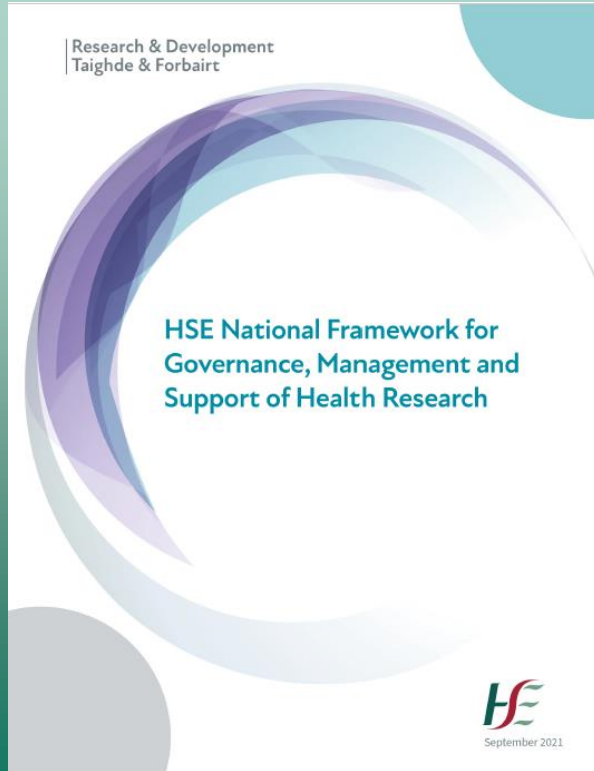


## **Implementation of the HSE National Framework for the Governance, Management and Support of Research**

# **Roadmap for the reform of the HSE Research Ethics Committees**

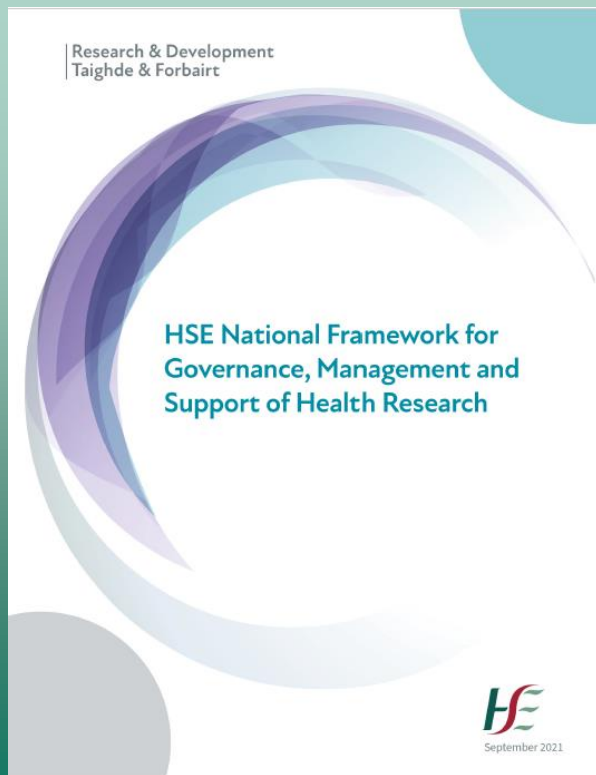
**Dr. Ana Terrés,  
Head of Research and Evidence**

**3 November 2021**



# The HSE framework for the Governance, Management and Support of Research

- **Principles** for the **governance** and **management** of health research in the HSE
- **Roles** and **responsibilities**
- **Structures** to put it into practice
- **Processes** to support staff



# RGMS Framework Implementation- national requirements:

- 1. Reform of the HSE Research Ethics Committee System
- 2. Establish RGMS functions at local level
- 3. Roll out a national electronic research management system
- 4. Establish the National RGMS oversight committee
- 5. Develop relevant policies and standard codes of practice.

# Research Ethics Committees in HSE and HSE funded services

## The current landscape

- **2021: Transition of authority from ‘recognised RECs’ to National Research Ethics Committee (NREC) for approvals of Clinical Trials of Investigational Medicinal products (CTIMPs)**
- **National Research Ethics Committee commenced operations in May 2021:**
  - Clinical Trials of Investigational Medicinal Products (NREC-CT)
  - Clinical Investigations of Medical Devices (NREC-MD)

## The current picture - continuation

- **All other studies (not under the NREC remit) are the responsibility of the Research Ethics Committees in HSE and HSE funded services.**
  - Approx. 32 RECs
  - Review approx. 2,000 proposals/ year
  - Combination of Regional RECs (CHO and Hospital cover) plus hospital/service based
- **Many deficits:**
  - Large areas of community services have no access to REC
  - Covid 19 Pandemic – severe pressure on existing RECs – Midlands REC stood down
  - Differences in approach to reviews and application forms
  - Demands placed on RECs due to lack of other research governance/management structures.
  - Multiple REC approvals required for studies involving several sites



## 16 Hospital RECs in this region but no coverage for community services

1. Cappagh Hospital REC
2. Children's Health Ireland
3. Connolly Hospital REC
4. Coombe Hospital REC
5. National Rehabilitation Hospital REC
6. Rotunda Hospital REC
7. Royal Victoria Eye & Ear REC
8. St Luke's REC
9. Stewards Hospital REC
10. St John of God REC
11. St Michaels House REC
12. Beaumont Hospital REC
13. National Maternity Hospital REC
14. St James/ Tallaght REC
15. St Vincent's REC
16. Mater Misericordiae REC

# The REC Reform Working Group

Name	Position	Representing
<b>Dr Ana Terrés (Chair)</b>	HSE Assistant National Director, Head of Research & Evidence	HSE Research and Evidence
<b>Dr Hazel A Smith (Project Manager)</b>	Senior R&D Manager (Research Ethics Governance and Support Services)	HSE Research and Development
<b>Dr Claire Collins</b>	Director of Research & Innovation, Irish College of General Practitioners	Irish College of General Practitioners
<b>Ms Fiona Clegg</b>	Quality and Regulatory Affairs Manager & Data Protection Officer	Health Research Board Clinical Research Co-ordination Ireland
<b>Dr Rachel Crowley</b>	Consultant Endocrinologist and former Chair of SVUH REC	Ireland East Hospital Group Rep
<b>Prof Gerard Curley</b>	Consultant in Anaesthesiology and Critical Care, Head of Department of Anaesthesia, RCSI & Beaumont Hospital	RCSI Hospital Group Rep
<b>Prof Patrick Dillon</b>	Consultant Anaesthesiologist and Chair of HSE Mid-Western Area REC	UL Hospital Group/ HSE Mid-Western Area
<b>Dr Úna Fallon</b>	Public Health Specialist and Chair of HSE Midlands Area REC	HSE Midlands Area REC
<b>Dr Jennifer Ralph James</b>	Head of Office	National Office for Research Ethics Committees
<b>Prof David Kerins</b>	Consultant Cardiologist and Chair of Cork Clinical REC	South/ South West Hospital Group Rep
<b>Ms Caroline Lamb</b>	Research Ethics Committee Coordinator, HSE South East Area REC	HSE South-Eastern Area Rep
<b>Peter Lennon</b>	Research Services and Policy Unit	Department of Health
<b>Prof Gerard Loftus</b>	Emeritus Professor of Paediatrics, NUIG and Chair of Galway Clinical REC	Saolta Hospital Group Rep

# The REC Reform Working Group

Name	Position	Representing
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 Advisory	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 Lukes 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



# Objectives of the HSE REC Reform

- **Equity of access** to ethical review for research : full coverage including all S38, S39 and HSE community services.
- **Effective and efficient system:**
  - Enable **single REC review for multi-site** studies.
  - Enable **standardised approach** to the review process
  - Integrated with other research ethics committees –**cohesive approach to a national mix model of RECs.**

# Objectives of the HSE REC Reform

- REC review **processes** integrated with overall processes for **research governance**.
- **Increase capacity** to ensure all projects involving patients, service users, their data or samples are reviewed by a HSE REC.
- **Increase consistency and quality** of research ethics review processes for the RECs.
- A sustainable REC system, built on existing structures, that is appropriately **valued, respected** and **supported**.

# The REC Reform Roadmap: a Phased Approach



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# HSE REC Reform –PHASE 1

- Establishment of **six HSE Reference RECs** aligned to each of Regional Health Areas.
- Reference RECs will be formed **building on existing RECs where possible**, by modifying and putting in place structures to support them.
- Reference RECs will cover **all HSE organisations and all S38 and S39 which do not currently have access to a REC.**



# What is a HSE Reference REC?

- HSE Reference RECs are RECs that:
  - operate to the same **standard Code of Practice, Management and Governance** –currently being developed
  - Are **supported** by the National HSE REC Coordination and Support office (currently being established)
  - **report** to a National Committee for the Governance, Management, and Support of Research (to be operational in early 2022) – **REC appointing authority.**

# HSE REC Standard Code of Practice – a summary

- **Explains the remit** of the HSE Reference RECs vs the National Research Ethics Committees, hospital based RECs and academic RECs
- **Governance and Management** of HSE Reference RECs
- **Membership and Recruitment** of Members for HSE Reference RECs
- **Financial** considerations for HSE Reference RECs
- **Integration** of the HSE REC review with **Research Governance, Management and Support Functions.**
- **Activities that REC review**
- **Standard Operating Procedures** for HSE Reference REC

# HSE RRECs Support and Coordination Office

- The office is currently being established as part of National HSE R&D
- Office will be responsible for **implementing the REC reform** according to the Roadmap.
- Will support HSE RRECs with **recruitment, training** of members and with implementation of all relevant **operational protocols**.
- The SCO will develop a **quality assurance program** to ensure RREC compliance with the standard code of practice.
- Provide supports to REC for the implementation and use of the **Electronic Research Management System**.

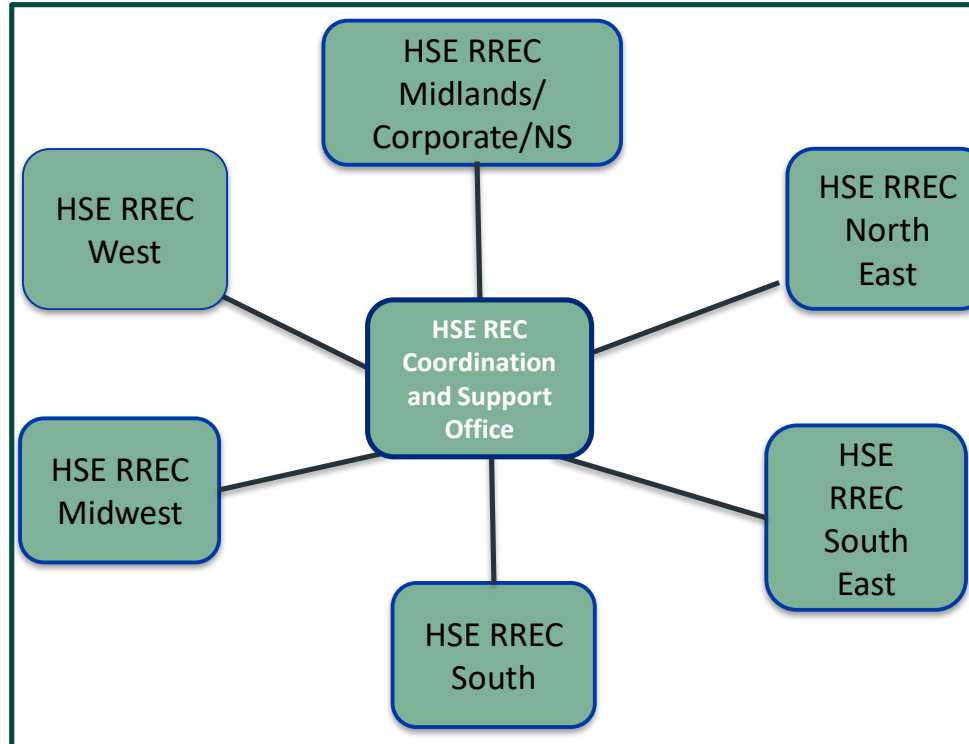


# HSE National RGMS Oversight Committee as the HSE RREC Appointing Authority

- Responsible for ensuring the implementation of the RGMS framework delivers a cohesive national research governance system.
- With respect to RECs:
  - RREC **oversight** but no role in ethical decision making
  - **Nomination/suspension** of HSE Reference RECs
  - Reviewing **annual reports**
  - Ensuring **sustainability**
  - Ensuring **compliance** with HSE RREC standard code of practice
  - Driving **integration** with other health RECs and cohesion with NREC
  - **Transparency** about HSE RREC activity with the public



# REC Appointing Authority



# HSE REC Reform –PHASE 2 - 3

- Establish agreed ways of working with other RECs to enable **single approval for multisite studies** by engagement with other RECs:
  - **S38 Hospitals**
  - **HSE Hospitals**
  - **Private Hospitals**
  - **Universities**
- Simplification of the dual approach to Academic/HSE REC approval by engagement with academic partners.



# The REC Reform Roadmap for each regional health area



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## Proposed new RHA A with its hospitals



### \* Hospitals in RHA A currently covered by HSE North East REC

- Cavan General Hospital
- Monaghan Hospital
- Connolly Hospital
- Louth County Hospital, Dundalk
- Our Ladies Hospital, Navan
- Our Ladies of Lourdes Hospital,

Drogheda

### Hospitals in RHA A with own REC\*

- Beaumont Hospital
- The Rotunda
- Cappagh Hospital
- Mater Hospital

## Proposed Reference REC for RHA A:

### HSE Reference REC for North East Area

- RHA A covers all of CHO 9, parts of CHO 8 and 1 and relevant hospitals \*
- There are 11 hospitals in this area and it involves 2 HGs (IEHG and RCSI)
- HSE North East Area REC already exist – New RREC will expand cover to include CHO 9 (currently has no REC cover).



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## Proposed new RHA B with its hospitals



### \* HSE Hospitals in RHA B

- MRH Mullingar
- MRH Portlaoise
- MRH Tullamore
- Naas General Hospital

### Hospitals in RHA B with own REC

- The Coombe
- Tallaght Hospital
- St James's Hospital
- St Luke's Hospital

## Proposed Reference REC for RHA B:

### HSE RREC for Midlands/Corporate/NS

- RHA B covers all of CHO 7 and parts of CHO 8 and hospitals \*
- There are 9 hospitals in this area (2 x model 4) and it involves 2 HGs (IEHG and DMHG)
- HSE Midlands REC existed before Covid 19 – New RREC will be re-established and **will expand cover to include CHO7 (currently has no REC cover).**

## Proposed new RHA C with its hospitals



### \* HSE Hospitals in RHA C

- Lourdes Orthopaedic Hospital, Kilcreene
- St Colmcilles Hospital
- St Lukes, Kilkenny
- South Tipperary Hospital
- Waterford UH
- Wexford General Hospital

### Hospitals in RHA B with own REC

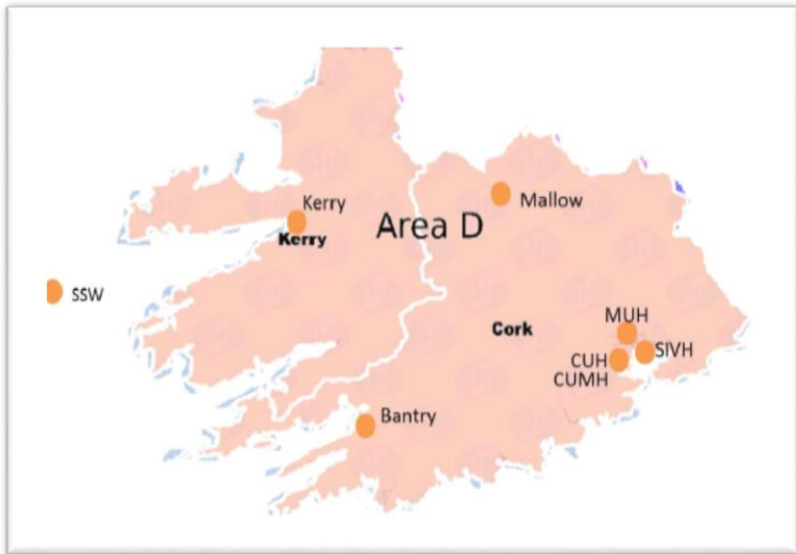
- National Maternity Hospital
- Royal Victoria E&E
- St Vincents UH
- St Michaels Hospital, Dun Laoghaire

## Proposed Reference REC for RHA C:

### HSE Reference REC for South East Area

- RHA C covers all of CHO 5 and CHO 6 and relevant hospitals\*
- There are 10 hospitals in this area and it involves 2 HGs (IEHG and SSWHG)
- HSE South East REC currently exist – New RREC will be **expand cover to include CHO6 (currently has no REC cover).**

## Proposed new RHA D with its hospitals



### \* HSE Hospitals in RHA D

- Bantry General Hospital
- CUH
- CUMH
- Mallow General Hospital
- UH Kerry
- Mercy UH
- South Infirmary Victoria UH

**No Hospital based RECs in this area.**

## Proposed Reference REC for RHA D:

### HSE Reference REC for South Area

- RHA D covers all of CHO 4 and hospitals \*
- There are 7 hospitals in this area and it involves 1 HG (SSWHG).
- Current REC for this area is the Clinical Research Ethics Committee of the Cork Teaching Hospitals (Academic REC)
- Only change is HSE RREC to (formally) include research in CHO 4. Need agreement with UCC.

## Proposed new RHA E with its hospitals



### HSE Hospitals in RHA E

- Croom Hospital
- Ennis Hospital;
- Nenagh Hospital
- University Hospital Limerick
- University Maternity Hospital Limerick
- St John's Hospital, Limerick

**No Hospital based RECs in this area.**

## Proposed Reference REC for RHA E: HSE Reference REC for the Midwestern Area

- RHA E covers all of CHO 3 and hospitals in the region.
- There are 6 hospitals in this area (1 x model 4) and it involves 1 HG (ULHG)
- This area is currently served by the HSE Midwest REC and the area of coverage for the HSE RREC for Midwestern Area would be the same.

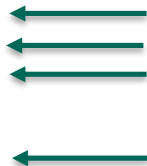


## Proposed new RHA F with its hospitals



### \* HSE Hospitals in RHA F

- Galway UH
- Letterkenny UH
- Mayo UH
- Portlincula UH
- Roscommon UH
- Sligo UH



Hospitals in RHA B  
with own REC (all  
HSE)

## Proposed Reference REC for RHA F:

### HSE Reference REC for West Area

- RHA F covers all of CHO 2 and part of CHO 1 and relevant hospitals \*
- There are 6 hospitals in this area and it involves 1 HG (Saolta)
- Various possible models for this area:
  - 1 HSE RREC + single hospitals RECs
  - Hub (GUH REC) – Spoke model
  - RECs merge into a single REC

# HSE REC Reform –PHASE 4-5

## Long term possibilities still to be scoped properly

- Mutual recognition between HSE RRECs and Hospital based RECs – possible or merge of HSE RRECs and Hospital based RECs
- Whole system operation as a single national HSE REC



# Proposed timeline for the implementation of the RoadMap

## 2021

- Finalise the Standard Code of Practice, Governance and management for HSE Reference RECs.
- Establishment of the National HSE REC Support and Coordination office
- Establishment of the REC Appointing Authority

## 2022-23

- Establishment of six HSE RRECs operating to the standard Code of Practice, to provide support to HSE services and S38 and S39 who do not already have a REC
- Establish the protocols with hospital RECs to enable HSE RREC approvals for multisite studies.
- Agreements with private hospitals
- Agreement with Universities for simplification.