

Research & Development
Taighde & Forbairt

HSE Roadmap for the Reform of Health and Social Care Research Ethics Committees



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1. Executive Summary

The HSE’s “National Framework for the Governance, Management and Support of Health Research” (RGMS Framework) was launched in September 2021. The implementation of the first framework for health research in the publicly funded health service represents a stepping-stone towards nurturing a research culture in the HSE, and recognising that research is a crucial activity, which contributes to the improvement of services and benefits patients, their families, and the public. Full implementation of the RGMS framework will require both reform of the HSE Research Ethics Committee (REC) system as well as the development of capability for research management and support within the service.

The HSE National Office for Research and Development in collaboration with the HSE REC Reform Working Group, (Appendix 1), has developed a “Roadmap for the Reform of Health and Social Care Research Ethics Committees” to enable this reform. This roadmap details how the HSE can establish an effective, efficient, and transparent REC system, for the HSE and associated organisations, that will provide an integrated system of the National Research Ethics Committees and the Research Governance Management Support functions for health research.

This roadmap outlines the development of six HSE Reference RECs, operating to a standard Code of Management and Governance¹ and with geographical cover aligned to the regional health areas as proposed in the Sláintecare action Plan². The roadmap capability will provide single approval for national or multisite studies, which do not come under the remit of National Research Ethics Committees (NRECs). Pending further discussions with the National Office for Research Ethics Committees and Children’s Health Ireland (CHI), this roadmap also includes the potential establishment of a HSE Reference REC for CHI.

¹ Standard Code of Management and Governance for the HSE Reference Research Ethics Committees 2021 – available in www.hseresearch.ie from January 2022.

² <https://www.gov.ie/en/publication/6996b-slaintecare-implementation-strategy-and-action-plan-2021-2023/>

2. Introduction and background

2.1 Context

Research involving patients, either directly or indirectly, requires ethical approval from a health Research Ethics Committee. Research ethics approval is an essential part of research governance and is essential to safeguard the rights, safety, and well-being of research participants and to ensure public confidence. As healthcare changes and develops, the requirement for more research evidence to meet the changing agenda will follow. Aspects of clinical research ethics, protection, approvals, and review must be reformed alongside these changes.

A scoping exercise carried out by the National Office for Research & Development during 2018 identified 32 RECs associated with the HSE or its funded organisations³. These RECs review circa 2,000 proposals per year, including both Hospital and Community Healthcare Organisation (CHO) based research. The majority of these RECs were established to review hospital-based research and only four of those were established with a dual purpose (i.e. for hospital and CHO based research). In some instances, hospital-based RECs expanded their remit to CHO based research, but this is not the case throughout the country. Currently there is no HSE REC coverage for community research in CHO6, CHO7, CHO9 and part of CHO8. The current structure causes significant challenges for researchers and sponsors. In addition, many RECs face significant resource challenges. They have minimal administrative support and funding, with low levels of support for the members, who act in a voluntary capacity, and recruitment can be difficult. The officers of the REC (Chair, Secretary) have roles that require a significant time commitment often outside working hours.

The HSE's "National Framework for the Governance, Management and Support of Health Research"⁴ (RGMS Framework) provides the foundation for the development of appropriate research governance in the HSE and its funded organisations. It stipulates that ethical approval from a HSE Research Ethics Committee is required for all health research studies involving HSE patients (as well as their samples or data), HSE staff (as well as their samples or data) or HSE premises. The RGMS Framework also articulates the difference between the responsibilities of the RECs and the governance and management responsibilities of the health services hosting the research activity. Both these activities are essential, and are interrelated, but are also distinct. Hence, it is important, when reading this roadmap, that the role of the HSE RECs is understood. RECs are responsible for the independent assessment of all ethical considerations of a study before it can commence. They are also responsible for ongoing oversight of research studies when amendments or changes to the original protocol or other relevant study documentation are required, when safety issues arise, or any other

³ <https://hseresearch.ie/wp-content/uploads/2019/12/Research-Activity-Report.pdf>

⁴ <http://hseresearch.ie/governance-framework/>

changes that may affect the benefit/ risk assessment of the study. RECs provide an ethical review of a study to determine if a study is to be approved and can continue. RECs do not provide governance review. The RGMS Framework states that “Research governance: provides organisational oversight for research that takes place in collaboration with, or independently of, third-level institutions. The function provides a reporting line for research activities that take place within the organisation”.

It is therefore paramount that the HSE REC system is reformed in order to comply with the RGMS Framework. This reform needs to consider the development of the National Office for Research Ethics Committees under the National Research Ethics Committees Bill (draft published by the Department of Health in July 2019). The initial priorities of the NRECs are clinical trials of medicinal products for human use and clinical investigations of medical devices (as required by Regulation EU No 536/2014 and Regulation EU No 2017/745, respectively). This development will reduce the workload as well as the revenue stream of some, but not all, existing RECs. Another development that will shape the reform of the HSE RECs is the Sláintecare Action Plan⁵. This is a major re-structure of the health service into regional health areas, that will integrate acute and community services into single regional structures for the purpose of facilitating the provision of integrated care. The enactment into Irish law of General Data Protection Regulation (GDPR)⁶, the Health Research Regulations (HRR) 2018⁷ and subsequent amendments (including S.I. No. 18/2021 - Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021), are another important consideration that will impact on the work of the committees and highlight the challenges under which many health RECs currently operate. In the absence of national guidelines, RECs have adopted different approaches to dealing with the new legislation, which has brought about further variations in protocols at local levels.

It is in this context of significant change that the HSE REC structures need to be revised to ensure that they are fit for purpose, and that they are structured and supported appropriately, to deliver optimal ways of working and to support research activity in the best and most efficient and effective manner.

2.2 Objectives

The specific objectives of this reform roadmap are to:

- Design a new model of sustainable structural reform to ensure that all hospital and community-based research projects can be reviewed by an appropriate REC in a timely manner.
- Establish a process to enable single REC review for studies, outside the remit of the NREC, which involve multiple sites or are of a national nature.
- Contribute to the implementation of the RGMS Framework to ensure appropriate

5 <https://www.gov.ie/en/news/95394a-minister-for-health-confirms-restructuring-of-health-services-and-de/>

6 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

7 <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>

integration of research ethical approval within the overall processes of research governance.

- Establish full REC coverage across the HSE to include those services that currently do not have formal access to REC services (i.e. CHO's 6, 7 and 9, National Services and Corporate Divisions, part of CHO8, and some hospitals in the Midlands region that lost access to a REC during the Covid-19 pandemic).
- Develop best standards of practice that will lead to increased capacity, efficiency, accessibility, consistency, and quality of research ethics processes for the RECs. This will be achieved through Standard Operating Procedures and a Standard Application Form to ensure consistent quality across RECs.
- Develop best practice guidelines to risk assess studies and create a standardised approach to proportionate review where appropriate.
- Develop support for RECs in terms of training for members, recruitment mechanisms, and compliance with all relevant Data Protection legislation.
- Develop a national approach to enable the operational integration of HSE RECs with those in Section 38 and 39 organisations, private hospitals, and academic RECs.
- Increase the transparency, communication, and cooperation between the different types of RECs in the system as well as transparency with the public, patients, and their families, and with service users in general.

3. Current REC Landscape in the HSE and S38 Hospitals

3.1. Institutional Approval vs Research Ethical Approval

As per 2019⁸, the management structures for research in the health service are, with some exceptions, significantly underdeveloped, and a research oversight function does not exist in most healthcare delivery sites. As a result, Research Ethics Committees have, in many cases, fulfilled this oversight function. This is particularly the case when the REC serves a single institution (i.e. a single hospital) rather than where RECs have regional coverage serving a multitude of organisations.

The RGMS Framework articulates institutional governance and oversight as a function distinct from ethical governance and oversight. The former should be aligned with the institution, while the latter should be independent. The research approval cycle for health research, proposed by the RGMS framework, requires that Institutional and REC approval take place before granting host institution authorisation to proceed. Hence, it is important that the reform of the RECs takes place in parallel with the development of appropriate governance structures for research at local level.

The granting of approval by the REC does not take precedence over the authority of a service to determine the priority of activities that take place within the organisation, and researchers should be aware that REC approval does not guarantee host site authorisation.

3.2 REC Approval for Multisite Studies

Due to the differences between RECs, and in some cases the roles of RECs, in the process of institutional governance, it is generally the case that studies not under the remit of the NREC, require approval by the REC associated with the institution where the research will take place. When the research involves multiple sites, this means that multiple REC approvals are required. This entails significant effort on the part of the researchers and the committees, can lead to significant delays, and involves multiple committee reviews of the same project with duplication of effort.

The current reform of the REC landscape for health-related research, described in the Roadmap, will reduce the need for multiple REC approvals for one study for those studies not under the remit of the statutory NREC (Clinical Trials for Investigational Medicinal Products and Clinical Investigations of Medical Devices), for which a single REC opinion is already provided. In the future, additional NRECs may be established in a range of health areas.

⁸ Governance of Research in the HSE and HSE funded healthcare services. A Scoping Report (January 2019). <http://hseresearch.ie/wp-content/uploads/2020/05/Governance-of-Research-in-the-HSE-and-HSE-Funded-Healthcare-Services.-A-Scoping-Report-compressed.pdf>

3.3 Current remit of existing RECs

3.3.1 HSE and S38 RECs

The current REC landscape in Ireland's health service is fragmented and uncoordinated. Many RECs were set up to address the needs of individual hospitals and others were set up to address the needs of the former regional health boards. The creation of the HSE, on 1st January 2005, was not followed by a parallel restructure of the RECs to align with new Community Healthcare Organisations (CHOs) or Hospital Groups (HGs). The current structure causes significant challenges for researchers and clinical trial sponsors.

In September 2021, there were only three regional HSE RECs that accepted community-based research as part of their terms of reference:

1. HSE North East Area REC (Counties Louth, Meath, Cavan, and Monaghan): Louth County Hospital, Our Lady of Lourdes Hospital Drogheda, Our Lady's Hospital Navan, Cavan General Hospital, and Monaghan Hospital.
2. HSE South East Area REC (Counties South Tipperary, Carlow, Kilkenny, Waterford, and Wexford): South Tipperary General Hospital, St. Luke's General Hospital Kilkenny, Lourdes Orthopaedic Hospital Kilcreene, University Hospital Waterford, and Wexford General Hospital.
3. HSE Mid-Western Area REC (Counties Limerick, Clare, and North Tipperary): University Hospital Limerick, University Maternity Hospital Limerick, Ennis Hospital, Nenagh Hospital, Croom Hospital, and St. John's Hospital Limerick.

The HSE Midlands REC regional committee ceased operations in March 2020 due to the Coronavirus (COVID-19) pandemic. This committee covered the HSE Midlands Area community services in Laois, Offaly, Longford, Westmeath, and acute services in Midlands Regional Hospital Portlaoise, Midlands Regional Hospital Tullamore, and Midland Regional Hospital Mullingar.

CHO research in the South/ South West and West/ North West are covered by RECs (including one university REC) that are currently accepting CHO applications outside of their formal terms of reference. These include:

- South/ South West: Clinical Research Ethics Committee (CREC) of Cork Teaching Hospitals at University College Cork covering the Cork Teaching Hospitals (Cork University Hospital/Cork University Maternity Hospital, University Hospital Kerry, Mercy University Hospital, South Infirmary Victoria University Hospital, Bantry General Hospital, Mallow General Hospital), and CHO4 (Counties Kerry and Cork).
- West/ North West: Galway University Hospitals REC covering hospitals in the Saolta Hospital Group (University Hospital Galway and Merlin Park University Hospital, Portiuncula University Hospital, Roscommon University Hospital) and

community areas in CHO 1 (counties Donegal, Leitrim, Sligo) and CHO 2 (counties Galway, Roscommon, and Mayo).

Note: Cavan and Monaghan are also CHO1 but are covered by the HSE North East Area REC.

- Sligo University Hospital, Letterkenny University Hospital and Mayo University Hospital all have RECs, and, in some cases, they will review proposals for their surrounding community areas too.

Further detail about the REC coverage for CHOs and Hospitals is included in Tables 1 and 2 in Appendix 2.

The East region has the highest density of health RECs in the country, but all are hospital-based and do not review CHO based research. As a result, there is no REC for research taking place in CHO6, CHO7 or CHO9.

- CHO6 (Wicklow, Dun Laoghaire, and Dublin South-East)
- CHO7 (Kildare, West Wicklow, Dublin West, South City and Dublin South-West)
- CHO9 (Dublin North, North Central and Dublin North-West).

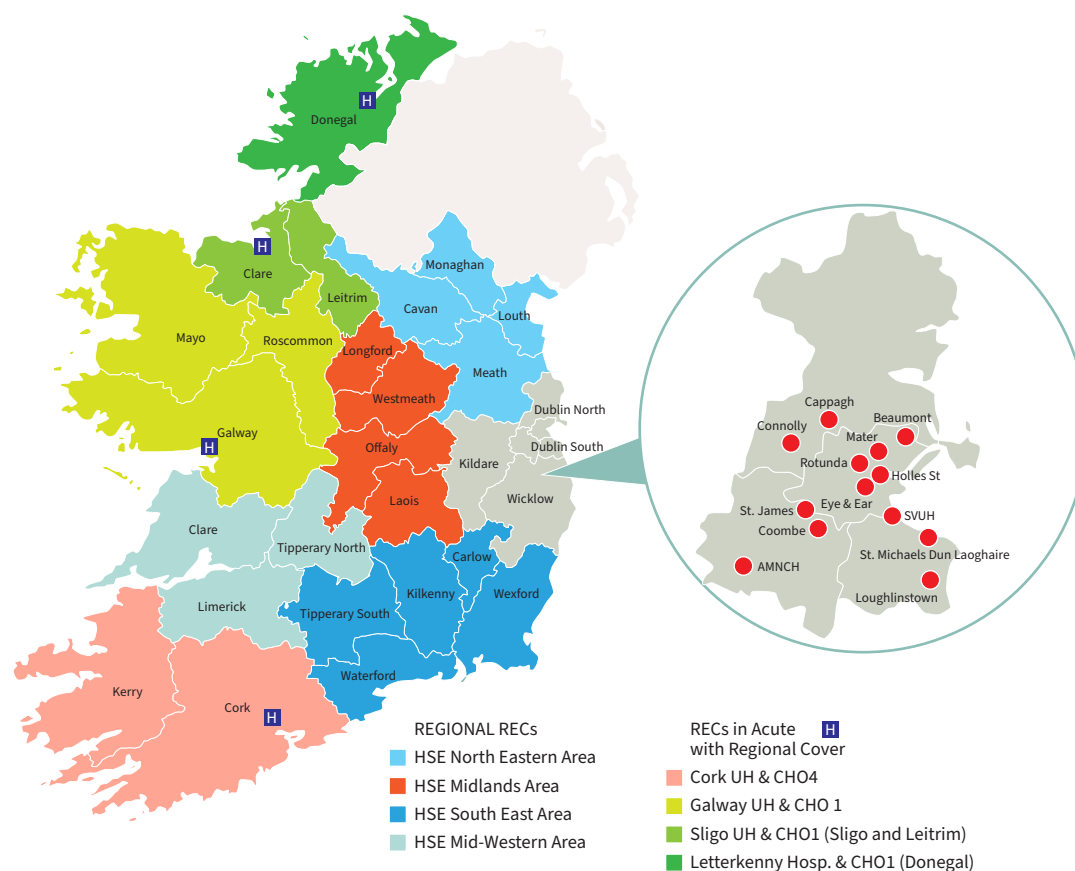


Figure 1: Regional REC CHO coverage, showing gap in (grey) in Ireland East region (Dublin, Kildare, and Wicklow)

3.3. National Statutory RECs

The National Office for Research Ethics Committees is an independent statutory office, established in 2020, tasked with operationalising National Research Ethics Committees (NRECs) for the ethical review of Clinical Trials of Investigational Medicinal Products (CTIMPs) and clinical investigations of Medical Devices (MD). It is envisaged that the NRECs' remit will centre on those health research areas subject to legal regulation. Prior to the NRECs, the Department of Health recognised 13 RECs, under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 for reviewing and approving CT-IMPs (See Table 3 in Appendix 2). Device investigations were approved by local RECs at each site where the investigation was taking place. Over a defined transition period, the NRECs and the 'recognised RECs' have concurrent authority to review CTIMPs until implementation of the EU Clinical Trial Regulation in January 2022.

4. Process of reform of the HSE REC structure

The proposed reform of the HSE Research ethics committee structure aims to address the aforementioned challenges. The reform will result in the establishment of the “HSE Reference RECs” and take place in several stages:

Phase 1:

- 1.1 Development of a Standard Code of Practice, Governance, and management for HSE Reference RECs.
- 1.2 Establishment of the National HSE REC Support and Coordination office (HSE REC SCO).
- 1.3 Establishment of the REC Appointing Authority.
- 1.4 Establishment of six HSE Reference RECs, to cover health services within the geographical areas aligned to the Sláintecare Regional Health Areas (RHA), operating to the standard Code of Practice, providing support to HSE, S38 and S39 services which do not already have a REC.

Phase 2

Commence engagement with hospital/institution based RECs in the HSE, HSE funded services and private healthcare providers to operationalise the authority of HSE Reference RECs to provide single approval for studies outside the remit of the NREC which involve multiple sites.

Phase 3.

Engagement with RECs in universities, and other third level education sectors, to establish formal ways of working to simplify the REC approval requirements for academic staff and students performing research under the remit of the HSE RGMS framework.

Phase 4

Scope the potential and requirements for HSE hospital based RECs becoming part of the HSE Reference REC system. This phase will explore the potential for a national committee to operate with multiple spokes, accepting proposals from any location and coordinated by the HSE Reference REC SCO.

4.1 HSE REC Reform Phase 1

4.1.1 Development of a Standard Code of Practice, Management & Governance

In 2020, the HSE National Office for Research and Development established a collaborative HSE REC Reform Working Group (see Appendix 1). One of the objectives of this group was to develop a Standard Code of Practice, Management and Governance for HSE Reference RECs. This code, which comprises the standards for the management and governance for all HSE Reference RECs, as well as detailed standard procedures for their operations, will be available on the HSE National R&D website⁹ from January 2022.

4.1.2 Establishment of the National HSE REC Support and Coordination office

The National HSE REC SCO will be an integral part of National HSE R&D and will provide:

1. 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.
2. Support to the HSE Reference RECs and secretarial support to the HSE Reference RECs Chairs Group.

Further details about the HSE REC SCO are included in the Standard Code of Practice, Management & Governance for HSE Reference RECs⁹.

4.1.3 Establishment of the REC Appointing Authority¹⁰

The appointing authority for the HSE Reference RECs will be the HSE National Committee for the Governance, Management and Support of Research (National RGMS Committee). This committee will have an important role in providing oversight for the HSE Reference RECs and will:

- 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.

In addition to the governance role for the HSE Reference RECs, the National RGMS Committee has overall responsibility for oversight of the implementation of the HSE Framework for the Governance, Management and Support of Research within the HSE and its funded organisations. Further detail about the role of this committee and the governance of HSE Reference RECs is included in the Standard Code of Practice, Management & Governance for HSE Reference RECs⁹ and the Terms of Reference (ToR), listed in Appendix 3.

⁹ Standard Code of Management and Governance for the HSE Reference Research Ethics Committees 2021 – available in www.hseresearch.ie from January 2022.

¹⁰ Appointing Authority (HSE National Committee for the Governance, Management and Support of Research) is the office within the HSE's Research and Development Department that has overall responsibility for research governance, management, and support at a national level.

4.1.4 Establishment of six HSE Reference RECs

A HSE Reference REC is a Research Ethics Committee which operates to the Standard Code of Practice, Governance and Management (section 4.1.1), is supported by the HSE National Reference REC Support and Coordination Office (section 4.1.2), reports to the HSE National RGMS Committee (section 4.1.3) and provides REC review to health and social care services within an area aligned to the *Sláintecare* regional health areas. Further detail about the HSE Reference RECs is included in the Standard Code of Practice, Management & Governance HSE Reference RECs⁹.

The following HSE Reference RECs will be created:

- HSE Reference REC for the North East Area.
- HSE Reference REC for the Midlands Area and Corporate Divisions.
- HSE Reference REC for the South East Area.
- HSE Reference REC for the Mid-Western Area.
- HSE Reference REC for the West and North West Area.
- HSE Reference REC for the South Area.

Where possible, HSE Reference RECs will be developed from existing RECs. This will enable the retention of existing resources and expertise. Some of the existing HSE regional RECs already cover an area aligned to the *Sláintecare* regional health areas which will lessen the impact of the reform. Furthermore, the alignment of the areas of REC coverage with the *Sláintecare* regions¹¹ will address the existing problem of lack of access to RECs in the community areas within CHO 6, 7 and 9 as well as the corporate divisions and for national studies.

The HSE REC SCO may identify, in consultation with relevant stakeholders, the need for additional HSE Reference RECs, and where possible, any additional HSE Reference RECs will be developed from existing RECs. At the date of publication of this roadmap, the possibility of establishing Children Health Ireland as a HSE Reference REC is being scoped.

HSE Reference RECs will accept applications for research outside the remit of the NREC. This includes those taking place:

- In HSE acute and community services located within each Reference REC's respective *Sláintecare* Regional Health Area.
- In funded services (i.e. S38 and S39) located within each Reference REC's respective *Sláintecare* Regional Health Area who do not have access to their own REC.
- In Corporate Divisions.
- Nationally (research studies of national scope).

¹¹ <https://www.gov.ie/en/publication/6996b-slaintecare-implementation-strategy-and-action-plan-2021-2023/>

In addition, HSE Reference RECs will have the authority to provide single REC approval for studies outside the remit of the individual HSE Reference REC, that involve multiple sites.

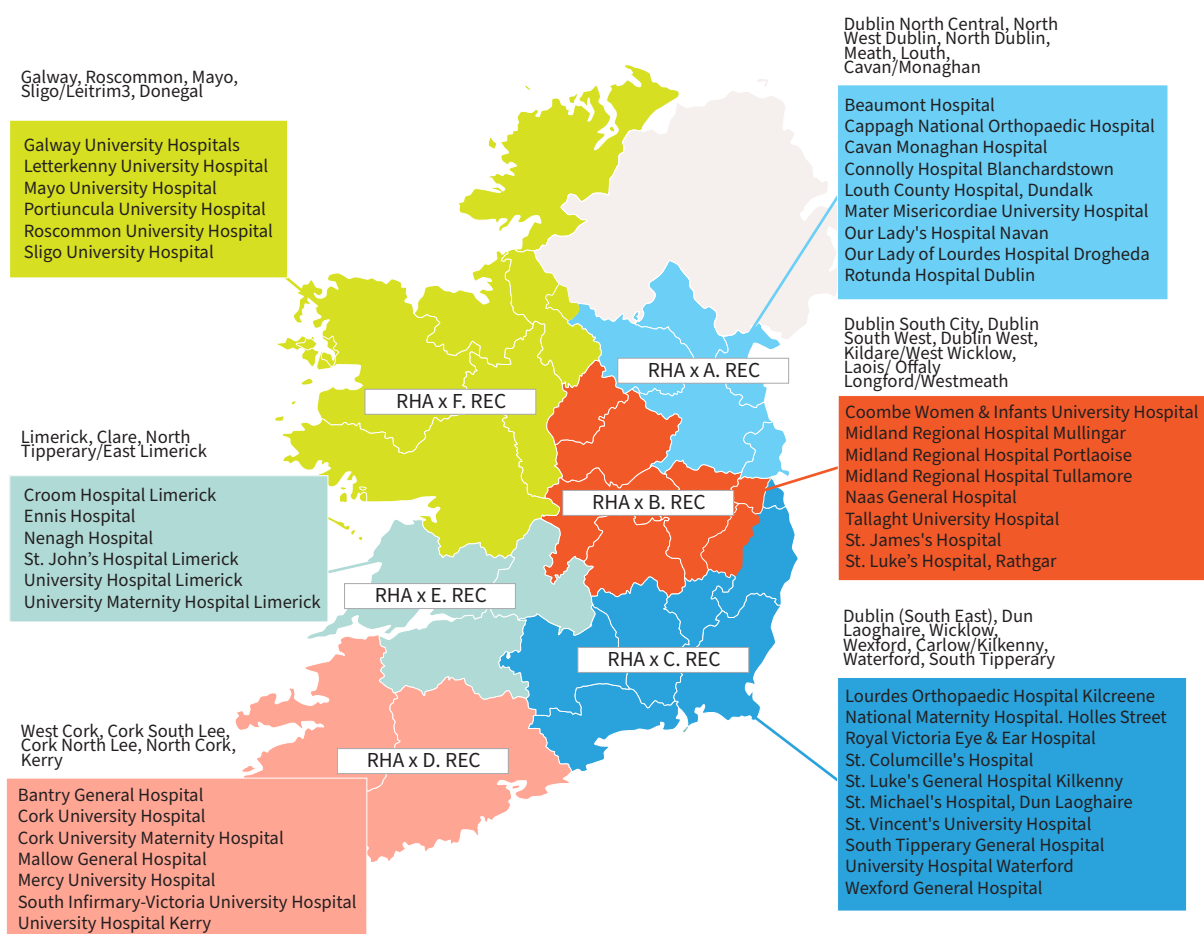


Figure 2: Geo-alignment of proposed HSE Reference RECs to Regional Health Areas

4.2 HSE REC Reform Phase 2

The objective of phase 2 of this roadmap is to operationalise the HSE Reference REC authority to provide single approval for research studies outside the remit of the NREC that involve multiple sites.

This will require engagement with hospital/institutionally based RECs in the HSE, HSE funded services and private healthcare providers to enable single REC approval for studies involving multiple sites without compromising institutional governance. Hence, agreement concerning protocols for ensuring, among other things, data protection compliance, will be necessary.

The institutional RECs that will be included in this process are listed in Appendix 3.

4.3 HSE REC Reform Phase 3

In order to simplify REC approval protocols for academic staff and students performing research that falls under the remit of the HSE National RGMS, this roadmap envisages to establish operational protocols between the HSE Reference RECs and the academic RECs which will simplify existing procedures. These procedures will refer only to health research projects¹² within the health and social care sciences, as well as social sciences, underpinned by the RGMS framework.

The list of academic institutions RECs that will be included in this engagement is included in Appendix 4.

4.4 HSE REC Reform Phase 4

Phase 4 is the final phase of this roadmap and will inform the next steps. During this phase the National HSE REC SCO, engaging with relevant stakeholders, will carry out a scoping exercise to determine the suitability and the requirements for all hospital based RECs becoming part of the HSE Reference REC system. The scoping exercise will consider a variety of models ranging from the merging of hospital RECs into the HSE Reference RECs to hospital RECs acquiring HSE Reference REC status. The results of this scoping exercise and relevant recommendations will be submitted to the HSE National RGMS committee for a decision on whether further reform would be possible or appropriate. Consideration will be given to developing the entirety of the health RECs, in the publicly funded health service, as a national committee with multiple spokes, accepting proposals from any location, and coordinated by the HSE Reference REC SCO.

4.5 Milestones and Roadmap time plan

The “Standard Code of Governance and Management Required for HSE Reference Research Ethics Committees” and “Roadmap for the Reform of Health and Social Care Research Ethics Committee” will be completed in late 2021. The timeline for the implementation of this plan is set out in Table 3.

¹² Health Research as defined in the HSE National Framework for the Governance, Management and Support of Research.

DATE	MILESTONE
2021	<ul style="list-style-type: none"> • Development of a Standard Code of Practice, Governance, and management for HSE Reference RECs. • Establishment of the National HSE REC Support and Coordination office. • Establishment of the HSE Reference REC Appointing Authority.
2022	<ul style="list-style-type: none"> • Establishment of six HSE Reference RECs. • Operationalisation of the HSE Reference REC authority to provide single HSE Reference REC approval for studies outside the remit of the NREC which involve multiple sites.
2023	<ul style="list-style-type: none"> • Scoping and Implementation of simplified approval protocols with academic RECs. • Further scoping the potential to operate all HSE/ S38 RECs as a national REC system for the public health service for those projects outside the remit of the NREC.

Table 3: Timeline for implementation of the Roadmap for the Reform of Health and Social Care Research Ethics Committee system.

5. Detailed plans for the establishment of a HSE Reference REC per Regional Health Area

5.1 HSE Reference REC for the North-East Area (Regional Health Area A)

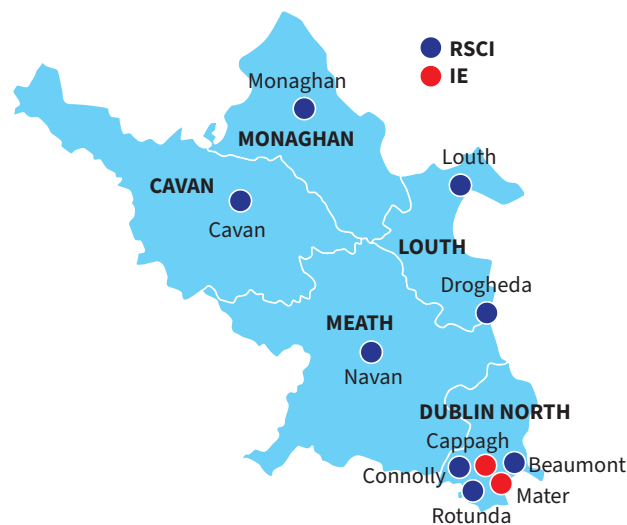


Figure 3: North-East Area (Regional Health Area A) with hospitals by hospital group.

Geographical Coverage of Regional Health Area A (RHA A): RHA A includes all of CHO9 Dublin North Central, North West Dublin and North Dublin), parts of CHO8 (Meath, Louth) and parts of CHO1 (Cavan¹³ and Monaghan), Figure 3.

Population and hospitals: According to the Census 2016, this area has a population of approximately 1,080,000 people. It comprises of two Model 4 hospitals and involves two different Hospital Groups, RCSI and Ireland East.

Academic Partners for Hospital groups in this area: The RCSI Hospital Group academic partner is the Royal College of Surgeons (RCSI), and Ireland East Hospital Group's academic partner is University College Dublin (UCD).

Existing HSE REC Cover for North-East Area.

The RECs providing cover in this area are:

¹³ A small portion of west county Cavan continues to be aligned with Sligo/ Leitrim for health services

- The HSE North East Area REC, which currently covers HSE services in counties Louth, Meath, Cavan, and Monaghan and HSE hospitals including Louth County Hospital, Our Lady of Lourdes Hospital Drogheda, Our Lady's Hospital Navan, Cavan General Hospital and Monaghan Hospital.
- Connolly Hospital REC, which covers research in Connolly Hospital.

REC reform proposed for Regional Health Area A: HSE Reference REC for the North East Area.

The HSE Reference REC for North-East Area (Regional Health Area A) will be developed from the HSE North East Area REC. This means that the new HSE Reference REC will increase the geographical area of cover to include CHO9 and will have authority to approve projects which are of national scale or involve multiple sites (at least one of which must be within the geographical area of RHA A), that are outside the remit of the NREC.

The HSE Reference REC for the North East Area (Regional Health Area A) will provide REC review to the following services:

- Community areas in: Dublin North, Dublin North Central and Dublin North West.
- After Phase 2, this REC will be authorised to provide single REC approval for studies outside the remit of the NREC which involve multiple sites and include at least one HSE funded health and social care service or one of the hospitals in this area:
 - o Beaumont Hospital
 - o Cappagh National Orthopaedic Hospital
 - o Cavan General Hospital
 - o Monaghan Hospital
 - o Connolly Hospital
 - o Louth County Hospital, Dundalk
 - o Mater Misericordiae University Hospital
 - o Our Lady's Hospital, Navan
 - o Our Lady of Lourdes Hospital Drogheda
 - o Rotunda Hospital

5.2 Midlands Area and Corporate (Regional Health Area B)

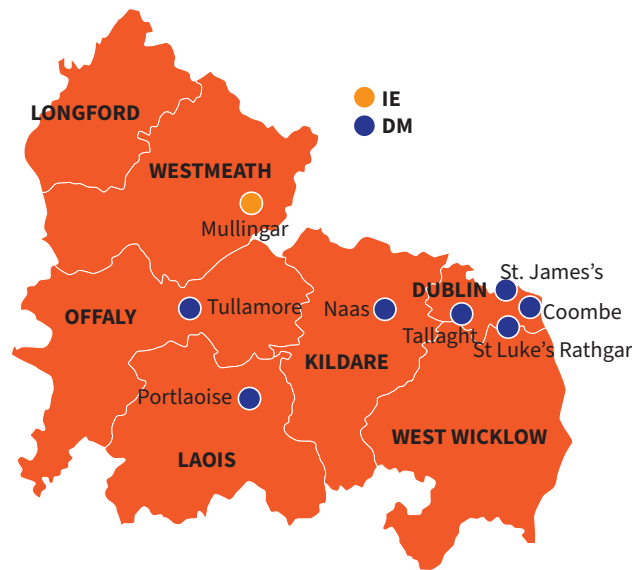


Figure 4: Midlands Area and Corporate (Regional Health Area B) with hospitals by hospital group.

Geographical Coverage of Regional Health Area B: RHA B includes all of CHO 7 (Dublin South City, Dublin South West, Dublin West, Kildare, West Wicklow) and parts of CHO8 (Laois, Offaly, Longford, Westmeath), as well as Corporate HSE Headquarters, Figure 4.

Population and hospitals: According to the Census 2016, this area has a population of approximately 1,000,000 people. It comprises two Model 4 hospitals and involves two different Hospital Groups (Ireland East and Dublin Midland). It also includes Dr Steevens' Hospital, which is the corporate headquarters of the HSE, the offices of the CEO and HSE senior leadership team, and operational headquarters of the HSE national services.

Academic Partners: Ireland East Hospital Group's academic partner is UCD, and Dublin Midland Hospital Group academic partner is Trinity College Dublin (TCD).

Existing HSE REC Cover for Midlands Area and Corporate Division (Regional Health Area B):

The RECs providing cover for this area:

- Naas General Hospital REC, which covers Naas General Hospital.
- The HSE Midlands Research Ethics Committee which currently covers counties Laois, Offaly, Longford, and Westmeath. Hospitals located in this area are the Midlands Regional Hospital Portlaoise, Midlands Regional Hospital Tullamore, and Midland Regional Hospital Mullingar. Note: since COVID-19 the HSE Midlands Research Ethics Committee has not been operational.

REC reform proposed for Regional Health Area B: HSE Reference REC for the Midlands and Corporate Divisions.

The HSE Midlands REC has not been operational due to the Covid-19 pandemic. Therefore, the HSE Reference REC for Midlands Area and Corporate Division (Regional Health Area B) will have to be re-established. The new HSE Reference REC will increase the geographical area to cover CHO 7, HSE Corporate Services and will have authority to approve projects outside the remit of the NREC which are of national scale or involve multiple sites (at least one of which must be within the geographical area of RHA B).

The HSE Reference REC for the Midlands Area and Corporate Division (Regional Health Area B) will provide REC review to the following services:

- Hospitals within the area which do not have a hospital REC: Midlands Regional Hospital Portlaoise, Midlands Regional Hospital Tullamore, and Midland Regional Hospital Mullingar.
- HSE services and funded services in community areas of Laois, Offaly, Longford and Westmeath, Dublin South City, Dublin South West, Dublin West, Kildare, West Wicklow.
- HSE Corporate Services.
- After Phase 2, this REC will be authorised to provide single REC approval for studies outside the remit of the NREC which involve multiple sites and include at least one HSE funded health and social care service or one of the hospitals in this area:
 - o Coombe Women & Infants University Hospital,
 - o St. Luke's Radiation Oncology Network,
 - o Tallaght University Hospital and St. James's Hospital Joint,
 - o Midlands Regional Hospital Portlaoise,
 - o Midlands Regional Hospital Tullamore,
 - o Midland Regional Hospital Mullingar,
 - o Naas General Hospital.

5.3 South-East Area (Regional Health Area C)



Figure 5: South-East Area (Regional Health Area C) with hospitals by hospital group.

Geographical Coverage of Regional Health Area C: South-East Area (Regional Health Area C) includes all of CHO 5 (Wexford, Carlow, Kilkenny, Waterford, South Tipperary) and parts of CHO6 (Dublin South East, Dun Laoghaire, Wicklow), Figure 5.

Population and hospitals: According to the Census 2016, this area has a population of approximately 900,000 people. It comprises two Model 4 hospitals and involves two different Hospital Groups (South/Southwest and Ireland East).

Academic Partners: The South/ Southwest academic partner is University College Cork (UCC), and Ireland East Hospital Group's academic partner is University College Dublin (UCD).

Existing HSE REC Cover for South East Area

The only REC providing cover for this area is the HSE South East Area REC covering HSE services in South Tipperary, Carlow, Kilkenny, Waterford, and Wexford. Hospitals within this REC remit are South Tipperary General Hospital, St Luke's General Hospital Kilkenny, Lourdes Orthopaedic Hospital Kilcreene, University Hospital Waterford and Wexford General Hospital.

REC reform proposed for Regional Health Area C: HSE Reference REC for the South East Area.

The HSE Reference REC for South East Area (Regional Health Area C) will be developed from the HSE South East Area REC. This means that the new HSE Reference REC will increase the geographical area of cover to include CHO 6 and will have authority to approve projects outside the remit of the NREC which are of national scale or involve multiple sites (at least one of which must be within the geographical area of RHA C). Hence, the HSE Reference REC for the South-East Area (Regional Health Area C) will provide REC review to the following services:

- Community areas in: South Tipperary, Carlow, Kilkenny, Waterford, Wexford, Dublin South East, Dun Laoghaire, Wicklow East, and South
- After Phase 2, this REC will be authorised to provide single REC approval for studies outside the remit of the NREC which involve multiple sites and include at least one HSE funded health and social care service or one of the hospitals in this area:
 - o St. Vincent's Healthcare Group (SVHG), and this includes National Rehabilitation Hospital in Dún Laoghaire, Dublin,
 - o National Maternity Hospital, Holles Street,
 - o Royal Victoria Eye & Ear Hospital,
 - o St. Michael's Hospital, Dun Laoghaire,
 - o Blackrock Clinic. Blackrock Clinic is associated with both the Royal College of Surgeons in Ireland and University College Dublin,
 - o Beacon Hospital is partnered with UCD (UCD Beacon Hospital Academy),
 - o St. John of God,
 - o South Tipperary General Hospital,
 - o St. Luke's General Hospital Kilkenny,
 - o Lourdes Orthopaedic Hospital Kilcreene,
 - o University Hospital Waterford,
 - o Wexford General Hospital,
 - o St. Columcille's Hospital Loughlinstown.

5.4 South Area (Regional Health Area D)

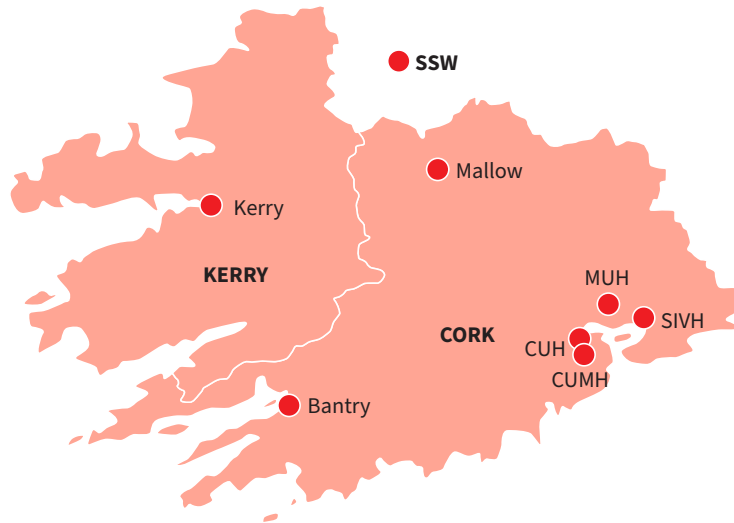


Figure 6: South Area (Regional Health Area D) with hospitals by hospital group.

Geographical Coverage of Regional Health Area D: South Area (Regional Health Area D) includes all of CHO4 (West Cork, Cork South Lee, Cork North Lee, North Cork, Kerry), Figure 6.

Population and hospitals: According to the Census 2016, this area has a population of approximately 690,000 people. It comprises one Model 4 hospitals and one Hospital Group (South/Southwest).

Academic Partners: The South/ Southwest HG academic partner is University College Cork (UCC).

Existing HSE REC Cover for South Area (Regional Health Area D):

The Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) at UCC covers:

- Cork Teaching Hospitals (comprising Cork University Hospital/Cork University Maternity Hospital, University Hospital Kerry, Mercy University Hospital, South Infirmary Victoria University Hospital, Bantry General Hospital, Mallow General Hospital)
- CHO4 (counties Kerry and Cork)

REC reform proposed for Regional Health Area D: HSE Reference REC for the South Area.

- The HSE Reference Rec for the South Area will be developed from the existing CREC. The CREC is a university based REC with responsibility for academic as well as hospital based health studies. Therefore, a Service Level Agreement (SLA), between CREC and HSE will be required to formalise the arrangement and agree on the responsibilities of each party with regards to enabling compliance with the HSE Reference REC code of practice, management, and governance.
- After Phase 2, this REC will be authorised to provide single REC approval for studies outside the remit of the NREC which involve multiple sites and include at least one HSE funded health and social care service or one of the hospitals in this area:
 - o Cork University Hospital,
 - o Cork University Maternity Hospital,
 - o University Hospital Kerry,
 - o Mercy University Hospital,
 - o South Infirmary Victoria University Hospital,
 - o Bantry General Hospital, Mallow General Hospital.

5.5 Mid-West Area (Regional Health Area E)

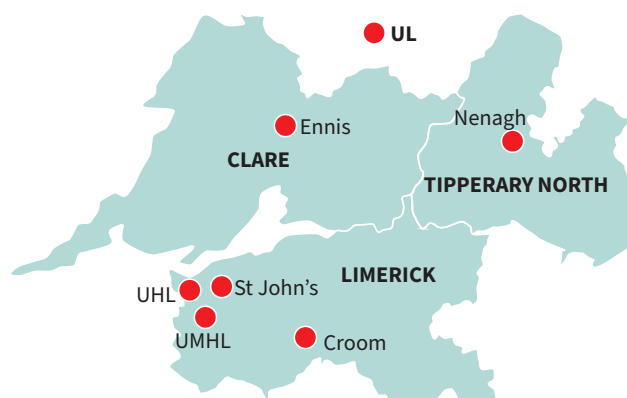


Figure 7: Mid-West Area (Regional Health Area E) with hospitals by hospital group.

Geographical Coverage for Regional Health Area E: Regional Health Area E includes all of CHO3 (Limerick, Clare, North Tipperary/East Limerick), Figure 7.

Population and hospitals: According to the Census 2016, this area has a population of approximately 390,000 people. It comprises one Model 4 hospital and one Hospital Group (University of Limerick).

Academic Partners: The University of Limerick Hospital Group's academic partner is University of Limerick (UL).

Existing HSE REC Cover for Mid-West Area (Regional Health Area E):

The HSE Mid-Western Area REC currently covers:

- Hospitals: University Hospital Limerick, University Maternity Hospital Limerick, Ennis General Hospital, Nenagh General Hospital, Croom Orthopaedic Hospital and St. John's Hospital Limerick.
- Community services in CHO 3 (Limerick, Clare, and North Tipperary)

REC reform proposed for Regional Health Area E: HSE Reference REC for the Mid-West Area.

- The HSE Reference REC for the Mid-West Area (Regional Health Area E) will be developed from the HSE Mid-Western Area REC. As the existing regional cover is already aligned to that of RHA E, there will be no changes to the geographical cover in the first instance.

- After Phase 2, this REC will be authorised to provide single REC approval for studies outside the remit of the NREC which involve multiple sites and include at least one HSE funded health and social care service or one of the hospitals in this area:
 - o University Hospital Limerick,
 - o University Maternity Hospital Limerick,
 - o Ennis General Hospital,
 - o Nenagh General Hospital,
 - o Croom Orthopaedic Hospital,
 - o St. John's Hospital Limerick.

5.6 West/ North West Area (Regional Health Area F)



Figure 8: West/ North West Area (Regional Health Area F) with hospitals by hospital group.

Geographical Coverage for Regional Health Area F: West/North-West Area (Regional Health Area F) includes all of CHO2 (Galway, Mayo, Roscommon) and part of CHO1 (Sligo, Leitrim, Donegal) (see Figure 8).

Population and hospitals: According to the Census 2016, this area has a population of approximately 710,000 people. It comprises one Model 4 hospital and one Hospital Group (Saolta).

Academic Partners: The Saolta Hospital Group academic partner is National University of Ireland, Galway (NUIG).

Existing HSE REC Cover for North/North-West Area (Regional Health Area F):

There are four HSE RECs in this area:

- Galway University Hospitals REC, which covers University Hospital Galway, Merlin Park University Hospital, Portiuncula University Hospital, Roscommon University Hospital, and HSE Community Services in Galway and surrounding areas.
- Mayo University Hospital REC, which covers research in Mayo University Hospital. It occasionally reviews research taking place in HSE Community Services in surrounding areas.
- Sligo University Hospital REC, which covers research in Sligo University Hospital. It occasionally covers research taking place in HSE Community Services in surrounding areas.
- Letterkenny University Hospital REC, which covers research in Letterkenny University Hospital. It occasionally covers research taking place in HSE Community Services in surrounding areas.

REC reform proposed for Regional Health Area F: HSE Reference REC for the West and North West. It is proposed that the HSE Reference REC for this area will be created from the existing HSE Galway University Hospitals REC as this is the REC with the largest amount of activity. As all the hospitals within this region already have a REC, the establishment of the Galway University Hospitals REC as a HSE Reference REC will increase the remit of the existing committee to cover HSE community Services in the whole region. The remainder of the RECs will continue operations as normal for hospital based research.

As all the hospitals within this area are HSE hospitals, a more effective model may involve the coordination of all the RECs in the area as a single committee or a single committee with hub and spokes. The best model for this area will be scoped during phase 2-4 of this roadmap in consultation with the relevant RECs.

After Phase 2, this REC will be authorised to provide single REC approval for studies, outside the remit of the NREC, which involve multiple sites and include at least one HSE funded health and social care service or one of the hospitals in this area:

- o University Hospital Galway,
- o Mayo University Hospital,
- o Sligo University Hospital,
- o Letterkenny University Hospital,
- o Roscommon University Hospital,
- o Portiuncula University Hospital.

5.7 Children's Health Ireland (CHI)

Geographical Coverage and Hospitals: Children's Health Ireland (CHI) was established, in December 2018, following the enactment of the Children's Health Act 2018 (No 27 of 2018) in November 2018. CHI is one of the seven hospital groups and operates as a single service across the existing Dublin children's hospitals, CHI at Crumlin, CHI at Temple Street, CHI at Tallaght and CHI at Connolly. CHI governs and operates local paediatric services for the Greater Dublin Area and all national paediatric specialist services, some of which are on an all-island basis.

The vision of the National Model of Care for Paediatric Healthcare Services in Ireland¹⁴ places the new children's hospital on a shared campus with St. James's Hospital, Dublin. This new site will be the epicentre of a network of care that will reach every community in Ireland, through satellites and regional centres, to deliver comprehensive paediatric care for Ireland's children and young people. It is planned that the new children's hospital will open in 2024. The first of the paediatric outpatients and urgent care centres, Connolly Hospital, was opened in July 2019 and Tallaght University Hospital opened in November 2021.

Population: CHI treats children from birth up to their 16th birthday. Neonates, infants, children, and adolescents from both the Republic of Ireland and Northern Ireland attend CHI.

Academic Partners: Dublin City University (DCU), Royal College of Surgeons in Ireland (RCSI), Trinity College Dublin (TCD), and University College Dublin (UCD).

Existing REC Cover for CHI: Prior to the establishment of CHI, each of the paediatric hospitals in Dublin had their own REC (see Appendix 2). These RECs were located in CHI at Crumlin and CHI at Temple Street. CHI at Tallaght submitted applications to the Tallaght University Hospital/St James Hospital Joint REC.

REC reform for CHI: Formation of a single unified REC for CHI. In September 2021 the existing REC in CHI at Crumlin (formerly Our Lady's Children's Hospital Crumlin) and CHI at Temple Street (formerly Temple Street Children's University Hospital) were amalgamated into a unified CHI REC and Research Ethics Office. This unified CHI REC will also review all paediatric research studies performed in both CHI at Tallaght University Hospital and CHI at Connolly hospitals. To facilitate this merger, a full-time Research Ethics Officer and Research Ethics Office Administrator were appointed. In October 2021, the unified CHI REC began reviewing research ethics application, thus, completing phase 1.

Engagement with CHI is ongoing to determine the suitability and practicalities of the CHI REC becoming a HSE Reference REC.

¹⁴ <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/vision-for-paediatric-health-services.pdf>

Appendices

Appendix 1: Members of the HSE REC Reform Working Group

Name	Position	Representing
Dr Ana Terrés (Chair)	Director of Research & Evidence, HSE	HSE Research and Evidence
Dr Claire Collins	Director of Research & Innovation, Irish College of General Practitioners	Irish College of General Practitioners
Dr Ruben E. Keane	Quality and Regulatory Affairs Manager	National Clinical Trials Office (NCTO)
Dr Rachel Crowley	Consultant Endocrinologist and Chair of SVUH REC	Ireland East Hospital Group Rep
Prof Gerard Curley	Consultant in Anaesthesiology and Critical Care, Head of Department of Anaesthesia, RCSI & Beaumont Hospital	RCSI Hospital Group Rep
Prof Patrick Dillon	Consultant Anaesthesiologist and Chair of HSE Mid-Western Area REC	ULHG/ 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
Prof David Kerins	Consultant Cardiologist and Chair of Cork Clinical REC	South/ South West Hospital Group Rep
Ms Caroline Lamb	Research Ethics Committee Coordinator, HSE South East Area REC	HSE South-Eastern Area Rep
Peter Lennon	Research Services and Policy Unit	Department of Health
Prof Gerard Loftus	Emeritus Professor of Paediatrics, NUIG and Chair of Galway University Hospitals REC	Saolta Hospital Group Rep
Ms Rosalie Smith-Lynch	Regional Manager Consumer Affairs, HSE Dublin North East, member of HSE North East Area REC	HSE North East Area REC

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 Rep
Kara Madden	Patient and Public Involvement Advisor	HSE Research and Development Patient and Public Involvement Reference Group
Dr Gemma Moore	Qualitative Evaluation and Research Officer	HSE National Quality Improvement Team
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 Rep
Lynne McGlynn	Research Ethics Officer, Beaumont REC	Beaumont Hospital REC
Dr Declan O'Hanlon	General Manager Research and Development, HSE	HSE Research and Development
Dr Sadhbh O'Neill	Co-ordinator of TUH/ SJH Joint Research Ethics Committee	Midlands Hospital Group Rep
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 Rep
Ms Aileen Sheehy	Programme Manager	National Office for Research Ethics Committees

This project has been managed by senior members of the HSE National R&D team from 2019 to date, including Mary Claire O'Hara, Maeve Smyth, Dr. Hazel Smyth and Dr. Virginia Minogue.

Appendix 2: Existing Research Ethics Committees

Table 1: RECs' Area of Responsibility for CHO-based Research (non-CTIMPs)

CHO	County/ Region	REC
1	Donegal	None currently available but Letterkenny University Hospital & Galway University Hospitals Research Ethics Committees will accept applications
1	Sligo	None currently available Sligo University Hospital & Galway University Hospitals Research Ethics Committees will accept applications
1	Leitrim	None currently available but Galway University Hospitals Research Ethics Committee will accept applications
1	Cavan	HSE North East Area Research Ethics Committee
1	Monahan	HSE North East Area Research Ethics Committee
2	Galway	Galway University Hospitals Research Ethics Committee
2	Roscommon	None currently available but Galway University Hospitals Research Ethics Committee will accept applications
2	Mayo	None currently available but Mayo University Hospital & Galway University Hospitals Research Ethics Committees will accept applications
3	Clare	HSE Mid-Western Area Research Ethics Committee
3	Limerick	HSE Mid-Western Area Research Ethics Committee
3	North Tipperary	HSE Mid-Western Area Research Ethics Committee
4	Kerry	None currently available but the Clinical Research Ethics Committee of Cork Teaching Hospitals at UCC will accept applications
4	North Cork	None currently available but the Clinical Research Ethics Committee of Cork Teaching Hospitals at UCC will accept applications
4	North Lee	None currently available but the Clinical Research Ethics Committee of Cork Teaching Hospitals at UCC will accept applications
4	South Lee	None currently available but the Clinical Research Ethics Committee of Cork Teaching Hospitals at UCC will accept applications
4	West Cork	None currently available but the Clinical Research Ethics Committee of Cork Teaching Hospitals at UCC will accept applications
5	South Tipperary	HSE South-Eastern Area Research Ethics Committee
5	Carlow	HSE South-Eastern Area Research Ethics Committee
5	Kilkenny	HSE South-Eastern Area Research Ethics Committee
5	Wexford	HSE South-Eastern Area Research Ethics Committee
5	Waterford	HSE South-Eastern Area Research Ethics Committee

6	Wicklow	None currently available
6	Dun Laoghaire	None currently available
6	Dublin South East	None currently available
7	Kildare	None currently available but Naas General Hospital Research Ethics Committee will sometimes accept applications
7	West Wicklow	None currently available but Tallaght University Hospital/ St James Hospital Joint Research Ethics Committee will sometimes accept applications
7	Dublin West	None currently available but Tallaght University Hospital/ St James Hospital Joint Research Ethics Committee will sometimes accept applications
7	Dublin South City	None currently available but Tallaght University Hospital/ St James Hospital Joint Research Ethics Committee will sometimes accept applications
7	Dublin South West	None currently available but Tallaght University Hospital/ St James Hospital Joint Research Ethics Committee will sometimes accept applications
8	Laois	None currently available -HSE Midlands Area Research Ethics Committee was suspended due to Covid-19 work and is to be re-formed
8	Offaly	None currently available - HSE Midlands Area Research Ethics Committee was suspended due to Covid-19 work and is to be re-formed
8	Westmeath	None currently available -HSE Midlands Area Research Ethics Committee was suspended due to Covid-19 work and is to be re-formed
8	Louth	HSE North East Area Research Ethics Committee
8	Meath	HSE North East Area Research Ethics Committee
9	Dublin North	None currently available
9	Dublin North Central	None currently available
9	Dublin North West	None currently available

Table 2: RECs' Areas of Responsibilities for Hospital-based Research (non-CTIMPs)

Hospitals	REC
Bantry General Hospital	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
Beaumont Hospital	Beaumont Hospital Ethics (Medical Research) Committee
Cappagh National Orthopaedic Hospital	Cappagh National Orthopaedic Hospital Research Ethics Committee
Cavan Monaghan Hospital	HSE North East Area Research Ethics Committee
CHI at Temple Street (formerly known as Children's University Hospital, Temple Street)	CHI Research Ethics Committee (formerly known as Temple Street Children's University Hospital Research Ethics Committee)*
Connolly Hospital, Blanchardstown	Connolly Hospital Research Ethics Committee
Coombe Women and Infants University Hospital	Coombe Women and Infants University Hospital Research Ethics Committee
Cork University Hospital	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
Cork University Maternity Hospital	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
Croom Orthopaedic Hospital	HSE Mid-Western Area and University of Limerick Hospital Group Research Ethics Committee
Ennis General Hospital	HSE Mid-Western Area and University of Limerick Hospital Group Research Ethics Committee
Galway University Hospitals (University Hospital Galway (UHG) and Merlin Park University Hospital (MPUH))	Galway University Hospitals Research Ethics Committee
Kerry General Hospital	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
Letterkenny University Hospital	Letterkenny University Hospital Research Ethics Committee
Lourdes Orthopaedic Hospital, Kilcreene	HSE South-Eastern Area Research Ethics Committee
Louth County Hospital, Dundalk	HSE North East Area Research Ethics Committee
Mallow General Hospital	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
Mater Misericordiae University Hospital	Mater Misericordiae University Hospital & Mater Private Hospital REC
Mayo University Hospital	Mayo University Hospital Research Ethics Committee
Mercy University Hospital, Cork	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork

Hospitals	REC
Midland Regional Hospital Mullingar	None currently available -Midlands Research Ethics Committee has not been operational due to the Covid-19 pandemic. It is in the process of being re-established.
Midland Regional Hospital Portlaoise	None currently available -Midlands Research Ethics Committee has not been operational due to the Covid-19 pandemic. It is in the process of being re-established.
Midland Regional Hospital Tullamore	None currently available -Midlands Research Ethics Committee has not been operational due to the Covid-19 pandemic. It is in the process of being re-established.
Naas General Hospital	Naas General Hospital Research Ethics Committee
National Maternity Hospital, Holles Street	National Maternity Hospital Ethics Research Committee,
Nenagh General Hospital	HSE Mid-Western Area and ULHG Research Ethics Committee
Our Lady Of Lourdes Hospital, Drogheda	HSE North East Area Research Ethics Committee
Our Lady's Hospital, Navan	HSE North East Area Research Ethics Committee
Children's Health Ireland at Crumlin (formerly known as Our Lady's Children's Hospital, Crumlin)	CHI Research Ethics Committee (formerly known as Our Lady's Children's Hospital Crumlin Research Ethics Committee)*
Portiuncula University Hospital, Ballinasloe	Galway University Hospitals Research Ethics Committee
Roscommon University Hospital	Galway University Hospitals Research Ethics Committee
Rotunda Hospital	Rotunda Hospital Research Ethics Committee
Royal Victoria Eye and Ear Hospital, Dublin	Royal Victoria Eye & Ear Hospital Research Ethics Committee
Sligo University Hospital	Sligo University Hospital Research Ethics Committee
South Infirmary-Victoria Hospital, Cork	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
South Tipperary General Hospital	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
St. Columille's Hospital, Loughlinstown	St. Vincent's Healthcare Group Ethics and Medical Research Committee
St. James's Hospital	Tallaght University Hospital/ St James Hospital Joint Research Ethics Committee
St. John's Hospital Limerick	HSE Mid-Western Area and University of Limerick Hospital Group Research Ethics Committee
St. Luke's General Hospital Carlow / Kilkenny	HSE South-Eastern Area Research Ethics Committee

Hospitals	REC
St. Luke's Hospital, Rathgar (Cancer Services)	St. Luke's Hospital Research Ethics Committee
St. Michael's, Dun Laoghaire	St. Vincent's Healthcare Group Ethics and Medical Research Committee
St. Vincent's University Hospital, Elm Park	St. Vincent's Healthcare Group Ethics and Medical Research Committee
Tallaght University Hospital	Tallaght University Hospital/ St James Hospital Joint Research Ethics Committee*
University Hospital Limerick	HSE Mid-Western Area and University of Limerick Hospital Group Research Ethics Committee
University Maternity Hospital Limerick	HSE Mid-Western Area and University of Limerick Hospital Group Research Ethics Committee
University Hospital Waterford	HSE South-Eastern Area Research Ethics Committee
Wexford General Hospital	HSE South-Eastern Area Research Ethics Committee

* With the establishment of Children's Health Ireland: CHI at Crumlin (formerly known as Our Lady's Children's Hospital Crumlin) and CHI at Temple Street (formerly known as Children's University Hospital, Temple Street) have amalgamated their RECs.

Table 3: RECs recognised under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 for reviewing and approving CT-IMPs by the Department of Health and currently operating in a mixed model system with the NREC until the end of 2021 for the approval of Clinical Trials of Investigational Medicinal Products.

1	Beaumont Hospital Ethics (Medical Research) Committee
2	Clinical Research Ethics Committee of the Cork Teaching Hospitals at University College Cork
3	Tallaght University Hospital/ St. James's Hospital Joint Research Ethics Committee
4	Galway University Hospitals Research Ethics Committee
5	HSE North East Area Research Ethics Committee
6	HSE South Eastern Area Research Ethics Committee
7	Irish College of General Practitioners Research Ethics Committee
8	Mater Misericordiae University Hospital/ Mater Private Hospital Institutional Review Board
9	National Maternity Hospital Holles Street Research Ethics Committee
10	Children's Health Ireland (previously known as Our Lady's Children's Hospital Crumlin) Research Ethics Committee
11	St. Vincent's Healthcare Group Ethics and Medical Research Committee
12	HSE Mid-Western Area and University of Limerick Hospital Group Research Ethics Committee
	Also REC(s) Recognised by the Department of Health for reviewing study of ionising radiation: St. Luke's Radiation Oncology Network Research Ethics Committee

Appendix 3: Phase 2 Engagement

The following RECs will be included in Phase 2 engagement:

RHA A

- Beaumont Hospital REC
- Cappagh National Orthopaedic Hospital REC
- The Mater Misericordiae University Hospital and Mater Private Hospital Institutional Review Board
- Rotunda Hospital Dublin REC
- Connolly Hospital REC
- Bon Secours Health System Research Ethics Sub-Committee (Hospital is Bon Secours Hospital, Dublin)
- The Mater Misericordiae University Hospital and Mater Private Hospital Institutional Review Board (Hospital is Mater Private Dublin)
- Sports Surgery Clinic REC (Hospital is Sports Surgery Clinic)

RHA B

- Coombe Women & Infants University Hospital REC
- St. Luke's Radiation Oncology Network REC
- Tallaght University Hospital and St. James's Hospital Joint REC

RHA C

- St. Vincent's Healthcare Group (SVHG) REC; this includes National Rehabilitation Hospital in Dún Laoghaire, Dublin
- National Maternity Hospital, Holles Street
- Royal Victoria Eye & Ear Hospital
- St. Michael's Hospital, Dun Laoghaire
- Blackrock Clinic REC. Blackrock Clinic is associated with both the Royal College of Surgeons in Ireland and University College Dublin
- Beacon Hospital REC. Beacon Hospital is partnered with UCD (UCD Beacon Hospital Academy)
- St. John of God REC.
- Laura Lynn REC.

RHA D

- Mercy University Hospital
- South Infirmary-Victoria University Hospital
- University College Cork
- Bon Secours Health System Research Ethics Sub-Committee (Hospitals are Bon Secours Hospital, Cork and Tralee)

RHA E

- University of Limerick Hospital Group REC
- St. John's Hospital, Limerick REC
- Bon Secours Health System Research Ethics Sub-Committee (Hospitals is Bon Secours Hospital Limerick at Barrington's)

RHA F

- Bon Secours Health System Research Ethics Sub-Committee (Hospitals is Bon Secours Hospital Galway)

Appendix 4: Phase 3 Engagement

List of academic institution health and social care RECs per Regional Health Area:

RHA A

- Royal College of Surgeons (RCSI)
- University College Dublin (UCD)
- Other providers of third level education, where applicable, within the North-East Area

RHA B

- University College Dublin (UCD)
- Trinity College Dublin (TCD)
- Other providers of third level education, where applicable, in the Midlands

RHA C:

- University College Dublin (UCD)
- University College Cork (UCC)
- Other providers of third level education, where applicable, in the South-East

RHA D:

- University College Cork (UCC)
- Other providers of third level education, where applicable, in the South

RHA E:

- University of Limerick (UL)
- Other providers of third level education, where applicable, in the Mid-West

RHA F:

- National University of Ireland, Galway (NUIG)
- Other providers of third level education, where applicable, in the West/ North-West

Glossary

CHI:	Children's Health Ireland (Children's Hospital Group)
COVID-19:	Coronavirus Disease
CRF/C:	Clinical Research Facility/ Centre
CTIMP:	Clinical Trial of Investigational Medicinal Product
CHOs:	Community Healthcare Organisations
GDPR:	General Data Protection Regulation
HPRA:	Health Products Regulatory Authority
HRR:	Health Research Regulations
HSE:	Health Service Executive
HSE Rec SCO	HSE Research Ethics Committee Support and Coordination office
HGs:	Hospital Groups
ICGP:	Irish College of General Practitioners
MoU:	Memorandum of Understanding
NCTO:	National Clinical Trials Organisation
NREC:	National Research Ethics Committee
NUIG:	National University of Ireland, Galway
PPI:	Patient and Public Involvement
REC:	Research Ethics Committee
RGMS:	Research Governance Management Support
RHA:	Regional Health Area
RREC:	Reference Research Ethics Committee
R&D:	Research and Development
R&E:	Research and Evidence
RCSI:	Royal College of Surgeons in Ireland
SJH:	Saint James's Hospital
SOP:	Standard Operating Procedure
TCD:	Trinity College Dublin
TUH:	Tallaght University Hospital
UCC:	University College Cork
UCD:	University College Dublin
UL:	University of Limerick