

2019

**Annual
Activities
Report**

Transparency
Trust
Confidence

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Foreword



I am pleased to present the first annual activities report of the Health Research Consent Declaration Committee (HRCDC), which was established in March 2019.

The HRCDC plays an important role in the new regulatory landscape for health research as a result of the landmark General Data Protection Regulations (GDPR) and subsequent Health Research Regulations (Regulations). At the core of our work is helping to support public and patient trust and confidence in health research as an important factor in a vibrant Irish health research ecosystem.

In 2019, as a new committee, we developed our operational and deliberative processes and we held nine HRCDC meetings. Our Committee deliberations for making a consent declaration are thorough and balanced, ensuring that health researchers are afforded an opportunity to conduct valuable and ethically approved research, using personal data without explicit consent. It is equally important to the HRCDC that vulnerable individuals and groups, who may not be able to provide consent, are not excluded from research that may benefit them significantly. The public interest and the rights of patient research participants are at the heart of all decisions made by the HRCDC.

We know from the applications submitted to the HRCDC and our contact with the research community that researchers are committed to conducting important research of public benefit, while respecting research participant rights. The commencement of GDPR and the Regulations has presented challenges for the health research community in learning to navigate the new legislative regulations in the context of conducting ethical and lawful research. The HRCDC Secretariat has worked with health researchers to support them in the application process and has engaged widely with the health research community.

As we develop, we will be keeping our processes and procedures under review in consultation with our health research stakeholders. The Secretariat has also ensured the public transparency of our work through the HRCDC website.

It wasn't only researchers who had to learn to navigate a new landscape. As a newly established committee there was a lot of work and learning for all of us on the Committee in developing our understanding of the multifaceted Irish research ecosystem, the data protection regulatory framework and in developing effective processes for reviewing and assessing applications. I want to acknowledge the huge commitment and collegiality of Committee members in undertaking this work. Our work would not have been possible without the hard work and expertise of our excellent Secretariat, Dr Emily Vereker, Mr Jonny Barrett and Ms Caroline Byrne, who supported the Committee's establishment, work and knowledge development, assessed applications, and engaged with applicants and the wider research community to ensure we delivered on our remit.

I want to thank the Department of Health for its support in the establishment of the Committee and, along with the Data Protection Commission, for providing advice and guidance to the HRCDC and the Secretariat on matters as they arise and pertain to the Regulations.

The support of the Health Research Board (HRB) in providing the Secretariat and other support services to the HRCDC is very important to us. The HRB's professionalism and exceptional reputation for supporting researchers in Ireland has benefited the Secretariat and the HRCDC in its operations.

While we undertook significant work in 2019, we do have a large number of applications on hand due to the volume of applications submitted to meet the 'transition period' deadline for current research that was ongoing prior to the Regulations. While we will prioritise applications for new research, we hope to clear the backlog of existing research applications during 2020. Looking ahead, a key action for the HRCDC is to continue to focus on ensuring that the consent declaration process is transparent and efficient. We, and the Secretariat, look forward to working in consultation with our health research stakeholders as the HRCDC matures.

Brigid McManus
Chairperson

The European Commission, which adopted its proposal for a General Data Protection Regulation in 2012, has stated:¹

“Informed consent is the cornerstone of research ethics. It requires you to explain to research participants what your research is about, what their participation in your project will entail and any risks that may be involved. Only after you have conveyed this information to the participants and they have fully understood it can you seek and obtain their express permission to include them in your project (Articles 4(11) and 7 GDPR).”

The European Data Protection Supervisor has stated:²

“Consent serves not only as a possible legal basis for the activity, it is also a safeguard – a means for giving individuals more control and choice and thereby for upholding society’s trust in science.”

¹ https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

² https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

2019 Snapshot



86
APPLICATIONS
SUBMITTED



3
APPLICATIONS
WITHDRAWN



30
DEFINED
RESEARCH AREAS



17
THEMATIC
RESEARCH AREAS



9
HRCDC
MEETINGS



23
HRCDC
DECISIONS



20
DECLARATION
(+/- CONDITIONS)



1
APPEAL
PANEL



75%
AVERAGE
HRCDC MEMBER
ATTENDANCE

1

The Health Research Consent Declaration Committee



The Health Research Consent Declaration Committee (HRCDC) is an independent statutory body established under the Health Research Regulations 2018 and is accountable to the Minister for Health.

The HRCDC members were appointed by the Minister for Health in March 2019. The Regulations provide for the HRCDC to make a consent declaration to a data controller organisation, to allow the ‘processing’ and use of personal data for health research where the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the research participant.

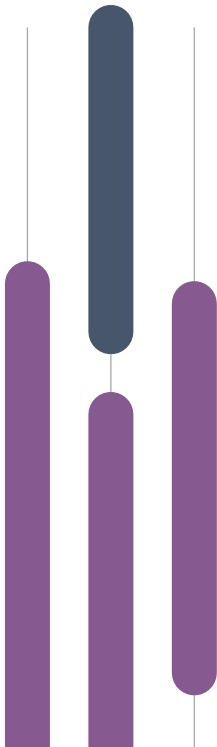
In 2019, the HRCDC comprised 15 individuals who are representative of the health research community, including three representatives of patients and the public. The HRCDC collectively brings to bear a variety of expertise and experience in areas such as carers, emergency and cancer research, general practice, socioeconomic health research, disability research, sociology, public policy, statistics and genomic medicine. A list of the HRCDC members can be found in Appendix A.

Full member profiles can be viewed on the HRCDC website: <https://hrcdc.ie/about-us/>

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The Health Research Regulations

Health research is essential to improve patient care and treatment, and for the development of innovative and life-saving therapies. For society to enjoy the benefits of research, public confidence and trust is essential. This can be achieved through a transparent and robust regulatory framework to underpin public confidence and trust in health research and ensure patient empowerment. This is especially important when individuals' personal data are necessary in health research studies to answer important research questions.



To ensure public confidence, trust and transparency in health research and ensure patient empowerment, the legislative action taken by the Minister of Health, Mr Simon Harris, introduced the Health Research Regulations. The Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018) were made under Section 36 of the Data Protection Act 2018. The Regulations came into effect on 8 August 2018, 2018 under Statutory Instrument (S.I. No. 314 of 2018 and as amended under S.I. No. 188 of 2019).

The Minister made the Regulations in relation to processing personal data, and makes explicit consent for the use of personal data in health research a requirement as a suitable and specific safeguard when processing personal data.

Data protection and privacy rights, and the ability of individuals to self-determine the use of data, are very important legal and ethical rights of individuals. However, it is recognised, as it is in other countries, that in limited situations it is not feasible to obtain explicit consent from research participants for the use of their data in health research.

To facilitate these scenarios and enable important research where explicit consent from individuals cannot be sought, the Regulations set out a clearly defined statutory consent declaration process, which is overseen by a ministerial appointed Health Research Consent Declaration Committee (HRCDC). The HRCDC is supported by a dedicated Secretariat (listed in Appendix A).

In April 2019, the Department of Health recognised the need to extend the transition period set out in the Regulations. Specifically, the transition period, or the time frame for obtaining explicit consent for the processing of personal data for a health research project that was ongoing on prior to the commencement of the Regulations, was extended to 7 August 2019.

3

The Secretariat



The HRCDC Secretariat service is provided by, and located in, the Health Research Board (HRB) and was established in January 2019. The Secretariat supports the HRCDC in all aspects of its work and acts as a central point of contact for the research community.

The Secretariat is responsible for the application process which enables researchers to seek a consent declaration from the HRCDC.

The Secretariat has a very close working relationship with the Department of Health and the Data Protection Commission, both of which have provided much-needed clarity and advice with respect to data protection matters and the Regulations. Much of this oft-needed clarity and guidance is provided on the HRCDC website as a resource for researchers.

The Standard Operating Procedures (SOPs) of the Secretariat and the HRCDC were developed collaboratively and formally approved for adoption in June 2019 by the HRCDC. The SOPs provide an overview of the specific roles and responsibilities of both the Secretariat and the HRCDC, and the procedures underpinning these roles.



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HRCDC Activities



4.1 HRCDC Meetings

The first meeting of the HRCDC was an induction meeting held on 27 March 2019 when the committee was joined by the HRB Executive Team, senior members of the Department of Health and the Data Protection Commission. The meeting provided an overview of the SOPs and an opportunity for the HRCDC to discuss their remit in the wider context of health research regulation.

The standard operating procedures of the Secretariat and HRCDC were developed collaboratively and formally approved for adoption in June 2019 by the HRCDC. The Secretariat plays a key role in ensuring that applications are complete and have adopted a triaging process to ensure Applicants provide relevant and key information to enable the HRCDC to make fully informed decisions.

In addition to the business of considering applications for a consent declaration, the HRCDC is also committed to engaging with subject matter experts on areas that are very much at the forefront of the HRCDC's decision-making role. In this regard, the HRCDC welcomed Sage Advocacy Chair Patricia Rickard-Clarke to the 5 November 2019 meeting. Ms Rickard-Clarke provided a valuable and insightful overview of the Assisted Decision-Making (Capacity) Act 2015 and deeper understanding regarding individuals who lack decision-making capacity.

The HRCDC have met in total 9 times in 2019 with an average attendance rate of 11 HRCDC members per meeting. Meetings are held on average every 5 weeks, allowing for applications to be triaged and reviewed by the HRCDC, with decisions and minutes then communicated to Applicants and the wider public.

4.2 The Consent Declaration Process

Since the Regulations commenced, a total of 86 applications were submitted to the HRCDC, through the Secretariat in 2019 (See Appendix B). A considerable number of applications were submitted in July and August 2019, to meet the transition period deadline for current research that was ongoing prior to the commencement of the Regulations. 3 applications were withdrawn prior to being validated for consideration by the HRCDC.

Application Type	Submitted	Reviewed	Withdrawn
AF1 - New Research	11	6	3
AF2 - Current (Consent)	58	11	-
AF3 - Current (No Consent)	17	6	-
TOTAL	86	23	3

'AF' denotes the Application Form submitted, specific to the research study that requires a consent declaration

* AF1 represents new research that commenced on or after 8 August 2018 - No Consent

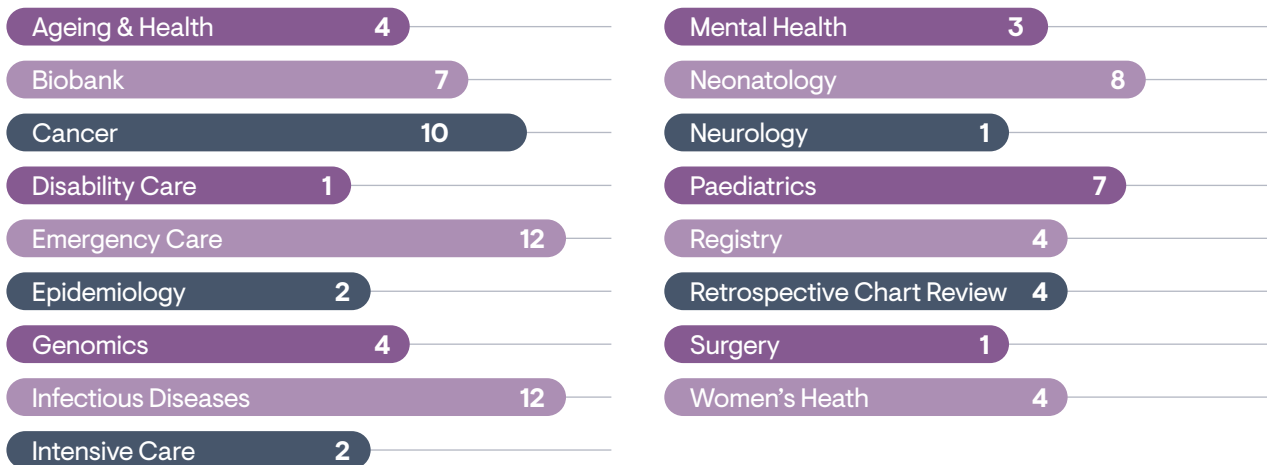
* AF2 represents research that commenced prior to 8 August 2018 - Consent Obtained

* AF3 represents research that commenced prior to 8 August 2018 - No Consent

The breadth and depth of research studies that require a consent declaration is evidenced by the number of thematic research areas and more defined research areas.

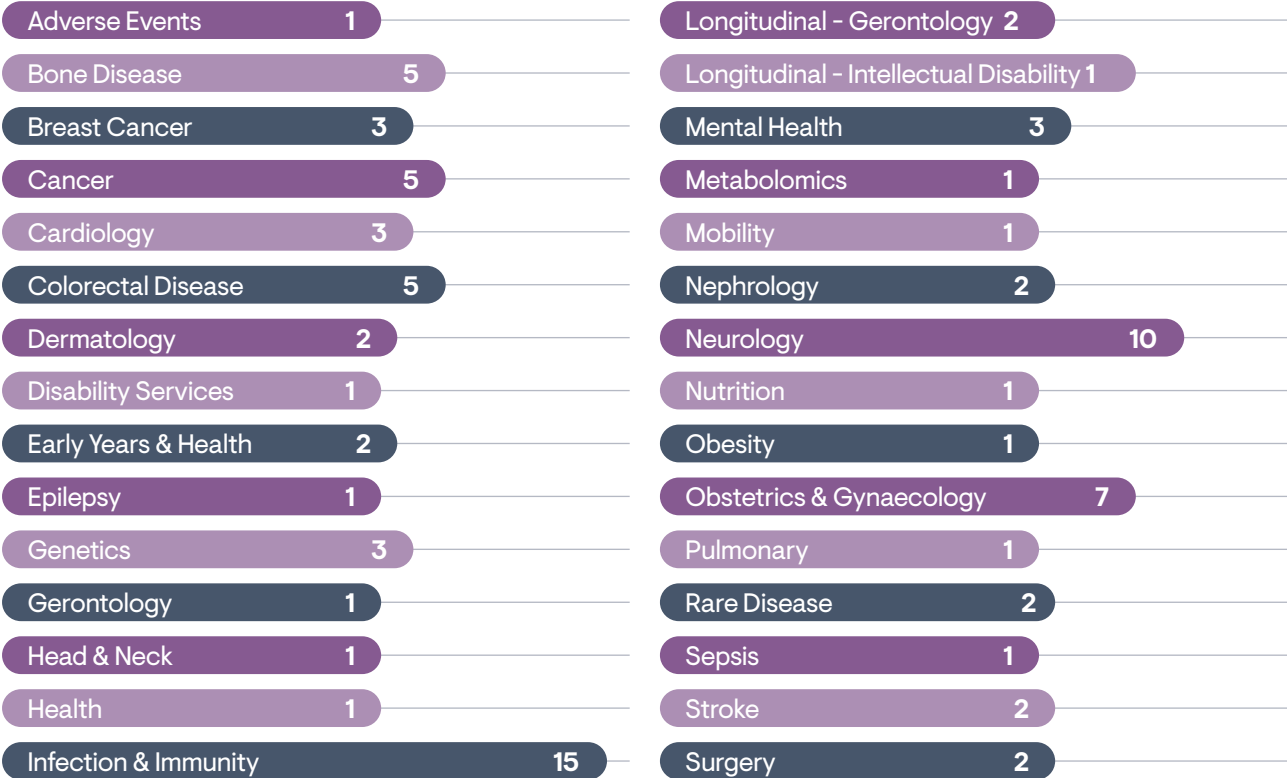
Thematic Areas

Number of Applications



Defined Research Areas

Number of Applications



Prior to making a consent declaration, the HRCDC must ensure that key principles of data protection underpin the health research, and that all appropriate safeguards, as set out on the Regulations, are in place. Meeting the necessary data protection requirements are necessary in order to ensure that fundamental rights and freedoms of individuals are safeguarded while their personal data are being used for the purpose of important health research.

In cases where obtaining explicit consent from individuals to use their personal data was not demonstrably feasible, 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 individual whose personal data are being used.

4.3 HRCDC Decisions

During 2019, the HRCDC made 23 decisions on applications that were submitted by applicants seeking a consent declaration. The reasons for seeking a consent declaration were varied and dependent on the nature of the research study, the feasibility of obtaining explicit consent, and the nature of processing, or use, of the personal data for the study.

HRCDC Decisions* by Application Type

	Declaration**	Conditional Declaration	No Declarations	Requested More Information	Total
AF1	1	4	-	1	6
AF2	2	9	-	-	11
AF3		4	1	1	6
Total	3	17	1	2	23

* These data do not include the decision of the Appeal Panel.

** A Conditional Declaration may convert to a Declaration once conditions have been met.

Of the 23 decisions made, 20 consent declarations made have specific conditions attached, 2 decisions were to request further information from the Applicant, and 1 decision was to not make a consent declaration.

Specific conditions attached to consent declarations are to ensure that all appropriate safeguards are in place to protect the data protection rights of individuals whose data are being used for the research study, where it is not feasible to obtain explicit consent and the research represents a substantial public interest.

Since the Regulations came into operation in 2018, data controllers have been working to adjust their existing practices to ensure that robust safeguards are in place to satisfy the requirements of the Regulations and GDPR. Conditions attached to consent declaration aim to strengthen and/or complement data protection measures undertaken by data controller organisations, to ensure the safeguarding of personal data for health research.

Typically, conditions attached relate to ensuring safeguards and measures such as:

- Transparency measures
- Arrangements between data controllers and/or data processors
- Clarity of information for patients who are consenting, or next of kin or families who are providing assent on behalf of individuals
- Engagement with patients and the public, or relevant advocacy groups.

In the case of 2 applications that were considered, the HRCDC deferred its decision, pending receipt of further information from the applicant. (These applications were subsequently withdrawn in 2020.)

Generally, where the HRCDC defers its decision pending receipt of further information, the Secretariat will correspond with the Applicant, formally by letter. The information provided by the Applicant will then return to the HRCDC for consideration at the next convened HRCDC meeting. It is for this reason that it may take more than one meeting for the HRCDC to make a final decision.

In the case of 1 application that was considered, the HRCDC did not make a declaration. This decision was appealed by the applicant, and the HRCDC decision was subsequently overturned by an independent Appeal Panel, which made a conditional declaration.

A detailed list of all applications submitted to the HRCDC for consideration in 2019 is detailed in Appendix B. For clarity, this information provides the current status of these applications. Applications with no status are still awaiting consideration by the HRCDC.


4.4 Transparency

To reinforce the intention of the Regulations, which is to promote public confidence and trust in health research, all decisions made, minutes of meetings and summaries of applications are publicly available on the HRCDC website for transparency purposes. The meeting minutes and status of the applications are updated every 6-8 weeks and as soon as practically possible.

5

Secretariat Activities





The Secretariat acts as the conduit between Applicants and the HRCDC to facilitate a streamlined process for applying for a consent declaration. Importantly, the Secretariat has adopted a prioritisation exercise such that all new research studies that require a consent declaration are triaged for HRCDC review ahead of current research studies that commenced prior to the Regulations and met the transition period deadline. While new research studies are being prioritised, current research studies are still being processed by the Secretariat as quickly as possible for HRCDC consideration.

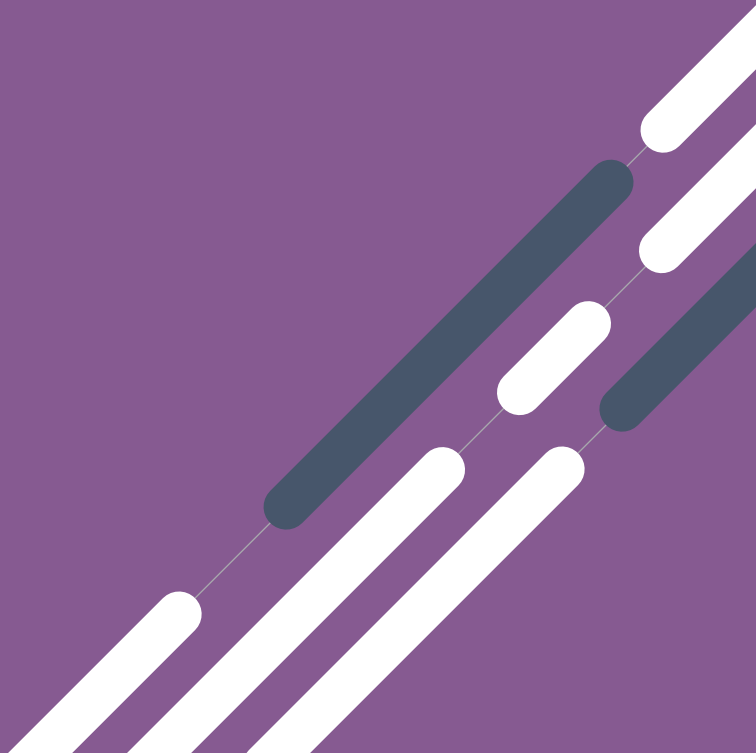
Given the frequently complex nature of each research study, navigating the Regulations and consent declaration process can be challenging. Accordingly, the Secretariat aims to engage with researchers in an open and direct manner. In 2019, the Secretariat provided seminars to health researchers outlining practical steps when applying to the HRCDC.

Since the Regulations came into effect, the Secretariat has engaged with many stakeholders across Ireland, including data protection officers, clinical and academic researchers, postdoctoral fellows, health and regulatory affairs professionals and research ethics committees. The Secretariat also engaged with organisations such as Health Research Charities Ireland and Clinical Research Development Ireland, which are integrally connected with the research ecosystem in Ireland.

In efforts to understand the current data protection landscape in the context of health research, the Secretariat has attended events nationally, such as those hosted by the Irish Health Research Forum. In December 2019, the Secretariat travelled to Brussels to attend a seminar on the challenges for health research arising from the GDPR.

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Key
Objectives
2020



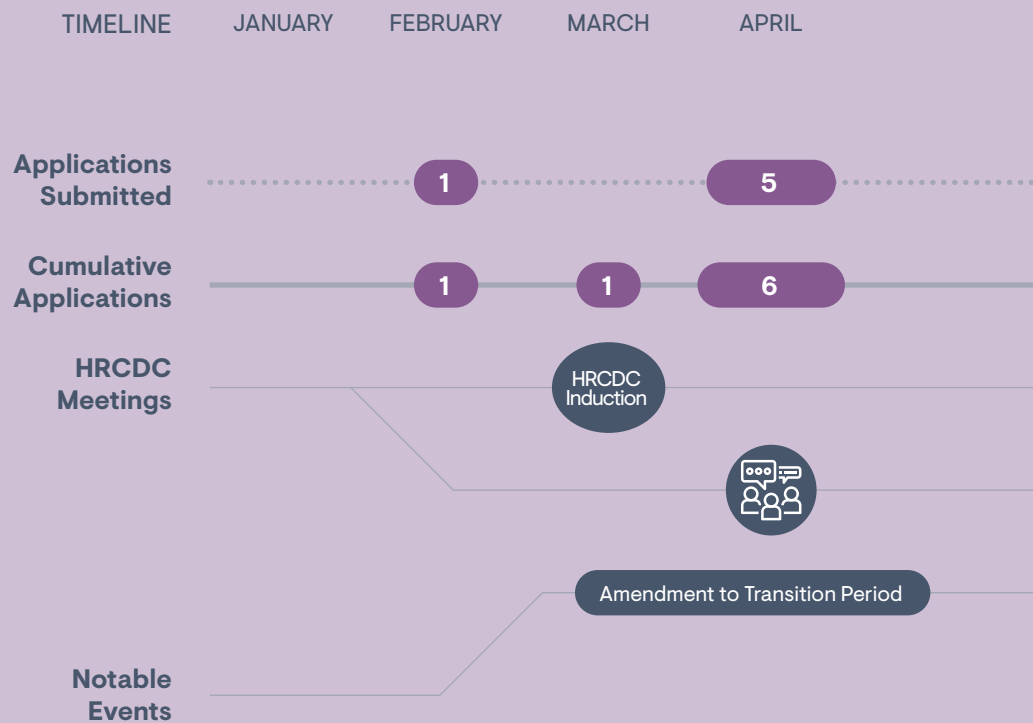
In 2020, the HRCDC, with the support of the Secretariat, will continue to consider applications that are currently awaiting decisions, with priority given to new applications.

The HRCDC is also committed to operating a rapid review process for assessing COVID-19 related research applications. The current guidance on the HRCDC website will be continuously under review and updated as new queries arise within the health research community. A new HRCDC application form and updated guidance will be finalised and adopted by Q2 2020.

The HRCDC will work closely with the Department of Health and the Data Protection Commission on matters as they may arise, including the anticipated amendments to the Regulations that are currently under development by the Department of Health.



Timeline of Activity 2019



MAY

JUNE

JULY

AUGUST

SEPTEMBER

OCTOBER

NOVEMBER

DECEMBER

4

5

51

17

1

2

10

15

66

83

83

84

84

86

Information Meeting



Extended Transition Period

7 July

7 August

Appendix A

HRCDC Members

Ms. Brigid McManus, HRCDC Chairperson
Prof. Evelyn Mahon, HRCDC Deputy Chairperson
Ms. Alyson Bailey, Patient & Public Involvement
Mr. Dan Rea, Patient & Public Involvement
Mr. Kevin Clarke, Patient & Public Involvement
Dr. Simon Furney, Biomedical Genomics
Dr. Aideen Hartney, Disability - Policy & Public Affairs
Dr. Claire Collins, **General Practice**
Dr. Sheelah Connolly, Economic & Social Research
Dr. Zubair Kabir, Epidemiology & Public Health
Ms. Kathy Brickell, Emergency & Intensive Care
Prof. Barry O'Sullivan, Data Analytics & Artificial Intelligence
Dr. John Ferguson, Biostatistics
Prof. Bert Gordjin* Ethics & Research Integrity

* (Stepped down from the HRCDC in September 2019)

Secretariat

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

Appendix B

Summary of Applications and Decisions 2019

The list of applications submitted to the HRCDC is an abridged summary for the purpose of the *Annual Activities Report*. A comprehensive list with further details can be viewed on <https://hrcdc.ie/decisions/>

* HRCDC Decisions made in 2019

± Current status of applications, including those withdrawn in 2020

Applications with no status are still awaiting consideration by the HRCDC.

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRCDC Decision	Appeal Decision	± Current status
19-001-AF3	Irish National Adverse Events Study (INAES-2)	Royal College of Surgeons in Ireland	David Williams	Retrospective Chart Review	Adverse Events	Conditional Declaration		Declaration No Longer Required
19-002-AF1	A retrospective analysis of adverse events in mental health services in the South East	Waterford Institute of Technology Health Service Executive	Neil Crowhurst	Retrospective Chart Review	Mental Health	Conditional Declaration		Declaration Live
19-003-AF2	Treatment of invasively ventilated adults with Early Activity and Mobilisation (TEAM) Trial	St Vincent's University Hospital, Dublin	Alistair Nichol	Emergency Care	Mobility	Conditional Declaration		Declaration Live
19-004-AF2	Randomised, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia	St Vincent's University Hospital, Dublin	Alistair Nichol	Emergency Care	Infection & immunity	Conditional Declaration		Declaration Live
19-005-AF2	All Ireland Cancer Biobank Network Consortium	St. James Hospital	Richard Flavin	Biobank	Cancer			
19-006-AF3	Whole Genome Sequencing for Brain Tumour Biology	Beaumont Hospital, Dublin Genomics Medicine Ireland Ltd	Michael Farrell	Genomics	Neurology	No Declaration	Conditional Declaration	Declaration Live
19-007-AF2	Targeted therapeutic mild hypercapnia after resuscitated cardiac arrest (TAME)	St Vincent's University Hospital, Dublin University College Dublin	Alistair Nichol	Emergency Care	Cardiology	Conditional Declaration		Declaration Live
19-008-AF2	Targeted Hypothermia versus targeted Normothermia after Out of Hospital Cardiac Arrest (TTM2)	St. Vincent's University Hospital, Dublin University College Dublin	Alistair Nichol	Emergency Care	Cardiology	Conditional Declaration		Declaration No Longer Required

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRDC Decision	Appeal Decision	± Current status
19-009-AF3	Moving In Study	National Disability Authority	Aideen Hartney	Disability Care	Disability Services	Conditional Declaration		Declaration Live
19-010-AF3	Analysis of clots retrieved from acute ischaemic stroke patients and mechanical thrombectomy	Beaumont Hospital, Dublin National University of Ireland, Galway	Karen Doyle	Emergency Care	Stroke	Conditional Declaration		Declaration Live
19-011-AF3	Irish Traveller History Study	Royal College of Surgeons in Ireland	Gianpiero Cavalleri	Genomics	Genetics	Requested More Information		Application Withdrawn
19-012-AF2	Breast Cancer Proteomics and Molecular Heterogeneity	Royal College of Surgeons in Ireland Beaumont Hospital, Dublin Health Service Executive South	Leonie Young Arnold Hill Bryan Hennessy	Cancer	Breast Cancer	Conditional Declaration		Declaration Live
19-013-AF2	Irish Omega 3 Study	University College Cork	Maeve Rooney	Mental Health	Nutrition	Conditional Declaration		Declaration Live
19-014-AF2	Colossus Study	Royal College of Surgeons in Ireland	Jochen Prehn Annette Byrne	Cancer	Colorectal Disease	Declaration		Declaration Live
19-015-AF2	IDS - TILDA	Trinity College Dublin	Mary McCarron	Ageing & Health	Longitudinal - Intellectual Disability	Declaration		Declaration Live
19-016-AF2	CERVIVA - HPV	Trinity College Dublin The Coombe Women and Infants University Hospital CervicalCheck	Cara Martin John O'Leary	Cancer	Obstetrics & Gynaecology			
19-017-AF2	Optimising prescribing in older community dwelling people	Royal College of Surgeons in Ireland	Tom Fahey	Ageing & Health	Gerontology	Conditional Declaration		Declaration Live
19-018-AF2	COMBINE	University College Cork	Mairead Kiely	Paediatrics	Early Years & Health			
19-019-AF2	IMPROVED Study	University College Cork	Fergus McCarthy	Women's Health	Obstetrics & Gynaecology			
19-020-AF2	BASELINE Study	University College Cork	Deirdre Murray	Paediatrics	Early Years & Health			
19-021-AF3	National Self Harm Registry Ireland	National Suicide Research Foundation	Paul Corcoran	Registry	Mental Health			
19-022-AF2	The Irish Longitudinal Study on Ageing (TILDA)	Trinity College Dublin	Rose Anne Kenny	Ageing & Health	Longitudinal - Gerontology	Conditional Declaration		Declaration Live

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRCDC Decision	Appeal Decision	± Current status
19-023-AF2	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in sepsis patients	Beaumont Hospital, Dublin Royal College of Surgeons in Ireland	Ger Curley	Emergency Care	Infection & Immunity			
19-024-AF2	Seizure detection for babies study	University College Cork	Geraldine Boylan	Neonatology	Neurology			
19-025-AF2	Alpha1 Registry	Alpha1 - Foundation Ireland Beaumont Hospital, Dublin	Gerry McElvaney	Registry	Rare disease			
19-026-AF2	MAMMI	Trinity College Dublin	Deirdre Daly	Women's Health	Obstetrics & Gynaecology			
19-027-AF3	Molecular Profiling of Breast Cancer	National University of Ireland, Galway Galway University Hospitals	Sharon Glynn	Cancer	Breast Cancer			
19-028-AF2	Future Neuro Epilepsy Studies	Royal College of Surgeons in Ireland Beaumont Hospital, Dublin	Norman Delanty	Neurology	Epilepsy			
19-029-AF2	BIGgeR Study	Mater Misericordiae University Hospital University College Dublin	Aoife Cotter	Infectious Diseases	Infection & Immunity			
19-030-AF2	The RCSI-Beaumont Hospital Tissue Biobank	The Royal College of Surgeons in Ireland Beaumont Hospital, Dublin	Tony O'Grady	Biobank	Cancer			
19-031-AF2	Bowel Disease Bio-resource Development: Biomarkers for Bowel Disease	The Royal College of Surgeons in Ireland Beaumont Hospital, Dublin	Deborah McNamara Jochen Prehn	Cancer	Colorectal Disease	Conditional Declaration		Declaration Live
19-032-AF2	Systems Modelling of Tumour Heterogeneity and Therapy Response in Colorectal Cancer	The Royal College of Surgeons in Ireland Beaumont Hospital, Dublin	Deborah McNamara Jochen Prehn	Cancer	Colorectal Disease			Application Withdrawn
19-033-AF3	Cardiac Arrest and Pre-Hospital Thrombolysis in Irish General Practice.	University College Dublin	Gerard Bury	Emergency Care	Cardiology			

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRDC Decision	Appeal Decision	± Current status
19-034-AF2	Evaluation of novel diagnostics and therapeutics for colorectal cancer by targeting signalling pathways	The Royal College of Surgeons in Ireland Beaumont Hospital, Dublin	Deborah McNamara Jochen Prehn	Cancer	Colorectal Disease			Application Withdrawn
19-035-AF2	Alendronate for Prevention of AntiRetroviral Therapy-associated bone loss	University College Dublin	Patrick Mallon	Infectious Diseases	Bone Disease			
19-036-AF2	NGS and Bone Infection -The use of next Generation Sequencing Techniques	University College Dublin	Patrick Mallon	Infectious Diseases	Bone Disease			
19-037-AF3	Risk and Prognostic Factors and outcomes of Head and Neck Cancers	South Infirmary Victoria University Hospital Cork University Hospital	Patrick Sheahan	Cancer	Head & Neck			
19-038-AF1	The Genomic Basis of Alzheimer's disease in Ireland	Genomics Medicine Ireland Ltd.	Emer Fallon	Genomics	Neurology	Conditional Declaration		Declaration Live
19-039-AF2	Identification of genetic and molecular factors associated with bowel diseases	St. Vincent's University Hospital, Dublin	Kieran Sheahan Desmond Winter	Cancer	Colorectal Disease			
19-040-AF3	The Interaction between Noradrenaline dosage, Troponin level and Mortality in Septic Shock	Galway University Hospitals	John Laffey	Emergency Care	Infection & Immunity			
19-041-AF2	The role of T-regulatory and mononuclear phagocyte cells causing immune dysfunction in sepsis	Galway University Hospitals	John Laffey	Emergency Care	Infection & Immunity			
19-042-AF2	HIV Reservoir Reactivation Study - "HIV Cure Study"	Mater Misericordiae University Hospital St Vincent's University Hospital, Dublin University College Dublin	Patrick Mallon	Infectious Diseases	Infection & Immunity			
19-043-AF3	The Irish Longitudinal Study on Ageing (TILDA) GRO Linkage	Trinity College Dublin	Rose Anne Kenny	Ageing & Health	Longitudinal - Gerontology	Conditional Declaration		Declaration Live

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRCDC Decision	Appeal Decision	± Current status
19-044-AF2	RKD Biobank and Registry	Trinity College Dublin	Mark Little	Biobank	Nephrology			
19-045-AF2	DISCOVERY Bioresource	Trinity College Dublin	Sharon O'Toole	Biobank	Obstetrics & Gynaecology			
19-046-AF2	Genomic study of neurodevelopmental disorders	Trinity College Dublin	Louise Gallagher	Genomics	Neurology			
19-047-AF2	Irritable Bowel Disease DOCHAS	Children's Health Ireland	Seamus Hussey	Paediatrics	Bowel Disease			
19-048-AF2	Deep Health and Imagining Epigenetics	Trinity College Dublin	Thomas Frodl	Mental Health	Genetics			
19-049-AF2	Genetics of Attention Deficit Hyperactivity Disorder	Trinity College Dublin	Micheal Gill	Mental Health	Genetics			
19-050-AF2	Thoracic Biobank	St James' Hospital	Stephen Finn	Biobank	Cancer			
19-051-AF2	Immune Response to Lung Disease	Trinity College Dublin and St James's Hospital	Joseph Keane	Infectious Diseases	Pulmonary			
19-052-AF1	GENESIS: the genomic landscape of neonatal Escherichia coli sepsis	National Maternity Hospital Trinity College Dublin	Susan Knowles Stephen Smith	Neonatology	Infection & Immunity	Requested More Information		Application Withdrawn
19-053-AF2	University College Dublin Cohort Project	University College Dublin Mater Misericordiae University Hospital	Patrick Mallon	Infectious Diseases	Infection & Immunity			
19-054-AF2	'TAISTR' Study	University College Dublin Mater Misericordiae University Hospital	Patrick Mallon	Infectious Diseases	Infection & Immunity			
19-055-AF2	Department of Surgery Biobank	St James's Hospital Trinity College Dublin	Jacintha O'Sullivan	Biobank	Surgery			
19-056-AF2	HIV UPBEAT CAD	St. Vincent's University Hospital, Dublin	Patrick Mallon	Infectious Diseases	Infection & Immunity			
19-057-AF2	MONIC Study	St. Vincent's University Hospital, Dublin	Patrick Mallon	Infectious Diseases	Infection & Immunity			

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRDC Decision	Appeal Decision	± Current status
19-058-AF2	TRACER	Mater Misericordiae University Hospital St. Vincent's University Hospital, Dublin University College Dublin	Aoife Cotter	Infectious Diseases	Bone Disease			
19-059-AF3	Paediatric Rare Disease	CHI at Temple Street Children's University Hospital	Sally Ann Lynch	Paediatrics	Rare Disease			
19-060-AF3	National Kidney Disease Surveillance System	University Hospital Limerick	Austin Stack	Registry	Nephrology			
19-061-AF2	BRiHT	St. Vincent's University Hospital, Dublin	Patrick Mallon	Emergency Care	Infection & Immunity			
19-062-AF1	Sub Epidermal Moisture (SEM) and Inflammatory markers in the early identification of Pressure Ulcers	Beaumont Hospital, Dublin Royal College of Surgeons in Ireland	Zena Moore Natalie McEvoy	Intensive Care	Infection & Immunity	Declaration		Declaration Live
19-063-AF2	Bone health in those undergoing Hepatitis C treatment with direct-acting antiviral therapy	University College Dublin Mater Misericordiae University Hospital, Dublin	Aoife Cotter	Infectious Diseases	Bone Disease			
19-064-AF1	Discussion Forum use for Public Health Surveillance	National University of Ireland, Galway	Paul Buitelaar	Epidemiology	Infection & immunity	Conditional Declaration		Declaration Live
19-065-AF2	NEMO Study	University College Cork	Geraldine Boylan	Neonatology	Neurology			
19-066-AF2	Algorithm for Neonatal Seizure Recognition	University College Cork	Geraldine Boylan	Neonatology	Neurology			
19-067-AF3	Presentation and prognosis of patients presenting in extreme acidosis to the ED and ICU of UHG	University Hospital Galway	John Bates	Emergency Care	Metabolomics			
19-068-AF2	Sleepi Study	University College Cork	Geraldine Boylan	Paediatrics	Neurology			
19-069-AF2	Management of Hypotension in the Preterm	University College Cork	Eugene Dempsey	Neonatology	Obstetrics & Gynaecology			
19-070-AF2	Screening of Pregnancy Endpoints - SCOPE	University College Cork	Fergus McCarthy	Women's Health	Obstetrics & Gynaecology			

Application ID	Short Title	Data Controller(s)	Applicant(s)	Thematic Research Area	Defined Research Area	*HRCDC Decision	Appeal Decision	± Current status
19-071-AF2	Skin Study: Skin Barrier Structure and Function in Infants	University College Cork	Jonathan Hourihane	Paediatrics	Dermatology			
19-072-AF2	Multimodal assessment of newborns at risk of neonatal hypoxic ischaemic encephalopathy	University College Cork	Eugene Dempsey	Neonatology	Neurology			
19-073-AF3	Incidences of new diagnosis of first seizures and epliepsey in Cork city and county in a one-year period	University College Cork	Daniel Costello	Epidemiology	Neurology			
19-074-AF2	Learning to evaluate and manage antenatal blood pressure at home (LEANBH)	University College Cork	Frederic Adam	Women's Health	Obstetrics & Gynaecology			
19-075-AF2	NUI Galway-Saolta: Cancer Managed Clinical and Academic Networks (MCANs) Biobank	University Hospital Galway	Michael Kerin	Biobank	Cancer			
19-076-AF2	CUPID: Clamping the umbilical cord in premature deliveries, a radomised controlled pilot trial	University College Cork	Eugene Dempsey	Neonatology	Health			
19-077-AF3	IPCOR Study	Clincial Research Development Ireland	David Galvin	Registry	Cancer			
19-078-AF2	Neonatal inflammation and multiorgan dysfunction and brain injury research group (NIMBUS)	Trinity College Dublin	Eleanor Molloy	Neonatology	Neurology			
19-079-AF2	Determination of susceptibility genes for atopic dermatitis, asthma and allergy	Trinity College Dublin	Alan Irvine	Paediatrics	Dermatology			
19-080-AF1	BRIDGES Study	National University of Ireland, Galway	Frances Finucane	Retrospective Chart Review	Obesity			Application Withdrawn
19-081-AF1	An analysis of patients brought to hospital under the Mental Health Act (2001) but not detained	Health Service Executive	Sudha Jain	Retrospective Chart Review	Mental Health			Application Withdrawn

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19-082-AF3	Surgical Video Library Analysis	University College Dublin Mater Misericordiae University Hospital	Ronan Cahill	Surgery	Surgical techniques			
19-083-AF1	Cancer	National Cancer Registry Ireland University College Dublin	Cathriona Kearns	Cancer	Breast Cancer			Application Withdrawn
19-084-AF1	Examining the impact and experiences of people 1 year post-sepsis diagnosis	Health Service Executive	Karn Cliffe	Infectious Diseases	Sepsis	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, Dublin	Shona Pfeiffer	Emergency Care	Stroke			
19-086-AF1	Sepsis Immunosuppression in Critically Ill Patients	St James's Hospital, Dublin	Ignacio Martin-Loeches	Intensive Care	Infection & Immunity			

Health Research Consent Declaration
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