Research & Development
Taighde & Forbairt

Governance of Research in the HSE and HSE Funded Healthcare Services

A Scoping Report

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Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

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Contents

Glossary

CAO	Chief Academic Officer
CEO	Chief Executive Officer
CHO	Community Healthcare Organisation
CTI	Cancer Trials Ireland
CIS	Clinical Indemnity Scheme
CRF/C	Clinical Research Facility / Centre
CRCI	Clinical Research Coordination Ireland
CRDI	Clinical Research Development Ireland
CTA	Clinical Trial Agreement
CTIMP	Clinical Trial of Investigational Medicinal Products
DoH	Department of Health
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
GDPR	General Data Protection Regulation
GIS	General Indemnity Scheme
GCP	Good Clinical Practice
HG	Hospital Group
HRB	Health Research Board
HSE	Health Service Executive
HR	Human Resources
IP	Intellectual Property
IRAS	Integrated Research Application System
MRCG	Medical Research Charities Group
NIHR	National Institute for Health Research
NHS	National Health Service
PCRC	Primary Care Research Committee
PI	Principal Investigator
PPI	Patient and Public Involvement
R&D	Research and Development
REC	Research Ethics Committee
RICO	Regional Integrated Care Organisation
SOP	Standard Operating Procedure
SCA	State Claims Agency

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Executive Summary

A significant level of health research activity is currently on-going in the Health Service Executive (HSE) and associated organisations, and a wide range of clinical and non-clinical staff members are engaged in this activity. However, a review of the existing research governance arrangements for research has identified many gaps and opportunities for improvement. Although there are some local examples of good practice, the existing research governance structures are by and large uncoordinated, fragmented and in some instances, non-existent.

Research Governance is the framework that enables institutions to approve and authorise health research, to ensure that research is of sufficient quality, and that the rights, dignity, safety and wellbeing of all those involved are protected. Health research governance processes must ensure that research is planned to the highest standards before it can start, and must provide mechanisms to enable relevant checks, which are essential to guarantee public confidence.

Examples of best practice in other countries demonstrate that effectively governed research can contribute to an evidence-based culture that recognises the added value of research to service improvement, recruitment and retention of staff, continuing professional development and income generation. Research into causes of disease, methods of prevention, techniques for diagnosis, and new approaches to treatment have increased life expectancy, reduced infant mortality, limited the toll of infectious diseases, and improved outcomes for patients. The lack of appropriate research governance mechanisms in the HSE may lead to wasted resources and duplication of effort, hence the beneficial impact of research on the service may not be fully realised.

The HSE and associated organisations have responsibilities for the research activity that they host, and the findings in this report have informed the development of the HSE Action Plan for Health Research which will aim to address the current shortfalls.

Key Findings

- **A research governance framework** which provides clarity in relation to roles and responsibilities as well as a standardised and reliable approach to research governance for all HSE and associated organisations **does not exist**. Given the large volume of on-going research activity, this poses a risk and creates significant difficulties for collaboration with the third level sector and with industry.
- There is a **deficit of research management staff, standardised processes, guidance and infrastructure** in place to adequately support, approve, monitor and report on research activity. This impacts on the capacity to comply with legislation and implementation of appropriate governance arrangements. The requirements for compliance with the new Data Protection Act and Health Research Regulations 2018 represent a significant challenge in this regard.
- The **research ethical approval landscape is uncoordinated, unsupported and fragmented,** posing a significant barrier to the effective initiation of research studies and a significant duplication of effort.
- **Current financial and human resource (HR) management practices are not tailored for research.** This has resulted in the development of ad hoc local arrangements without clear lines of responsibility or accountability. Existing processes are a significant barrier for research capacity building and HSE mechanisms to facilitate the financial and HR management of research need to be created.

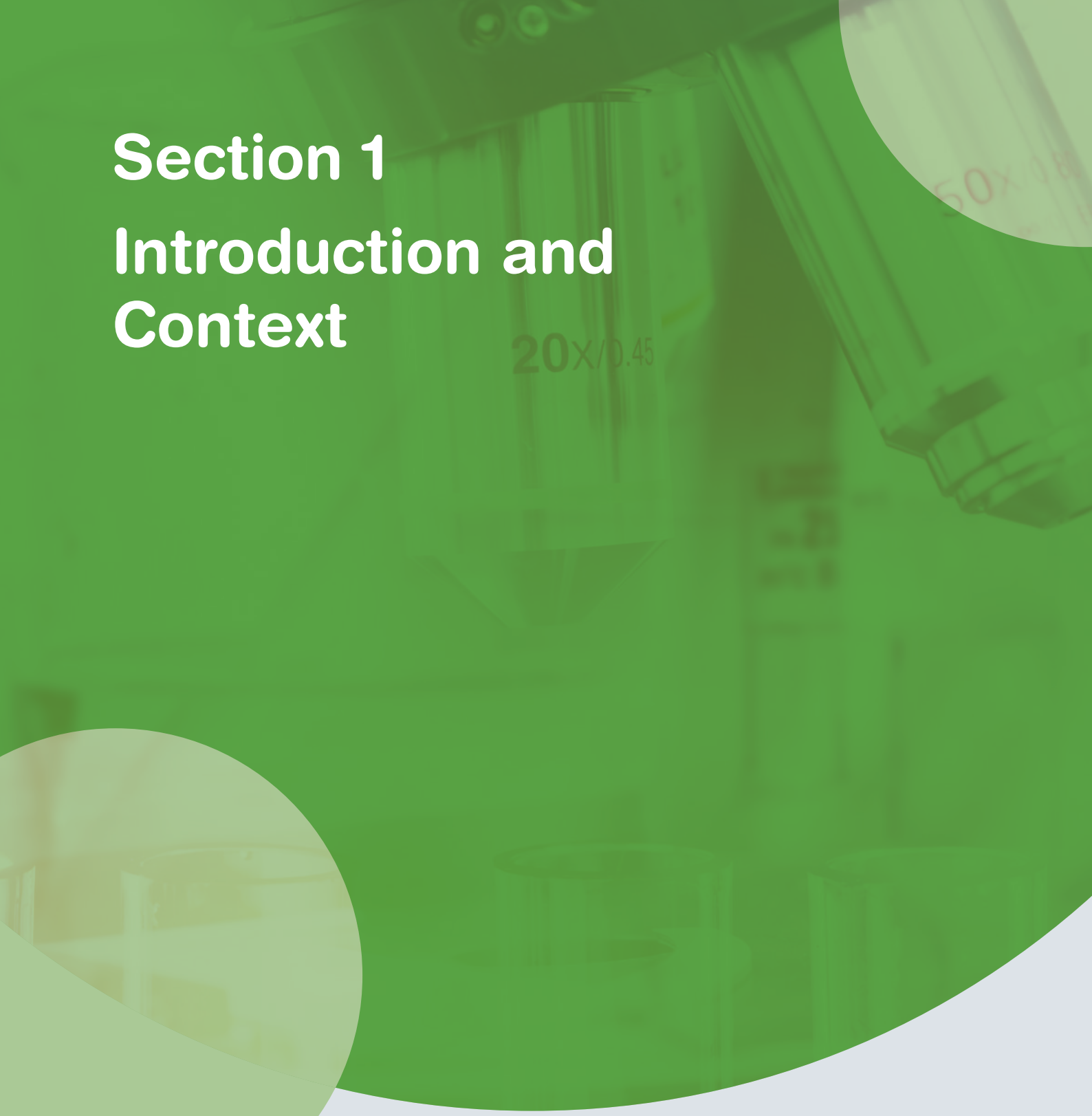
- The development of academic Clinical Research Facilities / Centres (CRFs/Cs) and the growing role of the universities in sponsoring clinical research have resulted in a **significant increase in clinical research without an appropriate joint approach to governance between the hospital and university sectors,** which leads to lack of clarity in relation to responsibility and accountability.
- **Suitable policies, guidelines and standards need to be developed** to support and govern the research activity within the service at national level.
- **Knowledge gaps and research priorities for the HSE and associated organisations need to be articulated** to facilitate the alignment between research activity and service needs, and to meaningfully contribute to the national discourse.

Recommendations

- **Governance Framework:** A framework for governance of health research needs to be designed and implemented to clarify accountability and responsibilities across the entire service. This will set the foundation for the implementation of further mechanisms for the effective management of research at national, local and regional level.
- **Research Policies and Guidelines:** The necessary policies, guidelines and standard operating procedures (SOPs) need to be developed to facilitate the governance of health research in the health service, including data governance and intellectual property management.
- **Development of Research Management Capability:**
  - Research information systems, including registration systems, need to be put in place to support research management and governance at local and national level.
  - Research offices need to be created at local or regional level to facilitate research management and to provide support, linking with HSE R&D and university research offices to ensure a consistent approach, and to provide information for national decision-making.
- **Third Level Sector:** Work with third level partners is required to maximise collaboration, to clarify the implications of staff affiliations, and to develop the required legal frameworks for appropriate research governance.
- **Research Ethical Approval:** The existing HSE Research ethical approval landscape needs to be reformed in the context of the upcoming National Research Ethics Committee.
  - Research Ethics Committees (RECs) need to be further embedded into research governance structures and supported in order to fulfil their role effectively.
  - The current shortfall of ethical approval mechanisms for community research requires immediate action.
- **Compliance with Legislation:** Staff need to be supported to comply with the Data Protection Act (2018) and the new Health Research Regulations (2018), as well as with other relevant legislation.
- **Financial Governance:** Appropriate procedures for the costing, receipt, hosting, management, usage and reporting of research funding need to be introduced to ensure compliance with funder requirements and effective use of financial resources.
- **HR Management:** Standardised processes to govern access of third party staff to healthcare services for the purpose of research as well as to facilitate the hiring of staff with external research funds need to be put in place. Mechanisms to facilitate existing staff to get involved in research need to be introduced.

- **Patient and Public Involvement (PPI) in research:** In line with best practice and following the lead of the Health Research Board (HRB), the development of PPI within research needs to be facilitated to enable the involvement of patients in research priority setting, research design, communication, etc.
- **Key Roles:** Research leadership roles, such as that of the Chief Academic Officer (CAO) for the hospital groups (HG) need to be created for the Community Healthcare Organisations (CHOs) or for integrated care structures that will be created as per Sláintecare. Overall these roles need further clarity regarding their responsibilities and further support to enable them to discharge their research related responsibilities.
- **Articulation of Research Priorities for the HSE:** It is important to articulate the HSE research priorities in order to contribute to the national discourse on research priorities and to enable alignment between research activity, health service priorities, and national strategies (i.e. Sláintecare), with a view to minimising research and resource wastage.

The establishment of HSE R&D represents an opportunity to address existing challenges and to build robust collaborative links with other key stakeholders within the national health research system to ensure success. These recommendations will be incorporated into the HSE Action Plan for Health Research and some will require financial resourcing, but they are absolutely necessary to ensure the safe conduct of high quality research and to deliver on the HSE and associated organisations' duties to safeguard the rights, dignity, safety and wellbeing of all those involved. Without the introduction of effective research governance, the benefits for patients and services that arise from high quality research and research active staff, the creation of an evidence-based culture, and the opportunity to derive economic benefit from research will fail to be realised.



Section 1

Introduction and Context

1.1 Introduction

A recent assessment of health research activity showed that a significant body of research is currently taking place in the HSE and its associated organisations.[1] This research activity has grown from the grass roots in all sectors of the health service, driven by individual interests, without a particular organisational strategy to govern or support it. As a result, the governance structures for research are significantly underdeveloped.

The HSE and its associated organisations have responsibilities regarding the research activity that they host. Good governance reduces the risk to participants and staff, and articulates clear lines of organisational, institutional and individual responsibility and accountability. Good governance is absolutely essential to safeguard patients and the public, to ensure the quality of the research, and to encourage participant's involvement in research.

Research Governance is the framework that enables institutions to approve and authorise health research, to ensure that research is of sufficient quality, and that the rights, dignity, safety and wellbeing of all those involved are protected.[2] Examples of best practice in other countries demonstrate that effectively governed research can contribute to an evidence-based culture that recognises the added value of research to service improvement, recruitment and retention of staff, continuing professional development, income generation, and improved outcomes for patients and staff.[3] [4] [5]

The purpose of this report is to provide an overview of the governance arrangements as they currently are in the HSE and its associated organisations, with a view to outlining the gaps in current provision and the opportunities to implement good practice and a consistent approach to research management. The report provides specific recommendations to address each of the issues identified. These recommendations will be considered in the development of the ten-year HSE Action Plan for Health Research.[6]

1.2 Methodology of the Report

Much of the information in this report was obtained while searching for data and information to benchmark the research activity currently being undertaken across the HSE and associated organisations.[1] This required an intensive process of engagement with many stakeholders throughout 2018 including HGs and their CAOs, CHOs and staff from national services, directors and staff of CRFs/Cs, university research offices, RECs, Cancer Trials Ireland (CTI), HRB, the State Claims Agency (SCA), HRB Clinical Research Coordination Ireland (CRCI), Clinical Research Development Ireland (CRDI) via the Corporate Enabling of Clinical Research Initiative, Medical Research Charities Group (MRCG), individual clinical trial networks and research groups, legal departments in universities and hospitals, the HSE Data Protection Officers (DPO), the Research Unit in the DoH, and individual researchers. While the process did not involve a systematic review of all sites and stakeholders, it provides a credible analysis of the national picture. The recommendations are based on some local examples of good practice, on the models for research governance that currently exist in the Irish academic sector, the UK model of governance for research in the National Health Service (NHS) and best practice advice from the NHS Research and Development Forum.[i]

1.3 Scope

For the purpose of this report, research is defined in accordance with the UK Research Governance Policy Framework as **"the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods"**.[7] It refers to research that takes places in the HSE and its associated organisations that involves patients, data, staff or infrastructure.

This includes:

- Activities that are carried out in preparation for, or as a consequence of, the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results.
- Non-interventional health and social care research (i.e. projects that do not involve any change in participants' standard treatment, care or other services).
- Projects that aim to generate hypotheses, methodological research and descriptive research.
- Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, which also fall into the definition of research.

During the course of this governance scoping exercise it was evident that activities which may involve investigative methodology but are not research (e.g. clinical audit, standard service evaluations), are often confused with research by many sectors of the service.

For the avoidance of doubt, these are only included in the scope of this report when they include a significant research component that fits the above definition.

1.4 National Strategy and Policy Context

Health research can make a significant contribution to the reform of the Irish health system by providing high quality clinical, population health, and health services research-based evidence. The Sláintecare Implementation Strategy[8] states:

> *"Health information and research, and the infrastructure and skills required for their generation and exploitation must become a national priority."*
>
> *"Health research is a key factor in promoting the health of the population, combating disease, reducing disability and improving the quality of care. It brings learning from international best practice and appropriate evaluation techniques and application. This evidence is essential to the creation of a fairer, more efficient health system and for the delivery of better health outcomes. In an environment that is dynamic and changing, health research in Ireland needs to be positioned to make its greatest contribution for patients, the health system and the economy."*

The Sláintecare Implementation Strategy articulates the intention to develop a new broad-based national health research strategy to develop and connect the health research system in Ireland. Critical to these deliberations will be the establishment of a Research and Development Forum, which will include representation from the health research and innovation system. This forum will continue the work of the

i http://www.rdforum.nhs.uk/content/

Health Research Group whose efforts resulted in the publication of the Action Plan for Health Research 2009-2013.[9] Unfortunately the HSE objectives articulated in the plan were not fully achieved. The HSE specific responsibilities as outlined in the plan were to:

- Lead a National Health Research System,
- Reform the health research governance structures; specifically to develop a Research Governance Framework for research in the health services that would include principles and standards of good practice.

The creation of HSE R&D provides an opportunity to provide support and coordination, so that the health service can become a key player within the national health research system. The findings of this report will inform the design of the programme of work to be carried out to enable effective management and governance of health research in the HSE. The university sector (though CRDI), the HRB, the DoH, and other stakeholders have shown strong willingness to collaborate and support the work of this new function. The improvements in health research governance will be dependent upon all key stakeholders working together in a collaborative fashion. The university sector is also conducting a review of current health research governance from the perspective of the universities (the Corporate Enablement of Clinical Research initiative).

The enactment of recent legislation puts a further onus on the HSE to address existing gaps in the governance of health research within the health service. Recent changes in health research legislation include the following:

- General Scheme Patient Safety Bill 2018.[ii]
- Clinical Trial (clinical trials on medicinal products for human use) Regulation EU No. 536/2014.[iii]
- General Data Protection Regulation (EU) 2016/679, May 2018.[iv]
- Data Protection Act 2018.[v]
- Health Research Regulation August 2018.[vi]

  The Health Research Regulations 2018 highlights the obligations of data controllers, including the need for REC approval,[vii] explicit patient consent, and a thorough assessment of the data protection implications. Hence, a robust set of governance procedures is needed to ensure compliance with legislation and policy.

ii https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

iii https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

iv https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679

v http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/pdf

v http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

vii Ethical approval is part of the process of research governance but is just one of a range of checks before approval is granted for research. Ethical review is to ensure research projects are scientifically sound and adhere to ethical principles.

1.5 Existing Research Activity in the HSE and Associated Organisations

Results from a research activity benchmarking exercise carried out by HSE R&D in 2018 indicate that a significant level of engagement with research currently exists, involving many different types of staff, both with and without academic appointments.[1] These include medical and nursing staff, health and social care professionals, and other non-clinical professions across the acute setting, in Community Healthcare Organisations and within national services and programmes.

In the absence of formal research activity registers, indicators of activity were used around four areas:

- **Staff involved in research**

  An online national survey carried out in the summer of 2018 captured nearly 2,000 responses of professionals who self-identified as being research active. The majority of respondents were both hospital and community-based. Health and Social Care Professions represented the highest number of respondents, but medical doctors accounted for the highest response rate (proportionate to the total number of professionals in the category). The majority of respondents reported spending between 1 and 10 hours conducting research per week.

- **Research studies undertaken**

  The number of projects approved in 2017 by the 32 Research Ethics Committees in the health service was in the region of 2,000 nationally. In the same year, the Health Research Board awarded 45 grants involving healthcare professionals as principal investigators (PI) or co-PI, and the HSE received six awards from the EU. In 2017 a total 27 clinical trials for investigational medicinal products started in Ireland, while 70 were on-going, and seven clinical investigations of medical devices were approved by the HPRA.

- **Publication outputs**

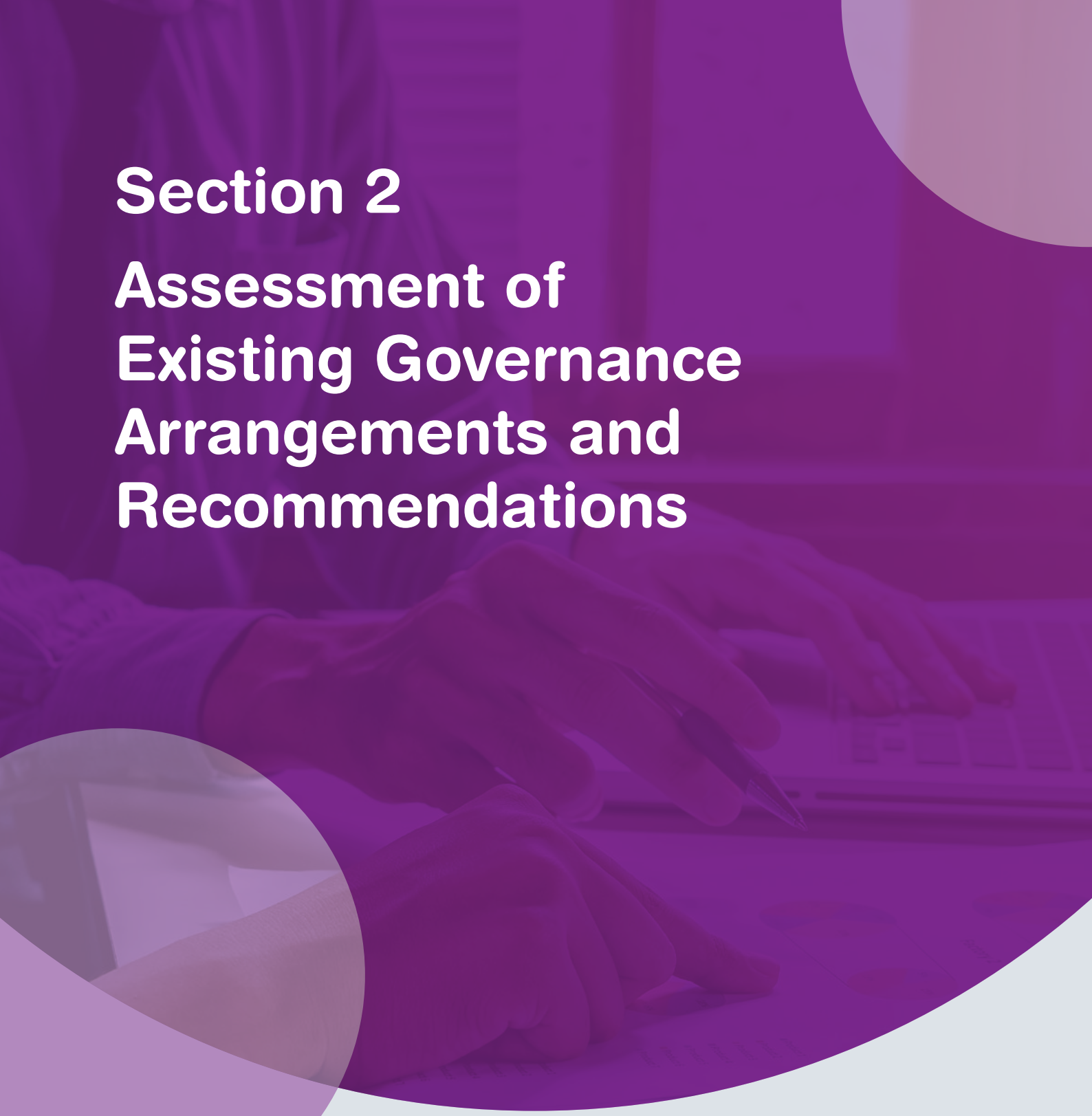
  Publication output by staff in the HSE and associated hospitals has increased slightly year-on-year over the last number of years. In 2017 the total number of journal articles nationally indexed in the Scopus database was 2,975, of which two thirds were produced by medical doctors with a university joint appointment.

- **Clinical research networks**

  An extensive number of Clinical Trial Networks and Collaborative Clinical Research Networks were in existence in 2018. These networks suggest a critical mass of research interest around specific diseases, and in addition to healthcare professionals many involve other actors such as academics, scientists, patients, professional bodies, etc.

  The HSE and its associated organisations have responsibilities with regard to this research activity and need to ensure that appropriate research governance is in place.

  The next section of the report assesses the findings of existing governance processes and highlights key recommendations for improvements. These recommendations will require cohesion, the creation and further development of existing capacity, and the development and sharing of knowledge and exemplars of good practice already in the system.



Section 2

Assessment of Existing Governance Arrangements and Recommendations

Good research governance helps to build research capacity, facilitates the translation of research into practice, reduces the risk of harm to participants and articulates clear lines of organisational, institutional and individual responsibility and accountability.[7] Proper governance of research is therefore essential to ensure the public can have confidence in, and benefit from, high quality research.

2.1 Roles and Responsibilities

The undertaking of health research involves a number of actors with individual and organisational responsibility. These include the principal investigator, members of the research team, the research sponsor, the funder, the host institution (i.e. the institution hosting the research), the employers, the organisation providing care, research participants, the research ethics committees, data protection officers, etc. In the HSE there is no clear designation of responsibility for research actors, clear lines of accountability for the research activity, nor clear processes of communication between all those involved. This results in ineffective practices and gaps in governance that create unnecessary risks and delays.

In the UK roles and responsibilities for research in health and social care are clearly articulated in the 'UK Policy Framework for Health and Social Care Research', which applies to Scotland, England, Wales and Northern Ireland.[7]

Recommendation

- Design and implement a framework for the governance of health research to clarify accountability and responsibilities across the entire service. This will set the foundation for the implementation of further mechanisms that will enable the effective management of health research at national, local and regional level.

2.2 Policies, Guidelines and Standard Operating Procedures (SOPs) for Health Research

Research policies, guidelines and SOPs set out principles of good practice and appropriate processes for the management and conduct of health research. These may be national or institutional.

In Ireland there are some national policy statements directly relevant to research including the following:

- National Policy Statement on Ensuring Research Integrity in Ireland [10]
- National Intellectual Property Protocol 2016 [11]
- National Principles for Open Access Policy Statement [12]

The first two have not been formally adopted or integrated into the research processes of the HSE. The third has been endorsed by the HSE via a position statement on Open Access and is supported by the availability of an open access publication repository (Lenus) in the HSE National Health Library and Knowledge Service.

Within the HSE there are a number of policies that have a direct impact on research activity, including:

- HSE Knowledge & Information Strategy [13]
- HSE Personal Data Protection Policy [14]
- HSE National Consent Policy – (currently under revision) [15]
- HSE Policy on the Management of Biological Agents in the Healthcare Sector [16]
- Child Protection and Welfare Policy [17]

However, the HSE does not have other key policies, guidelines or procedures that are essential to enable organisations to manage and govern their research activity, for example:

- Code of good research practice and scientific integrity
- Procedure for dealing with allegations of research misconduct
- Costing guidelines for research activity (e.g. for Clinical Trials of Investigational Medicinal Products)
- Guidelines for the financial management of research funds
- Clinical trials policy
- Data governance policy
- Research dissemination and knowledge translation guidelines
- Intellectual property policy
- Research ethics policy

In the absence of guidelines and a policy framework, confusion ensues and processes are developed at local level, leading to organisational inconsistencies.

Recommendation

- Development of the necessary policies, guidelines and SOPs to facilitate the governance of health research in the HSE and its associated organisations.

2.3 Registration and Study Approval

Registration of research projects with the host institution is the first basic step to enable oversight. Apart from a very small number of exceptions, a formal registration process for research does not exist in most hospitals, CHOs or within national or corporate functions in the HSE. As a result, the processes of approval for research activity are not formalised in most healthcare delivery sections of the organisation.

Research approval processes can ensure that the research:

- Places service users and staff safety to the fore of all activity.
- Is ethically sound and has received appropriate ethical approval.
- Is compliant with relevant legislation.
- Does not have a negative impact on local service delivery.
- Does not represent an unwarranted risk for the organisation, the service users or staff.
- Has appropriate insurance cover.
- Is properly funded.

Research approval process also can ensure that:

- The person or institution with overall responsibility for the study has been clearly articulated.
- The legal agreements required for the performance of the research have been put in place and properly assessed.

While formal registration does not exist, site approval is required for clinical trials for investigational medicinal products (CTIMPs). For these, a Clinical Trial Indemnity Form, which is required by the SCA, must be executed by the hospital Chief Executive. In addition a Site Specific Assessment form is also completed by the Investigator at each site. In the case of a multi-centre clinical trial, the Site Specific Assessment form for each site must be submitted to the Recognised Ethics Committee (REC) by the Chief Investigator for his or her application to be valid. Hence, before a regulated clinical trial can commence at a site, the CEO or person acting on his/her behalf at that site must have signed both the CT indemnity form and the Site Impact Assessment form.

However, this process applies only to regulated clinical trials, and not to other non-regulated clinical studies or investigations. Without formal processes in place, there is little local and national understanding of the breadth or intensity of research activity, and also little oversight. This poses a series of potential risks of litigation and financial exposure due to non-compliance with the data protection regulations. There are also additional impacts associated with duplication of research activity and the wasting of resources, poor research quality, a lack of transparency and deficits with regard to publication, knowledge mobilisation, impact and the translation of knowledge to improve patient care and organisational efficiencies.

In the UK, there is a standard national submission portal for the approval of research; the Integrated Research Application System (IRAS)[viii] which enables registration and approval to ensure that all research is ethically sound and compliant with legislation. Furthermore, research offices or departments exist in NHS trusts and hospitals, primary care, ambulance services or jointly with the universities, thus enabling appropriate local approval processes, oversight and the provision of support.

viii https://www.myresearchproject.org.uk/

In Ireland, research offices (or research management posts for this purpose) associated with healthcare delivery organisations do not generally exist, with the exception of a few examples, (i.e. Temple Street Children's University Hospital, Rotunda Hospital and St James's Hospital). In the area of primary care, the Primary Care Research Committee (PCRC) performed this role with regard to research taking place in CHOs (note as of January 2019 this committee is not active, see Section 3 of this report for further detail).

Recommendation

- Processes for registration and approval of research activity need to be put in place at local and national level. Ideally there should be a common process, enabled by an appropriate research information management system.
- Research offices need to be created at local or regional level to enable the implementation of local governance processes for research activity.

2.4 Research Ethics Approval

Research Ethics Committees have an important role in ensuring that proposed research activity will comply with ethical principles. They provide an independent assessment of the proposal with the intention of protecting the rights, safety, dignity and wellbeing of patients / participants. These committees evaluate the process of obtaining consent from the participants, and in the absence of other institutional approval protocols, they currently represent the only mechanism overseeing research activity.

In Ireland, there are at least 32 RECs associated with the HSE and Section 38 and 39 organisations (this excludes university RECs and those of private healthcare providers). These RECs vary greatly in relation to the research topics, the catchment area and the volume of applications that they review per year. Twelve of these RECs are recognised by the Department of Health to approve CTIMPs, so national trials or trials involving more than one site require approval from only one of these RECs.[ix] For all other research activity, REC approval must be sought for every local site where research is taking place. This impacts significantly on national studies involving multiple locations. In order to alleviate this situation and in an attempt to facilitate applicants, many RECs (22 out of the 32) use a common Standard Application Form for studies other than CTIMPs. Due to the existing lack of research governance structures, some of these RECs also ensure a certain level of general compliance with GDPR, but this is outside their terms of reference.

This REC structure was mainly designed to approve hospital based research, and only four of the 32 RECs have a formal mandate to approve CHO-based research. Some hospital-based RECs are currently reviewing CHO based research outside their terms of reference, which imposes a significant drain on existing resources. Despite this, CHO6 (Wicklow, Dun Laoghaire & Dublin South East), CHO7 (Kildare, West Wicklow, Dublin West, South City & South West) and CHO9 (Dublin North, North Central & North West) have no designated REC, which significantly hinders community-based research and the roll out of national studies in these settings. In addition, research based on national HSE services or corporate divisions have no designated REC for approval.

ix https://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/

These RECs are, for the most part, poorly resourced and poorly supported, and as a consequence many struggle to deliver on their obligations due to the sheer number of applications that they receive. RECs operate as independent structures with very little oversight or reporting requirements.

As of January 2019, the government has approved a proposal to prepare legislation underpinning the establishment of a National REC. The legislation will be drafted during 2019 to enable Ireland's compliance with the EU Clinical Trial regulations. It is envisaged that this committee will expand their remit beyond clinical trials to include multi-site clinical studies. This is a welcome development that will reduce the workload of existing RECs and will remove the need to apply to multiple RECs for projects involving multiple sites. Local RECs will however continue to be needed.

Recommendation

- Further support needs to be provided to existing RECs (support with recruitment of members, availability of administrative support, training for members, guidelines, etc.).
- The REC structure should be aligned to the new regional integrated care organisations (RICOs) by ensuring that there is at least one Regional REC per region in addition to the hospital RECs. This will address the existing lack of CHO coverage.
- Appropriate reporting structures need to be established for all RECs.
- The use of a Standard Application Form and SOPs needs to be promoted to ensure consistency of approach to REC review processes and operations.
- Appropriate training and support for members of RECs needs to be provided.
- All HSE RECs should have common procedures and standards of practice.

2.5 Research Data Governance – Compliance with GDPR and the Health Research Regulation

The European Union General Data Protection Regulation(GDPR) came into force across the EU on 25th May 2018 and brought with it significant reforms to previous data protection legislation. The GDPR was implemented in Ireland via the Data Protection Act 2018 which gave provisions of the GDPR further effect under Irish law. Together the GDPR and the Data Protection Act provide for higher standards of data protection for individuals and impose increased obligations on organisations that process personal data. Section 36[(2)] of the Data Protection Act allowed for the making of certain regulations relating to health research. These "Health Research Regulations" were signed by the Minister in August 2018 under S.I. No. 314 of 2018. The new legislation has highlighted in particular the health sectors difficulties at a sectorial level to appropriately govern personal data. Where other industries such as banking, finance and IT have functional data protection processes and procedures in place for decades, the health sector has been highlighted as being primitive when it comes to data governance, knowledge and training. The lack of a HSE Data Governance Policy for research has contributed to exacerbate the situation, as roles, responsibilities and liabilities have not been clearly understood.

The obligations of the Data Controller (defined under existing data protection legislation) have increased under GDPR. In the context of research, a Data Controller is the person or the institution with responsibility for ensuring that the research activity is compliant with the data protection legislation. A data controller may be an individual person (e.g. a General Practitioner) or an organisation (e.g. a Section 38 Hospital or the HSE). Individual investigators employed by a hospital or the HSE are not the data controllers and it is the responsibility of the organisation that employs them (as data controller) to ensure that the proposed research protocols are compliant with the legislation and data processing regulations. A "data processor" refers to a person, company, or other body which processes personal data on behalf of a data controller. The HSE similarly could be acting as a data processor in a given health research scenario. Under GDPR, a data controller or a data processor can be fined for breaches of the data protection legislation.

The new legislation has brought to the fore many questions in relation to data protection requirements, consent and data management.

2.5.1 Consent

A health researcher planning to use an individual's information for health research must obtain the explicit (informed and documented) consent of the individual to do so (note the term "explicit" it is often confused with "specific" but their meaning is totally different).

Explicit consent is the default position for all processing and further processing of personal data for health research purposes (unless the personal data is wholly anonymised or there is specific legal provision authorising the health research in question). The Health Research Regulations 2018 provided for a transition period (Amendment No. 1 – S.I.188) to allow for current health research projects that commenced on or before 7 August 2018, to reach the consent standard laid down by the GDPR.

It is recognised – as it is in other countries – that sometimes, in limited situations, obtaining consent is not possible and that the public interest of doing the research significantly outweighs the need for explicit consent. In order to cater for these types of situations a Health Research Consent Declaration Committee will be established, and the secretariat will be hosted by the Health Research Board.

2.5.2 Data Processing and Management

While Research Ethics Committees play an important role in ensuring compliance with regard to consent related matters, ensuring compliance with other GDPR aspects is not the role of the RECs, and the Data Protection Officers (DPOs) within organisations play a key advisory role. However there is a significant degree of misunderstanding within the research community about the nature of such roles.

All health research requires an examination of the data protection implications of the study. Studies that are classified as high-risk require the completion and retention of a Data Protection Impact Assessment (DPIA) document, which serves as a risk assessment tool, and requires DPO engagement. The approach to DPIAs requirements varies among organisations. This is complicated by the fact that some Section 38 organisations still do not have a formal DPO (as required by legislation) and there is only one DPO with four Deputy DPOs for all of the HSE organisations around the country. There is further complexity with regard to studies involving external organisations (e.g. universities), which may be designated as data controllers, joint data controllers, or data processors.

The HSE and associated healthcare organisations hold a vast amount of data which can potentially be used for research. The large and diverse range of processes and tools for data collection, management and local governance arrangements makes accessing data for research a very difficult process. Technology enablement and robust data governance arrangements are essential for this, and the emerging HSE's Integrated Information Service will be a critical enabler in this regard.

The Data Protection Commissioner of Ireland is the regulatory body responsible for monitoring compliance with GDPR and potential multi-million euro penalties apply to both the data controller and the processor found to be in breach of GDPR. Potential financial liabilities incurred as a result of GDPR breaches are not covered by the State Claims Agency. Hence the current governance gaps represent a significant financial risk to the HSE and associated healthcare organisations. It should be noted that some of the first GDPR fines recorded across the EU were to Hospitals.

Recommendation

- Development of a Data Governance Policy for the health service to include research activity and clarification of roles, responsibilities and liabilities in relation to data management and legislation.
- Development of standard operating procedures to manage the research approval process to include robust data governance arrangements.
- An appropriate communication strategy to articulate the role of data controllers, joint data controllers and data processors to highlight the requirements for compliance with GDPR and the Health Research Regulation, as well as appropriate delegation orders for the role of local data controller on behalf of the HSE.
- Introduction of a transparency programme to inform patients that their records may be accessed for the purpose of research-related pre-screening activities. This will need to include amending the Privacy Statement, and may include other measures such as the use of leaflets, posters, and online resources. This should be part of a wider national campaign to inform the public about the benefits of health research which will highlight research as an activity commonly taking place in Irish hospitals.
- Development of a research specific suite of standard templates for Data Protection Impact Assessments, Participant Information Leaflets and Consent Forms.
- Development of appropriate training on the Health Research Regulations and Consent for staff conducting health research involving data subjects.
- Introduction of an institutional contractual framework to enable research collaboration and data sharing between the HSE, section 38/39 organisations and universities.
- Development of robust mechanisms to manage patient consent and to ensure that this is built in as part of any future electronic health record for both acute and community settings.
- Development of a research data management and governance policy to clarify requirements in relation to archiving, storage and access.

2.6 Sponsorship, Indemnity and Insurance

2.6.1 Research projects with a formal Sponsor

The role of *Sponsor* is defined in both the national and EU legislation in the context of regulated clinical trials, i.e. clinical drug trials (involving investigational medicinal products) and regulated clinical investigations of medical devices. A sponsor is legally accountable for the project, and it takes responsibility for the initiation and management of a clinical trial and ensures that the funds are in place and are managed appropriately. This type of research is regulated by the Health Products Regulatory Authority (HPRA) and the sponsor must ensure that the trial is carried out in compliance with regulatory requirements.

In Ireland, most of the clinical trials of investigational medicinal products are sponsored by external organisations, including pharmaceutical companies, universities and Cancer Trials Ireland. Due to the onerous responsibilities, the role of sponsor for a regulated trial is rarely taken on by individual hospitals or individual research staff members.

The sponsors of regulated studies must have insurance cover in place that is specifically for clinical trials and investigations (including protocol insurance, product liability insurance, and 'no fault' insurance). This cover supplements the State Claims Agency's Clinical Indemnity Scheme (CIS) (covering personal injury from medical malpractice or negligence), and the General Indemnity Scheme (GIS) (covering employers and public liability), which is in place for the HSE and voluntary hospitals. The sponsor is also required to indemnify 'and hold harmless' the hospital and the HSE by completing the Clinical Trial Indemnity Form, which forms part of the Clinical Trial Agreement (CTA) or contract.

As regulated projects always have a sponsor (which duties are defined in legislation) who is legally responsible for the project, these are of relatively low risk for the hospital or the HSE from the perspective of indemnity and insurance. From the perspective of safety for patients, the risk would have been explicitly explained during the consent process, evaluated by an ethics committee and the sponsor, and minimised by virtue of the stringent conditions imposed by the regulator. However, there may be some reputational and other considerations that should be assessed by the hospitals before the research starts.

For the purpose of this report, the term non-regulated research refers to all other research that is not regulated by the HPRA. For these studies, the role of sponsor is not formally defined in national policy or legislation, or by the HSE, but the term "sponsor" is also used with the same meaning for non-regulated studies which are sponsored by the universities.

The role of universities as sponsor has brought to the fore the current gaps in institutional governance arrangements for clinical research in hospitals, and the lack of clarity in relation to roles and responsibilities. This is especially relevant when the studies are led by a member of staff with a joint appointment between the hospital and the university as the roles and responsibilities of both as employers has not been clearly articulated.

Sponsors are responsible for providing the necessary insurance for clinical trials and research studies:

- Commercial companies have their own private insurance arrangements.
- Cancer trials Ireland is insured by the State Claims Agency.
- Universities must currently provide their own insurance when sponsoring clinical research. However, the State Claims Agency is considering the future provision of insurance for university sponsored studies taking place in the academic clinical research facilities.

In all the above cases, the sponsor signs off on the SCA Clinical Trial Indemnity form, which is also executed by the Hospital CEO, hence providing a certain level of oversight.

2.6.2 Research projects without a formal Sponsor

In the UK all health-related research must have a formal institutional sponsor, regardless of whether it is regulated or non-regulated.[7] NHS organisations do not allow individual staff members to assume the role of sponsor because of the risks and liabilities involved. In Ireland however, there is no formal requirement for non-regulated research projects (which make up the vast majority of studies) to have an institutional sponsor.

In Ireland there is no specific requirement to define the role of sponsors for studies other than regulated clinical trials. Hence confusion in relation to responsibility and liability arises for non-regulated studies, for example in situations where the Principal Investigator has a joint contractual appointment between a hospital and an academic institution, or when academic institutions take responsibility for research funds for HSE/hospital employees who have an honorary or adjunct (non-legally binding) appointment.

Recommendations

- Development of protocols to ensure that roles, responsibilities and liabilities are articulated for all research projects before the project starts. This will involve the development of appropriate risk assessment, and approval and registration processes within healthcare delivery institutions. The creation of local or regional research offices will be important in this regard (see Section 2.3).
- Further clarity in relation to the SCA cover for all types of clinical research studies is required.

2.7 Financial Governance of Research Funds

Research funds can be received from a variety of sources; from national (e.g. the HRB) or international funders (e.g. the EU Commission), to commercial funding (i.e. pharmaceutical funding of clinical trials). Currently there are no formal institutional practices to regulate applications for external funding or indeed to manage the award once it is received.

In general, the normal practices and rules that apply to the management of recurring annual HSE division budgets, make the management of research funds very difficult due to the multi-annual nature of the budgets and the impact of additional income on institutional balance sheets at year-end. This generally results in one of two scenarios:

a) Healthcare organisations manage research funding via an external agency; a foundation or university.

b) Healthcare organisations receive the award (e.g. EU awards) and make local ad hoc arrangements to enable the management of the funds.

In either of the above scenarios the lack of governance represents a risk which may arise from financial mismanagement of the funds by the principal investigator, or non-compliance with the awarding body rules and contracting terms. This may result in fines or reputational damage for the host organisation.

It also represents a significant missed opportunity for the health service organisations to benefit from funding, for example:

a) The HRB does not consider the HSE or associated hospitals to be suitable host institutions capable of managing research awards. As a result, HSE staff members are not able to apply for HRB funding unless they are affiliated with a university so that the funds can be channelled via the third level institution.

b) Clinical research projects could represent a significant source of income but there are no formal arrangements in place to recoup costs, nor agreements with universities to facilitate the sharing of overhead income.

c) The lack of an agreed costing template for costs associated with the running of clinical trials may result in under-budgeting, and projects being subsidised "in kind" by health care organisations (i.e. staff time, etc.), which represents a financial loss and may even contravene State Aid rules.[x] It also erodes the capacity of the health sector to negotiate effectively with pharmaceutical companies.

d) The ability to receive research funding is essential to enable capacity building and the lack of support mechanisms hinders the availability of opportunities in this regard.

There are examples of good practice in other jurisdictions, for example, the National Institute of Health Research (NIHR) in the UK has tools that support study set-up including study costing and commercial costing templates.[xi] The NHS is required to recover from industry, all costs over and above the standard NHS Treatment Cost. For non-commercial studies, guidance called ACoRD (Attributing the costs of health and social care Research and Development) has been developed.[xii]

Recommendations

- Development of institutional mechanisms to enable good financial governance of research funds including:
  - Appropriate financial policies and procedures that enable the management of research funding.
  - Procedures to ensure adherence to financial policies, as well as compliance with tax or other relevant national regulations as well as with funder guidelines.
  - Assessment of the financial implications of research activity and potential surplus generation for healthcare organisations.
  - Procedures for authorisation of engagement in commercial activity.
  - Organisational procedures for receiving, managing, using and reporting on research funding.
- Development of a common research project standard costing template and distribution policy for indirect costs (overhead) income.
- Development of organisational capability for the financial management of external research funds.

x State Aid refers to forms of public assistance, using taxpayer-funded resources, given to undertakings on a discretionary basis, with the potential to distort competition and affect trade between member states of the European Union.

xi https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm

xii https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/acord/

2.8 Human Resource Management

The issues related to the management of human resources in the context of research are many. These include:

a) Lack of clarity regarding responsibilities and accountability for organisations employing staff with multiple appointments or affiliations (HSE, Voluntary Hospitals, universities, etc.). This includes professional reporting, data access rights, staff employment rights and intellectual property rights.

b) Lack of standard authorisation processes for external research staff (i.e. from universities) to access healthcare premises and data.

c) The need for assessment of the capability and qualifications of staff within healthcare organisations to undertake research, in particular clinical research, clinical trials and investigations. Researchers should be adequately qualified and supervised to ensure safety, quality, and competence. Sponsors should be assured that a research team is competent enough to undertake the research, which should be validated as part of study sign-off procedures. Where necessary researchers should have completed Good Clinical Practice (GCP) training.

d) Lack of appropriate guidelines, including the required management, medical supervision and responsibilities for overseeing research projects by early stage researchers.

e) Lack of formal mechanisms to enable secondment of clinical staff with a permanent contract of employment to research projects on a temporary basis.

f) Lack of a HSE salary scales for researchers.

g) Standard recruitment process are too long for the requirements and timelines associated to research projects.

h) Controls are needed to manage the demands placed on staff involved in supporting research studies, and the impact on their time commitment to service delivery, especially for research studies originating externally.

The Follett Principles[18] and the UK's NIHR HR Good Practice Resource provide guidance on working across organisations and the use of honorary contracts and 'research passports'.[19]

Recommendations

- Development of a HR research capacity building framework in collaboration with relevant internal and external stakeholders to address HR governance issues currently hindering research, including:
  - A recruitment framework for researchers hired via externally funded research projects.
  - Enabling mechanisms for secondments or research time "buy-out" for research active healthcare staff.
- Implementation of the EU charter and code of HR practices for researchers within the HSE.
- Clear articulation of research related roles, responsibilities and reporting lines for staff with multiple affiliations.

2.9 Legal Governance

An enabling collaborative legal framework for research activity does not exist, and this significantly hinders the potential for collaboration between the HSE and section 38/39 organisations as well as collaborating with academic institutions.

Funded research is usually underpinned by contracts or legal agreements between funders, sponsors, universities and healthcare organisations. These range from service level agreements for the commissioning of research activity from a third party, to complex legal agreements for clinical trials with pharmaceutical companies.

The sign-off of these documents represents the primary form of governance within most public health sector organisations, and it may require legal negotiations with a third party to ensure that the interests of the healthcare organisation are protected. Governance issues arise in a number of scenarios, for example:

a) Commissioning of research services from the third level sector:

The standard Service Level Agreement (SLA) templates issued by the HSE procurement division are not tailored for research activity. This leads to protracted negotiations due to onerous terms and conditions placed upon the academic institutions, which are also public institutions, and may not be in a position to accede to them. As they are generic SLAs for the provision of services, they are not specific enough for research activity.

b) Clinical trials sponsored by third parties:

Regulated clinical trials require a clinical trial agreement which is generally signed-off by the hospital CEO or another authorised person. These are not standard and are generally complex documents that need to be reviewed by external legal firms before they can be signed-off by the hospital. The development of an agreed national template for clinical trials would significantly reduce the legal costs for the HSE and associated organisations. It would also reduce the complexity of setting up multi-site studies, where agreements are negotiated individually with each centre.

c) Memorandum of Understanding (MOU) and data sharing frameworks for research engagement with the third level sector and section 38 and 39 organisations:

Universities are an important partner in much of the research that takes place in the health service. They are responsible for the staff in the Clinical Research Facilities and are often formal sponsors of clinical trials and clinical research. These relationships are not underpinned by a formal contractual agreement between the university and the hospital group outlining the roles and responsibilities of each partner in the collaboration. This adds a significant level of complexity to these relationships which could hinder future collaborations.

Data sharing frameworks for research are also required between the HSE and Section 38 and 39 organisations, as these are independent data controllers and separate from the HSE.

d) Funding awards from government funding bodies (European Union):

The HSE is currently in receipt of 12 research awards from the European Union. These are projects involving multiple European partners and require the execution of a legal consortium agreement that legally binds the HSE to comply with EU grants terms and conditions. A standard process for the negotiation of these agreements does not exist, nor does a process to ensure that the institution is compliant with the terms of such agreements.

Recommendations

- Development of an agreed research legal framework or MOU for research activity involving the third level sector to articulate responsibilities, processes, and accountability with respect to patient safety, healthcare and research staff, and the management of research funds. Contracts should be in place for research being conducted with external partners, outlining conditions, roles and responsibilities.
- Work should be completed with relevant parties to develop an agreed national template for clinical trials.
- Development of research legal capability as part of HSE R&D for the specific support of research activity.
- Implementation of appropriate governance processes to ensure that research agreements with funding organisations are signed-off by an appropriate, informed and authorised representative.

2.10 Intellectual Property Management

Research may lead to innovations that can generate intellectual property (IP). IP can be bought, sold or commercialised by licensing, and this may result in income generation. The HSE has no IP policy, no mechanism to support IP protection, and no process to enable technology transfer, which generally results in the healthcare organisation handing over the rights to third parties, thereby missing out on a potential revenue opportunities.

Recommendations

- Development of a HSE Intellectual Property Policy in consultation with the university sector and Technology Transfer Ireland to ensure alignment with the National Intellectual Property Protocol.[11]
- Development of capacity for IP management and technology transfer. This could be done nationally via HSE R&D.

2.11 Local Monitoring and Quality Audits of Research Activity

Monitoring of health research is particularly important for clinical research to ensure that researchers are adhering to the research protocol, to ensure the dignity, rights, safety and wellbeing of participants, and to ensure the maintenance of good data governance.

The collection of appropriate information is required to be able to assess compliance, which can take the form of reporting via agreed reporting lines and / or audit. While examples of best practice exist in the CRFs/Cs, it is not clear how or if this is done for other clinical research activity elsewhere in hospitals and CHOs.

Recommendation

- Introduction of local mechanisms or quality systems for relevant clinical research in hospitals to support study setup, registration and approval, recruitment, incident reporting, review, and close out. Systems that are introduced need to be proportionate to the type of study and not increase the burden of bureaucracy.

2.12 Research Dissemination and Impact Governance

2.12.1 Dissemination

A key purpose of effective health research is to inform practice and policy, therefore the results of research can only have impact on health outcomes if they are communicated to the healthcare system, to clinicians and to organisations.[20] In the Irish health service there are two challenges in relation to this:

*a) **Publication of results:*** the HSE has no policy for the dissemination of research findings to guide researchers, but it does have a national repository of health research and a policy statement on open access which could be exploited to facilitate dissemination. While the HRB requires that all of their funded research is published in open access outlets, much of the research that takes place in the health service is not HRB funded.

b) ***Access to publications for healthcare staff:*** current access to publications for healthcare staff in the HSE or associated organisations is not equal:

- HSE organisations are serviced by the HSE National Library and Knowledge Service. This was a regional service which is currently in the process of merging into a coherent national service to provide equity of access to all HSE staff with centralised national procurement.
- Some but not all Section 38/39 organisations have their own libraries, with a varied level of access to journals and other electronic resources.

This situation creates significant inequities in the capacity to access information and knowledge resources between healthcare professionals in the HSE and in associated organisations.

xiii Intellectual Property is the output of any intellectual activity and can include inventions, processes, written work, designs, images, software and data.

2.12.2 Impact

Good research governance promotes the delivery of high quality research and enables the application of findings to the healthcare system. However, in order to align research activity with organisational needs, the organisation needs to articulate the knowledge gaps and its information priorities. In this regard, the HSE has not articulated what these priorities are from a National Health Service perspective, but some of the hospital groups are currently in the process of developing their own research strategies. The implementation of the national Sláintecare plan will further highlight information gaps and needs, helping to identify additional research priorities.

Recommendations

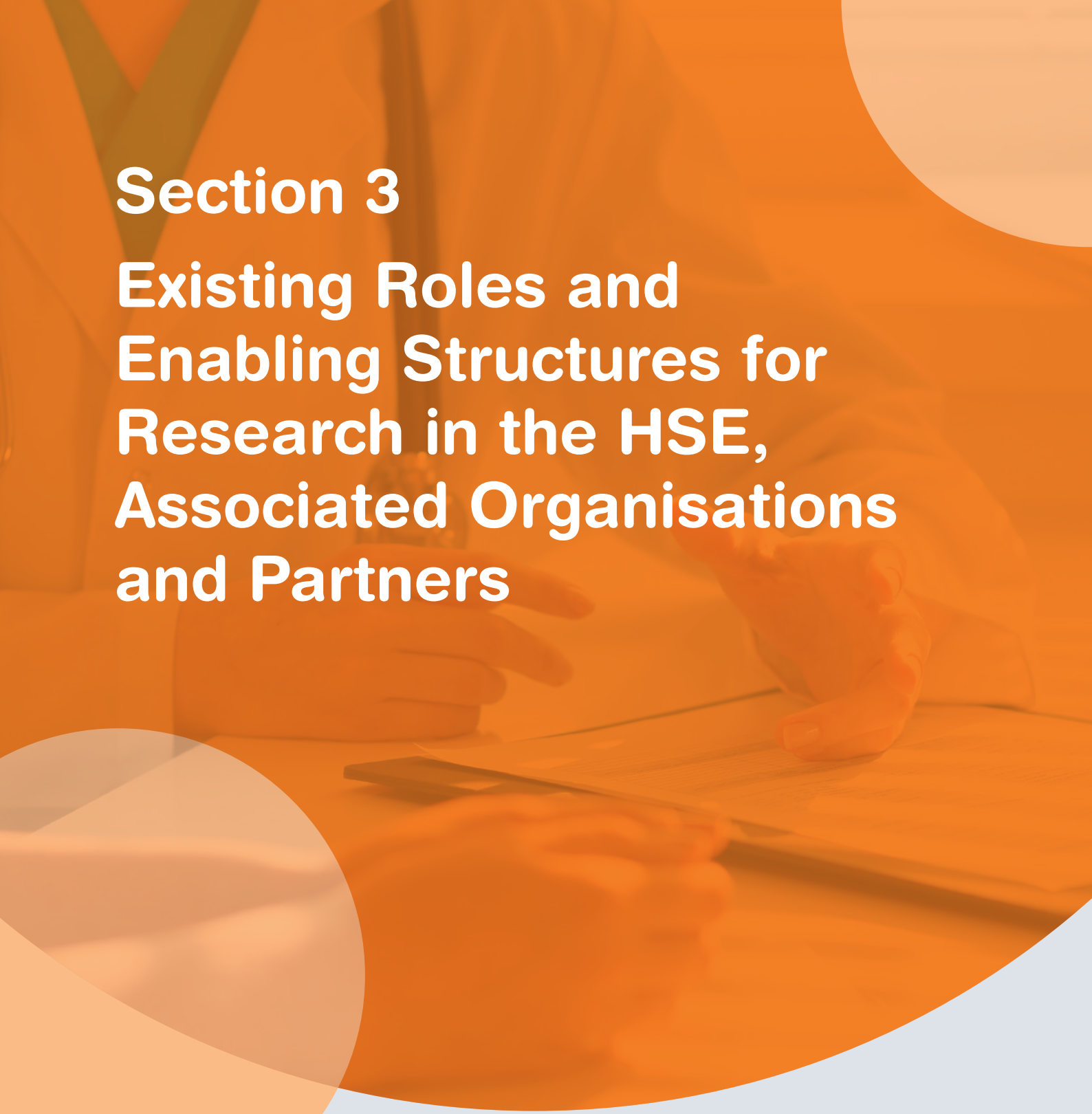
- Establishment of a digital national library for health to ensure that key resources that are needed to enable evidence-based practice are available for all health and social care professionals.
- Development of a dissemination policy to guide staff on the optimal and most effective mechanism to disseminate research outputs to achieve the maximum impact.
- Implementation of institutional strategies to facilitate dissemination and impact.
- Articulation of the research priorities for the health service in order to contribute to the national discourse in a meaningful way.
- Alignment of research activity with research priorities at national, regional and local level.

2.13 Patient and Public Involvement

Patient and Public Involvement (PPI) in research is defined as research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.[21] Patients, their families and the public should be given the opportunity to participate in and contribute towards the design, management, conduct and dissemination of research. In Ireland PPI in research is still developing but there are many patient advocacy groups and charities such as Irish Platform for Patient Organisations, Science & Industry (IPPOSI) engaged in PPI, and the HRB has also recently funded the PPI Ignite initiative. In other health systems, PPI is considered to be a fundamental part of the funding and REC approval process.

Recommendations

- Development of a PPI strategy for health research and collaboration with external partners in leveraging resources for implementation.
- Provision of support to the research community to engage in PPI.
- Involvement of patients and the public in the development of research priorities.



Section 3

Existing Roles and Enabling Structures for Research in the HSE, Associated Organisations and Partners

The delivery of a new governance framework and an associated operational plan for health research requires changes and improvements with regard to processes, personnel and organisational structures to enable it. A number of good examples in this regard already exist within the health research system, some within the HSE and others within associated organisations and external partner organisations.

3.1 HSE R&D

The HSE R&D function commenced operations in 2018. The establishment of this function represents a unique opportunity to build collaborations to achieve improvements in health research governance, support and strategy development.

HSE R&D aims to develop a framework of governance and support to enable existing, and to grow future research activity within the HSE and associated organisations. The objective is to embed a culture of research and evidence-based practice and innovation within the health service so that research becomes a critical enabler of health service delivery by contributing to:

- Attracting and retaining the best healthcare staff.
- Improving the quality and process of care.
- Increasing levels of productivity and efficiency.
- Delivering a more comprehensive range of services.
- Increasing patient engagement and satisfaction.

This function is currently developing and is composed of a single national office which is part of HSE Research and Evidence (which includes the HSE National Health Library & Knowledge Service and the Health Intelligence Unit).

The development of HSE R&D provides a unique opportunity to align and support existing, albeit fragmented, roles and enabling structures and is already working closely with key internal and external actors, such as the Department of Health R&D and Health Analytics Division, Health Research Board, Cancer Trials Ireland, States Claims Agency, etc.

The following are key (albeit not exhaustive) existing roles and structures that can be leveraged to initiate this reform:

1. Primary Care Research Committee
2. Chief Academic Officers (CAO)
3. Research Ethics Committees
4. Third Level Sector

Recommendations

- The development of future local and regional research management and governance roles and offices, associated with existing or new health service structures, will be crucial for the success of any implementation plan. Some of these roles are or will be appointed shortly. Local and regional research support arrangements should be linked to HSE R&D to ensure coordination, to avoid duplication and to optimise the use of resources.

3.2 Primary Care Research Committee

The Primary Care Research Committee (PCRC) has functioned as a governance body for research in Primary Care. The committee has been responsible for reviewing and approving REC endorsed research projects. Their approval process has focused on non-ethical considerations, such as ensuring that the research project has been assessed and approved by management at local level, assessment of potential risks, compliance with legislation, and alignment of the research with service objectives. The committee has also overseen the publication output of approved projects. A similar arrangement for research based in other community areas, such as Mental Health and Social Care has not yet been established.

As of January 2019 however, the PCRC is no longer in operation due to staffing shortages and the primary responsibilities previously carried out by the committee have been devolved to the CHO heads of service.

Recommendations

- Governance protocols for research in the community need to be put in place. The development of RICOS may facilitate an integrated approach to governance with hospital based research.

3.3 Chief Academic Officers (CAO)

The Higgins Report (2013) introduced the role of the Chief Academic Officer with responsibility for education, research and innovation functions. The CAO role is important and can provide a vehicle for increased engagement with the academic sector but this role is restricted to the acute sector only. [22]

By January 2019, five out of the seven Hospital Groups had a CAO, but each of them has a slightly different focus. The posts are generally not full-time and include other demanding responsibilities. In order to establish a National Research Governance Framework, the role of the CAO needs to be standardised and further supported by full-time research management staff at local level, as well as by the establishment of additional local structures (Research Approval Boards, Scientific Committees, etc.).

The Community Healthcare Organisations do not have roles similar to the CAO or anyone with responsibility for research management or governance, which will hinder the development of research governance and support mechanisms in the community.

In the context of evolving healthcare structures, the development of regional R&D Offices within RICOs, connected into HSE R&D to provide support to each hospital group and associated community areas, would offer an optimal structure to facilitate local research approval and support, as well as national reporting and oversight. These offices will also facilitate engagement with the third level sector and the alignment of research governance protocols.

Recommendation

- Appropriate leadership roles for research are required at both at hospital group/CHO level. The development of RICOS may provide an opportunity for a more integrated model that enables research leadership across the two areas.
- Engagement with and among the CAOs is required to agree a governance model that is wide-reaching and consistent.
- There is a need for the introduction of associated regional R&D Offices to enable research governance, provide local research support, link with the university sector and with HSE R&D.

3.4 Research Ethics Committees

The lack of a national framework for RECs hinders uniformity and consistency in the process of ethical approval, and delays in approval are leading to pharmaceutical companies undertaking research elsewhere in the EU. This represents a lost opportunity for patients and for researchers. To address these issues and also to enable compliance with the new EU clinical trials regulations, the Department of Health will lead the enactment of new legislation to establish a National REC. Further information on RECs has been included in Section 2.4.

Recommendation

- HSE R&D will work closely with the Department of Health to provide support for the establishment of a national REC.
- See further recommendations in section 2.4.

3.5 Third Level Sector

Establishing strong collaborative links and mechanisms for knowledge exchange with the third level sector is essential to ensure that research is of high quality, that it makes an impact and to leverage opportunities for capacity building. Many acute hospitals have strong relationships with academic partners but their relationship is usually restricted to clinical research (as opposed to other types of health research), and historically driven by the relationship with the medical school and the medical training programmes. Hence the relationship with the academic partner is not equal across the Hospital Groups.

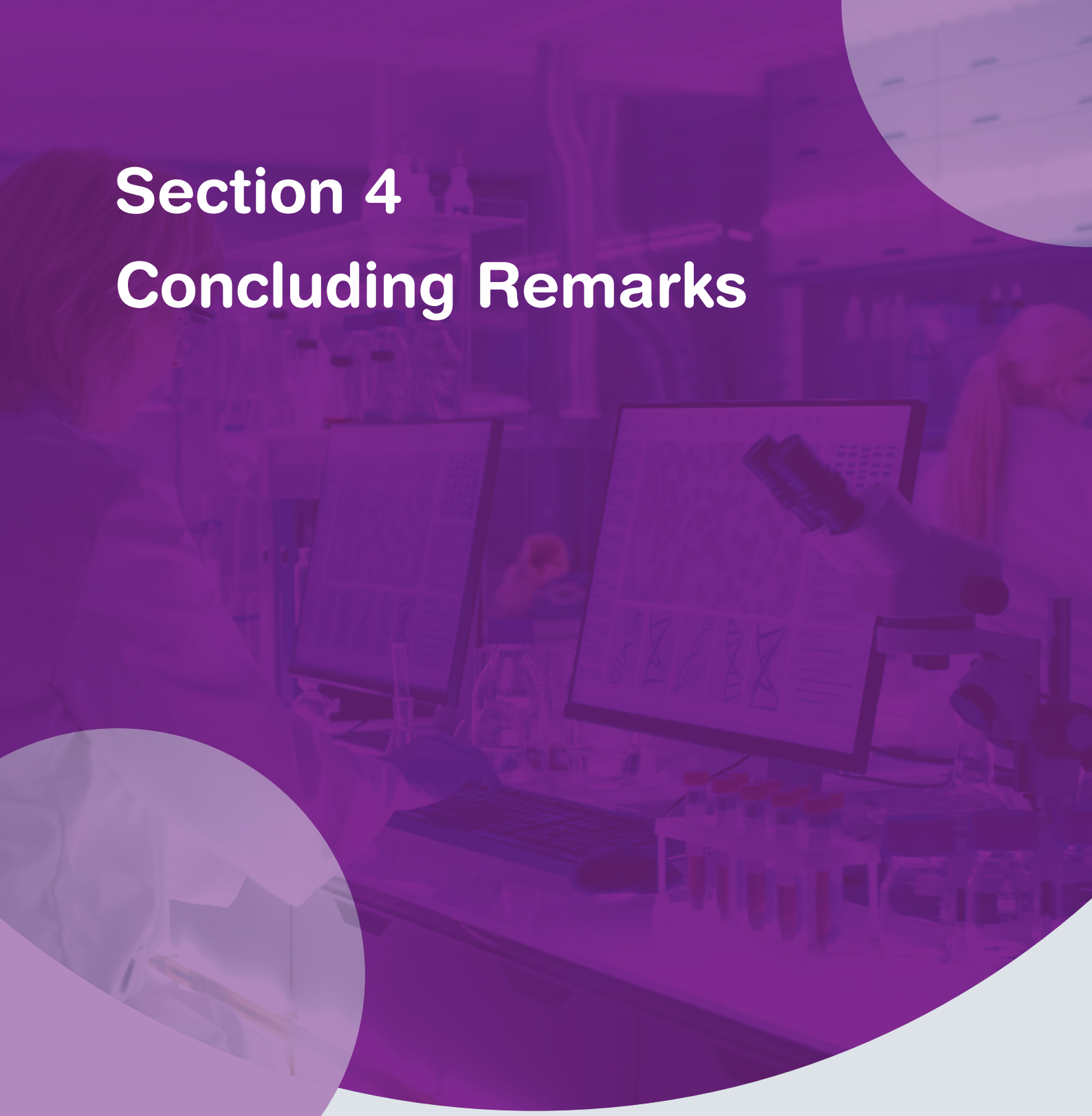
The involvement of universities in clinical research, and in particular their capability and willingness to take up the role of clinical trial Sponsor, has increased over the last ten years. This has been driven mainly by government policy, whereby, since 2009 funding for health research has been re-directed from translational biomedical research to more applied population and clinically-based research. The HRB has invested over €100 million in the development of a clinical research infrastructure, with approximately 30-40% of all clinical trials now take place using the support of academic Clinical Research Facilities. The interests of the university sector and the CRFs/Cs are represented by Clinical Research Development Ireland (CRDI), which plays an important role in driving and facilitating the involvement of academic institutions in clinical research.

In a scoping exercise carried out by CRDI entitled “Corporate Enabling of Clinical Research” a number of difficulties related to engagement with the healthcare sector were identified, and many of the issues highlighted reflect those identified in this report: lack of clarity in relation to responsibilities, access to data, authority for decision making, escalation of issues, insurance responsibilities, intellectual property management, etc.[23]

Recommendation

The academic and healthcare sector should agree on the principles of good clinical research practice i.e.:

- Put in place a collaboration framework which sets out the terms and scope of their collaboration and formalises it with a memorandum of understanding which would provide clarity regarding all aspects of research governance and management.
- Consistency of contractual approaches across the academic and healthcare sector and a more efficient inter-institutional approval pathway enabling smoother contracting processes and ensuring clinical studies begin within a reasonable timeframe.
- A governance and management plan to deliver Sponsor functions, to ensure Sponsor responsibilities are delivered throughout the lifecycle of the study.
- Alignment of healthcare sector and academic clinical research strategies with a shared mission to improve patient outcomes and healthcare delivery.



Section 4
Concluding Remarks

This report highlights significant opportunities for the improvement of research governance within the public health service. It also identifies shortfalls in relation to management and support infrastructure that are necessary for the health service to reap the benefits of the research activity that it currently hosts. A research governance framework together with appropriate policies, processes and collaborations needs to be developed and established to create the foundations upon which health research in the broadest sense can be sustained and grow into the future.

Without the necessary action to progress the implementation of the recommendations outlined in this report, the HSE will fail to realise the potential benefit that arises for patients and services from having high quality research and research active staff, the creation of an evidence-based culture, and the opportunity to derive economic benefit from research. Furthermore, the lack of suitable governance structures also represents a risk to the organisation, the research participants and staff.

The findings in this report have contributed to the design of a ten year HSE Action Plan for Health Research, to be published in 2019. A primary objective of the plan is to address the shortfalls articulated in this report with a view to embedding research and evidence-based practice into service delivery, to improve healthcare and to better provide for the needs of patients. The leveraging of existing partnerships and structures within the stakeholder organisations highlighted in this report will facilitate the implementation of the HSE Action Plan for Health Research.

The intention is to develop and implement a robust research governance framework, via support and management infrastructure, and to protect and promote the interests of patients and the public at local and national level. Patients and the public will play a key role in ensuring the relevance of the research conducted.

There is an opportunity now to build research capacity, to build the reputation of the HSE as a workplace offering staff development and innovation through research, and to make Ireland an attractive place for industry and international research activity.[24] [25]

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