Building the organisational infrastructure for Research as part of the RHAs

Dr. Ana Terrés, AND Head of Research and Evidence &, Dr. Philip Crowley, ND Strategy and Research, HSE 23/6/22

Purpose

The design of the Regional Health Areas is underway as a collaborative process between the DoH and the HSE. The process is expected to be completed by 2022, with a view becoming fully operational from 2024.
The purpose of this document is to articulate the proposed design of the organisational structures underpinning research activity in the health service, so that research can become a critical enabler of service delivery and decision making.

Introduction

Healthcare systems that have a culture of research and have research formally embedded within their processes deliver better care[1] [2] [3] [4] [5] [6] - and the delivery of better care is a key aim of *Slaintecare*. The HSE Action Plan for Health Research 2019-2029 aims to embed research and evidence based practice into the fabric of healthcare, and the HSE National Framework for the Governance, management and support of research (RGMS Framework) is one of the first outputs of this plan.

The implementation of the HSE Framework for the Governance, Management and Support of Research 2021 (RGMS framework) is not only essential to enable the HSE and its funded organisations to comply with its legal, regulatory and ethical obligations, but also to foster the translation of research into policy and practice in order to deliver quality and evidence- informed care suited to population needs. This will contribute to achieve key strategic objectives of the *Slaintecare* implementation plan, including objective #1 "Patient is Paramount" and #8 "Accountability".

> *"Effective organisational alignment and good governance are central to the organisation and functioning of the health system" Slaintecare Implementation Plan May 2021*

Organisational infrastructure for research includes four key components:

- Research Ethics Committees
- Research Governance, Management and Support (RGMS) functions[7]
- Leadership.
- Information and IT systems

Current structures.

The structures currently existing to govern, manage and support research in the health service (acute, community, corporate and national services) have developed individually and ad hoc over time without national direction nor standards, and are not sufficient to ensure compliance with ethical, legal and regulatory requirements. The administrative misalignment between the Hospital Groups and the community services, as well as the complexity of the health service structure with

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[1] Hanney S, Boaz A, Jones T, Soper B. Engagement in research: an innovative three-stage review of the benefits for health-care performance. *Health Serv Deliv Res* 2013, **1**:(8)
[2] Boaz A, Hanney S, Jones T, Soper B. Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review. BMJ Open 2015,5:e009415. doi: 10.1136/bmjopen-2015-009415
[3] Christmas C, Durso SC, Kravet SJ, Wright SM. Advantages and challenges of working as a clinician in an academic department of medicine: academic clinicians' perspectives. J Grad Med Educ 2010, 2(3):478-84
[4] Harding K, Lynch L, Porter J, Taylor NF. Organisational benefits of a strong research culture in a health service: a systematic review. Australian Health Review 2016, 41(1):45-53
[5] Krzyzanowska MK, Kaplan R, Sullivan R. How may clinical research improve healthcare outcomes? Annals of Oncology 2011, 22(Suppl 7):vii10–vii15. https://doi.org/10.1093/annonc/mdr420
[6] Redmond B, Guerin S, Nolan B Devitt C and Egan A. The Retention of Social Workers in the Health Services: An Evidence-Based Assessment. Project Report 2010, University College Dublin (unpublished). Available via http://trap.ncirl.ie/id/eprint/1695, accessed Feb 20, 2019
[7] Definition of RGMS functions in Page 26 of the HSE National Framework for the Governance, Management and Support of Research (https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf)

multiple independent legal entities currently pose challenges that are impossible to overcome with the current arrangements. The involvement of the university sector, while it has been invaluable in supporting research activity, poses additional challenges and adds confusion with regards to ownership of responsibilities. In a nutshell, the current structures are as follows:

- ***Research Ethics Committees*** (RECs): Since May 2021 the statutory National Research Ethics Committees (NRECs) provide a single national ethical review and approval for regulated Clinical Trials and Investigations with Medical Devices. The reminder of research activity taking place in the service is reviewed by 30 RECs with an approximate throughput of 2,000 proposals per year[8] and which fail to provide a REC service for community services in several CHOs. The current structure causes significant challenges for researchers and sponsors. The research ethics committees are poorly resourced, with minimal administrative support and oversight. As a result, recruitment of REC Chairs and members, who act in a voluntary capacity and dedicate significant time commitment, is extremely difficult. Furthermore, multiple REC approvals are required for studies involving multiple sites, with the consequent duplication of effort and inevitable delays.

- ***RGMS Functions****:* While the amount of research currently hosted by the health service is significant, the existing governance protocols are reactive in nature, and the system is struggling to comply with legal requirements (i.e. GDPR, Health Research Regulations, Clinical Trial Regulations, etc.). Current protocols do not conform to international best practice either and Ireland compares badly with European counterparts as a clinical trial destination for sponsors. The lack of expertise and capacity for research management is problematic and all of these factors represents a significant risk to the organisations.

  Legal review of research agreements is sub-contracted to external firms, who often review the same agreement for multiple HSE sites at a significant cost. There is also a severe lack of capacity and expertise for research data protection and overall governance, especially for HSE organisations which depend on the service of 4 regional Deputy Data protection Officers, serving multiple acute and community services and discharging their role on a part-time basis. Financial governance is difficult as there is no financial regulations for research income. Community services have practically no governance arrangements for the research activity they host. Cumulatively, these factors represent a risk and increase the complexity, delays and cost to conducting research in the health service, impeding the translation of research into practice. In 2021 three Hospital Groups (ULHG, S/SW HG and CHI) received seed funding from National HSE R&D to establish Research Offices and commence the implementation of the RGMS framework. The Saolta HG launched the first HG research office in Q1 2022.

- ***Information and IT systems:*** The majority of HSE and S38 organisations have no information about the research that they host. There is no local, regional nor national repositories of research activity. No electronic systems exist and processes are paper based, using different approval protocols and different templates for every step in every site. This represent a significant barrier for the conduct of collaborative research and clinical trials involving multiple sites.

- ***Leadership.*** By and large, research leadership is not formally embedded within management structures of community or acute services. Some Hospital Groups have appointed Chief Academic Officers whose responsibilities differ across HGs. Two HGs have appointed Directors of Research. No roles of

[8] https://hseresearch.ie/wp-content/uploads/2019/12/Research-Activity-Report.pdf

similar nature exist within the community services. At national level the HSE R&D office provides leadership to implement the HSE Action Plan for Health Research and the National Framework for the Governance, Management and Support of Research.

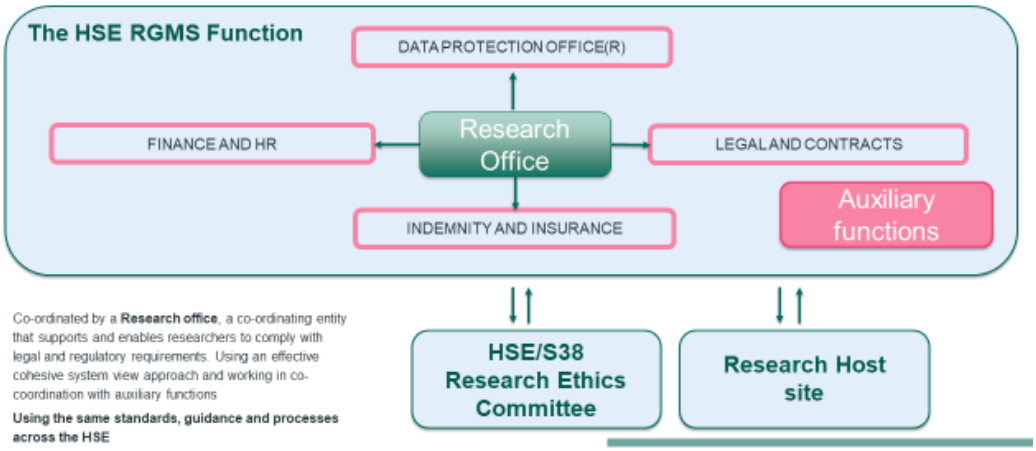
Proposed RHA structures for Research.

The formal establishment of the Regional Health Areas is a unique opportunity to embed organisational structures and leadership for research at regional and local level and address the multiple problems that currently exist. As explained above, the preparations for the establishment of research structures has already began. The vision for RHAs is as follows

- ***Research Ethics Committees***: The REC HSE Roadmap for the Reform of Health and Social Care Research Ethics Committees[9] outlines a process by which the current fragmented system is replaced by 6 RHA aligned HSE References RECS which formally report to the National RGMS Committee (see below-*Leadership*) and cover all HSE organisations. These will co-exist with existing S38 hospital RECs, and formal agreements will be put in place to enable single REC approval for national studies and for studies involving multiple sites, hence minimising the duplication of work. The reform of the REC system has already commenced with the establishment of the first HSE Reference REC for RHA B in early 2022[10].

- ***RGMS Functions***. The RHA RGMS Function will be constructed around the RHA Research Office (RHA RO), which has the fundamental function of coordinating all aspects of research governance for the organisations under its geographical area. The RHA RO will enable the registration of proposals, review and oversight. Oversight will be proportionate to the study risk. RHA Research Offices will coordinate with individual host sites, which will also be required to have an RGMS function, the complexity of which will be proportionate to the level of research activity of the site (i.e. a large academic teaching hospital may need dedicated resource/office but a less research active hospital may be served by a part time resource who liaises with the regional RHA Research Office).

  The RHA RO will be managed by a Research Office Manager who will report to the RHA Director of Research (see below-Leadership). Each RO will also be staffed with a number of key roles including a Data Governance and Contracts Officer and a Research Support Officer.



It is envisaged that the Research Offices underway for the hospital groups (Saolta, South/SW, Limerick) will evolve to become the RO for the RHAs D, E and F. Research Offices for RHA A, B and C will have to be set up the novo. Finally, each RHA should have at least one HSE DPO with allocated responsibility for research.

[9]HSE Roadmap for the Reform of Health and Social Care Research Ethics Committees https://hseresearch.ie/wp-content/uploads/2022/02/HSE-REC-Reform-Roadmap-V0.7-February-2022.pdf

[10] RREC for the Midlands Area and Corporate Division (Regional Health Area B https://hseresearch.ie/research-ethics/research-ethics-committees-cho-based-research/hse-midland-area-research-ethics-committee/

- ***Information and IT systems:*** The governance, management and support of research in the RHAs will be enabled by the roll out of the National Electronic Research Management System (NERMS). NERMS will allow the integration of the ethical and RGMS approval protocols and will facilitate collaboration between organisations, including HSE, S38 and Universities.

  NERMS will provide a portal for researchers to apply for approval from the Research Office and the REC before the research commences. The electronic system will have much needed functionality, including the management and storage of documents, the enablement of review workflows, and it will capture metrics and generate reports for research being conducted in the Irish healthcare system. The procurement of the system is currently underway.

- ***Leadership:*** Research leadership is essential to ensure the development of a culture of research in the HSE. Leadership will be built into the RHA structures at several levels:

  - ***Nationally:*** The National Committee for the Governance, Management and Support of Research (National RGMS Committee), chaired by the HSE National Director for Strategy and Research and reporting directly to the HSE Quality and Patient Subcommittee of the board, will act as the reporting authority for the both the RGMS structure and HSE RREC, and oversee the implementation of the RGMS Framework to ensure that national cohesiveness is achieved. This committee commenced operations in May 2022. The National Research and Development office, led by the AND Head of Research and Evidence, has a key role in providing national leadership. The office will be responsible for providing strategic national direction and standards, as well as empowering RHAs to do research through a mutually supportive relationship
  - ***Regionally (RHA level):*** *Leadership will be provided by the roles of RHA Chief Academic Officer, with responsibility for research and teaching, who has a strategic role and sits in the senior management team of the RHA. Operational leadership will be provided by the* RHA Director of Research. Oversight at Regional level will be provided by the RHA Research governance Board, containing representatives from Hospital, community and academic partners including the CAO.

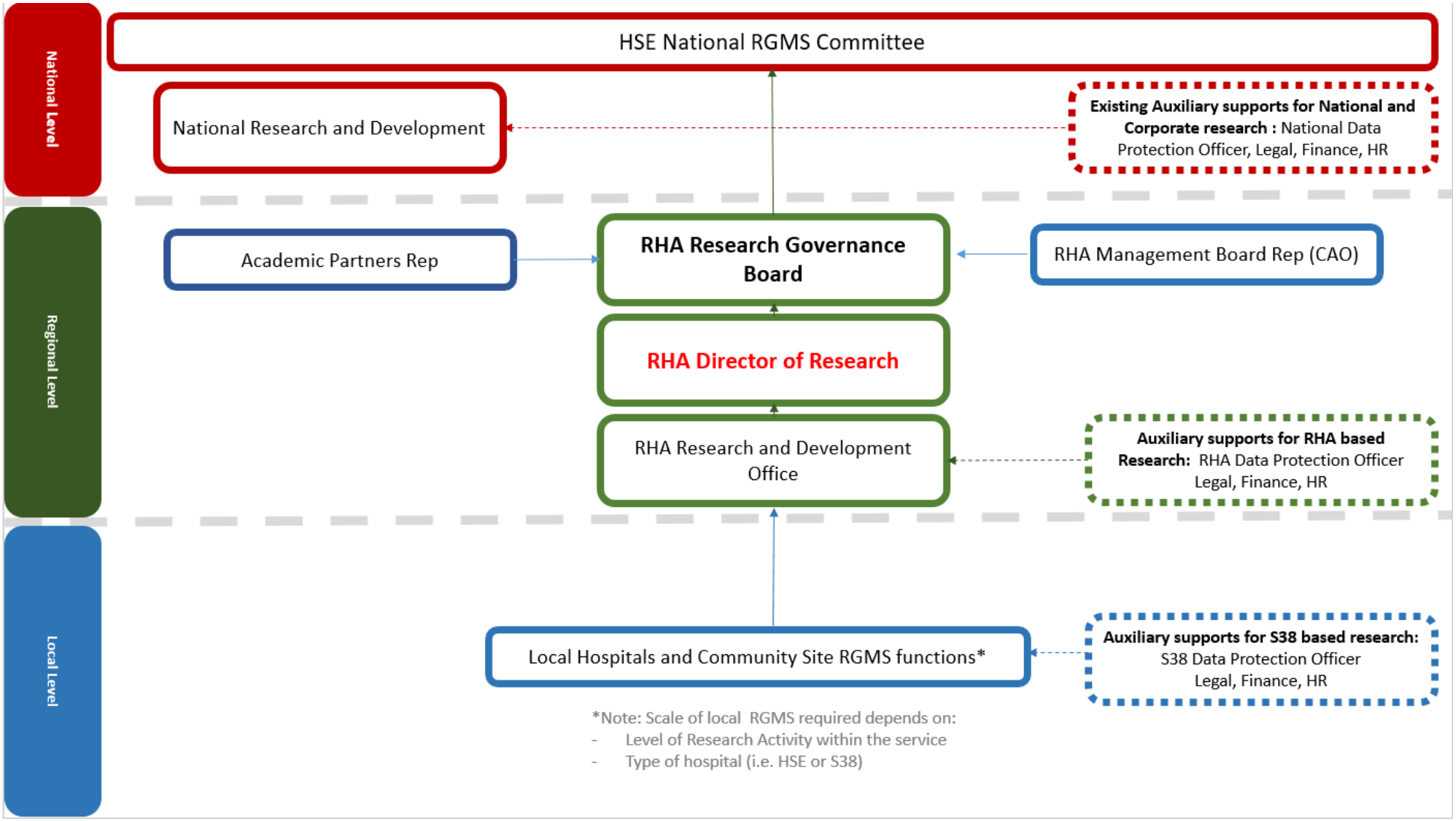
  Figure 1 in Page 5 represents graphically the concepts articulated above.

. Conclusion

Health research is a critical, but often underestimated, enabler of health service delivery and decision making. Countries with the most advanced healthcare services around the world have the highest numbers of researcher active staff per capita which also contributes to attract and retain the best staff. Research generates critical evidence to inform decision making and clinical practice but in order for this to happen, research needs to be part and parcel of everything we do. The implementation of the HSE Action Plan for Research 2019-2029 aims to realise the potential impact of research activity in full.

In the context of Slaintecare, it is imperative that we bring innovative solutions to deliver the care and treatment necessary to successfully address service demands and pressures arising of increasing life expectancy and demographic changes in our population. Hence, the conditions for sustainable research and innovation growth need to be an integral part of the design of the Slaintecare RHAs.

This proposal represent a realistic approach to build the foundation for those conditions to develop. It embeds research leaders within the decision making parts of the organisation, while at the same time establishing the supports, governance and oversight required to underpin high quality research activity. This proposal sets out an achievable path forward to drive a culture of research and innovation throughout the HSE and its funded organisations that will allow research to have the maximum impact into policy and practice.


National Level
Regional Level
Local Level
HSE National RGMS Committee
National Research and Development
Existing Auxiliary supports for National and Corporate research : National Data Protection Officer, Legal, Finance, HR
Academic Partners Rep
RHA Research Governance Board
RHA Management Board Rep (CAO)
RHA Director of Research
RHA Research and Development Office
Auxiliary supports for RHA based Research: RHA Data Protection Officer Legal, Finance, HR
Local Hospitals and Community Site RGMS functions*
Auxiliary supports for S38 based research: S38 Data Protection Officer Legal, Finance, HR
*Note: Scale of local RGMS required depends on:
- Level of Research Activity within the service
- Type of hospital (i.e. HSE or S38)

Appendix 1. How does the proposed RHA research structures fit within the overall national context?

The proposed RHA structures are an essential part of the overall national research infrastructure. This model is replicated in other EU countries such as UK or Spain. The different parts of this landscape have distinct and clear functions:

Department of Health– Government department responsible for

- development of National Legislation for health research (i.e Health Research Regulations, Research Ethics Committee Bill)
- input into other legislation to include health research (i.e Human Tissue Bill, Health Information Bill, Assisted decision making Bill,…etc)
- national health research related policy and strategy (i.e input into Impact 2030, etc).
- The Research Unit also provides a research service to the department to inform decisions.

Health Research Board – Main Government agency responsible for

- funding Health and Social care research in Ireland, who provides funding exclusively via the university sector.
- provides evidence base to the Department of Health to inform decisions
- managing data collections in the areas of alcohol and drug treatment and deaths, disability and psychiatric admissions and discharges.

Universities – Key partners in the research and education process with a unique role in capacity building not only in research but in training of health and social care professionals of the future.

National HSE Research and Development – This HSE function has several roles.

- Development of HSE national research strategies, policies, frameworks and standard operating protocols (i.e National HSE Consent for Research Policy, HSE National Framework for the Governance, Management and Support of Research... etc) and for providing leadership for implementation and ensuring a cohesive approach to research support, management and governance at national level.
- Providing a Coordination, oversight and support service for the Regional Research Offices and the Regional Research Ethics Committeess. This includes the provision of support, the implementation of a quality assurance programme for both the HSE Research Ethics Committees and the regional and local research governance structures and the development of training programmes for RHA Research Office Staff and research Ethics committee members to address skill shortages in this area.
- Provide appropriate governance to the research activity within national and corporate HSE divisions (i.e commissioning of research, research data sharing protocols, legal agreements, etc).

RHA Research Structures

- ***Research Offices, RECs, Data Protection Officers***-
  - These provide appropriate infrastructure for the governance to the research activity of hospitals and community services within a regional health area, to ensure compliance with ethical, legal and regulatory requirements. It also supports the local sites with the management of research, including research funding (research funding is received from commercial and university sponsors).
- ***Research leadership*** (RHA Research governance board, Director of Research, Chief Academic Officer) - These roles are essential for :
  - Accountability for research governance for the RHA
  - Research strategy and priority setting for the RHA
  - Leading engagement and collaboration with academic sector to address the RHA research priorities.

Local research structures - These provide research support for staff and research management for staff at the sites and the liaison with the RHA research office. These include (not exclusively) the HRB funded Clinical Research Facilities.

Appendix 2. Proposed Research Roles, responsibilities and remuneration within the RHA.

1. Regional Health Area Chief Academic Officer

The RHA Chief Academic Officer is a key member of the RHA Senior Executive Management Team responsible for establishing a formal channel for cooperation and collaboration between the RHA hospital and community sites within the RHA and relevant academic partners for the purpose of research and education. While existing hospital groups are strongly aligned to one academic partner for educational purposes, it is anticipated that the RHA structure may also establish collaborative research links with a broader array of academic partners inside and outside of the geographical limits of the RHA. The CAO will be a pivotal role in maintaining those links and relationships.

This is a strategic role with responsibility for academic and research policy and strategic planning for the RHA, which should liaise regularly with National HSE R&D and the Department of Health to ensure national strategic alignment and to contribute to national policy both at departmental and HSE levels.

Essential Duties and Responsibilities

- Contribute to the development of National and RHA strategies and ensure the strategic intent for research and education is aligned to health service needs.
- Drive the establishment of strong links with academic partners for the purpose of research and education and ensure that such links are formally established by way of relevant legal agreements or Memorandum of Understanding, as appropriate, between the relevant Institutions.
- Represent the RHA institutions, and engage strategically at a national level (e.g. with the HSE National Research Governance, Management and Support Committee, the HSE National Office for Research and Development, the Department of Health, the Department of Further and Higher Education, Research, Innovation and Science, etc.).

Line management and reporting

- The RHA Chief Academic Officer reports directly to the Chief Executive Officer of the RHA as a member of the RHA senior management team.

  [NOTE: Further discussion required to determine the following: Is a joint post with the university sector appropriate? Does a joint post facilitate integration with university structures? Does a joint post create a conflict of interest? Should this person be a research leader involved in research activity while in post? Does the post need to be a consultant post considering the broad remit of the role incorporating community and social care?]

Remuneration

It is proposed that this post will be remunerated at Consultant level [*to be discussed further*]. ***0.5FTE***

2. Director of Research

The Director of Research will take overall responsibility for the governance of research activity in the relevant hospitals and community services within the RHA and ensure that the appropriate systems and safeguards are in place to allow for safe and effective research. The Director of Research will promote research internally and externally to relevant external stakeholders and seek to further develop capacity and avail of important external opportunities for development. The Director is also responsible for the smooth running of the RHA Research and Development Office and the management of its staff.

The Director of Research is responsible for the implementation of national HSE policies and frameworks at RHA and local level, and for the development of systems, and frameworks at RHA and local level as appropriate for the conduct of clinical research, notwithstanding that the ultimate responsibility for the regulatory and ethical integrity of research carried out by researchers at the RHA and aligned University partner(s) lies with the relevant Principal Investigator and Sponsor.

The Director of Research will establish strong links (as relevant to the location of the role) with:

a) Academics partners as required:
   a. To ensure the smooth and coordinated approach to research governance for collaborative projects or those involving staff with a joint academic-clinical appointment,
   b. to ensure effective and joint oversight of the academic HRB funded clinical research facilities.
   c. To implement HSE research and innovation related policies in a coordinated fashion with the academic policies.

b) RHA Management Team, including the RHA Clinical Director, the RHA Chief Academic Officer, the CEOs of the relevant hospitals and Community healthcare services management teams, including the Head of Services and Chief Office within the group and any individuals in research management related roles at local level.

c) National HSE Research and Development to contribute to the development of national research related protocols, frameworks and policies.

The Director of Research is responsible for the implementation of national HSE policies and frameworks at RHA and local level, and for the development of systems, and frameworks at RHA and local level as appropriate for the conduct of clinical research, notwithstanding that the ultimate responsibility for the regulatory and ethical integrity of research carried out by researchers at the RHA and aligned University partner(s) lies with the relevant Principal Investigator and Sponsor.

The Director of Research will be a key member of the RHA Research Governance Board.

Essential Duties and Responsibilities

- All staff engaged in research will be accountable to the Director of Research with respect to their research activities via the structures provided by the RHA R&D Office.
- Be responsible for the development and management of clinical research governance, risk management and oversight functions within the RHA.
- Implement national research policies or develop local policies and procedures when appropriate as they relate to clinical research. When relevant it should be a priority to ensure there is integration with relevant processes of the University partner, and alignment with both local and national bodies as much as is possible
- Oversee the day to day running of the RHA R&D Office and review Clinical Research applications referred by staff within the RHA R&D Office, in particular those deemed medium to high risk and chair the RHA Research Risk Management committee.
- Develop and lead on audit and regulatory functions and oversee any external regulatory reviews (e.g. HPRA)
- Oversee and manage any external enquiries relating to corporate and generic research and related issues e.g. from the media, other agencies and Government departments, PQs, etc.
- Ensure research in the RHA is underpin by the highest principles of research integrity.
- Promote the health and social care research interests of the HSE/ Service provider at a local, national, and international level by engaging with relevant bodies, committees, and working groups.
- Create an appropriate culture to promote and enhance health and social care research and development across health service and University sector.
- Ensure the appropriate structures are in place to facilitate research and innovation in acute and community sites.

Line management and reporting

It is proposed that the appropriate line manager for the Director of Research should be either the RHA Chief Academic Officer with a dotted reporting line to the RHA Clinical Director of Research.

The Director of Research reports directly to the HSE senior management of the RHA via the RHA Research Governance Board.

Conflict of Interest

It is recommended that the post holder will not be involved in own research activities for the duration of the tenure, in order to ensure the integrity of the office and avoid any potential conflict of interests.

Remuneration

It is proposed that this post will be remunerated at a minimum at Assistant National Director level. (IMPORTANT NOTE: Existing Directors of Research for Hospital Groups are Clinical consultants so this scale may not be appropriate – this needs further discussion). **1FTE - €129,572.**

3. RHA Data Protection Officer **(NOTE: This role is required at RHA level for all HSE organisations within the RHA. All S38 and S39 organisations within the RHA have to have their own DPO as they are independent legal entities.)**

The primary role of the DPO is to ensure that the HSE processes the personal data of staff, health service users and any other data subject in compliance with the data protection legislation. The DPO will be responsible for establishing a privacy framework for the RHA. Such framework should harmonize the data protection compliance protocols with those of the S38 and academic partners for the purpose of research activity. The DPO will delegate responsibility for the review of Research Related Data Protection Impact Assessments to the RHA Research Office, and only in specific and complex situations research DPIAS will be referred to the Regional DPO from the Research Office.

Full time role – **1 FTE, GM level. €91,630**

4. Regional Health Area Research Office Manager and Contracts and Data Governance Lead (GVIII) –

The post holder will have a key role in implementing the HSE national policies and protocols for the governance, management and support of research activity at the level of the Regional Health Area under the direction of the RHA

Director of Research. He/She will line manage the research office staff and will have technical knowledge of data protection and legal requirements for research activity.

Essential Duties and Responsibilities

- Lead the implementation of national Research and development policies and standards of practice as well as development of local guidance or standard of practice to suit the requirements of each service in alignment with the research governance framework. .
- Implement the national guidelines for the registration, monitoring and oversight of the clinical research activity. This will involve a registration process of clinical research that will ensure regulatory issues are transparently addressed and responsibilities of the different legal entities clarified before research is undertaken.
- Work with the RHA Director of Research to ensure that there are processes in place for the management of the financial oversight of research occurring within the RHA/HSE service as appropriate.
- Key responsibility for providing legal oversight and support, as well as contract management, including:
    - Prepare, review, advise, negotiate and execute a range of Contracts, including but not limited to Clinical Trial Agreements, Data Sharing Agreements, Industry, Non-Disclosure Agreements, Material Transfer Agreements, Services Agreements, Memorandums of understanding, and other legal documentation associated with health research.
    - To review and negotiate Contracts offered by partner and funding organisations to assess their fitness for purpose, understand Contract Law and Data Protection Law, and advise on the same.
    - Understand and advise on insurance and Clinical Indemnity scheme in line with the State Claims Agency guidelines. Ensuring the correct forms and documentation are compiled for the research to be correctly insured and indemnified by the State Claims Agency.
    - Review agreements and contracts to identify risks, liabilities, or gaps in information and resolve these issues.
    - Ensure that Contract documentation is developed and executed in a timely and efficient manner, liaising closely with researchers and administration as appropriate, keeping them fully informed of progress. That all legal and regulatory requirements are met.
    - Be responsible for ensuring that Contract amendments and reviews are monitored, gathered, and acted upon as appropriate.
    - Assist in the direct negotiation of disputed contractual clauses, working with colleagues within and outside the organisation to bring agreements and contracts to mutually acceptable conclusions.
    - Provide advice and assistance to staff on contractual issues and key legal contractual obligations and any public administration implications.
    - Following the National system for the management and administration of research contracts and ensuring that it is updated during negotiations to acceptance of Contract and that all appropriate data is recorded for the effective administration of the project.
    - Work closely with academic and funders and Professional Services colleagues to advise on and interpret clauses within the wider context of a project. Implement and monitor effective Contract Management and exception reporting of the Research Contract function.
- Key responsibility for research data governance.
    - Support, follow, and implement the Data Protection and Information Security Policies for Research (including vulnerability management, internal audit, procedures, and guidelines) as part of the development of the HSE Data Governance Framework to ensure regulatory compliance is embedded throughout the organisation and relevant reports are issued for control and statistical purposes.
    - Provide Data Protection and Information Security support and advice to your research functions in relation to GDPR and Health Research Regulations compliance.
    - Assist the HSE regional Deputy Data Protection Officer with any research legal matters related to data protection and research.
- Manage the research team and provide support and guidance for the data sharing, data processing, and material transfer agreements, and engage with relevant stakeholders in ensuring the national Research and Development templates are being used correctly.
- Provide advice and information and where required support to the research teams in all research data protection-related issues and associated legal instruments as they relate to research, including GDPR, Health Research Regulations, etc.
- Provide data protection advice to the regional HSE Reference Research Ethics Committees as required.
- Support staff training on data protection in the context of research.

Line management and remuneration

- This post will report directly to the RHA Director of Research.
- This post will be remunerated at a minimum as a GVIII (1FTE €85,909).
- A legal qualification and experience with data protection matters are essential for this post.

5. RHA Research Office - Research Support Officer (GVII)

The post holder will have a key role in supporting the establishment of the RHA R&D Office and embedding its activities within the overall operational systems already in existence.

The support of the R&D Office and researchers within the RHA will include

- Supporting RHA R&D Office activity under the direction of the RHA Research Office Manager/Regulations and Compliance Regional Lead
- Manage the reporting requirements for Research related activity for the RHA, including research Key Performance Indicators and metrics
- Supporting the regional implementing the national protocols for the governance, management and support of research.
- Provide a support service for internal and external researchers to help them navigate the complex regulatory, ethical and regulatory requirements.
- Manage the research registration process and review applications upon receipt to determine the level of risk and the appropriate approval pathway proportionate to such risk.
- Oversee the roll out and management of electronic research management system to the Regional Health area and provide oversight for the set-up of roles, approval workflows and host institutions in line with national HSE R&D policy.
- Oversee the validation of Principal Investigators to ensure all researchers involved in clinical research are qualified by education, training, and experience to perform their respective tasks
- Work with the RHA Research Regulations and Compliance Regional Lead to ensure the implementation of the governance structure for clinical research activities occurring within the service are aligned with the HSE Research Governance Framework.
- Support the researcher community on the completion of Data Protection Impact Assessments for research activity and other sections of the research registration form.
- Support the implementation of the national guidelines for the registration, monitoring and oversight of the clinical research activity. This will involve a registration process of clinical research that will ensure regulatory issues are transparently addressed before research is undertaken.
- Liaise with local sites and research ethics committees to ensure effective implementation of research approval and authorization workflows.
- Collaborate with National R&D in the implementation of the quality assurance framework for research governance.
- Supporting systems for the management of complaints about clinical research including clinical research misconduct and fraud.
- Conducting or coordinating audits of research projects, where required
- Support the preparation of reports to regulatory bodies, as required
- Liaison with HRB funded clinical research facilities, host sites, national research ethics committee, etc.
- Support the implementation of the HSE Research Integrity Policy and Code of Good Research Practice (to be developed by National HSE R&D in 2023) at RHA level.
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Line management and remuneration

- This post will report directly to the RHA Research Office Manager/Legal and Data governance Lead.
- This post will be remunerated at a minimum as a GVII (1FTE €66,689).
- A legal qualification and experience with data protection matters are essential for this post.

6. RHA Research Office - Administrative Support Officer (GV) – 1FTE

The Research Office Administrator is responsible for providing professional research administration support and ensuring the smooth operation of the RHA R&D Office, as well as providing administrative support to the RHA Director of Research and the staff within the RHA R&D Office. They will play a key role in implementing efficient office systems, and managing general administration, queries and the back office requirements for the electronic research management system.

Essential Duties and Responsibilities

- To provide the RHA R&D Office with a comprehensive and professional office administration support including assistance in preparing reports, correspondence and other documents as necessary and providing administrative support for meetings and taking minutes when required.
- Provision of support to users of the national electronic research information management system (NERMS) with super-user permissions to manage the set up and maintaining up to date approval workflows within the RHA, validating system users, etc.
- Extraction of metrics from the NERMS system for the purpose of elaborating regular reports on research activity for the attention of management.
- Provide support as necessary to RHA R&D Office in facilitating Research promotion & dissemination .This may include, but is not limited to, scheduling training events, arranging promotional events, and managing web-based resources for the promotion & dissemination of information relating to Research across the RHA.
- Diary management for the Director of Research, the Chief Academic Officer and the RHA Research Office Manager.

Line management and reporting

- The Administrator will be line managed and report to the RHA Research Office Manager.

Remuneration

- This post will be remunerated in the HSE GV scale –FTE annual costs €54,847

7. Research Ethics Committee Manager. (GVII) (start with 0.5 FTE – progress to 1 FTE)

The Reference REC Manager is responsible for:

- Reviewing applications as they are received to ensure they are complete, presented clearly, and ready for REC review, in order to improve the efficiency of the committee.
- Supporting the researcher community with the completing of the research ethics application and ensuring the submissions to the Research Ethics Committee are of high quality.
- Management of the HSE Reference REC office and line management of the REC administrative support officer.
- Ensuring compliance of operations with the HSE Reference REC Code of Management and Governance.
- Ensuring effective recruitment strategies are put in place to maintain appropriate HSE Reference REC membership as per agreed guidelines.
- Supporting the Chair and Deputy Chair as appropriate.
- Ensuring appropriate communication with relevant parties (i.e. local Research Office, HSE REC SCO).
- This post will be remunerated as a GVII (1FTE €66,689).

Line management and reporting

- The Research Ethics Committee Manager reports either to the Director of Research and to the Chair of the Research Ethics Committee.

8. Research Ethics Committee Administrative Support Officer. (GIV – 0.5FTE)

The Administrative Support Officer provides administrative support for the REC office and supports the work of the REC Manager.

The REC Administrative Support Officer is responsible for:

- Providing administrative support to the Chair and Deputy Chair, and managing the administrative tasks associated with the REC office. • Providing administrative support to the REC office.
- Providing support to HSE Reference REC members and Principal Investigators in using the REC information systems.
- Providing administrative support for the compilation of the annual report, recruitment processes, appeals, etc.
- The administrative support officer could be a member of the research office and, if workload allowed, have shared administrative support responsibilities (Research Office and REC).
- Managing the electronic research information management system and providing support to system users including researchers and research committee members.

Line management and reporting

- The Research Ethics Committee administrative support officers reports to the Research Ethics Committee Manager
- This role is a GIV, 0.5 FTE. (€22,101).