HRCDC
Health Research Consent Declaration Committee

2025

Annual Activities Report

Transparency Confidence Trust

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Foreword

As newly appointed Chairperson of the Health Research Consent Declaration Committee (HRCDC), it is my pleasure to present this report on the Committee's activities during 2025.

2025 marked 6 years of operation for the HRCDC and encompassed some significant changes in the Committee's membership. The inaugural Chairperson of the Committee, Ms Brigid McManus, stepped down in July, having provided sterling service since 2019 in establishing the HRCDC and its policies, procedures and rules of engagement. I would like to take this opportunity to pay tribute to her leadership and to wish her well in her future activities.

During 2025, a number of original Committee members also reached the end of their maximum terms of service. Thanks are owed to each of them for their hard work and commitment since 2019, during which time the Committee's practice of robust but collegiate engagement with each application was embedded. I would like to thank Ms Alyson Bailey, Ms Kathy Brickell, Dr Sheelah Connolly, Dr Cornelius Cooney, Dr Simon Furney, Dr Zubair Kabir, Dr Barry Lyons and Mr Dan Rea for their role in this process.

I would also like to welcome the new members who were appointed to the Committee by the Minister for Health during 2025 following a public expression of interest process. This has seen the appointment of members with relevant research, clinical and epidemiological expertise, as well as ensuring the continued input of patient and public involvement (PPI) representatives in the review of every application. Ms Sarah Barnes Aabø, Mr Jim Blighe, Dr Jonathan Briody, Dr Barbara Clyne, Dr Fionnuala Gough, Dr Ross McMullan and Dr Antoinette O'Connor have each settled into the work of the Committee quickly and expertly, and I believe they will ensure that the HRCDC is in good standing for this next phase of activity.

During 2025 the HRCDC reviewed 20 new applications and 21 amendments to existing consent declarations, bringing the total number of consent declarations made since the Committee's inception to 145. There are currently 79 live consent declarations across a wide range of health and social care research. As Chairperson, I am pleased to see ongoing improvements in the research landscape in recognising the importance of managing consent processes in line with the relevant legislation, as well as increasing examples of good practice in engaging with research

participants. The HRCDC is proud to play its part in encouraging the further development of a vibrant health and social care research culture that recognises the privacy rights of participants as well as the value to the public in progressing projects across such a wide field.

Other developments in the research sector in 2025 included an increase in applications to use the Central Statistics Office's (CSO's) research data hub, thus maximising the analysis of previously collected data in ways that advance knowledge while also recognising the privacy rights of those whose data have been collected and stored. The HRCDC is pleased to be collaborating with the CSO in the process to approve such research, thereby ensuring high standards of research data management and use.

The work of the HRCDC could not progress without the support of its Secretariat. Our thanks are owed to Ms Bríd Burke, Mr Jonny Barrett and Ms Caroline Byrne for their continued diligence and care in engaging with research applicants in order to manage the submission process in advance of the Committee's review. Personally, I also wish to thank the members of the Secretariat for their support in these early months of my term as Chairperson, as they have done much to smooth the transition and assist me in taking on these new duties.

Finally, I would like to thank the Health Research Board for its support of the HRCDC's structures, and the Department of Health for its collegiate engagement when needed during 2025.

I look forward to our continued work in 2026 to facilitate research that is in the public interest, while also safeguarding the data privacy rights of research participants. The HRCDC and the Secretariat will continue to engage with a wide range of stakeholders during the year ahead in order to support this work. I trust that you will find the following report of our activities during 2025 to be of interest.

Dr Aideen Hartney
Chairperson

2025 snapshot

21 applications for consent declaration submitted

20 amendment requests submitted

4 applications deemed withdrawn

HRCDC decisions

20 Consent declarations made

21 Amendments approved*

10 HRCDC meetings

68 Annual reviews submitted

Average attendance per meeting **12**

*The HRCDC approved 21 amendment requests in 2025, of which 1 was submitted in 2024 and 20 were submitted in 2025.

01

Health Research Regulations 2018

The Health Research Regulations 2018 ("the Regulations"), which established the legal framework for safeguarding personal data within health research in Ireland, came into force on 8 August 2018. They were enacted to operate in addition to the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), which came into effect across the European Union (EU) in May 2018.

The Regulations seek to enhance public trust and ensure transparency in the processing of personal data for health research purposes. By doing so, they support all stakeholders who are engaged in research and uphold public and patient confidence in Ireland's health research system.

In circumstances where obtaining explicit consent is not practicable and where the continuation of research is deemed to be in the public interest, the Regulations empower the Health Research Consent Declaration Committee (HRCDC) to issue a consent declaration. This mechanism permits the lawful processing of personal data without explicit consent. Such situations may arise when a participant lacks decision making capacity (whether temporarily or permanently), or when securing consent from a large cohort would be operationally unfeasible. These consent declarations ensure that valuable research – especially studies that could improve care or benefit specific groups – is facilitated. They also prevent certain populations from being inadvertently excluded from research that could provide meaningful benefits.

Following the initial introduction of the Regulations, amendments were made in April 2019 (S.I. No. 188 of 2019) and further substantive revisions were enacted in January 2021 (S.I. No. 18 of 2021). The 2021 amendments resulted from extensive consultation between the Department of Health and the research community, which highlighted operational challenges arising from the mandatory explicit consent requirement. In response, exemptions were introduced for defined categories of research, subject to conditions. Comprehensive information regarding these amendments can be found on the HRCDC and Department of Health websites.

02

The Health Research Consent Declaration Committee

The HRCDC has been operational since 2019 and has established itself as a key component of the evolving regulatory framework for health research in Ireland.

The Committee held 10 meetings in 2025, 2 of which were in person.

The Committee membership is diverse, encompassing a wide range of professional expertise, such as critical care medicine, anaesthesiology, data protection, medico-legal issues, general practice, epidemiology, genomics, social care research, and more. This variety ensures comprehensive representation of the health research community. Additionally, the Committee includes three patient and public involvement (PPI) representatives, whose perspectives as members of the public, caregivers, and users of health and social care services are important for ensuring that HRCDC decisions reflect a balanced, inclusive approach.

A full list of the Committee members in 2025 is available in Appendix A, and their profiles can be found on the HRCDC website: https://hrcdc.ie/who-we-are/the-committee/.

When considering applications, the HRCDC continues to carefully assess the public interest, ensuring that the personal data rights of research participants are protected while also allowing important research to proceed in situations where explicit consent cannot be obtained. The Committee's decisions are guided by a collaborative, consensus driven approach.

The Committee reviews public interest on a case-by-case basis, taking into account the unique circumstances of each study. Under the Health Research Regulations 2018, a consent declaration may only be issued where the HRCDC determines that the public interest in carrying out the research substantially outweighs the public interest in requiring explicit consent from participants.

PPI remains central to ensuring that health research is shaped around the needs and perspectives of patients and the public. It reinforces the principle that research should be conducted with people rather than on them. PPI also acts as an important safeguard for data protection, helping to ensure that the views and interests of potential participants are represented – especially in cases where consent cannot be obtained.

In order to support transparency, the HRCDC publishes a decision log and meeting minutes outlining the reasoning behind its determinations. This open approach to information provision helps to strengthen public confidence in health research in Ireland, assuring patients, carers and the wider public that their rights and interests are protected through the Committee's oversight.

Profile of HRCDC members

The HRCDC's members represent a range of areas:

- Medical
- Data protection
- Ethics
- General practice medicine (public health)
- Epidemiology
- Genomics
- Social care research
- Lay/PPI
- Research involving people lacking decision-making capacity
- Legal
- IT systems
- Disability care
- Community care
- Evidence synthesis
- Clinical trials

33% Male

66% Female

Members' perspectives and insights

This section of the report focuses on highlighting the personal perspectives and insights of some of the Committee members who have contributed greatly to the work of the HRCDC since their appointment. As evidenced by their personal contributions set out below, these members have both lived and professional experiences that position them to offer input on the research studies under consideration. These particular members were also appointed in 2025.

Dr Ross McMullan

As an anaesthetic and intensive care registrar in Northern Ireland, I work in perioperative and critical care settings where capacity may be impaired and where decisions are often time-critical. Alongside clinical training, I am undertaking a PhD in sepsis and precision medicine in critical illness with the Critical Care and Respiratory Research Group at Queen's University Belfast. This combination of clinical and research experience has reinforced the importance of enabling high-quality, ethically robust research in circumstances where explicit consent cannot be obtained, while ensuring that participants' rights, dignity and data protection safeguards remain central.

Serving on the HRCDC has been a rewarding experience and has strengthened my appreciation of the careful balance the Committee must strike when considering applications for consent declarations. I have been consistently impressed by the diligence, expertise and professionalism with which submissions are reviewed, and by the thoughtful, consensus-based discussions that underpin decision-making. The Committee's focus on proportionality and clear governance is particularly important in supporting research that is in the public interest while maintaining appropriate oversight and accountability.

I have also valued the contribution of PPI representatives, whose perspectives help to ensure that deliberations remain grounded in the experiences of patients, families, carers and the wider public. This input is especially important when considering how information is communicated, how participants' interests are protected and how trust is maintained in settings where research may proceed without prior consent.

Overall, my experience with the HRCDC has been of a constructive and collaborative forum that supports innovation while upholding high standards. I am proud to contribute to work that helps important health research to proceed responsibly, strengthens public confidence, and ultimately improves care for patients.

"Overall, my experience with the HRCDC has been of a constructive and collaborative forum that supports innovation while upholding high standards."

Dr Barbara Clyne

Health, well-being and the experience of healthcare profoundly shape individuals and communities. Having the highest attainable standard of health is a fundamental right for all. As a health researcher for more than two decades, I have had the privilege of collecting, analysing and interpreting people's health-related data in order to generate evidence that informs policy and healthcare delivery. Across various projects, people have trusted me with their stories – their views, voice, and the details of their health and illness journeys. This trust is something I never take for granted. Every research participant deserves to have their data treated with respect and dignity, and their rights and well-being safeguarded – especially where it is not possible or feasible to obtain their explicit consent.

This is why I believe the HRCDC plays such an important role in Ireland's vibrant health research environment. My involvement in the HRCDC has been a unique and rewarding experience. The Committee members bring a variety of experiences and perspectives as we collectively tackle the complex issues of advancing health research while protecting and promoting the rights of the public and patients. These discussions have challenged and enriched my own thinking, and I have learned so much from the breadth of experience represented on the Committee. I have also appreciated the professionalism and warmth of the Secretariat members. Their support ensures that our deliberations are well-informed and focused.

Serving on the HRCDC has reinforced for me the importance of trustworthiness and transparency in health research. It is a privilege to contribute to work that not only enables valuable research to proceed but also upholds the rights and dignity of those whose data make that research possible.

"Serving on the HRCDC has reinforced for me the importance of trustworthiness and transparency in health research."

Mr Jim Blighe

I joined the HRCDC in March 2025 and am one of three PPI representatives on the Committee. My personal experience with serious illness and successful treatment in recent years led to an awareness of the vital importance of medical research and clinical trials, and I have since been contributing as a PPI representative to a number of initiatives.

The role of the HRCDC is very important in this space; its role is to ensure that proposals for research comply with safeguards to data privacy and the public interest. In particular, the Committee provides a consent declaration where research participants are unable to give consent themselves. The goal is to facilitate research proposals while ensuring that the interests of the public and individuals are protected.

The Committee comprises a range of experts from relevant fields. I have been greatly impressed with the way in which the Committee and Secretariat operate, each drawing on its own area of expertise and experience. Applications considered by the Committee can be very detailed and require careful study. The care and diligence with which everyone approaches their work is really impressive. The ethos is one of openness, diligence, respect for all views and determination to do the right thing. It is very rewarding to be in a position to bring a public and patient perspective to the table.

It is increasingly obvious that health research is becoming more complex all the time, with advances in genomics and artificial intelligence, greater availability of data, and research collaboration taking place on an international level both within the EU and more widely. This is very encouraging and no doubt will bring great benefits for health service users in the future. It will inevitably also bring challenges and increased focus on the protection of the public and individual interests. The role of the HRCDC will become more important as these advances take shape.

"The (HRCDC) ethos is one of openness, diligence, respect for all views and determination to do the right thing. It is very rewarding to be in a position to bring a public and patient perspective to the table."

03

HRCDC activities

HRCDC meetings

The HRCDC convened 10 times in 2025. The Regulations require a quorum of at least seven members at a meeting. In 2025, the average attendance at a meeting was 12 members. There were 17 members on the HRCDC between January and April 2025, and there were 16 members from June to October 2025. As of 31 December 2025, the number of members stood at 15.

HRCDC meetings in 2025

Number of meetings	10
Average number of attendees per meeting	12

Applications submitted in 2025

In 2025, the HRCDC received 21 valid applications seeking a consent declaration for new research studies, and 20 applications requesting an amendment to an existing declaration.

Applications submitted in 2025

New applications for consent declarations	21
Amendment requests for consent declarations previously made	20
Total submissions	**41**

HRCDC decisions

As set out in the Regulations, the HRCDC may make a consent declaration, and it may attach specific conditions to further strengthen data protection safeguards in the interest of research participants affected by the consent declaration; it may also refuse to make a declaration.

Final decisions made as of 31 December 2025

	New applications	Amendments	Total
Consent declarations made	20	–	20
Further information requested	1	–	1
Amendment requests approved	–	21	21
Total decisions	**21**	**21**	**42**

The HRCDC made a total of 42 decisions in 2025. Of these, 20 were new consent declarations, of which 17 were submitted in 2025 and 3 were submitted in 2024.

All the consent declarations made in 2025 had specific conditions attached, and some also had additional recommendations made, in order to bolster personal data protection safeguarding measures for the study participants.

The HRCDC approved 21 amendment requests in 2025, of which 20 were submitted in 2025 and 1 was submitted in 2024.

Applications withdrawn or deemed to be withdrawn in 2025

In 2025, a total of three new applications and one amendment application were withdrawn or deemed to be withdrawn from the consent declaration process; two of these applications were submitted in 2024 and two were submitted in 2025.

Scope of research

In 2025, the HRCDC received applications for consent declarations across a diverse range of biomedical and health research areas, spanning different health categories and research activities.

Using the United Kingdom (UK) Clinical Research Collaboration Health Research Classification System[1], the Secretariat categorises each research study into a certain health category and research activities. The following two tables illustrate the range of health and social care research studies that requested a consent declaration from the HRCDC in 2025.

Health categories[2]

Blood 1	Infection 2	Inflammatory and immune system 1	Injuries and accidents 2	Mental health 2
Metabolic and endocrine 2	Neurological 2	Oral and gastrointestinal 2	Renal and urogenital 5	Reproductive health and childbirth 1
Respiratory 2	Stroke 2	Generic health relevance 3		

Research activities

Aetiology 9	Detection, screening and diagnosis 5	Evaluation of treatments and therapeutic interventions 2	Management of diseases and conditions 6	Health and social care services research 3

1 https://www.ukcrc.org/research-coordination/health-research-classification-system/

2 Some research studies have been categorised under one or more health categories and research activity areas.

04

Annual reviews: Monitoring consent declarations

Since its establishment in 2019, the HRCDC has issued 145 consent declarations for research studies compliant with the Regulations. By the end of 2025, 79 of these declarations were still active. In addition, another 14 decisions have been made by the HRCDC; this includes decisions not to make a consent declaration, or to request further information, and instances where the application was withdrawn prior to a final decision being made by the HRCDC.

According to Regulation 13(1) of the Health Research Regulations 2018, the HRCDC is responsible for monitoring the ongoing implementation of consent declarations, as is deemed necessary. This is done through an annual review process. This process ensures that the applicants provide an update on their compliance with any conditions of the consent declaration throughout the research study.

Annual reviews submitted in 2025

In 2025, the HRCDC received a total of 68 annual reviews, 65 of which were reviews that were due in 2025 and 3 of which were reviews due in 2024 but that were submitted in 2025. A total of 67 annual reviews were considered completed in 2025, indicating that the research studies were in compliance with the HRCDC's requirements and that the conditions were being met or were in progress.

Scope and conditions of a consent declaration

In considering applications, the HRCDC ensures that research participants' data protection rights are upheld while their personal data are being processed for health research without their explicit consent. Therefore, it is critical that the necessary data protection measures, as outlined in the Regulations, are in place to support this process of safeguarding participants' data protection rights.

In its review of applications, the HRCDC may attach specific conditions and recommendations to consent declarations in order to reinforce the protection of personal data. Common examples of these conditions include:

- Implementing data agreements and arrangements between all parties involved in the research
- Implementing transparency measures in order to inform participants and the public about the study, the use of their data and their data protection rights
- Informing participants of their right to withdraw from any health or social care research study and how this can be done
- When studies involve participants with reduced decision-making capacity, ensuring that their families or close friends are involved in the study's decision-making process as much as possible and making every effort to respect and understand the participant's will and preferences
- Detailing the appropriate safeguards that need to be in place in order to protect the security and privacy of personal data during the research, and
- Ensuring PPI in order to maintain a patient-centred approach in the research, especially where obtaining explicit consent is not feasible.

The HRCDC would like to sincerely thank all consent declaration holders for their cooperation in 2025 with this annual review process. It is pleased to report that data controllers have successfully implemented the consent declarations as required.

The Secretariat continues to actively engage with the data controllers and researchers in order to ensure the timely submission of reviews and the provision of the required information.

05

Spotlight on research

In 2025, the HRCDC considered a wide range of interesting research applications from research groups based both inside and outside Ireland. The research studies comprised single- and multi-site collaborative studies, as well as a mix of national and international data controllers.

The types of research studies included observational and interventional clinical trials, retrospective data reviews, biomarkers, devices, and other applications related to the development and use of artificial intelligence and machine learning.

The following examples show the array of research consent declarations made by the Committee in 2025.

Reference: 25-007-AF1: Clinical feasibility study of a prototype Device (SepTec) system for early detection of sepsis in critically ill patients

The HRCDC made a consent declaration for Novus Diagnostics for its proof-of-concept study for the SepTec device – a new bedside device that rapidly detects bloodstream infection, which is a leading cause of sepsis, a life-threatening condition where early and accurate diagnosis is critical. SepTec aims to deliver results within 15 minutes and therefore enable clinicians to initiate targeted antimicrobial treatments promptly; targeted treatment will also help reduce the use of broad-spectrum antibiotics, mitigating antimicrobial resistance.

This study involves the analysis of whole blood samples from patients with suspected bloodstream infection using SepTec, as well as the processing of their personal data; however, the results produced by the SepTec device within this study will not influence the patients' care decisions. The participants enrolled in the study lack decision-making capacity due to the nature of their critical illness; a process of deferred proxy assent will be implemented as a safeguard. The declaration was made to process the personal data of those participants who lack decision-making capacity.

Reference: 25-014-AF1: In-Touch: Implementation of a person-centered palliative care iNtervention to imprOve comfort, QUality of Life and social engagement of people with advanced dementia in Care Homes

In-Touch is an international research study involving a consortium of members that includes University College Cork. Other countries involved in this study include the Czech Republic, Italy, the Netherlands, Portugal, and the UK.

The project aims to improve palliative care for nursing home residents with advanced dementia. It will test a new approach combining daily sensory-based activities with family meetings to support decision-making and care planning. The study will assess whether In-Touch improves residents' comfort, levels of agitation, and quality of life, while also benefiting families (satisfaction with care) and staff (job satisfaction and well-being).

The trial will take place in nursing homes across Europe (including eight in Ireland), involving residents, family members and staff. Nursing homes will be randomly assigned to either the

In-Touch programme or standard care. Researchers will collect data over 12 months from health records, staff surveys, family interviews, and observations. The study will also examine costs and participant experiences. The findings will aim to guide better dementia care in nursing homes, and results will be shared with healthcare professionals, policy-makers and families through publications, training materials and public engagement.

The consent declaration was made to cover the processing of the personal/pseudonymised data of participants with dementia who will lack decision-making capacity to provide consent – for these participants, proxy assent will be obtained on their behalf.

Reference: 25-021-AF1: Biomarkers in the identification of Alzheimer's Disease in people with Down Syndrome (Bio-MinDS)

A consent declaration was made to Tallaght University Hospital and Trinity College Dublin for the Bio-MinDS study, which aims to identify reliable biomarkers in order to improve the early detection, diagnosis and monitoring of Alzheimer's disease in people with Down syndrome. The study involves adults with and without Down syndrome attending annual study visits where they will complete health checks and memory and thinking tests and will provide blood samples. Samples and data will also be shared with trusted academic collaborators in Sweden and the UK. The findings of this research aim to guide future clinical trials and contribute to better treatments, as well as deepen understanding of healthy brain ageing. The consent declaration was sought as many of the potential participants will lack the decision-making capacity to provide explicit consent for data processing.

For studies that already have a consent declaration in place, an amendment request may need to be submitted to the HRCDC if changes are made to the study that affect the existing consent declaration. This could be the addition of new data controllers or processors, changes to the study itself, or changes to the time and duration of the study. The following are examples of amendments considered by the Committee in 2025.

Reference: 19-004-AF2/AMD4: Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia (REMAP-CAP)

The REMAP-CAP study is a clinical trial aimed at finding the most optimal treatment for severe community-acquired pneumonia in the adult intensive care unit population. In comparison with a conventional trial, the REMAP-CAP study combines a number of novel design features and has been termed a randomised, embedded, multifactorial adaptive platform trial. These features are designed to enhance the efficiency of trial conduct, generate new knowledge more quickly and improve outcomes for participants within the trial.

The controllers for the study are St Vincent's University Hospital; University Medical Center Utrecht, the Netherlands;

and Monash University, Australia. In addition, a number of other hospital sites in Ireland are now involved.

A number of amendments have been approved by the HRCDC since the original consent declaration was made in 2019. In 2025, a further amendment was submitted in order to: (i) add Tallaght University Hospital and Wexford General Hospital to the study, (ii) include new treatment domains in the trial, and (iii) extend the period of data storage to 25 years.

Reference: 19-015-AF2/AMD3: Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing (IDS-TILDA)

IDS-TILDA is a longitudinal study researching ageing in Ireland among a representative sample of people with an intellectual disability aged 40 years and over at all levels of functioning and in all living situations. IDS-TILDA aims to identify the principal influences on successful ageing in persons with an intellectual disability, and to then determine if they are the same or different influences as those for the general population.

Data are examined in order to determine similarities to and differences from the influences on the ageing lives of the general population and if there are changes in influences over time for people with an intellectual disability, and also to analyse the data in order to inform and guide the planning, implementation and evaluation of future national policies, programmes and services.

In 2025, a consent declaration amendment was requested and approved to cover the processing of the personal data of those who lack decision-making capacity for a sixth wave of the IDS-TILDA study.

Wave 6 includes additional intellectual disability service providers that will be sites for data collection, and the inclusion of some additional personal data (e.g. new questions added to the Wave 6 study questionnaires/surveys and data from additional health measures).

The amendment also includes the following new data processors and data providers that are involved in Wave 6:

- National Cancer Registry Ireland
- Digital Gait Labs/Azure, and
- The participants' general practitioners.

06

Portfolio of consent declarations

Since the establishment of the HRCDC in March 2019, and up to 31 December 2025, a total of 145 consent declarations were made for research studies considered to be in accordance with the Regulations. At the end of 2025 there were 79 live consent declarations and 66 that were no longer required or had expired.

By 31 December 2025, 69 individual data controller organisations from various sectors and geographical regions across Ireland and internationally had received consent declarations for health research studies. A data controller/joint data controllers may have received a consent declaration for more than one research study by year ending 31 December 2025.

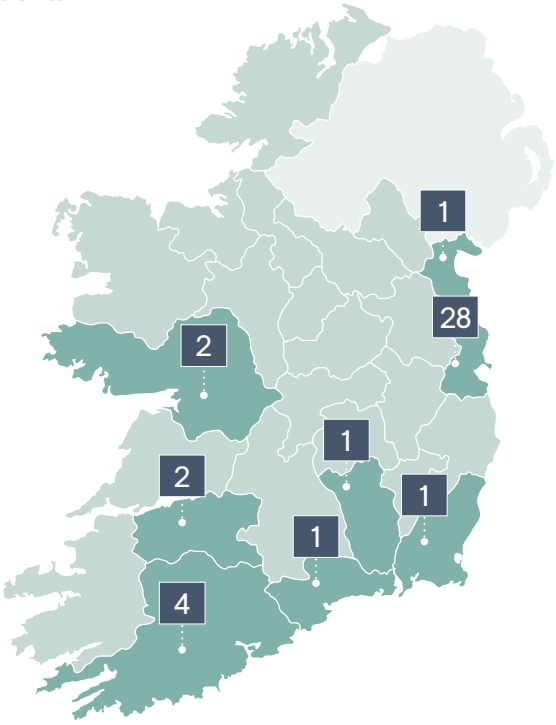
The HRCDC continues to see international data controllers applying for consent declarations to process the data of research participants in Ireland for research studies. They applied either as a sole data controller or as joint data controllers with another Irish data controller.

Sectoral type of data controllers with consent declarations

Sectoral breakdown of data controllers with consent declarations	Higher education institution 18	Hospital/ healthcare service 28	
Commercial organisation 9	Charity 3	Government Department 1	State agency 1
Research institute 6	Professional body 1	Other statutory body 2	Total 69

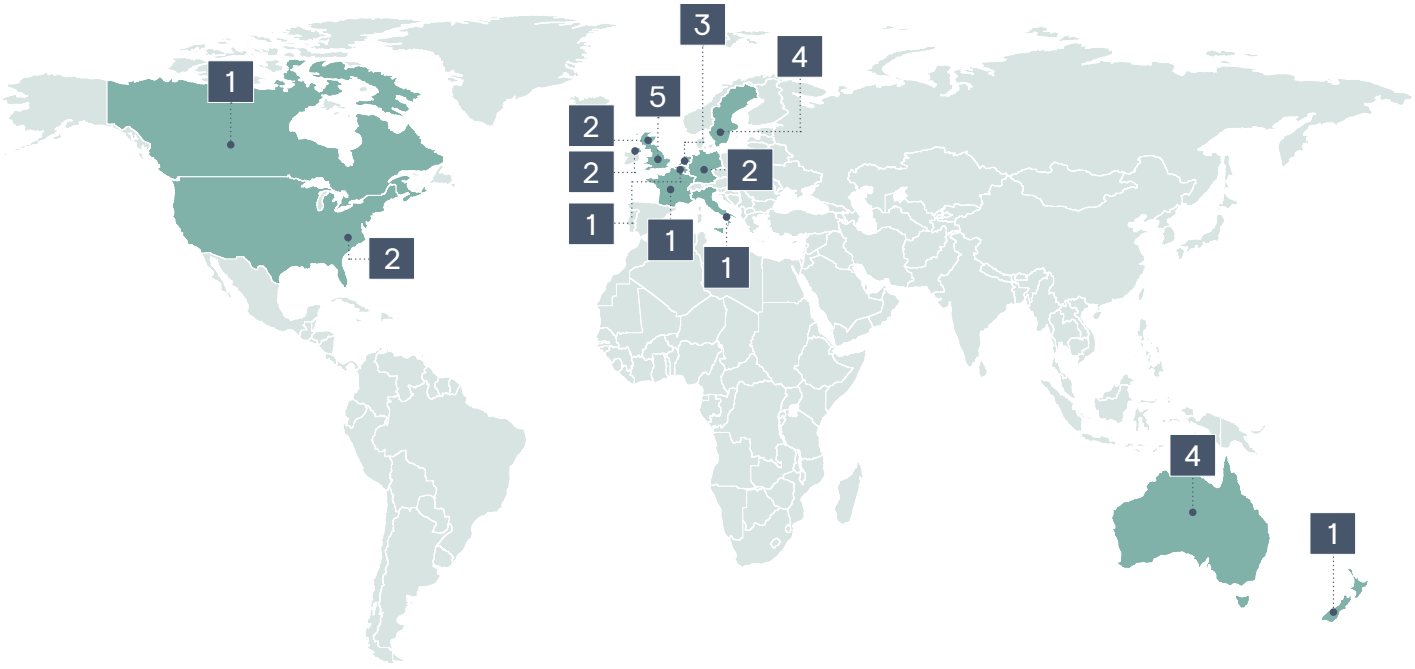
Geographical spread of data controllers with consent declarations

National



National	Institutions
Dublin	28
Wexford	1
Galway	2
Waterford	1
Limerick	2
Cork	4
Kilkenny	1
Louth	1
International	
Australia	4
United States of America	2
Sweden	4
England	5
Scotland	2
Northern Ireland	2
New Zealand	1
France	1
The Netherlands	3
Canada	1
Germany	2
Italy	1
Belgium	1
Total	**69**

International



07

The Secretariat

The Secretariat's primary objective is to support the HRCDC in delivering its mandate in a manner that fosters trust, transparency and public confidence in the governance of health research.

The Secretariat was established in 2019 as a business unit within the Health Research Board (HRB), Ireland's leading agency responsible for supporting and funding health research, generating health information and promoting the use of evidence in policy and practice. The HRB supports and enables the operational and strategic work of the Secretariat team. This support function is formally recognised within the HRB Strategy 2026–2030 and reflects the HRB's ongoing commitment to enabling the efficient operation of the HRCDC.

Throughout the reporting year, the Secretariat continued to act as the principal point of contact for the research community, members of the public, and a wide range of stakeholders on behalf of the HRCDC. It worked closely with both existing and prospective researcher applicants, providing guidance and support throughout the consent declaration application process. This engagement is a core function of the Secretariat and is essential to ensuring that applications submitted to the HRCDC are comprehensive, accurate and aligned with the requirements of the Regulations. Strong collaborative relationships between the HRCDC, the Secretariat and researchers help to promote consistency, clarity and confidence in the regulatory framework governing health research.

The Secretariat is responsible for the administration and oversight of the consent declaration application process from end to end. Key activities during 2025 included the receipt and triage of applications, the preparation of information packs for HRCDC consideration, the coordination of Committee meetings, and the issuance of formal decision letters on behalf of the HRCDC.

In line with the HRCDC's commitment to openness and accountability, the Secretariat supported transparency in the Committee's work by maintaining up to date and publicly accessible records through the HRCDC website. This included the publication of meeting minutes and details of consent declarations granted.

During the reporting period, the Secretariat oversaw the ongoing management of a portfolio of 79 live consent declarations for research studies. This involved monitoring compliance with data protection safeguards and other conditions stipulated by the HRCDC, in line with the fundamental principles of the Regulations.

In addition, the Secretariat supported the HRCDC by identifying and disseminating information on relevant developments throughout the year. This included sharing information on upcoming events, providing awareness raising and training on topics of interest, and monitoring updates in health research and data protection law and practice within Ireland and across other European jurisdictions. Specific activities in 2025 are detailed in the following section.

Secretariat activities

In 2025, the Secretariat continued to engage actively with stakeholders across a wide range of initiatives aimed at informing and strengthening the future work of the HRCDC. The following is an overview of the key activities undertaken to support applicants, the Committee and other stakeholders throughout the year.

A major focus in Q1 2025 was the onboarding of six new HRCDC members following a successful public expression of interest campaign. An additional new member also joined later in the year. This represents a significant change in the composition of the Committee; however, each new member brings experience from highly relevant research areas, thus ensuring that the diversity of perspectives, which is a core strength of the HRCDC, is maintained.

The European Health Data Space (EHDS) Regulation came into force in March 2025. The Secretariat is supporting Ireland's implementation of the EHDS Regulation in several ways. First, the Secretariat sits on the steering group for the national project to establish health data access services for HealthData@EU and the EHDS. Second, the Secretariat's Programme Manager is project lead for the work package that aims to develop a nationally and EU aligned specification for a Data Access Application Management System (DAAMS) to support the operations of Ireland's Health Data Access Body (HDAB). Once completed, this specification will help shape a national IT system to enable the HDAB to receive, process and respond to data access applications from researchers and other users both within and outside Ireland. This involvement ensures that the Secretariat and the HRCDC remain informed of developments related to the EHDS and can contribute meaningfully as Ireland progresses towards full implementation of this regulation.

In 2025, the HRCDC continued to receive applications from the Central Statistics Office (CSO) Health Research Data Centre (Health RDC). It is encouraging to see an increase in the number of such applications compared with 2024, reflecting the growing use of this important national resource. The continued development and expansion of secure processing environments (such as the CSO Health RDC) for secondary data analysis will remain a key area of focus as Ireland implements the EHDS Regulation's requirements.

Building and strengthening relationships with current and potential applicants also remained a priority for the Secretariat. We continued to offer pre submission meetings for applicants, as well as information sessions on the HRCDC process for research groups when required. This engagement helps ensure that applications submitted to the Committee contain sufficient detail to support informed decision making, and may reduce the number of conditions required for any consent declaration issued.

Collaboration on GDPR compliance and the Health Research Regulations 2018 continued throughout 2025. The Secretariat worked closely with the Data Protection Commission and the Department of Health to clarify regulatory requirements related to data protection. Secretariat staff also participated in a range of professional development activities, including PDP training courses and the EU Health Data Protection Congress, providing opportunities to exchange insights with data protection professionals across a variety of sectors and EU countries. These engagements strengthened understanding of how data protection requirements are being applied in practice and helped inform the Secretariat's approach to supporting health research here in Ireland.

The Secretariat also remained involved in the development of the Consent, Ethics and Research Application System (CERAS), an electronic application and review system designed in partnership with the National Office for Research Ethics Committees.

Throughout 2025, Secretariat staff attended a wide range of seminars, conferences and events organised by the Health Service Executive; the Irish Platform for Patients Organisations, Science and Industry (IPPOSI); Biobanking Ireland; Health Research Charities Ireland; and various data protection bodies. The Secretariat also participated in the Steering Group for the National Policy for Consent in Health Research. These engagements provided valuable insights into ethics, governance, PPI, consent, and data protection, supporting the Secretariat's ongoing efforts to remain informed about evolving practices and emerging trends in health research.

08

Key objectives for 2026

Strategic priorities and key objectives for 2026

As the HRCDC looks ahead to 2026, it will continue to play a central role in ensuring that its work supports the responsible, transparent and secure use of personal health data for research. This commitment includes maintaining the highest standards of privacy and confidentiality for individuals while also protecting the broader interests of patients, carers and the public.

The Secretariat will further strengthen its communication efforts by actively engaging with the public, patient advocacy groups, established research networks and the wider research community. A key priority will be ensuring that both researchers and members of the public are well informed about the data protection safeguards required under the relevant regulations, as well as the conditions under which consent declarations may be made.

A major focus for 2026 will be sustaining meaningful dialogue with the research community. The HRCDC Secretariat will continue to support researchers through pre submission meetings, clear guidance and constructive feedback on applications. By providing ongoing education and direction, the Secretariat aims to ensure that researchers fully understand legislative requirements, data protection obligations and the processes involved in managing consent declaration applications. This proactive engagement is vital for maintaining compliance, promoting transparency and strengthening the overall health data research ecosystem.

Aligned with the HRB's Strategy 2026–2030, the HRCDC will also contribute to developing agile procedures that enable swift and coordinated responses to health emergencies and emerging threats. Working closely with colleagues in the National Office, the Secretariat will support efforts to deliver accelerated national decisions on ethics and consent in line with national and international best practice as the need arises.

Beyond internal developments, the HRCDC and its Secretariat will remain actively engaged with legislative and policy changes in Ireland and across Europe. This includes monitoring progress on the EHDS, which continues to evolve at pace. The Secretariat will maintain its participation in the EU4Health Steering Committee and the DAAMS Work Package 5 project, thereby ensuring that Ireland's perspective is represented. The interaction between the EHDS, GDPR and national regulations will be an area of particular interest, given their potential impact on the future governance and oversight of health data research.

Internally, the Secretariat will continue to ensure that HRCDC operations remain robust, efficient and fit for purpose. This includes the ongoing review and refinement of policies, procedures and governance structures to support the HRCDC's mission and the evolving needs of the health research landscape.

Looking ahead to 2026, the HRCDC remains firmly committed to strengthening its relationships across the health research community. Through collaboration, engagement and continued support for researchers, the HRCDC will work to ensure that high quality research can progress while safeguarding the rights and interests of the public.

Appendices

Appendix A

Current HRCDC members

Dr Aideen Hartney, Health Research Consent Declaration Committee Chairperson

Emeritus Professor Evelyn Mahon, Health Research Consent Declaration Committee Deputy Chairperson

Dr Mary Tumelty, Health Research Consent Declaration Committee Deputy Chairperson

Dr Aisling McMahon, intensive care medicine

Dr Antoinette O'Connor, Clinician and Researcher (joined March 2025)

Dr Barbara Clyne, epidemiology and public health research (joined March 2025)

Dr Fionnuala Gough, Lecturer in Medical Ethics (joined October 2025)

Mr Jim Blighe, Public and Patient Representative (joined March 2025)

Mr John Woods, Data Protection Officer

Dr Jonathan Briody, epidemiology, public health, data protection and artificial intelligence (joined March 2025)

Ms Patricia O'Beirne, Public and Patient Representative

Professor Paul Stynes, IT systems

Dr Ross McMullan, Clinician and Researcher (joined March 2025)

Ms Sarah Barnes Aabø, Public and Patient Representative (joined March 2025)

Professor Susan Smith, General Practitioner, research

The following HRCDC members left the Committee during 2025:

Ms Brigid McManus, Health Research Consent Declaration Committee Chairperson

Ms Alyson Bailey, public and patient involvement

Dr Barry Lyons, paediatrics, anaesthesiology and critical care

Dr Cornelius Cooney, anaesthesiology and intensive care medicine

Mr Dan Rea, public and patient involvement

Ms Kathy Brickell, emergency and intensive care research

Dr Sheelah Connolly, economic and social research

Dr Simon Furney, biomedical genomics

Dr Zubair Kabir, epidemiology and public health

Secretariat team

Ms Bríd Burke, Programme Manager

Mr Jonny Barrett, Project Officer

Ms Caroline Byrne, Administrative Assistant

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