HRCDC
Health Research Consent
Declaration Committee

Annual Activities Report 2023

Transparency
Confidence
Trust

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Foreword

As the Chairperson of the Health Research Consent Declaration Committee (HRCDC), I am pleased to present the annual activities report on the work of the HRCDC and its Secretariat throughout 2023.

The HRCDC had a busy year in 2023, with a significant increase in applications and amendments for the Committee to consider in comparison with 2022. With this increase, the Committee reviewed a much broader range of applications from a variety of health categories and research activities.

2023 marked 5 years since the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) came into force in the European Union (EU). It also marked 5 years since the introduction of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 in Ireland. Since then, the HRCDC has made a total of 113 consent declarations with a total of 75 live declarations still in place. We are looking forward to continuing to cooperate with the health research community in order to facilitate health research in cases when it is not possible to obtain explicit consent from participants.

A significant development in relation to health research was the implementation of the Assisted Decision-Making (Capacity) Act 2015 in April 2023. This will have an impact on how research in Ireland is conducted. The HRCDC has published information in order to support health researchers in this area and provide information on how this newly implemented legislation may affect applications to the HRCDC in the future.

Stakeholder engagement continues to develop, which is a testament to the increased activity of the Secretariat in representing the perspectives and insights of the HRCDC in a variety of working groups and initiatives. These include interaction with the Department of Health and the Data Protection Commission, as well as linking in with working groups in order to develop the approach for the European Health Data Space. This work will continue to evolve in 2024.

There was a significant increase in the number of annual reviews submitted by applicants in 2023, the management of which is undertaken by the Secretariat on behalf of the Committee. There is a considerable body of work involved in examining the annual reviews in order to monitor the operation of consent declarations on behalf of the HRCDC.

"The Committee looks forward to continuing to engage with current and future applicants within the research community and other stakeholders in 2024. Public interest, balanced with safeguarding the use of health research participants' personal data, will, as always, be at the core of our work and decision-making "

The HRCDC's work is made possible by the strong commitment of individual Committee members in terms of their thorough consideration of applications and constructive engagement and discussion at meetings with balanced, consensus-based decision-making. I thank them all for the valuable contribution they make to this important work.

We were delighted to welcome two new members to the Committee during 2023: Ms Patricia O'Beirne and Professor Susan Smith. Dr Claire Collins and Professor Barry O'Sullivan resigned from the Committee in 2023; on my own behalf and on behalf of the Committee and Secretariat, I want to thank both Claire and Barry for their valuable work during their time with the HRCDC.

On my own behalf as Chair and on behalf of the Committee, I want to particularly acknowledge and thank our Secretariat – Ms Bríd Burke, Mr Jonny Barrett, and Ms Caroline Byrne – for their expert and effective support of the Committee. Their work is critical to ensuring that the HRCDC's operations are seamless and robust. The proactive engagement of the Secretariat with applicants and the research community, as well as with national and international stakeholders and counterparts, has helped position the HRCDC as a recognised statutory committee that is integrated in the regulatory research environment in Ireland.

My thanks also go to the Health Research Board and the Department of Health for their strong support of the HRCDC and its Secretariat.

The Committee looks forward to continuing to engage with current and future applicants within the research community and other stakeholders in 2024. Public interest, balanced with safeguarding the use of health research participants' personal data, will, as always, be at the core of our work and decision-making.

Brigid McManus
Chairperson

2023 snapshot

24 applications for consent declaration submitted

24 amendment requests submitted

6 applications withdrawn

HRCDC decisions

22 Consent declarations made

18 Amendments approved

10 HRCDC meetings

65 Annual reviews submitted

Average attendance per meeting **10**

01

Health Research Regulations 2018

The Health Research Regulations 2018 [1] (the Regulations), which set out the safeguarding of personal data for health research in Ireland, came into operation on 8 August 2018. The Regulations were introduced following on from and as a support to the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), which came into force in the European Union (EU) in May 2018.

The Health Research Regulations 2018 aim to bring trust and transparency to the forefront of health research in relation to the processing of personal data. This benefits all those involved in research and ensures patient and public trust in the health research environment in Ireland.

There are cases where explicit consent cannot be practicably obtained but where it would be in the public interest for the research concerned to proceed. In such exceptional cases, the Regulations provide that the Health Research Consent Declaration Committee (HRCDC) may make a consent declaration where the public interest in conducting the research significantly outweighs the requirement to obtain explicit consent from research participants.

This consent declaration allows researchers to lawfully process personal data for health research in the absence of explicit consent. Examples of when it may not be practicable or possible to obtain explicit consent includes where the participant may lack decision-making capacity, either temporarily or permanently, or where a researcher wishes to process the personal data of a large number of participants, and it is not practicable to contact each of them in order to obtain their consent.

These declarations make an important contribution to health research, as their absence could result in the exclusion of specific groups from valuable research that could benefit their lives.

Following the enactment of the Regulations in August 2018, amendments to the Regulations were enacted in April 2019 (S.I. No. 188 of 2019),[2] with further substantive amendments made by the Minister for Health being enacted in January 2021 (S.I. No. 18 of 2021). [3] The substantive amendments of January 2021 were the result of engagement between the Department of Health and the research community, which identified challenges arising from the Regulations that have impacted on certain areas of health research. The January 2021 amendments acknowledge that the mandatory safeguard of obtaining explicit consent presents an array of practical challenges, and accordingly provide that certain specific types of research studies may be exempt from the requirement to obtain explicit consent subject to meeting strict, specific criteria. More information on the January 2021 amendments is available on the HRCDC website.[4]

1 https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
2 https://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf
3 https://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf
4 https://hrcdc.ie/guidance/

2023 marked 5 years since the introduction of the GDPR and the Regulations in Ireland. In 2023, referring to the GDPR, the European Commission stated that

‘this landmark legislation has empowered citizens to truly gain control over their data’

and

‘not only have we set global standards for the safe regulation of data flows, but we have also created the foundation for a human-centric approach to the use of technology. At the heart of the GDPR lies trust. Trust for citizens that their personal data are safe’

https://ec.europa.eu/commission/presscorner/detail/en/statement_23_2884.

02

The Health Research Consent Declaration Committee

The HRCDC has been in operation since 2019 and has become an integral part of the evolving health research regulatory environment in Ireland.

At the beginning of 2023, there were 15 members of the HRCDC. This number increased to 16 with an additional patient and public involvement (PPI) representative joining the Committee in June 2023. There were a total of 10 meetings held in 2023, 2 of which were held in person.

The HRCDC membership consists of individuals with a diverse range of professional backgrounds and experiences, including critical care medicine and anaesthesiology, data protection and medico-legal expertise, general practice medicine, epidemiology, genomics, social care research, and other areas, thus providing a broad representation of the health research community. The Committee's three PPI representative members bring complementary perspectives as members of the public, as carers, and as users of health and social care services in Ireland, and they are integral to ensuring that balanced HRCDC decisions are delivered.

A list of the HRCDC members during 2023 is provided in Appendix A. Full profiles of the current HRCDC members can also be viewed on the HRCDC website: https://hrcdc.ie/about-us/#Committee

In taking its decisions, the HRCDC continues to ensure that the public interest is at the fore of the research it considers, balanced with the data protection rights and freedoms of the research participants whose explicit consent for the research cannot be obtained. The decision-making process of the HRCDC continues to be one that is consensus-based.

The HRCDC assesses the public interest based on the specifics of each distinct research study and the circumstances under which each study is being conducted. As per Regulation 5(5of the Health Research Regulations 2018, in order to make a consent declaration, the HRCDC must determine that the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the data subject(s).

In carrying out its function, the HRCDC also considers the data safeguards in place for each study in order to ensure that personal data are handled appropriately and according to regulatory requirements. One of the safeguards that the Committee places emphasis on is in the area of PPI. PPI in research fosters a more patient- and public-centred approach to research, and it reinforces the concept of research being carried out in collaboration with patients and the public. It is an important data protection safeguard in order to ensure that the perspective of the participant is always considered where their consent cannot be obtained.

The Committee ensures full transparency of its role through the publication of the log of decisions and applications on hand, including meeting minutes that capture the rationale behind the decisions made. The HRCDC is committed to fostering public, patient, and carer trust and confidence in the research being carried out in Ireland through the role it undertakes.

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

44% Male

56% Female

Members' perspectives and insights

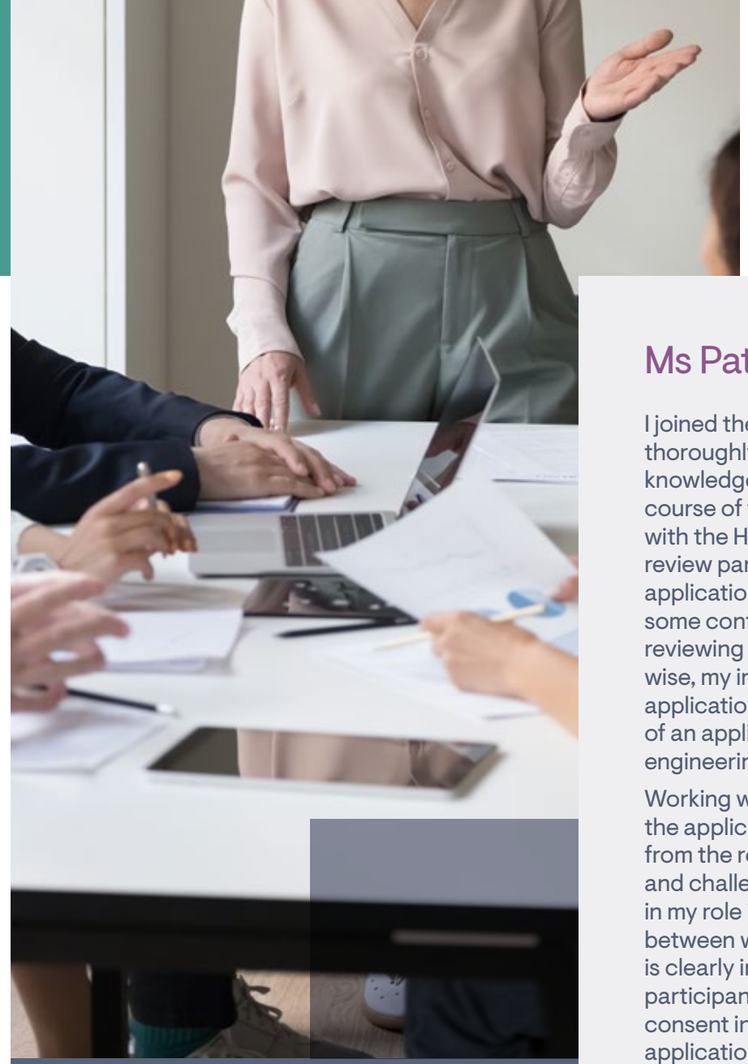
This section of the report focuses on highlighting the personal perspectives and insights of some of the Committee members who have contributed tirelessly to the work of the HRCDC since their appointment. As evidenced by their personal contributions set out in this section, these members have lived and professional experiences that position them to offer valuable input on the research studies under consideration.

"Over the years, I have learned the critical importance of placing patient perspectives and patient safety at the centre of all of our research."

Professor Susan Smith

I have 30 years of experience as a general practitioner and as a researcher with an interest in generating evidence to inform policy and clinical practice. I have conducted numerous randomised trials of interventions in primary care settings in order to support the management of people living with multiple chronic conditions and taking multiple medicines. Over the years, I have learned the critical importance of placing patient perspectives and patient safety at the centre of all of our research.

I joined the HRCDC in the summer of 2023 and was immediately impressed by the diligence, expertise, and care the Committee takes in reviewing applications. It is so important that the most vulnerable groups of patients are protected if they are involved in research, but it is equally important that they are not excluded from research based on the challenges around ensuring their ethical treatment and security of data management. Otherwise, research will fail to address their needs and we will not be able to generate evidence to improve services being delivered to these groups. I have already learned a lot from the wide range of experts involved in the Committee. I hope that my experience as a general practitioner and a primary care researcher will contribute to ensuring that we have a safe, effective, and inclusive health research environment in Ireland.



"...a key responsibility in my role is to evaluate the appropriate balance between worthwhile, significant research which is clearly in the public interest against the use of participants' personal data without their explicit consent in limited situations."

Ms Patricia O'Beirne

I joined the HRCDC in June of 2023 and have thoroughly enjoyed working with the diverse and knowledgeable Committee and Chair over the course of the year. I had previously been involved with the Health Research Board (HRB) public review panel since 2017, reviewing research grant applications from a PPI perspective. This gave me some confidence and experience in patient-first reviewing and critiquing of applications. Career-wise, my involvement with research funding applications is solely from the perspective of an applicant, previously in medical device engineering and currently in the humanities.

Working with the HRCDC, I find that approaching the applications for clinical and research trials from the reviewer perspective is both interesting and challenging. I believe that a key responsibility in my role is to evaluate the appropriate balance between worthwhile, significant research which is clearly in the public interest against the use of participants' personal data without their explicit consent in limited situations. The majority of our applications are very much in the public interest and address critical issues around public health concerns. As a voice for the patient, I can call on my personal experience of several family members living with life-altering, long-term conditions, and of course I very much wish to see clinical trials carried out which will improve the outcome for any such (and all) diseases. But protection of patients' personal data is key to ensuring that any person considering entering a trial or anyone assenting on behalf of a loved one has confidence and trust in the legal protections around such trials; I am happy to be able to contribute to the HRCDC's work in protecting the data rights of the most vulnerable research participants.

Mr John Woods

As a data protection officer working with St Patrick's Mental Health Services (SPMHS) and a member of the SPMHS Research Ethics Committee, I am very much aware of the need for balance between ensuring that the data protection rights and freedoms of research participants are fully respected and facilitating important health and social care research.

Data protection can be quite complex, especially in the area of health research, and it is critical to ensure that the processing of personal data is aligned to the Health Research Regulations 2018, ethical values, and the principles of the GDPR. I have very much enjoyed reviewing the applications to date, contributing to the HRCDC's constructive discussions, and learning from the different expertise and lived experiences of the other HRCDC members.

The HRCDC places great emphasis on research studies, including PPI in health research and being fully transparent to patients, along with, of course, upholding patients' rights and respecting the need for the research being carried out to have a public interest where it is not possible to obtain explicit consent. This is reflected in its workings with both the research community and patients. In that regard, I believe that the HRCDC's work will help to build confidence and trust within the health research community.

"Data protection can be quite complex, especially in the area of health research, and it is critical to ensure that the processing of personal data is aligned to the Health Research Regulations 2018, ethical values, and the principles of the GDPR"

03

HRCDC activities

HRCDC meetings

The HRCDC convened 10 times in 2023. The Regulations require a quorum of at least 7 members at each meeting, and in 2023, the average attendance at HRCDC meetings was 10 members.

HRCDC meetings in 2022

Number of meetings	10
Average number of members per meeting	10

Over the course of the year, the HRCDC also invited subject matter experts to give presentations on specific topics of relevance to the Committee. Ms Áine Flynn, Director of the Decision Support Service, provided information on the implementation of the Assisted Decision-Making (Capacity) Act 2015, which came into force in April 2023, and Professor Alistair Nichol, Chair of the Irish Critical Care Clinical Trials Network, provided the Committee with valuable insights into how international clinical trials are operating in Ireland.

Applications submitted in 2023

In 2023, the HRCDC received 24 applications seeking a consent declaration for new research studies. The HRCDC also received 24 applications for consideration that were requesting an amendment to a consent declaration that had previously been made.

Applications submitted in 2023

New applications for consent declarations	24
Amendment requests for consent declarations previously made	24
Total submissions	**48**

Applications submitted prior to 2023

At the start of 2023, there were seven applications pending consideration by the HRCDC. These included three applications seeking a consent declaration for new research studies that had been submitted in 2022. The HRCDC was awaiting additional information on these applications in order to progress the applications to decision.

One of these applications was an outstanding AF2 application, submitted in 2019. Outstanding information was submitted in January 2023, concluding those AF2 applications submitted to the HRCDC in 2019.

Three amendment request submissions related to consent declarations that had previously been made by the HRCDC were also pending HRCDC consideration at the beginning of 2023. Two of these amendment requests were submitted in 2022, and the third was submitted in 2021. Again, the Secretariat was awaiting additional information on these applications in order to progress to HRCDC consideration.

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.

Decisions made in 2023

	AF1*	AF2**	AMD***	TOTAL
Consent declarations made	21	1	-	22
Further information requested	-	-	1	1
Amendment requests approved	-	-	18	18
Total decisions	**21**	**1**	**19**	**41**

* Applications for new research

** Applications submitted under transitional arrangements; consent had been obtained for the research under the previous Data Protection Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995)

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

A total of 41 decisions were made by the HRCDC in 2023, of which 22 consent declarations were made. All the consent declarations made in 2023 had specific conditions attached, and some also had additional recommendations made in order to bolster data protection safeguarding measures in the interest of the study participants.

The HRCDC approved 18 amendment requests in 2023, all of which were submitted in 2023. At the end of 2023, there were four AF1 applications and four amendment requests to existing declarations still pending additional information from the applicants before HRCDC consideration.

In January 2024, a consent declaration was made for one of the AF1 applications, and another was withdrawn. At the end of February 2024, two AF1 applications from 2023 remained pending and all of the amendment requests from 2023 had been approved.

Applications withdrawn or deemed to be withdrawn

In 2023, a total of two new applications were withdrawn or deemed to be withdrawn from the consent declaration process. Four amendment requests were also deemed to be withdrawn.

Applications deemed withdrawn in 2023

AF1*	AMDs	Total
2	4	6

* Applications for new research

Scope of research

In 2023, 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,[5] the Secretariat sorts each research study into a certain health category and research activities. The following two tables illustrate the range of health research studies that requested a consent declaration from the HRCDC in 2023.

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

Health categories[6]

Health categories

Blood 2	Cancer and neoplasms 4	Cardiovascular 4	Infection 1
Inflammatory and immune system 2	Mental health 1	Musculoskeletal 1	Neurological 4
Oral and gastrointestinal 1	Reproductive health and childbirth 1	Respiratory 4	Stroke 1
Generic health relevance 4			

Research activities

Underpinning research 1	Aetiology 6	Prevention 1	Detection 2
Development 3	Evaluation 8	Management 3	Health and social care services 1

6 Some research studies have been categorised under multiple health categories and research activity areas.

04

Annual reviews – monitoring consent declarations

Since the establishment of the HRCDC in 2019, and up to the year ending 31 December 2023, the Committee has made a total of 113 consent declarations for research studies that it considered to be in accordance with the Regulations. One consent declaration was made by the Appeal Panel in 2019, in accordance with Regulation 11 of the Health Research Regulations 2018. Of these consent declarations, 75 were live at the end of 2023.

Regulation 13(1) of the Health Research Regulations 2018 provides for the HRCDC to monitor and review the operation of a consent declaration. The HRCDC completes this monitoring using the annual review process. These annual reviews are an important mechanism to determine whether a consent declaration and attached conditions are being complied with for the duration of the health research study.

Annual reviews submitted in 2023

During 2023, a total of 65 annual reviews were submitted to the HRCDC; this total includes 58 annual reviews due in 2023 and 7 annual reviews due in 2022 that were submitted in 2023.

In total, 67 annual reviews were deemed completed during 2023, denoting that a consent declaration was being complied with in accordance with the HRCDC's requirements, that conditions were met or being progressed, and that those recommendations made by the HRCDC had been considered. Of those 67 annual reviews deemed completed, 47 were 2023 annual reviews and 20 were 2022 annual reviews.

As of 31 December 2023, 15 annual reviews for 2023 have been requested, are pending Secretariat review, or require additional information from the applicant/data controller.

Implementing a consent declaration

The HRCDC must be satisfied that the fundamental data protection rights and freedoms of research participants are safeguarded while their personal data are being processed without explicit consent for the purpose of important health research. It is therefore important that the necessary data protection safeguarding measures, as set out in the Regulations, bolster the health research that is undertaken.

As with consent declaration decisions made in preceding years, in order to reinforce safeguarding measures, the HRCDC continues to attach conditions and recommendations to consent declarations; such conditions and recommendations include:

- Limiting the scope of the consent declaration such that personal data could not be further processed, including being shared with, or accessed by, third parties, and reinforcing that a consent declaration does not override the decision of a participant to withdraw from the study
- Ensuring that the appropriate data agreements and arrangements are in place between the parties involved in the study
- Reinforcing the principle of data minimisation such that only a minimal amount of personal data should be processed for the purpose of the research study
- Implementing enhanced transparency measures in order to inform participants and the public about the study, the use of their personal data, and their data protection rights
- Ensuring that there is a presumption of capacity of the participant, unless determined otherwise, according to the principles set out in the Assisted Decision-Making (Capacity) Act 2015[7]
- Ensuring that participants who lack decision-making capacity, and their families, are involved in the decision-making process and study activities to the greatest extent possible and ensuring that all efforts are made to hear and understand the participants' will and preferences
- Implementing appropriate safeguards in order to protect the security and privacy of personal data
- Enhancing PPI engagement activities in order to ensure that a patient-centric approach is adopted, and
- Recommending changes to study information leaflets and proxy assent or consent forms in order to help ensure clarity and consistency of information.

The HRCDC acknowledges the receipt of annual reviews submitted by data controller applicants throughout 2023. It is also pleased to report that, in most cases, the data controllers continue to implement consent declarations satisfactorily.

Where annual reviews were not submitted in a timely manner or were incomplete, or where there were challenges or a lack of satisfactory progress in advancing or meeting attached conditions, the Secretariat aimed to engage directly with the data controllers and researchers in order to ensure that annual reviews were submitted and missing information provided, or to highlight deficiencies and reinforce the importance of meeting the conditions attached by the HRCDC.

7 https://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/html

05

Spotlight on research

In 2023, the HRCDC considered a wide range of interesting research applications from data controllers based both inside and outside of Ireland. Further details are available from our website (www.hrcdc.ie).

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 research consent declarations made by the Committee in 2023.

The HRCDC made a consent declaration in 2023 for the National Disability Authority to process the personal data of participants who may lack capacity (HRCDC reference ID 23-005-AF1). The National Disability Authority's research explored the process by which people who were previously declared wards of court are being transitioned to a system of supported decision-making, which commenced on 26 April 2023. The new system of supported decision-making is aligned with Article 12 (Equal recognition before the law) of the United Nations Convention on the Rights of Persons with Disabilities. This change will mean that people will no longer be deemed unable to exercise legal capacity, and appropriate and dynamic decision-making supports will instead be provided.

This research was designed to critically assess the process of transition from wardship. It included a mix of interviews with a range of participants, as well as observations of court hearings. Participants included were wards of court and the committees that act on their behalf, as well as key informants who have knowledge of or experience regarding wardship or the Decision Support Service.

The HRCDC made a consent declaration to the University of Nottingham in order to enable Professor Ronan Collins (Tallaght University Hospital) to access the personal data of patients who may have been incapacitated due to the nature of their illness (HRCDC reference ID 23-019-AF1).

The project, TICH-3, is a randomised clinical trial investigating the efficacy of tranexamic acid in treating hyperacute spontaneous intracerebral haemorrhage. This condition involves sudden bleeding within the brain, which can lead to severe health complications or death. The aim of the trial is to determine if tranexamic acid can provide a beneficial treatment option for patients experiencing this type of haemorrhage.

The HRCDC made a consent declaration to Beaumont Hospital in order to enable Professor Norman Delanty to process the personal data of participants affected by epilepsy who may lack decision-making capacity (HRCDC reference ID 23-012-AF1).

The project aims to advance the knowledge of the causes, risk factors, and treatments of epilepsy by reanalysing existing clinical data and genetic testing with the aim of discovering new genetic causes. These findings could then be translated into practical clinical treatments for individuals affected by this particular condition.

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 in place. This could include the addition of new data controllers or processors, changes to the study itself, or changes to the timing and duration of the study. The following is an example of an amendment considered by the Committee in 2023.

An amendment to a study which previously had a consent declaration since 2020 was made in 2023. The original declaration enabled the data controllers (Monash University (Australia) and University College Dublin) to process the data of participants who may lack capacity due to the nature of their illness (HRCDC reference ID 20-036-AF1).

The study aims to investigate the use of erythropoiesis-stimulating agents to improve the outcome of patients surviving severe trauma and reduce the risk of disability in those who survive.

It is an international multicentre trial in Australia, New Zealand, and Europe. The amendment request was to include new hospital sites in Ireland in the trial, expanding the trial to a total of seven hospitals in Ireland.

06

Portfolio of consent declarations

Since the HRCDC was established in March 2019, and up to 31 December 2023, a total of 114 consent declarations were made for research studies considered to be in accordance with the Regulations. At the end of 2023, 75 of these were live consent declarations and 39 consent declarations that had previously been made were no longer required for the research studies or had expired.

By 31 December 2023, 62 individual data controller organisations from various sectors and geographical regions across Ireland and internationally had received consent declarations for health research studies.

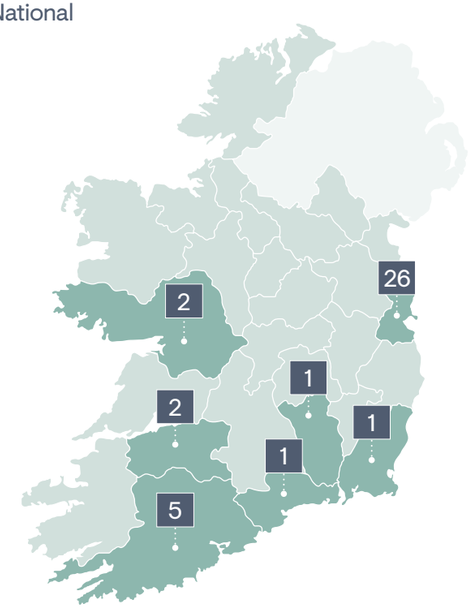
International data controllers continue to apply to the HRCDC for consent declarations to process the data of research participants in Ireland for research studies. They have applied either as a sole data controller or as joint data controllers with another Irish data controller.

Sectoral type of data controllers with consent declarations[8]

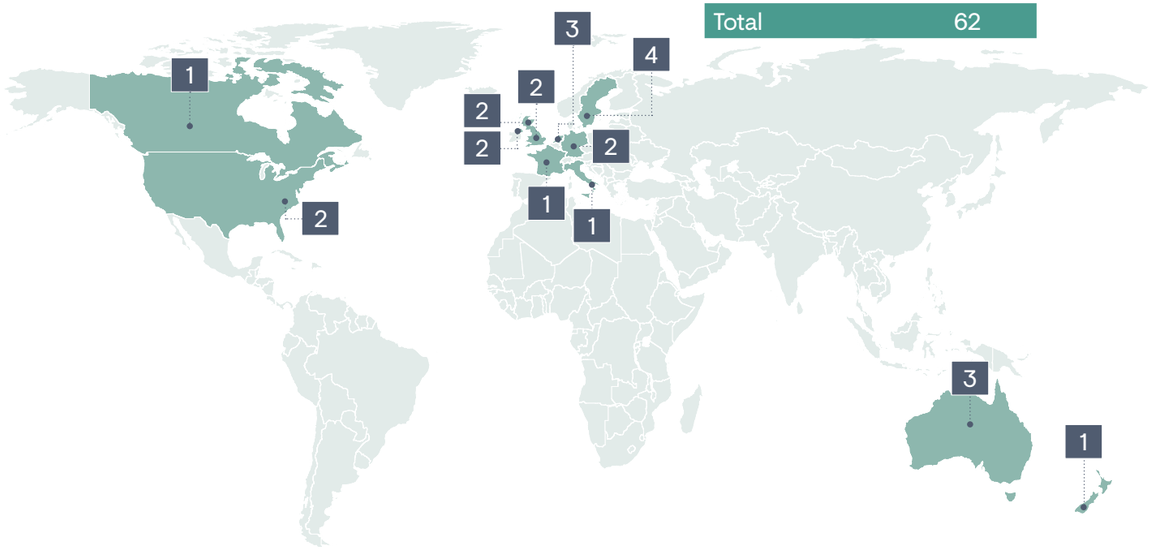
Sectoral type of data controllers with consent declarations	Higher education institution 16	Hospital/ healthcare service 26	
Commercial organisation 8	Charity 3	Government Department 1	State agency 1
Research institute 4	Professional body 1	Other statutory body 2	Total 62

Geographical spread of data controllers with consent declarations

National



International



National	Institutions
Dublin	26
Wexford	1
Galway	2
Waterford	1
Limerick	2
Cork	5
Kilkenny	1

International	
Australia	3
United States of America	2
Sweden	4
England	2
Scotland	2
Northern Ireland	2
New Zealand	1
France	1
The Netherlands	3
Canada	1
Germany	2
Italy	1
Total	62

8 A data controller/joint data controllers may have received a consent declaration for more than one research study by year ending 31 December 2023.

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 HRB since the Secretariat's operations commenced in January 2019. This function is captured in the report *HRB Strategy 2021–2025: Health Research – making an impact*[9] 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 the 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 2018. Establishing strong relationships among the HRCDC, the Secretariat, and researchers contributes to maintaining consistency and clarity within the regulatory framework governing health research activities.

The Secretariat is tasked with overseeing the complete application process through which researchers seek 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 accessible. 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 75 live consent declarations for research studies. This entails tracking actionable data protection safeguarding measures that are required by the HRCDC and that reflect the fundamental principles of the Health Research Regulations 2018.

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 both from within Ireland and from other countries in Europe.

Secretariat activities

Throughout 2023, the Secretariat continued to engage with stakeholders on various activities or initiatives that may impact the work of the HRCDC now or in the future. The following is a summary of the main activities in which the Secretariat was involved throughout the year.

Research groups/research ethics committees

The HRCDC Secretariat met with research groups in order to encourage closer collaboration with the health research community outside of the formal HRCDC application process. This is an initiative that will be developed further in 2024. The Secretariat engaged with the following groups in 2023:

- Cancer Trials Ireland
- Dementia Trials Ireland, and
- FutureNeuro.

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

Similarly, more structured communication and engagement with various research ethics committees began in 2023 and will be expanded in 2024 in order to ensure greater cooperation with and awareness of the HRCDC's requirements within the research ethics community. One example is the National Office for Research Ethics Committees. While the HRCDC and the National Office for Research Ethics Committees remain wholly independent entities governed by separate legislation and with different roles and remits, both play an integral part within the overall health research governance landscape in Ireland. Accordingly, there will be opportunities for the HRCDC and the National Office for Research Ethics Committees to collaborate on appropriate and relevant activities. One specific area of collaboration in 2023 was in the implementation of the EU-wide Clinical Trials Information System (CTIS). The Secretariat ensured that the changes introduced by the CTIS were brought to the attention of the HRCDC, enabling a more streamlined review and decision-making process.

Policy development and clarification

The Secretariat continues to update and provide information to the HRCDC in areas that may affect its work. Examples in 2023 include the implementation of the Health Research Regulations amendments (2021), with discussions continuing with the Department of Health and the Data Protection Commission in this area.

The new Health Information Bill is also being developed by the Department of Health. The Secretariat is involved in ensuring that the HRCDC is informed of developments in this area in terms of how the Health Information Bill may influence the HRCDC's processes as the Bill develops in Ireland in the coming years.

The implementation of the Assisted Decision-Making (Capacity) Act 2015 also occurred in April 2023. Through consultation with the Decision Support Service, the Secretariat developed an information bulletin for health researchers detailing how the decision supports as defined in the Act link with the Health Research Regulations 2018 and the operation of the HRCDC.[10]

The Secretariat is also responsible for ensuring that the HRCDC is updated on developments in Europe in the area of health data collection, sharing, and protection. One significant area of development is the European Health Data Space Regulation. To this end, the Secretariat participates in the following two groups:

1. HRB cross-organisational data group, and
2. TEHDAS2 (Second Joint Action Towards the European Health Data Space).

More generally, members of the Secretariat team attended events (including seminars and presentations) hosted by the Health Service Executive; the Irish Platform for Patients Organisations, Science and Industry; and Health Research Charities Ireland, as well as the Data Protection Conference and others on topics that included ethics, governance, and patient and public involvement in research.

10 https://hrcdc.ie/wp-content/uploads/2023/11/ADMA-HRCDC-information-Version-1-November-2023-FINAL-for-website.pdf

08

Key objectives for 2024

As the HRCDC looks forward to 2024, it will continue to progress the mandate as outlined in the HRB strategy and ensure that its regulatory work is contributing to personal health data being used for research in a transparent, trusted, and safeguarded manner and in the interest of patients, carers, and the public. The Secretariat will communicate the business of the HRCDC through contact and engagement with the public, patient advocacy groups, research forums and networks, and the wider research community. It is also committed to informing the research community and the public about the data protection safeguards that are expected to be implemented as a requirement of the Regulations and as a condition of consent declarations.

There is an increase in outreach activity planned for 2024 with the aim of ensuring that there is close collaboration with the health research community in terms of providing assistance in applying for health consent declarations. The aim is to have information sessions on the HRCDC process for health researchers, and this will hopefully also provide a forum to gain knowledge and awareness of the preparation of an application.

Much progress has been made in the background on enhancing the HRCDC website. The Secretariat plans on further improving the HRCDC website in 2024, as well as providing improved guidance for researchers, raising awareness of the HRCDC, and ensuring that the public is aware of the Committee's activities. Development of an electronic application system is also planned for 2024.

Another activity of the Secretariat and the HRCDC in 2024 will be increasing involvement with and awareness of relevant legislative and policy developments in both Ireland and Europe, specifically in relation to developments regarding the Health Information Bill, TEHDAS2 and the National Strategy for Accelerating Genetic and Genomic Medicine in Ireland. TEHDAS2 is being advanced significantly and aims to develop and promote the cross-border sharing of health data. How this initiative interplays with the GDPR and the Health Research Regulations 2018 will be of material interest to the HRCDC.

The Secretariat will also ensure that the HRCDC's membership continues to be sufficient and that policies and procedures are fit for purpose and streamlined where possible.

The HRCDC looks forward to the year ahead, and it will continue to build upon its stakeholder relationships and engage collaboratively in order to support and promote health research policy and robust governance in research for the benefit of the research community and the public good.

Appendix I

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, patient and public involvement
Dr Barry Lyons, paediatrics, anaesthesiology, and critical care
Professor Barry O'Sullivan, data analytics and artificial intelligence*
Dr Claire Collins, general practice*
Dr Cornelius Cooney, anaesthesiology and intensive care medicine
Mr Dan Rea, patient and public 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, patient and public involvement
Professor Susan Smith, general practitioner, research
* Resigned from the HRCDC in 2023

Secretariat team

Ms Bríd Burke,† Programme Manager
Mr Jonny Barrett, Project Officer
Ms Caroline Byrne, Administrative Assistant

†Joined the Secretariat in April 2023

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