Regulations 2018, research ethics committees can no longer conduct Expedited Reviews of health research by Chair approval. However, it is recommended that HSE Reference RECs conduct reviews in a manner that is proportionate to the level of risk the study presents. In order to assess the level of ethical risk, HSE Reference RECs can use the "Screening Questions for Proportionate REC Review", (see Appendix 5).

Using this tool, the risk assessment can be done by the REC Manager, the Chair, or the Deputy Chair. Applications deemed of low risk can then be pre-assessed by the Chair, Deputy Chair, or a sub-committee set up for that purpose. Those individuals responsible for reviewing the low risk applications will present them in an expedited manner at the REC meeting for approval by the full committee and committee members will have the opportunity to comment. Alternatively, if the volume of low risk applications is very large, a subcommittee meeting chaired by the Chair, or the Deputy Chair, can be set up in advance of the main meeting to pre-review and make decisions about the applications.

8.5 HSE Reference RECs Meeting Procedures

Please see Section 5.1 HSE Reference REC Membership for information on attendance at HSE Reference RECs.

- HSE Reference RECS should have 8 to 10 members per meeting, out of a panel of 15 to 20, who are expected to attend a minimum of two thirds of the meetings per

annum. It may be necessary for HSE Reference RECs with a higher throughput of applications to have more members to facilitate timely reviews.

- At the meeting, and under the direction of the Chair, the minutes of the previous meeting and any matters arising are discussed.
- Reference REC members are asked to declare any conflict of interest with regard to the specific applications tabled. If a Reference REC member declares a conflict of interest, they will leave the meeting while the other REC members discuss the application. This must be documented in the minutes of the meeting.
- If applicants are provided with a time to address the HSE Reference REC on their application, they can only be in the meeting during their assigned period and cannot remain in the room while the HSE Reference REC discuss their application or when another applicant is presenting their application.
- Sufficient time should be allowed to review all applications on the agenda.
- Decisions taken are recorded by the HSE Reference REC manager and circulated to all members of the committee.
- Minutes of the meetings are recorded by the HSE Reference REC administration support officer and circulated to all members of the committee in advance of the following meeting.
- Decisions and feedback are provided to applicants not more than 10 working days after the meeting.
- The decision to approve a research application by the HSE Reference REC will usually be arrived at by consensus. If agreement cannot be reached in this manner, a majority vote of more than two thirds is required. If this cannot be reached, further information should be sought from the applicant.

8.6 Outcomes from HSE Reference REC review

- **Favourable opinion** - allowing a Principal Investigator to conduct the research as outlined in the research protocol.
- **Provisional favourable opinion:**
  - The applicant is asked for further information or to make minor changes. The Chair reviews the further information, and then issues full approval, and this is noted at the next Reference REC meeting.
- Request for more information -
  - **No opinion** with a request for significant further information, changes to be made, or a resubmission. The responses will be assessed by the full Reference REC at the next scheduled meeting.
  - **No opinion** pending a consultation(s) with an external referee(s) or expert(s).
- **Unfavourable opinion** - the research may not go ahead. The decision can be appealed (see "Section 8.10 Process for appealing the decision of a HSE Reference REC").

8.7 HSE Reference RECs Process for Amendments

The NREC's Operational Framework (September 2021)[24] defines an amendment as any modification made to the study protocol or any other material information arising after the study has started, that may have an impact on the conduct of the study. An amendment can be categorised as substantial or non-substantial.

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

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

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

Researchers who wish to submit an amendment to a HSE Reference REC should track changes to their original application, with a summary cover letter, which should also stipulate if and how re-consent will be sought[25].

Amendments will be reviewed by two committee members, preferably two members who undertook the initial review. The same procedure as stated in "Section 9.6: Outcomes from HSE Reference REC review" will apply when reviewing amendments.

8.8 Process for Safety Reporting

- The HSE incident management guidance[26] states "… 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 National Incident Management System (NIMS) if available."
- It is recommended that the 'HSE Integrated Risk Management Policy: Incorporating an overview of the Risk Management process'[27] is adhered to and all investigators should comply with the HSE Incident Management Framework 202021.
- For any research study, the Principal Investigator must report, using the template in Appendix 6, serious adverse reactions related to study drug/ intervention/

24 https://www.nrecoffice.ie/wp-content/uploads/NREC-Operational-Framework-DRAFT-v1.1-Final-1.pdf
25 Will change with ERMS
26 https://www.hse.ie/eng/about/qavd/incident-management/hse-2020-incident-management-framework-guidance.pdf
27 Health Service Executive. HSE Integrated Risk Management Policy: Incorporating an overview of the Risk Management process. Dublin: Health Service Executive; 2017. Available from: https://www.hse.ie/eng/about/qavd/riskmanagement/risk-management-documentation/hse%20integrated%20risk%20management%20policy%202017.pdf

procedures, including Suspected Unexpected Serious Adverse Reactions (SUSARs) or unforeseen events that might affect the risk/benefits profile of the study, to the HSE Reference REC that issued ethical approval. These are reviewed by the Chair who may escalate them for full HSE Reference REC review if required.

- The HSE Reference REC 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).

8.9 Process for notifying the HSE Reference REC of the termination of research

- HSE Reference RECs will require final reports for all research projects using the template included in Appendix 7.
- It is the responsibility of the researcher to notify the HSE Reference REC when a study is completed or terminated early using the template in Appendix 7.
- Reasons for early termination should be specified.
- Failure to provide a report may result in refusal by the committee to review any future applications until final reports are submitted.
- Reminders for final report submission can be generated automatically through ERMS.

8.10 Process for appealing the decision of a HSE Reference REC

- The HSE Reference REC SCO will co-ordinate the appeals process, including the selection of the three other HSE Reference RECs.
- In the case of an appeal of a HSE Reference REC decision, the application is sent to three other HSE Reference RECs for review. A decision of at least two out of the three RECs dealing with the appeal will be final.

8.11 Process for handling complaints

- Institutions may receive complaints about researchers or the ethical conduct of research. Complaints may be made by patients, their family members/ next of kin, research participants or their family members/ next of kin, researchers, staff of institutions, or others, to the relevant HSE Reference REC. All complaints should be handled promptly and sensitively by the HSE Reference REC.
- Complaints should be submitted in writing to the relevant HSE Reference REC.
- The HSE Reference REC will acknowledge the complaint, and inform the HSE Reference REC SCO, within five working days of its submission and outline the course of action in response to the complaint.
- The HSE Reference REC will keep the HSE Reference REC SCO informed of any actions and decisions made in relation to the complaint. If the HSE Reference REC SCO needs any additional information, it will be supplied by the HSE Reference REC.

- Support in managing the complaint is available from the HSE Reference REC SCO.
- Information related to the management of complaints should be visible on the REC website and HSE's Research & Development website.
- Should any patients, research participants, researchers, staff of institutions, or others, be dissatisfied with the response of the respective HSE Reference REC to their complaint, they can approach the HSE Reference REC SCO.

8.12 Record Keeping and Archiving

- Paper Records (i.e. application form and additional documentation submitted by the applicant) should be kept for five years after completion of the study, and then destroyed. Minutes and correspondence can be archived for the time that is necessary. This is usually for a minimum of seven years to accommodate any potential audits or other activities that will involve a review of the HSE Reference REC's minutes and correspondence.
- The duration records are kept and archived within ERMS when it is in use will be determined.

8.13 Training for HSE Reference REC members

- Training will be facilitated by the National HSE Reference REC SCO.
- HSE Reference REC members should complete eight hours of learning each year. To meet the minimum requirement for training, learning must be linked to the work of the REC and relate to either issues of ethical principle or legislation relevant to ethical review. Reference REC members are encouraged to take part in relevant training either by attending face-to-face training, completing e-learning, or undertaking independent self-directed learning.
- Members can obtain CPD points from their professional body by submitting certificates of attendance to training events and also attendance at REC meetings:
  - Certificates of attendance at meetings can be obtained from the respective REC Manager upon request.
  - Certificates of attendance at training events will be automatically provided by the National HSE REC SCO.
  - HSE Reference RECs are required to keep meeting attendance records to verify attendance.
- All HSE Reference REC members (including experienced members) will need to complete Standard REC training. Training includes:
  - Induction training on the role and responsibilities of Research Ethics Committee members, introduction to the standard code of management and practice required for HSE Reference RECs, 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

- Other recommended training includes, but is not limited to, Equality, Diversity and Human Rights training, Research Integrity training, and Principles of Good Clinical Practice.
- The Chair should complete operational training to facilitate adherence to the Standard Code of Governance and Management Required for HSE Reference REC.
- Training records must be kept by each HSE Reference REC office and supplied upon request to the National HSE REC SCO during the process of quality assurance.

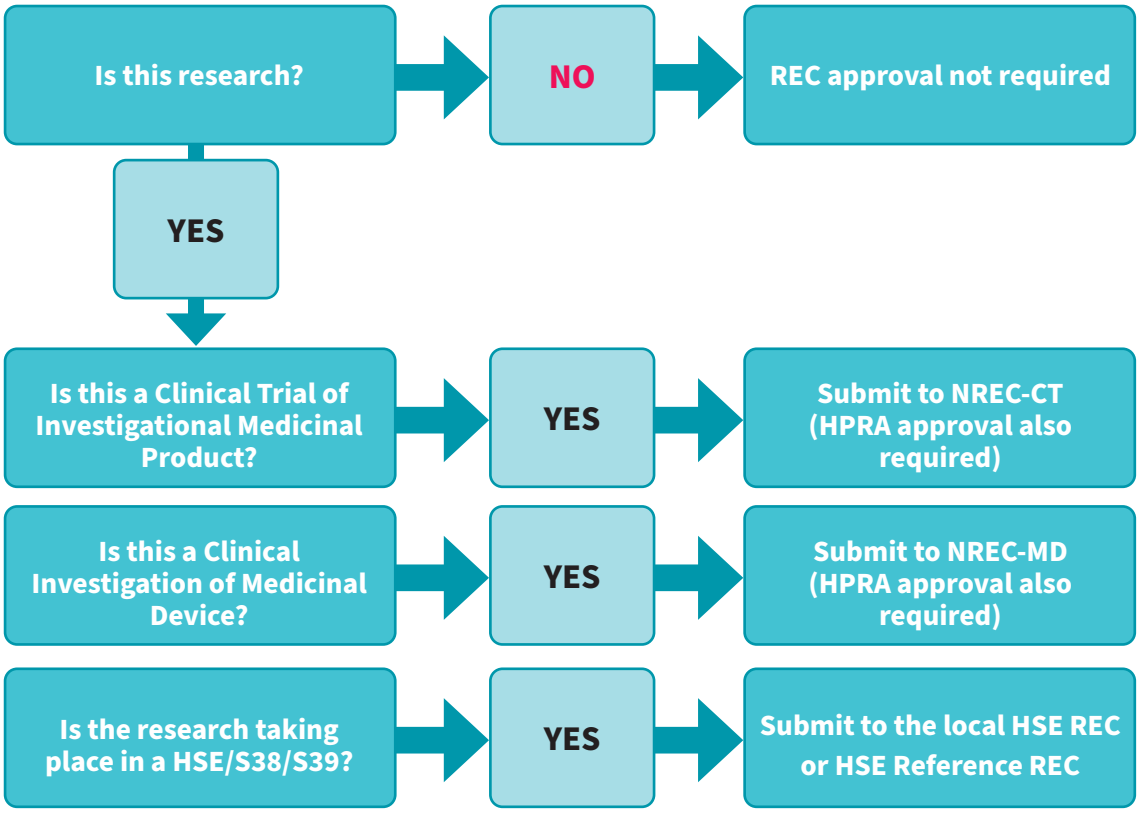
SECTION D. Appendices

Appendix 1 – HSE REC Reform Working Group Membership

Name	Position	Representing
Dr Ana Terrés (Chair)	HSE Assistant National Director, Head of Research & Evidence	HSE Research and Evidence
Dr Hazel A Smith (Project Manager to December 2021) Dr Virginia Minogue (January 2022)	Senior R&D Manager (Research Ethics Governance and Support Services)	HSE Research and Development
Dr Claire Collins	Director of Research & Innovation, Irish College of General Practitioners	Irish College of General Practitioners
Ms Fiona Cregg/ Dr Ruben E. Keane	Quality and Regulatory Affairs Manager	Health Research Board -National Clinical Trials Office
Dr Rachel Crowley	Consultant Endocrinologist and former Chair of SVUH REC	Ireland East Hospital Group Representative
Prof Gerard Curley	Consultant in Anaesthesiology and Critical Care, Head of Department of Anaesthesia, RCSI & Beaumont Hospital	RCSI Hospital Group Representative
Prof Patrick Dillon	Consultant Anaesthesiologist and Chair of HSE Mid-Western Area REC	UL Hospital Group/ HSE Mid-Western Area
Dr Úna Fallon	Public Health Specialist and Chair of HSE Midlands Area REC	HSE Midlands Area REC
Dr Jennifer Ralph James	Head of Office	National Office for Research Ethics Committees
Dr Fionnuala Keane	Chief Operating Officer	Health Research Board -National Clinical Trials Office
Prof David Kerins	Consultant Cardiologist and Chair of Cork Clinical REC	South/ South West Hospital Group Representative
Ms Caroline Lamb	Research Ethics Committee Coordinator, HSE South East Area REC	HSE South-Eastern Area Representative
Mr Peter Lennon	Research Services and Policy Unit	Department of Health
Prof Gerard Loftus	Emeritus Professor of Paediatrics, NUIG and Chair of Galway Clinical REC	Saolta Hospital Group Representative
Ms Rosalie Smith-Lynch	Regional Manager Consumer Affairs, HSE Dublin North East, member of HSE North East Area REC	HSE North East Area REC

Name	Position	Representing
Dr Barry Lyons	Consultant Paediatric Anaesthesiologist, Chair of Children's Health Ireland at Crumlin REC, and lecturer in Medical Ethics at Trinity College Dublin	Children's Health Ireland Representative
Ms Kara Madden	Patient and Public Involvement Advisory	HSE Research and Development Patient and Public Involvement Reference Group
Dr Gemma Moore	Qualitative Evaluation and Research Officer	HSE National Quality Improvement Team
Ms Máiréad Murray	Senior R&D Manager, Research & Development	HSE Research and Development
Prof Brendan McClean	Director of Physics at Saint Luke's Radiation Oncology Network	Midlands Hospital Group Representative
Ms Lynne McGlynn	Research Ethics Officer, Beaumont REC	Beaumont Hospital REC
Ms Joanne O Connor	Research Ethics and Clinical Trial Co-Ordinator, Quality & Safety Department	UL Hospitals Group
Dr Declan O'Hanlon	General Manager Research and Development, HSE	HSE Research and Development
Dr Sadhbh O'Neill/ Chita Murray	Co-ordinator of TUH/ SJH Joint Research Ethics Committee	Midlands Hospital Group Representative
Ms Ciara O Reilly	Patient and Public Involvement Advisory	HSE Research and Development Patient and Public Involvement Reference Group
Dr Lucia Prihodova	Programme Manager	National Office for Research Ethics Committees
Dr Jean Saunders	Director CSCS & CSTAR@UL and Deputy Chair of HSE Mid-Western Area REC	UL/ HSE Mid-Western Area Representative
Ms Aileen Sheehy	Programme Manager	National Office for Research Ethics Committees

Appendix 2 - Principal Investigator Process



Appendix 3 - Terms of Reference for HSE National Committee for the Governance, Management and Support of Research (DRAFT)

Context and background	• Research activity is significant within the HSE and its funded organisations but the level of awareness, oversight, and governance of the activity at both local and national level is poor and the organisational infrastructure to enable it is very under-developed. • The HSE National Framework for the Governance, Management and Support of Research (RGMS Framework) sets up the context for the development of appropriate environment of research in the health service that will allow to place the service users, patients, their families, and carers at the centre of the research activity, while supporting our staff and enabling organisations to comply with ethical, legal, and regulatory requirements. • The implementation of the RGMS Framework will require a nationally integrated approach to the establishment of RGMS functions at local level, the reform of the Research Ethics committee system and the roll out of an electronic information management system. Equally, implementation will require the development of research related policies, standardised codes of practice as well as guidance and resources for staff.
Objectives of the group	The HSE National Committee for the Governance, Management and Support of Research will oversee the implementation of the RGMS Framework in the publicly funded health service with the aim of achieving national cohesiveness for health research governance. The objectives of this group are to: • Support and oversee the implementation of the HSE Strategic Action Plan for Research 2019-29 and the HSE National Framework for the Governance, Management and Support of Research. • Supporting approaches for research governance and management that overcome existing complexities and challenges for collaboration and lead to the implementation of efficient and effective processes for collaboration between HSE and S38 and S39 services, academic partners, research charities, patient groups and other stakeholders. • Act as champions for research at senior management level with a view to promote a research culture within the HSE and its funded organisations. • Provide guidance and advice to all the working groups led by HSE National R&D. • Provide a reporting line for the new HSE Reference Research Ethics Committees, oversee the development of RGMS structures and implementation of the national research information management system. • Support Patient Representatives and Lay members and the translation of research into policy and practice.

Reporting and Governance	• The HSE National Committee for the Governance, Management and Support of Research will report to HSE Senior Management Team and relevant subcommittees of the HSE Board on an annual basis. • The group will be Chaired by the National Director of Research and Strategy and will have a minimum of one patient representative. • Decision-making will be based in the majority: a course of action will require the support of more than 50% members. • Decisions will be taken at meetings or by email if attendance is not possible. When engaging remotely, lack of answer will imply support of whatever decision is put forward for a vote. • A quorum of at least four members will be required.
Meetings	• Meetings will take place every three months. • Meetings will take place via teleconferencing until public health guidelines advise otherwise. • Additional meetings maybe scheduled if required. • Secretariat will be provided by National HSE R&D.
Members (TBC)	• HSE National Director for Strategy and Research – Chair. • HSE Head of HSE Research & Evidence (Deputy Chair). • National Finance nominee. • National HR nominee. • Acute Operations nominee. • Community Operations nominee. • Chief Clinical Officer nominee. • Data Protection Officer nominee. • Chair of the Chief Academic Officers Group. • Two Patient/PPI representatives. • Chair of National Clinical Trials Office. • Chair of the IUA VPRI group. • One Researcher representative.

Appendix 4 - HSE Reference REC Member Application Form

Expression of Interest for membership of the HSE Reference Research Ethics Committees

Forms must be returned with any continuation sheets to HSE Reference RECs Support and Coordination Office at HSE.REC@hse.ie Please include 'HSE Reference REC Member EoI' in the subject line.

Are you applying to be (please only tick one box)**?**

Expert member ☐ Lay member ☐ Patient Representative ☐

If applying as an expert member, which position are you applying for (can tick more than one box):

Chair ☐ Deputy Chair ☐ Committee Member ☐

If you would like to apply for the role of Chair, Deputy Chair or Committee Member:

Do you intend to carry out your committee work during your normal working hours and have received permission to do so by your line manager?

Yes ☐ No ☐

If not, will you carry out your committee preparatory work[28] outside working hours?

Yes ☐ No ☐

If you would like to apply for the role of Chair or Deputy Chair or Expert Committee Member, are you fully aware that financial compensation for your REC work may not be possible?

Yes ☐ No ☐

Are you a staff member of HSE or HSE funded S38 organisation (i.e. voluntary hospitals)?

Yes ☐ No ☐

If yes, please indicate the name of your service:

28 While preparatory work may take place outside working hours, REC meetings may take place during working hours.

If you would like to apply for the role of Lay Member or Patient Representative, are you fully aware that financial compensation for your REC work is currently not possible?

Yes ☐ No ☐

Are you, or have you been, a member of a research ethics committee?

Yes ☐ No ☐

If so, please indicate the name of the committee:

Part 1: Your personal details

Surname:			
Forenames:			
Title:			

Which address are you using for correspondence?

Home Address ☐ Business Address ☐

Address (including Eircode):		
Contacts	Email:	
	Phone:	Mobile:

Career history

Please attach your two-page CV at the end of application submission and not as a separate document.

Other Relevant Experience

Please give any further information that is relevant to your application explaining briefly what you are able to offer as a member, highlighting work on committees, boards, or other relevant experience. Expert applicants may wish to detail their experience in research or ethics. Patient Representatives or Lay applicants may wish to describe any involvement as a patient or carer of a patient or in research or ethics that they feel is relevant to the role. (Please continue on a separate sheet if required)

Motivation to Apply

Please provide details on why you would like to be a Research Ethics Committee member. (Please continue on a separate sheet if required)

Part 2: Specific requirements for the role

Please describe an example of when you used the following skills:

1. Read, understood, and analysed complex issues and weighed up conflicting opinions.
2. Have discussed issues with people who may not agree with you, including influencing others from a range of backgrounds.

Part 3: References

Please give details of two Referees. Referees do not need to be employment related but can be any person (who is not a relative) that can attest to your character. An appointment will not be offered until we have received satisfactory references.

We will contact your referees prior to engaging with you to discuss your application unless you request otherwise. Please cross the following box if you would prefer us not to contact your referees prior to the initial conversation: ☐

Name	
Address	
Eircode	
Telephone number	
Email	
How do you know he/she/they	

Name	
Address	
Eircode	
Telephone number	
Email	
How do you know he/she/they	

Part 4: Declaration of Interests

Please declare any personal, business, or professional interests, or legal impediment, that would likely interfere with your ability to play a full and proper role on an HSE Reference REC. The purpose of this declaration is to ensure that the functions of the HSE Reference REC can be exercised free of bias that could affect their independence in reaching decisions, and to ensure public confidence in the independence of the HSE Reference REC.

I have no interest to declare ☐

I wish to declare the following interests:

Use of your personal information

The HSE Data Protection Policy is in line with the requirements of the Data Protection Act 2018 and the General Data Protection Regulations (GDPR). We will store your information for monitoring and audit purposes as follows:

- Your initial contact details will be held by the HSE for a period of at least 12 months
- If you submit an application form, the form and any supporting documentation will be held by the HSE for at least 12 months.
- Information held electronically, including your contact details and the monitoring information provided will also be held for at least 12 months.
- If you are appointed, your personal information including a copy of this application form will be retained on file by the HSE Reference REC Support and Coordination Office for the length of your appointment as a member. HSE Reference REC Member information is only accessible to staff employed by the HSE Reference REC Support and Coordination Office.
- Copies of the documentation related to your appointment will be retained electronically for seven years after the end of your service.
- In the case of an unsuccessful application, if you would like these details to be removed from our records as soon as this recruitment exercise is complete, please contact the HSE Reference REC Support and Coordination Office.

Part 5: Declaration

I hereby declare that the information given in my application is correct to the best of my knowledge. I understand that falsification of information contained on this form may result in my appointment as REC member being terminated.

Signature.....

Date .....

How did you hear about becoming a HSE Reference REC Member?

Please indicate below how you heard about becoming a HSE Reference REC Member, this information will be useful to the HSE for future HSE Reference REC Member recruitment campaigns.

HSE (R&D) Website: ☐

Twitter: ☐

Email: ☐

Your Employer: ☐

Local organisation/ Volunteer organisation: ☐

Patient and Public Involvement Group: ☐

Word of Month: ☐

Advert (please provide details): ☐

Other (please specify) ☐

Appendix 5 - Proportionate REC Review (ethically low risk studies) Screener Questions*:

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 that 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

* If the Chair, or any member of the HSE Reference REC, answers 'No' to any questions 1-3 and/or answers 'Yes' to any questions 4-13 than the research study is not for proportionate REC Review (it is not ethically a low risk study)

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.

Appendix 6 –Safety Reporting

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:

Email:

Date (dd/mm/yyyy):

Title:

Email:

Date (dd/mm/yyyy):

Signature:

Appendix 7 – 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 related, or potentially 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 reviewed by the Chair was it escalated for full HSE Reference REC review? Yes ☐ No ☐

5.) Has the research been published? Please elaborate

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: