

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

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What if...



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

*RGMS framework for short
what is it?*

The RGMS Framework in context – the HSE Action Plan for Health Research

Action Plan for Health Research

2019-2029 | 6 key pillars



Develop and implement a **robust governance framework** for research activity in the context of evolving healthcare structures to protect and promote the interests of patients and the public in health and social care research.



Implement institutional measures to facilitate the **translation of research and innovation into policy and practice** and increase dissemination of knowledge.



Create **research support** and **management** roles, and develop the **infrastructure** required to underpin, enable and manage the research activity in the HSE.



Support and promote the **involvement of patients and the public** in all levels of research activity.



Build **research capacity** in terms of human and financial capital to enable the sustainable growth of research activity into the future.



Establish strong **collaborations** with key external stakeholders and contribute to the national health research system in a meaningful way.

The HSE National RGMS Framework

- **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**



What is the RGMS Framework?



Provides a **strong foundation** for research activity in the HSE

Developed with **extensive internal and external consultation**

Applicable in all different health and social care settings

Why is the RGMS Framework needed?



- Large **volume of health research**
- **capacity and expertise to support it** and manage it is **underdeveloped**.



- Complex regulatory and legal landscape: **Guidance and clarity** for both researchers and host services



- Staff need support
- Collaboration with **academic partners, patients and other internal and external stakeholders** needs to improve

Why is the RGMS Framework needed?

The framework is needed to:

- promote **good practice**,
- Improve research **quality**
- **Facilitate collaboration**
- **Support staff**
- **Participants as key partners** in the research process.
- Safeguard patients
- Increase **public trust**.

Why is the RGMS Framework needed?



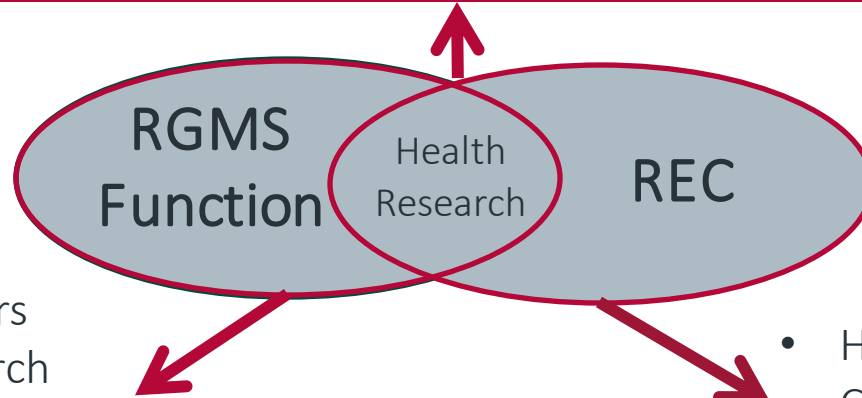
Essential to create an environment where research can be sustained and flourish.

Key principles of the RGMS Framework

- Research activity needs to be **registered and risk assessed**
- **Oversight should be proportionate to the risk.**
- Legal entity responsibility should be identified up front.
- Both institutions are REC have a distinct and complementary role in research governance
- oversight should take place **through the life cycle** of the project
- Research participants and patients **are key partners in the research process**

Key functions for Research Oversight

Involving HSE service users, their samples or data, staff or services



- Research offices/ officers
- Legal services for research
- Finance support for research
- Data protection/data governance officers for research
- Clinical Research Facilities

- HSE Research Ethics Committees
- Voluntary (S38) Hospital RECs
- National RECs

Institutional oversight: The RGMS function

- Registration
- **risk assessment**
- **data protection** compliance
- Clarify **insurance and indemnity** requirements
- **Legal agreement requirements**
- **financial management**
- compliance with funder rules
- Supporting compliance with regulatory authorities (i.e. HPRA)
- Assessment of Impact in host site
- **Host site authorisation**

New: Research Office
responsible for the
coordination of
institutional approval
processes

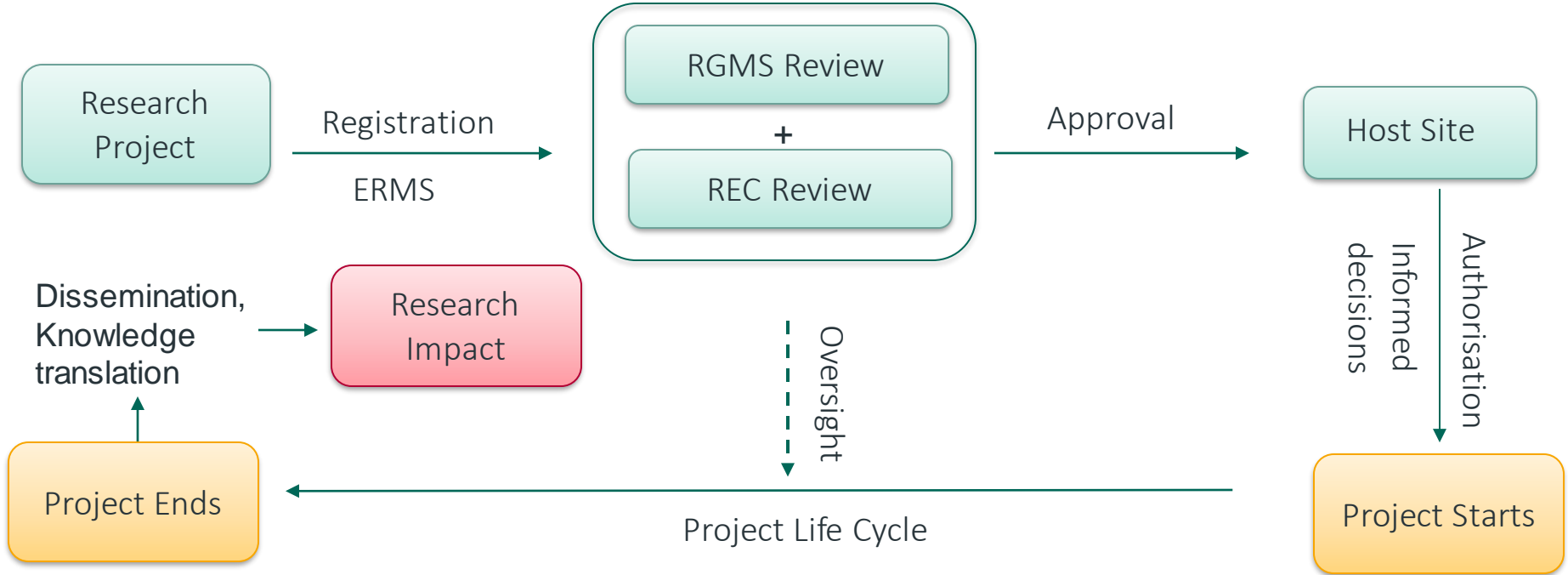
Ethical oversight: The Research Ethics Committees

- Ensuring research complies **with ethical standards** and principles to **protect the dignity and rights of participants**.
- Assessment of **Consent protocols**
- The Framework **differentiates** the responsibilities of the Research Ethics Committees (RECs) vs the RGMS function and articulates the principles that should underpin ethical oversight.
- Currently many RECs are hospital based and have acquired a broader role in institutional governance of research – multiple approvals are required.

Key RGMS Roles and Responsibilities

- **Responsible legal entity/Sponsor**
- **Principal Investigator**
- **Research host site**
- **Research site responsible officer**
- **Research Ethics Committee**
- **Health Products Regulatory Authority**
- **Research Funder**
- **Employers**
- **State Claims Agency**
- **Data controller**
- **Data processor**
- **RGMS function**
- **National R&D**

The Framework's research governance and oversight cycle.



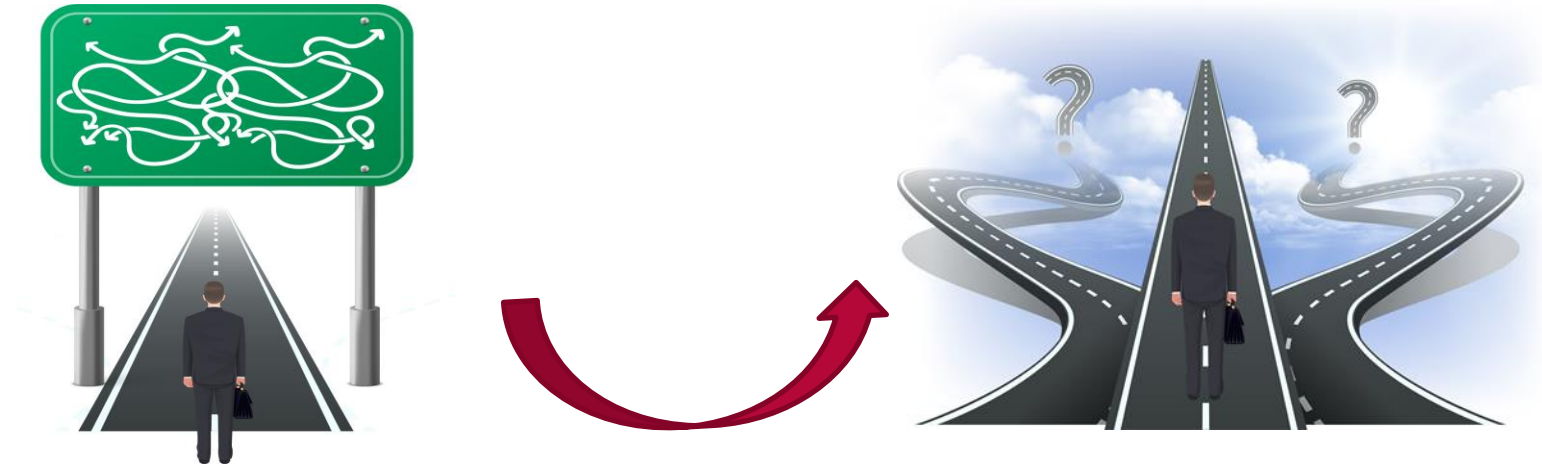
Many elements of this cycle already take place but processes and coordination are not optimised – significant delays

Implementation of the Framework

- The framework will provide **clarity to researchers and host organisations** with regards to roles and responsibilities.
- Full Implementation will take place over a number of years and it will require **investment and capacity building** to:
 1. **Reform of the HSE Research Ethics Committee System.**
 2. Development of **further RGMS functions** at local, regional and national levels.
 3. Roll out the national **Electronic Research Information Management System.**
 4. Establishment of a **National RGMS Board** to oversee the process and ensure a coordinated approach to implementation.

What will the implementation of the RGMS framework mean to you?

Research active staff and external researchers



Guidance and clarity, simplification of approval processes, faster REC approval and project set up, access to support and increase in value placed in research activity

Healthcare Services



- Risk management and minimisation
- Awareness about research activity in your service will lead to knowledge translation.
- Attract staff – facilitate recruitment
- Opportunities for patients to participate in research
- Access to new ideas, new technologies, new treatments, new opportunities to improve.

Patients, families, carers, service users



Assurances that:

- The research involving you in any way is **ethical and safe**
- Your **data and your rights** as an individual are **protected**
- Any **risks** associated with research activity are **minimised** and appropriately **managed**
- **Opportunities** to participate in **clinical trials** when other therapeutic options may have failed.
- Opportunities to be **real partners** in the research process

Funders, sponsors, charities, agencies, academic and commercial partners, etc.



- **Effective governance**
- **Efficient processes**
- Research **supports** in place for staff
- Pathway to **Impact**
- Established processes to facilitate **collaboration**

Concluding remarks

The framework will contribute to embedding research activity into the fabric of health care – this in turn, will improve the quality of the service that we deliver, and will benefit patients, their families and carers, service users and staff.

Further information in progress so far:

- **Online information sessions** on progress so far will take place in November 2021 to include:
 - Roadmap for the reform of the HSE research ethics committees and the establishment of RGMS functions and progress so far,
 - The National Electronic Research Management System
 - The national HSE Research Governance and Oversight board
 - The HSE National Consent for research policy
 - Etc.
- **Information in all our work streams** will be available on our website from November 2021
- **FAQs** received during and after the webinar will be answered via our website www.HSEReserach.ie as soon as possible after today.

“The journey of one thousand miles begins with a single step”

Lao Tzu