HSE Research & Development

Making Research Governance Easier

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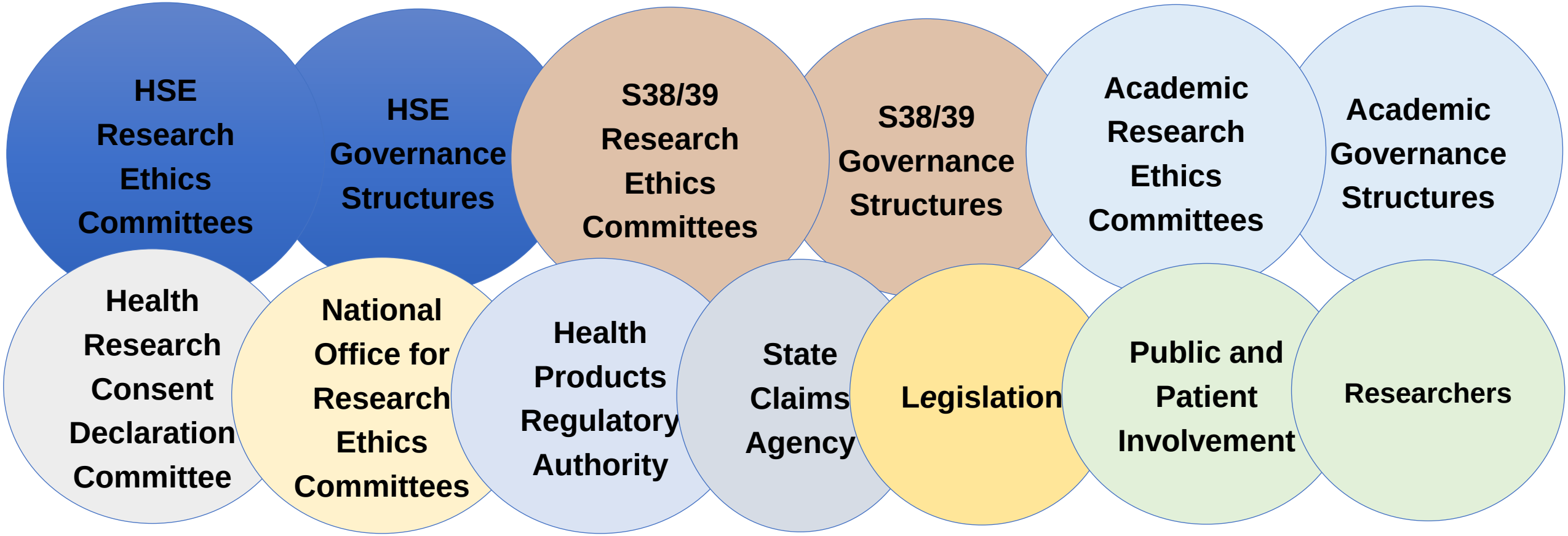
Many stakeholders but do we have a research enabling system?



"the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods"

Basic and Applied Biomedical

Understanding normal & abnormal functioning at the mollecular, cellular, organ system & whole body levels.

Health Service

Improving the efficiency & effectiveness of health professionals & the healthcare system.

Population Health

Improving the health of the population through a better understanding of the ways in which social, cultural, environmental, occupational & economic factors determine health outcomes.

Clinical

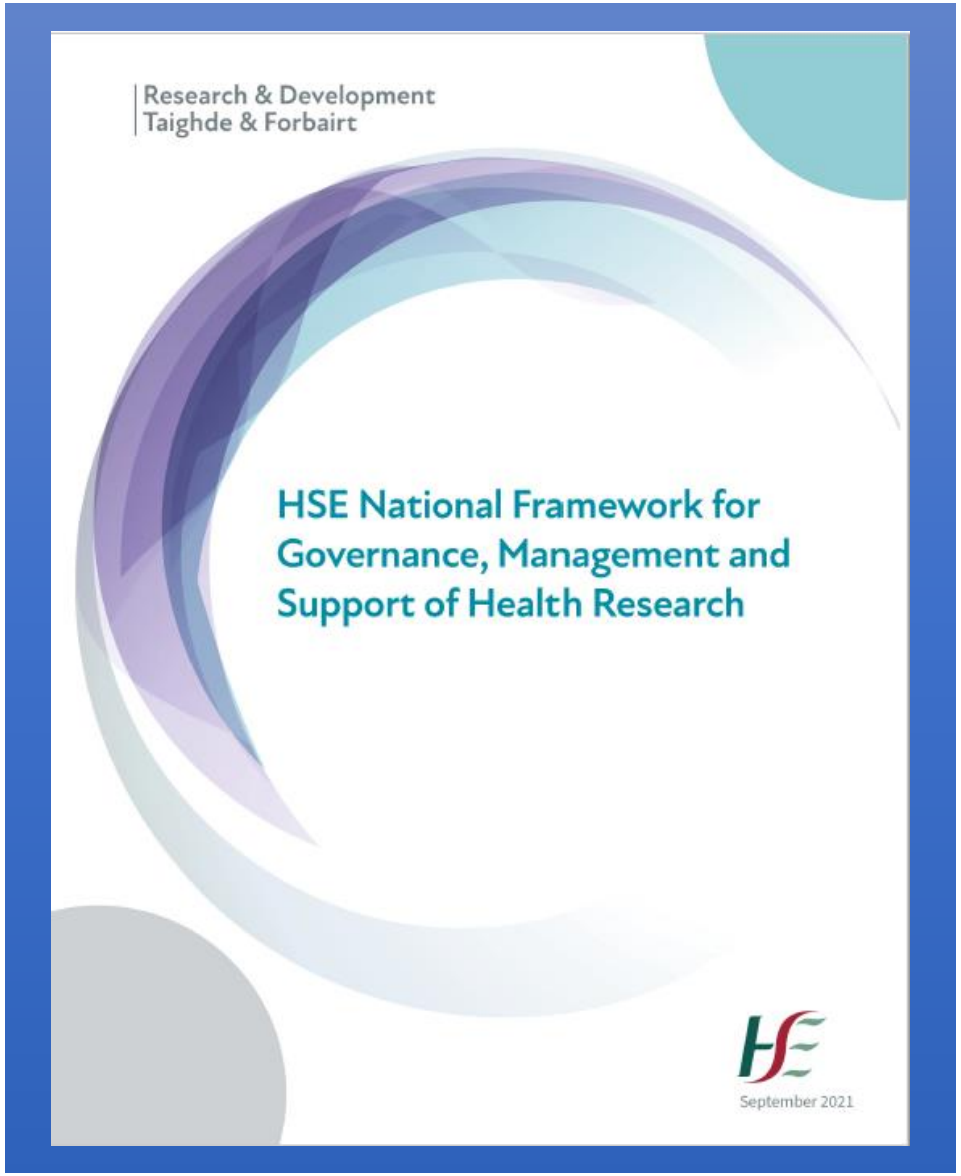
Improving the diagnosis & treatment of human illness & disease.

New Technologies

Innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury

Be careful to differentiate **research** from other activities

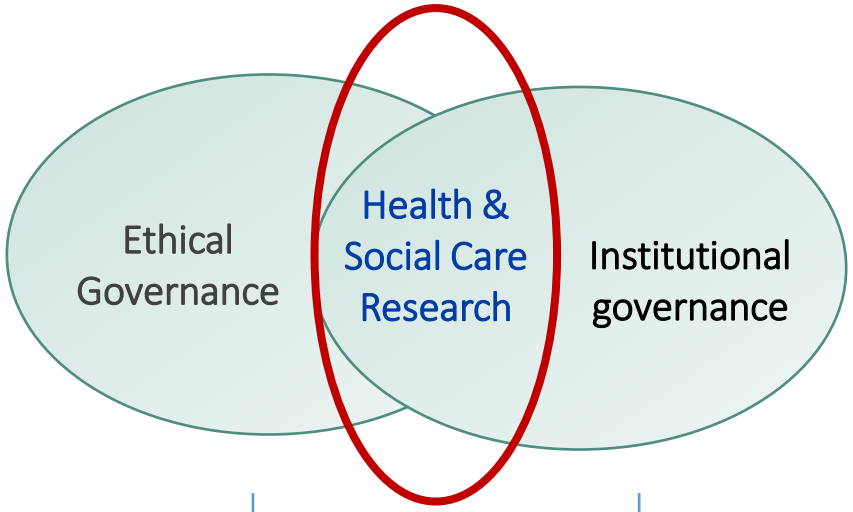
Dr. Ana M. Terrés, Assistant National Director
Head of Research and Evidence



- Research needs to be **registered** to enable coordination of local functions engaged in research governance.
- Projects to be risk assessed before they commence and the level of **oversight should be proportionate to the risk**.
- The organisations responsible for **legal, data protection, insurance and regulatory compliance** should be identified up front.
- Both the host **institution** and the **research ethics committee** have a role in research governance, and their **roles** is **distinct** and **complementary.**
- Proportionate oversight should take place **through the life cycle** of the project, not just before project start.
- Research participants and patients **are key partners in the research process** and their opinions and needs should be considered throughout.

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

- Ethical Standards
- Protecting the dignity, welfare and rights of participants
- Consent Protocols
- Assent Protocols
- Ethical risk



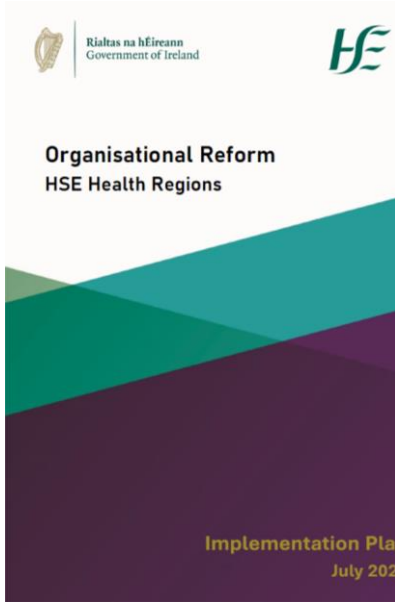
- Institutional risk
- Data Protection Compliance
- Financial and HR governance
- Contractual obligations
- Indemnity and Insurance requirements

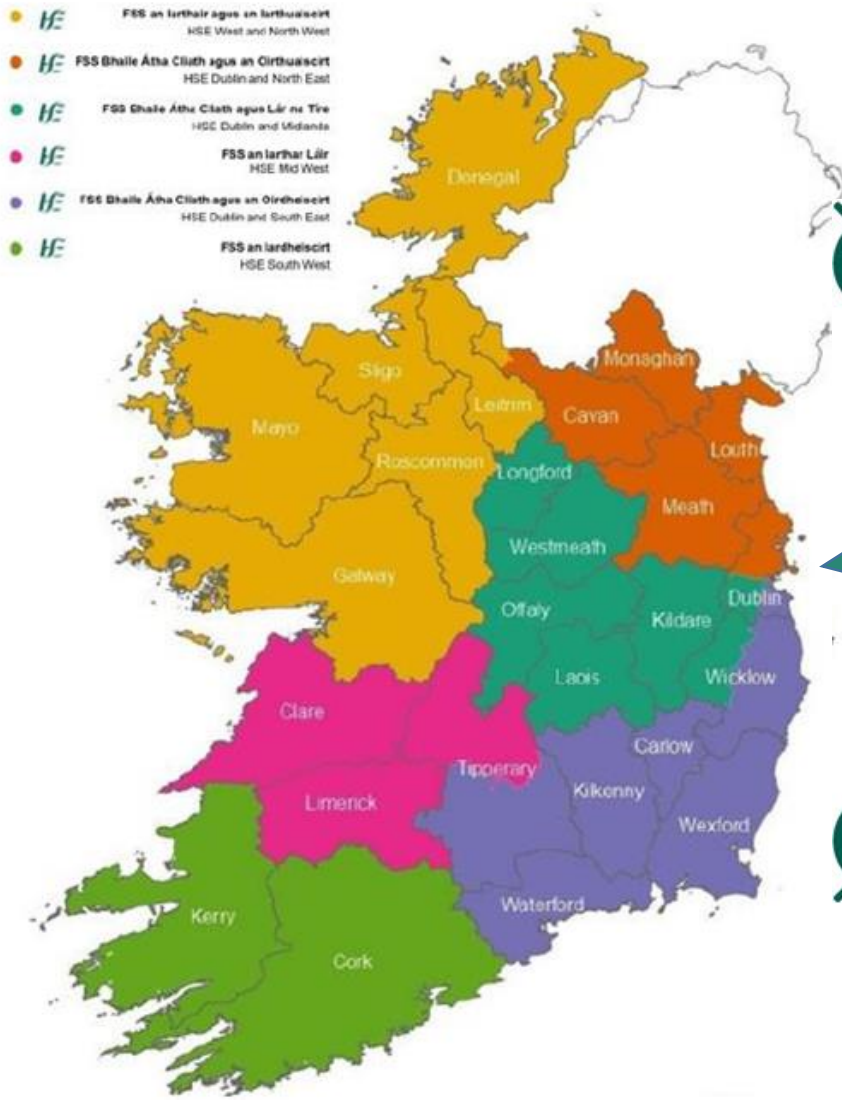
Research Ethics Committee

Research Office

Risk Committee
Support Services

Sláintecare: Reorganising to Health Regions





Health Regions will be tasked with harnessing the resources and skills available across health service providers in their region to provide for research ethical oversight, governance, management, and support services to promote research, transformation, and innovation within their region.

Implementation of the HSE RGMS Framework in the HSE Health Regions: *Key Elements*

Reform of the HSE Research Ethics Committee System

Increase capacity for research governance at local, regional and national levels

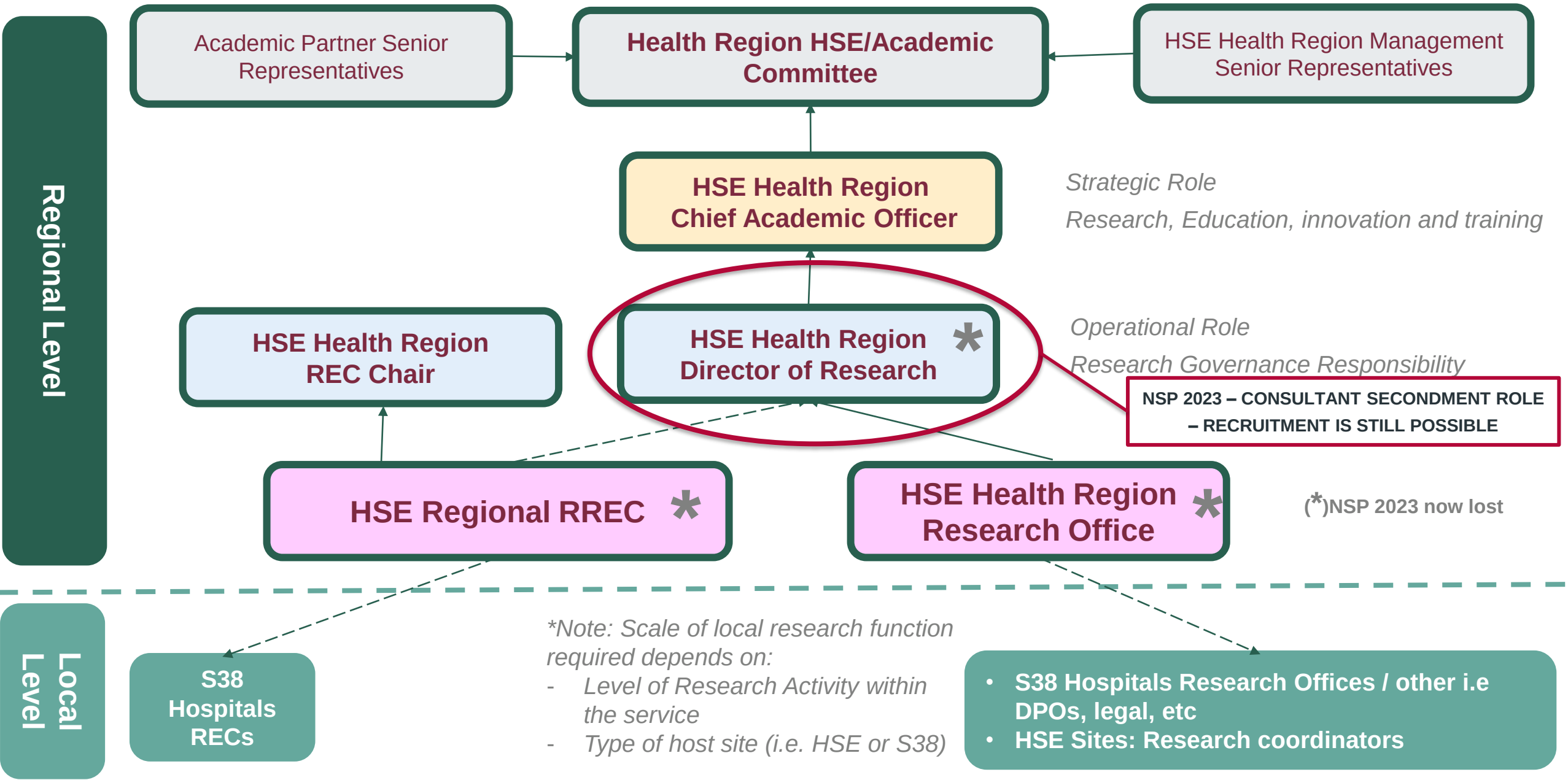
Enabling infrastructure – National Electronic Research Management System

Development of national research related policies, standard protocols, practices & support programmes

Governance of implementation – National RGMS Committee. Dr P. Crowley (Chair). Reports to HSE Board.

Key Stakeholders – engagement, consultation, collaboration, partnership

2. Regional Management of Research: Target Operating Model



National harmonisation of research management practice

National harmonisation of operational practice in research governance

NATIONAL CLINICAL TRIAL AGREEMENT TEMPLATES

- ✓ Commercial sponsors
- ✓ CRO/CRFs
- ✓ Academic sponsors
- ✓ DSA

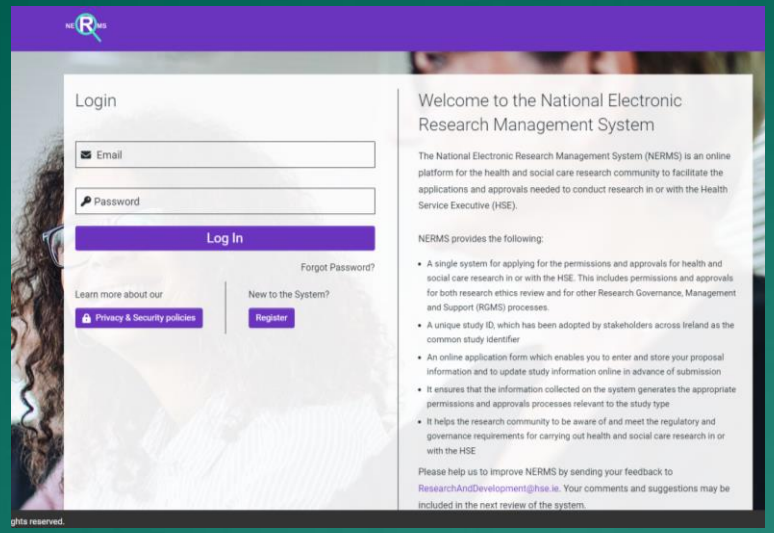
DATA PROTECTION COMPLIANCE FRAMEWORK FOR RESEARCH

- ✓ National Research DPIA Template
- ✓ National Research DPIA Review Protocol for multisite trials.
- ✓ TIA Tools
- ✓ Data Protection compliance in Health Research Code of practice

Standard Code of Practice for RRECs – operating as a system – towards single REC approvals for multisite studies

Difficult process: engagement, consultation, collaboration, partnership and agreement with multiple key stakeholders

National Electronic Research Management System



Three Phases of Iterative Development

- ✓2024: Phase 1 (RECSAF May 2023)
- ✓2025: Phase 2 – RGMS & Phase 1 continuous process & quality improvement
- ✓2026: Phase 3 – Integrated REC and RGMS

'Continuous Improvement is better than delayed perfection'

Mark Twain

Health Research Board NCTO National Clinical Trials Office

UCC Coláiste na hOllscoile Corcaigh University College Cork, Ireland | Clinical Research Ethics Committee

Mater Misericordiae University Hospital

Mater Private Network

University Hospital Waterford

Sláinte Leanaí Éireann CHI Children's Health Ireland

Midlands Regional Hospital Tullamore

HSE Research & Development Taighde & Forbairt

Clinical Research Ethics UL Hospitals Group and Mid-West Community Healthcare
University of Limerick Ollscoil Luimnigh

Benefits of an Electronic Research Management System

"not just a tool, your research companion"

REC System	Operational	Community	Governance
Standardised practices, consistency, organised work, professionalism, efficiencies, embedded help text & paperless	Accessibility, single point of entry for ethical & institutional approvals – time saving	Shared goals/ values of research ethics community & raises profile of RECs	Study registration – demonstrating research impact
Compliance with 'Code' & national standards – ability to introduce standards	Efficient application & validation management	Collaboration	Reporting, auditing & storage - analytics & impact
Phase II- separate of institutional RGMS functions	Document and data management	Communication	Security benefits
Standard process for workflows between RREC and other RECs	Member management	Training & CPD	Trust and transparency
In time - single REC approval for multisite studies	Meeting and review management	Global reputation	Financial
Agile, fully configurable & developmental updates streamlined	Automatic alerts, emails and minutes to end-users	Collaborative editing and review	QC, QA & QD

Standardised National Training Initiatives

IPPOSI

Research Ethics for PPI Committee Members

Effective Meeting Management for Chairs/ Deputies

Policy revisions and case study resource packs

NERMS

Training videos for all end-users

equality diversity inclusion

Research Ethics

History of research ethics, general principles, what makes research ethical

Research ethics landscape in Ireland and regulations

Principles in Practice

- Respect for person & informed consent
- Respect for person & data protection
- Beneficence and minimising risks/ maximising benefits
- Justice and fair subject selection

Mock Research Ethics Committee Meeting

Ethical concerns in different populations

- Children
- Genetics/ genomics
- Population health
- Artificial intelligence
- Social care research

Case Studies

Research & Development
Taighde & Forbairt

IPPOSI

4 Modules, 15 lessons, 4 virtual meetings, knowledge checks and quizzes, 12 hours

Module Coordinator

Content Developers

Editorial Board

Seeking PPI input into development

Publicly accessible platform

Contact and Further Information

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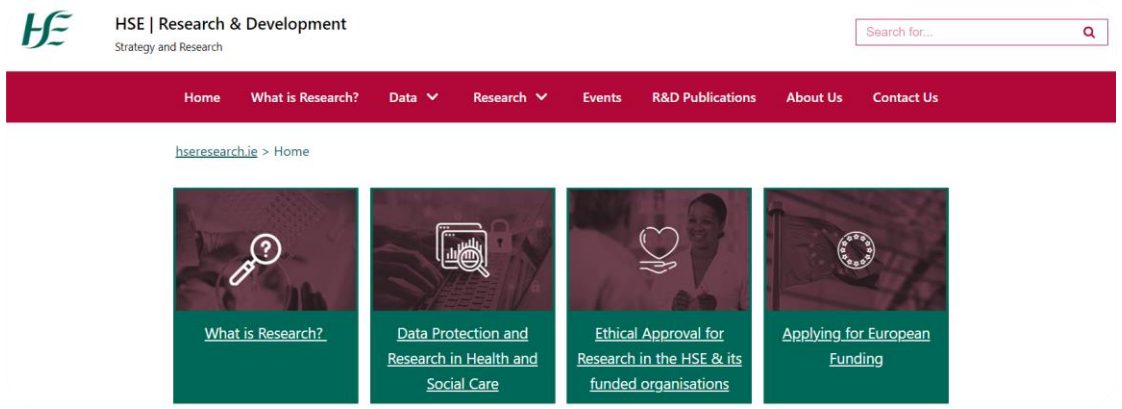

https://hseresearch.ie/patient-and-public-involvement-in-research/