HRCDC

Health Research Consent Declaration Committee

Annual Activities Report 2021

Transparency
Trust
Confidence

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Foreword

As Chair of the Health Research Consent Declaration Committee (HRCDC), I am pleased to present our third annual activities report, highlighting the work of the HRCDC and its Secretariat in 2021.

During 2021 the COVID-19 pandemic continued to dominate and affect every facet of society including the Committee's work. The critical importance of health research and the collaborative efforts of the research community, in Ireland and on a global scale, was highlighted to all with the successful development of innovative COVID-19 vaccines and therapies.

2021 was a busy year for the Committee and brought changes to some of our work. In January 2021 amendments to the Health Research Regulations introduced some substantive changes enabling researchers to process personal health data without the requirement for consent, in specific circumstances, and subject to data protection safeguards being met. The HRCDC Secretariat worked collaboratively with the Department of Health, the Health Research Board (HRB) and the Health Service Executive (HSE) Research & Development Unit, and in consultation with the Data Protection Commission, on amendment-specific guidance for the research community and stakeholders. This report includes an overview of the impact the amendments have made to the work of the Committee.

In February 2021, processes were put in place to allow the secondary use of COVID-19 health data, held by the Central Statistics Office (CSO), for health research purposes. As a result of these new access provisions, the HRCDC considered consent declaration applications for studies seeking to access CSO-held COVID-19 data for health research, where these studies were deemed to be in the public interest. The HRCDC, through its Secretariat,

"Public interest and safeguarding the use of personal data for health research will, as always, be at the core of our work and decision-making."

worked closely with the CSO, the HRB and newly formed independent Research Data Governance Board to enable streamlined application processes, and facilitate safeguarded, secure, and controlled access by researchers to this valuable data.

Stakeholder engagement was further strengthened in 2021, 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, such as HSE's consent for research policy development, patient, public and carer involvement activity, and data governance.

2021 saw a significant increase in the annual reviews submitted by applicants, 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 to ensure the operation and implementation of consent declarations is monitored on behalf of the HRCDC.

In accordance with public health guidelines, the HRCDC continued to hold its meetings remotely in 2021 and convened 11 times. We were delighted to welcome four new members to the Committee, adding additional and complementary expertise and perspectives. The Committee's work is made possible by the strong commitment of the individual Committee members and their thorough consideration of applications and constructive engagement and discussion at meetings with balanced consensus-based decision-making. I thank them for the valuable contribution they make to this important work.

On my own behalf as Chair and on behalf of the Committee, I want to particularly acknowledge and thank our Secretariat, Dr Emily Vereker, Mr Jonny Barrett and Ms Caroline Byrne,

for their expert and effective support to the Committee. Their work is critical to ensuring that the operations of the HRCDC are seamless and robust. The proactive engagement of the Secretariat with applicants and the research community, and 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 to the Department of Health and the HRB for their strong support for the HRCDC and its Secretariat.

Looking ahead, as stewards of the consent declaration process, the Committee looks forward to continuing to engage with our current and future applicants within the research community and to supporting them as much as possible. Given the increased demand for the use of health data within the Irish research landscape and across Europe, we will continue to look towards emerging legislation and guidance from opinion leaders and national and international stakeholders, to understand how data sharing and governance will further evolve. Public interest and safeguarding the use of personal data for health research will, as always, be at the core of our work and decision-making.

Brigid McManus
Chairperson

2021 snapshot

19 Applications for consent declaration submitted

11 Amendment requests sbmitted

20 Applications withdrawn

HRCDC decisions

26 Consent declaration made

0 No declaration made

2 Requests for further information

8 Amendment requests approved

11 HRCDC meetings

48 Annual reviews submitted

Average HRCDC member attendance **75%**

1 The Health Research Regulations

The Health Research Regulations[1] ('Regulations') are set down in Irish legislation for over three and a half years and provide for the safeguarding of personal data for health and social care research in Ireland. Building on existing clinical and corporate governance safeguarding practices, the Regulations bring consistency and transparency to the forefront of health research, and concomitantly precipitate public and patient trust in the research environment in Ireland.

The Regulations were amended in April 2019 (S.I. No 118 of 2019[2]), with further substantive amendments enacted in January 2021 (S.I. No 188 of 2021[3]). The amendments are discussed in further detail in Section 1.1 of this report.

The Regulations provide for a holistic set of suitable and specific safeguards that must be implemented to ensure that the data protection and privacy rights of individuals are respected and can be exercised. A key element of the Regulations is the mandatory safeguard of obtaining explicit consent from participants – consent that is informed and recorded. This feature of the Regulations reinforces the principle of an individual's autonomy in terms of data use and protection.

Under the Regulations, in exceptional cases where consent cannot be obtained the Health Research Consent Declaration Committee (HRCDC) may make a consent declaration where the public interest in conducting the research significantly outweighs 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.

In 2021, the European Data Protection Board (EDPB[4]) issued an Opinion on the application of the General Data Protection Regulation (GDPR[5]) with a specific focus on scientific health research.[6] The EDPB is the highest authority on the interpretation and application of the GDPR and it recognises that health research presents its own complex scenarios for data processing that can arise in a health research environment when collecting, sharing, analysing, and safeguarding personal data. Such complexities manifest further when research involves cross-border data sharing, multiple collaborators or 'data controllers', or varied opinions as to how the GDPR should be interpreted and complied with. In attempts to bring consistency and clarity to the health research community, the EDPB Opinion addressed where possible areas such as managing broad consent with requisite safeguards, the legal basis for processing health data, transparency, and storage limitation.

The EDPB provided a compelling statement on the importance of consent as a safeguard, where consent is not the legal basis for processing personal data for health research purposes. As ethical standards in research aim to protect and empower individuals when gifting their participation in research, informed consent is an important requirement. The view of the EDPB emphasises the importance of consent, not just as an ethical requirement but also in the framework of data protection, and as an additional safeguard when processing personal data for health research.

1 http://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://edpb.europa.eu/edpb_en
5 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN
6 https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf
See section 7, page 4.

Opinion of the European Data Protection Board 2021, on health research[7]

'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'

7 https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf. See sections 26 and 27, p. 8.

"The public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the data subject."[8]

1.1 Amendments to the Health Research Regulations

January 2021 saw five substantive amendments to the Regulations made by the Minister for Health[9] in response to particular challenges that have impacted on certain areas of research. Other more technical amendments on operational aspects of the Regulations were also introduced.

When the Regulations were enacted in 2018, the legislative requirement to obtain explicit consent, or to apply for a consent declaration in exceptional cases where consent cannot be feasibly obtained, applied to all health and social care studies.

The Department of Health, which has responsibility for the Regulations, engaged with the research community to understand bone fide challenges posed when implementing the Regulations, and also to understand the impact of the Regulations on health researchers and health research studies. It was acknowledged that in certain research environments and study-specific scenarios, implementing the mandatory safeguard of explicit consent presented an array of challenges.

To ensure consistency with the GDPR and the robust protection of participants' rights, the amendments were made in consultation with the Data Protection Commission (DPC) and the Department of Justice.

8 https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
9 https://www.gov.ie/en/press-release/32a11-minister-for-health-amends-health-research-regulations-on-personal-information/

Areas of research considered	Amendment made
The requirement to obtain consent for the activity of pre-screening of 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 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[10] (October1995 to 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 to be regarded as **continuing to be valid**.

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

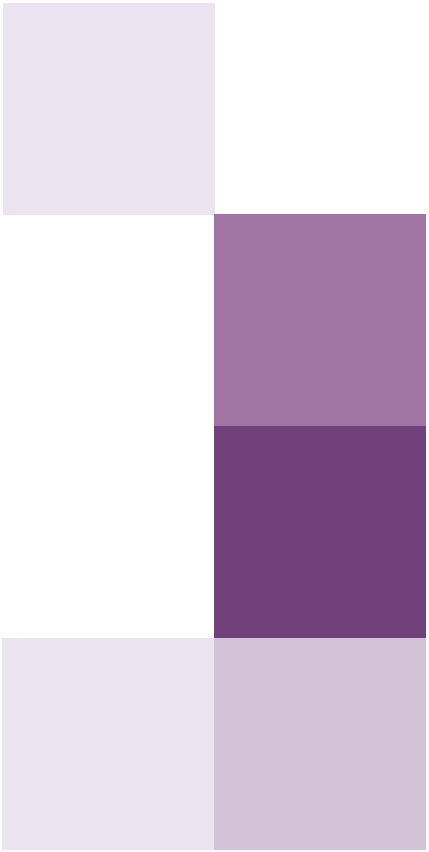
1.2 **HRCDC response to the amendments**

In advance of the enactment of the amendments[11] to the principal Regulations, the Department of Health prepared dedicated guidance on each of the substantive amendments.[12, 13] The Secretariat, the HRCDC, and the HSE Research & Development Unit engaged collaboratively on the guidance with the Department of Health and in consultation with the DPC. This collaborative and consultative approach endeavoured to provide stakeholders with consistent and clear guidance on how the amendments may be applied to health research.

It was recognised by the HRCDC that the amendments would be applicable to a number of research studies that were the subject of applications seeking a consent declaration following the establishment of the Committee in 2019.

A communication exercise was carried out by the Secretariat on behalf of the HRCDC. This involved contacting all data controller applicants to make them aware of the amendments and of the associated guidance prepared by the Department of Health. Applicants were advised to consider whether a consent declaration was still required i) where consent declarations had already been made for a health research study, or ii) where applications were still pending consideration by the HRCDC.

The impact of the amendments on the portfolio of consent declaration applications is further detailed in Section 3.4.



11 https://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf
12 https://www.gov.ie/en/publication/b46c2-amendments-to-health-research-regulations/
13 https://hrcdc.ie/guidance/

2 The Health Research Consent Declaration Committee

The HRCDC has been in operation since 2019 and it continues to play a distinct and meaningful role in an evolving health research regulatory environment in Ireland. The HRCDC members are widely representative of the health and social care research community, and collectively contribute a diverse range of expertise and experience to the work of the Committee.

2021 saw an additional four members appointed to the Committee, thus increasing its membership from 13 to 17, with each member contributing wide-ranging perspectives and insights that enable robust and balanced decisions to be delivered. The new members appointed by the Minister for Health offer complementary expertise and insights in areas of research such as critical care medicine and anaesthesiology, data protection, and medico-legal aspects of health and social care.

The Committee's three public and patient involvement (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 is provided in Appendix A. Full member profiles can be viewed on the HRCDC website: https://hrcdc.ie/about-us/

Through a strong consensus-based decision-making process, the HRCDC undertakes to ensure that the public interest is at the forefront of the research it considers, on balance with the data protection rights and freedoms of the research participants, whose consent for research cannot be obtained.

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 nuances of, and circumstances under which, each distinct research study is being conducted.

The consent declaration can only be made where there are significant countervailing public interest grounds for conducting the research that outweigh the public interest in requiring explicit consent from the research participant.

Understanding the degree of public interest in a research study can be greatly aided by engaging with patients, families, carers, and the public. Public, patient and carer involvement (PPI) in research is an important data protection safeguard to ensure that the perspective of the prospective participant is always considered where consent cannot be obtained. PPI in research fosters a more patient and public-centred approach to research and it reinforces the concept of research carried out 'with' or 'by' patients and the public.

The Committee prides itself on full transparency of its role through the publication of the log of decisions and applications on hand, including detailed 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.

In 2021, the HRCDC invited subject matter experts to give a presentation on specific topics of relevance to the HRCDC. Subsequently, Dr Michaela Th. Mayrhofer, BBMRI-ERIC,[14] gave a presentation on the ethical, legal and societal issues of biobanking, an important field in research that requires robust and trustworthy governance, patient and public engagement, and transparency. Dr John Dunne, Central Statistics Office (CSO), gave a presentation on the physical infrastructure, governance and data journey that forms the COVID-19 Data Research Hub under the custodianship of the CSO.

14 https://www.bbmri-eric.eu/

Health Research Regulations 2018[15]

‘A controller who is processing or further processing personal data for the purposes of health research shall ensure that the following suitable and specific measures are taken to safeguard the fundamental rights and freedoms of the data subject’

governance structures	ethical approval	assessment of data protection	training in data protection	
data minimisation	limit access	protect the security	anonymise	
processed in a transparent manner	explicit consent	technical and organisational measures	consent declaration	

15 https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

2.2 **Members' perspectives and insights**

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

"Being a parent and ongoing carer of two adult children, I have a somewhat vested interest in health research. "

Mr Kevin Clarke, patient, public and carer representative

"Being a parent and ongoing carer of two adult children, I have a somewhat vested interest in health research. Both children were diagnosed in their early teens with a rare and progressive neurological condition that affects their physical, but not mental, abilities and both are now wheelchair bound. They have participated in some limited research programmes, so I have experience of the need for proper and full patient information on issues surrounding consent, and of the need to protect their personal data. As a former long-serving civil servant, I also have wide experience of working to, and implementing, various pieces of legislation, including data protection legislation, and sitting on boards and committees.

My range of skills, experience and perspectives have made a positive and meaningful contribution to the important work of the Committee. It is of public importance that researchers have the opportunity to obtain a consent declaration in cases where they can show that the public interest in the research is far outweighed by the requirement to obtain explicit consent from prospective research candidates.

I have found discussions in the considerations of applications to have been open, transparent, and inclusive of all views."

Dr Zubair Kabir, epidemiology and public health

"As an epidemiologist, I crunch numbers, counting heads in health research, but I often forget the source of these data. I am closely associated with the Global Burden of Disease (GBD) Study, comprising billions of data points, all of which are seemingly 'anonymised'. However, membership of the HRCDC has given me a unique opportunity to have a 'lived' experience of how non-epidemiologists, carers, and patient and public representatives view personal data and privacy. It has also given me an opportunity to explore further the uncharted territory of the 'consenting' process in health research.

The COVID-19 pandemic has created untold stories, but for me, the HRCDC has provided new ways of looking differently at the ethical and logistical challenges of undertaking health research during the pandemic. I found myself in a professionally challenged situation, not only using my subject matter expertise to make impactful scientific discoveries in relation to this global pandemic but, more importantly, protecting and honouring patients' privacy and adhering to the highest ethical and professional standards.

Thinking out of my 'epidemiological box' has given me greater insights into making that right decision – using all the ingredients of transparent, confident, and trustworthy health research – the fine balance of advancing knowledge and protecting data subjects. Each data point is a human life!"

"Each data point is a human life!"

"the HRCDC is crucial to ensuring the experiences of people who may not have the capacity to consent are still represented in research..."

Dr Aideen Hartney, disability policy and public affairs

"For most of my career I have been involved in managing research for the public good. At the National Disability Authority (NDA), our role is to provide evidence-informed advice to government on matters relevant to disability. Establishing the evidence base through research is essential to ensuring that policy decisions or service design are implemented with full awareness and recognition of their impacts on people with disabilities. Yet, some of those most likely to be affected by these decisions may not have the capacity to consent to participate in a research project.

I am also keen to ensure that health research is considered as broadly as possible, encompassing the area of social care, which can be just as relevant as clinical research to many people with disabilities.

At present, the HRCDC is a crucial part of the research infrastructure in Ireland, ensuring that the experiences of people who may not have the capacity to consent are still captured and reflected in research findings. The different perspectives brought by Committee members also ensure that where a consent declaration is given it is because the public interest of the project is clear, and the data rights of research participants are robustly protected.

My time on the Committee has broadened my own perspectives on different kinds of research, and I hope that I have had some impact on ensuring that the importance of people with disabilities as research participants is not overlooked."

3 HRCDC activities

3.1 HRCDC meetings

The HRCDC convened 11 times in 2021.

The Regulations require a quorum of at least seven members at a meeting. The average attendance at the HRCDC meetings was 13 members.

Number of meetings	11
Average number of members per meeting	13
Percentage attendance	75

3.2 Applications submitted

At the beginning of 2021, there were 34 applications pending consideration by the HRCDC.

A number of these applications were submitted in 2019, seeking a consent declaration for research studies that had begun prior to the commencement of the Regulations in 2018. Transitional arrangements enabled researchers to apply for a consent declaration for two categories of research studies by an application deadline in August 2019. These categories were:

- research studies where consent had not been obtained under the previous Data Protection Directive 95/46/EC of the European Parliament16 (submission of Application Form 3 – AF3)
- research studies where consent had been obtained under the previous Data Protection Directive 95/46/EC of the European Parliament prior to implementation of the Regulations but was not deemed to be the standard of explicit consent[17] under the Regulations (submission of Application Form 2 – AF2).

In 2021, the HRCDC received 19 applications seeking a consent declaration for new research studies (submission of Application Form 1 – AF1).

Of these 19 applications, two were subsequently withdrawn in 2021, as the data controller determined that a consent declaration was not required.

Five of these applications were seeking a consent declaration for accessing the CSO COVID-19 Data Research Hub. Further detailed information on this data source is set out in Section 5.

Eleven applications requesting an amendment to a live consent declaration were received for consideration.

Applications submitted in 2021

New applications for consent declarations	19
Amendment requests for live consent declarations	11
Total submissions	30

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

17 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.

3.3 HRCDC decisions

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

In 2021, the HRCDC continued to give priority consideration to COVID-19-focused research studies and other new research studies seeking a consent declaration. The Committee was cognisant that AF2 and AF3 applications submitted under the transitional arrangements in 2019 remained pending consideration. After the amendments to the Regulations came into effect, the Secretariat engaged closely with and supported data controller applicants in order to establish what applications would proceed for HRCDC consideration.

Decisions made in 2021

	AF1*	AF2±	AF3†	AMD^	TOTAL
Declarations made	19	5	2		26
No declaration	-	-	-		-
Request for further information	1	-	-	1	2
Amendments approved				8	8
Total decisions					**36**

* 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.

† Applications submitted under transitional arrangements – consent had not been obtained for the research under the previous Data Protection Directive 95/46/EC of the European Parliament.

^Applications seeking an amendment to a consent declaration.

A total of 36 decisions were made by the HRCDC in 2021.

Of these, the HRCDC made a total of 26 consent declarations, all of which had specific conditions attached, some of which had recommendations made, to bolster data protection safeguarding measures, in the interests of the participants.

Of the 26 consent declarations made, the HRCDC made 19 consent declarations for AF1 research studies (submitted in 2020 and 2021); five consent declarations were made for AF2 research studies, and two consent declarations were made for AF3 research studies.

In the case of one consent declaration application, the decision of the HRCDC was to formally request further information. This application was subsequently withdrawn by the applicant, as a consent declaration was deemed not to be required.

Five of the consent declarations were made for research studies seeking to access and analyse pseudonymised COVID-19 health data under the custodianship of the CSO.

Eight amendment requests were approved by the HRCDC in 2021.

One amendment request resulted in the HRCDC making the decision to formally request further information, where the final decision of the HRCDC was made at the next available meeting in 2022.

One amendment request submitted in 2021 was approved in 2022.

At the time of publication of this report, one amendment request application is pending consideration by the HRCDC

At the time of publication of this report, all AF3 applications submitted have since been considered by the HRCDC.

Of the AF2 applications submitted, six are pending consideration. Engagement is underway with the applicants to determine whether these applications should proceed for HRCDC consideration or be withdrawn.

3.4 Applications withdrawn

In 2021, a total of 20 applications (including 2019 and 2020 submissions) were withdrawn by applicants after further consultation with the Secretariat and their institutional data protection officers or equivalent. Of these applications, three were withdrawn following consideration by the HRCDC, but a final HRCDC decision remained pending.

The amendments made to the Regulations affected AF2 research studies that had obtained consent in accordance with Data Protection Directive 95/46/EC of the European Parliament but were deemed not to be the standard of explicit consent under the Regulations. In accordance with the new Regulation 6A of S.I. No. 18 of 2021, participant consent obtained in accordance with the previous Data Protection Directive now continued to be valid.

At the time the amendments came into effect, 25 AF2 applications were pending HRCDC consideration. The new Regulation 6A resulted in 12 applications being formally withdrawn from the HRCDC process by applicants on behalf of their data controller organisations, as a consent declaration was no longer required.

Notably, a small number of research studies that obtained consent under the previous Data Protection Directive 95/46/EC of the European Parliament were not withdrawn from the consent declaration process. Upon reviewing the consent obtained at that time, applicant researchers determined that valid consent for elements of the research study had not been obtained, and the amendment in the new Regulation 6A could not be applied. Therefore, a consent declaration was still required for all or certain elements of the research. For these applications that proceeded to the HRCDC for consideration, a public interest case was made for the data processing being carried out for these research studies.

Applications withdrawn or invalid in 2021

AF1*	AF2±	AF3 †	Total
4	14	2	**20**

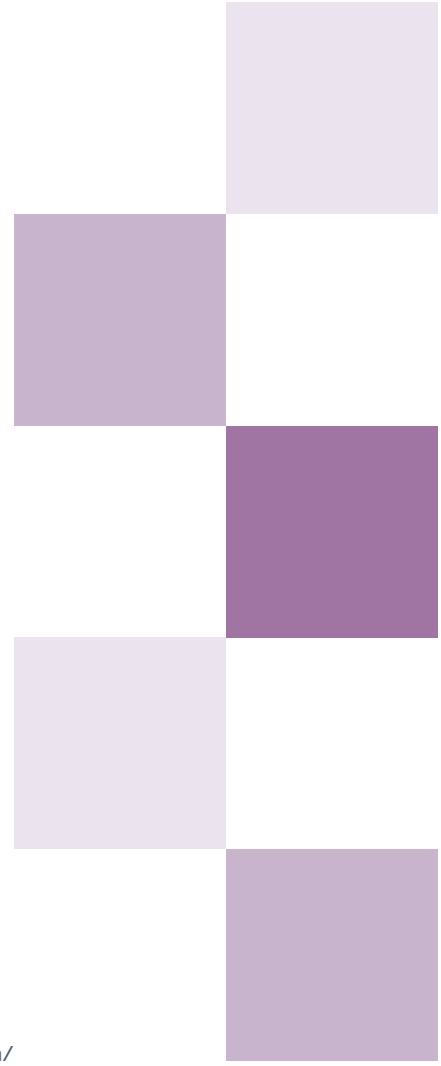
* Applications for new research – consent is not being sought.

± 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.

† Applications submitted under transitional arrangements – consent had not been obtained for the research under the previous Data Protection Directive 95/46/EC of the European Parliament.

3.5 Scope of research and geographical spread of data controllers

In 2021, the HRCDC received applications across a spectrum of biomedical and health research areas, spanning many health categories and research activities. The Secretariat categorises each research study in accordance the UK Clinical Research Collaboration (UKCRC) Health Research Classification System.[18] The following infographic illustrates the diversity of health research studies that required a consent declaration from the HRCDC in 2021.



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

Diversity of health research[19]

Health categories			
	Cancer and neoplasms **3**	Infection **9**	Neurological **3**
	Mental health **1**	Respiratory **2**	Inflammatory and immune system **1**
	Stroke **1**	Renal and urogenital **2**	Generic health relevance **1**

Research activities		
	Health and social care services research **3**	Evaluation of treatments and therapeutic interventions **6**
	Detection, screening and diagnosis **3**	Aetiology **6**	Management of diseases and conditions **3**
	Underpinning research **2**	Prevention of disease and conditions, and promotion of well-being **2**

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

4

Annual reviews – monitoring live consent declarations

Since the establishment of the HRCDC in March 2019 and up to year ending 31 December 2021, the Committee has made a total of 80 consent declarations for research studies that it considered were in accordance with the Regulations. One consent declaration was made by the Appeal Panel in 2019, in accordance with Regulation 11.

Regulation 13(1) of the Regulations provides for the HRCDC to monitor and review the operation of a consent declaration in order to ensure that it is being implemented and that any conditions attached are met and that recommendations are considered.

The submission of the annual review by data controllers is a requirement that the HRCDC relies upon to enable it to review the operation of a consent declaration and to ensure that conditions are met, and that recommendations made have been considered by the data controller.

As the annual review must be submitted on the anniversary of the date the consent declaration was made, the HRCDC saw a steady rate of between two and three annual reviews submitted each week throughout 2021.

4.1 Annual reviews submitted

During 2021, the total number of annual reviews submitted to the HRCDC as a reporting requirement was 48.

Of the 48 annual reviews submitted, 38 were deemed satisfactory in 2021. A satisfactory review denoted that a consent declaration was being complied with, in accordance with the HRCDC's requirements; that conditions had been met or were in progress; and that recommendations made by the HRCDC had been considered.

Five annual reviews submitted required additional information to be requested from the applicant and are pending further consideration. At the end of 2021, five were still pending Secretariat review.

In addition to the 38 annual reviews considered during 2021, five annual reviews carried over from 2020 were reviewed and deemed satisfactory. Thus, a total 43 annual reviews were considered in 2021 and deemed satisfactory.

4.2 Implementing a consent declaration

The HRCDC must be satisfied that all the necessary data protection safeguarding measures, as set out in the Regulations, underpin the health research, such that the fundamental rights and freedoms of individuals are safeguarded while their personal data are being processed without consent for the purpose of important health research.

Many of the conditions and recommendations set out by the HRCDC aim to reinforce safeguarding measures. For example:

- ensuring that appropriate controller-to-controller arrangements, controller-to-processor arrangements, or legal agreements are in place

- minimising the data being processed, to reduce data protection risks
- making recommendations in relation to information leaflets and consent and assent forms, in order to ensure clarity of information and transparency for research participants, and for those assenting on their behalf, on research activities carried out
- limiting the scope of the consent declaration to specific processing activities
- ensuring that adequate transparency measures have been introduced to highlight how personal health data may be used in a research environment, and to empower individuals to exercise their data protection rights in accordance with Irish data protection legislation, including the Regulations
- ensuring safeguards for individuals who may have diminished decision-making capacity, either temporarily or permanently as a result of their physical, intellectual or mental health status, and are unable to provide consent
- ensuring that meaningful patient, public and carer involvement in the research study is at the forefront of the research, reinforcing the concept of research carried out 'with' or 'by' patients and the public, rather than 'to', 'about' or 'for' them.

The HRCDC gratefully acknowledges receipt of annual reviews diligently submitted by the data controller applicants throughout 2021. It is pleased to report that the implementation of consent declarations, and meeting the conditions attached, was broadly carried out satisfactorily by data controllers and researchers, in accordance with the expectations of the HRCDC.

It is notable from the annual reviews submitted that the COVID-19 pandemic affected the commencement and progress of some research studies. This in turn affected the operationalisation of some consent declarations and therefore the ability to substantively or partially meet the conditions attached. Furthermore, the disruption caused by the HSE cyberattack also affected the ability of some researchers to meet the HRCDC's deadline-driven requirements.

The Secretariat engaged directly with data controllers and researchers where there were well-recognised challenges with submitting annual reviews in a timely manner, or with implementing a consent declaration and meeting conditions attached to it. Mindful of extenuating circumstances faced by researchers, a degree of leniency was applied at the discretion of the HRCDC to support researchers and their data controller organisations in meeting relevant deadlines.

Following the assessment of some annual reviews, further information was requested by the HRCDC to determine the adequacy of the requisite data protection safeguards applied to a particular research study, as required under the consent declaration made by the HRCDC. For these cases, it was important for researchers to understand where deficiencies in data protection measures may be evident and what additional measures would ensure satisfactory implementation of a consent declaration and conditions attached.

With the support of the Secretariat, the HRCDC maintained an open dialogue and provided constructive guidance to researchers and the data controller organisations in relation to the requirements of the HRCDC.

5 Safeguarding COVID-19 statistical health data for research

There is increasing demand for health data from researchers who are seeking to harness the value that health data can offer to address essential research questions in attempts to understand diseases, develop therapeutic interventions, and assist vaccine development as well as the development of evidence-based public health and social care solutions. Maximising the use of health data in a trusted, safeguarded and transparent manner for the public good has become even more important since the beginning of the COVID-19 pandemic.

In 2021 the Minister for Health launched a national initiative, with the support of the HRB and the CSO, to enable researchers to apply for access to COVID-19 health data. These valuable, pseudonymised data are compiled by the CSO from a variety of health sector sources and made available in the form of research microdata files, housed within the CSO COVID-19 Data Research Hub.[20] Access to the data for secondary use research purposes facilitates a greater and much-needed understanding of COVID-19 for the benefit of public health and patient care, as well as to inform and shape health and social care policy and planning.

The application process that was developed integrated stringent safeguards to protect the privacy and data protection rights of patients and the public. Central to this safeguarding was the establishment of the Research Data Governance Board (RDGB), an independent oversight body tasked with screening and reviewing the data requests for suitability.

The COVID-19 data are rigorously pseudonymised and collected from the Irish population whose health data reside under the custodianship of the CSO within the CSO COVID-19 Data Research Hub. It was recognised that obtaining the mandatory safeguard of explicit consent from individuals would not be practicably possible given the extent of the data that have been collected since the beginning of the COVID-19 health crisis in 2020. For this reason, a consent declaration is a necessary safeguard required under the Regulations for processing COVID-19 data from within the CSO COVID-19 Data Research Hub.

It was recognised by the HRCDC that researchers will be accessing a highly controlled and secure data environment. Many of the technical and organisational safeguards and measures required under the Regulations are already implemented by the CSO.

The Secretariat developed a bespoke application form for researchers seeking a consent declaration for accessing and analysing pseudonymised COVID-19 research microdata files. This bespoke application form pre-populated many of the CSO's technical and organisational data protection safeguards that are specific to the COVID-19 Data Research Hub, thus removing the requirement for researchers to complete these sections. Working collaboratively with the CSO and the RDGB Secretariat, the development of a dedicated consent declaration application form was a constructive endeavour by the HRCDC and its Secretariat, to ensure that the journey of data access for researchers, that includes applying for a consent declaration from the HRCDC, was as efficient and seamless as possible.

The number of consent declarations made by the HRCDC to enable the processing of COVID-19 data from within the CSO COVID-19 Data Research Hub is further detailed in Section 3.3.

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

6 Spotlight on research

In 2021, 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 is illustrated in Section 3.5 of this report. Further details can be found in Appendix B and also on the HRCDC website.

To give a flavour of the nature of the applications the HRCDC has considered, the following studies received a consent declaration or an amendment approval from the HRCDC in 2021:

- The HRCDC made a consent declaration to Trinity College Dublin to enable Professor Mary McCarron, School of Nursing & Midwifery, to process personal data of participants who may have limited decision-making capacity to provide explicit consent for data processing. The research study[21] is examining post-diagnostic supports for people with an intellectual disability and dementia through the development of accessible best practice guidelines. In addition to examining the current landscape of post-diagnostic care and best practice for post-diagnostic care, a central element of this research involves understanding the experiences and recommendations of people with an intellectual disability who are living with dementia.
- The HRCDC approved an amendment request for an existing consent declaration that was made to Clinical Research Development Ireland (CRDI) in 2020 for the Irish Prostate Cancer Outcomes Research (IPCOR) study.[22] As CRDI wound down its operations in 2021, and in order that the IPCOR data could continue to be processed within an appropriate data governance framework, an amendment was approved for a change in controllership from CRDI to University College Dublin (UCD), under the supervision of Assistant Professor David Galvin.
- The HRCDC made a consent declaration to the Economic and Social Research Institute (ESRI), acting through Professor Seamus McGuinness, for the purposes of accessing and obtaining pseudonymised data research microdata files from the CSO COVID-19 Data Research Hub. By analysing COVID-19 data, this research study[23] aims to elucidate the relationship between the COVID-19 pandemic and spatial variations in social deprivation. In addition, it aims to further examine the correlation between COVID-19 infection rates, hospitalisation, and socially deprived areas and influencing factors.
- A consent declaration was made to joint data controllers, the Royal College of Surgeons in Ireland (RCSI) and the National Screening Service, for the purpose of examining mammographic breast density measures among women who participated in the breast screening programme in Ireland. The study[24] aims to review the radiological features of breast density in order to investigate how they can be used to identify women at higher risk of developing breast cancer.

21 HRCDC Ref ID: 21-009-AF1 'Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability'
22 HRCDC Ref ID: 19-077-AF1 'Irish Prostate Cancer Outcomes Research'
23 HRCDC Ref ID: 21-011-AF1/CSO 'Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland'
24 HRCDC Ref ID: 21-013-AF1 'Mammographic breast density and breast cancer outcomes in a population-based breast screening programme'

7 Portfolio of consent declarations

Since the establishment of the HRCDC in March 2019 and up to 31 December 2021, a total of 81 consent declarations[25] were made for research studies considered to be in accordance with the Regulations. Of these, 68 were live consent declarations at the end of 2021.

Thirteen consent declarations were no longer required for the research studies.

By 31 December 2021, 43 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.

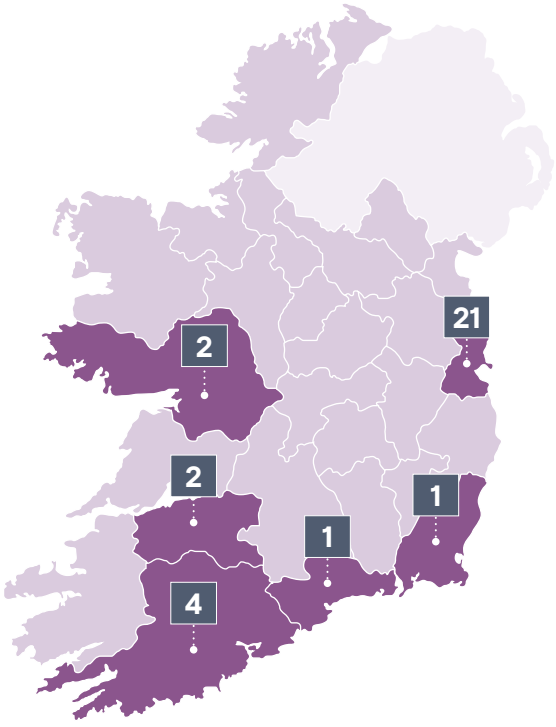
Sectoral type of data controllers with consent declarations[26]

Higher education institution	12
Hospital/healthcare service provider	19
Commercial organisation	4
Charity	3
Government department	1
State agency	1
Research institute	1
Professional body	1
Statutory body	1
Total	**43**

25 80 consent declarations were made by the HRCDC, 1 consent declaration was made by an independent appeal panel (in 2019).
26 A data controller/joint data controllers may have received a consent declaration for a number of research studies by year ending 31 December 2021.

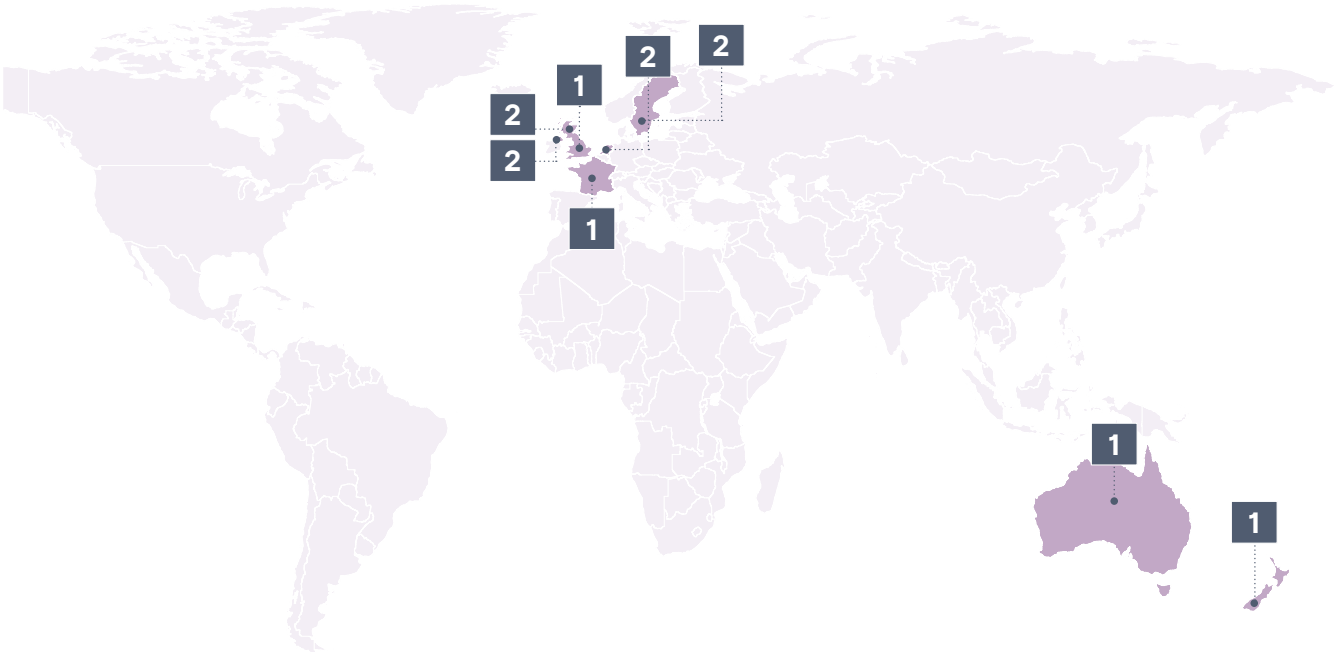
Geographical spread of data controllers with consent declarations

National



National	Institutions
Dublin	21
Wexford	1
Galway	2
Waterford	1
Limerick	2
Cork	4
International	
Australia	1
Sweden	2
England	1
Scotland	2
Northern Ireland	2
New Zealand	1
France	1
The Netherlands	2
Total	**43**

International



8 The Secretariat

8.1 **Secretariat supports**

The staffing resources for the HRCDC Secretariat have been provided by the HRB since the Secretariat's operations commenced in January 2019. 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. This function is captured in *HRB Strategy 2021–2025: Health Research – making an impact*–[27] under Strategic Objective 3.5.

The Secretariat acts as a principal point of contact for the research community, the public, and other stakeholders on behalf of the HRCDC. Given the nuanced nature of research studies and the multifaceted data processing activities that are carried out in any given research study, the Secretariat engages closely with existing and potential researcher applicants to offer guidance and support as necessary to navigate the consent declaration application process. This close liaison with applicants is a core function of the Secretariat and it ensures that the HRCDC is in receipt of clear and detailed information for the purpose of its decision-making role under the Regulations. Building these relationships between the HRCDC, the Secretariat and researchers brings consistency and clarity to the regulatory framework under which health research is carried out.

The Secretariat holds responsibility for the entire application process that enables researchers to apply for consent declaration from the HRCDC. The varied administrative activities carried out by the Secretariat range from triaging applications to the preparation of the application packs for HRCDC consideration and issuing decision letters on behalf of the HRCDC.

The transparency of the business of the HRCDC, which is essential for building public trust, is underpinned by the Secretariat's role in publishing the minutes of all HRCDC meetings and in ensuring that the status of the portfolio of applications is updated, publicly available, and easily accessible.

Management of the portfolio of 68 live consent declarations for research studies is overseen by the Secretariat. This entails tracking actionable data protection safeguarding measures that are required by the HRCDC and reflect the fundamental principles of the Regulations.

As discussed in Section 4, 2021 saw a significant increase in the number of annual reviews submitted by data controllers, the management and oversight of which is carried out by the Secretariat, in consultation with the HRCDC.

Some of the supports provided to the HRCDC in 2021 were designed to create awareness of events, conferences and publications in areas of particular relevance to the business of the HRCDC.

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

8.2 **Secretariat activities**

Throughout 2021, the Secretariat continued to engage with national stakeholders on various initiatives directly related to, or peripheral to, the work of the HRCDC. The following provide an overview of the contribution of the Secretariat to these initiatives that aim to support and drive health research policy and robust governance in research.

National initiatives

Beginning in January 2021, the Secretariat worked closely with the CSO, the HRB and the RDGB Secretariat to facilitate a streamlined process for the requisite approvals required by researchers seeking to access the CSO COVID-19 Data Research Hub. The development of a custom-made consent declaration application form, as described in Section 5, demonstrated an agile and practical approach to facilitating an efficient application process for researchers. It also enables the HRCDC to consider applications seeking a consent declaration to access to the CSO COVID-19 Data Research Hub, more efficiently.

Policy development

The Secretariat continued to contribute to the revision and development of the research consent policy through its participation in a dedicated working group overseen by the HSE Research & Development Unit.

Public consultations

In Q2 2021, the Secretariat worked collaboratively with the HRB to submit observations[28] to the Data Protection Commission's Regulatory Strategy 2022-2027.[29]

As health research is underpinned by a legislative framework regulated by the DPC, both the HRB and the HRCDC have complementary vested interests in how the final strategy may deliver further clarity and consistency in the navigation and interpretation of data protection legislation, while fostering confidence and public trust in health research.

Speaking engagements

Following the enactment of the amendments to the Regulations, the Secretariat and the Department of Health delivered a coordinated overview of the amendments to the Regulations to the Health Research Data Protection Network in February 2021.

In April 2021, the Secretariat was invited to participate in two 'Trinity Roundtable'[30] webinar series hosted by the Trinity Centre for Ageing and Intellectual Disability at Trinity College Dublin. These events aimed to provide guidance and clarity to stakeholders on the amendments to the Regulations, and to explore how the amendments should be interpreted and applied, including examining in depth the concept of consent. The Secretariat Programme Manager joined a representative from the Department of Health and the DPC to deliver coordinated and comprehensive webinars on these regulatory matters.

As part of its mandate to inform the research community about the Regulations, the HRCDC, and the consent declaration process, the Secretariat delivered information seminars to the Irish Clinical Academic Training Programme research fellows, the National Rehabilitation Hospital, and also to the National Office for Research Ethics Committees.

28 https://www.dataprotection.ie/sites/default/files/uploads/2021-12/Regulatory%20Strategy_Final%20Consultation%20Report.pdf. See pages 111–117.
29 https://www.dataprotection.ie/sites/default/files/uploads/2021-12/DPC_Regulatory%20Strategy_2022-2027.pdf
30 https://www.tcd.ie/tcaid/research/healthresearchregulations.php

The Secretariat Programme Manager participated as a panellist at the Irish Research Nurses & Midwives 13th Annual Conference, highlighting the work of the HRCDC and the importance of data protection safeguards in the context of the Regulations.

National groups

As of 31 December 2021, the Secretariat's participation in a number of groups led by national organisations had expanded to include the following:

- Irish Health Research Forum Steering Group
- National Consent for Research Policy Working Group
- RDGB oversight group
- HRB cross-organisational health data group

Through its participation in these groups, the Secretariat contributes the perspectives and learnings of the HRCDC. This participation helps to influence and shape important and progressive national research initiatives led by these groups.

More generally, throughout 2021, the Secretariat attended a number of events and conferences on topics ranging from biobanking to international data transfers and genomics research.

9 Key objectives for 2022

As the HRCDC looks ahead to 2022, it will continue to deliver on its mandate 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.

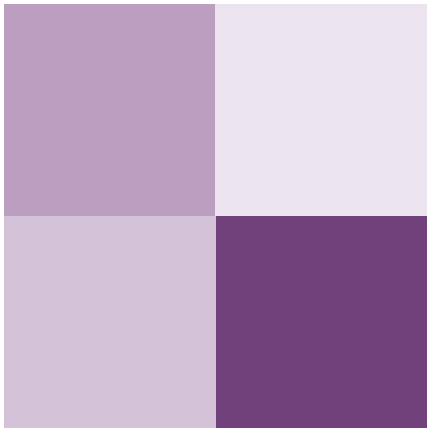
The HRCDC will communicate the business of the HRCDC through contact and engagement with the public, patient advocacy groups, research forums and networks, and the wider research community.

The HRCDC is 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 declaration.

A complementary and important activity of the Secretariat and the HRCDC in 2022 will be horizon scanning for relevant emerging legislative and policy developments, nationally and internationally, in the area of health data sharing and governance. The HRCDC and the Secretariat recognise the need to be fully informed and prepared for future legislative developments such as the European Health Data Space (EHDS).[31] The EHDS is being advanced significantly and aims to develop and promote elements on the cross-border sharing of health data in secondary use. How this initiative interplays with the GDPR and the Regulations will be of material interest to the HRCDC.

As the amended Assisted Decision-Making (Capacity) Act 2015 will fully commence in June 2022, it will be important to understand how this legislation coexists with the Regulations. Importantly, the Assisted Decision-making (Capacity) Amendment Bill 2021[32] now provides for participation in health and social care research for individuals with diminished decision-making capacity and this is included in a decision-making support arrangement under the Act.

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



31 https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en
32 https://www.gov.ie/pdf/?file=https://assets.gov.ie/205177/7bc1a7de-8674-4911-a0c0-7418ba807056.pdf#page=null
See pages 9–10.

Appendices

Appendix A

HRCDC members

Ms Brigid McManus, HRCDC Chairperson

Prof. Evelyn Mahon, HRCDC Deputy Chairperson

Ms Alyson Bailey, patient and public involvement

Ms Kathy Brickell, emergency and intensive care research

Mr Kevin Clarke*, patient and public involvement

Dr Claire Collins, general practice

Dr Sheelah Connolly, economic and social research

Dr John Ferguson*, biostatistics

Dr Simon Furney, biomedical genomics

Dr Aideen Hartney, disability policy and public affairs

Dr Zubair Kabir, epidemiology and public health

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

Mr Dan Rea, patient and public involvement

Dr Cornelius Cooney†, anaesthesiology and intensive care medicine

Dr Barry Lyons†, paediatrics – anaesthesiology and critical care

Dr Mary Tumelty†, medicolegal research

Mr John Woods†, data protection

* Membership term will end in March 2022. All other members have either been reappointed, or their term has not yet finished. Any changes to the membership made in 2022 will be updated on the HRCDC website at https://hrcdc.ie/about-us/#Committee

† Appointed to the Committee in January 2021.

Secretariat team

Dr Emily Vereker, Programme Manager

Mr Jonny Barrett, Project Officer

Ms Caroline Byrne, Administrative Assistant

Appendix B

Summary of applications and decisions 2021

This appendix lists all applications submitted to the HRCDC in 2021 and all decisions made in 2021. 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.

i) New applications and decisions in 2021

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
21-001-AF1	Determination of HPV status of oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)	South Infirmary Victoria University Hospital (SIVUH)	Patrick Sheahan	Infection/cancer and neoplasms	Detection, screening and diagnosis	Conditional declaration	Declaration live
21-002-AF1	The Mega Randomised Registry Trial Comparing Conservative vs. Liberal OXygenation Targets (Mega-ROX)	Medical Research Institute of New Zealand (MRINZ)	Alistair Nichol	Respiratory	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
21-003-AF1	Investigating the Epidemiology of *Mycobacterium bovis* Infection in Humans	St James's Hospital	Tom Rogers	Infection	Aetiology	Conditional declaration	Declaration live
21-004-AF1	AP-recAP-AKI-03-01 (REVIVAL)	AM-Pharma B.V.	Alistair Nichol	Inflammatory and immune system/ renal and urogenital	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
21-005-AF1	Collaboration to reduce antimicrobial use and Resistance and identify opportunities for improvement and Awareness (CARA study)	National University of Ireland Galway	Akke Vellinga	Infection	Underpinning research/ aetiology	Conditional declaration	Declaration live
21-006-AF1/CSO	SARS-CoV-2 clusters and superspreading events in workplaces in Ireland: a retrospective analysis	University College Dublin	Carla Perrotta	Infection	Aetiology	Conditional declaration	Declaration live
21-007-AF1/COV	Irish National Pandemic Biological Sampling in critically ill COVID-19 patients (INPBS-COVID-19)	University College Dublin	Alistair Nichol	Infection	Aetiology	Conditional declaration	Declaration live
21-008-AF1	Evaluation of the 24/7 EEGTM SubQ system in subjects with uncontrolled epilepsy across two important common epilepsy syndromes	The Royal College of Surgeons in Ireland	Norman Delanty	Neurological	Evaluation of treatments and therapeutic interventions	Requested more information	Application withdrawn
21-009-AF1	Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability	Trinity College Dublin	Mary McCarron	Neurological/ mental health	Management of diseases and conditions/ 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
21-010-AF1	A Phase 3, Multi-Arm Multi-Stage Covariate-Adjusted Response-Adaptive Randomised Trial to Determine Optimal Early Mobility Training after Stroke (AVERT DOSE)	University of Limerick Hospitals Groups	Edel Hennessy, Fiona Lucey	Stroke	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
21-011-AF1/CSO	Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland	Economic and Social Research Institute	Seamus McGuinness	Infection	Underpinning research	Conditional declaration	Declaration live
21-012-AF1	Everolimus for drug-resistant seizures associated with GATOR1 complex epilepsies	Beaumont Hospital	Norman Delanty	Neurological	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
21-013-AF1	Mammographic breast density and breast cancer outcomes in a population-based breast screening programme	National Screening Service/Royal College of Surgeons in Ireland	Maeve Mullooly	Cancer and neoplasms	Detection, screening and diagnosis	Conditional declaration	Declaration live
21-014-AF1	PNOrate: Characteristics of pneumothorax associated with transthoracic percutaneous lung biopsy in standard of care	University Hospital of Besançon/St James's Hospital	Peter Beddy	Respiratory	Detection, screening and diagnosis/ management of diseases and conditions	n/a	Application withdrawn

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
21-015-AF1/CSO	UPCOM (Understanding and Preventing Covid-19 Outbreaks in Meat Processing Plants – Prepared for the Future)	Dublin City University/ University College Dublin	Andrew McCarren	Infection	Prevention of disease and conditions, and promotion of well-being	Conditional declaration	Declaration live
21-016-AF1	Medication review for frail older adults in primary care: use of the STOPPFrail (version 2) tool in nursing home populations	University College Cork	Elaine Walsh	Generic health relevance	Management of diseases and conditions/ health and social care services research	Conditional declaration	Declaration live
21-017-AF1/CSO	COVID-19 in Ireland: A retrospective analysis of general practice's contribution to assessment and testing	Irish College of General Practitioners	Michael O'Callaghan	Infection	Health and social care services research	Conditional declaration	Declaration live
21-018-AF1/CSO	Quantifying the effects of public health interventions in Ireland	National University of Ireland Galway	Alberto Alvarez-Iglesias	Infection	Aetiology/ Prevention of disease and conditions, and promotion of well-being	Conditional declaration	Declaration live
21-019-AF1	A study to determine the effects of a lymphoedema early intervention service in UHL	University Hospital Limerick	Anne Merrigan	Cancer and neoplasms	Aetiology/ evaluation of treatments and therapeutic interventions	Pending	

ii) Amendment requests and decisions in 2021

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Consent declaration status
19-020-AF2/ AMD1	BASELINE Study (The IDEA Study – a joint amendment to the BASELINE and SCOPE studies)	University College Cork	Elaine McCarthy, Deirdre Murray, Fergus McCarthy	Reproductive health and childbirth/ generic health relevance	Underpinning research/ aetiology	Amendment approved	Declaration live
19-070-AF2/ AMD1	Screening of Pregnancy Endpoints – SCOPE study (The IDEA Study – a joint amendment to the BASELINE and SCOPE studies)	University College Cork	Elaine McCarthy, Deirdre Murray, Fergus McCarthy	Reproductive health and childbirth	Detection, screening and diagnosis	Amendment approved	Declaration live
19-077-AF3/ AMD1	Irish Prostate Cancer Outcomes Research (IPCOR Study)	New Data Controller: University College Dublin	David Galvin	Cancer and neoplasms	Aetiology	Amendment approved	Declaration live
19-085-AF1/ AMD1	Validation of microRNAs as novel diagnostic and therapeutic targets in ischaemic brain injury (blood biomarkers to predict recovery from ischaemic stroke)	Royal College of Surgeons in Ireland	Shona Pfeiffer	Stroke	Aetiology/ detection/ screening and diagnosis	Amendment approved	Declaration live
19-086-AF1/ AMD1	Sepsis immunosuppression in critically ill patients	St James's Hospital	Ignacio Martin-Loeches	Inflammatory and immune system	Detection, screening and diagnosis	Amendment approved	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Consent declaration status
20-022-AF1/AMD1	PHIND Study	Queen's University Belfast/St Vincent's University Hospital/Belfast Health and Social Care Trust	Alistair Nichol	Respiratory	Detection, screening and diagnosis	Amendment approved	Declaration live
20-026-AF1-COV/AMD1	CHARTER-Irl Study	National University of Ireland Galway	John Laffey	Infection	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
20-031-AF1/AMD1	Resuscitation with 20% albumin fluid versus crystalloid fluid for septic shock treatment	St James's Hospital	Ignacio Martin-Loeches	Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Requested* more information	Declaration live
20-035-AF1/AMD1	Effectiveness of treatment for infusion in ICU patients with complicated influenza (IV Zanamivir Effectiveness Study)	GlaxoSmithKline Research and Development Ltd	Ignacio Martin-Loeches	Infection	Evaluation of treatments and therapeutic interventions/management of diseases and conditions	Pending*	Declaration live
20-036-AF1-AMD1	EPO-TRAUMA	Monash University/University College Dublin	Alistair Nichol	Injuries and accidents	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
21-004-AF1/AMD1	AP-recAP-AKI-03-01 (REVIVAL)	AM-Pharma B.V.	Alistair Nichol	Inflammatory and immune system/renal and urogenital	Evaluation of treatments and therapeutic interventions	Pending	Declaration live

*An initial decision by the HRCDC was made in 2021, and/or the amendment was approved in 2022.

iii) Applications submitted in 2019 and 2020, with HRCDC decisions in 2021

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Current status
19-005-AF2	St James's Hospital Cancer Biobank (SJHCB)	St James's Hospital	Richard Flavin	Cancer and neoplasms	Development of treatments and therapeutic interventions	Conditional declaration	Declaration live
19-020-AF2	BASELINE Study	University College Cork	Deirdre Murray	Reproductive health and childbirth/ generic health relevance	Underpinning research/ aetiology	Conditional declaration	Declaration live
19-027-AF3	Identification of predictive and prognostic biomarkers in triple negative breast cancer	National University of Ireland Galway/ Galway University Hospitals	Sharon Glynn	Cancer and neoplasms	Detection, screening and diagnosis	Conditional declaration	Declaration live
19-033-AF3	The Medical Emergencies Responder – Integration and Training (MERIT) programme study (Cardiac arrest and pre-hospital thrombolysis in Irish General Practice)	University College Dublin	Gerard Bury	Cardiovascular	Health and social care services research	Conditional declaration	Declaration live
19-044-AF2	Rare Kidney Disease (RKD) Registry and Bioresource (collaborative study with Firalis SAS – the HELICAL Study)	Trinity College Dublin/Firalis SAS	Mark Little	Renal and urogenital	Aetiology	Conditional declaration	Declaration live
19-045-AF2	The Gynaecological Cancer Bioresource (DISCOVARY Bioresource) and ongoing studies	Trinity College Dublin/St James's Hospital	Sharon O'Toole	Cancer and neoplasms	Aetiology/ detection, screening and diagnosis	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Current status
19-070-AF2	Screening of Pregnancy Endpoints – SCOPE study	University College Cork	Fergus McCarthy	Reproductive health and childbirth	Detection, screening and diagnosis	Conditional declaration	Declaration live
20-005-AF1/COV	The All-Ireland Infectious Diseases Cohort Project (AIID Cohort Project)	University College Dublin/St Vincent's University Hospital/ Mater Misericordiae University Hospital/ Cork University Hospital/Beaumont Hospital/Wexford General Hospital/ Children's Health Ireland	Patrick Mallon	Infection	Aetiology	Conditional declaration	Declaration live
20-035-AF1	Effectiveness of treatment for infusion in ICU patients with complicated influenza (IV Zanamivir Effectiveness Study)	GlaxoSmithKline Research and Development Ltd	Ignacio Martin-Loeches	Infection	Evaluation of treatments and therapeutic interventions/ management of diseases and conditions	Conditional declaration	Declaration live
20-039-AF1	A pilot multicentre randomised controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock	Galway University Hospitals, Saolta University Health Care Group	Bairbre McNicholas	Cardiovascular/ inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live

Appendix C

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 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 a being a corporate state body as defined in the Practice for the Governance of State Bodies[33] ("the Code") as published by the Department of Public Expenditure and Reform in August 2016, it nonetheless operates and conducts its business where relevant, appropriate and possible, in line with principles contained within 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[34] 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 which 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 (PDA). The

33 https://govacc.per.gov.ie/wp-content/uploads/Combined-Code-Online-Version.pdf
34 https://www.hrb.ie/fileadmin/2._Plugin_related_files/Publications/2021_publications/2021_Corp/Strategy_2021_2025_Health_research_making_an_impact.pdf

Secretariat business unit contributes to the delivery of the service plan and required quarterly reporting.

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 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 which sets out 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 the 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 weakness 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.

Renumeration of travel and expenses for members

The HRCDC comply with the Department of Public Expenditure 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 under 'Principles of HRCDC and Secretariat'.

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 in advance of the meeting. Where there is a conflict of interest, or potential conflict of interest, the HRCDC member will absent themselves from the relevant part of the meeting. This is further set out in the HRCDC standard operating procedures under 'Conflict of Interest'.

Business reporting and transparency

The HRCDC publishes an annual activities report in accordance with its statutory obligations under Regulation 12(1) of the Health Research Regulations 2018. 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 which 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 an appropriate period of time as 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 for records held by the HRCDC. The HRCDC receives and accesses records for the purpose of its business through a secure information technology (IT) 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 one freedom of information (FOI) request in 2021.

Notes

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