Research & Development
Taighde & Forbairt

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

August 2025

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Contents

1 Glossary

Operational Definitions: For the purposes of this document, the following terms are defined as follows:

Identifying: Actions taken to identify or provide access to individuals who may potentially be interested in participating in a research study and / or who may fall in the general study population for example a list of patients discharged from a day unit or access to a health centre. To clarify, for the purposes of this document, identifying potential participants is a recruitment activity.

Examples of identifying actions

(a) Approaching an individual to determine their interest in participation in a specific study on behalf of the research team.

(b) Sharing the identity of an individual with the research team on a confidential basis where the individual has consented to be contacted by the research team.

(c) Providing information from a 'consent to be approached' or 'consent for consent' registry / database of people who are willing to be contacted about opportunities to take part in research.

Pre-screen: Actions taken in the period prior to an individual's consent to a health research study to determine whether an individual (prospective research participant) is suitable or eligible for inclusion in the study. To clarify, for the purposes of this document, pre-screening potential participants is a recruitment activity.

Some examples of pre-screening actions

(a) Reviewing the personal data of a data subject in order to assess whether they might be suitable or eligible for inclusion in a health research study.

(b) Analysing the pre-screening data and documenting the findings.

(c) Sharing the findings (in a non-identifiable way) with others involved in the research team.

(d) Approaching an individual found to be eligible or suitable to determine their interest in participation in the study.

(e) Sharing the identity of the individual found to be eligible or suitable with the research team on a confidential basis where the individual has consented to be contacted by the research team.

Publicly funded health and social care service: This refers to the HSE and organisations it funds under Section 38 and Section 39 of the Health Act 2004 to deliver a range of health and social care services

Research: The HSE Action Plan for Health Research 2019–2029[1], adopted the NHS Health Research Authority, 2017 definition of research as that of "the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods."

Note: A key feature of research is that it is intentionally planned and designed using documented methodology which will allow results to be extrapolated or applied from the study sample to a larger population. This extrapolation / application is what the terms 'generalisable' and 'transferable' refer to. In the case of quantitative research, statistical methods are used to achieve results that are 'generalisable'

[1] https://hseresearch.ie/wp-content/uploads/2020/02/10-Year-Action-Plan-V2P1-2.pdf

from a sample to the sampled population. In the case of qualitative research, the context and findings are described and defined so that the conclusions can be applied or transferred to other settings.[2]

Service Provider: A publicly funded health and social care service providing health and social care (i.e. Medical Care, Social Care, Mental Health Services, Rehabilitation Services, Public Health Services, etc.).

Service User: A service user refers to an individual who utilizes health and social care services provided by the publicly funded health and social care service in Ireland. This term encompasses a broad range of individuals, including:

- Patients: Individuals receiving medical treatment or care in hospitals, clinics, or other healthcare settings.
- Clients: Those accessing social care services, such as support for disabilities, mental health issues, or elderly care.
- Residents: Individuals living in residential care facilities or nursing homes.
- Families and Carers: Those who may be involved in the care process or decision-making for the primary service user.

2 Purpose of this document.

Research in scope of the HSE Framework for the Governance, Management and Support of Research[3] (RGMS Framework) needs to be approved by a HSE or S38/39 Research Ethics Committee and requires institutional oversight by the sites hosting the research, which is provided by the RGMS function[4].

The aim of this document is to support Researchers, Research Ethics Committees and host sites to determine when a research activity falls within the scope of the Framework.

Only Research Studies in Scope of the RGMS Framework require approval by the HSE RGMS Function and HSE/S38 Research Ethics Committees.

Some knowledge-generating activities outside the scope of the RGMS Framework may also require ethical oversight, and organisations should have in place appropriate governance arrangements for these activities at local level. Where no other ethical oversight arrangement is in place at local level, the relevant REC may agree to provide such. Please see the HSE National Research and Development website for additional guidance (https://hseresearch.ie/research-ethics/#Projects-that-require-approval-by-a-HSE).

[2] https://www.hra-decisiontools.org.uk/research/question4b.html
[3] https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf
[4] This refers to the functions that establish research governance for services hosting research, which may be centralized within a Research Office or distributed across various departments. These functions are responsible for tasks such as conducting legal reviews, verifying insurance arrangements, and ensuring compliance with data protection legislation, among other responsibilities.

3 The Scope of the RGMS Framework

This RGMS Framework applies to all health and social care research activities hosted, enabled or conducted by the publicly funded health and social care service. For clarification this is when at least one of the following applies to the study or any part of the study;

1. requires recruitment of participants via the publicly funded health and social care service
2. requires the processing of personal data from service users' healthcare records for research purposes
3. requires the use of biological samples from service users for research purposes
4. involves health and social care staff in the publicly funded health and social care service;
   i. as participants.
   ii. as researchers, when that research falls within the RGMS Scope.
5. is hosted within the publicly funded health and social care service and/or makes use of health and social care services infrastructure or requires support by healthcare services staff.

This also applies to health research taking place in external institutions such as third-level collaborative institutions and/or clinical research facilities (CRFs) when the research activities involve any of the aforementioned factors.

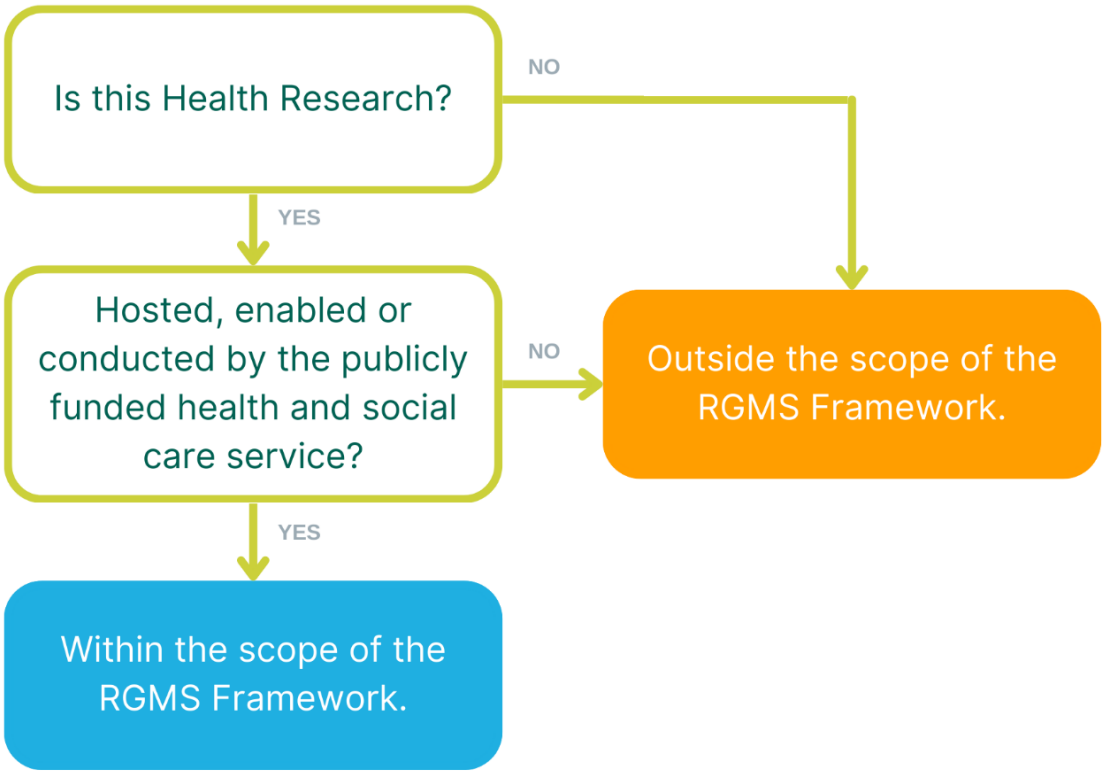

Figure 1- Scope of the RGMS Function and the HSE Research Ethics Committees

So, in order to determine if the project falls under the remit of the framework the following questions need to be asked:

3.1 Is this activity considered health and social care research in the context of HSE RGMS Framework?

Research is defined in the HSE Action Plan for Health Research 2019–2029[5], as "the attempt to derive generalizable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods". Health and social care research is further defined in the HSE RGMS Framework to include:

1. Basic and Applied Biomedical research
2. New Technology research
3. Clinical research
4. Health Service research
5. Population Health research

These are hereinafter referred to as 'The five pillars of health and social care research' (Figure 2.)

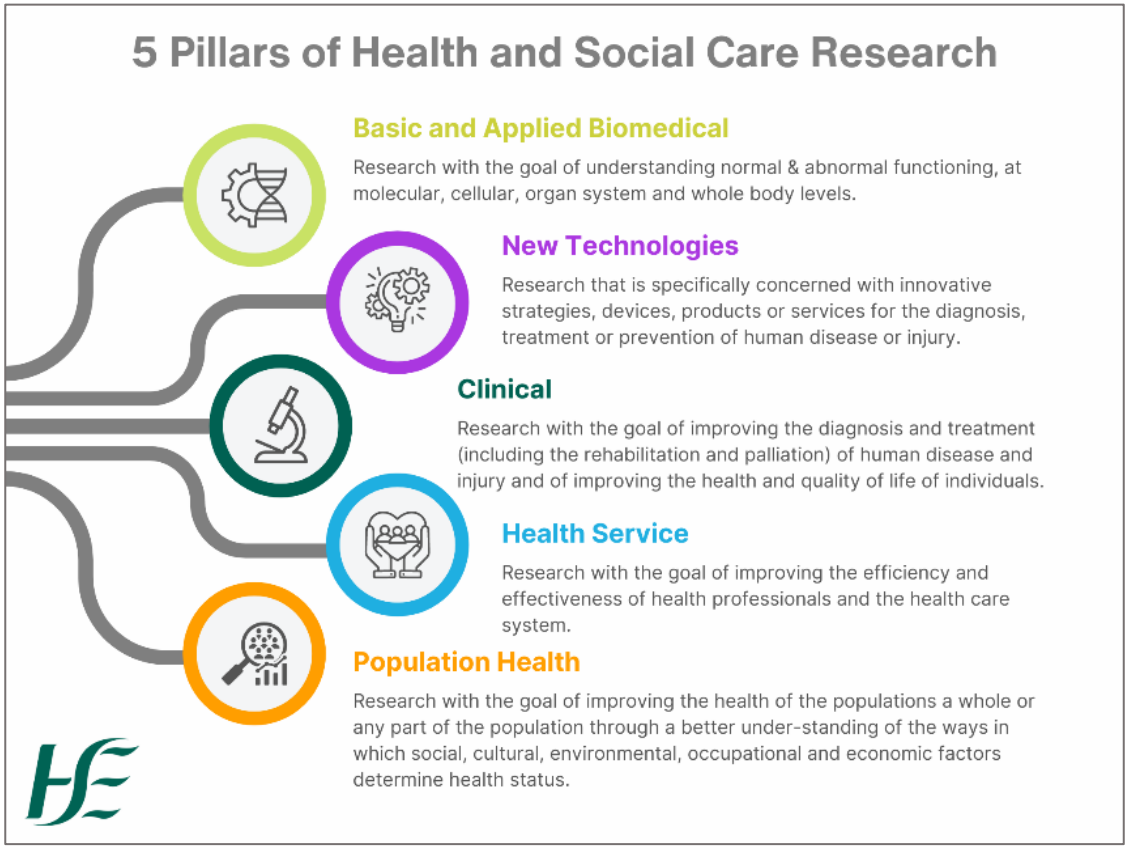

Figure 2 - 5 Pillars of Health Research in Ireland

The scope of the RGMS Framework **does not extend to** clinical audits, standard service evaluations, and quality improvement projects, public health work, or advanced health analytics routinely carried out by the HSE or its funded organisations for the purpose of discharging their legal obligations for the planning and delivery of health and social care services. The HSE National Centre of Clinical Audit –

[5] https://hseresearch.ie/wp-content/uploads/2020/02/10-Year-Action-Plan-V2P1-2.pdf

Nomenclature – A Glossary Review of Clinical Audit (revised 2025)[6] provides further detail on clinical audit, service evaluation and quality improvement.

IMPORTANT NOTE: Further guidance on when a Service Evaluation is within the scope of the RGMS framework is to be developed.

3.2 Is it hosted, enabled or conducted by the publicly funded health and social care service?

The Scope of the HSE Framework extends to health & social care research where any of the factors below are met;

3.2.1 The study requires recruitment of participants via the publicly funded health and social care service

Recruitment of service users for research from a health and social care service refers to the process of identifying, screening or enrolling individuals who are receiving, or by virtue of the fact that they have received, care or treatment within the public health and social care service, to participate in a research study.

Recruitment is deemed to be any of the following:

- **Identification of potential participants**: The research team or healthcare staff identify or pre-screen service users who meet specific eligibility criteria for the study. This may involve reviewing healthcare records, screening diagnostic data, or relying on referrals from healthcare professionals. However, this does not include participants identified solely based on a condition diagnosed by the Health Service if the research is conducted independently. For example, cancer patients diagnosed by the publicly-funded Health Service, and/or receiving treatment from same, but identified through a cancer charity for an independent research project are excluded.
- **Approach and consent:** the research team or healthcare providers approach potentially eligible service users within the health and social care setting and provide them with information about the research study, including the purpose, procedures, potential risks and benefits, and their rights as research participants. Service users are then invited to voluntarily consent to participate in the study.
- **Enrolment and data collection:** Once a service user has consented to participate, they are enrolled in the research study. This may involve collecting various types of data from service user's healthcare records, such as medical history, physical examinations, laboratory tests, or clinical observations, as specified in the research protocol.

Research projects led by academic institutions or other bodies but NOT hosted, enabled or conducted by the publicly funded health and social care service are **not** within the scope of the HSE RGMS Framework. Disseminating information about these studies — such as via an advertisement poster, leaflet, QR codes etc. within HSE premises or circulating via email — does **not** qualify as recruitment under the HSE RGMS Framework. However, it is recommended that;

a) Health services ensure that any such research project has REC approval(s) in place by requesting the REC Approval Decision Letter (noting that in these cases it is not necessary that it is a HSE REC approval). This approval may be from the relevant Higher Education Institute, or other appropriate institution.

[6] https://www.hse.ie/eng/about/who/nqpsd/ncca/nomenclature-a-glossary-of-terms-for-clinical-audit.pdf

b) Permission is obtained from the relevant hospital, service, or department to display/distribute a relevant study advertisement. When requesting permission researchers should support the request with the Researchers Confirmation form (see Appendix 1). If the manager with delegated responsibility for approving dissemination of the advertising material is in doubt, they can get advice from their Regional Clinical Director, Regional Director of Nursing and Midwifery, Regional Director of Population and Public Health, the Director of Research, or their relevant Research Office or Research Ethics Committee Office.
c) The advertising material should contain a disclaimer stating that the study is not endorsed or conducted by the HSE. For clarity, the study must not be seeking to recruit HSE staff by virtue of their employment in the HSE or individuals by virtue of the fact that they are receiving, or have received, care or treatment the public health and social care service.
d) The advertising material should name the REC that has approved the study.
e) No items beyond simple advertising material can be displayed or circulated, for clarity this means that a; letter of invitation, Participant Information Leaflet, Informed Consent Form etc. cannot be included as this would represent recruitment from HSE services.

Examples

1) A University, undertaking a research project recruiting new mothers for an educational intervention which will be delivered post discharge by University staff, requests to advertise the study in a Maternity Hospital – **Out of Scope**

2) A University undertaking a research project recruiting frail older people using HSE provided home support for a dietary and exercise intervention delivered by University staff requests to advertise the study in health centres – **In Scope**

3.2.2 The study requires the processing of personal data from service users' healthcare records for research purposes

This includes research which requires secondary use of service users' personal data, use of data originally collected for clinical audit/quality improvement purposes including data subsequently anonymised, access to clinical registry data, Retrospective Chart Reviews (conducted for research purposes), and pre-screening of health records to identify potential participants.

For further information to determine when retrospective chart reviews and pre-screening activities are within the scope of the HSE RGMS Framework see https://hseresearch.ie/data-protection-and-research/#retrospective and https://hseresearch.ie/data-protection-and-research/#Access-to-patient-personal-data).

Registries and databases only fall within the scope of the RGMS framework when the primary or secondary purpose of the registry or database is research. The consent process used to collect the data for the registry must then comply with the requirements of the HSE National Policy for Consent in Health and Social Care Research.[5]

Examples:

1) A consultant in nephrology working in a public hospital wishes to establish a registry of patients with Polycystic Kidney Disease to enable tracking of health-related information for this patient cohort for the purpose of enabling clinical audit and evaluation of the service provided for this cohort of patients within the hospital. – **Out of Scope**

2) A consultant in nephrology working in a public hospital wishes to establish a registry in collaboration with TCD of patients with Polycystic Kidney Disease with the intention of doing longitudinal research studies on disease progression and outcomes. – **In Scope**

IMPORTANT NOTE: Further guidance on Registries and Databases is to be developed.

3.2.3 The study requires the use of human biological samples from service users for research purposes

This includes (subject to the requirements of the HSE National Policy for Consent in Health and Social Care Research[7]) any of the below:

- secondary use of patient's samples collected during clinical care,
- access to samples bio-banked by a healthcare facility (i.e. histopathology collections)
- collection of samples for research purposes by the research team or healthcare staff during provision of care
- collection of samples for research purposes by the research team or healthcare providers outside the provision of care process.

This excludes the extraction of microbiome from a human sample collected during clinical care when the micro-organism is to be used for the purpose of translational research, providing that neither the human biosample nor the patient data are required for the research itself, and there is no possibility of identifying the sample owner from the microorganism.

It also excludes the use of existing / biobanked samples that at the time of the research, are not under the remit of the publicly funded health and social care service, even if the initial research study under which the samples were collected was under the RGMS Framework.

Examples

1) Mouth swab from patients suffering from gingivitis are taken at HSE dental clinics for research purposes. The samples will be used to grow the bacterial populations associated to it for the purpose of identifying and characterizing virulence factors in bacteria associated with gingivitis. No human tissue nor patient data is required by the researchers for the research study. **– Out of scope**

2) Gut flora is collected from patients with Crohn's disease during surgery for the purpose of assessing how the expression of microbial genes correlates with patient symptoms or treatment outcomes, potentially linking specific gene expressions to individual patient profiles. No human tissue is required but access to patient clinical history is required. **- In Scope**

[7] https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research/

3) Bio-samples are collected from patients with diabetes at a HSE hospital by a member of HSE staff who is creating a research biobank at a UCC research centre. The consent form and the participant information leaflet explicitly indicate that UCC would be the custodians of the samples.

- Biobank set up process (approach to consent, data collection… etc.) **– In scope**
- Subsequent use of bio-banked samples **– Out of scope**

IMPORTANT NOTE: Further guidance on Biobanks is to be developed.

3.2.4 The study involves health and social care staff in publicly funded health and social care services

Research studies recruiting health and social care service staff **as participants** in their capacity as employees of the publicly funded health and social care service fall under the RGMS Framework, if recruited via the publicly funded health and social care service

Examples

1) An academic researcher uses social media to recruit any nurses in Ireland to do research on the impact of night shifts on their wellbeing – **Out of scope**.

2) An academic researcher uses social media to specifically recruit nurses in HSE and S38 hospitals to do research on the working experiences and its impact on wellbeing in both settings. **In Scope.**

Research studies carried out by staff in pursuit of an academic qualification, or in any other personal capacity as a researcher outside of their professional role, and not in scope of the framework for any other reason under any of the headings in this document, are outside the scope of the RGMS framework.

Examples

1) A HSE physiotherapist who also has a private clinic is recruiting private patients in their private clinic to do an observational study as part of a master's qualification, or as part of an independently-funded research project **– Out of scope**.

2) A HSE physiotherapist is recruiting HSE patients in an academic Clinical Research Facility to do an observational study as part of a master's qualification – **In scope**

3) An academic physiotherapist is recruiting HSE patients in an academic Clinical Research Facility to do an observational study **– In scope.**

Research studies carried out by staff from the public health and social care service for reasons associated to their role are under the scope of the RGMS Framework. However, if the study is done for reasons not associated to their role and would fall outside the framework for any other reason, are outside of Scope of the framework.

Examples

1) As part of their role as a HSE community health nurse, a nurse is doing an online survey recruiting members of the general public by way of social media channels to determine the public perception of HSE home-help service to the elderly. **– In scope.**

2) A HSE community health nurse is conducting a research project in her personal capacity and in her spare time about older adult's perceptions of aging. **– Out of scope.**

3.2.5 The study is hosted within the health service and/or makes use of health and social care services infrastructure or requires support by healthcare services staff.

Studies hosted within the health service and/or make use of health and social care services infrastructure or require support by healthcare services staff would generally fall within the scope of the framework by virtue of the fact that the conditions in 3.2.1 to 3.2.4 above would apply. However, there are exceptions when they may not apply, for example:

- Health Research studies that require use of healthcare equipment, laboratory, clinical or office space to conduct a research study involving participants that are not service users of the public health service

Example

1) Participants for a research study are recruited at a private clinic and provide a blood sample. The blood sample is subsequently processed in a HSE laboratory. **– Out of Scope.**

- External research studies independent of the publicly funded health and social care service that request distribution though an official HSE communication channel such as a HSE email list or LinkedIn account (see section 3.2.1 above)
- Situations where healthcare staff refer/sign post potential participants to an external research study, independent of the publicly funded health and social care service, as part of normal clinical activity (e.g. routine clinics) in order to gain access to clinical interventions but are not involved in the process of seeking consent etc.

While these activities do not fall under the scope of the Framework, appropriate governance should be observed, as some of these activities may require approval by the appropriate authorised person.

4 Abbreviations

HSE	Health Service Executive
REC	Research Ethics Committee
RGMS Framework	The HSE Framework for the Governance, Management and Support of Research

5 Acknowledgements

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HSE National Research and Development (R&D)

- Dr Olga Cleary, Snr Research and Development Manager, National Research and Development
- Ms Caroline Lamb, National Research & Development Officer, Research Ethics, HSE National Research and Development
- Ms Máiréad Murray, Senior Manager, HSE National Research and Development
- Ms Mary Clare O'Hara, National R&D Programme Manager, National Research and Development
- Dr Maria Quinlan, General Manager, National Research and Development
- Dr Ana Terrés, HSE Assistant National Director, Head of Research and Evidence

HSE Research Governance, Management and Support Implementation Working Group (Past and Present Members**)**

- Dr Ana Terrés (WG Chair) HSE Assistant National Director, Head of Research and Evidence
- Ms Máiréad Murray, (Workstream Lead) Senior Manager HSE National Research and Development
- Dr Suzanne Bracken, Programme Manager, HSE Dublin and Midlands Health Region
- Dr Charles Brand, Research Officer, National Ambulance Service
- Ms Rafaela Carapeto, Research Manager, HSE South West Health Region
- Mr Paddy Clerkin, Chief Operations Officer, Beaumont Hospital
- Mr Donal Conway, Patient Participant Involvement Representative
- Ms Mary Costello, Programme Manager, Children's Health Ireland
- Dr Joanne Crowley Walsh, Director, Clinical Research Facility-Cork at University College Cork
- Prof Gerald Curley, Professor and Chair, Department of Anaesthesia and Critical Care, Royal College of Surgeons in Ireland
- Ms Erin Daly, Operations Manager PILLAR Centre, Mater Misericordiae University Hospital
- Prof Eamon Dolan, Regional Clinical Director, HSE Dublin North East Health Region
- Prof Peter Doran, Director of Clinical Trials institute, University of Galway
- Ms Emer Fallon, Clinical Research Support Office (CRSO) Unit Manager, Mater Misericordiae University Hospital
- Dr Evelyn Flanagan, Research Manager, Mercy University Hospital
- Prof Hilary Humphreys, Vice-Dean of Research, Royal College of Surgeons in Ireland
- Ms Paula Keating, HSE Community Operations
- Ms Caroline Kelly, Senior Manager, Senior Manager Clinical Research & Development Office, Saolta University Health Group
- Dr Patricia Kenny, Programme Manager, Office of the National Research Ethics Committee

- Dr Brendan Kinsley, Clinical Director of the Pillar Centre for Transformative Healthcare
- Prof John Laffey, Director of Research, Saolta Hospital Group
- Prof Olive Lennon, Academic Lead, National Rehabilitation Hospital
- Prof Declan Lyons, Director of Research, Mid-West Research Directorate
- Dr Anna Malara, Business Development Manager, University College Dublin, Clinical Research Centre
- Dr Siobhan Masterson, Lead for Clinical Strategy and Evaluation, National Ambulance Service
- Ms Miriam McCarthy, Health Sciences Academy Manager, University of Limerick and UL Hospital Group
- Prof Paul McNally, Director of Research and Innovation, Children's Health Ireland
- Ms Fiona Melia, HSCP Assistant National Lead, National Health & Social Care Professions Office
- Ms Katie O'Byrne, Research Nurse, Dublin and Midlands
- Ms Joanne O'Connor, Research Manager, Mid-West Research Directorate
- Ms Mary Claire O'Regan, Interim Director of Operations & Clinical Trials, Clinical Research Facility-Cork at University College Cork
- Ms Ciara O'Toole, Contracts Manager Quality and Patient Safety, Beaumont
- Dr Robert O'Connor, Programme Manager National Clinical Trial Office
- Prof Denis O'Mahony, Director of Research, HSE South West Health Region
- Dr Liam Townsend, Regional Director of Research, HSE Dublin and Midlands Region
- Ms Mary Vasseghi, Patient Participant Involvement Representative
- Dr Austin Warters, Research Lead, HSE Dublin North City and County Community Care Organisation (CHO9)
- Prof Helen Whelton, Chief Academic Officer, HSE South West Health Region

HSE Research Ethics Committee Reform Working

- Dr Ana Terrés (WG Chair) HSE Assistant National Director, Head of Research and Evidence
- Dr Olga Cleary, (Workstream Lead) Snr Research and Development Manager, National Research and Development
- Ms Mary Clare O'Hara, (Interim Workstream Lead) National R&D Programme Manager, HSE National Research and Development
- Dr Aileen Barrett, Academic Lead, Research, Policy and Information Department, Irish College of General Practitioners
- Prof Gerard Curley, Royal College of Surgeons in Ireland Hospital Group representative
- Dr Úna Fallon, Chair, Reference Research Ethics Committee Dublin and Midlands and HSE Centre
- Mr Peter Gallagher, Head of Research Support Services, St John of God Research Foundation
- Ms Leona Heaphy, Manager, Clinical Research Ethics Committee of the Cork Teaching Hospitals, University College Cork
- Dr Bridget Johnston, Researcher Representative, Public Health & Primary Care, Trinity College Dublin
- Dr Ruben Keane, Quality and Regulatory Affairs Manager, Health Research Board National Clinical Trials Office
- Ms Caroline Lamb, National Research & Development Officer, Research Ethics, HSE National Research and Development
- Ms Jenny Lee, Manager, RREC Dublin and Midlands and HSE Centre
- Dr Barry Lyons, Chair, Children's Health Ireland REC
- Ms Kara Madden, HSE R&D PPI Representative

- Prof Brendan McClean, Chair, St. Luke's Radiation Oncology Network REC
- Ms Lynne McGlynn, Research Ethics Officer, Beaumont Hospital Ethics (Medical) Research Committee
- Dr Shane McInerney, Chair, Galway University Hospital REC
- Ms Nicola Moloney, Manager, HSE Midwest REC
- Dr Gemma Moore, Qualitative Evaluation and Research for Quality Improvement, HSE
- Dr David Murphy, Chair, St Vincent's University Hospital
- Ms Ursula Nagle, Researcher Representative, Rotunda Specialist Perinatal Mental Health Service
- Dr Angela Noonan, Chair, HSE Dublin North City & County Mental Health Services REC
- Dr Robert O'Connor, Manager, Health Research Board National Clinical Trials Office
- Dr Sadhbh O'Neill, REC Office Manager, Joint St James's Hospital/ Tallaght University Hospital REC
- Ms Ciara O'Reilly, HSE R&D PPI Representative
- Dr Colin Pierce, Chair HSE Midwest REC
- Ms Pauline Prendergast, Manager, HSE South East Area REC
- Dr Jean Saunders, Deputy Chair, ULHG and Midwest CHO REC
- Ms Rosalie Smith-Lynch, Chair, HSE North East Area REC
- Dr Emily Vereker, Head of Office, Office of the National Research Ethics Committee

6 Appendix 1: Researcher Confirmation for the dissemination of research opportunities via the HSE that are outside the scope of the RGMS Framework.

Researcher confirmation	
I confirm that this Research Study is NOT within the scope of the HSE Framework for the Governance, Management and Support of Research.	☐
I confirm that REC approval(s) is in place for this Research study and I am attaching a REC Full Approval decision letter to support this. Note: This approval may be from the relevant Higher Education Institute, or other appropriate institution.	☐
I confirm that the advertising material contains the disclaimer; **The findings and conclusions that may arise of this study are independent of the HSE.** **This communication should not be construed as an endorsement or recommendation by the HSE to participate in the study.**	☐
I confirm that the advertising material names the REC that has approved the study.	☐
I confirm that no items beyond simple advertising material are being displayed or circulated, that is a; letter of invitation, Participant Information Leaflet, Informed Consent Form etc. are NOT included.	☐
Name:	
Date:	