The Vision for Implementation of the HSE Research Governance, Management and Support Function

Dr Ana Terrés
Máiréad Murray

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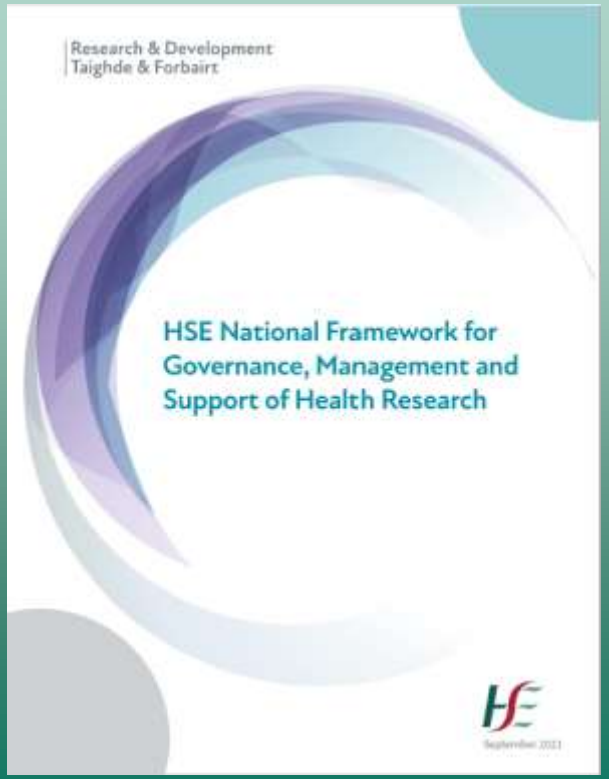
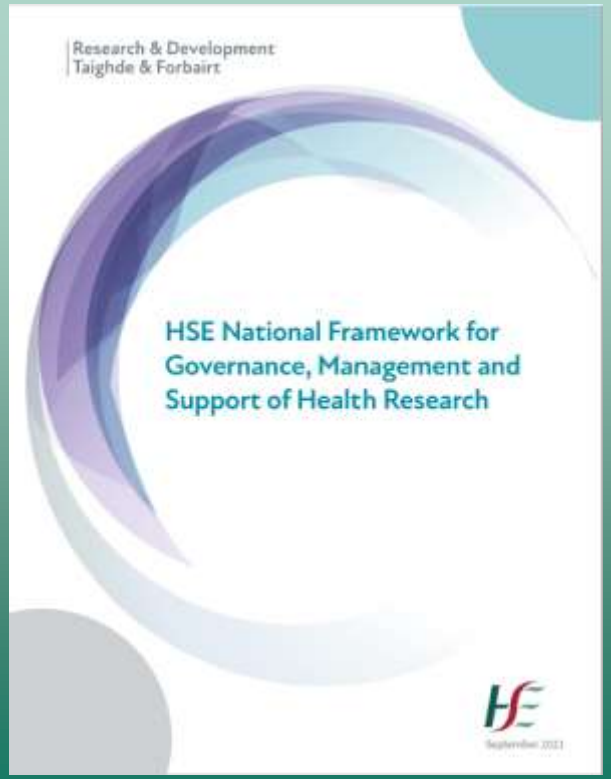
HSE National Framework for the Governance, Management and Support of Health Research



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**



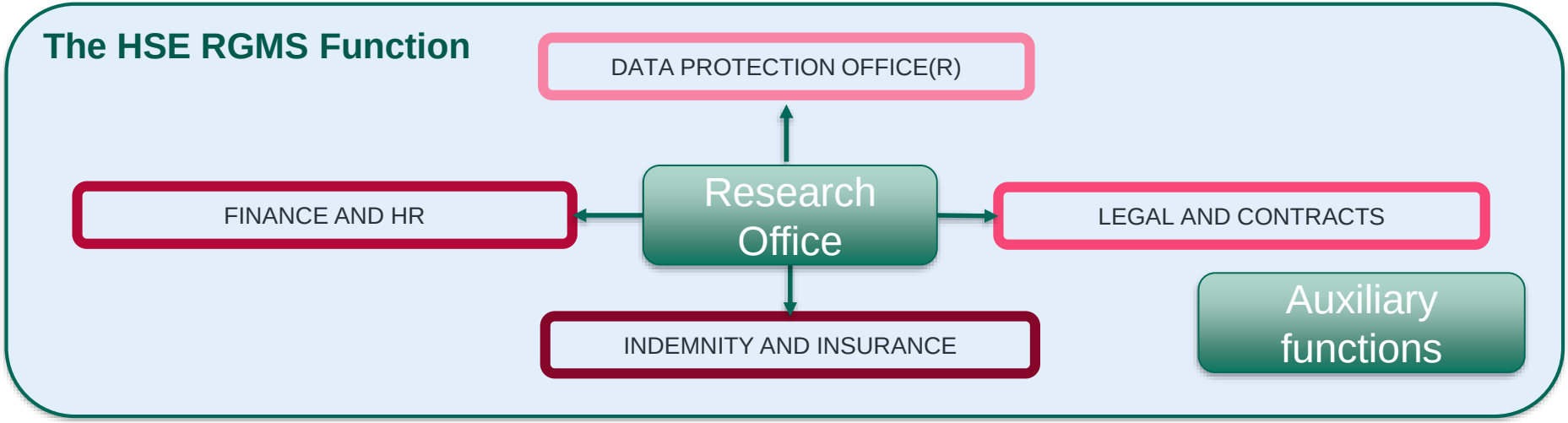
Implementation of the RGMS Framework requires:

- 1. Reform of the HSE Research Ethics Committee System
- **2. Develop cohesive 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.

The Role of Research Governance, Management and Support (RGMS) Function

The RGMS Function works in parallel with the HSE/S38 Research Ethics Committees to ensure that the research activity hosted, enabled or conducted by the publicly funded health service is ethically sound, safe and compliant with regulatory and legal requirements.

The HSE RGMS Function



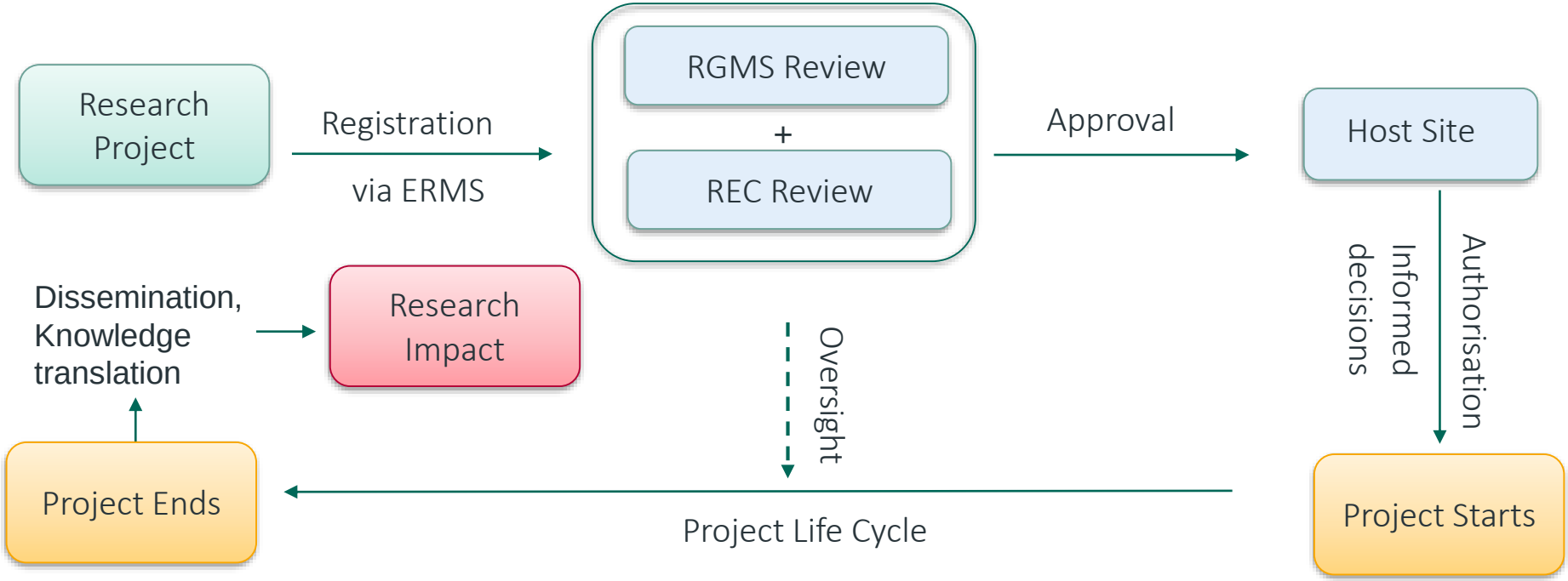
Co-ordinated by a **Research office**, a co-ordinating entity that supports and enables researchers to comply with legal and regulatory requirements. Using an effective cohesive system view approach and working in co-coordination with auxiliary functions

Using the same standards, guidance and processes across the HSE

HSE/S38 Research Ethics Committee

Research Host site

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

Current Picture

- Same cumbersome process for simple and complex projects
- Different approval workflows in each service
- Lack of HSE national guidance to enable standardised approach
- Approval processes difficult to navigate leading to long delays to project start up

Time consuming

Complicated

Inefficient

Impacting on ability to conduct research and Ireland's international reputation.

Example 1

Hospital Based Research

University sponsored interventional non-regulated clinical trial involving 3 hospitals, one of them is a HSE hospital and the other two are S38 hospitals.

Current Picture

Congratulations

You've got funding, Designed the protocol, the consent documents and identified a Sponsor, PIs and sites for your study

You can now start your research project

Current Picture

Congratulations

Study Data Protection

Require a DPIA for Ethics application in relation to the Study Data reviewed by the Sponsor's DPO and using the Sponsor DPIA template

Current Picture

Study Data Protection

Congratulations

Ethics

Application Site A HSE	Application Site B S38	Application Site C S38
REC Form	REC Form	REC Form
Protocol	Protocol	Protocol
PIL/ICF	PIL/ICF	PIL/ICF
Indemnity Cert	Indemnity Cert	Indemnity Cert
DPIA	DPIA	DPIA

Ethics

Approval Site A HSE	Conditional Site B S38	Conditional Site C S38
REC Form	REC Form	REC Form
Protocol	Protocol	Protocol
PIL/ICF	PIL/ICF	PIL/ICF
Indemnity Cert	Indemnity Cert	Indemnity Cert
DPIA	DPIA	DPIA

Legal

Approval Site A HSE	Approval Site B S38	Approval Site C S38
REC Form	REC Form	REC Form
Protocol V2	Protocol V2	Protocol V2
PIL/ICF V1A	PIL/ICF V2B	PIL/ICF V2C
Indemnity Cert	Indemnity Cert	Indemnity Cert
DPIA	DPIA	DPIA

Current Picture

Study Data Protection

Congratulations

Ethics

Legal

Site A HSE	Site B S38	Site C S38
Agreement	Agreement	Agreement
HSE DPIA	Site B DPIA	Site C DPIA
Indemnity	Indemnity	Indemnity
REC Approval	REC Approval	REC Approval
Resourcing	Resourcing	Resourcing

Site Data Protection

Site A HSE	Site B S38	Site C S38
HSE DDPO	Site B DPO	Site C DPO
HSE DPIA	Site B DPIA	Site C DPIA
Agreements	Agreements	Agreements
Protocol	Protocol	Protocol
PIL/ICF	PIL/ICF	PIL/ICF
REC	REC	REC

Current Picture

Study Data Protection

Congratulations

Ethics

Site A HSE	Site B S38	Site C S38
REC Form	REC Form	REC Form
Protocol V2	Protocol V2	Protocol V2
PIL/ICF V2A	**PIL/ICF V3B**	**PIL/ICF V3C**
Indemnity Cert	Indemnity Cert	Indemnity Cert
DPIA	DPIA	DPIA

Legal

Site Data Protection

Site A HSE	Site B S38	Site C S38
HSE DDPO	Site B DPO	Site C DPO
HSE DPIA	Site B DPIA	Site C DPIA
Agreements	Agreements	Agreements
Protocol	Protocol	Protocol
PIL/ICF	PIL/ICF	PIL/ICF
REC	REC	REC

Current Picture

Study Data Protection

Congratulations

CIS

Site A HSE	Site B HSE	Site C HSE
REC	REC	REC
Agreements	Agreements	Agreements
Indemnity	Indemnity	Indemnity

Site Data Protection

Legal

Agreement Parties	Agreement Parties	Agreement Parties
Site A	Site B	Site C
HSE	S38	S38
University	University	University
Reference	Reference	Reference
Funding T&C	Funding T&C	Funding T&C

Current Picture

Congratulations

Congratulations you can now start your research project

CIS

Site Data Protection

Study Data Protection

Ethics

Legal

Example 2

Community Based Research

National research study commissioned by the HSE and led by an academic institution, and involving survey of staff and users of community based HSE care services.

Current Picture

So, the HSE commissioned you to do a research project that will contribute to inform future service development strategies.

Congratulations

You've succeeded in your tender bid and the HSE is sponsoring your project. You have designed the protocol in collaboration with your HSE partners, the consent documents, and the resources and sites for your study have been identified.

Data Protection	University DPO Review	HSE DPO Review
	✓ University DPIA	✓ HSE DPIA.

REC Approval	University REC Approval	HSE REC approval (7 RECs)
	✓	CHO 1 ✓ CHO2 ✓ CHO3 ✓ CHO4 ✓ CHO5 ✓ CHO6 ✗ CHO7 ✗ CHO8 ✗ CHO9 ✗

Options

Study cannot proceed	Study can proceed once sites without a REC are excluded	Alternative local arrangements, **not aligned with the RGMS framework**, are put in place for the study to proceed.

Next Steps

HSE National Office for Research and Development

REC Reform

RGMS Development

Next Steps

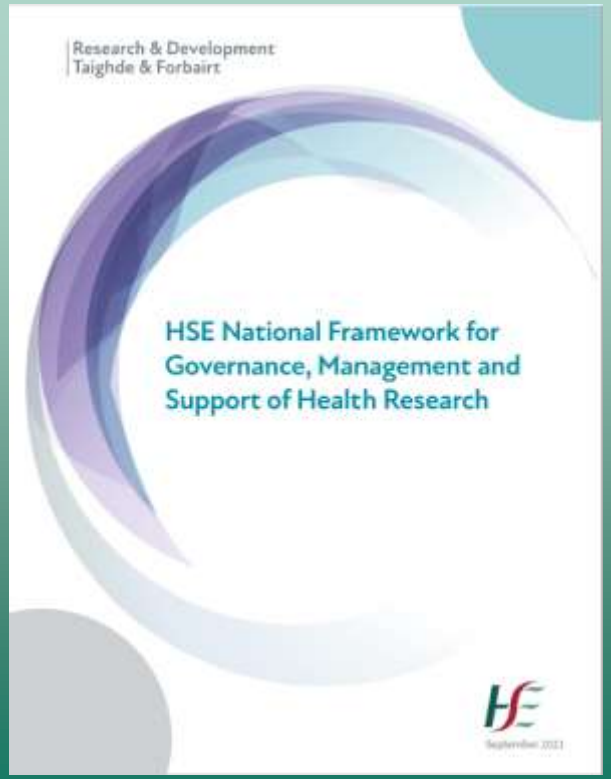
HSE National Office for Research and Development

1. **Roadmap for the Reform of the HSE Research Ethics Committees** ✓
2. **HSE National Standard Code of Governance and Management for the HSE Reference Research Ethics Committees** ✓
3. **Roadmap for the establishment of RGMS functions – in progress**
4. **HSE National Standard Code of Practice for the Implementation of the Research Governance, Management and Support Functions – in progress**

HSE National Standard Code of Practice for the RGMS Function

The Scope of HSE RGMS Function and expertise required
The function of the Research and Development Office
Approval work flows (including REC)
Standard Operating Procedures and relevant guidance:

- Study Risk Assessment
- Sponsorship/Responsible Legal Entity: Roles and Responsibility
- PPI involvement
- Indemnity and Insurance requirements
- Data Protection
- Contracts and Legal Requirements
- Financial Management
- Human Resources and Recruitment Considerations
- Site Approval



RGMS Framework Implementation- national requirements:

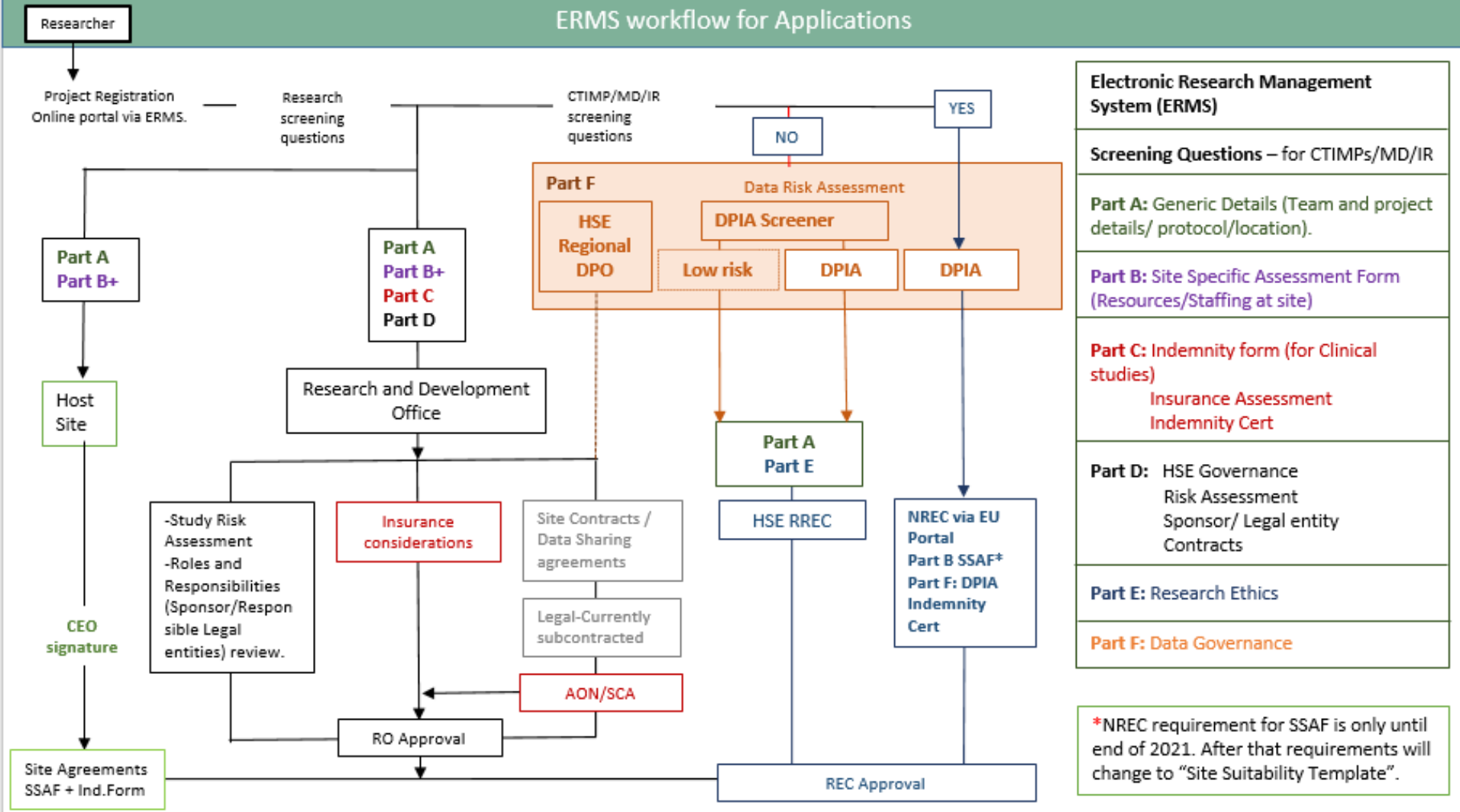
- 1. Reform of the HSE Research Ethics Committee System
- 2. Establish RGMS functions at local level
- 3. Roll out a national electronic research management system
- 4. Establish the National RGMS oversight committee
- 5. Develop relevant policies and standard codes of practice.

Electronic Research Management System

Single Portal for Research Governance, Management and Support Function and Research Ethics Committee applications (not NREC)

- National System
- National, Regional and Local level implementation
- One application
- One document set

ERMS workflow for Applications



Electronic Research Management System (ERMS)

Screening Questions – for CTIMPs/MD/IR

Part A: Generic Details (Team and project details/ protocol/location).

Part B: Site Specific Assessment Form (Resources/Staffing at site)

Part C: Indemnity form (for Clinical studies)
- Insurance Assessment
- Indemnity Cert

Part D: HSE Governance
- Risk Assessment
- Sponsor/ Legal entity Contracts

Part E: Research Ethics

Part F: Data Governance

*NREC requirement for SSAF is only until end of 2021. After that requirements will change to "Site Suitability Template".

	REC	DDPO/DPO	LEGAL	Aon/SCA	SITE
Rec Form	Rec Form				
DPIA	DPIA*	DPIA*			DPIA*
CI CV	CI CV				
PI CV					PI CV
PIL/ICF	PIL/ICF	PIL/ICF			PIL/ICF
Protocol	Protocol	Protocol			
Indemnity Cert	Indemnity Cert		Indemnity Cert	Indemnity Cert	
SSA Form	SSA Form			SSA Form	SSA Form
Site resources	Site resources				Site resources
Staff Qualifications	Staff Qualifications				Staff Qualifications
Data Form	Data Form	Data Form			
CTIF			CTIF	CTIF	CTIF
Site Agreement		Site Agreement	Site Agreement	Site Agreement	Site Agreement
Budget			Budget		Budget
Data Agreement		Data Agreement	Data Agreement		Data Agreement
Funding Agreement			Funding Agreement		

ERMS

Screening

RGMS
Research
NREC

Part A

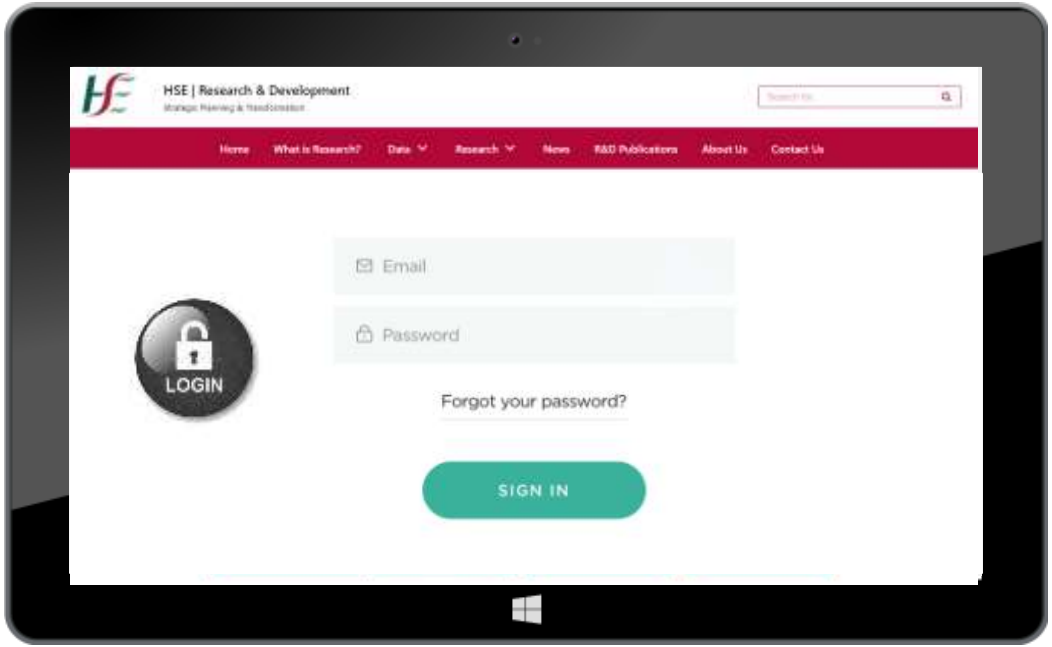
Generic Details
(Team and project details/ protocol/location).

Part B

Site Specific Assessment
Site Approval.

Part C

Indemnity



Part D

Governance
Risk Assessment
Sponsor/ Legal entity
Contracts
.

Part E

Ethics

Part F

Data Governance

The Vision–

- One online application (to include application to REC) for Acute, Community, National and Corporate services
- Upload additional documentation (protocol, PIL/ICF, indemnity cert) once
- National standardised approach by using agreed templates (DPIA, etc) – facilitate multisite studies – Health Research Data Protection Network- HSE DPO
- Nationally agreed and standardised approval workflows
- Proposals risk assessed – low risk proposals expedited
- SCA Indemnity review only once even if multiple HSE/S38 org involved
- **HSE Governance protocols (coordinated with University protocols)**
- **Research activity data – Impact – Strategy**
- **Research will be focused on Irish Healthcare users and Healthcare system**

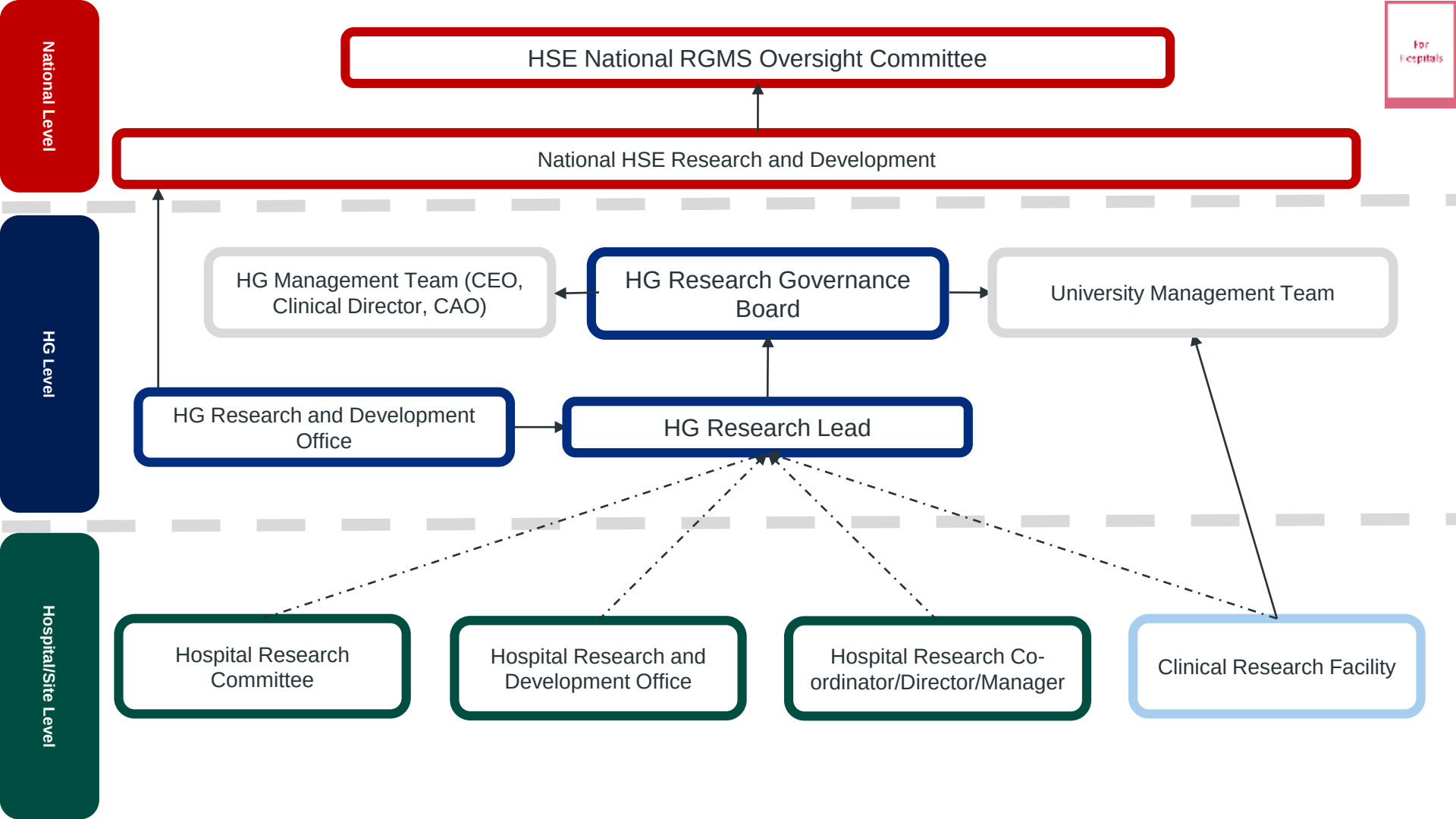
The Vision–

Organisational Structures required for the development of appropriate RGMS functions

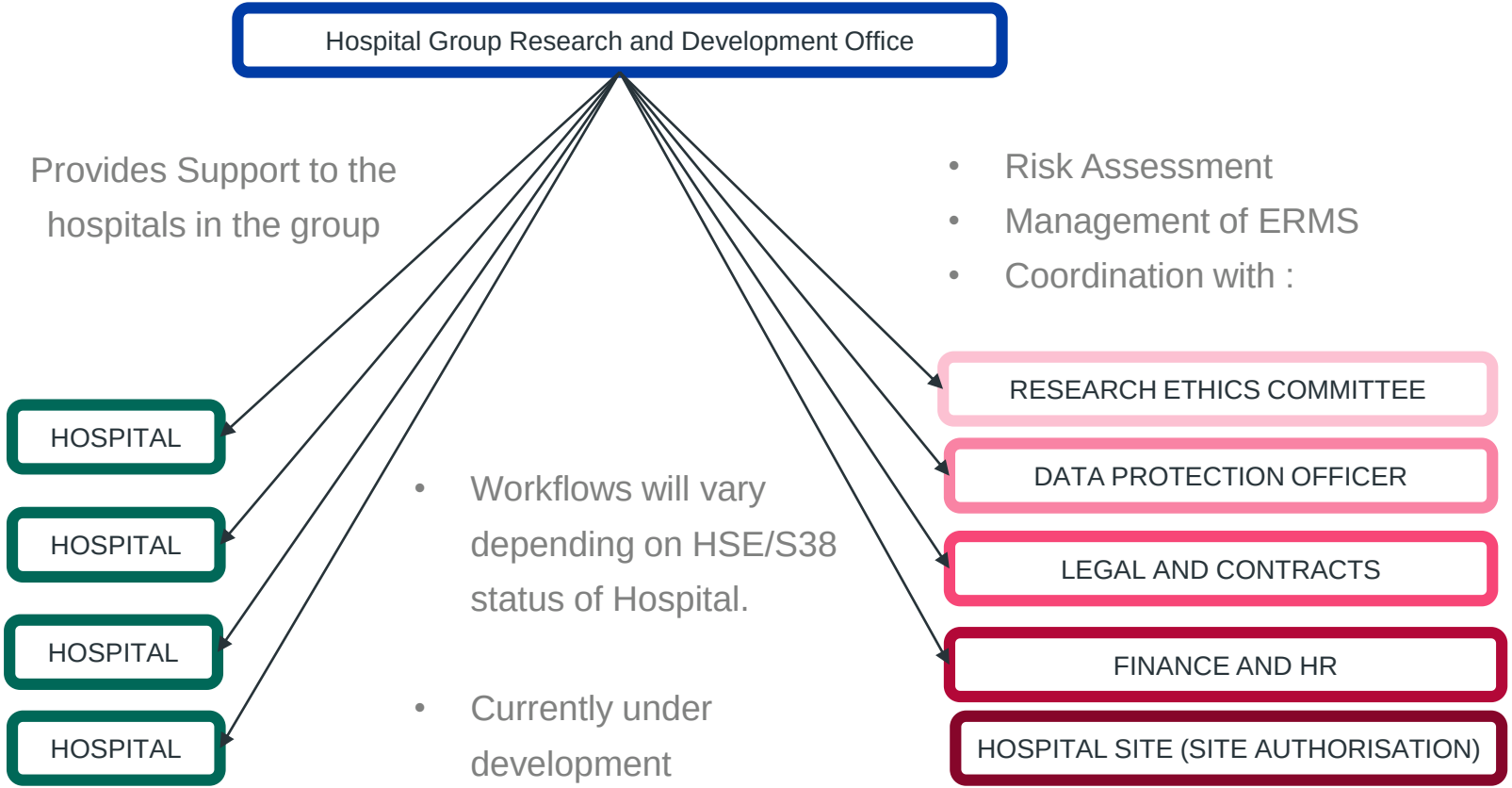
For Hospitals

For Community services

For National/ Corporate


National Level
HSE National RGMS Oversight Committee
National HSE Research and Development
HG Level
HG Management Team (CEO, Clinical Director, CAO)
HG Research Governance Board
University Management Team
HG Research and Development Office
HG Research Lead
Hospital/Site Level
Hospital Research Committee
Hospital Research and Development Office
Hospital Research Co-ordinator/Director/Manager
Clinical Research Facility

RGMS structure for HG



National Level

HSE National RGMS Oversight Committee

National HSE Research and Development

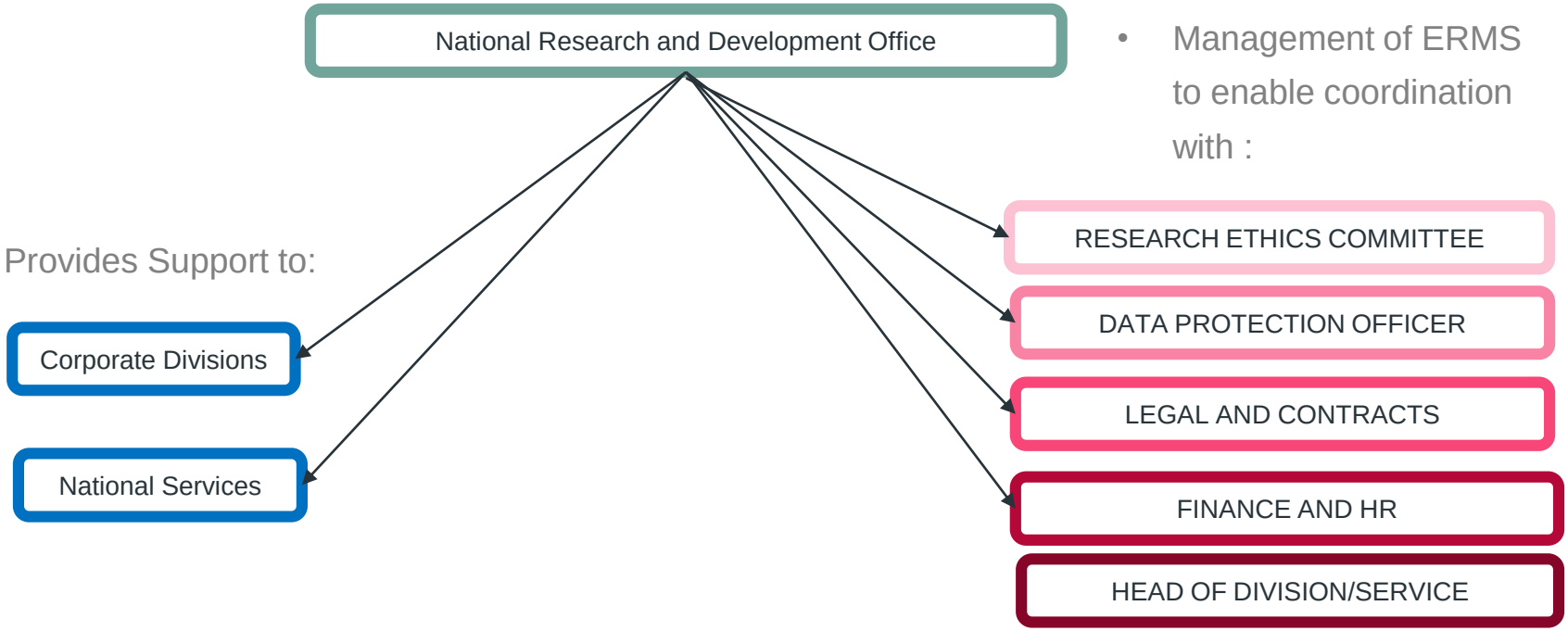
TO BE SCOPED IN 2022

Pilot in a community area

RGMS structure for Community Services

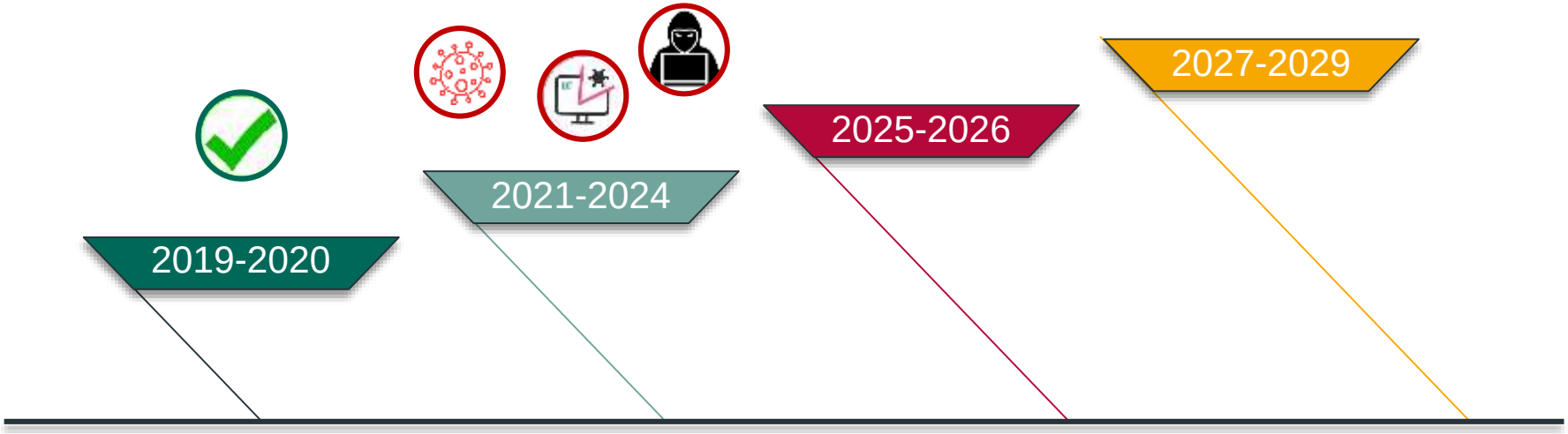
For Community services

RGMS structure for HSE National and Corporate Divisions



- Risk Assessment
- Management of ERMS to enable coordination with :

Timelines



Establishment
Planning and scoping underway
Development of the Framework

Development
Implementation of the Framework
Develop implementation plan for Financial /HR capacity

Embedding
Implementation of Financial and HR capacity planning

Consolidation
Structures in place and functioning, KPIs

RGMS Implementation Working Group

- **Representation** from Hospital Groups, Chief Academic Officers, Community Services, National Services, HRB National Clinical Trials Office (NCTO),Office of the National Research Ethics Committee, Third-level Academic institutions and Service users and Public Representatives and other key stakeholders within the national health research system.

- Led by the **HSE National Office for Research And Development**

- Building on the work of the **Corporate Enabling of Clinical Research** (CECR) Working Groups (CECR Report published October 2019)

- HSE Research & Development would like to thank all the Members of the RGMS Implementation Working Group for their support and continuing participation, the CECR working groups, the **Health Research Data Protection Network and other groups** for all the work done to date to enable standardisation of research governance approaches.

Questions

Contact us

ResearchandDevelopment@hse.ie

Links

@HSEResearch

https://www.youtube.com/channel/UCWN5MFqd6dUqkwdZC9BDonQ/videos/

https://hseresearch.ie//

More information