HRCDC
Health Research Consent Declaration Committee

Annual Activities Report

2020

Transparency
Trust
Confidence

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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
t 353 1 2345 257
www.hrcdc.ie
@hrcdc_Ireland

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Foreword

It is my pleasure to present the second Health Research Consent Declaration Committee (HRCDC) annual activities report.

Building on the work carried out in 2019, the HRCDC continues to play an important role within the health research regulatory environment. The Committee operates a rigorous consensus-based decision-making process, in order to ensure that patient and public interest in the research it considers is balanced with the data protection rights of the research participants. The Committee's strength lies in its ability to draw from a diverse pool of perspectives that each member contributes towards delivering robust and balanced decisions. Central to the work of the Committee is ensuring that there is full transparency around its role in fostering public and patient trust and confidence in health research being carried out in Ireland.

The year under review (2020) was an extraordinary and challenging year, with the world experiencing the full effects of the COVID-19 pandemic. The essential role of health and social care and its intrinsic link to health research are central to providing an evidence-based approach to understanding and managing the pandemic at national level, as it significantly impacts health and social systems and the wider economy. The research community responded rapidly to the pandemic by focusing on health research studies that addressed key questions, in order to enable the delivery of essential clinical care and treatment, and to understand the incidence of COVID-19.

It was recognised that COVID-19 research would present many challenges to researchers, including the ability to seek explicit consent from research participants, some of whom may lack decision-making capacity due to the severity of their disease. Such critical care research studies would require a consent declaration from the HRCDC. A proactive approach was taken by the HRCDC in March 2020 to fully support the research community and prioritise COVID-19-focused research studies, where a consent declaration would be required in the absence of explicit consent. This prioritisation exercise was formalised by the HRCDC through its collaboration with the COVID-19 National Research Ethics Committee (NREC). Both the HRCDC and the NREC worked

to deliver their respective and independent decisions on COVID-19 health research studies using an expedited, integrated review process.

It is notable that the Government's publication *Ethical framework for decision-making in a pandemic*[1] reinforces the importance of informed consent, coupled with the need to continue to adhere to the highest ethical standards and ensure that a patient-centred approach to healthcare is not compromised, even in the most challenging of circumstances. The Committee's work in 2020 has, and continues to be, aligned with and complementary to the principles of this ethical framework.

The HRCDC convened an unprecedented 17 times in 2020, which included both standard meetings and COVID-19-dedicated meetings. I would like to pay tribute to the enormous commitment, diligence, hard work and collegiality of the Committee members in progressing our work.

The transition to convening our meetings remotely was made seamless by the Secretariat and facilitated by the continued support of the Health Research Board (HRB), which hosts the Secretariat. We very much appreciate the strong support of the HRB for our work.

I want to particularly acknowledge and thank our Secretariat, comprising Dr Emily Vereker, Mr Jonny Barrett and Ms Caroline Byrne, for their very dedicated, knowledgeable and professional support for the Committee's work and for their proactive engagement with applicants and the wider research community in relation to the HRCDC's remit.

I thank the Department of Health for its continued support for the Committee. I would also like to thank the Data Protection Commission for providing advice and guidance to the HRCDC and the Secretariat on matters as they arise and pertain to the Health Research Regulations. Importantly, there has been a significant amount of consultation and collaborative work between the Secretariat, the Department of Health, and the Research and Development Unit of the Health Service Executive (HSE) to develop guidance for researchers on the amendments[2] to the Health Research Regulations made in January 2021.

Looking ahead, we will continue to prioritise COVID-19 research studies in addition to considering all other new and existing research studies, including COVID-19 research studies, seeking a consent declaration. While our current and future applicants consider the new amendments as they may apply to research, the Secretariat will work closely with researchers to provide support and guidance where possible, as it pertains to pending applications.

Both the Committee and the Secretariat look forward to continuing to engage with our health research stakeholders and to building new relationships with national and international bodies to support health research in Ireland.

Brigid McManus
Chairperson

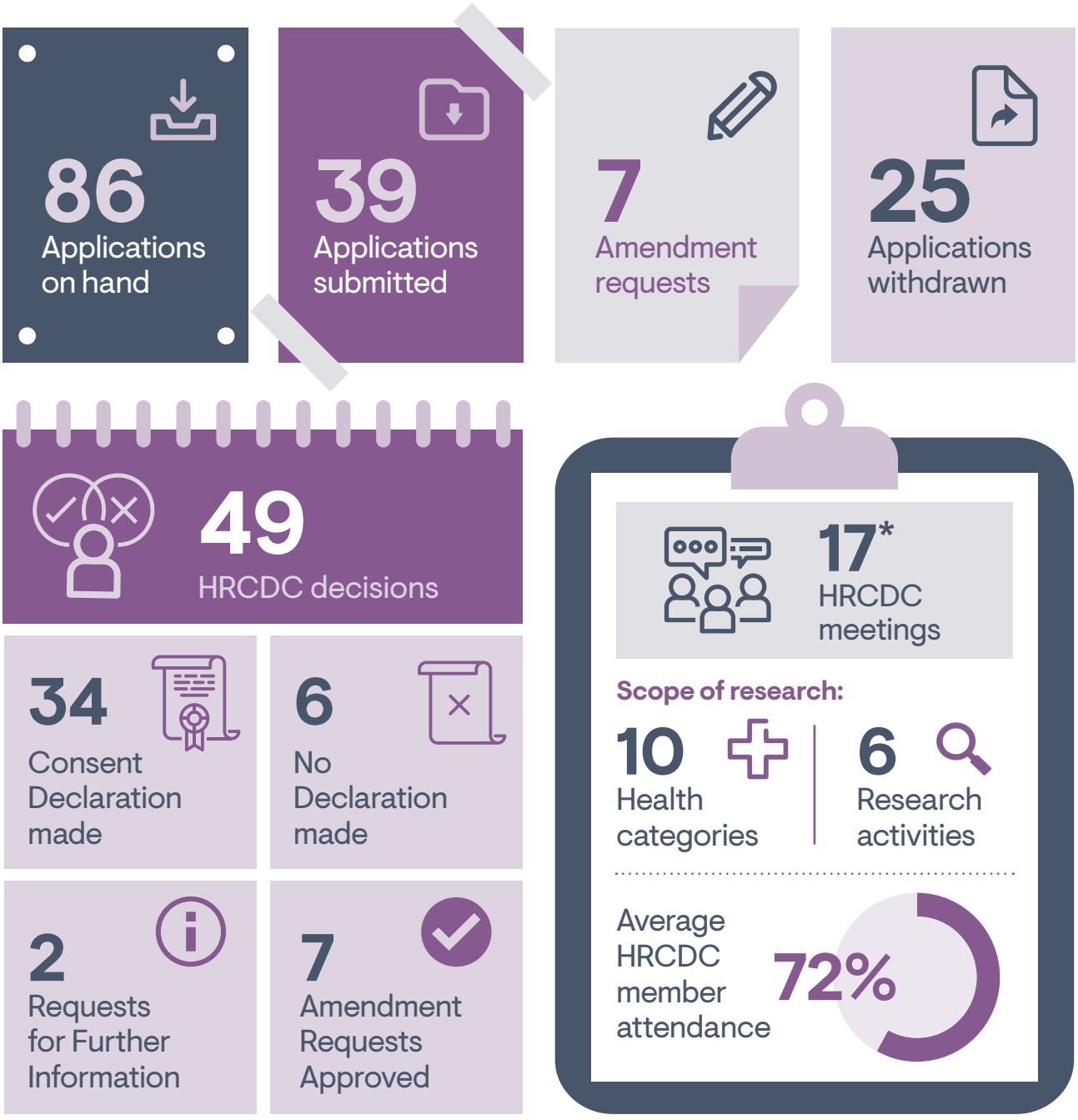
In 2021, the European Data Protection Board[3] has stated:

> 'When relying on another legal basis in Article 6 other than consent and one of the other exemptions in Article 9 (2) GDPR, the 'ethical' requirement of informed consent for participation in the medical research project will still have to be met. In the GDPR-framework, this can be perceived as one of such additional safeguards as foreseen in Article 89(1) GDPR that should be in place when processing personal data for scientific research purposes.'

In 2020, the Department of Health[4] has stated:

> 'In pandemic situations the usual protections afforded to research participants should be upheld, as should standards for research integrity. The principles of fairness, reciprocity and privacy are most relevant in this context.'

2020 snapshot



* One meeting had 6 members in attendance and was not quorate. No decisions were made at this meeting.

1 The Health Research Regulations

The Health Research Regulations[5] ('Regulations') were adopted on 8 August 2018 and, for the first time in Irish law, regulations to safeguard the use of personal data for research were implemented. Building on existing clinical and corporate governance safeguarding practices, the Regulations bring consistency and transparency to the fore of health research, in order to engender public and patient trust in the research environment in Ireland. These Regulations were amended in April 2019 (S.I. 118 of 2019) and have recently been further amended in January 2021 (S.I. 18 of 2021).

Data protection and privacy rights, and the ability of individuals to self-determine the use of their data for health research purposes, are essential legal and ethical rights of individuals. The Regulations provide for a mandatory requirement for explicit consent – consent that is informed and recorded, as a safeguard, when processing personal data for health research purposes.

The principle of informed consent for healthcare and research is grounded in many international legal instruments and policies. The European Convention on Human Rights and Biomedicine of 1997,[6] more commonly known as the Oviedo Convention, was the first internationally legally binding document to formalise the long-established rule that medical treatment "may only be carried out after the person concerned has given free and informed consent" and where "appropriate information" has been given to the participant in advance of treatment. This principle holds true for consent for health research.

The doctrine and meaning of informed consent are further enshrined in the Declaration of Helsinki (2013) under Principle 26.[7] In 2016, the World Medical Association set out further principles of informed consent more specifically in relation to the collection, storage and use of personal data for health databases and biobanks.[8] These principles are further recognised by the European Commission, which established the General Data Protection Regulations (GDPR; Regulation (EU) 2016/679),[9] having stated that "Informed consent is the cornerstone of research ethics."[10]

It is notable that in 2021, the European Data Protection Board[11] provided a formal opinion on the importance of consent as a safeguard, where consent is not the legal basis for processing data for health research purposes.

However, as is recognised in Ireland and other countries, in certain situations it is not feasible to obtain explicit consent from research participants for the use of their data in health research. It is for this reason that the Regulations provide for a transparent and well-defined statutory consent declaration process. This process is overseen by a Ministerial appointed Health Research Consent Declaration Committee (HRCDC) to enable researchers to lawfully process personal data for research in the absence of explicit consent, subject to meeting all the requirements under the Regulations, primarily that the HRCDC must be satisfied that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the data subject.

2 The Health Research Consent Declaration Committee

The HRCDC is an independent statutory body established under the Regulations and is accountable to the Minister for Health. The Regulations provide for the HRCDC to make a consent declaration to a data controller organisation, or joint data controllers, to allow the 'processing' and use of personal data for health research purposes in cases where obtaining explicit consent from individuals to process their personal data is not practicable or possible.

The consent declaration can only be made where there are significant countervailing public interest grounds in terms of carrying out research that outweighs the public interest in requiring explicit consent from the research participant.

In 2020, the Committee comprised 14 members. Currently, it comprises 17 members, following the recent appointment by the Minister of Health of an additional 4 new members, and the resignation of 1 member. The members are widely representative of the health research community. Of the 17 members, 3 are representative of patients and the public.

The HRCDC collectively draws upon a diverse range of expertise and experience in areas such as critical care medicine and research, anaesthesiology, general practice medicine, socioeconomic health research, disability research, sociology, public policy, statistical and genomic research, data protection, and medicolegal aspects of healthcare. The patient and public involvement (PPI) representative members bring to bear lived experiences and perspectives as members of the public, as carers and also as users of the healthcare system in Ireland.

The HRCDC is tasked with making informed and balanced decisions in the interest of patients and the public regarding the use of personal data without explicit consent from the individuals whose data are being used for health research purposes. The consensus-based decisions of the HRCDC benefit from, and are informed by, the different perspectives and views of all members, including the PPI members.

A list of the HRCDC members is listed in Appendix A. Full member profiles can be viewed on the HRCDC website: https://hrcdc.ie/about-us/.

3 HRCDC response to COVID-19

In early March 2020, the HRCDC proactively communicated to the research community that it was committed to prioritising COVID-19-focused research studies seeking a consent declaration.

The HRCDC was cognisant that health research studies on COVID-19 were a matter of national and international importance and were urgently required in order to provide a full understanding of the novel coronavirus SARS-CoV-2. It committed to rapidly review COVID-19-related research applications seeking a consent declaration, and it convened additional meetings to deliver rapid decisions. Given the serious disease profile of COVID-19 and its potential to leave individuals with diminished decision-making capacity due to their physical and/or mental health status, it was evident that some research studies which relied on participant consent would require a consent declaration for the use of participants' data for important COVID-19 research studies.

From April to September 2020, the HRCDC's process was formally integrated with the ministerially appointed National Research Ethics Committee for COVID-19 (NREC COVID-19).[12] In line with a recommendation in the World Health Organization's *A Coordinated Global Research Roadmap,*[13] the HRCDC and NREC COVID-19 delivered rapid decisions for both consent declarations and ethics approval for COVID-19-related health research, simultaneously and independently, through an integrated expedited process.

The HRCDC Secretariat worked closely with the National Office for Research Ethics Committees to ensure that the operations of the integrated review process were efficient and streamlined, and were underpinned by a single integrated NREC-HRCDC application form and coordinated processes. The average time from application submission to receipt of a HRCDC decision letter was 13 business days, when applying through the integrated HRCDC/NREC COVID-19 review process.

4 HRCDC activities

4.1 HRCDC meetings

The HRCDC convened an unprecedented 17 times* in 2020. Between April and September, the HRCDC convened an additional six times outside of the already prescheduled meetings, specifically to expedite consideration of COVID-19-related research applications for studies seeking a consent declaration.

The Regulations require a quorum of at least seven members at a meeting. The average attendance at the meetings was 10 members.

Number of meetings	**17**
Average number of members per meeting	**10**
Percentage attendance	**72**

* One meeting had six members in attendance and was not quorate. No decisions were made at this meeting.

4.2 Applications submitted

At the start of 2020, there were 86 applications on hand. 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 Parliament (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 explicit consent[14] under the Regulations (submission of Application Form 2 - AF2).

In 2020, the HRCDC received 39 applications seeking a consent declaration for new research studies (submission of Application Form 1 - AF1). Of these 39 applications, 6 were subsequently withdrawn in 2020 after further engagement with applicants, where it was determined that a consent declaration was not required.

Twenty-three were COVID-19-focused applications, 14 of which were submitted through the NREC COVID-19/HRCDC integrated rapid review process.

Seven applications requesting an amendment to a live consent declaration were received; of these, four were COVID-19 focused.

Applications submitted in 2020		COVID-19 breakdown
New applications for consent declarations	**39**	23
Amendment requests for live consent declarations	**7**	4
Total submissions	**46**	**27**

In 2020, a total of 25 applications (2019 and 2020 submissions) were either withdrawn by the applicant after further consultation with the Secretariat and their institutional data protection officers or equivalent, or were deemed invalid by the Secretariat for not meeting the minimum requirements as set out in the Regulations.

Applications withdrawn or invalid in 2020

7 AF1*	**14** AF2±	**4** AF3†	**25** TOTAL

* Applications for new research that commenced following enactment of the Regulations - consent is not being sought.

± Applications under transitional arrangements - consent had been obtained for the research under the previous Data Protection Directive 95/46/EC of the European Parliament.

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

4.3 **HRCDC decisions**

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

The HRCDC gave 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. It continued to consider these applications despite the increased volume of COVID-19 and other new research studies seeking consent declarations.

Seven consent declarations were made for AF2 research studies and five consent declarations were made for AF3 research studies.

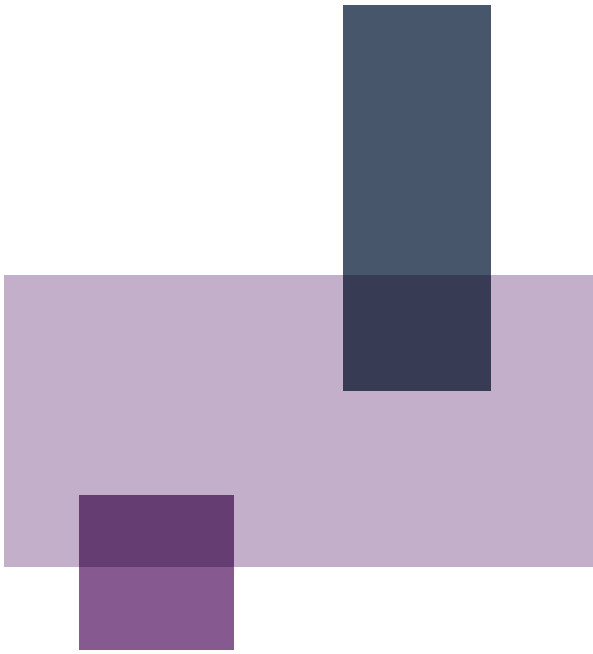
In 2020, the HRCDC made a total of 34 consent declarations, 31 of which had specific conditions attached in order to enhance data protection safeguarding measures.

All seven amendment requests were approved by the HRCDC.

Of the total consent declarations made, 12 consent declarations were made for COVID-19 research studies in 2020.

Six applications considered by the HRCDC did not receive a consent declaration and in the case of two applications, at the end of 2020, the final decision of the HRCDC was deferred pending a formal request for further information. Where the decision was deferred pending further information from the applicant, and where the responses were provided, the final decision of the HRCDC was made at the next available meeting.

At the time of publication of this report, all AF3 applications submitted have been considered by the HRCDC. Of the AF2 applications submitted, 23 are pending consideration. Since its establishment, the HRCDC has made a total of 56 consent declarations.



Decisions made in 2020	AF1*	AF2±	AF3†	TOTAL	COVID-19 breakdown
Declaration made	22	7	5	34	12
No declaration	6	0	0	6	4
Request for further information	1	0	1	2	0
Amendment approvals	1	6	0	7	4
Total decisions	**30**	**13**	**6**	**49**	**20**

* Applications for new research that commenced following enactment of the Regulations - consent is not being sought.

± Applications under transitional arrangements - consent had been obtained for the research under the previous Data Protection Directive 95/46/EC of the European Parliament.

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

4.4 Scope of research and geographical spread of data controllers

In 2020, the HRCDC received applications across a spectrum of biomedical and health research areas, spanning many health categories and research activities. The Secretariat carried out a categorisation exercise based on the UK Clinical Research Collaboration (UKCRC) Health Research Classification System.[15] The following infographic illustrates the diversity of health research studies across Ireland that submitted an application for a consent declaration from the HRCDC in 2020. (Please note that applications may fall into more than one health category and research activity.)

Diversity of health research*

Health categories			
Cardiovascular **3**	Cancer and neoplasms **6**	Injuries and accidents **2**	
Neurological **1**	Infection **24**	Generic health relevance **2**	Oral and gastrointestinal **2**
Respiratory **4**	Inflammatory and immune system **5**	Mental health and immune system **1**	

Research activities			
Aetiology **20**	Management of diseases and conditions **5**	Underpinning research **1**	
Health and social care services research **6**	Evaluation of treatments and therapeutic interventions **12**	Detection, screening and diagnosis **3**	

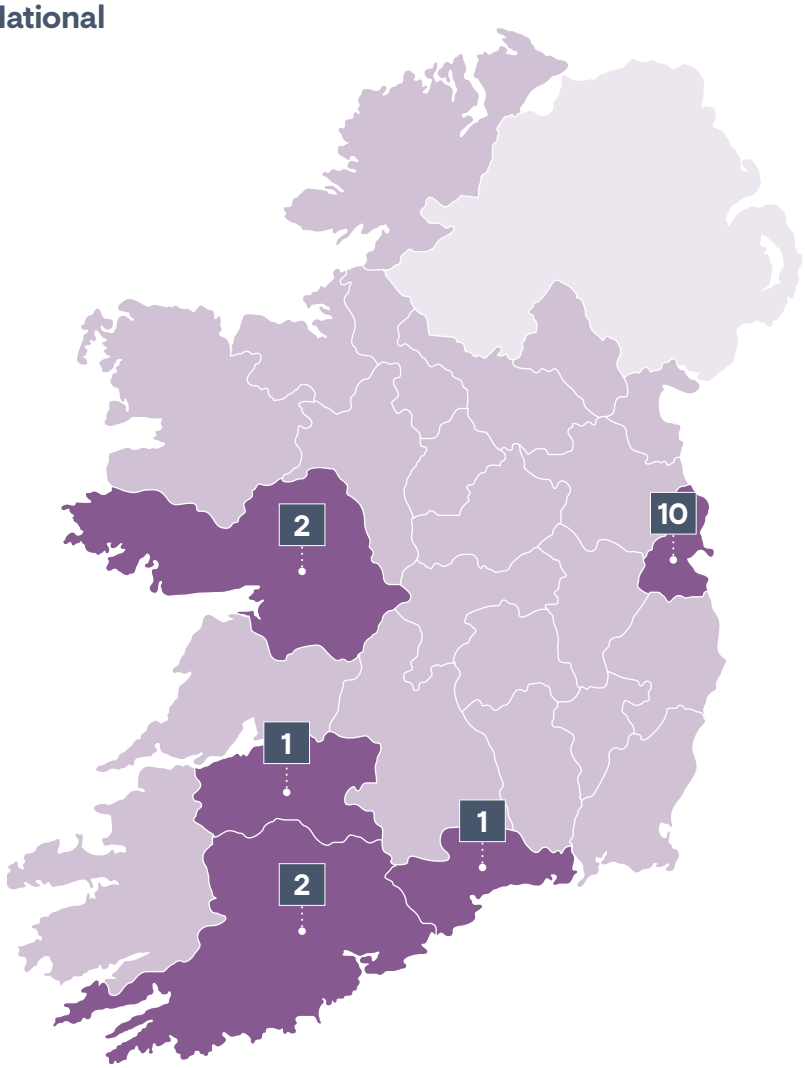
* Some research studies have been categorised under one or more health categories and research activity areas.

The data controllers across the spectrum of health research studies seeking a consent declaration were from many geographical regions across Ireland. While a consent declaration is made to a data controller of a research study, many of the research studies involved other clinical and academic research organisations within Ireland and internationally, acting as data processors for the study.

2020 saw a significant increase in the number of 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.

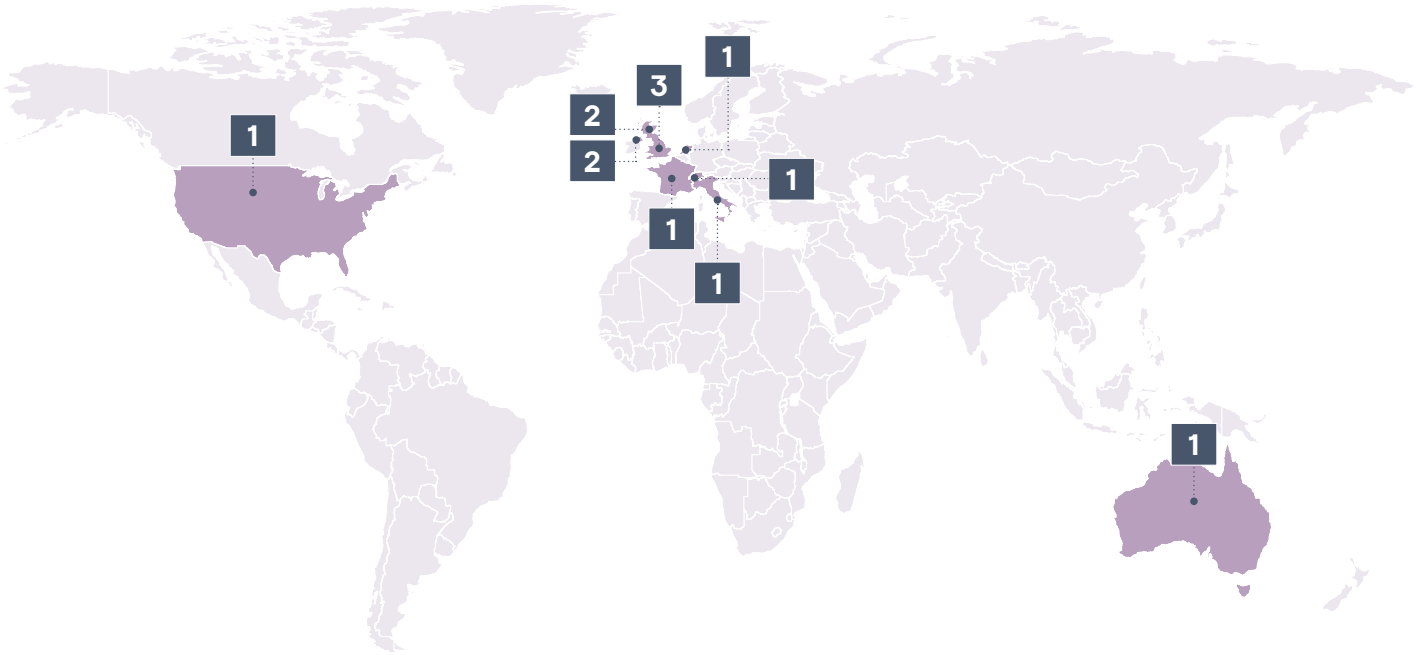
Geographical spread of national and international data controllers

National



National	Institutions
Dublin	10
Cork	2
Galway	2
Limerick	1
Waterford	1

International



International	Institutions
England	3
Northern Ireland	2
Scotland	2
France	1
The Netherlands	1

International	Institutions
Switzerland	1
Italy	1
United States	1
Australia	1

The implementation of a consent declaration, including any conditions attached, made to an international data controller who is seeking to obtain the personal data of Irish participants for health research purposes must be enforceable in Ireland. This may be challenging, depending on the jurisdiction and data protection safeguards in place.

In the interest of safeguarding research participants' data protection rights in the jurisdiction of Ireland, there should be accountability regarding compliance with a consent declaration.

The HRCDC must be satisfied that there is a data controller or data processor organisation in Ireland that is willing to be jointly responsible and accountable for the implementation of, and compliance with, the consent declaration. Often, the organisation may be a lead clinical site involved in coordinating data collection for the research study. The onus is on the parties involved in the research study to ensure that appropriate arrangements are in place to ensure that the research participants' data protection rights are upheld under the consent declaration.

5 Enhancing data protection safeguards

Over the past year, the HRCDC has built upon its experience and learnings following its establishment in 2019. It continues to ensure that, when considering applications, there is a consensus-based approach to all decisions made. As part of its deliberative process, 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 enhance 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, in order 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.

The following subsections elaborate on some of the more specific conditions that the HRCDC may attach to a consent declaration, or recommendations made to an applicant in order to bolster data protection safeguards. The implementation of conditions attached to a declaration, and any recommendations made, is a reporting requirement for the applicant as part of an annual review.

5.1 Transparency measures

Transparency is one of the key principles of data protection legislation, thus ensuring that an individual has autonomy and control over the use of their data. There are many means by which transparency measures can be enhanced, such as through the use of publicity campaigns, public notices, updating websites and other public platforms. In doing this, particular consideration should be given to using the most appropriate communication platforms to maximise the opportunity for the public and patients to become aware of a particular research study, as it may relate to them. Ultimately, it should be transparent to an individual how their personal health data may be used in a research environment, and how they can exercise their data protection rights in accordance with Irish data protection legislation, including the Regulations.

5.2 Safeguards for individuals who lack decision-making capacity

Many applications submitted to the HRCDC are seeking consent declarations because the research participants may have diminished decision-making capacity, either temporarily or permanently, as a result of their physical or mental health status and being unable to provide consent for health research. The HRCDC must be satisfied that, where possible, the will and preferences of the individuals who lack decision-making capacity are placed at the forefront of the research, and that all appropriate data protection safeguards are in place. Once an individual regains decision-making capacity, it is expected that deferred consent is obtained as soon as is appropriate. Communicating unambiguous and transparent information is fundamental to ensuring that the individual is fully empowered to make decisions regarding their participation in the research study, and to enabling them to exercise their data protection rights, such as withdrawing from the study if they wish to do so.

While there is no lawful basis for next-of-kin, friends or relatives to provide consent for the use of an individual's personal data for health research purposes, the HRCDC considers the provision of proxy assent an important safeguard. An identified proxy should be an individual who can communicate on behalf of the research participant and understands their will and preferences.

Where a study participant continues to lack capacity for a prolonged period of time, and where proxy assent remains in place, the researcher should seek confirmation from the individual who provided assent that they wish for the study participant's personal data to continue to be processed as part of the study. Confirmation should be obtained at an appropriate stage of the study - i.e. at a stage that does not cause undue distress or harm to the individual concerned.

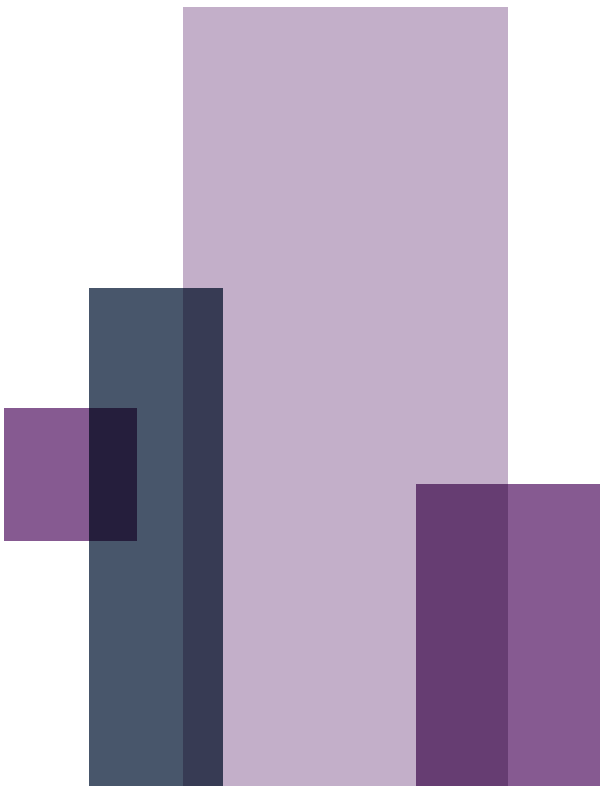
5.3 **Importance of patient and public involvement**

The HRCDC views the inclusion of patients and the public in research as 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, rather than 'to', 'about' or 'for' them, as defined by the National Institute for Health Research and endorsed by the Health Research Board (HRB).

PPI is important, as it helps to disseminate research findings beyond academia and enhance the level of transparency of health research. Importantly, in January 2021, an amendment to the Health Research Regulations was made, which specifically requires researchers to detail in their application to the HRCDC any consultations that have taken place with patients and the public regarding the health research study in question.

6 HRCDC observations on obtaining consent

Since the HRCDC was established in March 2019, and as it matured into its role in 2020, it has considered 75 applications and amendments, many of which have presented a case to the HRCDC as to why obtaining consent from individuals, or re-consenting individuals, was not practicable or possible. Apart from cases where an individual lacks decision-making capacity, there may be other legitimate and clear rationales as to why consent or re-consent cannot be obtained.



The context and nuances of each research study are reviewed holistically by the HRCDC, and on a case-by-case basis. A number of influencing factors may be proposed by researchers to explain why consent or re-consent cannot be sought:

- the number of participants involved in the study
- the vulnerability of participant groups
- infection control measures mitigate the ability to obtain consent at a point in time
- type of study
- nature and volume of data being processed
- ethical considerations
- no follow-up care and engagement with research participants to present an opportunity to consent or re-consent
- data being processed was collected for care and treatment at an earlier point in time
- potential to compromise the integrity of the study by decreasing the validity or quality of the data.

When the HRCDC is considering the rationale for not seeking consent, citing insufficient resources alone may not be a sufficient reason for not seeking consent. Equally, assuming that seeking consent will cause potential distress or annoyance, or general reasons focused on impracticalities, may not be adequate reasons. Any reason for not seeking, or attempting to seek, consent should be fully substantiated.

Engagement with patient and public representatives and/or appropriate patient advocacy groups to determine whether seeking consent is feasible or ethical is advisable, in order to ensure that the perspectives and views of those unable to provide consent are fully understood.

7 Spotlight on research

In 2020, 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 2020 is illustrated in section 4.3 of this report. Further details can be found in Appendix B and also on the HRCDC website.

Notably, 58% of the applications and amendments submitted in 2020 were in relation to COVID-19-focused research studies, which is indicative of the concerted national efforts to understand the epidemiology of COVID-19, to accelerate new treatments, and improve clinical outcomes for COVID-19 patient groups. The research studies comprised single, dual and multi-site collaborative studies across Ireland, as well as international studies involving one or more Irish clinical sites.

To give a flavour of the nature of the applications the HRCDC has considered, it is worth highlighting some specific studies that received a consent declaration from the HRCDC in 2020. Details as follows:

- The HRCDC made a consent declaration to the Department of Health, and University College Cork, which are joint data controllers for the Irish arm of the WHO-led Solidarity Trial[16] (HRCDC Ref 20-013-AF1/COV). This is one of the largest international randomised clinical trials for COVID-19, focused on evaluating potential COVID-19 treatments. Ireland is one of 30 participating countries, with the Irish arm of the trial led by Professor Joe Eustace, University College Cork HRB-Clinical Research Facility.
- The HRCDC approved a series of amendment requests for an existing consent declaration made for the international REMAP-CAP Trial[17] (HRCDC Ref 19-004-AF2) led by Professor Alistair Nichol, University College Dublin Clinical Research Centre, St. Vincent's University Hospital, Dublin. REMAP-CAP uses an innovative trial design to efficiently evaluate multiple treatments simultaneously for community-acquired pneumonia. Amendments to the existing consent declaration were sought; these included new hospital sites joining the trial; specific domains for COVID-19 treatments; and the need to adapt the protocol for seeking proxy assent and deferred consent from research participants who lack decision-making capacity due to challenges of highly infectious hospital settings.
- The HRCDC made a consent declaration to University College Cork (HRCDC Ref 20-034-AF1) in order to enable Professor Ivan Perry, School of Epidemiology and Public Health to process health data for the purpose of estimating the number of problematic opiate drug users, as well as trends in problematic opiate drug use, in the Republic of Ireland from 2015 to 2019. This is a retrospective, observational research study funded by the HRB. It aims to compare trends in opiate use over time and inform government, policy-makers and service providers about the scale of the problem and how to direct resources in various regions in Ireland.

In the case of many of the COVID-19 studies it is notable that the more traditional face-to-face consent and assent protocols used to engage with research participants had to be readjusted due to the implementation of strict infection control measures, coupled with the critically ill status of patients, visiting restrictions, and time-sensitivity in relation to commencing treatment. Verbal consent and proxy assent were obtained by telephone, often using a specific script to ensure the consistency and clarity of information being provided. As an additional measure, some studies ensured that participants' verbal consent/assent was witnessed.

8 The Secretariat

8.1 Secretariat supports

The staffing resources for the HRCDC Secretariat service have been provided by the HRB since the Secretariat's operations commenced in January 2019. The Secretariat continues to support the HRCDC in all aspects of its work and acts as a central point of contact for the research community on behalf of the HRCDC. It is responsible for the application process that enables researchers to apply for consent declaration from the HRCDC.

Given the complex nature of research studies and the multifaceted data processing activities that are carried out in any given research study, the Secretariat continues to engage closely with and guide existing and potential applicants. Often, further clarification is sought, and applicants are requested to elaborate on information provided as part the Secretariat's procedures for processing applications. This close liaison with applicants is a core function of the Secretariat and ensures that the HRCDC is in receipt of clear and detailed information for the purpose of its decision-making role under the Regulations.

On behalf of the HRCDC, the Secretariat further monitors the implementation of all consent declarations made to the data controllers for a health research study. Much of this oversight is achieved through the completion of the annual review each data controller must submit on the anniversary of when the consent declaration was made, and also for every year or part year for which the consent declaration is valid. This is a standard condition of a consent declaration. In 2020, the Secretariat received 20 annual reviews for the consent declarations made in 2019. These annual reviews were deemed acceptable, demonstrating implementation of the consent declaration and any conditions attached.

The transparency of the business of the HRCDC, which is essential for public trust, is enhanced 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.

8.2 Secretariat stakeholder activities

2020 was a particularly busy period for the Secretariat, as it engaged with a number of key national stakeholder bodies on various initiatives directly related to or peripheral to the work of the HRCDC.

The Secretariat worked closely with the National Office for Research Ethics Committees to operationalise a seamless integrated rapid review process that researchers could avail of in order to apply for both a consent declaration and ethics approval simultaneously.

It worked with the Health Service Executive (HSE) through a dedicated working group to contribute to the revision and development of the Research Consent Policy.

The Secretariat has had significant collaborative engagement with the Department of Health, the HSE, and the HRB to collectively develop clear and succinct guidance for researchers on the recently made amendments[18] to the Regulations. Importantly, this guidance was developed in consultation with the Data Protection Commission (DPC).

In September 2020, both the Secretariat and the DPC were invited to attend the Health Research Data Protection Network for a discussion on pertinent research topics in the context of data protection, the Regulations, and the consent declaration process.

Given the composition of the HRCDC membership, which includes public and patient involvement (PPI) representatives, and the importance of their contribution to the work of the HRCDC, the Secretariat worked with the HRCDC's PPI representatives to respond to the PPI mapping project[19] being conducted by the Irish Platform for Patient Organisations, Science and Industry (IPPOSI).

9 Key objectives for 2021

As the HRCDC looks ahead to 2021, it will continue to ensure that its regulatory work is contributing to health data being used in a transparent, trusted and safeguarded manner, and in the public interest. The HRCDC will communicate the business of the HRCDC with transparency and clarity through contact and engagement with the public, patient advocacy groups, research forums and networks, and the wider research community.

With the support of the Secretariat, 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.

The HRCDC will progress applications that are currently pending a decision, while continuing to prioritise new and COVID-19-related research studies seeking a consent declaration.

The Regulations have only recently been amended (in January 2021) (S.I 18 of 2021) and it is yet to be seen how these amendments will impact on the number of applications the HRCDC will need to consider. The amendments are a welcome and positive development for the Regulations; they will introduce clarity for researchers, and they will also allow certain derogations from the need to obtain explicit consent, subject to specified data protection provisions.

The HRCDC will build upon its existing stakeholder relationships with the Department of Health, the HSE, the DPC, and other national and international stakeholders, as necessary, to support and drive health research policy and robust governance in research. It looks forward to engaging collaboratively with new stakeholders, such as the Central Statistics Office (CSO), that are equally committed to working with the research community as it facilitates researcher access to the national COVID-19 Data Research Hub.

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 are 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
Prof. Malcolm Kell,** consultant surgeon oncology

*Appointed in January 2021.
**Stepped down from the HRCDC in January 2021.

Secretariat

Dr Emily Vereker, Programme Manager
Mr Jonny Barrett, Project Officer
Ms Caroline Byrne, Administrative Assistant

Appendix B

Summary of applications and decisions 2020

The following appendices list all applications submitted to the HRCDC in 2020 and all decisions made in 2020. This is an abridged summary for the purpose of this annual activities report. A comprehensive list with further details 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) Summary of new applications and HRCDC decisions in 2020

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-001-AF1	A retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) Programme database	Royal College of Surgeons in Ireland	Jack Laffan	Cardiovascular	Health and social care services research	Conditional declaration	Declaration live
20-002-AF1	Epidemiology of non-muscle invasive bladder cancer in Ireland, and trends and outcomes of the use of intravesical BCG in its treatment	University Hospital Waterford	Padraig Daly	Cancer and neoplasms	Evaluation of treatments and therapeutic interventions/ aetiology	n/a	Application withdrawn
20-003-AF1	Blood brain barrier (BBB) disruption and dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) changes in severe traumatic brain injury (TBI)	Beaumont Hospital	Gerard Curley	Injuries and accidents	Detection, screening and diagnosis	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-004-AF1	Outcome for older people with cognitive impairment attending the emergency department	Tallaght University Hospital	Sean Kennelly	Neurological	Health and social care services research	Declaration made	Declaration live
20-005-AF1/COV	The University College Dublin Infectious Diseases Cohort Project (COVID-19 cohort)	St. Vincent's University Hospital/ Mater Misericordiae University Hospital/ University College Dublin	Patrick Mallon	Infection	Aetiology	Pending	
20-006-AF1/COV	A randomised double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness	Royal College of Surgeons in Ireland	Gerard Curley	Infection/ Respiratory/ Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
20-007-AF1/COV	Integration of data analytics in critically ill patients with COVID-19 infection (INTEGRATOMICS)	St James's Hospital	Ignacio Martin-Loeches	Infection	Management of diseases and conditions/ aetiology	No declaration	n/a
20-008-AF1/COV	Clinical, laboratory and radiological characteristics as predictors of outcome in patients with COVID-19	Tallaght University Hospital	Ana Rakovac	Infection	Aetiology	Conditional declaration	Declaration live
20-009-AF1/COV	Progression of imaging findings in COVID-19	St James's Hospital	Michael Courtney	Infection	Aetiology	n/a	Application withdrawn

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-010-AF1/COV	COVID-IYON Study	University Hospital Limerick	Linda Coate	Cancer and neoplasms/ Infection	Aetiology/Health and social care services research	Conditional declaration	Declaration live
20-011-AF1/COV	Development of a validation panel to compare SARS-CoV-2 antibody assays	Beaumont Hospital	Mary Keogan	Infection	Detection, screening and diagnosis	n/a	Application withdrawn
20-012-AF1/COV	COVID-19 Bioresource	St James's Hospital	Clíona Ní Cheallaigh	Infection	Underpinning research/ Aetiology	Conditional declaration	Declaration live
20-013-AF1/COV	WHO Solidarity Trial	Department of Health, Ireland/ University College Cork	Joe Eustace	Infection	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
20-014-AF1/COV	Clinical characteristics and outcomes of hospitalised older people during the COVID-19 pandemic	Tallaght University Hospital	Sean Kennelly	Generic health relevance	Health and social care services research	Pending	
20-015-AF1-COV	The ESMO-CoCARE Registry for patients with a malignancy who are diagnosed with COVID-19	European Society for Medical Oncology (ESMO)	Maccon Keane	Cancer and neoplasms/ Infection	Aetiology/ Health and social care services research	No declaration	n/a
20-016-AF1-COV	Clinical characteristics of dysphagia and communication difficulties among hospitalised adults with COVID-19 in Ireland: an observational cohort study	Trinity College Dublin	Julie Regan	Infection/Oral and gastrointestinal	Aetiology/ Management of diseases and conditions	No declaration	n/a

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-017-AF1-COV	TERAVOLT: Thoracic cancers international COVID-19 collaboration	The IRCCS National Cancer Institute/Vanderbilt University Medical Centre/ University Hospital Lim erick (Lead Irish Data Controller)	Linda Coate	Cancer and neoplasms/ infection	Aetiology	n/a	Application withdrawn
20-018-AF1-COV	EIR-CS-003 (Human Convalescent Plasma Study)	St. Vincent's University Hospital	Mark Coyne	Infection	Evaluation of treatments and therapeutic interventions	n/a	Application withdrawn
20-019-AF1-COV	A Review of Irish patients presenting with acute coronary syndrome during the COVID-19 pandemic – The SARS-CoV-2 ACS Study	St James's Hospital	Stephen O'Connor	Infection/ cardiovascular	Aetiology	Pending	
20-020-AF1-COV	Irish Coronavirus Sequencing Consortium	Teagasc	Paul Cotter	Infection	Aetiology	Conditional declaration	Declaration live
20-021-AF1-COV	ReCaP: Rectal cancer management during the COVID-19 pandemic	University Hospital Waterford	Fiachra Cooke	Cancer and neoplasms	Management of diseases and conditions	No declaration	n/a
20-022-AF1	PHIND Study	Queen's University Belfast/St. Vincent's University Hospital/Belfast Health and Social Care Trust	Alistair Nichol	Respiratory	Detection, screening and diagnosis	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-023 AF1-COV	Dysphagia and communication difficulties amongst adults hospitalisedwith COVID-19 across Ireland (DISCOVER): A multi-site retrospective cohort study	Trinity College Dublin	Julie Regan	Infection/ Oral and gastrointestinal	Aetiology/ Management of diseases and conditions	Conditional declaration	Declaration live
20-024 AF1-COV	Genetics of Mortality in Critical Care (GenOMICC)	St. Vincent's University Hospital/University of Edinburgh/NHS Lothian Health Board	Alistair Nichol	Infection	Aetiology	Conditional declaration	Declaration live
20-025-AF1-COV	Using contact tracing data to gain insights into the epidemiology of COVID-19 infection in Ireland	University College Dublin	Conor McAloon	Infection	Aetiology	Declaration made	Declaration live
20-026-AF1-COV	CHARTER-Irl Study	NUI Galway/Galway University Hospital	John Laffey	Infection	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
20-027-AF1	Immune dysfunction in acute brain injury	Beaumont Hospital	Ger Curley	Inflammatory and immune system	Aetiology	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-028-AF1	Non-interventional study to assess the safety profile of idelalisib in patients with refractory follicular lymphoma (FL)	Gilead Sciences Europe Ltd	Elisabeth Vandenberghe, Perera Meegahage Ratnakanth	Cancer and neoplasms	Evaluation of treatments and therapeutic interventions	n/a	Application withdrawn
20-029-AF1	Models of care for people ageing with an intellectual disability	Trinity College Dublin/ National Disability Authority	Fintan Sheerin	Generic health relevance	Health and social care services research	No declaration	n/a
20-030-AF1	The 'ASTONISH' Study	INOTREM S.A.	INOTREM S.A.	Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
20-031-AF1	Fluid resuscitation with 20% albumin versus crystalloid septic shock	St James's Hospital	Ignacio Martin-Loeches	Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
20-032-AF1	Molecular epidemiology of mumps in Dublin, Ireland	St James's Hospital	Deirdre Broderick	Infection	Aetiology	Requested more information	Application withdrawn
20-033-AF1	Epidemiologic study of LGV	St James's Hospital	Deirdre Broderick	Infection	Aetiology	No Declaration	n/a
20-034-AF1	A capture-recapture study to estimate the prevalence of problem opiate use in Ireland (2015–2019)	University College Cork	Ivan Perry	Mental health	Aetiology	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
20-035-AF1	Clinical effectiveness of treatment in a cohort of ICU patients with complicated influenza infection	GlaxoSmithKline Research & Development Ltd	Ignacio Martin-Loeches	Infection	Evaluation of treatments and therapeutic interventions/ Management of diseases and conditions	*Requested more information	Decision pending further information
20-036-AF1	EPO-TRAUMA	Monash University/ University College Dublin	Alistair Nichol	Injuries and accidents	Evaluation of treatments and therapeutic interventions	Conditional declaration	Declaration live
20-037-AF1-COV	Home monitoring of respiration in COVID-19 patients using smartphone technology: analysis of retrospective data	University College Dublin	Emer Doheny	Infection/ Respiratory	Aetiology	Conditional declaration	Declaration live
20-038-AF1-COV	RECOVERY-RS study	University of Warwick	Alistair Nichol	Infection/ Respiratory	Evaluation of treatments and therapeutic interventions	n/a	*Application withdrawn
20-039-AF1	A pilot multicentre randomised controlled trial comparing an approach of individualised blood pressure targets to standard	Galway University Hospital	Bairbre McNicholas	Cardiovascular / Inflammatory and immune system	Evaluation of treatments and therapeutic interventions	*Conditional declaration	Declaration live

* Applications submitted in 2020 and were either withdrawn or considered by the HRCDC in 2021

ii) Summary of amendment requests and HRCDC decisions in 2020

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
19-003-AF2/AMD1	Treatment of invasively ventilated adults with Early Activity and Mobilisation (TEAM) Trial	St. Vincent's University Hospital/ Monash University, Melbourne	Alistair Nichol	Generic health relevance	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
19-004-AF2/AMD1/COV	REMAP CAP: COVID-19 domains and consent models	St. Vincent's University Hospital/ University Medical Centre Utrecht/ Monash University, Australia	Alistair Nichol	Infection/ Respiratory	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
19-004-AF2/AMD2/COV	REMAP CAP: COVID-19 domains and consent models	St. Vincent's University Hospital/ University Medical Centre Utrecht/ Monash University, Australia	Alistair Nichol	Infection/ Respiratory	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
19-004-AF2/AMD3/COV	REMAP CAP: COVID-19 domains and consent models	St. Vincent's University Hospital/ University Medical Centre Utrecht/ Monash University, Australia	Alistair Nichol	Infection/ Respiratory	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live
19-015-AF2/AMD1	IDS – TILDA	Trinity College Dublin	Mary McCarron	Mental health/ Infection	Aetiology	Amendment approved	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
19-023-AF2/AMD1	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis	Beaumont Hospital/	Ger Curley	Inflammatory and immune system/ Respiratory	Aetiology	Amendment approved	Declaration live
20-006-AF1/ AMD1/ COV	A randomised double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness	Royal College of Surgeons in Ireland	Gerard Curley	Inflammatory and immune system/ Respiratory	Evaluation of treatments and therapeutic interventions	Amendment approved	Declaration live

iii) Summary of AF1, AF2 and AF3 applications submitted in 2019 with HRCDC decisions in 2020

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
19-016-AF2	CERVIVA – HPV	Trinity College Dublin/The Coombe Women and Infants University Hospital/ Cervical Check	Cara Martin John O'Leary	Cancer and neoplasms	Detection, screening and diagnosis	Conditional declaration	Declaration live
19-018-AF2	COMBINE Study	University College Cork	Mairead Kiely	Generic Health Relevance	Prevention of disease and conditions, and promotion of well-being	Conditional declaration	Declaration live
19-019-AF2	IMPROvED Study	University College Cork	Fergus McCarthy	Reproductive health and childbirth	Detection, screening and diagnosis	Declaration made	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
19-021-AF3	National Self-Harm Harm Registry Ireland	National Suicide Research Foundation	Paul Corcoran	Mental Health	Aetiology	Conditional declaration	Declaration live
19-023-AF2	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis	Beaumont Hospital/ Royal College of Surgeons in Ireland	Ger Curley	Inflammatory and immune system / Respiratory	Aetiology	Conditional declaration	Declaration live
19-024-AF2	Development of a real-time seizure detection algorithm for neonates	University College Cork	Geraldine Boylan	Reproductive health and childbirth	Detection, screening and diagnosis	Conditional declaration	Declaration live
19-025-AF2	Irish National AATD Registry (Alpha-1)	Alpha1 - Foundation Ireland	Gerry McElvaney	Congenital disorders	Aetiology	Conditional declaration	Declaration live
19-040-AF3	The interaction between noradrenaline dosage, troponin level and mortality in septic shock	Saolta Hospital -Galway University Hospital	John Laffey	Inflammatory and immune system/ Cardiovascular	Aetiology	Requested more information	Decision pending further information
19-041-AF3/COV	The role of t-regulatory and mononuclear phagocyte cells causing immune dysfunction in sepsis (A study on the role of immune dysfunction in sepsis and COVID-19)	Saolta Hospital -Galway University Hospital	John Laffey	Inflammatory and immune system/ Cardiovascular	Aetiology	Conditional declaration	Declaration live
19-060-AF3	National Kidney Disease Surveillance System (NKDSS) and Quality Assurance (QA) Programme	University of Limerick	Austin Stack	Renal and urogenital	Aetiology	Conditional declaration	Declaration live

HRCDC ID	Short title	Data controller(s)	Applicant(s)	Health category	Research activity	HRCDC decision	Status
19-072-AF2	The Monitor Study: Multimodal assessment of newborns at risk of neonatal hypoxic ischaemic encephalopathy	University College Cork	Eugene Dempsey	Reproductive health and childbirth	Aetiology	Conditional declaration	Declaration live
19-073-AF3	Incidences of new diagnosis of first seizures and epilepsy in Cork City and county over a one-year period	University College Cork	Daniel Costello	Neurological	Aetiology	Conditional declaration	Declaration live
19-077-AF3	IPCOR Study	Clinical Research Development Ireland	David Galvin	Cancer and neoplasms	Aetiology	Conditional declaration	Declaration live
19-085-AF1	Validation of microRNAs as novel diagnostic and therapeutic targets in ischaemic brain injury	Royal College of Surgeons in Ireland/ Beaumont Hospital	Shona Pfeiffer	Stroke	Aetiology/ Detection/ screening and diagnosis	Conditional declaration	Declaration live
19-086-AF1	Sepsis immunosuppression in critically ill patients	St James's Hospital	Ignacio Martin-Loeches	Inflammatory and immune system	Detection, screening and diagnosis	Conditional declaration	Declaration live

Appendix C

Governance

The Health Research Consent Declaration Committee (HRCDC) was established in 2018 under the Health Research Regulations (S.I. 314 of 2018 and as amended under S.I. 188 of 2019 and S.I. 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.

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 Secretariat staff and all employment-related matters fall within the remit of the HRB.

The HRCDC's operational budget is managed by the HRB, through the Secretariat, and in accordance with the policies and procedures of the HRB. The HRB has policies and procedures in place for its practices, in order to ensure compliance with the Code of Practice for the Governance of State Bodies. Many of the operations that underpin the business of the HRCDC, as carried out by the Secretariat, follow HRB procedures. The activities of the Secretariat that support the business of the HRCDC are described under Strategic Objective 3.5 in the HRB Strategy 2021-2025.[20]

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.

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, are the data processors for any personal data it receives and processes for the purpose of HRCDC business.

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 Committee 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.

Freedom of Information Act 2014

In 2020, the HRCDC received seven requests under the Freedom of Information Act 2014. Of these requests, four were granted, and records were released in full, or partially released. One freedom of information (FOI) HRCDC decision was appealed to the Office of the Information Commissioner. Two FOI requests were withdrawn.

References

1 https://www.gov.ie/en/publication/dbf3fb-ethical-framework-for-decision-making-in-a-pandemic/

2 http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

3 https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

4 https://www.gov.ie/en/publication/dbf3fb-ethical-framework-for-decision-making-in-a-pandemic/

5 http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

6 https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164

7 https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

8 https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

9 https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN

10 https://ec.europa.eu/info/sites/info/files/5._h2020_ethics_and_data_protection.pdf

11 https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

12 https://www.nrecoffice.ie/committees/nrec-covid-19/

13 https://www.who.int/publications/m/item/a-coordinated-global-research-roadmap

14 Under the recent amendments to the Regulations (S.I. 18 of 2021), where a data controller has obtained consent in accordance with the previous data protection, that consent is now considered valid.

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

16 https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

17 https://www.remapcap.org/

18 http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

19 https://www.ipposi.ie/2020/06/27/ipposimappingproject/

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

Notes

Health Research Consent Declaration
Committee, Ireland

Gratton House
67-72 Lower Mount Street
Dublin 2
D02 H638

e secretariat@hrcdc.ie
t +353 1 2345 179 or 353 1 2345 257
w www.hrcdc.ie

@hrcdc_Ireland