NATIONAL OFFICE FOR **RESEARCH ETHICS** COMMITTEES

Annual Report 2024

Enabling a trusted national ethics opinion

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National Office for
Research Ethics Committees

Contents

List of abbreviations

ACT EU	Accelerating Clinical Trials in the European Union
CTD	Clinical Trials Directive
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulations
DCU	Dublin City University
EU	European Union
EUREC	European Network of Research Ethics Committees
HPRA	Health Products Regulatory Authority
HRB	Health Research Board
HRCDC	Health Research Consent Declaration Committee
HSE	Health Service Executive
IPPOSI	Irish Platform for Patients Organisations, Science and Industry
IT	information technology
IVDR	In Vitro Diagnostic Medical Devices Regulation
MDR	Medical Devices Regulation
NICB	National Irish COVID-19 Biobank
NICB-REC	National Irish COVID-19 Biobank Research Ethics Committee
NREC	National Research Ethics Committee
NREC-CT	National Research Ethics Committee for Clinical Trials on Medicinal Products for Human Use
NREC-MD	National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies of In Vitro Diagnostic Medical Devices
PPI	public and patient involvement
RCSI	Royal College of Surgeons in Ireland
REC	research ethics committee
TCD	Trinity College Dublin
UCC	University College Cork
UCD	University College Dublin

Foreword

Dr Emily Vereker,
Head, National Office for Research Ethics Committees

As Head of the National Office for Research Ethics Committees, it is my pleasure to present our fifth annual report, for the year 2024. The report reviews notable activities of both the National Office and the National Research Ethics Committees (NRECs) it supports.

Through close collaboration with our committees, we have advanced and strengthened the national research ethics system in Ireland and continued to drive ethical health research practices in order to safeguard the rights, dignity, and welfare of health research participants.

Sustainability, agility, and capacity building were key focal points for the National Office in 2024, with the aim of ensuring that the NRECs were supported to deliver a single national ethics opinion for regulated research studies conducted in Ireland within the frameworks of the European Union's Clinical Trials Regulation, Medical Devices Regulation, and In Vitro Diagnostic Medical Devices Regulation.

As part of our capacity building initiative, we implemented new committee structures and procedures for clinical trial studies in order to enable the complex administration and ethical oversight of clinical trial studies that were transitioning from the Clinical Trials Directive to the Clinical Trials Regulation.

The NRECs reviewed 491 ethics applications over the course of 53 meetings in 2024 and supported the transition of 194 clinical trial studies from the Clinical Trials Directive to the Clinical Trials Regulation.

We supported the National Irish COVID-19 Biobank Research Ethics Committee to deliver its final favourable national ethics opinion for the National Irish COVID-19 Biobank, which was underpinned by the first national framework for ethical biobanking and grounded in best international ethics principles.

2024 saw the National Office work collaboratively with our counterparts in European Union member states through our participation on ethics forums and expert working groups coordinated by the European Medicines Agency, the Heads of Medicines Agencies, and the European Commission, as well as through our membership of the European Network of Research Ethics Committees.

“The National Office’s involvement at a European level has become a critical and enabling component of the work we do and is already delivering tangible benefits. By working together with our European counterparts, we are shaping best practices, informing procedures, and ensuring that health research remains rooted in strong ethical foundations, while keeping the interests of participants at the centre of what we do.”

The National Office continued to invest much time engaging with stakeholders nationally, which is critical to our overall mission of delivering a robust, trustworthy national research ethics system in Ireland.

With our colleagues in the Secretariat to the Health Research Consent Declaration Committee, we co-hosted a World Café-style Members’ Forum that brought NREC and Health Research Consent Declaration Committee members together to socialise and discuss aspects of ethics and consent, and to further inform both the National Office and the Secretariat on guidance and best practice in research ethics.

In 2024, the National Office supported a total of 113 members. We welcomed nine additional ministerially appointed members across the NRECs, who brought with them complementary expertise and experiential knowledge. While 8 members completed full and final terms with the NRECs, 22 members were reappointed for second terms in office, which is a testament to these members’ continued commitment to supporting the national research ethics system. The national ethics review system would not succeed without the continued commitment of all of our committee members. It is a privilege for the National Office team to support all our committee members in this vital work, and we are truly grateful for their valuable and respected contribution to driving best-practice ethical health research in Ireland.

The National Office team is to be commended for its operational excellence and professionalism in supporting the NREC members and the wider national ethics system. Its engagement with the research community and with national and international stakeholders has positioned the National Office as a reputable and trusted body within the Irish health research environment. In order to help support the increasing workload of the National Office and the NRECs, we were delighted to welcome three new team members to the National Office in 2024.

On behalf of the NREC members and the team at the National Office, I would like to express my gratitude to our colleagues in the Department of Health, with whom we work closely to develop and progress legislative, strategic, and operational priorities for the National Office.

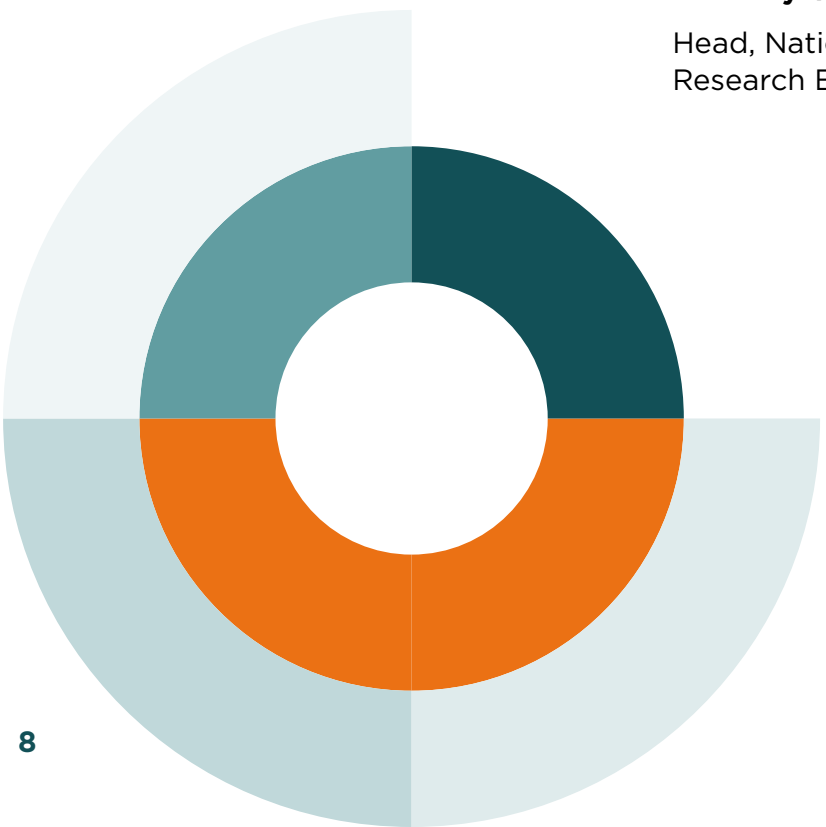
The Health Products Regulatory Authority (HPRA) is a valued collaborative partner for the work we do at a European level, and its support is greatly appreciated.

We are especially grateful for the continued and valued strategic and operational support provided by our colleagues in the Health Research Board under the leadership of the Executive Team and the Chief Executive Officer, Dr Mairéad O'Driscoll.

As we look ahead, we will continue to support our members and advance the national research ethics system, ensuring that it is agile and adaptable in response to the needs of the research community. A key focus will to be on leveraging our expertise, findings, and insight in all areas of research ethics and thereby developing our education, communication, and outreach capabilities.

Dr Emily Vereker

Head, National Office for Research Ethics Committees



National Office for Research Ethics Committees

The National Office for Research Ethics Committees was established in early 2020 as a key component in the reform of the research ethics committee framework in Ireland, led by the Department of Health.

The National Office is a business unit within the Health Research Board (HRB), Ireland's leading agency that funds research and delivers evidence in order to advance health and social care in Ireland. We have an independent statutory function that serves to support and drive best ethical practices in conducting primarily regulated health research in Ireland.

As, the National Office has a remit to establish and operationalise National Research Ethics Committees (NRECs) in regulated areas of health research, which include:

- clinical investigations of medical devices, which are assessed by the National Research Ethics Committee for Medical Devices (NREC-MD)
- performance studies of *in vitro* diagnostic medical devices, which are assessed by the NREC-MD
- clinical trials on medicinal products for human use, which are assessed by the National Research Ethics Committees for Clinical Trials on Medicinal Products for Human Use (NREC-CTs).

The NRECs are mandated under legislation, or by ministerial instruction, to deliver a single national ethics opinion that is respected nationally. The NRECs are a key component of the Irish national health research infrastructure, working in parallel with local research ethics committees (RECs) within a mixed model ethics system in Ireland.

We work closely with our national competent authority, the Health Products Regulatory Authority (HPRA), to ensure that the delivery of all national ethics opinions for regulated research areas is achieved in a parallel and coordinated manner, in accordance with national and European Union (EU) legislation.

In 2024, the National Office also supported COVID-19 research, an area that is of national strategic importance, through the following:

- ✓ the National Irish COVID-19 Biobank (NICB), which was assessed by the NICB Research Ethics Committee (NICB-REC)
- ✓ COVID-19 research studies where a national opinion has been issued previously by the former NREC COVID-19, which were assessed by the COVID-19 Subcommittee.[1]

1 The NREC COVID-19 subcommittee was dissolved in 2024.

The core business of the National Office involves:

establishing NRECs in specific areas of health research

constituting the membership of the NRECs with requisite expertise and lived experience

supporting national and European initiatives of strategic importance

providing a national voice in EU expert groups in order to harmonise and implement EU regulations

providing operational and technical support to the NRECs

issuing guidelines for the work of the NRECs and the research community

delivering education and outreach on research ethics more broadly.

With a steadfast commitment to our vision and mission, we work to ensure that the dignity, safety, autonomy, and well-being of research participants is front and centre of the national research ethics system in Ireland. An ethical framework that is underpinned by a participant-centred approach to research fosters trust in this system.

Our vision

Ireland's national system of research ethics review for health research promotes the highest ethical standards in health research to ensure the safety, dignity, autonomy, and well-being of the people who participate in research – patients, carers, and other members of the public from all walks of life in society.

Our mission

The National Office drives a robust, transparent, and cohesive national research ethics review system that strengthens the national health research infrastructure in the best interests of patients and the public.

2024 snapshot

Committees' work at a glance

53 meetings convened

491 applications reviewed

134 new studies

357 substantial modifications

95% of new studies were approved, of which:

- **75%** were clinical trials on medicinal products
- **17%** were clinical investigations of medical devices
- **9%** were performance studies of in vitro diagnostic devices

113 committee members supported in 2024[2], of which:

- **22** members reappointed for a second term
- **8** members stepped down after their first term
- **9** new members appointed

Breadth of committees' knowledge:

- artificial intelligence
- computer science
- engineering
- medicine
- emergency care
- nursing and midwifery
- pharmacology
- radiology
- economics
- ethics and law
- medical device development
- regulations
- molecular medicine
- genetics
- public and patient involvement
- statistics
- epidemiology
- biobanking
- ophthalmology
- obstetrics and gynaecology
- paediatrics
- data protection
- genomics
- social research
- general practice
- epidemiology
- psychology and psychiatry

2 Includes members whose terms finished and members who stepped down in 2024.

Highlights from the National Office in 2024

European engagement and alignment

Throughout 2024, the National Office expanded its role at a European level, participating in key expert groups to represent Ireland's interests in pertinent research ethics matters and helping to ensure the harmonisation of best research ethics practices for regulated research across EU member states. These efforts have reinforced Ireland's reputation as an active and trusted EU member state in the field of research ethics.

The National Office attended the inaugural MedEthicsEU[3] meeting, which was officially launched by Ms Sandra Gallina, Director General of the European Commission's Directorate-General for Health and Food Safety (SANTE). This group has representatives from 26 European countries and aims to share and harmonise best-practice procedures for ethics assessment and ethics committee operations among EU member states. The National Office has representation on the Board of MedEthicsEU, as well as representatives within the wider group.

Having representation in MedEthicsEU further enabled the National Office to be appointed in 2024 as an observer to the Working Group on Clinical Investigation and Evaluation of the Medical Device Coordination Group.[4]

This is an important appointment for the National Office because it gives Ireland the right to participate in, contribute to, and gain insights into finding ways to support the harmonised conduct of medical devices and *in vitro* diagnostics research across Europe.

"The medical device and in-vitro diagnostic device regulations have brought significant and fast-paced changes to ethics and regulatory assessment processes within Ireland and across Europe. The aims of ongoing initiatives supported by key European agencies such as the MedEthicsEU or the COMBINE project are to work towards harmonisation."

Dr Lucia Prihodova,
Programme Manager NREC-MD,
National Office

3 MedEthicsEU
4 Medical Device Coordination Group

Other EU initiatives that are also mission critical to the National Office include the COMBINE project,[5] the Accelerating Clinical Trials in the EU (ACT EU) initiative,[6] and the Clinical Trials Regulation Collaborate project.[7] These initiatives aim to foster interaction and alignment between national competent authorities and ethics committees, thereby driving higher-quality and volume of regulated studies and improving efficiencies across Europe.

The National Office has also had the privilege of collaborating with the European Network of Research Ethics Committees (EUREC),[8] a network committed to sharing knowledge and developing best ethical practices for current and emerging methodologies and technologies. As a formal member of EUREC, we helped shape its webinar series on the topic of vulnerability and inclusivity in health and social care research participants. The National Office team further contributed to a position paper that addressed the ethical considerations surrounding the compensation of research participants.

Through its involvement in such strategic European collaborations, the National Office continues to elevate Ireland's research ethics framework, ensuring that it aligns with international standards while safeguarding the rights and well-being of research participants.

Public consultations: Contributing to advancements of international policy and practice

In addition to its participation at an EU level, the National Office is always keen to put forward its views on public consultations, surveys, and benchmarking initiatives in relation to ethical and clinical practices.

In 2024, we contributed to one of the most important and respected international instruments in the history of research ethics, the World Medical Association's Declaration of Helsinki.[9] The National Office submitted its views on the proposed revisions to the Declaration of Helsinki, which were aimed at modernising and addressing evolving global ethical challenges.

5 COMBINE project
6 Accelerating Clinical Trials in the EU
7 Collaborate project
8 EUREC
9 Declaration of Helsinki

It is extremely heartening to see that some of the National Office's suggestions are reflected in the newly adopted amendments.

The National Office also contributed to the welcome revisions made to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) *Guideline for Good Clinical Practice E6(R3),*[10] an internationally recognised regulatory guideline setting out the requirements of modern good clinical practice.

One significant revision made to both of these key documents is the replacement of the outdated term 'data subject' with the more appropriate term 'participant'.

Research ethics: Education for patients and the public

The National Office collaborated with the Health Service Executive (HSE) Research and Development[11] team, the Irish Platform for Patients Organisations, Science & Industry (IPPOSI),[12] and other stakeholders to co-develop and co-deliver a 6-week blended learning research ethics pilot course[13] for patients and the public.

This course, which comprises several modules on the wider ethical and regulatory landscape for health and social care research in Ireland, is aimed at empowering the public and patients who wish to support and be involved in research and research ethics by providing them with key knowledge on the fundamentals of research ethics.

Some examples of the modules delivered include the fundamentals of research ethics, the history of ethics in Ireland, informed consent, biobanking, data protection, diversity and inclusion in research, and research with young people and vulnerable groups.

Although this pilot course was initially limited to 25 PPI participants, it offers a valuable foundation of essential learning that will be further accessible to the wider research community in 2025.

10 ICH GCP E6(R3)
11 HSE Research & Development
12 IPPOSI
13 Research Ethics Course

Knowledge sharing and education

We further built on our communication and outreach activities in 2024 by publishing a series of insightful blog posts[14] that are accessible to the public, and we also developed specific guidance[15] on complex ethical topics for the benefit of NREC members and the sponsors of regulated studies in Ireland.

Building on our ambition to support student education in the area of research ethics, we had the pleasure of hosting a third-year undergraduate student from the Biomedical and Molecular Diagnostics degree programme at Technological University Dublin. These placements offer a rewarding and positive experience for students and enable them to gain insights into the NREC meetings, the national and EU regulatory landscape, and the role of the National Office.

As part of its mission to foster an inclusive community of ethics practice and promote shared learnings, the National Office hosted six Lunch and Learn educational presentations for the benefit of the NREC members and wider REC community members. The following topics were covered:

Topic	Speaker
The START Dublin Phase 1 oncology clinical trials centre, Ireland	Dr Austin Duffy, Mater Misericordiae University Hospital
Ethical assessment of risks associated with exposure to ionising radiation	Dr Christina Skourou, St. Luke's Radiation Oncology Network
Office for Research Ethics Committees Northern Ireland	Dr Karen Beattie, Office for Research Ethics Committees Northern Ireland
VolREthics Initiative: Healthy Research Volunteers and Ethics	Prof. François Hirsch, Inserm
Overview of the stages of clinical investigations of medical devices and performance studies of *in vitro* diagnostics	Dr Gearóid O'Connor, Dr Gearóid McGauran, HPRA
Genomic best practices in research	Dr Maili Raven-Adams, Nuffield Council on Bioethics

We are very grateful to all our 2024 speakers for their time and valuable expert contributions on these topics that inform the ethical conduct of health research.

14 National Office blog series
15 Guidance

Connecting our community of committee members

We closed out the year by hosting a World Café-style forum for our committee members. The National Office and the Secretariat of the Health Research Consent Declaration Committee (HRCDC) co-hosted this event, which gave members of the NRECs, the NICB-REC, and the HRCDC the opportunity to socialise, discuss areas of ethics and consent, and build on consensus views on various ethical and regulatory matters relevant to all health and social care research in Ireland.

With more than 60 members in attendance, the day featured robust and informative discussions on a wide range of complex topics, such as:

- studies that investigate both medicinal products and accompanying devices
- the ethics of healthy volunteers and phase I clinical trials
- how PPI can be further supported and embedded in research and research ethics
- the recruitment of participants and the creation of template information leaflets and consent forms.

The outcomes of these discussions have given the National Office and the Secretariat information as to what further guidance on ethics and consent can be developed and how to support our committees to deliver robust national decisions, thereby ensuring best ethical practices and safeguards for research.

Transitioning from the Clinical Trials Directive to the Clinical Trials Regulation

2024 was a period of change for the National Office and the NREC-CTs, as it marked the final year of the EU Clinical Trials Directive[16] and the full applicability of the EU Clinical Trials Regulation[17].

The CTR came into force on 31 January 2022 to replace the CTD for the purpose of harmonising the way in which clinical trials are conducted across the EU, thereby improving transparency, efficiencies, and cross-border collaboration, and providing innovative healthcare.

2024 was the final year by which clinical trials approved under the previous CTD had to be completed, or else transition to compliance under the CTR by 30 January 2025.

The CTR has been transformative and introduced several notable features that enable EU member states to achieve greater harmonisation and consistency in the conduct of clinical trials, including:

- the Clinical Trials Information System (CTIS),[18] a centralised portal that enables sponsors conducting clinical trials to submit a single dossier for both regulatory and ethics reviews
- the standardisation of documentation as either 'Part I' documentation (for scientific and regulatory assessment) or 'Part II' documentation (National documentation for ethics assessment)
- the reduction of duplication of effort by sponsors and the respective ethics and clinical assessments
- enhanced transparency requirements in order to ensure that all clinical trials conducted in Ireland and across the EU are registered in CTIS, with results made available publicly.

According to Dr Susan Quinn, Programme Manager NREC-CT, "The transition to the EU Clinical Trials Regulation was a transformative step forward for clinical research in Ireland, bringing greater alignment with our European counterparts. The CTR and CTIS have together improved efficiency, transparency, and consistency in the application submission and review process, and we are thankful to our colleagues in the HPRA for their close collaboration. With this more coordinated system in place in Ireland and in the EU, we believe patient access to clinical trials is being greatly improved."

16 Clinical Trials Directive
17 Clinical trials Regulation
18 CTIS

Supporting stakeholders to conduct robust and efficient studies

In 2024, the National Office participated in a collaborative initiative called HYPERCARE that is being led by the Institute for Clinical Trials at the University of Galway.[19] This initiative involves the HPRA and the National Office working collaboratively with the Institute for Clinical Trials in order to provide dedicated 'hypercare' support and guidance to pilot studies driven by large multinational and small to medium-sized enterprises in the medical technology sector. The aim of testing the effectiveness of this model for the ethics and regulatory application processes is to enhance the efficiency and seamless execution of regulated studies, and this should inform how the HYPERCARE model could be introduced for future regulated studies.

NRECs in action: Supporting ethical research in Ireland

All of the studies that received a favourable ethics opinion from the NRECs in 2024 sought to develop and advance innovative medical treatments and medical device technologies across a wide range of healthcare areas. The following are examples of studies that received a favourable single national ethics opinion from the NRECs in 2024.

Validating artificial intelligence in classifying cancer in real-time surgery

This study was ethically assessed by the NREC-MD. [20]

The University College Dublin (UCD) Clinical Research Centre, along with its international partners, has developed a device called the CLASSICA-OR that aims to analyse the perfusion patterns of blood within large rectal polyps and tumours before their removal in order to improve the accuracy of identification of cancer in these lesions.

As differences in tissue perfusion analysis can indicate the presence of cancer, this study uses software and mathematical methods to examine how blood flows through the tissues of the rectum during an endoscopic examination. This study will explore whether this information could be useful in determining if cancer is present and in guiding surgeons to take more accurate biopsies.

19 Institute for Clinical Trials, University of Galway - HYPERCARE

20 National Office reference number: 24-NREC-MD-020

The Irish arm of this international study[21] is led by Professor Ronan Cahill, Professor of Surgery and Consultant General & Colorectal Surgeon at UCD and Mater Misericordiae University Hospital. The study includes additional sites at Beaumont Hospital and University Hospital Waterford, and the project aims to recruit 127 participants in Ireland.

A study to evaluate the efficacy and safety of nipocalimab in pregnancies at risk for severe haemolytic disease of the foetus and newborn combined with the use of the foetal antigen Non-Invasive Prenatal Test (NIPT) clinical trial assay

This combined study involves an investigational medicinal product and a medical device and/or an *in vitro diagnostic medical device.* [22] Currently, combined studies such as this one require separate ethics assessments by both the NREC-CT and the NREC-MD due to the scope of such trials falling within the remits of both the CTR and the Medical Devices Regulation (MDR).

Janssen Research & Development LLC is conducting a clinical trial to understand the possible effectiveness and safety of the drug nipocalimab in patients with severe haemolytic disease of the foetus and newborn (HDFN), a rare and potentially life-threatening condition that occurs when the blood type of the mother and the blood type of the foetus are not compatible.

The mother's immune system makes antibodies against the red blood cell proteins of the foetus, causing them to break down, which can in turn cause foetal jaundice, anaemia, and, in severe cases, foetal death.

The study drug, nipocalimab, is being evaluated in order to determine whether it will reduce the level of harmful antibodies in the mother's bloodstream, including those that cause haemolytic anaemia and harm the foetus. This element of the study was reviewed by the NREC-CT.

Additionally, a related study was also assessed by the NREC-MD, as an investigational *in vitro* diagnostic medical device called Foetal Antigen NIPT Clinical Trial Assay is used for enrolment to the trial. The assay is a next-generation sequencing test aimed at detecting specific markers in the blood of pregnant women whose pregnancies are at risk of HDFN. The results of this test will help to identify those who are suitable for enrolment in the clinical trial aspect of the study.

The performance study of the Foetal Antigen NIPT Clinical Trial Assay is sponsored by BillionToOne and is being conducted in parallel with the clinical trial on nipocalimab.

This combined study is an international study with the Irish arm being overseen by Professor Fergal Malone in the Rotunda Hospital. Approximately 120 participants will take part in the clinical trial study worldwide.

21 CLASSICA project

22 National Office reference number: 24-NREC-MD-025; EU Clinical Trial number: 2022-502629-16-00

A Phase 1, First-in-Human, Open-Label, Dose-Escalation and Expansion Study of IMGN151 (anti-FRα antibody drug conjugate) in adult patients with recurrent endometrial cancer and recurrent, high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancers

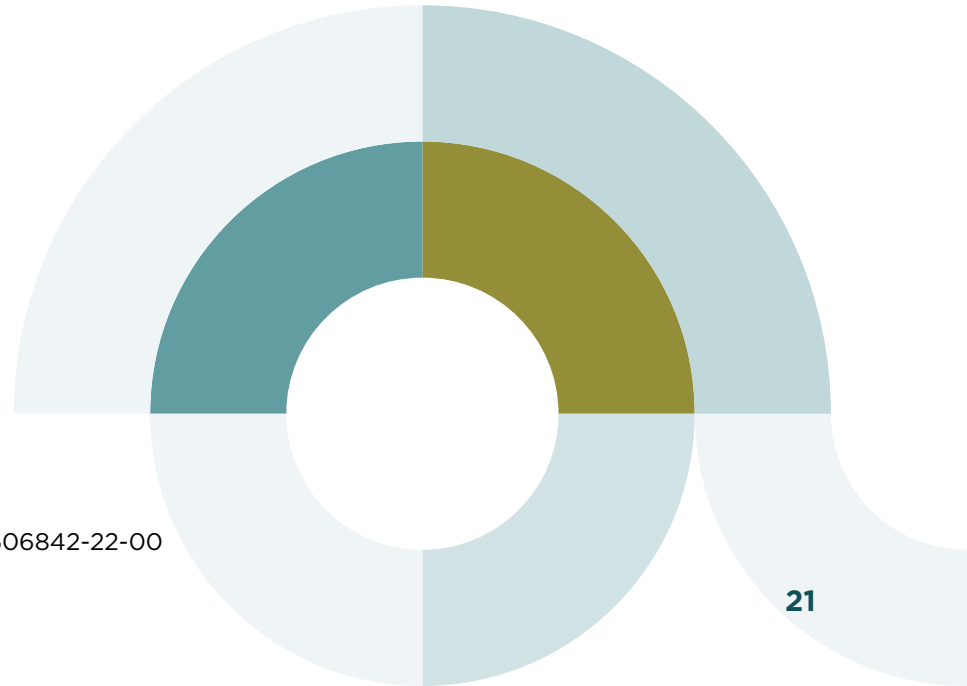
This study was ethically assessed by the NREC-CT.

ImmunoGen, Inc. is conducting a study to test the safety and effectiveness of the drug IMGN151.[23] This study is the first time the drug IMGN151 is being tested in humans as a possible treatment for recurrent endometrial cancer, high-grade serous epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancers.

This type of drug is an antibody-drug conjugate, which is an antibody with a drug attached, typically an anti-cancer drug. Cancer cells make proteins that are not usually made by other cells, and this drug binds to these proteins and releases the anti-cancer drug inside the cancer cells. This type of targeted delivery helps to prevent the drug from harming normal cells.

This study will help researchers to understand how the drug works, how safe it is, what kinds of side effects may be experienced, and what the highest dose is that can be given to patients without causing severe side effects. Importantly, the study will ultimately help researchers to understand the effect that the drug has on recurrent cancer.

This is an international study, with the Irish arm being overseen by Dr Michael McCarthy in University Hospital Galway, and by Dr Austin Duffy in START Dublin at the Mater Misericordiae University Hospital.



23 EU Clinical Trial number: 2023-506842-22-00

National Research Ethics Committees for Clinical Trials on Medicinal Products

Overview of activity in 2024

National Research Ethics Committees for Clinical Trials on Medicinal Products for Human Use

The NREC-CTs have a legislative remit to carry out ethics reviews of clinical trials on medicinal products for human use that fall within the legislative framework of the CTR. The NREC-CTs were originally established as two committees in May 2021 by ministerial appointment and are recognised under Irish law.[24]

2024 brought a significant change for the NREC-CTs and the National Office team, as the two-committee structure was changed to a four-committee structure in order to create a more sustainable, adaptable ethics review model and enable greater capacity across the NREC-CTs.

With the support of the Department of Health, the National Office worked alongside Professor Alistair Nichol and Dr Cliona McGovern, Chairpersons of the NREC-CT A and NREC-CT B, respectively, to devise an operational strategy to reorganise the two NRECs into four NRECs. It was of critical importance to ensure that each committee had a diversity of expertise and experiential knowledge and was constituted in accordance with the legislative requirements.

In order to ensure the success of the restructure and expansion of the NREC-CTs to four committees, we welcomed eight new ministerially appointed members, who brought complementary expertise and experiences to the committees. In addition, we also welcomed the ministerial appointments of Professor Mary Donnelly and Professor David Brayden as Chairpersons of the newly established NREC-CT C and NREC-CT D, respectively. We were also pleased to welcome our newly appointed Deputy Chairpersons across the four committees, as listed on the following pages 25 to 28.

This step-change and the expansion of NREC-CT capacity enabled the NREC-CTs and the National Office team to manage an increased volume of applications for ethics reviews, meet the stringent timelines of the CTR, and manage the complex national requirements and demands of CTIS.[25]

The restructure has been very successful for the NREC-CTs, with all CTR timelines met as of May 2025 for Ireland. In 2024, the 4 committees convened 40 times, reviewing 95 new clinical trial applications and 320 substantial modification applications.

As 2023 was the final year in which to conduct new clinical trials under the CTD, 2024 was the final transition year period, during which substantial modification applications for clinical trials approved under the CTD continued to be submitted for ethics review. In addition, the number of clinical trials that were transitioning to compliance in accordance with the CTR, or that were being conducted under the CTR, resulted in a high volume of substantial modification application submissions

24 European Union (Clinical Trials on Medicinal Products For Human Use) (National Research Ethics Committees) Regulations 2022

25 The Clinical Trials Information System

for the NREC-CTs to review. The National Office, in conjunction with the HPRA, coordinated the administrative processes required to facilitate the transition of 194 clinical trials from the CTD to the CTR.

The NREC-CT members responded to both the restructure and the diverse workload with agility and expertise. The committee members provided ethics reviews throughout 2024 for clinical trials being conducted under the legislative frameworks of both the CTD and the CTR, while meeting all timelines and bringing diverse expertise, lived experience, and learnings to their ethics assessments and to their new committee colleagues. Overall, the transition process from the CTD to the CTR has been a very busy but highly positive experience for the National Office and the NREC-CTs.

With the final transition of all CTD applications taking place in early 2025, the foundations are set for the NREC-CTs to fully embrace this new system and wider EU engagement, while keeping participants at the heart of the process.

At a glance: The NREC-CTs' work in 2024

	New Studies **95**		Substantial modifications **320**	
Number of applications submitted under legislation (%)	**CTR**	**CTD**	**CTR**	**CTD**
	95 (100%)	N/A*	184 (57.5%)	136 (42.5%)**
Number approved (%)	94 (99%)	N/A	182 (99%)	134 (98.5%)
Number refused (%)	0 (0%)	N/A	0 (0%)	0 (0%)
Number withdrawn (%)	1 (1%)	N/A	2 (1%)	2 (1.5%)

* New studies were no longer permitted to be conducted under the CTD as of 31 January 2024.

** Substantial modifications to applcations approved under the CTD were permitted throughout 2024 prior to the final transition to the CTR.

The following members served on the NREC-CTs in 2024.

NREC-CT A

Prof. Alistair Nichol
Chairperson
Consultant Anaesthetist and Intensivist, Professor of Critical Care Medicine, Director of the Irish Critical Care Clinical Trials Network, St Vincent's University Hospital/UCD

Prof. Eugene Dempsey
Deputy Chairperson
Consultant Neonatologist, Cork University Maternity Hospital/Horgan Chair of Neonatology, University College Cork (UCC)

Ms Caoimhe Gleeson
Deputy Chairperson
General Manager, National Office for Human Rights and Equality Policy, HSE

Ms Erica Bennett
Oncology Clinical Research Lead, Bon Secours Radiotherapy Centre/UPMC Hillman Cancer Centre

Dr Brian Bird
Consultant Medical Oncologist, Bon Secours Hospital Cork/Senior Lecturer in Clinical Education, UCC

Dr David Byrne**
General Practitioner Researcher and Palliative Medicine Physician, Royal College of Surgeons in Ireland (RCSI)/Our Lady's Hospice, Harold's Cross

Ms Margaret Cooney**
Medical Student and Clinical Development Operations Advisor, University of Galway

Dr Darren Dahly
Principal Statistician and Senior Lecturer, HRB Clinical Research Facility/ UCC

Ms Mandy Daly
Founder, Irish Neonatal Health Alliance

Ms Dympna Devenney
Practicing Barrister, Practicing Paediatric Nurse, and Casual Lecturer, UCD/The Bar of Ireland

Dr Lorna Fanning*
Career break (pharmaceutical industry)

Dr Heike Felzmann*
Senior Lecturer in Philosophy/Ethics, University of Galway

Dr Geraldine Foley*
Associate Professor in Occupational Therapy, School of Medicine, Trinity College Dublin (TCD)

Dr Maeve Kelleher
Consultant in Paediatric Allergy, Children's Health Ireland at Crumlin

Dr Seán Lacey
Research Integrity & Compliance Officer, Munster Technological University

Prof. Aisling McMahon**
Professor of Health Law and Intellectual Property Law, School of Law and Criminology, Maynooth University

Ms Muireann Ó Briain
Retired barrister

Dr Dawn Swan
Haematology Clinical Research Fellow, Beaumont Hospital/ Austin Health, Melbourne, Australia

* Tenure ended in 2024/stepped down in 2024.

** New member appointed in 2024.

NREC-CT B

Dr Cliona McGovern
Chairperson
Head of Subject for Forensic and Legal Medicine, UCD

Dr John Hayden
Deputy Chairperson
Senior Lecturer, School of Pharmacy and Biomolecular Sciences, RCSI

Prof. Colm O'Donnell
Deputy Chairperson
Consultant Neonatologist, National Maternity Hospital; Professor, UCD School of Medicine

Ms Serena Bennett
Barrister, Law Library, Dublin

Dr Katherine Benson*
Lecturer, RCSI

Dr Áine de Róiste**
Senior Lecturer, Department of Applied Social Studies, Munster Technological University

Dr Karina Halley**
Clinical Research Ethics Lead, FutureNeuro, RCSI

Prof. Catherine Hayes*
Associate Professor in Public Health, TCD

Prof. Michaela Higgins
Consultant Medical Oncologist, St Vincent's University Hospital

Ms Jasmine Joseph
Dementia Trial Clinical Nurse Manager, Tallaght University Hospital

Dr Ciaran Lee**
Lecturer, School of Biochemistry and Cell Biology, UCC

Dr Andrew Lindsay
Director of Genetics Programme, UCC

Dr Niall McGuinness
Self-employed Clinical Research Scientist

Prof. Seamus O'Reilly
Consultant Medical Oncologist, Cork University Hospital, Mercy University Hospital, and South Infirmary Victoria University Hospital

Ms Evelyn O'Shea
National Radiation Oncology Programme Manager, National Cancer Control Programme, HSE

Prof. Abhay Pandit*
Scientific Director, CÚRAM Research Ireland Centre for Medical Devices

Ms Ann Twomey
Director, The Alzheimer Society of Ireland

Prof. John SG Wells
Head of the School of Health Sciences (Waterford), SouthEast Technological University

* Tenure ended in 2024/stepped down in 2024.

** New member appointed in 2024.

NREC-CT C

Prof. Mary Donnelly
Chairperson
Professor, School of Law, UCC

Prof. John Faul
Deputy Chairperson
Consultant Respiratory Physician, Connolly Hospital Blanchardstown

Dr Jean Saunders
Deputy Chairperson
Director, CS-Squared Statistical Consulting

Mr Philip Berman
Retired – Health Services Policy and Management

Prof. Fionnuala
Breathnach
Consultant Obstetrician Gynaecologist, Rotunda Hospital/RCSI

Prof. Austin Duffy
Consultant Medical Oncologist, Mater Misericordiae University Hospital/UCD

Mr Gerard Eastwood
Retired - Engineer/ Academic Lecturer, Member of Fighting Blindness

Dr Susan Finnerty
Consultant Psychiatrist, Retired Inspector of Mental Health Services

Dr Dervla Kelly
Associate Professor, School of Medicine, University of Limerick

Ms Susan Kelly
National Maternal and Newborn Clinical Management System Training Manager, HSE

Prof. Anne Matthews
School of Nursing, Psychotherapy and Community Health, Dublin City University (DCU)

Dr Steve Meaney
Head of Research Ethics and Integrity, Technological University Dublin

Dr Paula Prendeville

Senior Educational Psychologist, Brothers of Charity, Cork

Prof. Andrew Smyth
Professor of Clinical Epidemiology, University of Galway; Consultant Nephrologist, Galway University Hospitals

Dr Deborah Wallace
Assistant Professor in Clinical Research, UCD

NREC-CT D

Prof. David Brayden
Chairperson
Professor, Advanced Drug Delivery, UCD

Dr Christina Skourou
Deputy Chairperson
Senior Medical Physicist, St Luke's Radiation Oncology Network

Prof. David Smith
Deputy Chairperson
Associate Professor of Health Care Ethics and Director of the MSc in Health Care Ethics and Law, RCSI

Mr Gerard Daly
Retired - Civil Servant

Dr Enda Dooley*
Retired – Assistant Inspector of Mental Health Services, Mental Health Commission

Prof. Andrew Green
Consultant in Medical Genetics, Children's Health Ireland at Crumlin and Temple Street/ Professor of Medical Genetics, UCD

Prof. Tina Hickey
Associate Professor Emeritus, School of Psychology, UCD/Patient Advocate

Ms Deirdre Mac Loughlin
Chief Executive Officer, Galway Chamber of Commerce, and Advocate for public involvement in health and social care research

Dr Mary McDonnell Naughton
Lecturer, Department of Nursing & Healthcare, Technological University of the Shannon: Midlands Midwest

Dr Jeff Moore**
Research Director, Jigsaw: The National Centre for Youth Mental Health

Prof. Deirdre Murray
Director, National Cancer Registry of Ireland

Dr Geraldine O'Dea
Retired - Former Medical Assessor with the HPRA

Dr Geraldine O'Sullivan Coyne
Consultant Medical Oncologist, Mater Misericordiae University Hospital

Dr Mark Robinson*
Associate Professor, Department of Biology, Maynooth University

Prof. Cathal Walsh
Professor of Biostatistics, TCD

Dr Chanel Watson**
Senior Lecturer/Deputy Director of Academic Affairs, RCSI University of Medicine and Health Sciences

Prof. Lina Zgaga
Associate Professor of Epidemiology, School of Medicine, TCD

* Tenure ended in 2024/stepped down in 2024.

** New member appointed in 2024.

National Research Ethics Committee for Medical Devices

Overview of activity in 2024

National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies of In Vitro Diagnostic Medical Devices

The NREC-MD was established in May 2021 in order to meet Ireland's requirements for the review of clinical investigations of medical devices as defined in the EU MDR (Regulation (EU) 2017/745).[26] The following year, the NREC-MD broadened its scope to accept applications seeking ethical approval for performance studies on *in vitro* diagnostic medical devices, as defined in the EU In Vitro Diagnostic Medical Devices Regulation (IVDR) (Regulation (EU) 2017/746).[27] The NREC-MD is chaired by Professor Barry O'Sullivan of the UCC School of Computer Science and Information Technology, and in 2024 it welcomed one new ministerially appointed member, while four members stepped down from the Committee due to their tenures ending.

In 2024, NREC-MD members convened over a total of 12 meetings and reviewed 38 new study applications. Just over one-third (35%) of all studies reviewed involved devices that would be utilised in the diagnosis of oncological disease. A further one-third (32%) of studies are investigating devices would be utilised in cardiology, followed by studies in obstetrics and gynaecology, endocrinology, musculoskeletal conditions, neurology, orthopaedics, paediatrics, urology, and other areas.

The volume of ethics applications grew in 2024 compared with 2023, particularly for applications submitted under the IVDR. The majority of these applications were related to performance studies of companion diagnostic devices, which were carried out in combination with a clinical trial of an investigational medicinal product. In order to address the complexity of assessing such combined studies, throughout 2024 the National Office team has been closely engaged with the European Commission's COMBINE project, which aims to analyse the root causes of the various challenges encountered by sponsors when conducting combined studies and identify possible solutions.

26 REGULATION (EU) 2017/745: Medical Devices Regulation

27 REGULATION (EU) 2017/746: In Vitro Diagnostics Regulations

Throughout 2024, the National Office team revised the supports that it offers to sponsors of clinical investigations and performance studies by implementing pre-validation checks of submitted applications, the aim being to reduce the volume of invalid applications and therefore reduce the turnaround time for the ethics review process. As a result of this, less than 20% of applications were deemed invalid in 2024, compared with 40% in 2023.

Through the delivery of robust and trustworthy ethics opinions, the NREC-MD sits alongside its counterparts in the EU, supporting the ethical conduct of health research and encouraging the development of medical innovations for patients in Ireland and for the public as a whole.

At a glance: The NREC-MD's work in 2024

	New Studies **38**		Substantial modifications **35**	
Number of applications submitted under legislation (%)	**MDR**	**IVDR**	**MDR**	**IVDR**
	25 (66%)	13 (34%)	26 (74%)	9 (26%)
Number approved (%)	21 (84%)	11 (85%)	26 (100%)	9 (100%)
Number refused (%)	3 (12%)	2 (15%)	0 (0%)	0 (0%)
Number withdrawn (%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)

The following members served on the NREC-MD in 2024.

Prof. Barry O'Sullivan, Chairperson
Professor, Constraints Programming, School of Computer Science and Information Technology, UCC

Prof. Mary Sharp
Deputy Chairperson
Research Fellow, School of Computer Science, TCD

Prof. Declan Patton
Deputy Chairperson
Director, Nursing and Midwifery Research, RCSI

Dr Caitriona Cahir
Lecturer, Biostatistics, Data Science Centre, RCSI

Dr Daniel Coakley
Consultant Ophthalmologist, Cork University Hospital, HSE

Dr Mireille Crampe
MedLIS Delivery & Support Lead, Technology and Transformation, HSE

Dr Ruth Davis
Barrister and Independent Law Consultant

Prof. Owen Doody
Senior Lecturer, School of Nursing & Midwifery, University of Limerick

Dr James Gilroy
Specialist Registrar, Public Health Medicine, Royal College of Physicians of Ireland

Dr Frank Houghton
Lecturer, Technological University of the Shannon

Dr Gloria Kirwan
Senior Lecturer, Graduate School of Healthcare Management, RCSI

Ms Orla Lane
Economist

Prof. Cara Martin
Associate Professor in Molecular Pathology, Tumour Biology and Cancer Screening, School of Medicine, TCD

Mr Billy McCann
Retired – Patient advocate

Dr Sarah McLoughlin*
Patient Advocate

Prof. Tom Melvin
Associate Professor in Medical Device Regulatory Science, University of Galway

Prof. Thérèse Murphy
Professor of Law and Director of the Health & Human Rights Unit, Queen's University Belfast

Dr Declan O'Callaghan
Retired – Medical Doctor and Specialist in Pharmaceutical Medicine

Prof. Susan O'Connell*
Consultant Endocrinologist, Children's Health Ireland

Dr Clare O'Connor
Retired – Molecular Medicine Researcher and Lecturer

Prof. Paul O'Connor
Psychologist and Senior Lecturer, University of Galway

Dr Joanne O'Dwyer**
Senior Lecturer in Pharmacy and Pharmaceutics, University of Galway

Prof. James O'Neill*
Connolly Hospital Blanchardstown/Mater Misericordiae University Hospital

Mr Damien Owens
Registrar, Engineers Ireland

Prof. Anne Parle-McDermott*
Professor, School of Biotechnology; Director, DCU Life Sciences Institute; Principal Investigator, Molecular Genetics Laboratory, DCU

Dr Ríona Tumelty*
Senior Pharmacist, Beacon Hospital

Prof. Mahendra Varma
Retired Cardiologist

Ms Simone Walsh
Chair and Programme Manager of the Irish Research Nurses and Midwives Network

Mr Peter Woulfe

Chief Medical Physicist, Galway Clinic

* Tenure ended in 2024/stepped down in 2024.

** New member appointed in 2024.

National Irish COVID-19 Biobank Research Ethics Committee

Overview of activity in 2024

National Irish COVID-19 Biobank Research Ethics Committee

Overview

In 2022 the National Office established a dedicated research ethics committee to ethically assess and deliver a single national ethics opinion on the governance and operations of the National Irish COVID-19 Biobank (NICB),[28] a multi-site, multi-legal entity biobanking infrastructure. The committee was established through ministerial appointment and was committee was fully operational in 2023.

In 2023, a phased and partitioned ethics opinion model was implemented by the NICB Research Ethics Committee (NICB-REC) as a pragmatic approach to enable specific operational and governance elements of the NICB to be ethically assessed as each element was developed.

2024 activity

In 2024, the NICB-REC continued its work and ethically assessed the final elements of the biobank: researcher access, public health impact, and commercialisation.

The following areas were considered by the NICB-REC:

- policies, as well as operational and governance procedures, that underpinned the biobank's model for researchers accessing biological samples and data from the biobank
- public engagement, sustainability, commercialisation, and societal impact.

The NICB-REC delivered a favourable single national ethics opinion on these final elements of the NICB in 2024.

Further information on the deliberation process and details of the opinions and conditions provided can be found in the minutes of the NICB-REC meetings.[29]

Phased and partitioned ethics assessment of the NICB activities	Year	Single national ethics opinion
Governance: Governance and oversight	2023	✓ Favourable with conditions
Participant recruitment: Prospective participants; participant-facing information and consent protocols	2023	
Biological samples and data: Collection, storage, processing, cataloguing, general curation, and security aspects	2023	
Researcher access, public health impact, and commercialisation	2024	

28 National Irish COVID-19 Biobank

29 NICB-REC Minutes – NREC (nrecoffice.ie)

The following members served on the NICB-REC in 2024.

Dr Georgina Flood
Chairperson
Consultant Anaesthetist, Mater Misericordiae University Hospital and Mater Private Hospital

Dr Anne Moore
Deputy Chairperson
Senior Lecturer in the School of Biochemistry and Cell Biology and Principal Investigator in vaccine development, UCC

Prof. Kathleen Bennet
Head of the Data Science Centre, Deputy Head of the School for Research, RCSI; Associate Professor in Biostatistics in the School of Population Health, RCSI

Dr Brian Clark*
Global Medical Head, Gastroenterology Therapeutic Area and Bioethics, Global Research & Medical, Ferring Pharmaceuticals A/S

Mr John Culliney
Retired businessperson

Dr Aisling de Paor
Associate Professor of Law, DCU

Prof. Sean Hynes
Professor of Pathology at University of Galway and Consultant Histopathologist at University Hospital Galway

Mrs Joan Jordan
Patient advocate, European Patients' Academy on Therapeutic Innovation/

Dr Sonja Khan
Lecturer in Clinical Research, University of Galway

Prof. Patrick Manning
Consultant Respiratory Physician, Ballinderry Clinic, Mullingar; Associate Clinical Professor, RCSI

Dr Kevin May
General Practitioner, Safetynet Primary Care

Prof. Shaun O'Keefe
Consultant Physician and Geriatrician, Department of Geriatric Medicine at Galway University Hospitals; Honorary Personal Professor in Medicine at University of Galway

Prof. Cathal Seoighe
Professor of Bioinformatics at the University of Galway; Director of the SFI Centre for Research Training in Genomics Data Science, University of Galway

Prof. Anthony Staines
Professor of Health Systems at the Centre for Integrated Care and School of Nursing, Psychotherapy and Community Health, DCU

Dr Ciara Staunton
Academic Consultant, Honorary Researcher at RCSI

* Stepped down in 2024.

COVID-19 Subcommittee

Overview of activity in 2024

COVID-19 Subcommittee

As an emergency measure in response to the COVID-19 pandemic, the National Research Ethics Committee for COVID-19[30] was established in 2020 in order to ensure that a rapid national ethics opinion could be delivered for emergency COVID-19 research studies to facilitate the growth of evidence that would support population health. Following the end of this NREC's tenure in August 2020, a standing COVID-19 Subcommittee was established in order to provide ethical oversight of further modifications to COVID-19 research studies.

In 2024, the COVID-19 Subcommittee reviewed two ethics applications for amendments to previously approved studies.

Over the course of its 4-year tenure, the standing COVID-19 Subcommittee reviewed a total of 49 amendments to approved studies. This represents a considerable contribution and enduring commitment from the Subcommittee members.

The COVID-19 Subcommittee was dissolved in 2024 under the instruction of the Department of Health, as the emergency circumstances that the NREC COVID-19 and the COVID-19 Subcommittee were set up to respond to were deemed no longer applicable.

Members of the NREC COVID-19 and the COVID-19 Subcommittee contributed significantly to the establishment of the national research ethics review system in Ireland and were integral to supporting the emergency pandemic response at a national level.

The following members served on the COVID-19 Subcommittee in 2024.

Prof. Mary Horgan
Interim Chief Medical Officer at the Department of Health, Professor of Infectious Diseases at UCD and Mater Misericordiae University Hospital

Prof. Anthony Staines
Professor of Health Systems at the Centre for Integrated Care and School of Nursing, Psychotherapy and Community Health, DCU

Prof. Hannah McGee
Deputy Vice Chancellor for Academic Affairs at RCSI

30 COVID-19 Subcommittee

The National Office team

The National Office team

The National Office comprises a vibrant team of dynamic and dedicated high-performing professionals whose core values of integrity, knowledge, collegiality, and transparency drive their work of delivering an agile and trusted office in the national public service.

The team is committed to providing excellent operational, technical, and strategic support and guidance to NREC members and the research community, with the aim of upholding and strengthening a robust and trustworthy national ethics committee review system for health research in Ireland.

There is a broad, complementary range of technical, scientific, and ethics systems expertise within the team that encompasses converging areas of health research, such as regulation, policy, practice, and prevailing legislation. This enables the team to provide guidance, insight, and constructive feedback to both applicants and NREC members at appropriate points in the review process.

The team expanded in 2024 in response to the significant growth in the number of applications and the operational complexity of the work required in order to deliver a robust and trustworthy national ethics review system in accordance with the applicable EU legislation. Specifically, the new Clinical Trials Regulation (CTR) has introduced nuanced and time-sensitive work that must be carefully coordinated operationally, scientifically, and collaboratively with the HPRA in order to deliver national opinions within rigid legislative timelines.

In order to provide the technical and operational support necessary for the NRECs to conduct their business efficiently, and to deliver robust and rationalised ethical opinions, the team undergoes continuing professional development and training in core areas such as EU legislation, informed consent, trials methodology, data protection, and good clinical practice.

The National Office is supported operationally by shared core services such as communications, information technology (IT), and finance through our organisation, the HRB.

Ms Aileen Sheehy, Programme Manager (NREC-CT) discussing 'Clinical Trials in Ireland - Creating a Sustainable Environment for Ethics Assessment' at the HRB NCTO International Clinical Trials Day 2024

Dr Lucia Prihodova, Programme Manager (NREC-MD) discussing 'Submitting an application to the National Research Ethics Committee for Medical Devices and In Vitro Diagnostic Medical Devices', at MedTech Advance: Transforming Clinical Investigations in Ireland, 2024.

National Office for Research Ethics Committees team members in 2024 included:

Dr Jane Bryant
Programme Officer

Dr Emma Heffernan
Project Officer

Dr Ciaran Horan
Interim Administrative Assistant

Dr Louise Houston
Project Officer

Ms Kathy Kelly
Administrative Assistant

Ms Patricia Kenny
Project Officer

Ms Suzanne Kenny
Communications Officer

Dr Laura Mackey
Programme Officer

Ms Rachel McDermott
Project Administrator

Dr Sarah McLoughlin
Programme Officer

Ms Deirdre Ní Floinn
Project Officer

Dr Lucia Prihodova
Programme Manager

Dr Susan Quinn
Programme Manager

Ms Aileen Sheehy
Programme Manager

Dr Emily Vereker
Head of National Office

Mr Peadar Rooney
Project Officer

Ms Aisling Collins*
Administrative Assistant

Dr Anne Costello*
Programme Manager

Ms Anna Dunne*
Communications Officer

Mr Tomás McElhinney*
Finance Officer

Ms Megan O'Neill*
Project Officer

* Finished in 2024.

National Office strategic objectives

2024 achievements and 2025 priorities

National Office strategic objectives: 2024 achievements and 2025 priorities

The work of the National Office for Research Ethics Committees is grounded by clear strategic objectives in order to maintain a sharp focus on success and to bring cohesion and clarity to the regulatory research environment in Ireland.

We remain committed to supporting and operating a national system for research ethics review in order to ensure that the safety, dignity, and well-being of research participants are ethically safeguarded and that they can exercise their autonomy, fundamental rights, and freedoms. The National Office team and the NRECs endeavour to support the full spectrum of health research through a rigorous and independent ethics review process in a timely and transparent manner.

There are five fundamental strategic priorities guiding the National Office to deliver a robust and trusted national research ethics system that we continued to foster in 2024 and into 2025.

Strategic priorities

01 **To be an agile and trusted office** in national public service

02 **To partner with health research stakeholders,** with the mutual objective of implementing best practice and adopting change under EU legislative frameworks

03 **To deliver a robust, timely, and transparent NREC review system** for clinical trials of investigational medicinal products, clinical investigations, and performance studies for medical devices

04 **To contribute to strategic initiatives of national and European importance** by sharing and driving best ethical practices

05 **To be a thought leader for research ethics** by providing trusted information, seeding discussion, and advancing debate; and by facilitating education and training

2024 key achievements

The National Office's key achievements in 2024, which are aligned with our strategic priorities, are summarised as follows:

- The NREC-CTs ethically reviewed 95 new clinical trial studies and 320 substantial modifications applications.
- The NREC-MD ethically reviewed 38 new medical and diagnostic device investigational studies and clinical investigations, and 35 substantial modifications applications.
- The National Office oversaw the transition of 194 clinical trial studies from the Clinical Trials Directive to the CTR.
- The National Office supported 53 NREC meetings to review 491 ethics submissions in 2024.
- The National Office implemented a new structure for the NREC-CTs, increasing them from two to four committees in order to enable greater capacity and sustainability to deliver ethics opinions.
- The National Office collaborated with the Secretariat of the Health Research Consent Declaration Committee (HRCDC) to commence the development of the Consent and Ethics Research Application System (CERAS) application management system.
- The NICB-REC convened once in 2024 and delivered a final favourable consensus-based ethics opinion, underpinned by best international ethics practices for biobanks.
- The National Office hosted a World Café-style Members' Forum on 6 December, bringing together NREC and HRCDC members to socialise and discuss aspects of ethics and consent and to further inform both the National Office and the Secretariat on guidance and best practice in research ethics.
- The National Office contributed to public consultations, surveys, and benchmarking initiatives set by the European Medicines Agency and the World Health Organization, most notably the modernisation of the Declaration of Helsinki.
- The National Office represented its own, NRECs', and Ireland's interests at an international level through participation in EU expert groups, such as the MedEthicsEU and Accelerating Clinical Trials in the EU (ACT EU) expert groups, as well as the COMBINE project, in order to harmonise the implementation of EU regulations and clinical trial research activity in Ireland.

- The National Office expanded its research ethics network to participant at the European National Ethics Council forum, and continued to collaborate with the European Network of Research Ethics Committees (EUREC) on ethics initiatives.
- The National Office collaborated with the HSE Research and Development team and the Irish Platform for Patients Organisations, Science & Industry (IPPOSI) to shape, develop, and deliver a health and social care research ethics training programme for public and patient involvement (PPI) representatives.
- The National Office hosted six Lunch and Learn educational sessions for the benefit of the NREC members and the wider research ethics community, discussing topics such as phase I studies, the ethics of ionising radiation exposure, healthy volunteers, and best practices in genomic research.

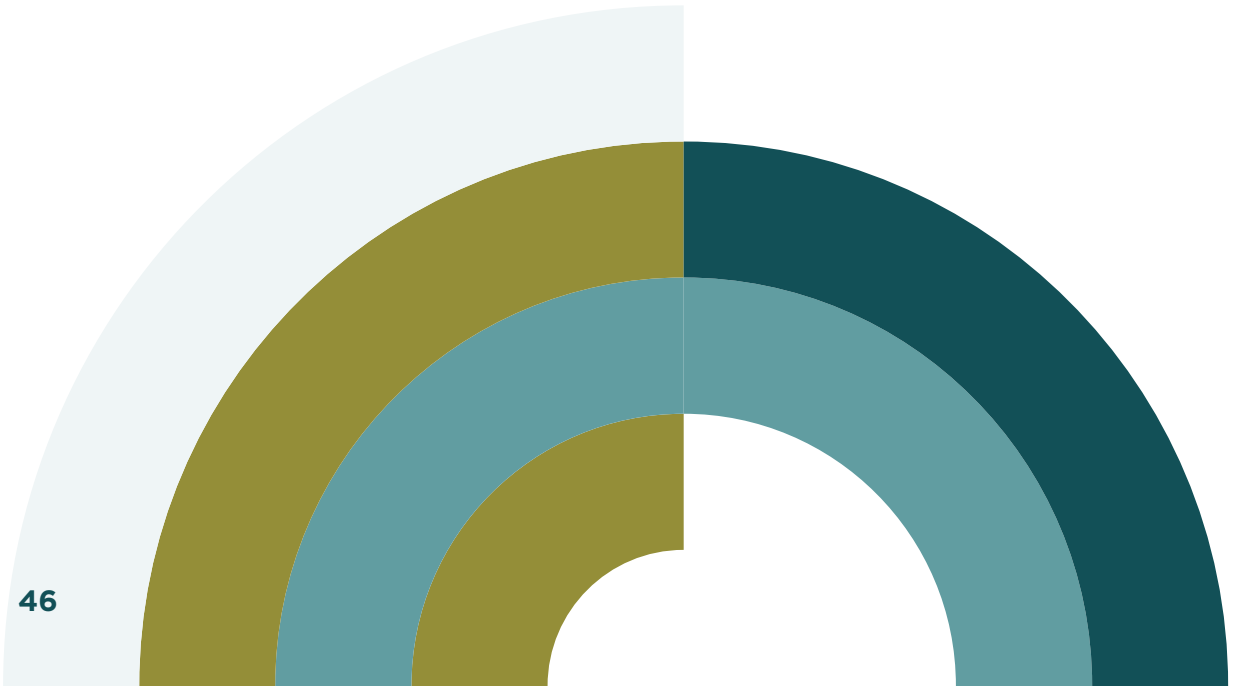
Next steps for 2025

As we look forward to the rest of 2025, the National Office will continue to deliver strategic and operational actions in order to support the success of the Irish national research ethics review system for the benefit of Ireland's wider health and social care research infrastructure.

In 2025, we will:

- ensure that the NRECs have the requisite expert knowledge and lived experiences to enable robust research ethics reviews of regulated research and work
- further the expertise of the National Office team and work collaboratively with the NRECs in delivering opinions in complex ethical areas of regulated research, underpinned by operational excellence and agile procedures, in order to ensure a predictable and sustainable national research ethics system
- implement the new CERAS application management system in collaboration with the Secretariat of the HRCDC
- co-develop a strategic framework with the Secretariat in order to enable operational and governance alignment, where appropriate, while ensuring the independence of the core work in supporting the respective NRECs and HRCDC

- continue to develop our partnerships with European member state counterparts through participation in expert groups (e.g. MedEthicsEU and the Medical Device Coordination Group) and EU initiatives (e.g. ACT EU, the CT CURE joint action, the COMBINE project, and the Clinical Trials Regulation Collaborate project) in order to inform best practice and influence a harmonised and practical approach to the implementation of EU regulations
- work with our parent Department (Department of Health) to inform and drive key legislative and policy changes that strengthen the research ecosystem in Ireland, and contribute to Department-led national working groups and strategic initiatives (e.g. the National Clinical Trials Oversight group and the 1+ Million Genomes (1+MG) initiative)
- pilot a joint NREC-CT and NREC-MD ethics assessment procedure for combined studies submitted under the dual legislative framework of the In Vitro Diagnostic Medical Devices Regulation and the CTR in order to inform a prospective and agile combined NREC
- leverage the work of the NICB-REC in order to inform and influence national policy and future legislative programmes on best practice governance and ethical biobanking
- engage with national and international bodies for future emergency health preparedness and emerging threats in order to establish coordinated and expedient decision-making processes
- develop, share, and promote trusted and expert-driven guidance on ethical best practices that is applicable to the conduct of both regulated and unregulated health research
- promote the necessity of PPI in research ethics, and health research more broadly, through engagement with national groups and organisations
- develop new relationships with international bodies, such as the World Health Organization, Science Europe, and the Council of Europe, and Bioethics Councils, to understand wider bioethics matters on a global level.



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