



ANNUAL REPORT 2020

Enabling a trusted
national ethics opinion



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Queries regarding this publication
should be sent by email to
nationaloffice@nrec.ie

**Copies of this publication
can be obtained from:**

National Office
for Research Ethics Committees
Grattan House
67-72 Lower Mount Street
Dublin 2
D02 H638
Ireland

+353 1 234 5753
nationaloffice@nrec.ie
www.nrecoffice.ie



@NREC_Office

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Foreword by the Head of the National Office for Research Ethics Committees



Dr Jennifer Ralph James
Head, National Office for Research Ethics Committees

It is a pleasure to present the first annual report of the National Office for Research Ethics Committees. Established in March 2020, the National Office has embarked on its important mission to strengthen research infrastructure in Ireland through a new statutory role in research ethics for the regulation of health research. This report summarises our activities over nine months of operation in what was a productive and energising first year for the National Office team.

A highly anticipated addition to the research environment, our establishment by the Department of Health last year is the culmination of a large body of preparatory work in strategic planning, horizon scanning, stakeholder input, and in-depth understanding of the needs of Irish health research. A system of National Research Ethics Committees (NRECs), supported by the [National Office](#), will build on the existing enablers of vibrant health research in Ireland: our wealth of scientific expertise, a strong industry presence, a meaningful research and development (R&D) investment, and importantly, our engaged and informed research participants, including those who are patients in the Irish health system. Collectively, these will ensure that Ireland represents a first-choice location to develop forefront medicines, medical devices, and healthcare services, meaning that such innovations will be accessible to Irish patients.

The National Office will be the cornerstone of a bespoke national system of research ethics review in Ireland that cultivates the benefits of health research for patients and the public – an ambition now defined in our vision statement. Within months of our establishment, we took the critical steps towards achieving this vision with the implementation of a roadmap of transition of review from a local to a national system, in partnership with the Department of Health and in

collaboration with the Health Products Regulatory Authority ([HPRA](#)) and local Research Ethics Committees (RECs). The National Office managed a public call seeking expressions of interest in NREC membership, the first initiative of its kind in Ireland, and we were heartened by the interest and enthusiasm for these important roles in public service. Operationally, we have established ourselves as a new public office with an independent role, hosted by the Health Research Board (HRB), and we are growing our team to ensure that the goals of the NREC system are served by a skilled, high-performing team.

The COVID-19 public health emergency provided an extraordinary backdrop for the National Office's first order of business. By operationalising a dedicated NREC for COVID-19-related health research from April to August 2020, we demonstrated the rigour, efficiency and transparency possible with a national approach to research ethics review. Significantly, the NREC COVID-19 provided 'proof of principle' of the value of a single national ethics opinion for Ireland. We sincerely thank the NREC COVID-19 members for their commitment and diligence in supporting Irish health research and its contribution to the global response to the COVID-19 pandemic.

“Delivering on our ambitious mission will mark a new chapter in Irish health research.”


Dr Jennifer Ralph James
Head, National Office for Research Ethics Committees

We gratefully acknowledge the continued guidance from the Department of Health, particularly Peter Lennon, Colm O'Loughlin and Dr Karen McNamara, in addition to the collaboration of the HPRA. We thank the HRB, led by Dr Mairéad O'Driscoll, for steadfast operational support. As the National Office delivers on the launch of NRECs in the areas of clinical trials and medical devices in 2021, we plan to rise to the challenge of the ambitious brief ahead of us and to reward the confidence that the research community and wider public has placed in us.

2020 snapshot

NREC COVID-19:

19
volunteer
committee
members



Met
14 times
Apr-Aug 2020



93
applications across
10 therapeutic area



85
applications
approved




Approved studies
were carried
out within


61 institutions 
across **20** counties
in the Republic
of Ireland



23
approved studies were
part of international
collaborations



Subcommittee
reviewed
13 substantial
amendments
Sept-Dec 2020




Almost all applicants
received a decision
letter within
1 or 2 days of a
committee meeting



4
applications
declined



National
Office:
Operates
under
5
strategic
priorities



Vision and mission

Our vision and mission are the pillars that will guide our decisions and actions. They focus on how we strengthen and streamline research ethics review in Ireland, and will grow to become a cohesive mixed-model system.

VISION

Ireland's system of research ethics review cultivates the benefits of health research for patients and the public.

Our aspiring vision requires building a robust system for national research ethics review that adheres to the highest ethical principles and standards of efficiency, and in doing so, fosters a health research environment that works with Irish patients and the wider public to deliver tangible health and economic benefits for all.

MISSION

The National Office will embed a robust, transparent and cohesive research ethics review system that strengthens the national research infrastructure.

Our ambitious mission is to bolster the research infrastructure in Ireland and deliver operational excellence by embedding a bespoke and robust national system for research ethics review, based on a commitment to transparency and cohesion. With a steadfast commitment to our vision and mission, we will work to ensure that the dignity, safety and well-being of research participants is front and centre of an NREC system that positions Ireland as the first-choice location for developing new medicines and technologies – all with the goal of improving access to emerging new treatments, cures, and preventions for Irish patients and the wider public.



Our story

Background on the National
Office for Research
Ethics Committees



The National Office for Research Ethics Committees was established in March 2020 as an important component of the reform of the research ethics committee framework in Ireland. Hosted by the HRB, the National Office has an independent role in the regulation of health research. Our establishment by the Department of Health is the culmination of a large body of preparatory work in strategic planning, horizon scanning, stakeholder input, and in-depth understanding of the needs of Irish health research.

A highly anticipated addition to the research environment, the [National Office](#) will be the cornerstone of a bespoke system of NRECs that will strengthen the infrastructure for health research. In partnership with the other regulators of health research, including the Department of Health and the [HPRA](#), we are implementing a roadmap of transition to a national system of research ethics review for areas of health research subject to legal regulation (regulated remits). We are also working closely with local Research Ethics Committees (RECs) to ensure that this transition is as seamless as possible to maintain research momentum in these important areas.

The research ethics review framework in Ireland will be modernised through a twin-track legislative approach. The initial priority NRECs will be in the areas of clinical trials of medicinal products (NREC-CT) and clinical investigations of medical devices (NREC-MD). These committees will operate on a statutory basis by amendments (secondary legislation) to be made by the Minister for Health to existing Statutory Instruments.

This first 'track' will enable Ireland to meet its obligations as a Member State to imminent EU Regulations for clinical trials of medicinal products (Regulation EU No 536/2014) and for clinical investigations of medical devices (Regulation EU No 2017/745). This includes the requirement to return a 'single national decision' following parallel regulatory and ethics review of research studies in these regulated areas within a defined timeframe. These EU Regulations will harmonise how research studies are conducted across the EU, and it is essential that Ireland is poised to implement them to maximally leverage health research outcomes and the socio-economic benefits of health research.

The second 'track' is the National Research Ethics Committees Bill. Drafted in July 2019, primary legislation based on this Bill will allow for NRECs to be established in other areas of health research over time. Work on the National Research Ethics Committees Bill is a priority and will continue throughout 2021. Until these legislative processes are complete, clinical trials in Ireland will continue to be regulated by S.I. No. 190/2004 and medical devices by S.I. No. 252/1994, respectively.



Our people

The team at the
National Office



An efficient and robust NREC system relies on dedicated and tailored operational support. The National Office is a diverse and inclusive workplace, staffed by a dynamic, high-performing team of programme managers, project officers, and an administrative assistant, under the leadership of the Head.

Driven by our values – integrity, transparency, partnership, knowledge, and independence – the [National Office](#) team is committed to establishing an agile and trusted office in national public service.

The National Office team represents a variety of professional and life experiences, united by the common goal to support a national system of research ethics review and to deliver

excellence in public service. The professional knowledge of our scientific staff means that applicants will engage with programme managers and project officers who are familiar with the nuances of the health research environment and can provide guidance, insight and constructive feedback at appropriate points in the review process to applicants submitting ethics applications. This peer-to-peer engagement will improve the implementation of best practice in research ethics in Ireland. Our scientific staff are also well placed to support the NREC membership with expert perspectives on REC operations, informed by international standards and prevailing law. Collectively, our team supports applications throughout the ethics review life cycle, and provides excellence in operational support to the NRECs. The National Office benefits from shared core services, such as communications and information technology (IT), through the HRB, our host organisation.

Team members within the National Office include:



Dr Jane Bryant
Project Officer



Dr Jennifer Ralph James
Head, National Office



Dr Melissa Jones
Project Officer



Kathy Kelly
Administrative Assistant



Dr Lucia Prihodova
Programme Manager



Aileen Sheehy
Programme Manager



Pivoting in response to the pandemic

NREC COVID-19: delivering
rapid ethics review



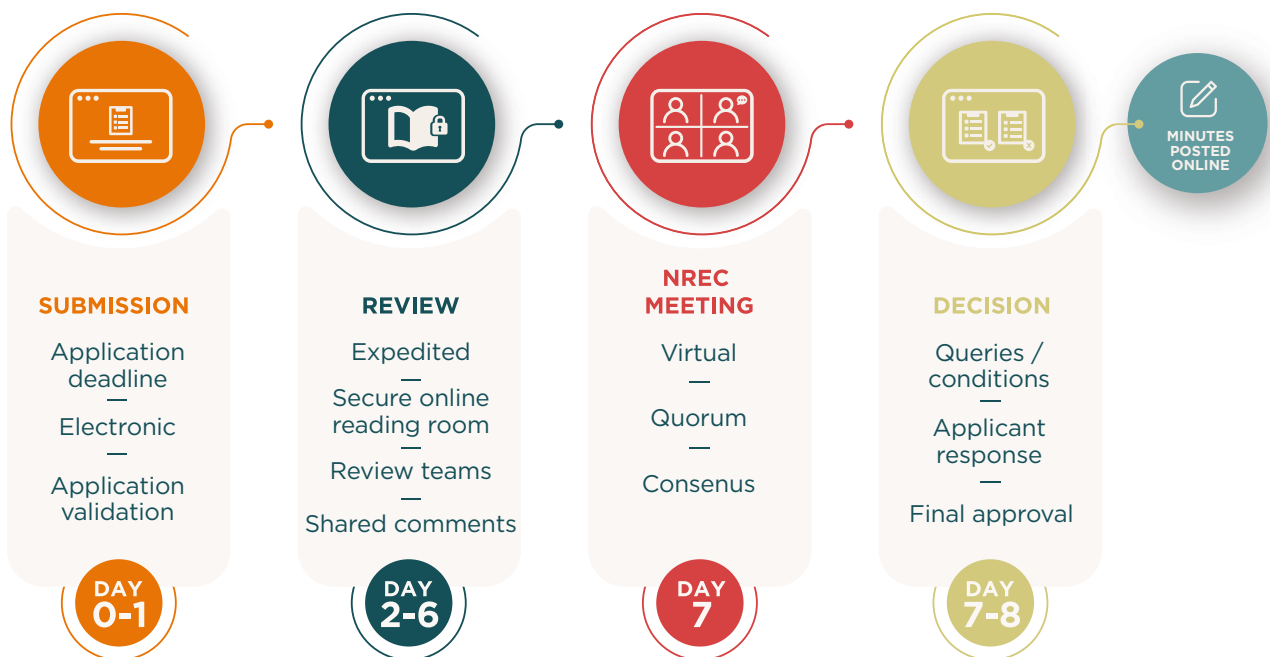
As part of Ireland’s response to the COVID-19 pandemic, and in accordance with a recommendation in the World Health Organization’s A Coordinated Global Research Roadmap: 2019 Novel Coronavirus¹, the then Minister for Health established a temporary National Research Ethics Committee (NREC) for COVID-19, to deliver an expedited process for review of COVID-19-related health research².

Its purpose is to accelerate Irish research to support immediate, evidence-based decision-making and to contribute to global efforts to counter the COVID-19 pandemic. The tenure of the NREC

COVID-19 extended from April to August 2020, and a subcommittee now sits periodically to meet the oversight responsibilities associated with the research approved by the Committee. The NREC COVID-19 is operationalised and supported by the [National Office](#) team and its decisions are entirely independent.

Hallmark features of the process underpinning the NREC COVID-19 included the expedited process, the coordination with other bodies involved in health research (namely, the [Health Research Consent Declaration Committee \(HRCDC\)](#) and the [Health Products Regulatory Authority \(HPRA\)](#)), and the mandate of the NREC COVID-19 to provide a ‘single national ethics opinion’; these advantages are not afforded by the existing system of local Research Ethics Committees (RECs).

NREC COVID-19 review process



1. World Health Organization (2020): A Coordinated Global Research Roadmap: 2019 Novel Coronavirus.
 2. Health research as defined by the Health Research Regulations 2018.

Importantly, NREC COVID-19 was established to accelerate the initiation and delivery of COVID-19 research while maintaining international best practice in ethics review. The Committee grounded its decisions in the fundamental ethical principles set out in the Declaration of Helsinki³ and drew from other trusted resources, including the Department of Health’s publication Ethical Framework for Decision-Making in a Pandemic.⁴ Sources of European guidance included the position paper The Responsibility of

Research Ethics Committees during the COVID-19 Pandemic, published by the European Network of Research Ethics Committees (EUREC),⁵ and Guidance on the Management of Clinical Trials during the Covid-19 (Coronavirus) Pandemic, published by the European Medicines Agency (EMA).⁶

Led by the Department of Health, the implementation of Ireland’s first National Research Ethics Committee is an exemplar of agile and focused cross-organisational collaboration.

Cross-organisational collaboration to launch NREC COVID-19

NATIONAL
COORDINATED
RESPONSE FOR
**RESEARCH
ETHICS**



3. World Medical Association (2013): Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. JAMA. 310 (20): 2191-2194.
4. Department of Health (2020): Ethical Framework for Decision-Making in a Pandemic
5. EUREC (2020): Position of the European Network of Research Ethics Committees (EUREC) on the Responsibility of Research Ethics Committees during the COVID-19 Pandemic.
6. European Medicines Agency (2020): Guidance On The Management Of Clinical Trials During The Covid-19 (Coronavirus) Pandemic



Message from the Chair of the National Research Ethics Committee for COVID-19



Professor Mary Horgan
Chair, NREC COVID-19 and President,
Royal College of Physicians of Ireland

The National Research Ethics Committee for COVID-19 was established in April 2020 by then Minister for Health Simon Harris as a crucial element of the national research response to the public health emergency. Research is an essential component of the global pandemic response to a new infectious disease.

The onset of a pandemic brings uncertainty and, with that, the need for a rapid response to understand and control infection that is scientifically robust, evidence-based and data driven. The usual protections that are in place to protect research participants and research integrity are sacrosanct and should be upheld at all costs during a national crisis. During its temporary tenure, the NREC COVID-19 committed to ensuring that the urgency of the COVID-19 pandemic did not compromise these protections; rather, it bolstered the need for rigorous ethical research.

Ireland's first NREC afforded researchers the opportunity to have a single harmonised approach to the review of their health research proposals. The NREC COVID-19 process involved coordinated interaction where necessary with the [HRCDC](#) and the [HPRA](#), which facilitated a streamlined approach for researchers during what was a challenging time for research. The remit of the Committee was to communicate ethics opinions in an agile way while ensuring that the trusted ethical principles for medical research involving human subjects were held to the highest standard. In the spirit of collaboration, the NREC COVID-19 shared its position statement on capacity to consent, a complex and timely topic, with the local Research Ethics Committees (RECs) and researchers. Furthermore, I am proud that our experience of implementing Ireland's

first national mechanism for research ethics review was published in the peer-reviewed journal, HRB Open Research.

Membership of the NREC COVID-19 was drawn from the scientific, medical, ethical, and legal communities. Of particular note and value was the participation by patient and public involvement (PPI) members. PPI is a key component of meaningful research, as patients and the public should be at the heart of every health system. It was a challenging time to set up a new committee, but thanks to the unwavering commitment and dedication of our members, operationally supported by our highly skilled [National Office](#) team, we achieved the goal set out in our Terms of Reference – all in a virtual format.

I would like to express my gratitude to the then Minister for Health for establishing the NREC COVID-19, and I would also like to thank the members of the Committee, and the National Office team. I also appreciate the collaboration of the HRCDC, chaired by Ms Brigid McManus, and the HPRA, in addition to the local REC community including Dr Sadhbh O’Neill (Tallaght University Hospital and St James’s Hospital REC) and Ms Gillian Vale (Beaumont Hospital REC). I gratefully acknowledge Professor Siobhán O’Sullivan and Dr Teresa Maguire for their work in support of the NREC COVID-19 during the past year.

Committee members

Under the leadership of Professor Mary Horgan, infectious diseases expert, the Committee is made up of nineteen volunteer members. They come from a diverse background of expertise, skills and experience, including ‘non-expert’ members and PPI representatives in line with best practice in research ethics review. Committee membership listed by name is included in Appendix I.

‘The patient voice is an essential part of ethical considerations on pandemic-related health research in Ireland. NREC COVID-19 was made up of a diverse group of members, who worked to ensure that patient and public involvement was a highly valued and core part of the decision-making process.’

Gráinne McGettrick

Member of NREC COVID-19; Policy and Research Manager, Acquired Brain Injury Ireland



‘The establishment of a national centralised mechanism of research ethics review is one of the most significant steps for clinical research over the past decade. It will allow for more efficient processing of research applications and will promote large-scale collaborative clinical trials that will increase the impact of health research in Ireland.’

Dr Donal O’Gorman

Member of NREC COVID-19; Director, Centre for Preventive Medicine; Interim Director, National Institute for Cellular Biotechnology, Dublin City University

Committee meetings

During the period of its tenure (from April to August 2020), the NREC COVID-19 met fourteen times.

The NREC COVID-19 was established under S.I. No. 190/2004,⁷ which meant that the Committee was committed to a quorum of seven persons at each meeting. The quorum was surpassed at every meeting of the NREC COVID-19. The average attendance at each meeting was approximately 16 members.

Applications received and decisions taken

Across the 14 meetings, the NREC COVID-19 reviewed 93 applications. Of these, four applications were declined, and 85 final approvals were issued. Four studies did not go beyond provisional approval stage.

Studies included basic scientific and social research, clinical trials, epidemiology research, and applied research. The breadth of studies reviewed by the NREC COVID-19 not only included those directly related to COVID-19, but also the secondary impacts that the pandemic had on other areas of healthcare. This is in line with the World Health Organization's A Coordinated Global Research Roadmap: 2019 Novel Coronavirus,⁸ in which a research objective was to investigate the 'non-intended consequences of epidemic-control decisions'.

7. S.I. No. 190/2004 - European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004.

8. World Health Organization (2020): A Coordinated Global Research Roadmap: 2019 Novel Coronavirus.

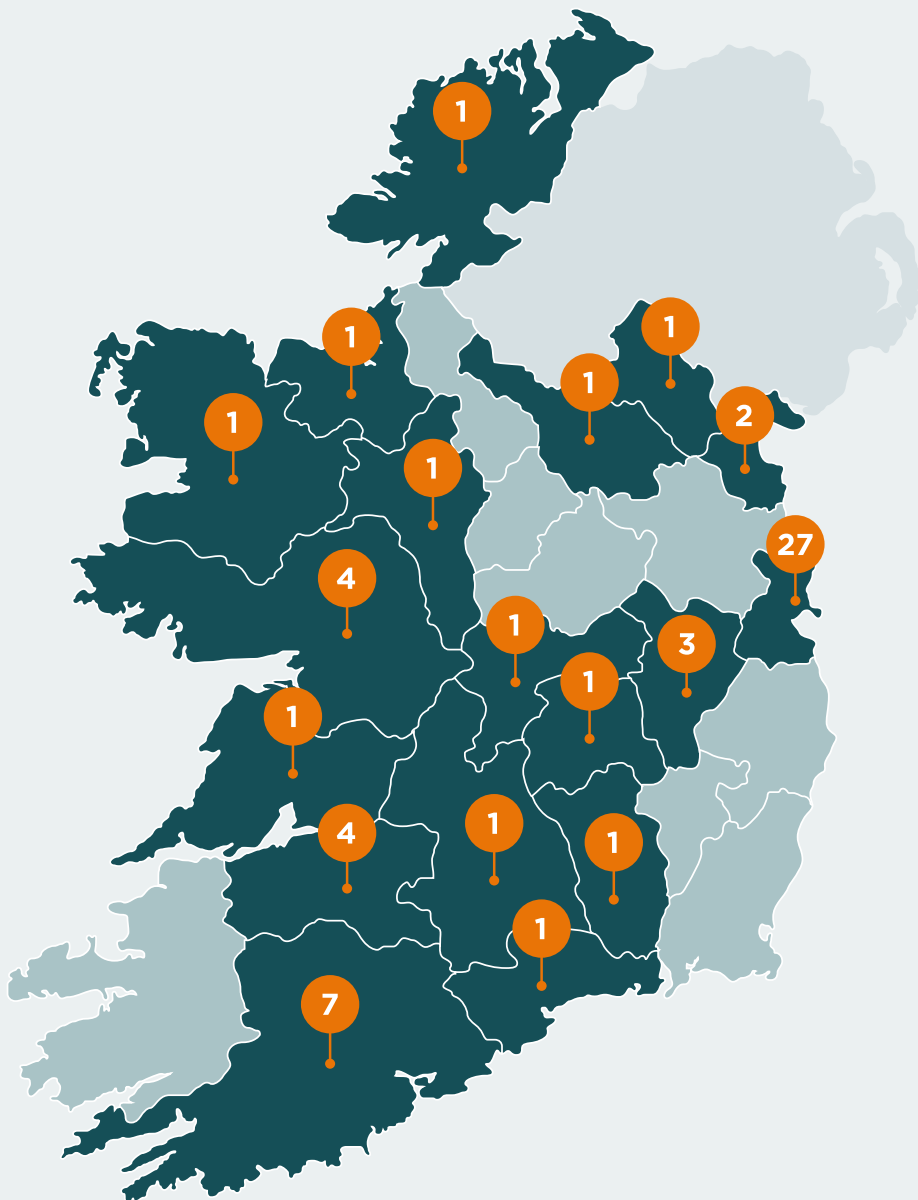
Diversity of research reviewed by NREC COVID-19



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

Research approved by the NREC COVID-19 was carried out within 61 institutions across 20 of the 26 counties in the Republic of Ireland.

Geographical spread of COVID-related research approved by NREC COVID-19



County	Institutions
Cavan	1
Clare	1
Cork	7
Donegal	1
Dublin	27
Galway	4
Kerry	1
Kildare	3
Kilkenny	1
Laois	1
Limerick	4
Louth	2
Mayo	1
Monaghan	1
Offaly	1
Roscommon	1
Sligo	1
Tipperary	1
Waterford	1
Wexford	1



The research approved by the NREC COVID-19 not only had national significance, it also highlighted Ireland's role in driving internationally relevant COVID-related research. A total of 23 studies approved by the NREC COVID-19 were part of international collaborations.

The tenure of the NREC COVID-19 came to an end in August 2020. A standing subcommittee was established to meet the oversight and related responsibilities with regard to studies approved by the NREC COVID-19 with the support of the National Office team. The NREC COVID-19 standing subcommittee includes the Chair and the two Deputy Chairs.

A key role of the standing subcommittee is the review of substantial amendments of ongoing studies. On occasion, additional members of the NREC COVID-19 are co-opted to support the review of substantial amendments. Between August and December 2020, the standing subcommittee reviewed a further 13 substantial amendments.



Key considerations

Prompt and efficient review

Internationally, an emphasis was placed on ethics committees in order to facilitate accelerated ethics review for essential COVID-related research without compromising human participants' protection. The NREC COVID-19 provided the Irish research community with an expedited and 'single national ethics opinion' for COVID-related health research.

All valid and complete applications that were submitted ahead of the weekly submission deadlines were reviewed within seven days of the deadline. The vast majority of the 93 applications reviewed received a decision letter within one-to-two days of a NREC COVID-19 meeting.

Ethics considerations

Research practices have had to adapt during the COVID-19 pandemic. This has meant that the NREC COVID-19 was faced with sometimes novel and complex ethics considerations. Some of these included capturing informed assent for research participants who lack decision-making capacity due to their physical or mental status; changes to consent models due to social restrictions guidelines; as well as ethical and data protection considerations for new digital communication and research platforms. Frequent areas of feedback from the Committee to applicants included clarifications on data security and protection, readability of patient information leaflets and consent forms, and other aspects of the research protocol including inclusion and exclusion criteria.

Where possible, the NREC COVID-19 endeavoured to provide consistent feedback to the research community and it discussed its shared alignment on complex issues with other regulatory bodies such as the [HRCDC](#) and the [HPRA](#).

Cross-organisational coordination

The [National Office](#) and the HRCDC Secretariat worked closely to ensure that the operations of the integrated review process were efficient, streamlined and coordinated. The National Office maintained close communication with the HPRA throughout its tenure, in order to share information, expertise, and solutions to ongoing challenges.

A coordinated approach and open communication channels from the outset across the various health research authorities meant that strong partnerships have been made for future endeavours. The mutual objective of accelerating Irish health research, despite the unprecedented environment for research, ensured that momentum was maintained throughout.

Logistical response

Establishing a new ethics review system during a pandemic presented several logistical challenges, largely due to restrictions on face-to-face meetings, travel, and consultations.

At the beginning of their tenure, committee members received IT training in both the selected videoconferencing facility and use of a secure online electronic reading room to ensure that remote meetings ran smoothly and diligently.

Notwithstanding the benefits of technology, the successful operation of the NREC COVID-19 relied both on the commitment and efficiency of the Chair and committee members, as well as the operational support provided by the National Office team.





National Office strategic priorities

Impact to date
and priorities over 2021



As a highly anticipated addition to health research infrastructure and with an ambitious brief, it is essential that the National Office for Research Ethics Committees maintains a sharp focus on its distinct new role in supporting health research. The regulatory and ethics considerations for health research can be complex, so it is essential that the National Office and the NRECs add cohesion and clarity to the research environment.

We are committed to driving the transition to a national system for research ethics review for health research remits of strategic importance for Ireland. The NRECs will work alongside local Research Ethics Committees (RECs) in a mixed-model system to support the spectrum of health research through rigorous independent review in a timely and transparent manner.

We have identified five strategic priorities to guide the NREC system, many of which we have already significantly advanced in our nine months of establishment in 2020.

Strategic Priorities



The summary below sets out several key actions taken in 2020 under each strategic priority, and offers a snapshot of how we plan to continue to address each focus area over 2021:

1. To deliver a robust and transparent system for NRECs that provides competent and timely ethics review.

Update 2020:

- The [National Office](#) operationalised the NREC COVID-19, Ireland's first national mechanism for research ethics review, which provided proof of principle of the value of a 'single national ethics opinion' to Irish health research. Convening mostly on a weekly basis, NREC COVID-19 returned 93 decisions on COVID-19-related health research during its four-month tenure.
- In partnership with the Department of Health and the [HPRA](#), and in collaboration with local Research Ethics Committees (RECs), we developed a roadmap of transition to a national system of research ethics review for the initial priority areas of clinical trials of investigational medicinal products and clinical investigations of medical devices.
- A notable milestone was our launch of a public call for Expressions of Interest for membership of NRECs, the first campaign of its kind, to inform a recommendation from the National Office for appointment by the Minister for Health.

Current steps over 2021:

- Informed by an expert assessment panel, the National Office made a recommendation to the Minister for Health for membership appointments to three NRECs, two for clinical trials of investigational medicinal products (NREC-CTs) and one for clinical investigations of medical devices (NREC-MD). Crucially, this recommendation represented a diversity of expertise and perspectives, reflective of contemporary Irish society.
- The National Office is operationalising the NREC-CTs (Committees A and B) and the NREC-MD following recent membership appointments made by the Minister for Health. We are ensuring that members receive appropriate training and are supported in their onboarding to work virtually in a secure and efficient manner.
- We will implement best practice operational procedures to ensure robust and efficient NREC review, in line with prevailing national and EU law, namely the EU Clinical Trials Regulation (EU CTR; Regulation EU No 536/2014) and EU Medical Device Regulation (EU MDR; Regulation EU No 2017/745).
- The National Office will work in partnership with the Department of Health to develop a national mechanism for research ethics review of studies involving medical application of ionising radiation, as a regulated health research remit.



2. To partner with health research stakeholders, with the mutual objective of ensuring that Ireland's ethics framework is poised to adopt international best practice and change.

Update 2020:

- The National Office secured representation on key European working groups, including those led by the European Medicines Agency, to ensure that our national preparedness for EU Regulations for clinical trials and medical devices is informed by timely and accurate information.
- The National Office benefited from regular engagement with the HPRA and the Department of Health to ensure that the independent processes for ethics and regulatory review can be coordinated where necessary to enable a 'single national opinion' in clinical trials and medical device research areas.
- The National Office has established regular and meaningful engagement with local REC colleagues, including through our participation in the HSE-led Local REC Reform Working Group.
- The National Office secured membership of EUREC, the European Network of Research Ethics Committees.
- Given our interest in the broader influences on the research environment, the National Office gained representation on fora with agendas beyond research ethics, including the Irish Health Research Forum.

Current steps over 2021:

- In partnership with the HPRA, the National Office jointly launched the Clinical Trial Regulation - National Collaboration Project to test Ireland's readiness for the EU CTR.
- As the EU landscape for health research evolves, we will continue to secure 'seats at the right tables', including internationally, to ensure both representation of our national interests and opportunities to leverage and shape developments in research ethics review.
- The National Office will continue to engage with key stakeholders involved in the conduct of research within the NRECs' scope, including Cancer Trials Ireland, the Irish Pharmaceutical Healthcare Association (IPHA), clinical trial networks, research-performing organisations, and the wider research community, to ensure that the NREC system is bespoke to the needs of the Irish research environment.
- We will continue to connect with patient advocacy organisations, including the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), and Health Research Charities Ireland (HRCI), to ensure that the NREC system is centred on the research participant and the patient, including ensuring appropriate PPI representation on the NRECs.

3. To engage with the REC community, researchers, and the wider public to facilitate education on ethical decision-making.

Update 2020:

- The Head of the National Office delivered a public webinar with Professor Mary Horgan, Chair of NREC COVID-19, facilitated by the HRB Trials Methodology Research Network (HRB-TMRN), to describe the implementation of Ireland's first NREC against the backdrop of the COVID-19 pandemic. In addition, these opportunities and challenges were further detailed in a peer-reviewed publication (Sheehy A et al. HRB Open Research 2020, 3:63).
- The National Office established a 'help desk' approach to assist researchers, where appropriate, with their applications, informed by the practical guidance and experience of the National Office team.

Current steps over 2021:

- The National Office hosted a student placement to provide meaningful work experience and enable insight into the role of research ethics as an important regulatory component of health research.
- We will seek opportunities to partner with educational stakeholders to foster public understanding of the role of research ethics review as an enabler of health research and its outcomes.
- Consistent with the scope of our remit in Education and Outreach, we will share learnings and best practice in research ethics review with local Research Ethics Committees (RECs).

- We will develop our website with tailored resources for researchers, research participants, students and the wider public, to improve understanding of research ethics throughout society.

4. To be a thought leader in the ethics arena by seeding discussion, advancing debate, and providing trusted information.

Update 2020:

- Health research can give rise to complex ethical considerations. The NREC COVID-19 shared its position statement on capacity to consent, a timely topic in a pandemic environment, with the local Research Ethics Committees (RECs) and researchers.
- The NREC COVID-19 endorsed the [Manifesto for EU COVID-19 Research](#), which emphasises the imperative to make scientific results publicly accessible without delay and encourages non-exclusive royalty-free licences on the intellectual property resulting from EU-funded research.

Current steps over 2021:

- The National Office will support the new NREC-CTs and NREC-MD to provide leadership and consensus where appropriate in pertinent or complex research ethics areas.
- The National Office team will stay abreast of regulations and guidelines relevant to research ethics and developments in the health research environment, so as to establish ourselves as a trusted information resource for the research community.

5. To be an agile and trusted office in national public service.

Update 2020:

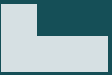
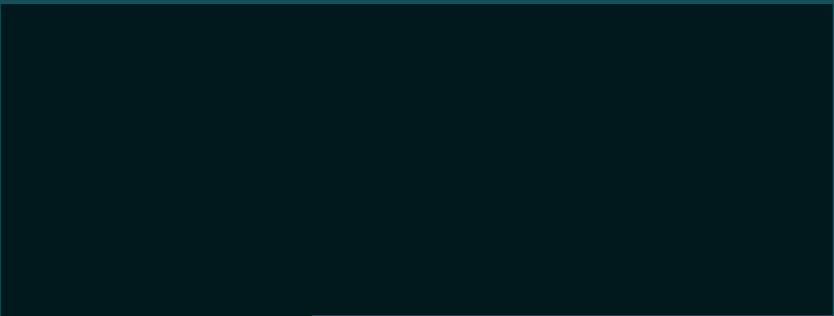
- Within days of its establishment, the National Office set about operationalising Ireland's first NREC as an important research component of the national coordinated response to the pandemic. In this way, we supported the research community to rapidly initiate robustly reviewed research, and in turn support immediate evidence-based decision-making during the COVID-19 pandemic.
- Based on our unique role in the research environment, we delineated our branding and values, which provide an important grounding for visibility and understanding of what we do to support health research.
- We launched our dedicated website, with broad accessibility, as an important tool for trusted information and transparency in NREC work.
- We recruited key team members to resource the National Office in the strategic and operational elements of its remit.

Current steps over 2021:

- The National Office team will continue to improve our website to ensure that it is a reliable platform for trusted information on research ethics for everyone. We will ensure that the minutes of NREC meetings are readily accessible, searchable and made available promptly.
- We will recruit the additional team members required to ensure that a core high-performing National Office team is in place to deliver on the launch of NRECs. Moreover, we will attract and retain the best talent in scientific research management.
- Informed by our experience of NREC COVID-19, we will remain agile and responsive to the dynamics of the research environment as it evolves with the challenges and opportunities to come in 2021.



Appendices





Appendix I.

NREC COVID-19: committee membership listed by name

Chairperson:

Professor Mary Horgan

Consultant Physician, Cork University Hospital; President, Royal College of Physicians of Ireland; and President, Infectious Diseases Society of Ireland

Deputy Chairpersons:

Professor Hannah McGee

Dean, Faculty of Medicine and Health Sciences, Royal College of Surgeons in Ireland

Professor Anthony Staines

Professor of Health Systems at the Centre for Integrated Care and School of Nursing, Psychotherapy and Community Health, Dublin City University

Members:

Professor Mary Donnelly

Professor of Law, School of Law, University College Cork

Professor Tom Fahey

Professor of General Practice, Department of General Practice, Royal College of Surgeons in Ireland

Ms Sharon Foley

CEO, Irish Hospice Foundation

Ms Caoimhe Gleeson

National Programme Lead for Assisted Decision Making and National Specialist in Accessibility, Health Service Executive

Professor Andrew Green

Professor of Medical Genetics, School of Medicine, University College Dublin; Consultant Clinical Geneticist at Children's Health Ireland (CHI) at Crumlin

Mr Gavin Lawler

Radiation Therapist and Clinical Trials Coordinator Team Leader, Beacon Hospital Dublin

Professor Patrick Manning

Consultant Respiratory Physician, Bon Secours Hospital Dublin and St Francis Private Hospital, Mullingar; Associate Professor of Medicine, Royal College of Surgeons in Ireland

Ms Gráinne McGettrick

Policy and Research Manager, Acquired Brain Injury Ireland

Ms Dympna Moran

Retired. Former Tús Supervisor, Dublin Northwest Area Partnership

Professor Suzanne Norris

Consultant Hepatologist, St James's Hospital; Professor in Gastroenterology and Hepatology, Trinity College Dublin

Dr Donal O'Gorman

Director, Centre for Preventive Medicine; Interim Director, National Institute for Cellular Biotechnology, Dublin City University

Professor Shaun O'Keeffe

Consultant Geriatrician, Department of Geriatric Medicine, Galway University Hospitals

Dr Jean Saunders

Director, Claddagh Statistical Consultancy and Training Services; Vice-Chair, University of Limerick Hospitals Group Research Ethics Committee; Adviser, Science and Engineering Faculty Research Ethics Committee, University of Limerick

Professor Orla Sheils

Dean, Faculty of Health Sciences; Professor of Molecular Diagnostics, Trinity College Dublin

Dr Akke Vellinga

Epidemiologist; Senior Lecturer, School of Medicine, NUI Galway; Chair, Irish College of General Practitioners Research Ethics Committee

Mr John Woods

Data Protection Officer, St Patrick's Mental Health Services, St Patrick's University Hospital, Dublin

Appendix II.

NREC COVID-19: final decisions following ethics review

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-001	A clinical risk score for monitoring and predicting respiratory failure in COVID-19 pneumonia, the COVID Clinical Index (CCI) score	Prof.	Richard Costello	Royal College of Surgeons in Ireland	Respiratory / Infection	22/04/2020	Approved
20-NREC-COV-001-AMEND	A clinical risk score for monitoring and predicting respiratory failure in COVID-19 pneumonia, the COVID Clinical Index (CCI) score	Prof.	Richard Costello	Royal College of Surgeons in Ireland	Respiratory / Infection	27/04/2020	Approved
20-NREC-COV-002	Anxiety and Resilience in Ear Nose and Throat departments during COVID-19	Mr	Mel Corbett	Royal College of Surgeons in Ireland	Mental Health	22/04/2020	Approved
20-NREC-COV-003	Progression of Imaging findings in COVID19	Dr	Michael Courtney	St. James's Hospital	Infection	06/05/2020	Approved
20-NREC-COV-004	Clinical Outcomes of hospitalised patients with covid-19 treated with hydroxychloroquine	Prof.	Colm Bergin	St. James's Hospital	Infection	29/04/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-005	Psychological impact of Covid 19 on healthcare staff working in ICU and coping strategies used.	Dr	Robert French-O'Carroll	Children's Health Ireland, Crumlin	Mental Health	29/04/2020	Approved
20-NREC-COV-006	SARS-CoV-2 Observational Study of community acquired acute respiratory tract infection during a time of widespread suspected COVID-19 in European primary care	Dr	Akke Vellinga	NUI Galway	Respiratory / Infection	29/04/2020	Declined
20-NREC-COV-008	CROWN CORONATION: Chloroquine Repurposing to healthworkers for Novel Coronavirus mitigation	Prof.	Ellen O'Sullivan	St. James's Hospital	Infection	29/04/2020	Approved
20-NREC-COV-009	COVID-IYON Study	Prof.	Linda Coate	University Hospital Limerick	Cancer / Infection	29/04/2020	Approved
20-NREC-COV-010	Rheumatology COVID-19 study	Prof.	Geraldine McCarthy	Mater Misericordiae University Hospital	Inflammatory and Immune System / Infection	29/04/2020	Approved
20-NREC-COV-013	Emergency department attendances during COVID-19: the impact of government pandemic measures	Dr	Kantikiran Dasari	Cork University Hospital	Generic Health Research	29/04/2020	Approved
20-NREC-COV-014	The impact of the COVID-19 pandemic on healthcare workers in the west of Ireland	Dr	Helen Tuite	Galway University Hospitals	Generic Health Research	06/05/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-015	COVID-19: Rapid evidence synthesis, identification and dissemination to support policy makers and frontline GP clinicians in the context of a global pandemic	Prof.	Susan Smith	Royal College of Surgeons in Ireland	Generic Health Research	29/04/2020	Approved
20-NREC-COV-016	Survey on autonomy and supervision on ICU's during the COVID-19 crisis	Prof.	Martina Hennessy	Trinity College Dublin	Generic Health Research	06/05/2020	Approved
20-NREC-COV-017	ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD)	Prof.	John Laffey	Galway University Hospitals	Respiratory / Infection	06/05/2020	Approved
20-NREC-COV-018	Surveillance Epidemiology of Coronavirus (COVID-19) Under Research Exclusion - Atopic Dermatitis (SECURE-AD)	Prof.	Alan Irvine	St. James's Hospital	Skin / Infection	06/05/2020	Approved
20-NREC-COV-019	Development of a validation panel to compare the sensitivity and specificity of SARS-CoV-2 antibody assays	Dr	Mary Keogh	Beaumont Hospital	Infection	06/05/2020	Approved
20-NREC-COV-020	A study on the role of immune dysfunction in sepsis and COVID-19	Dr	Bairbre McNicholas	Galway University Hospitals	Infection	06/05/2020	Approved
20-NREC-COV-022	Assessment of accuracy of portable chest x-ray in the diagnosis of COVID-19	Dr	Barry Hutchinson	Mater Misericordiae University Hospital	Infection	06/05/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-024	Percutaneous Coronary Intervention patterns in the Republic of Ireland during the COVID-19 outbreak	Dr	Liesbeth Rossell	Galway University Hospitals	Cardiovascular	13/05/2020	Approved
20-NREC-COV-025	Rapid response and learning for later: establishing high quality information networks and evaluation frameworks for the National Ambulance Service response to COVID-19	Dr	Siobhán Masterson	NUI Galway	Generic Health Research	06/05/2020	Approved
20-NREC-COV-026	Emergency transition of hospital-based Immunoglobulin replacement therapy to home based self-administration due to COVID-19; impact on disease management and patient satisfaction	Dr	Fionnuala Cox	St. James's Hospital	Inflammatory and Immune System	13/05/2020	Approved
20-NREC-COV-030/1	Altered lives in a time of crisis: Preparing for recovery from the impact of the COVID-19 pandemic on the lives of older adults	Dr	Nollaig Burke	Trinity College Dublin	Generic Health Relevance	13/05/2020	Approved
20-NREC-COV-030/2	Altered lives in a time of crisis: Preparing for recovery from the impact of the COVID-19 pandemic on the lives of older adults	Prof.	Roseanne Kenny	Trinity College Dublin	Generic Health Relevance	10/06/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-031	APPROVE-CARE Awake Prone Positioning to Reduce invasive Ventilation in COVID-19 induced Acute Respiratory failure	Dr	Bairbre McNicholas	Galway University Hospitals	Respiratory / Infection	13/05/2020	Declined
20-NREC-COV-032	CONTINUUM: Covid-19 neonatal, child and adult: understanding immune responses	Prof.	Eleanor Molloy	"Tallaght University Hospital"	Inflammatory and Immune System	13/05/2020	Approved
20-NREC-COV-034	CUPID COVID-19	Dr	Emma Nicholson	University College Dublin	Generic Health Relevance	13/05/2020	Approved
20-NREC-COV-035	An assessment of Neurological illness during a pandemic of severe acute respiratory syndrome - coronavirus - 2	Prof.	Tim Lynch	Dublin Neurological Institute	Neurological / Infection	13/05/2020	Approved
20-NREC-COV-037	Creating an evidence-based toolbox for targeted public health interventions during COVID-19: a cross-border analysis to disentangle psychological, behavioural, media and governmental responses.	Prof.	Catherine Darker	Trinity College Dublin	Generic Health Relevance	13/05/2020	Approved
20-NREC-COV-038	Compassion, social connectedness and trauma resilience during the COVID-19 pandemic: A multi-national study	Dr	Marcela Matos	University of Coimbra, Portugal	Mental Health	13/05/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-040	Platform Randomised trial of interventions against COVID-19 in older people (PRINCIPLE)	Prof. Andrew Murphy	NUI Galway	Infection	13/05/2020	Approved	
20-NREC-COV-041	Short period incidence study of Severe Acute Respiratory Infection (SPRINTSARI)	Prof. Alistair Nichol	St Vincent's University Hospital	Respiratory / Infection	20/05/2020	Approved	
20-NREC-COV-042	SARS-CoV-2 Observational Study of community acquired acute respiratory tract infection during a time of widespread suspected COVID-19 in European primary care	Dr Akke Vellinga	NUI Galway	Respiratory / Infection	20/05/2020	Approved	
20-NREC-COV-043	A Review of Irish Patients Presenting with Acute Coronary Syndrome During the COVID-19 Pandemic - The SARS-CoV-2 ACS Study.	Dr Stephen O'Connor	St James's Hospital	Cardiovascular	03/06/2020	Approved	
20-NREC-COV-044	COVID19 in healthcare workers, utility of serology and exhaled breath condensate in informing staffing	Dr Eoghan de Barra	Royal College of Surgeons in Ireland	Infection	20/05/2020	Approved	
20-NREC-COV-045	The ESMO-CoCARE Registry for patients with a Malignancy who are diagnosed with COVID-19	Prof. Maccon Keane	Galway University Hospitals	Cancer / Infection	27/05/2020	Approved	

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-047	Study to investigate COVID-19 infection in people in Ireland (SCOPI)	Dr	Derval Igoe	HSE Health Protection Surveillance Centre	Infection	27/05/2020	Approved
20-NREC-COV-050	Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)	Prof.	Mary McCarron	Trinity College Dublin	Generic Health Relevance	27/05/2020	Approved
20-NREC-COV-051	Clinical Characteristics of Dysphagia and Communication Difficulties among Hospitalised Adults with COVID-19 in Ireland: An Observational Cohort Study	Dr	Julie Regan	Trinity College Dublin	Respiratory / Infection	27/05/2020	Approved
20-NREC-COV-051-AMEND	Clinical Characteristics of Dysphagia and Communication Difficulties among Hospitalised Adults with COVID-19 in Ireland: An Observational Cohort Study	Dr	Julie Regan	Trinity College Dublin	Respiratory / Infection	01/07/2020	Approved
20-NREC-COV-052	TERAVOLT: Thoracic cancers international Covid-19 collaboration	Prof.	Linda Coate	University Hospital Limerick	Cancer / Infection	27/05/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-053	A randomised controlled trial of the impact of the availability of procalcitonin testing on antimicrobial prescribing in the treatment of patients admitted to hospital with Covid-19 infection	Dr	Aoife Fleming	University College Cork	Infection	03/06/2020	Approved
20-NREC-COV-054	Awake Prone Positioning to Reduce invasive Ventilation in COVID-19 induced Acute Respiratory failure- APPROVE-CARE	Dr	Bairbre McNicholas	Galway University Hospitals	Respiratory / Infection	27/05/2020	Approved
20-NREC-COV-055	Burden of COVID-19 Infection in a Roma Population in an Urban Irish Setting: A Retrospective Review	Dr	Niamh Reidy	Royal College of Surgeons in Ireland/ Beaumont Hospital	Infection	27/05/2020	Approved
20-NREC-COV-056	The All Ireland Infectious Diseases Cohort Project (AIID Cohort Project)	Dr	Patrick Mallon	St Vincent's University Hospital	Infection	27/05/2020	Approved
20-NREC-COV-057	Anxiety levels among health care workers within Irish mental health service during covid-19: A Survey.	Dr	Alin Dumitrescu	South Lee Mental Health Services	Mental Health	03/06/2020	Approved
20-NREC-COV-058	Enhancing serology surveillance and biomarker monitoring in SARS-CoV-2 pandemic	Prof.	Maria Fitzgibbon	Mater Private Hospital	Infection	03/06/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-059	European Paediatric Cardiology Multisystem Inflammatory Syndrome Survey Cardiovascular manifestations during COVID-19 Pandemia	Dr	Colin McMahon	Children's Health Ireland, Crumlin	Cardiovascular / Infection	03/06/2020	Approved
20-NREC-COV-060	ICE: Impact of COVID 19 on ENT Surgery in Ireland	Prof.	Patrick Sheehan	Victoria University Hospital	Infection	03/06/2020	Declined
20-NREC-COV-061	COVID-19: (Space Time) Scanning, Mobility and Intervention Diagnosis (CO/SMID)	Dr	Paul Hynds	Environmental Sustainability and Health Institute	Infection	10/06/2020	Approved
20-NREC-COV-062	Home Administration of Omalizumab in patients with Chronic Spontaneous Urticaria and Angioedema during the COVID-19 Pandemic: A Patient Experience Questionnaire	Dr	Catherine King	St. James's Hospital	Skin	17/06/2020	Approved
20-NREC-COV-064	"Irish SARS-CoV-2 serology study of children with pneumonia during COVID-19 pandemic Short Title: SOCKs Study (Serology Of COVID in Kids)"	Dr	Muireann Ní Chróinín	Cork University Hospital	Respiratory / Infection	17/06/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-065	A cross section observational study on the seroprevalence of the antibodies to SARS-CoV-2 in a cohort of patients receiving Opiate Substitution Therapy: Consideration of possible protective effects of Opiate Substitution Treatment (OST) drugs on clinical manifestation of SARS-CoV-2.	Dr	Fiona Fenton	National Drug Treatment Centre	Infection	24/06/2020	Approved
20-NREC-COV-067	Impact of Corona Virus Pandemic on Allergic and Autoimmune Dysregulation in Infants Born During Lockdown	Prof.	Jonathan Hourihane	Royal College of Surgeons in Ireland	Inflammatory and Immune System	24/06/2020	Approved
20-NREC-COV-068	Staff mental health while providing care to people with intellectual disability during the COVID-19 pandemic	Dr	Fintan Sheerin	Trinity College Dublin	Mental Health	24/06/2020	Approved
20-NREC-COV-069	Irish Coronavirus Sequencing Consortium	Prof.	Paul Cotter	Teagasc	Infection	24/06/2020	Approved
20-NREC-COV-070	Surveillance Epidemiology of Coronavirus (COVID-19) Under Research Exclusion - Alopecia (SECURE-Alopecia)	Dr	Dmitri Wall	University College Dublin	Inflammatory and Immune System	24/06/2020	Approved
20-NREC-COV-071	Covid-19: " A Frontline Worker's Perspective"	Dr	Conor Loftus	HSE Limerick/ Midwest HSE	Infection	01/07/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-072	Post-Intensive Care Nutrition Status in Patients with COVID-19	Prof.	Alistair Nichol	"St Vincent's University Hospital UCD"	Infection	01/07/2020	Approved
20-NREC-COV-073	Global Rheumatology Alliance survey on impact of COVID-19 on rheumatology trainees	Dr	Richard Conway	St. James's Hospital	Infection	01/07/2020	Approved
20-NREC-COV-074	European Society Of Intensive Care Medicine COVID-19 Project (UNITE-COVID)	Prof.	Alistair Nichol	St Vincent's University Hospital	Infection	01/07/2020	Approved
20-NREC-COV-076	Assessment of patients with COVID-19 undergoing CTPA	Dr	Afshin Nasoodi	St James's Hospital	Cardiovascular /Infection	01/07/2020	Declined
20-NREC-COV-077	PPE Safe	Dr	Joan Cahill	Trinity College Dublin	Generic Health Relevance	01/07/2020	Approved
20-NREC-COV-078	COVID-19: Exploring the psychosocial impact of the pandemic on women with breast cancer	Dr	Caitriona Cahir	Royal College of Surgeons in Ireland	Cancer / Mental Health	22/07/2020	Approved
20-NREC-COV-079	The Relationship of Social Deprivation to Outcomes in COVID-19 in an Urban Irish Setting	Dr	Eoghan De Barra	Royal College of Surgeons in Ireland	Generic Health Relevance	22/07/2020	Approved
20-NREC-COV-080	Health Literacy Survey in Ireland	Dr	Sarah Gibney	Department of Health	Generic Health Relevance	22/07/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-081	Professional Identity Formation of Junior Doctors during the COVID Crisis, the Role of Agency and preparing for Follow-up.	Prof.	Martina Hennessey	Trinity College Dublin	Mental Health	22/07/2020	Approved
20-NREC-COV-082	Perspectives of parents / guardians and nurses of respite services for children with complex care needs in CHO1	Prof.	Maria Brenner	Trinity College Dublin	Generic Health Relevance	22/07/2020	Approved
20-NREC-COV-083	Burnout on the Frontline, The impact of COVID-19 on Emergency Department staff wellbeing	Dr	Ann Payne	St Stephen's Hospital	Mental Health	22/07/2020	Approved
20-NREC-COV-084	Anti-SARS-CoV-2 IgG Seroprevalence in Irish Blood Donors	Dr	Niamh O'Flaherty	Irish Blood Transfusion Service	Infection	22/07/2020	Approved
20-NREC-COV-085	Evaluating Factors Associated with Mental Health Outcomes among Dublin Hospital Healthcare Workers Exposed to the COVID-19 Pandemic	Dr	Damien Lowry	Mater Misericordiae University Hospital	Mental Health	22/07/2020	Approved
20-NREC-COV-086	COPE-CORONA: Identifying and strengthening personal resources among international healthcare workers to cope with the Corona pandemic	Dr	Padraic Dunne	Royal College of Surgeons in Ireland	Mental Health	05/08/2020	Approved
20-NREC-COV-087	ICE: Impact of COVID 19 on ENT Surgery in Ireland	Prof.	Patrick Sheahan	Victoria University Hospital	Generic Health Relevance / Infection	05/08/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-088	ReCaP: Rectal cancer Management During the COVID-19 Pandemic	Prof.	Fiachra Cooke	University Hospital Waterford	Cancer	05/08/2020	Approved
20-NREC-COV-089	Epidemiology, severity and outcomes of children presenting to emergency departments across Europe during the SARS-CoV-2 pandemic	Prof.	Michael Barrett	Children's Health Ireland, Crumlin	Generic Health Relevance	05/08/2020	Approved
20-NREC-COV-090	Analysis of the impact of COVID-19 pandemic on people with cystic fibrosis and parents of children with cystic fibrosis.	Prof.	Patricia Fitzpatrick	University College Dublin	Respiratory / Generic Health Relevance	05/08/2020	Approved
20-NREC-COV-091	Rapid assessment of the Implications of Covid-19 for People who use Drugs & Service Providers. (Survey)	Mr	Jim Walsh	Department of Health	Mental Health	05/08/2020	Approved
20-NREC-COV-092	Genetics of Mortality in Critical Care (GenOMICC)	Prof.	Alastair Nichol	St. Vincent's University Hospital	Infection	05/08/2020	Approved
20-NREC-COV-093	Expanding Care Capacity through Remote Monitoring of COVID-19 Patients	Prof.	Eilish McAuliffe	University College Dublin	Infection	19/08/2020	Approved
20-NREC-COV-094	Case studies for the Rapid assessment of the Implications of Covid-19 for People who use Drugs & Service Providers	Mr	Jim Walsh	Department of Health	Mental Health	05/08/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-095	Coagulopathy of COVID-19: A Pragmatic Randomized Controlled Trial of Therapeutic Anticoagulation versus Standard Care as a Rapid Response to the COVID-19 Pandemic (RAPID COVID COAG)	Prof.	Fionnuala Ní Áinle	"Mater Misericordiae University Hospital"	Infection	19/08/2020	Approved
20-NREC-COV-096	An exploration of service users' and psychologists' experiences of tele-therapy during Covid-19 within HSE Psychology services	Dr	Elaine Smith	HSE	Mental Health	19/08/2020	Approved
20-NREC-COV-098	A cross-sectional patient-reported study to assess the impact of the COVID-19 pandemic on the attitudes and preferences for administration of Somatostatin Analogues (SSAs) at home or in a healthcare setting for patients with a diagnosis of Neuroendocrine Tumours (NETs) or Acromegaly	Ms	Charlotte Ryan	University of Limerick	Metabolic	19/08/2020	Approved
20-NREC-COV-099	Using contact tracing data to gain insights into the epidemiology of COVID-19 infection in Ireland	Dr	Conor McAloon	University College Dublin	Infection	19/08/2020	Approved

NREC Reference ID	Title of Research Study	Title	Applicant Name	Institution(s)	Health Category	Date considered by NREC COVID-19	Final Decision
20-NREC-COV-100	What is the impact of the Covid 19 pandemic on the number and the nature of Admissions to Acute Psychiatric Units for Inpatient Care?	Dr	Niamh Liddy	HSE-West	Mental Health	19/08/2020	Approved
20-NREC-COV-101	Prevalence of COVID-19 Antibodies in Irish Healthcare Workers (PRECISE)	Dr	Niamh Allen	St. Vincent's University Hospital	Infection	19/08/2020	Approved
20-NREC-COV-102	Irish Attitudes to Privacy in Times of COVID19	Dr	Irina Tal	Dublin City University	Generic Health Relevance	19/08/2020	Approved
20-NREC-COV-103	Analysing blood-brain barrier integrity to inform on protection from COVID-19 associated encephalopathy.	Prof.	Colin Doherty	Trinity College Dublin	Infection / Neurological	19/08/2020	Approved
20-NREC-COV-104	Charter Trial - Can Nebulised HepArim Reduce acuTE lung injury in Patients with SARS-CoV-2 Requiring Mechanical Ventilation in Ireland (CHARTER-IrI)	Prof.	John Laffey	"NUI Galway Galway University Hospitals"	Infection / Respiratory	19/08/2020	Approved
20-NREC-COV-105	A study to determine the perceived value, impact, use and the effect of the Fluid Heart Tracker App on patients with heart failure and on service providers.	Ms	Norma Caples	"University Hospital Waterford / Trinity College Dublin"	Cardiovascular	19/08/2020	Approved

Appendix III.

NREC COVID-19: substantial amendments reviewed by the standing subcommittee (September–August 2020)

NREC Application Number	Applicant Title	Applicant Name	Institution(s)	Health Category	NREC COVID-19 Date of Initial Approval	Amendment Type	Amendment Approval Date
20-NREC-COV-072-AMEND 1	Prof.	Alistair Nichol	St Vincent's University Hospital / University College Dublin	Infection	08/07/2020	1. Addition of sites	01/10/2020
20-NREC-COV-068-AMEND	Dr	Fintan Sheerin	Trinity College Dublin	Mental Health	15/07/2020	1. Addition of sites	01/10/2020
20-NREC-COV-067-AMEND	Prof.	Jonathan Hourihane	Royal College of Surgeons in Ireland	Inflammatory and Immune System	13/07/2020	2. Notification of delay to start date	01/10/2020
20-NREC-COV-054-AMEND	Dr	Bairbre McNicholas	Galway University Hospitals	Respiratory / Infection	03/06/2020	"1. Addition of sites 2. Change of sponsor 3. Minor text change to consent form"	05/10/2020
20-NREC-COV-047-AMEND	Dr	Derval Igoe	HSE Health Protection Surveillance Centre	Infection	12/06/2020	1. Addition of sites	02/09/2020

NREC Application Number	Applicant Title	Applicant Name	Institution(s)	Health Category	NREC COVID-19 Date of Initial Approval	Amendment Type	Amendment Approval Date
20-NREC-COV-065-AMEND	Dr	Fiona Fenton	National Drug Treatment Centre	Infection	06/07/2020	Geographically extend the study to encompass an allied Dublin 2 HSE addiction clinic	03/11/2020
20-NREC-COV-010-AMEND	Prof.	Geraldine McCarthy	Mater Misericordiae University Hospital	Inflammatory and Immune System / Infection	06/06/2020	Collecting pseudonymised data as opposed to anonymous data	03/11/2020
20-NREC-COV-102-AMEND	Dr	Irina Tal	Dublin City University	Generic Health Relevance	25/08/2020	Modifications to the questionnaire	03/11/2020
20-NREC-COV-093-AMEND	Prof.	Eilish McAuliffe	University College Dublin	Infection	14/08/2020	Additional question added to questionnaire	03/11/2020
20-NREC-COV-008-AMEND	Prof.	Eileen O'Sullivan	St. James's Hospital	Infection	Study was not approved on first submission	1. Change of investigational medicinal product	Declined
20-NREC-COV-041-AMEND	Prof.	Alistair Nichol	St Vincent's University Hospital	Respiratory / Infection	22/05/2020	Short Period Incidence Study of Severe Acute Respiratory Infection (SPRINT-SARI)	10/12/2020
20-NREC-COV-072-AMEND 2	Prof.	Alistair Nichol	St Vincent's University Hospital / University College Dublin	Infection	30/07/2020	1. Addition of sites	10/12/2020
20-NREC-COV-104-AMEND 1	Prof.	John Laffey	"NUI Galway Galway University Hospitals"	Infection / Respiratory	03/09/2020	"1. Changes of Protocol 2. Changes to PIL"	10/12/2020



National Office
for Research Ethics Committees
Grattan House
67-72 Lower Mount Street
Dublin 2
D02 H638
Ireland

+353 1 234 5753
nationaloffice@nrec.ie
www.nrecoffice.ie

  @NREC_Office