Annual Activities Report 2024

HRCDC

Health Research Consent Declaration Committee

Transparency
Confidence
Trust

Contents

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Foreword

As Chairperson of the Health Research Consent Declaration Committee (HRCDC), I am pleased to present our annual report, highlighting the achievements and progress of the HRCDC and its Secretariat throughout 2024.

The HRCDC saw another year of significant activity in 2024, with a diverse range of applications reviewed across multiple health research domains, including projects both within Ireland and internationally. This reflects the growing complexity and scope of health research today.

Since its formation in 2019, the HRCDC has consistently benefitted from the expertise of our members, whose contributions continue to play a pivotal role in our work. Their experience in reviewing health research applications for consent declarations remains invaluable. At the same time, the HRCDC has been enriched by the addition of new members, who have introduced fresh insights and helped to drive forward our deliberations and decision-making.

In 2024, we were pleased to welcome Professor Paul Stynes and Dr Aisling McMahon to the Committee. Both bring specialist knowledge that aligns closely with the evolving needs of health research, and we look forward to their continued contributions in shaping our work.

With the terms of six current members expiring in early 2025, we launched a targeted expression of interest campaign in late 2024. I am happy to report that the response has been encouraging, and we look forward to welcoming a new cohort of members who will bring their expertise and perspectives to the Committee, starting in March 2025.

Since its establishment, the HRCDC has issued 125 consent declarations, 67 of which are still active. We remain focused on our critical role in facilitating health research, particularly in circumstances where obtaining explicit consent is not feasible, by which we seek to contribute to the advancement of scientific research.

In 2024, the HRCDC Secretariat dedicated significant efforts to developing and refining a new application management system, CERAS (Consent and Ethics Review Application System). This system will streamline the application process for both researchers and the Committee, making it easier to track and manage consent declarations. We believe this system will significantly enhance the efficiency of the Committee's work, and we look forward to implementing it throughout 2025.

Stakeholder engagement was another key focus of 2024. The Secretariat's increased involvement in various working groups and initiatives reflects the growing influence of the HRCDC within the broader research landscape. In 2024, the Secretariat organised six in-person information seminars aimed at directly supporting researchers applying for consent declarations. These seminars provided valuable insights into the HRCDC process, as well as the key regulatory considerations researchers must be aware of. Given the success of this initiative, we plan to continue this programme in 2025.

We also stay informed about ongoing work in the developing landscape of the European Health Data Space (EHDS) and how this innovative ecosystem will interact with the work of the HRCDC. The Secretariat Programme Manager's role on the National Steering Group for EU4Health is an example of the proactive stance we are taking to prepare for the upcoming implementation of the EHDS. This initiative is critical for ensuring that Ireland's health research infrastructure aligns with EU standards on data privacy and security.

We also wish to acknowledge the continued cooperation of our consent declaration holders, who have worked closely with the HRCDC throughout the annual review process. In 2024, 70 annual reviews were submitted, and the Secretariat's management of these submissions ensures that consent declarations continue to be monitored effectively.

The success of the HRCDC is built on the dedication of our members, whose careful and thorough review of applications, combined with their collaborative approach to decision-making, ensures that we continue to reach balanced, evidence-based outcomes. I want to personally thank each Committee member for their unwavering commitment to this important work.

On behalf of the HRCDC, I would also like to express my sincere appreciation for the support provided by our Secretariat: Ms Bríd Burke, Mr Jonny Barrett, and Ms Caroline Byrne. Their expertise, professionalism, and commitment to the Committee's goals are indispensable to the smooth functioning of the HRCDC. I wish to highlight in particular their proactive engagement with our applicants and other stakeholders, the significant updates to our website for which they have been responsible, and their delivery of information seminars to applicants and research groups across Ireland.

The Secretariat's proactive engagement with these groups has been instrumental in strengthening the HRCDC's reputation as a key player within Ireland's research regulation framework.

Finally, I would like to extend my gratitude to the Health Research Board (HRB) and the Department of Health for their ongoing support and collaboration, which has been critical to the continued success of the HRCDC.

Looking ahead to 2025, the HRCDC remains dedicated to fostering an adaptable and transparent research environment. We will continue to engage with both current and future applicants, while upholding the principles of public interest and safeguarding health research participants' personal data. These values will remain at the core of our decision-making and guide us as we move forward into the next phase of our work.

Brigid McManus
Chairperson

2024 snapshot

15 applications for consent declaration submitted

21 amendment requests submitted

3 applications withdrawn

HRCDC decisions

12 Consent declarations made

25 Amendments approved*

10 HRCDC meetings

70 Annual reviews submitted

Average attendance per meeting **12**

*The HRCDC approved 25 amendment requests in 2024, 5 of which were submitted in 2023 and 20 in 2024.

01

Health Research Regulations 2018

02

The Health Research Consent Declaration Committee

The Health Research Regulations 2018 ('the Regulations'), which govern the protection of personal data in health research in Ireland, were implemented on 8 August 2018. These regulations were introduced to complement the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), which became effective across the European Union (EU) in May 2018.

The Health Research Regulations aim to instil trust and promote transparency in the processing of personal data within health research. This framework benefits all parties involved in research and plays a crucial role in maintaining public and patient confidence in the health research sector in Ireland.

In certain situations, where obtaining explicit consent is not feasible, and where it is in the public interest for research to proceed, the Health Research Regulations permit the Health Research Consent Declaration Committee (HRCDC) to issue a consent declaration. This declaration enables researchers to lawfully process the personal data of research participants for health research purposes without their explicit consent. Such scenarios might include cases where a participant lacks decision-making capacity – either temporarily or permanently – or where obtaining consent from a large group of participants is impractical.

These consent declarations are essential for ensuring that important health research can proceed, as their absence could result in certain groups being excluded from studies that could benefit them.

The Health Research Regulations were introduced in August 2018, and amendments were made in April 2019 (S.I. No. 188 of 2019), with further substantive changes introduced by the Minister for Health in January 2021 (S.I. No. 18 of 2021). The January 2021 amendments were the result of consultations between the Department of Health and the research community, which highlighted challenges faced by the Health Research Regulations in specific areas of health research. These amendments recognised that the mandatory requirement for explicit consent from research participants presented practical obstacles. As a result, specific types of research studies were granted exemptions from the need for explicit consent, provided they met stringent criteria. Detailed information regarding these amendments is available on the HRCDC and Department of Health websites.

The approach taken to the security of processing of personal data is recognised and supported by the European Data Protection Board (EDPB) and the European Commission. The Commission published its second report on the application of the GDPR in July 2024[1]. The EDPB is pleased to concur with the Commission's finding that, despite all of the challenges in implementing it, the application of the GDPR has given individuals more control over their data, created a level playing field for businesses, provided a cornerstone for the EU's digital transition, and contributed to the emergence of high international standards in data protection.

1 https://www.edpb.europa.eu/system/files/2024-12/edpb_statement_20241203_ec_2nd_gdpr_evaluation_report_en.pdf

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.

At the start of 2024, the Committee had 15 members, which increased to 17 over the course of the year. The Committee held 10 meetings in 2024, 2 of which were in person.

The HRCDC has a diverse membership, 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 as of 2024 is available in Appendix A, and their profiles can be found on the HRCDC website: https:/hrcdc.ie/who-we-are/the-committee/

The HRCDC continues to consider the public interest in its decision-making, ensuring that the protection of research participants' data rights is balanced with the need to conduct vital research in cases where explicit consent cannot be obtained. The Committee's decision-making process remains rooted in consensus-building.

The HRCDC evaluates the public interest of each research study, on a case-by-case basis, considering the specific circumstances of each. In line with the Health Research Regulations 2018, the Committee can only issue a consent declaration if it deems that the public interest in conducting the research outweighs the public interest in requiring explicit consent from the participant(s).

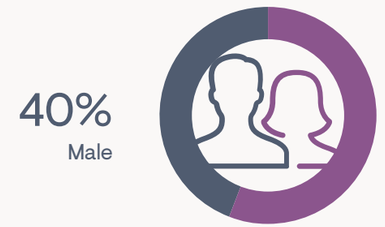
PPI plays a crucial role in ensuring that health research remains patient- and public-centred. It strengthens the notion that research should be conducted 'with' or 'by' patients and the public, rather than 'on' them. PPI serves as an important safeguard in data protection, ensuring that the interests and perspectives of prospective participants are always taken into account, particularly when consent cannot be obtained.

To ensure transparency, the HRCDC publishes a log of decisions, along with meeting minutes that detail the rationale behind its decisions. This commitment to openness helps build public trust in research conducted in Ireland, assuring the public, patients, and carers that the HRCDC's oversight is safeguarding their interests.

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
- PPI
- People lacking decision-making capacity
- Legal
- IT systems



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 tirelessly to the work of the HRCDC since their appointment. As evidenced by their personal contributions set out in this section, these members have lived and professional experiences that position them to offer valuable input on the research studies under consideration.

Professor Paul Stynes

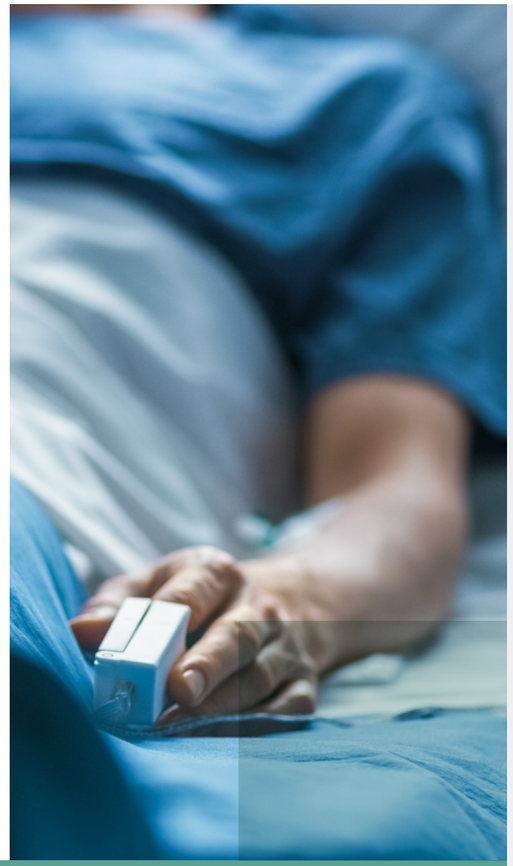
As Dean of the School of Computing at the National College of Ireland, I bring a technical perspective to the HRCDC, which focuses on ensuring data privacy and security in the sharing and storage of health data across computer networks. My expertise lies in artificial intelligence and computing, with a strong emphasis on compliance with the principles of the Health Research Regulations and GDPR in order to safeguard participants' rights.

Since joining the HRCDC in January 2024, I have been actively involved in reviewing applications to ensure that the processing of personal data complies with GDPR requirements and adheres to the Health Research Regulations. This includes critically assessing data handling frameworks, from anonymisation techniques to secure storage and transfer protocols, in order to maintain the highest standards of data protection.

The HRCDC's dedication to transparency and accountability has greatly impressed me, particularly its commitment to fostering public trust in health research. Through collaborative discussions with members from diverse disciplines, I have gained valuable insights into how technical safeguards intersect with ethical considerations. These deliberations ensure that health research not only protects individual data rights but also delivers benefits that are both meaningful and in the public interest.

Being part of the HRCDC has strengthened my resolve to promote responsible data governance practices in health research. I am proud to contribute to the Committee's mission of enabling innovative and impactful research while ensuring the security and ethical use of personal health data, thereby fostering a vibrant and trustworthy health research environment in Ireland.

"Being part of the HRCDC has strengthened my resolve to promote responsible data governance practices in health research."



Dr Aisling McMahon

As a Consultant in Intensive Care Medicine, I routinely care for critically ill patients who are often unable to provide consent due to their medical condition. This has deepened my awareness of the delicate balance between advancing medical research and safeguarding patient autonomy. My experience in conducting clinical research has also provided me with valuable insights into the practicalities of study design, ethics, and regulatory compliance.

Serving as a member on the HRCDC over the past year has been a rewarding and insightful experience. I have been impressed by the diligence, dedication, and comprehensiveness with which the Committee and HRCDC Secretariat approach each submission. Each Committee member draws on their area of expertise and brings their own unique perspective to the deliberations, all of which are carefully and respectfully considered. I have found the viewpoints of the public and patient representatives to be of particular benefit, and for me this has reinforced the importance of PPI in research. The work of the HRCDC supports health research in a transparent fashion, while promoting patient confidence and trust.

As a member of the HRCDC, I have had the opportunity to draw from my professional experience and contribute to thoughtful deliberations, in order to ensure that proposed research aligns with ethical standards and the public interest while addressing the unique needs of patients who are unable to give consent. This role has strengthened my commitment to fostering research that is both innovative and ethically sound, protects and promotes the rights of patients, and ultimately improves patient outcomes and advances the field of medicine.

“...to ensure that proposed research aligns with ethical standards and the public interest while addressing the unique needs of patients who are unable to give consent. ”

Ms Alyson Bailey

The HRCDC was set up to consider the exceptional circumstances in which consent, which is required by law, either cannot be sought or cannot be provided by research participants themselves. To waive this requirement, researchers must demonstrate that their work is of sufficient importance that it warrants an exemption. This is where our discussions begin. If, and only if, the HRCDC collectively decides that an application has successfully argued for it being in the public interest will the Committee move on to the next phase, judging if the research warrants a consent declaration.

I have been a member of the HRCDC since it was first established in 2018, and I serve as one of its public/patient representatives. From the outset, our Chairperson fostered an environment of trust, openness, and mutual respect, where each voice is heard and each contribution given equal weight.

Throughout my time on the Committee, I have been unfailingly impressed by the care each of my colleagues takes in considering the applications which come before us, and the shared focus on safeguarding the rights of the individual research participant. We each keenly feel the dual responsibility of facilitating important research – realising that patients are the ultimate beneficiaries of knowledge gained this way – and of ensuring that research participants’ interests are considered, protected, and promoted to the greatest extent possible.

I believe that in its work to date the HRCDC has demonstrated its commitment to fostering public/patient confidence in research, safeguarding participants’ data rights, and facilitating valuable health and social care research, and I have every confidence it will continue to do so going forward.

“... impressed by the care each of my colleagues takes in considering the applications which come before us, and the shared focus on safeguarding the rights of the individual research participant”

03

HRCDC activities

HRCDC meetings

The HRCDC convened 10 times in 2024. The Health Research Regulations require a quorum of at least 7 members at each meeting, and in 2024 the average attendance at HRCDC meetings was 12 members. There were 15 members on the HRCDC between in January 2024, and this had increased to 17 members by May 2024.

HRCDC meetings in 2024

Number of meetings	10
Average number of attendees per meeting	12

As part of ongoing awareness of developments in the area of health research, the HRCDC invited the Department of Health to provide an update on the latest developments of the European Health Data Space (EHDS). The Central Statistics Office (CSO) was also invited to provide information on the newly launched CSO Health Research Data Centre.

Applications submitted in 2024

In 2024, the HRCDC received 15 applications seeking a consent declaration for new research studies. The HRCDC also received 21 applications for consideration that were requesting an amendment to a consent declaration that had previously been made. In some cases, additional applications were submitted which were incomplete. The Secretariat has engaged with the researchers who submitted incomplete applications to inform them on the requirements for submission.

Applications submitted in 2024

New applications for consent declarations	15
Amendment requests for consent declarations previously made	21
Total submissions	**36**

HRCDC decisions

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

Final decisions made as of 31 December 2024

	AF1*	AMD**	Total
Declarations made	12	-	12
Request for further information	1	-	1
Amendments approved	-	25	25
Total decisions	**13**	**25**	**38**

* Applications for new research

** Applications seeking an amendment to a consent declaration that had been granted previously

The HRCDC made a total of 38 decisions in 2024, which included 12 consent declarations. All the consent declarations made in 2024 had specific conditions attached, and some also included additional recommendations in order to bolster personal data protection safeguarding measures for the study participants.

The HRCDC approved 25 amendment requests in 2024, 5 of which were submitted in 2023 and 20 in 2024.

Scope of research

In 2024, 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 UK Clinical Research Collaboration's Health Research Classification System,[2] the following two tables illustrate the range of health research studies that requested a consent declaration from the HRCDC in 2024.

Please note: Some research studies have been categorised under multiple health categories and research activity areas.

Health categories

Blood 2	Cancer and neoplasms 2	Infection 1	Musculoskeletal 1	Neurological 2
Reproductive health and childbirth 1	Respiratory 3	Skin 1	Stroke 1	Generic health relevance 3

Research activities

Aetiology 4	Detection 6	Evaluation 4	Management 1	Health and social care services 1

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

04

Annual reviews: Monitoring consent declarations

Since its establishment in 2019, the HRCDC has issued 125 consent declarations for research studies compliant with the Health Research Regulations. By the end of 2024, 67 of these declarations were still active. In addition, since 2019 the HRCDC has made another 14 decisions, which include decisions not to make a consent declaration, or to request further information and where the application was then withdrawn prior to the HRCDC making a final decision.

According to Regulation 13(1) of the Health Research Regulations, 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 provides assurance that the applicant continues to comply with any conditions of the consent declaration throughout the research study.

Annual reviews submitted in 2024

In 2024, the HRCDC received a total of 70 annual reviews. This includes 66 reviews due in 2024 and 4 reviews from 2023 that were submitted in 2024. In total, 78 annual reviews were considered completed in 2024, indicating that the research studies were compliant with the HRCDC's requirements, the conditions attached to consent declarations were being met or worked on, and any HRCDC recommendations had been addressed. Of these 78 completed reviews, 63 were from 2024 and 15 were from 2023.

By 31 December 2024, six annual reviews were still pending submission, or they either were awaiting Secretariat review or required additional information from the applicant or data controller.

Scope and conditions of a consent declaration

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

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

- Implementing data agreements and arrangements between all parties involved in the research
- Implementing transparency measures to inform participants and the public about the study, the use of their data, and their data protection rights
- Informing any participant on their right to withdraw from any health or social care research study and how this can be done
- When studies involve participants with impaired decision-making capacity, ensuring that their families 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 preference
- Detailing the appropriate safeguards that need to be in place to protect the security and privacy of personal data during the research, and
- Carrying out PPI to maintain a patient-centred approach in the research, especially as explicit consent is not available.

The HRCDC would sincerely like to thank all consent declaration holders for their cooperation in 2024 with this annual review process.

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

05

Spotlight on research

In 2024, the HRCDC considered a wide range of interesting research applications from research groups based both inside and outside of Ireland. Further details are available from the publicly available information on our website. 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, and applications related to the establishment of biobanks.

The following examples show the array of applications for which the HRCDC made consent declarations in 2024.

24-005-AF1 – Lung Health Check

The HRCDC made a consent declaration for the Royal College of Surgeons in Ireland (RCSI), Beaumont Hospital, and Centric Health to process patient contact details for the purpose of undertaking a lung health check pilot study. The goal of this study is to assess the feasibility of lung cancer screening in Ireland, with a focus on individuals aged 55–74 years who are current or former smokers, as they are at an increased risk for lung cancer.

Early detection of lung cancer through screening can significantly improve survival rates, as it allows for more effective treatment when the cancer is in its early stages.

The study's objective is to identify lung cancer in individuals without symptoms, using criteria such as age, smoking history, and relevant medical background to select participants. The pilot study will take place through a mobile unit in the North Dublin/ Dublin North East region, in line with international best practices for lung cancer screening.

To meet the target number of participants for lung checks in this pilot, 30,000 patients aged 55–74 years will need to be contacted to determine their eligibility. Prospective participants will be contacted by a third party with the necessary infrastructure to do so. The consent declaration is therefore necessary to cover this third party obtaining and using individuals' personal data in order to contact potential participants for this pilot.

The research team will then assess the potential participants' suitability and eligibility for this pilot study. The aim of the study is to improve the chances of early lung cancer detection and enhance the effectiveness of potential treatments.

24-011-AF1 – A feasibility assessment of the Echolight bone screening device for individuals with intellectual disabilities

The HRCDC made a consent declaration for Trinity College Dublin for the study 'A feasibility assessment of the Echolight bone screening device for individuals with intellectual disabilities'. This study aims to evaluate the feasibility of the Echolight bone health assessment system, which utilises advanced technology to measure an individual's bone density without the use of radiation. In contrast to traditional dual energy X-ray absorptiometry (DXA) scanning, which requires patients to maintain a fixed position for an extended period of time, the Echolight device is portable and more comfortable, and reduces patient discomfort, making it a potentially more suitable option for individuals with intellectual disabilities.

Osteoporosis has become a significant health concern for individuals with intellectual disabilities. This participant cohort experiences a higher prevalence of osteoporosis, and it often presents at an earlier age due to various factors such as comorbid health conditions and the limited promotion of bone health over a lifetime, for people with intellectual disabilities.

The study will involve 80 participants representing a broad spectrum of intellectual disabilities and will include participants with varying levels of intellectual ability. The researchers running this study have deemed this essential to assess the device's applicability and efficacy in scanning bone density across the entire population. This inclusive approach will also allow for a comprehensive demographic analysis, exploring the correlation between the severity of intellectual disabilities and bone health issues. The consent declaration made covers the processing of personal data of participants with a severe or profound level of intellectual disability, who will be unable to provide explicit consent, for the purpose of this study. It is estimated that there will be approximately 20 participants taking part in this study.

24-006-AF1 – Determining the impact of the Thrombocalc VTE risk assessment on the incidence of postpartum VTE in the Rotunda Hospital, and derivation of a novel postpartum VTE risk prediction model

The HRCDC made a consent declaration to the Rotunda Hospital for research to determine the impact of Thrombocalc – a risk assessment electronic tool for post-partum venous thromboembolism (VTE) – and to refine this tool to ensure that it is used in the best way to estimate a person's risk of developing VTE in the 6 weeks after pregnancy.

VTE is a pregnancy-associated blood clot, which is the leading cause of direct maternal death in both Ireland and the United Kingdom (UK). The management of VTE during pregnancy and the post-partum period is a critical issue in maternal health, as blood clots can lead to severe complications if not identified and managed appropriately.

Thrombocalc was developed by a multidisciplinary team at the Rotunda Hospital and has since been integrated into routine care. This tool calculates a simple risk score based on a woman's individual VTE risk factors, and it provides tailored recommendations for thromboprophylaxis (i.e. preventative treatment to reduce the risk of blood clot formation). The integration of Thrombocalc into clinical practice has streamlined the decision-making process and contributed to improved patient care.

The current project builds on the success of Thrombocalc by conducting further analysis of its effectiveness in preventing VTE during pregnancy. Additionally, the project aims to develop a new tool that specifically estimates a woman's risk of developing a blood clot in the 6 weeks following pregnancy, a critical period when women remain at heightened risk due to changes in their circulatory and hormonal systems.

The research will generate valuable insights into how to optimise thrombosis prevention strategies, ensuring that women receive the right treatment based on their individual risk profiles. By enabling a more accurate assessment of the risk of VTE, the project aims to prevent dangerous blood clots among those who are at high risk,

while also ensuring that women who do not require thromboprophylaxis are not subjected to unnecessary blood thinner injections. Ultimately, the findings from this study will contribute to more personalised and effective care for women during the post-partum period, reducing unnecessary interventions while safeguarding maternal health.

AMENDMENT REQUESTS

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 consent declaration. For example, the addition of new data controllers or processors, changes to the study itself, or changes to the time and duration of the study are all developments that could result in the need to apply for an amendment request. The following is an example of an amendment request considered by the HRCDC in 2024.

21-002-AF1 Amendment

The Mega-ROX study is a clinical trial aimed at determining the effect of two different approaches to oxygen therapy on the risk of death in patients requiring emergency life support, specifically those on mechanical ventilation in the intensive care unit (ICU). Oxygen is essential for sustaining life, and it is routinely administered to all patients on life support in order to maintain normal blood oxygen levels. However, the optimal amount of oxygen needed to achieve the best outcomes for critically ill patients remains a subject of debate. Some studies suggest that providing more oxygen than necessary could be harmful, while others indicate that it may not be detrimental and could even be beneficial.

This study seeks to compare two oxygen therapy strategies for ICU patients: one that delivers slightly more oxygen than required, and another that provides slightly less. Both approaches are considered safe, but it is unclear which one is more effective in improving survival outcomes. Patients in the study are randomly assigned to one of these two oxygen therapy strategies, with the goal being to identify the optimal approach for patients on life support.

Since the study began recruiting participants at St Vincent's University Hospital in January 2022, 102 patients have been enrolled. The trial has expanded internationally, with a total of 22,476 patients enrolled across 116 sites worldwide.

A recent HRCDC amendment approved the addition of Mater Misericordiae University Hospital as a new site and data processor, further expanding the study's reach and allowing for the inclusion of more participants. This expansion will help to provide valuable insights as to the most effective oxygen therapy strategy for critically ill patients in the ICU.

06

Portfolio of consent declarations

Since the HRCDC was established in March 2019, and up to 31 December 2024, a total of 125 consent declarations were made for research studies considered to be in accordance with the Health Research Regulations. At the end of 2024, 67 of these were live consent declarations, and 58 consent declarations that had previously been made were no longer required for the research studies or had expired.

By 31 December 2024, 64 individual data controller organisations from various sectors and geographical regions across Ireland and internationally had received consent declarations for health research studies.

International data controllers continue to apply to the HRCDC for consent declarations to process the data of research participants in Ireland for research studies. They have applied either as a sole data controller or as joint data controllers with another Irish data controller.

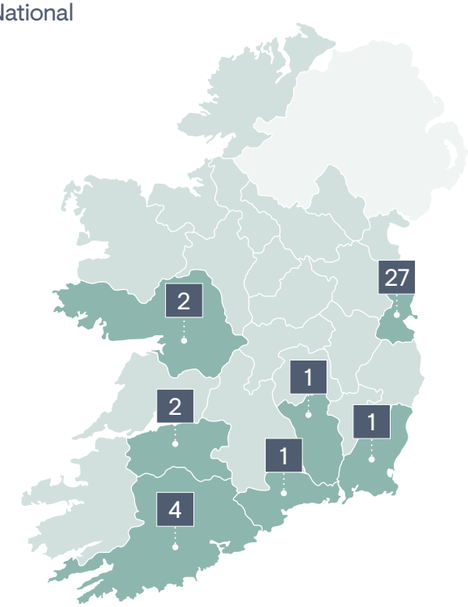
Sectoral type of data controllers with consent declarations

Sectoral type of data controllers with consent declarations	Higher education institution 17	Hospital/ healthcare service 26	
Commercial organisation 8	Charity 3	Government Department 1	State agency 1
Research institute 5	Professional body 1	Other statutory body 2	Total 64

Note : A data controller/joint data controllers may have received a consent declaration for multiple research studies by year ending 31 December 2024.

Geographical spread of data controllers with consent declarations

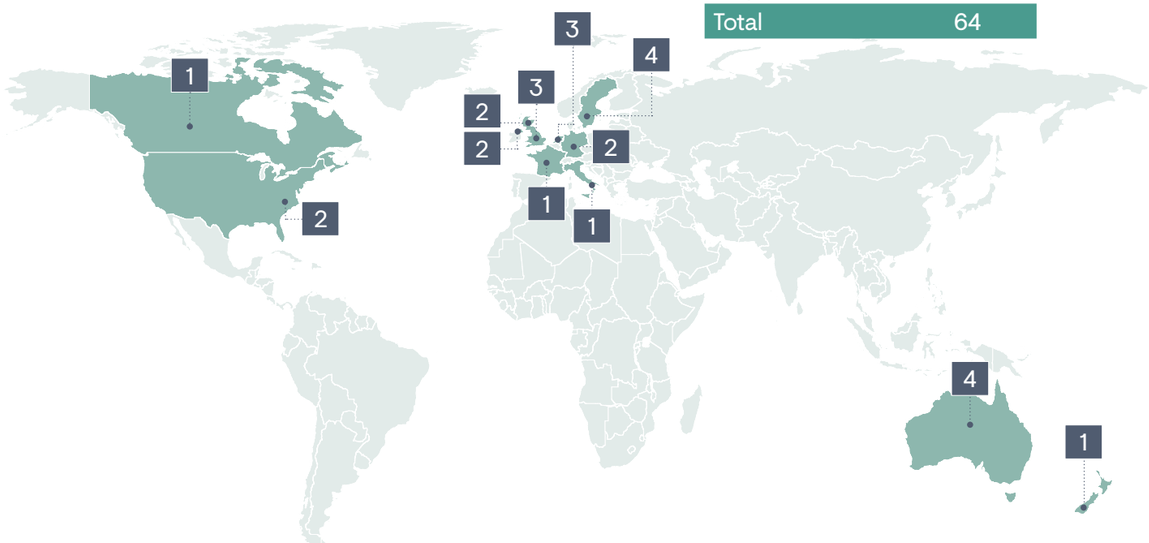
National



National	Institutions
Dublin	27
Wexford	1
Galway	2
Waterford	1
Limerick	2
Cork	4
Kilkenny	1

International	
Australia	4
United States of America	2
Sweden	4
England	3
Scotland	2
Northern Ireland	2
New Zealand	1
France	1
The Netherlands	3
Canada	1
Germany	2
Italy	1
Total	64

International



07

The Secretariat

The Secretariat's primary objective is to support the HRCDC to deliver on its mandate in a manner that engenders trust, transparency, and public confidence.

Staff resources for the HRCDC Secretariat have been provided by the Health Research Board (HRB) since the Secretariat's operations commenced in January 2019. This function is captured in the HRB report *Strategy 2021–2025: Health Research – making an impact*[3] under Strategic Objective 3.5.

The Secretariat acts as the principal point of contact for the research community, the public, and various stakeholders on behalf of the HRCDC. It actively collaborates with both current and potential researcher applicants, providing necessary guidance and support in order to facilitate the consent declaration application process. This close interaction with applicants is one of the Secretariat's fundamental responsibilities, guaranteeing that the HRCDC receives comprehensive and precise information for effective decision-making in accordance with the Health Research Regulations. Establishing strong relationships among the HRCDC, the Secretariat, and researchers contribute to maintaining consistency and clarity within the regulatory framework governing health research activities.

The Secretariat is tasked with overseeing the application process by which researchers request consent declarations from the HRCDC. This includes receiving and triaging applications, assembling application packs for HRCDC review, and issuing decision letters on behalf of the HRCDC.

The HRCDC conducts its affairs with a commitment to transparency, ensuring that decisions made in the public interest are always open and transparent. In pursuit of this goal, the Secretariat maintains regular and public updates of meeting minutes, applicant information, and consent declarations.

The Secretariat oversees management of the portfolio of 67 live consent declarations for research studies. This entails tracking actionable data protection safeguarding measures and other conditions that are required by the HRCDC and that reflect the fundamental principles of the Health Research Regulations.

The Secretariat also organises and provides information on upcoming events of interest to the HRCDC, raises awareness/conducts training on topics of interest, and provides updates on relevant areas of health research and data protection from both within Ireland and other countries in Europe.

Secretariat activities

In 2024, the Secretariat actively engaged with stakeholders on a range of initiatives and activities designed to influence and enhance the future work of the HRCDC. Below is an overview of the key activities it was involved with, undertaken to support applicants, the HRCDC, and other key stakeholders.

At the beginning of 2024, the Secretariat focused on strengthening relationships with current and prospective applicants by offering in-person training sessions on the documentation and other requirements for HRCDC applications. Six successful seminars were held across Dublin, Galway, and Cork, providing valuable opportunities for the Secretariat to engage directly with applicants. These interactions proved beneficial to all involved, and the Secretariat will continue to prioritise similar outreach efforts in 2025.

3 https://www.hrb.ie/fileadmin/2._Plugin_related_files/Publications/2021_publications/2021_Corp/Strategy_2021_2025_Health_research_making_an_impact.pdf

The Secretariat also undertook a major redesign of its website to improve the clarity and accessibility of information for applicants. The revamped site now offers more transparent guidance on the application process, the role of the HRCDC, and the rationale behind our decision-making. In addition to updating the frequently-asked-questions section, which will continue to be reviewed and updated periodically, the Secretariat introduced new sections that focused on PPI, developed in collaboration with the PPI Ignite Network. These enhancements aim to better support applicants and the broader research community.

As part of the ongoing review of HRCDC operating procedures, the Secretariat and HRCDC have introduced a chairperson approval process for minor amendments to an existing consent declaration. This will improve turnaround time for processing these types of amendments, as their approval is not dependant on the HRCDC meeting schedule; requests for such amendments are processed separately and as soon as they are received.

There was a continued focus on GDPR compliance and the Health Research Regulations. The Secretariat worked closely with the Data Protection Commission and the Department of Health to clarify regulatory requirements around data protection. Secretariat staff also participated in professional development seminars, including professional training courses, which provided opportunities to exchange insights with data protection professionals from various industry sectors. These interactions enhanced the Secretariat's understanding of how data protection regulations are being implemented across industries, further informing the approach to health research.

The Secretariat Programme Manager is a member of the Steering Group for the national project focused on setting up health data access services for the HealthData@EU Pilot project and the EHDS. This involvement with the Steering Group enables the Secretariat to stay informed about developments related to the EHDS and to provide input as Ireland moves towards implementing Regulation (EU) 2025/327 (the EHDS Regulation) in the coming years.

In addition to expanding collaborations within Ireland, the Secretariat also fostered international partnerships, engaging with the Health Research Authority in the UK and other European organisations working in the eHealth sector.

The Secretariat also collaborated closely with the CSO on their development of the Health Research Data Centre (HRDC), which was launched in November 2024. The HRCDC anticipates processing applications for research related to these new datasets as we move into 2025.

A major initiative for the Secretariat in 2024 was the development of CERAS (Consent and Ethics Review Application System), an electronic application management system that will be launched in 2025. The system, designed in collaboration with the National Office for Research Ethics, aims to streamline the application and annual review processes. The Secretariat along with the National Office for Research Ethics invested significant time and resources in ensuring that CERAS will be intuitive, accessible, and efficient, thus enhancing the overall experience for applicants and ensuring greater transparency in our processes.

Throughout 2024, Secretariat members attended numerous seminars, conferences, and events organised by the Health Service Executive (HSE); the Irish Platform for Patients Organisations, Science & Industry (IPPOSI); Biobank Ireland; Health Research Charities Ireland; and various data protection events. These gatherings provided valuable insights on topics such as ethics, governance, and PPI in research, thus contributing to the Secretariat's ongoing efforts to stay informed about evolving trends in health research and data protection

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Key objectives for 2025

Strategic priorities and key objectives for 2025

As the HRCDC looks ahead to 2025, it will continue to play a central role in ensuring that its regulatory functions contribute to the responsible, transparent, and secure use of personal health data for research purposes. This will be done in a manner that respects the protection of individual privacy and confidentiality, while also safeguarding the broader interests of patients, carers, and the general public.

The Secretariat will engage in effective communication efforts to highlight and disseminate the HRCDC's work through direct interaction with the public, patient advocacy groups, established research forums, various networks, and the wider research community. In addition, the Secretariat is dedicated to ensuring that both the research community and the general public are fully informed about the data protection safeguards that must be implemented, as stipulated by the Health Research Regulations, as well as the conditions under which consent declarations are required.

In 2025, one of the HRCDC's primary objectives will be to maintain a sustained and open dialogue with the research community. This includes providing ongoing education and guidance to researchers, to ensure that they have a clear understanding of legislative requirements, data protection safeguards, and the necessary processes to efficiently manage the consent declaration process. This proactive engagement is essential in order to ensure compliance, foster transparency, and support the health data research community overall.

A significant milestone in 2025 will be the full implementation of the new application management system, CERAS, which is designed to enhance the efficiency of the application and approval process for consent declarations. CERAS will provide an intuitive, user-friendly interface that streamlines procedures, reduces administrative burden, and ensures a more efficient and timely service for applicants. This system is expected to contribute significantly to improving the overall experience for those involved in both submitting and reviewing for approval health research data applications for consent declarations.

The HRCDC also looks forward to welcoming six new committee members in the first quarter of 2025. In late 2024, an expression of interest campaign took place, which sought to attract individuals with diverse skill sets and backgrounds to support the HRCDC's ongoing work. This new cohort of members will be selected based on the results of that campaign.

Beyond the internal developments within the HRCDC, throughout 2025 the Secretariat and the Committee will remain closely engaged with relevant legislative and policy developments, both within Ireland and across the EU. This includes the evolving EHDS, which is advancing with significant momentum. As part of this, the HRCDC will maintain an active role in the Steering Committee of the EU4Health programme. The interplay between the EHDS, the GDPR, and the specific requirements of the Health Research Regulations 2018 will be a matter of considerable interest, as it may have direct implications for the governance and oversight of health data use in research.

With regard to external legislative developments, the Secretariat will continue to ensure that HRCDC operations are sufficient. This includes ensuring that all policies, procedures, and governance structures are fit for purpose, up to date, and streamlined wherever possible so as to ensure operational efficiency and effectiveness. The Secretariat will prioritise the ongoing assessment and enhancement of the HRCDC's processes in order to support its evolving mission and the broader goals of health research.

Looking ahead to 2025, the HRCDC remains fully committed to fostering and strengthening its relationships with stakeholders across the health research landscape. Through continued collaboration and engagement, the HRCDC will ensure that the research community is supported, and the public interest respected.

Appendices

Appendix A

HRCDC members

Ms Brigid McManus, Health Research Consent Declaration Committee Chairperson

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

Dr Aideen Hartney, Health Research Consent Declaration Committee Deputy 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

Mr John Woods, data protection

Ms Kathy Brickell, emergency and intensive care research

Dr Mary Tumelty, medico-legal research

Dr Sheelah Connolly, economic and social research

Dr Simon Furney, biomedical genomics

Dr Zubair Kabir, epidemiology and public health

Ms Patricia O'Beirne, Public and Patient Involvement

Professor Susan Smith, general practitioner, research

Dr Aisling McMahon, intensive care medicine

Professor Paul Stynes, IT systems

Secretariat team

Ms Bríd Burke, Programme Manager

Mr Jonny Barrett, Project Officer

Ms Caroline Byrne, Administrative Assistant

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