



Health Research Consent
Declaration Committee

2022

**Annual
Activities
Report**

**Transparency
Confidence
Trust**

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**Queries regarding this publication
should be emailed to secretariat@hrcdc.ie**

Copies of this publication can be obtained from:
The Secretariat
Health Research Consent Declaration Committee
Grattan House
67–72 Lower Mount Street
Dublin 2
D02 H638
Ireland

e secretariat@hrcdc.ie
t +353 1 2345–179/257
www.hrcdc.ie

 [@hrcdc_Ireland](https://twitter.com/hrcdc_Ireland)

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Foreword



It is my pleasure as Chairperson of the Health Research Consent Declaration Committee (HRCDC) to present the fourth annual activities report on the work of the HRCDC and its Secretariat.

After two years when our work reflected the impact of the COVID-19 pandemic, 2022 was a year when the work of the HRCDC and Secretariat began to return to a more normal footing. It was also the first full year of operation following the introduction of substantial amendments to the Health Research Regulations, which enable researchers to process personal health data in specific circumstances without the requirement for explicit consent, subject to meeting other data protection safeguards.

The Committee met ten times during 2022 and considered applications for new research studies across a variety of different health research areas, although there were fewer applications relating to COVID-19-focused research than in the previous two years. There was an increase in the number of applications for amendments to existing declarations. With more HRCDC consent declarations in place, 2022 also saw a continuing increase in the volume of annual reviews submitted by applicants, which are a core component in monitoring the operation and implementation of consent declarations. The HRCDC reviewed and updated a number of its core operating procedures over the course of 2022, including those for consent declaration amendment requests and applications considered by written procedure. For the first time since March 2020, the Committee was able to hold two meetings in person in 2022 and looks forward to convening in the future via a hybrid model of remote and in-person meetings.

April 2022 saw the end of the first three-year term of several Committee members who were appointed to the HRCDC when it was established in 2019. It is a testament to the work and contribution of individual Committee members that the Minister for Health reappointed them for a second term. As Chairperson, I warmly welcome their reappointments and am delighted to continue to work with them. The Committee's work is made possible by the commitment, work and expertise of all the individual Committee members, and their consideration of applications within a consensus-based process that listens to and respects individual views. I thank each of the Committee members for their contribution to the HRCDC.

Two members who joined the Committee in 2019, Professor John Ferguson and Mr Kevin Clarke, were not available for

“The Committee reaffirms its commitment to continue to operate in an open and transparent manner and to ensure that the public interest, balanced with safeguarding the use of personal data of health research participants, remains at the centre of its deliberations. ”

reappointment to a second term. On my own behalf, and on behalf of the Committee and Secretariat, I want to thank both John and Kevin for their valuable work with the HRCDC.

My thanks and appreciation also go to our Secretariat staff, who continued to undertake a sizeable amount of work on behalf of the HRCDC, including managing the application and annual review processes, the substantial pre-review and examination of submissions to the HRCDC, the organisation of HRCDC meetings, and extensive engagement with applicants and the research community. The Secretariat also represents the perspectives and insights of the HRCDC on relevant working groups.

In May 2022, Dr Emily Vereker, Head of the HRCDC Secretariat since it was established in 2019, left to become Head of the National Office for Research Ethics Committees (NREC). Dr Vereker played a key role in supporting the establishment of the HRCDC, developing and implementing the processes and procedures for its work and ensuring that it became operational. As Chairperson, I know how important her contribution was to the Committee’s work and to our relationship with the wider research community. On my own behalf, and on behalf of the HRCDC as a whole, I want to thank her for the expertise and huge commitment she brought to the successful establishment of the HRCDC and the effective and warm support she gave us all. Mr Jonny Barrett ensured that the Secretariat’s work continued smoothly and effectively for the rest of the year. I want to thank him and Ms Caroline Byrne, along with Ms Noreen O’Brien and Dr Marta Pisarska, who worked on the team for part of the year, for their expert and effective support in the continued operations of the Committee.

My thanks, as always, also to the Department of Health and the Health Research Board (HRB) for their strong support for the HRCDC and its Secretariat during 2022.

We look forward to continued engagement with policy-makers and experts on upcoming new legislation and policy developments, including the Health Information and Patient Safety Bill that will transform the health information system in Ireland and reform how certain health information is made available for specified purposes, as well as the related European Health Data Space. We also look forward to full commencement of the amended Assisted Decision Making (Capacity) Act 2015 this year.

The Committee will continue to engage with the research community on the consent declaration process and seek to ensure that its processes and procedures remain fit for purpose. We also hope to enhance communication and outreach with wider stakeholders on the work and role of the HRCDC, as the capacity of the Secretariat increases and as Ireland emerges from the effects of the pandemic.

The Committee reaffirms its commitment to continue to operate in an open and transparent manner and to ensure that the public interest, balanced with safeguarding the use of personal data of health research participants, remains at the centre of its deliberations. Through this, we hope to continue to help foster trust and confidence in health research in Ireland for the benefit of patients and the public.

Brigid McManus
Chairperson

2022 snapshot

14

applications for
consent declaration
submitted

15

amendment
requests
submitted

7

applications
withdrawn

HRCDC decisions

11

Consent
declarations
made

1

No
declaration
made

1

amendment
not
approved

14

amendments
approved



10

HRCDC meetings

67

Annual reviews
submitted



Average
attendance
per meeting

10



01

**Health
Research
Regulations
2018**

The Health Research Regulations 2018¹ ('the Regulations'), which set out the safeguarding of personal data for health research in Ireland, came into operation on 8 August 2018. The Regulations aim to bring consistency and transparency to the forefront of health research in relation to the processing of personal data, for the benefit of researchers and also to foster public and patient trust in the research environment in Ireland.

The Regulations set out a series of suitable and specific safeguards that must be implemented in order to ensure that the data protection and privacy rights of individuals are respected and can be exercised. A core safeguard within the Regulations is the mandatory obtaining of explicit consent from research participants – consent that is informed and recorded. This safeguard reinforces the principle of an individual's autonomy in terms of data processing and the protection of their data.

It is recognised that there are exceptional cases where explicit consent cannot be practicably obtained and 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 public interest in the requirement for consent. 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 in a temporary or permanent manner, or where a researcher wishes to retrospectively process the personal data of a large number of participants where it is not practicable to contact them in order to obtain consent.

Following the enactment of the Regulations in August 2018, amendments to the Regulations were enacted in April 2019 (S.I. No. 188 of 2019²), with further substantive amendments made by the Minister for Health enacted in January 2021 (S.I. No. 18 of 2021³). 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 certain health research areas. The January 2021 amendments acknowledge that the mandatory safeguard of obtaining explicit consent presents an array of practical challenges, and accordingly provides 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 can be found in Appendix C. Guidance prepared by the Department of Health on the amendments is also available on the HRCDC website.⁴

In 2021, the European Data Protection Board (EDPB⁵) – the highest authority on the interpretation and application of the General Data Protection Regulation (GDPR⁶) – issued an Opinion on the application of the GDPR, with a specific focus on scientific health research.⁷ The EDPB Opinion aims to bring a level of clarity and consistency to the health research sector, including the issue of 'broad consent', the legal basis for data processing, and other data processing principles and safeguards.

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/>

5 https://edpb.europa.eu/edpb_en

6 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

7 https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf (see point 7, page 4).

The EDPB Opinion provided a compelling statement on the importance of consent, not just as an ethical requirement but also as an additional data protection safeguard, including where consent is not the legal basis for processing personal data for health research purposes.



Opinion of the EDPB on health research, 2021⁸

‘Therefore, when research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset’

‘**adequate safeguards** should be in place to enhance the transparency of the processing during the research project and to ensure that the requirements on specificity of consent are met as best and as soon as reasonably possible’



8 https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaire-research_final.pdf (see points 26 & 27, page 8).

02

HRCDC

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

At the beginning of 2022, there were 17 members of the HRCDC. For several members, April 2022 saw the end of their first three-year term of office and their reappointment by the Minister for Health to a second three-year term, as provided for in Schedule 5 of the Regulations, and two members of the Committee were not available for reappointment to a second term after April 2022. At the end of 2022, there were 15 HRCDC members.

The HRCDC membership comprises a diverse range of professional backgrounds and experiences, including critical care medicine and anaesthesiology, data protection and medico-legal aspects, general practice medicine, epidemiology, genomics, social research and other areas, thus providing a broad representation of the health research community. The two public and patient involvement (PPI) representative members on the Committee are integral to the HRCDC's decision-making process. A list of HRCDC members during 2022 is provided in Appendix A. Full profiles of the current HRCDC membership can also be viewed on the HRCDC website: <https://hrcdc.ie/about-us/>.

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 research participants whose consent for research cannot be obtained. The decision-making process of the HRCDC continues to be consensus based, taking on board and considering the experience, views and expertise of each member.

While the application of a public interest test of the research studies seeking a consent

declaration is not prescribed in the Regulations, the HRCDC assesses the public interest based on the specifics of, and circumstances under which, each distinct research study is being conducted. As per Regulation 5(5), to make a consent declaration, the HRCDC must consider whether the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the data subject.

In making its decision on the degree of public interest, the HRCDC also continues to have due regard to any PPI engagement that may have occurred with patients, families, carers, the public or other representative groups. Such PPI engagement in health research is considered an important data protection safeguard, helping to foster a more patient and public-centred approach and to ensure that the perspective of the prospective participant is always considered where consent cannot be obtained. Where it is not practicable to obtain the explicit consent of the participant, transparency also remains an important data protection principle and safeguard. The HRCDC therefore considers what transparency measures will be in place to help ensure that participants may be informed about the relevant study, the use of their personal data and their data protection rights.

As always, in 2022 the Committee strived to ensure that it remained fully transparent in its role and its decision-making. It does this via the continued publication of the HRCDC log of decisions and pending applications, in addition to the publication of detailed meeting minutes that capture the rationale behind its decision-making. These are available on the HRCDC website: <https://hrcdc.ie/decisions/>.

For the most part, 2022 saw the HRCDC continue to operate remotely, with the majority of meetings held by video conference. The Committee convened in person for the first time since March 2020, with two in-person meetings held in April and December 2022.

Members' perspectives and insights

This section of the report focuses on highlighting the personal perspectives and insights of some Committee members who have diligently contributed and committed to the work of the HRCDC. The perspectives provided include reflections from some members on their first term of office with the HRCDC.



“I’ve had personal experience of the improved quality of care that results from the approach where the patient, doctor, specialist and nurses form part of an overall care team”

Mr Dan Rea

“A motto I developed early on in my work life was “innovation is the road to success”. Throughout my career in industry, I’ve seen how those organisations with closer bonds between their customers and their innovation and research teams as well as with their manufacturing operations have shown themselves to be the most successful, simply because the customer is at the centre of everything they do. It’s the customer’s relationship with the industry’s innovation and research teams in particular that is key to its success.

Likewise, research is vital to improving the quality of every aspect of our care systems. Through my role as a carer when a family member developed a life-changing illness, I’ve had personal experience of the improved quality of care that results from the approach where the patient, doctor, specialist and nurses form part of an overall care team that is patient centred combined with treatment, rather than delivery of treatment being the focal point.

Over time, the importance of maintaining focus on the needs and wishes of research participants has also become more understood. Today, more and more research funding decisions seek public and patient involvement (PPI). PPI forms a core principle in the work of the HRCDC, and one which I feel I have been able to contribute through my work-life experience as well as being a carer and health service user. I feel privileged to be part of the work of the HRCDC, where my primary aim is to ensure that PPI safeguards are encouraged and that the voice of the patients, their carers and the public is heard.”



Dr Sheelah Connolly

“Throughout my career as a health services researcher, I have been involved in numerous research projects to answer questions about the factors influencing health and health service usage in order to identify potential ways of improving population health. Using large-scale datasets, researchers (including myself) can sometimes forget that each piece of data represents an individual and their own unique experiences. My involvement in the HRCDC has been a unique and rewarding learning experience. In particular, hearing from the patient representatives has provided me with insights about how patients and their carers may view research and the use of their data and reminds me to always keep the patient and their rights at the forefront. While each member of the Committee comes with their own experience and perspective, I have found members to be respectful of others’ opinions. In my experience, the Committee seeks to work together in a way that facilitates and promotes health research while protecting and promoting the rights of patients. Working in an open and transparent manner with the research community and patients, I believe that the HRCDC can help ensure a vibrant health research environment in Ireland into the future.”

“...hearing from the patient representatives has provided me with insights about how patients and their carers may view research and the use of their data and reminds me to always keep the patient and their rights at the forefront.”

Dr Mary Tumelty

“As a legal academic working in the area of medical law and ethics, I am keenly aware of the need for a balance between the protection of research participants (including protection of their personal health data) and facilitating important health and social care research. My time on the HRCDC has provided me with first-hand experience of the tension that often exists between enabling health research and ensuring that the data rights of research participants are robustly protected, where consent cannot be obtained. Since joining the Committee in 2021, I have found that a nuanced and considered approach to the balancing of these interests is adopted. Central to this, I believe, is the wide range of expertise and experience of the members, including, importantly, public, patient and carer representatives. The constructive engagement and considered approach to decision-making ensures that both the public interest and safeguarding of research participants’ personal health data are at the core of the Committee’s considerations.

Membership of the HRCDC has also further exposed me to the valuable and significant research undertaken by health and social care researchers in Ireland. The HRCDC plays an important role within the health research environment in Ireland and I am very happy to contribute to the work of the Committee in increasing transparency and trustworthiness in health research.”

“The constructive engagement and considered approach to decision-making ensures that both the public interest and safeguarding of research participants’ personal health data are at the core of the Committee’s considerations.”



03

HRCDC activities

HRCDC meetings

The HRCDC convened 10 times in 2022 and the Regulations require a quorum of at least 7 members at a meeting. In 2022, the average attendance at the HRCDC was 10 members. There were 17 members on the HRCDC between January and March 2022, while, between April and December 2022, the HRCDC had 15 members.

HRCDC meetings in 2022

Number of meetings	10
Average number of members per meeting	10

In 2022, the HRCDC also invited subject matter expert Dr Annie Sorbie⁹ from the University of Edinburgh to give a presentation on public interest in the context of health research, which is the fundamental area considered by the HRCDC when determining whether a consent declaration should be made. Mr Peter Lennon, Department of Health, also presented to the HRCDC on the upcoming Health Information and Patient Safety Bill and European Health Data Space.

Applications submitted in 2022

In 2022, the HRCDC received 14 applications¹⁰ seeking a consent declaration for new research studies (via submission of Application Form 1 – AF1). One of these applications sought a consent declaration for accessing the Central Statistics Office (CSO) COVID-19 Data Research Hub.¹¹

In 2022, 15 applications requesting an amendment to a consent declaration previously made by the HRCDC were received for consideration. Of these 15 amendment applications, 2 were amendments to a consent declaration for accessing the CSO COVID-19 Data Research Hub.

Applications submitted in 2022

New applications for consent declarations	14
Amendment requests for consent declarations previously made	15
Total submissions	29

⁹ <https://www.law.ed.ac.uk/people/annie-sorbie>

¹⁰ One of these AF1 applications submitted in 2022 was subsequently deemed withdrawn in January 2023.

¹¹ <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/covid-19dataresearchhub/>

Applications submitted prior to 2022

There were a total of 12 applications pending consideration by the HRCDC at the beginning of 2022.

These included six applications that sought a consent declaration for research studies that had begun prior to the commencement of the Regulations in 2018, and where consent had been obtained under the previous Data Protection Directive 95/46/EC¹² of the European Parliament and of the Council of 24 October 1995 prior to the implementation of the Regulations, but the consent was not deemed to meet the standard of explicit consent¹³ under the Regulations. These studies were submitted in 2019 using Application Form 2 – AF2, under the transitional arrangements that enabled researchers to apply for a consent declaration for such research studies by August 2019.

Following the announcement of the substantial amendments to be made to the Regulations, it was anticipated that the AF2 applications submitted to the HRCDC, which remained pending consideration, would no longer require a consent declaration. Following the enactment of these substantial amendments in January 2021,¹⁴ the Secretariat engaged extensively with the remaining AF2 applicants in order to understand and determine whether a consent declaration was still required; the amendment made to the Regulations (Regulation 6A of S.I. No. 18 of 2021) provides that participant consent obtained in accordance with the previous Data Protection Directive continued to be valid.

Many AF2 applications submitted to the HRCDC withdrew from the consent declaration process during 2021 and the Secretariat continued to engage with the other AF2 applicants during 2022.

Following this exercise by the Secretariat, four of the six AF2 applications that remained pending HRCDC consideration at the beginning of 2022 were later deemed withdrawn from the consent declaration process during 2022; this is also noted in the ‘Applications withdrawn’ section of this report.

For the two AF2 applications that were not deemed withdrawn, the applicant researchers determined that valid consent for elements of the research study had not been obtained, and the amendment to the new Regulation 6A could not be applied. Therefore, a consent declaration was still required for all or certain elements of the research, and the applications were processed by the Secretariat and proceeded to the HRCDC for consideration once ready. The latest status of these two AF2 applications is provided in the ‘HRCDC decisions’ section of this report. The data controller applicants for these applications were required to make a public interest case for the data processing being carried out for their research studies.

In addition to the AF2 applications submitted in 2019, other applications that were pending consideration at the beginning of 2022 included a small number seeking a consent declaration for new research studies (submission of Application Form 1 – AF1) as well as applications seeking amendments to consent declarations previously made by the HRCDC that were submitted during 2021.

12 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN>

13 Under the recent amendments to the Regulations (S.I. No. 18 of 2021), where a data controller has obtained consent in accordance with the previous Data Protection Directive, that consent is now considered valid.

14 <https://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf>

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 2022

	AF1*	AF2**	AMD***	TOTAL
Declarations made	10	1	-	11
No declaration made	1	-	-	1
Request for further information	-	-	-	-
Amendments approved	-	-	14	14
Amendments not approved	-	-	1	1
Total decisions	11	1	15	27

* Applications for new research – consent is not being sought for the study

** Applications submitted under transitional arrangements – consent had been obtained for the research under the previous Data Protection 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 has been granted previously

A total of 27 decisions were made by the HRCDC in 2022, of which 11 consent declarations were made. All the consent declarations made in 2022 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.

Of the 11 consent declarations made by the HRCDC in 2022, 10 were for AF1 research studies, all of which were submitted in 2022, and 1 consent declaration was made for an AF2 research study that was submitted in 2019.

One of the consent declarations made was for a research study seeking to access and analyse pseudonymised COVID-19 health data under the custodianship of the CSO.

The HRCDC approved 14 amendment requests in 2022, of which 2 had been submitted in 2021. One amendment request submitted to the HRCDC in 2022 was not approved.

At the end of 2022, one AF2 application that was submitted in 2019 remained pending consideration by the HRCDC. Following engagement with the data controller, this AF2 application was considered by the HRCDC in February 2023 and a consent declaration with specific conditions attached was made. Accordingly, at the time of publication of this report, all AF2 applications submitted to the HRCDC in 2019 have been concluded.

At the end of 2022, two amendment requests and three AF1 applications submitted in 2022 were also pending consideration by the HRCDC.

Of the three AF1 applications, one was deemed withdrawn in January 2023 and another was considered at the first HRCDC meeting of 2023 and a consent declaration made.

Applications withdrawn

In 2022, a total of seven applications (including 2019, 2020 and 2021 submissions) were withdrawn or deemed to be withdrawn from the consent declaration process.

As noted in the section 'Applications submitted prior to 2022', following efforts by the Secretariat to engage with the data controller applicants, four of these seven applications were AF2 applications that had been submitted in 2019. Three AF1 applications for new research were also withdrawn or deemed to be withdrawn in 2022.

Applications withdrawn or invalid in 2021

AF1*	AF2**	Total
3	4	7

* Applications for new research – consent is not being sought

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

Scope of research

In 2022, the HRCDC received applications for consent declarations across a diverse range of biomedical and health research areas, spanning different health categories and research activities. While applications for a consent declaration relate to health research studies as defined in Regulation 3(2)(a),¹⁵ it is noteworthy that many of the applications submitted to the HRCDC also involve research elements or study objectives related to social care; for example, a health research study may include an examination of social care services and its effect on individual health outcomes. This illustrates the close relationship that can exist between health research and social care research.

Using the UK Clinical Research Collaboration Health Research Classification System,¹⁶ 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 2022.

¹⁵ <https://hrcdc.ie/wp-content/uploads/2019/01/STATUTORY-INSTRUMENTS.pdf>

¹⁶ <https://www.ukcrc.org/research-coordination/health-research-classification-system/>

Health categories¹⁷



¹⁷ Some research studies have been categorised under one or more 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 2022, the Committee has made a total of 91 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 these consent declarations, 67 were live at the end of 2022.

Regulation 13(1) of the Regulations provides for the HRCDC to monitor and review the operation of a consent declaration; this is to ensure that the consent declaration is being implemented, that any conditions attached are being met and that recommendations are being considered. Annual reviews are an important mechanism the HRCDC uses to determine whether a consent declaration and attached conditions are being complied with.

The annual review is due to be submitted by the applicant data controller on the anniversary of the date the consent declaration was made. In 2022, the rate of annual reviews submitted increased by comparison with 2021; this increase is to be expected given the number of consent declarations made by the HRCDC in 2021, which were due to submit a first annual review in 2022.

Annual reviews submitted in 2022

During 2022, the total number of annual reviews submitted to the HRCDC as a reporting requirement was 67; this total includes 61 annual reviews due in 2022 and 6 annual reviews due in 2021 that were submitted in 2022.

Of the total 67 annual reviews submitted in 2022, 53 were deemed completed, 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 recommendations made by the HRCDC had been considered.

In addition to the 53 annual reviews submitted in 2022 and deemed completed, 8 annual reviews submitted in 2021 carried over into 2022 and were reviewed and deemed completed. Thus, a total of 61 annual reviews were deemed completed in 2022.

As of 31 December 2022, seven annual reviews that were submitted in 2022 were incomplete or required additional information from the applicant and were pending further consideration in 2023. At the end of 2022, seven annual reviews submitted in 2022 were still pending Secretariat review.

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 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 the preceding years, the HRCDC continues to attach conditions and recommendations to a consent declaration in order to reinforce safeguarding measures that 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 the minimal amount of personal data should be processed for the purpose of the research study
- Implementing enhanced transparency measures to inform participants and the public about the study, the use of their personal data and their data protection rights
- 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 participant's will and preferences

- Not automatically assuming that the research participant lacks decision-making capacity and assessing capacity from a functional, rather than a medical, perspective
- Implementing appropriate safeguards to protect the security and privacy of personal data
- Enhancing PPI engagement activities to ensure that a patient-centric approach is adopted
- 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 2022. It is also pleased to report, again, that the data controllers continue to implement consent declarations satisfactorily, with COVID-19 appearing to have had a lesser effect on the progress of research studies and the progression of attached conditions in 2022 compared with the preceding years.

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

05

Spotlight on research

In 2022, the HRCDC considered a diverse range of research applications from data controllers seeking a consent declaration. The range of health categories and research activities seeking a consent declaration in 2021 was outlined in the ‘Scope of research’ section of this report. Further details on the submitted applications can be found in Appendix B and on the HRCDC website

To give a flavour of the nature of the applications the HRCDC has considered, the following studies were among those that received a consent declaration from the HRCDC in 2022:

- The HRCDC made a consent declaration to University College Dublin to enable Professor Patricia Fitzpatrick, School of Public Health Physiotherapy and Sports Science, to access pseudonymised data from the CSO COVID-19 Data Research Hub. Her research study aims to assess the impact of modifiable risk factors on outcomes of COVID-19, including weight, height and body mass index (BMI), and smoking status, considering the effect of age, gender, ethnicity and co-morbidities including diabetes, hypertension, cancer and hypertension. The available pseudonymised dataset includes follow-up data by COVID-19 case on hospitalisation and intensive care unit admission with associated data.¹⁸
- The HRCDC made a consent declaration to Avista, St Anne’s Centre, Co. Tipperary (formerly the Daughters of Charity Disability Support Services), acting through Michelle O’Brien, in order to process the personal data of service user participants who lack decision-making capacity. The research study aims to gather data in relation to people being supported for their health and well-being and their age profile and how that will impact on their changing needs in the future. It will assess where they currently live, the services they receive and how those residences and services meet their current and anticipated future needs.¹⁹
- The HRCDC made a consent declaration to joint data controllers Royal College of Surgeons in Ireland (RCSI), National Office of Clinical Audit (NOCA) and the Health Service Executive (HSE) National Ambulance Service (NAS) for the purpose of transferring and merging two personal datasets (the NAS electronic Patient Care Record (ePCR) and the Major Trauma Audit). This aim of the study is to support the development of the national trauma care system in Ireland by combining, anonymising and then analysing two currently separated datasets. The study plans to analyse the data in order to map the patient journey from the scene of the incident to discharge from hospital and to identify which characteristics determine the need to bring patients to major trauma centres.²⁰

¹⁸ HRCDC Ref ID: 22-001-AF1/CSO.

¹⁹ HRCDC Ref ID: 22-002-AF1.

²⁰ HRCDC Ref ID: 22-012-AF1.

For studies that have a consent declaration in place, an amendment request form may need to be submitted to the HRCDC for consideration if changes are made to the study that affect the consent declaration: for example, a change in the controllership of the study, an expansion of the study and data processing activities, or a change in the proxy assent or consent process. The following is an example of an amendment considered and approved by the HRCDC in 2022:

- The HRCDC approved an amendment request for an existing consent declaration that was made to St James's Hospital in 2020 for the Sepsis Immunosuppression in Critically Ill Patients study²¹ under the supervision of Professor Ignacio Martin-Loeches. The amendment to the consent declaration was approved for (i) the addition of new study collaborators, (ii) increasing the number of study participants to be recruited, (iii) extending the duration of the declaration and (iv) the use of verbal/telephone assent.

21 HRCDC Ref ID: 19-086-AF1.

06

Portfolio of consent declarations

Since the establishment of the HRCDC in March 2019, and up to 31 December 2022, a total of 92 consent declarations²² were made for research studies considered to be in accordance with the Regulations. At the end of 2022, 67 of these were live consent declarations and 25 consent declarations previously made were no longer required for the research studies or had expired. By 31 December 2022, 48 unique data controller organisations from various sectors

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

22 Ninety-one consent declarations were made by the HRCDC; one consent declaration was made by an independent appeal panel (in 2019).

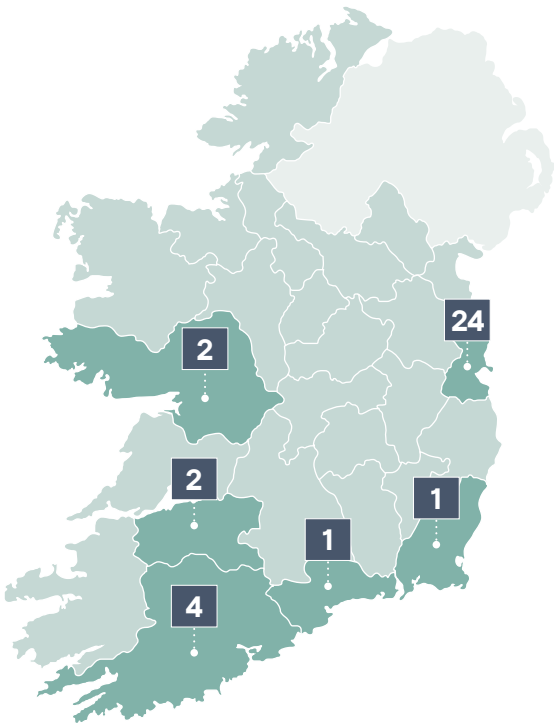
Sectoral type of data controllers with consent declarations²³



23 A data controller/joint data controllers may have received a consent declaration for a number of research studies by year ending 31 December 2022.

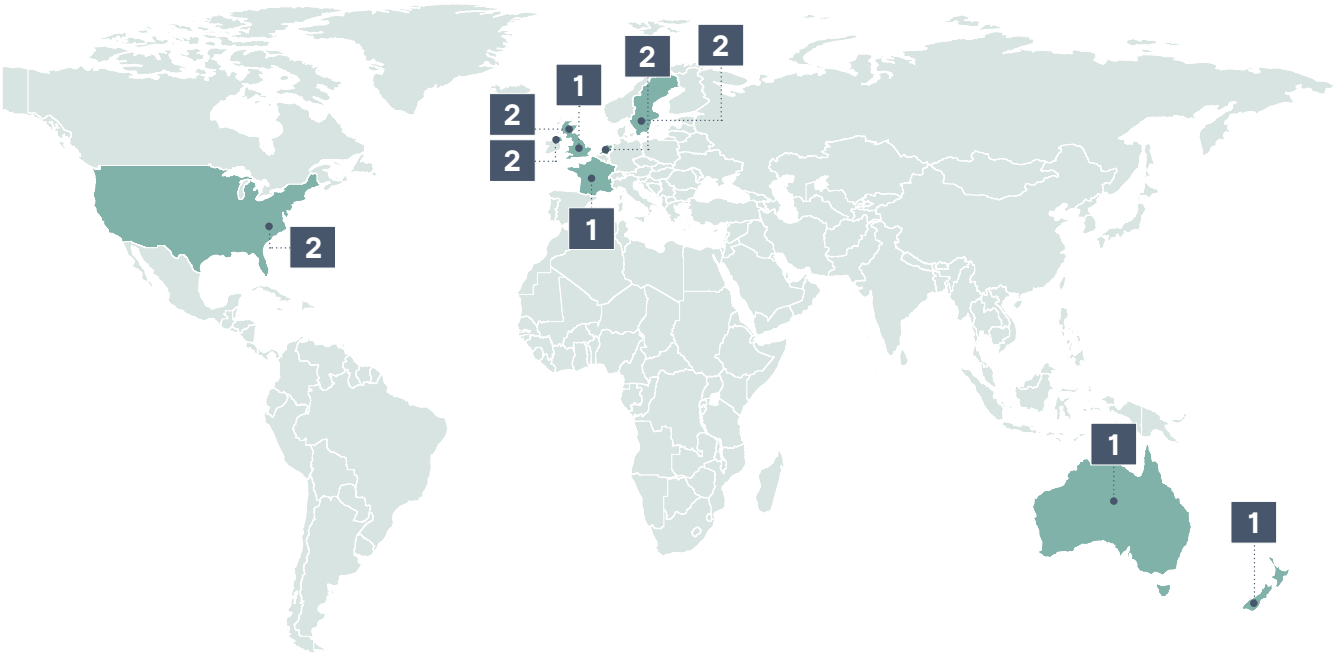
Geographical spread of data controllers with consent declarations

National



National	Institutions
Dublin	24
Wexford	1
Galway	2
Waterford	1
Limerick	2
Cork	4
International	
Australia	1
United States	2
Sweden	2
England	1
Scotland	2
Northern Ireland	2
New Zealand	1
France	1
The Netherlands	2
Total	48

International





The Secretariat

Secretariat supports

The Secretariat's role is to support the operations of the HRCDC and to manage the consent declaration application process. On behalf of the HRCDC, the Secretariat also acts as a central point of contact for the research community, the public and other stakeholders in relation to the consent declaration process. Staffing resources for the HRCDC Secretariat have been provided by the Health Research Board (HRB) since the Secretariat's operations commenced in January 2019, and its function is captured under Strategic Objective 3.5 in the HRB's *Strategy 2021-2025: Health Research - making an impact*.²⁴

A central duty of the Secretariat is to offer guidance on the consent declaration application process and to ensure that the applications that are submitted are as complete and clear as possible so that the HRCDC has the required information it needs to determine whether a consent declaration should be made. This is achieved through close engagement with potential and existing research applicants and by undertaking an extensive pre-review and validation assessment process of each application submitted. The research studies submitted, or that may be submitted, to the HRCDC encompass a diverse range of subject matters and research objectives as well as differing and oftentimes complex data processing activities. Close engagement with

researchers, therefore, is intended to help applicants with the process and to support effective HRCDC decision-making.

The Secretariat manages, and is responsible for, administration of the entire consent declaration application process, from receiving and acknowledging submitted applications to issuing decision letters on behalf of the HRCDC.

It also continues to oversee the management of the portfolio of live consent declarations on record on behalf of the Committee; this includes tracking deadlines that data controllers may be required to meet for certain attached conditions as well as overseeing the monitoring of the implementation of consent declarations and compliance with conditions via the annual review process. These core functions of the Secretariat are carried out in consultation with the HRCDC.

Part of the HRCDC's mandate is to operate in a transparent manner and to build public trust and confidence. The Regulations also require the HRCDC to publish information about the applications submitted to it and the decisions it has made. The Secretariat therefore publishes detailed minutes of all the HRCDC meetings and provides a log of applications on its website.

The Secretariat also informs the HRCDC about events, conferences and publications that may be of interest.

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<https://www.hrb.ie/about/strategy-2025/#:~:text=Introducing%20our%20Strategy%202025&text=Research%20provides%20hope,.,Ireland's%20people%2C%20society%20and%20economy.>

Secretariat activities

In addition to activities relating to the day-to-day operations of the HRCDC and the consent declaration process, the Secretariat also contributed to, was involved in, or attended, other related activities and initiatives.

Events

At the HRB's Annual 2022 National Conference, the Secretariat was present to discuss and provide information on the role of the HRCDC and the consent declaration process for delegates. It also actively participated in a roundtable discussion hosted by the Irish Health Research Forum, titled 'Maximising societal benefit from health research'. More generally, members of the Secretariat team attended seminars and presentations from the University of Galway, the HSE, the Irish Platform for Patient Organisations, Science & Industry (IPPOSI) and others, on topics including ethics and governance, PPI and cancer trials.

National initiatives and groups

The Secretariat continued to participate in a dedicated working group on the revision and development of the HSE's consent policy for health and social care research. It also worked closely with the Research Data Governance Board, which oversees the process for researchers seeking access to the CSO COVID-19 Data Research Hub. During 2022, the Secretariat also continued to participate in the Irish Health Research Forum Steering Group and the HRB cross-organisational health data group.

From Q1 to Q2 2022, the Secretariat participated in the early stages of an evaluation group in order to discuss and explore specifications of an Electronic Research Management System (ERMS), in order to facilitate the implementation of the HSE National Framework for the Governance, Management and Support of Health Research,²⁵ and the reform of the HSE Research Ethics Committees. The Secretariat was also a member of an oversight panel for the IPPOSI Citizens' Jury on Genomics.²⁶

Public consultations

In 2022, the Secretariat engaged with the HRCDC to provide feedback to the Health Information and Quality Authority's (HIQA) public consultation on its *Draft Standards for Information Management in Health and Social Care*.²⁷ The draft standards aim to provide a roadmap for improving the quality of health and social care information, in order to ultimately contribute to the delivery of safe and reliable care. The submission made by the Secretariat on behalf of the HRCDC provided feedback on the principles contained within the draft standards and focused on the management and use of such data in the context of health research. A submission was also made to HIQA's public consultation on *Draft recommendations on a consent model for the collection, use and sharing of health information in Ireland*.²⁸

²⁵ <https://hseresearch.ie/governance-framework/>

²⁶ <https://www.ipposi.ie/our-work/policy/health-information/2022-citizens-jury-on-genomics/#:~:text=The%20jury%20explored%20to%20what,the%20benefits%20and%20the%20risks.>

²⁷ <https://www.hiqa.ie/reports-and-publications/consultation/draft-national-standards-information-management-health-and>

²⁸ <https://www.hiqa.ie/reports-and-publications/consultation/draft-recommendations-consent-model-collection-use-and>

Other activities

Alongside the National Office for Research Ethics Committees (NREC), the Secretariat was involved in a module assessment by students at Maynooth University known as 'Project Live'. The assessment involved conducting a short literature review and lay summary on the topic of informed consent, with the Secretariat and NREC collaborating to provide feedback on the literature that was identified and on the students' final papers. The Secretariat welcomed this collaboration with the NREC and looks forward to identifying further collaborative opportunities in the future.

For the first time, the Secretariat to the HRCDC participated in the HRB's post-doctoral internship programme, which aims to provide early career researchers the opportunity to gain first-hand experience of working in a State agency. The Secretariat welcomed Dr Marta Pisarska to the team for a 6-month period as part of her internship programme rotation.

Lastly, the Secretariat engaged closely with the Committee to update the HRCDC's standard operating procedures in order to ensure that they remain fit for purpose and reflect the Committee's and Secretariat's internal processes. In addition, to ensure the HRCDC's continued operations, a procurement process to secure a provider of a suitable 'reading room' software for the next period of the Committee's work was undertaken. Following the procurement process in Q2-Q3 2022, Decision Time was selected as the reading room software provider.

08

Key objectives for 2023

As we look forward to the rest of 2023, the Committee remains committed to delivering on its mandate and ensuring that it puts patients and the public at the centre of its decision-making process, while enabling researchers to process personal data for the purposes of health research studies that are considered to be in the public interest, in a manner that considers the safeguarding of data.

The Secretariat, on behalf of the HRCDC, will continue to communicate the business and decisions of the HRCDC in a transparent manner through the timely publication of meeting minutes and the application log.

Following on from the objectives that were noted for 2022, it is also committed to exploring how to further enhance its communications and engagement activities. This includes reviewing the information and guidance available to stakeholders on our website; for example, the Secretariat will explore how the website can further inform the research community about the key issues considered by the HRCDC when deciding whether a consent declaration can be made and the importance of transparency, PPI, and data agreements as key data protection safeguards. It will also identify potential opportunities to undertake stakeholder engagement and outreach activities. Stakeholders include the research community, patient representatives, advocacy groups and the wider public.

The Secretariat and HRCDC will continue to closely engage and communicate with colleagues from the Department of Health and the Data Protection Commission (DPC) on questions that may arise on data protection matters and the Regulations. Close engagement will be important for understanding and

remaining informed about emerging legislative and policy developments in the area of health research and data processing, and how these may interplay with the GDPR, the Regulations and the work of the HRCDC. This includes already announced legislative developments such as the Health Information and Patient Safety Bill and the amended Assisted Decision Making (Capacity) Act 2015, as well as new developments that may emerge during the remainder of 2023.

While the HRCDC and NREC remain wholly independent entities governed by separate legislation and with different roles and remits, both committees play an integral role within the overall health research governance landscape in Ireland. Accordingly, there may be opportunities for the HRCDC and NREC to collaborate on appropriate and relevant activities and the Secretariat commits to collaborating with the NREC when appropriate opportunities arise.

The HRCDC looks forward to building upon the work that has been undertaken to date and continuing to fulfil its role within an evolving Irish health research environment through a collaborative approach that fosters trust and confidence in research in Ireland.

Appendices

Appendix A

HRCDC members

Ms Brigid McManus, Health Research Consent Declaration Committee Chairperson
Emeritus Prof. Evelyn Mahon, Health Research Consent Declaration Committee Deputy Chairperson

Dr Aideen Hartney, disability policy and public affairs

Ms Alyson Bailey, public and patient involvement

Dr Barry Lyons, paediatrics – anaesthesiology and critical care

Prof. Barry O’Sullivan, data analytics and artificial intelligence

Dr Claire Collins, general practice

Dr Cornelius Cooney, anaesthesiology and intensive care medicine

Mr Dan Rea, public and patient involvement

Mr John Woods, data protection

Dr John Ferguson,* biostatistics

Ms Kathy Brickell, emergency and intensive care research

Mr Kevin Clarke,* public and patient involvement

Dr Mary Tumelty, medicolegal research

Dr Sheelah Connolly, economic and social research

Dr Simon Furney, biomedical genomics

Dr Zubair Kabir, epidemiology and public health

* Term of office ended in April 2022.

Any changes to the membership made in 2023 will be updated on the HRCDC website at <https://hrcdc.ie/about-us/#Committee>.

Secretariat team

Dr Emily Vereker,† Programme Manager

Mr Jonny Barrett, Programme Officer

Ms Caroline Byrne, Administrative assistant

Ms Noreen O’Brien,^ Temporary Project Officer

Dr Marta Pisarska,‡ postdoctoral Intern

†Departed the Secretariat in May 2022.

^Was in the Secretariat, May 2022–January 2023.

‡Was in the Secretariat, May 2022–December 2022.

Appendix B

Summary of applications and decisions, 2022

This appendix lists all applications submitted to the HRCDC in 2022 and all decisions made in 2022. It is an abridged summary for the purpose of this annual activities report. A comprehensive up-to-date list of all applications can be viewed on <https://hrcdc.ie/decisions/>.

The applications submitted for consideration have been categorised in accordance with the UK Clinical Research Collaboration Health Research Classification System.

Note: the HRCDC's decision on, and status of, each consent declaration is based on the decision and status as of 31 December 2022. The decision and status of the application may therefore have changed; for the most up-to-date information on each application, please visit <https://hrcdc.ie/decisions/>.

(i) New applications submitted in 2022 and corresponding decisions

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
22-001-AF1/CSO	Study of the impact of lifestyle factors on COVID-19 outcomes	University College Dublin	Prof. Patricia Fitzpatrick	Infection	Aetiology	Conditional declaration	Declaration live
22-002-AF1	Understanding the wishes and support needs of people with intellectual disability as they grow older	Avista – St Anne's Centre, Co. Tipperary (formerly the Daughters of Charity Disability Support Services)	Dr Michelle O'Brien	Generic health relevance	Health and social care services research	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
22-003-AF1	A Phase 3, multi-centre, randomised, double-blind, placebo-controlled study to assess the efficacy, safety and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6-DM]/quinidine sulfate [Q]) for the treatment of agitation in patients with dementia of the Alzheimer's disease type	Otsuka Pharmaceutical Development & Commercialization, Inc. (Avanir Pharmaceuticals is no longer involved in this study)	Caroline Mason	Neurological	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
22-004-AF1	Albumin and prognosis of severe burn patients - ALBUBURN study	Hôpital Saint-Louis, Paris St James's Hospital	Dr François Dépret	Injuries and accidents	Evaluation of treatments and therapeutic interventions		
22-005-AF1	Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2)	Royal College of Surgeons in Ireland	Prof. Norman Delanty	Neurological	Aetiology/ Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
22-006-AF1	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age	Royal College of Surgeons in Ireland	Prof. Gianpiero Cavalleri	Neurological	Aetiology	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
22-007-AF1	Optimization of Medication by Transdisciplinary Assessment of Drug Treatment in Elderly Hospitalized Patients (OPTIMATE study).	University College Cork	Prof. Denis O'Mahony	Generic health relevance	Management of diseases and conditions	Conditional declaration	Declaration live
22-008-AF1	Evaluation of policies and practices to support safe and appropriate controlled drug prescribing	Royal College of Surgeons in Ireland	Dr Frank Moriarty	Generic health relevance	Health and social care services research	Conditional declaration	Declaration live
22-009-AF1	Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest	University College Dublin	Assoc Prof. Tomás Barry	Cardiovascular	Health and social care services research	Conditional declaration	Declaration live
22-010-AF1	Blockchain and AI Enabled Stratified Trials System (BESTS): A pilot study	Royal College of Surgeons in Ireland Beaumont Hospital St James's Hospital	Prof. Gianpiero Cavalleri	Generic health relevance	Underpinning research	No declaration	
22-011-AF1	SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia	Trinity College Dublin	Prof. Iracema Lero	Neurological/ Ear/Eye	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
22-012-AF1	Targeted Review and Amalgamation of Unmapped Major Trauma and Ambulance Data in Ireland: TRAUMA Study	National Office of Clinical Audit (NOCA) Health Service Executive (HSE) National Ambulance Service (NAS)	Prof. Frank Doyle	Injuries and accidents	Health and social care services research	Conditional declaration	Declaration live
22-013-AF1	Maximising equity and accessibility of acute stroke care pathways in Ireland (Part C): Patient outcome and experience	Royal College of Surgeons in Ireland,	Prof. David Williams	Stroke	Health and social care services research		
22-014-AF1	Secondary Analyses of Anonymised Data from Four Historical Studies of Electroconvulsive Therapy	St Patrick's Mental Health Services	Prof. Declan McLoughlin	Mental health	Aetiology/ Evaluation of treatments and therapeutic interventions		

(ii) Amendment requests submitted in 2022 and corresponding decisions

Application number	Application title	Data controller(s)	Applicant(s)	Health categories	Research activity	HRCDC decision	Status
19-019-AF2/ AMD1	IMPROVED Study	University College Cork	Dr Fergus McCarthy	Reproductive health and childbirth	Detection, screening and diagnosis	Amendment approved	Declaration live
19-021-AF3/ AMD1	National Self-Harm Registry Ireland	National Suicide Research Foundation	Dr Paul Corcoran	Mental health	Aetiology	Amendment approved	Declaration live
19-031-AF2/ AMD1	Bowel Disease Bio-resource Development: Identification of Potential Biomarkers for Bowel Disease	The Royal College of Surgeons in Ireland Beaumont Hospital	Prof. Deborah McNamara Prof. Jochen Prehn	Cancer and neoplasms	Aetiology/ Detection, screening and diagnosis	Amendment approved	Declaration live
19-086-AF1/ AMD2	Sepsis Immunosuppression in Critically Ill Patients	St James's Hospital	Prof. Ignacio Martin-Loeches	Inflammatory and immune system	Detection, screening and diagnosis	Amendment approved	Declaration live
20-001-AF1/ AMD1	A retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database	Royal College of Surgeons in Ireland	Dr Jack Laffan	Cardiovascular	Health and social care services research	No amendment made	
20-008-AF1/ COV/AMD1	Clinical, laboratory and radiological characteristics as predictors of outcome in patients with COVID-19	Tallaght University Hospital	Dr Ana Rakovac	Infection	Aetiology		
20-013-AF1/ COV/AMD1	WHO Solidarity Trial	Department of Health University College Cork	Prof. Joe Eustace	Infection	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live

Application number	Application title	Data controller(s)	Applicant(s)	Health categories	Research activity	HRCDC decision	Status
20-024-AF1-COV-AMD1	Genetics of Mortality in Critical Care (GenOMICC)	St Vincent's University Hospital University of Edinburgh NHS Lothian Health Board	Prof. Alistair Nichol	Infection	Aetiology	Amendment approved	Declaration live
20-039-AF1/AMD1	A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock	Galway University Hospitals, Saoilta West	Dr Bairbre McNicholas	Cardiovascular/ Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
21-003-AF1-AMD1	Investigating the Epidemiology of Mycobacterium bovis Infection in Humans	St James's Hospital New data controller: Trinity College Dublin	Prof. Tom Rogers	Infection	Aetiology	Amendment approved	Declaration live
21-005-AF1/AMD1	Collaboration to reduce Antimicrobial use and Resistance and identify opportunities for improvement and Awareness (CARA study)	National University of Ireland Galway	Prof. Akke Vellinga	Infection	Underpinning research/ Aetiology		
21-009-AF1/AMD1	Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability	Trinity College Dublin	Prof. Mary McCarron	Neurological/ Mental health	Management of diseases and conditions/ Health and social care services research	Amendment approved	Declaration no longer required or expired

Application number	Application title	Data controller(s)	Applicant(s)	Health categories	Research activity	HRCDC decision	Status
21-011-AF1/ CSO/AMD1	Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland	Economic and Social Research Institute	Prof. Seamus McGuinness	Infection	Underpinning research	Amendment approved	Declaration live
22-001-AF1/ CSO/AMD1	Study of the impact of lifestyle factors on COVID-19 outcomes	University College Dublin	Prof. Patricia Fitzpatrick	Infection	Aetiology	Amendment approved	Declaration live
22-005-AF1/ AMD1	Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2)	Royal College of Surgeons in Ireland	Prof. Norman Delanty	Neurological	Aetiology/ Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live

(iii) Applications submitted prior to 2022 that were considered in 2022

Application number	Application title	Data controller(s)	Applicant(s)	Health categories	Research activity	HRCDC decision	Status
19-026-AF2	MAMMI [Maternal health And Maternal Morbidity in Ireland] study (data processing for sub-studies with University of Gothenburg and Murdoch Children's Research Institute, Australia)	A. Trinity College Dublin B. The following collaborators are joint controllers with Trinity College Dublin for the respective academic sub-studies utilising MAMMI data: (i) University of Gothenburg, Sweden (ii) Murdoch Children's Research Institute, Australia	Prof. Deirdre Daly	Reproductive health and childbirth	Aetiology/Health and social care services research	Conditional declaration	Declaration live

(iv) Amendment requests submitted prior to 2022 that were considered in 2022

Application number	Application title	Data controller(s)	Applicant(s)	Health categories	Research activity	HRCDC decision	Status
20-031-AF1/AMD1	Fluid resuscitation with 20% albumin versus crystalloid Septic Shock	St James's Hospital	Prof. Ignacio Martin-Loeches	Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
20-035-AF1/AMD1	Effectiveness of treatment for infusion in ICU patients with complicated influenza ("IV Zanamivir Effectiveness Study")	GlaxoSmithKline Research & Development Ltd	Prof. Ignacio Martin-Loeches	Infection	Evaluation of treatments and therapeutic interventions/Management of diseases and conditions	Amendment approved	Declaration live

Appendix C

Overview of January 2021 amendments to the Health Research Regulations 2018

Areas of research considered	Amendment made
The requirement to obtain consent for the activity of pre-screening medical records to determine eligibility or suitability of a prospective participant for inclusion in research	Exemption from obtaining consent to facilitate the actions required to determine suitability or eligibility of a prospective research participant for inclusion in the substantive part of the research
The requirement to obtain consent for generally low-risk retrospective chart reviews of existing, patient-centred data for the purposes of addressing a research question	Exemption from obtaining consent to facilitate low-risk retrospective chart reviews that have been approved by a research ethics committee and meet specified transparency requirements
The requirement to obtain consent or apply for a consent declaration for research in the vital interests of the participants	To allow deferred consent for the processing of personal data for health research in exceptional and specified circumstances where an individual is unable to give consent by reason of physical or mental incapacity and where his or her vital (health) interests are engaged
Clarity required around the meaning of explicit consent	To add clarity to, and to formulate, the requirement for explicit consent in a way that is more familiar to health researchers
The validity of informed consent obtained for ongoing health research in the period covered by the EU Data Protection Directive ²⁹ (October 1995–May 2018)	To provide that informed consent, including legitimate broad informed consent, for the processing of personal data during the period covered by, and in accordance with, the EU Data Protection Directive, is continuing to be valid

²⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN>

Appendix D

Governance of the HRCDC

The Health Research Consent Declaration Committee (HRCDC) was established in 2019 under the Health Research Regulations (S.I. No. 314 of 2018 and as amended under S.I. No. 188 of 2019 and S.I. No. 18 of 2021). The role and composition of the HRCDC is set out in this statutory instrument. The HRCDC is accountable to the Minister for Health and is responsible for fulfilling its remit as set out in the Regulations. In accordance with the Regulations, the HRCDC is empowered to determine its own procedures and to define the level of autonomy and independence required for the purpose of pursuing its objectives. The HRCDC has autonomy in how it delivers on its mandate and does so while also ensuring proper and effective operational oversight and accountabilities. While the HRCDC would not fulfil the criteria of being a corporate State body as defined in the Practice for the Governance of State Bodies³⁰ (“the Code”), published by the Department of Public Expenditure, National Development Plan Delivery and Reform in August 2016, it nonetheless operates and conducts its business where relevant, appropriate and possible, in line with the principles of the Code.

Alignment with the Code

The Regulations set out the role of the HRCDC under the aegis of the Minister for Health and his/her Department. The day-to-day management and operation of the business of the HRCDC is carried out by the Secretariat staff provided by the HRB. The HRB, and therefore the Secretariat staff, comply with the requirements of the Code. The HRB has robust policies and procedures in place for its practices, in order to ensure compliance with the Code. Therefore, the management and operation of the business of the HRCDC, as carried out by the Secretariat business unit, is achieved to the standards of corporate governance set out in the Code in the following areas.

Statement of strategy and service plan

The HRCDC has a defined remit as set out in the Regulations. The Secretariat’s role in supporting the HRCDC to deliver on its mandate in a manner that engenders trust, transparency and public confidence is captured in HRB Strategy 2021–2025: Health Research – making an impact, under Strategic Objective 3.5: “Support the regulatory work of the Health Research Consent Declaration Committee (HRCDC) in contributing to health data being used in a transparent, trusted and safeguarded manner, and in the public interest.” This objective, and the associated implementation actions for the Secretariat, were developed in consultation with the HRCDC Chairperson. A detailed service plan that captures the role of the Secretariat business unit is mapped against the HRB Strategy 2021–2025. This service plan, as approved by the HRB Board, is submitted to the Department of Health and is underpinned by a performance delivery agreement. The Secretariat business unit contributes to the delivery of the service plan and required quarterly reporting.

30 <https://www.gov.ie/en/publication/7adff-governance/?referrer=http://www.govacc.per.gov.ie/wp-content/uploads/Combined-Code-Online-Version.pdf>

Operational budget

The HRCDC's operational budget is managed by the HRB, through the Secretariat and in accordance with the HRB's policies and procedures. The operational budget is directly linked to a detailed business service plan and is managed in accordance with the HRB's reporting requirements for the Department of Health and in compliance with current procurement rules and guidelines. The controlled responsibility of managing this budget is assigned at management level, with corresponding accountability.

Financial reporting

The financial budget that supports the Secretariat business unit and the operation of the HRCDC is managed in accordance with HRB policies and procedures. HRB-audited financial statements, which encompass the HRCDC's operational budget, are presented to the Minister for Health annually.

Internal financial controls – audit and risk

The operation of the HRCDC, as supported through the Secretariat, falls within the framework of the HRB internal control system for risk management. The system of internal control implemented by the HRB is in accordance with guidance issued by the Department of Public Expenditure, National Development Plan Delivery and Reform. The Secretariat business unit and the supports it provides to the HRCDC is part of the HRB internal audit function. The HRB Audit and Risk Committee has developed a risk management policy that outlines its risk appetite and the risk management processes in place. The policy, which also details the roles and responsibilities of staff in relation to risk, has been issued to all staff, including Secretariat staff, who are expected to operate in line with the HRB's risk management policies. The HRB shall inform the HRCDC as soon as is reasonably practicable of any weaknesses or potential weaknesses that it identifies.

Procurement

Through the HRB policies and procedures, the HRCDC financial budget spend, as managed by the Secretariat, complies with the Department of Public Expenditure and Reform circulars and office notices.

Remuneration of travel and expenses for members

The HRCDC complies with the Department of Public Expenditure, National Development Plan Delivery and Reform circulars and office notices, as amended from time to time, regarding travel and subsistence and official entertainment. All HRCDC expenses and honorariums are processed by the Secretariat in accordance with HRB policies and procedures.

Code of conduct

The HRCDC carries out its duties as per the Regulations with due diligence and care, and in the public interest, having due regard to its legal responsibilities and remit under the Regulations. This ethos is further set out in the HRCDC standard operating procedures.

Conflict of interest

The HRCDC has procedures for dealing with conflicts of interest in accordance with Schedule 5(3) of the Regulations. The HRCDC member will notify the Secretariat and the HRCDC Chairperson of any potential or actual conflict of interest. Where there is a conflict, or potential conflict, of interest, the HRCDC member will absent themselves from the relevant part of the meeting that is called to address the situation. This is further set out in the HRCDC standard operating procedures.

Business reporting and transparency

The HRCDC publishes an annual activities report in accordance with its statutory obligations under Regulation 12(1) of the Regulations. It also publishes detailed minutes of its meetings and decisions on all applications it receives for consideration on the HRCDC website: www.hrcdc.ie.

Data protection

The HRCDC is the data controller for personal data it receives and processes in the course of its duties under the Regulations. The HRB, through the provision of the Secretariat service that supports the HRCDC function, is the data processor for any personal data it receives and processes for the purpose of HRCDC business.

Document management and retention

Records created, received and held by the HRCDC shall remain under the control of the HRCDC. Records are held for the appropriate period of time that is necessary for the HRCDC to deliver on its business mandate. The Secretariat liaises with the HRB management team to ensure that best practice in document retention is applied to records held by the HRCDC. The HRCDC receives and accesses records for the purpose of its business through a secure information technology reading room called Decision Time.

Freedom of information

The HRCDC is a body that is subject to the Freedom of Information Act 2014 and is registered as such: https://foi.gov.ie/foi_units/health-research-consent-declaration-committee/. The HRCDC received three freedom of information requests in 2022.

Notes

**Health Research Consent Declaration
Committee, Ireland**

Grattan House
67-72 Lower Mount Street
Dublin 2
D02 H638
Ireland

e secretariat@hrcdc.ie
t +353 1 2345- 179/257
www.hrcdc.ie

 [@hrcdc_Ireland](https://twitter.com/hrcdc_Ireland)

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