NATIONAL OFFICE FOR **RESEARCH ETHICS** COMMITTEES

Annual Report 2023

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

nationaloffice@nrec.ie

www.nrecoffice.ie

@NREC_Office

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List of Abbreviations

ACT EU	Accelerating Clinical Trials in the European Union
CTCG	Clinical Trials Coordination Group
CTD	Clinical Trials Directive
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation
CUH	Cork University Hospital
DCU	Dublin City University
EEG	electroencephalogram
EMA	European Medicines Agency
EU	European Union
EUREC	European Network of Research Ethics Committees
HHS	US Department of Health and Human Services
HPRA	Health Products Regulatory Authority
HRB	Health Research Board
HRCDC	Health Research Consent Declaration Committee
HSE	Health Service Executive
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-CTs	National Research Ethics Committees for Clinical Trials on Medicinal Products for Human Use
NREC-MD	National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies for *In Vitro* Diagnostic Medical Devices
NRECs	National Research Ethics Committees
OHRP	Office for Human Research Protections
PPI	public and patient involvement
RCSI	Royal College of Surgeons in Ireland
RECs	research ethics committees
TCD	Trinity College Dublin
UCC	University College Cork
UCD	University College Dublin
UKCRC	United Kingdom Clinical Research Collaboration
US	United States
WHO	World Health Organization

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 fourth annual report, for the year 2023. The report highlights the achievements and milestones of the National Research Ethics Committees (NRECs) and the National Office, which worked closely throughout 2023 to advance and strengthen the national research ethics system in Ireland and to drive ethical health research practices aimed at safeguarding the rights, dignity, and welfare of health research participants.

The work carried out in 2023 builds on that of the previous few years, from embedding a robust national research ethics system to advancing a sustainable, agile system with capacity to deliver single national ethics opinions for regulated research studies. We implemented new procedures for efficiency and flexibility in preparedness for the entry into force of the European Union's (EU) Clinical Trials Regulation, Medical Devices Regulation, and *In Vitro* Diagnostic Regulation.

2023 was a progressive year for the National Office and the NRECs, where significant expertise was garnered to navigate the complexity of the EU Regulations and align with our EU Member State counterparts, and to ensure the conduct and ethical oversight of regulated studies were achieved in a harmonised and expedient manner.

We are particularly grateful for the exceptional working relationship we have with our colleagues in the Health Products Regulatory Authority, who have supported and collaborated with us so that Ireland delivers on its legislative obligations within the regulated timelines.

2023 saw the National Office engage with our colleagues in EU Member States, through our participation on ethics forums and working groups coordinated by the European Medicines Agency and European Commission, and also through our membership of the European Network of Research Ethics Committees (EUREC). The National Office team works closely with these organisations to represent Ireland's interests, informing discussions and supporting the common goal of a harmonised, ethical health research environment.

The report further highlights the support provided for areas of national strategic importance, specifically COVID-19 research. Further to the establishment of the National Irish COVID-19 Biobank Research Ethics Committee (NICB-REC), it was a significant achievement for this committee to deliver a first national ethics opinion for a national biobank, ensuring its establishment, governance, and operations are grounded in the highest ethical standards.

The National Office has invested much time engaging with stakeholders nationally, which is critical to the overall mission of delivering a robust, trustworthy national research ethics system in Ireland. To connect our stakeholders and the research community in Ireland, the National Office and the Health Research Board were proud to co-host a national conference for research ethics, offering a forum for over 250 attendees to raise awareness of and debate key ethical considerations, challenges, opportunities, and practices in this fast-paced environment.

The national ethics review system would not succeed without the hard work and dedication of our committee members. This year alone, they have delivered a single national ethics opinion for over 115 new studies and 501 study substantial modifications, across medicinal products, medical devices and *in vitro* diagnostics.

In response to the complexity and intensity of the work necessary to deliver a national ethics opinion for all regulated areas of research, and to build capacity, the National Office welcomed the additional 22 ministerially appointed members across the NRECs, bringing with them complementary expertise and experiential knowledge.

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 and technical excellence, continued drive, and professionalism in supporting the NREC members and the wider national ethics system. Its engagement with the research community and national and international stakeholders has positioned the National Office as a reputable and trusted body within the Irish health research environment.

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.

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

The operational and strategic accomplishments of 2023 have undoubtedly positioned the National Office and the NRECs to continue to promote the highest ethical standards of practice for health research in Ireland.

As we look ahead, we will continue to support our members and advance the national research ethics system. A key focus for the National Office will be to establish deeper connections with the wider research ethics committee community across Ireland and abroad, while continuing to collaborate with our European partners.

Dr Emily Vereker

Head, National Office for Research Ethics Committees

"We remain committed to driving a harmonised and robust regulated health research ecosystem in Ireland, grounded in best ethical principles. In doing so, the need to safeguard participants' safety, dignity, autonomy, and well-being is balanced with the need to support the advancement of innovative healthcare treatments and technologies."

National Office for Research Ethics Committees

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

Hosted by the Health Research Board (HRB), the National Office is an independent unit with a statutory function that serves to support and drive best ethical practices in conducting primarily regulated health research in Ireland. As such, we are tasked with establishing and operationalising National Research Ethics Committees (NRECs) in assigned areas of health research.

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.

The areas of research that fall under the remit of the National Office and the committees that we support are:

- Clinical investigations of medical devices; assessed by the National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies for *In Vitro* Diagnostic Medical Devices (NREC-MD)
- Performance studies of *in vitro* diagnostic medical devices; assessed by the NREC-MD
- Clinical trials on medicinal products for human use; assessed by the National Research Ethics Committees for Clinical Trials on Medicinal Products for Human Use (NREC-CTs)
- The National Irish COVID-19 Biobank (NICB); assessed by the National Irish COVID-19 Biobank Research Ethics Committee (NICB-REC), and
- COVID-19 research studies where a national opinion has been issued previously by the former NREC COVID-19; assessed by the NREC COVID-19 standing subcommittee.

The core business of the National Office involves:

- Establishing NRECs in specific areas of health research
- Constituting the membership of the NRECs
- Supporting national and European initiatives of strategic importance
- Providing operational and technical support to NRECs
- Issuing guidelines for the work of NRECs and applicants, and
- 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 and human rights-based approach to research engenders 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.

2023 snapshot

Committees' work at a glance

61 meetings convened

643 applications submitted

160 new studies
483 substantial modifications

501 opinions delivered

115 new studies
501 substantial modifications

Health research areas that formed the basis of applications submitted for assessment include:

- eye
- cancer and neoplasms
- blood
- inflammatory and immune system
- respiratory
- oral and gastrointestinal
- infection
- neurological
- congenital disorders
- metabolic and endocrine
- cardiovascular
- renal and urogenital
- skin
- reproductive health and childbirth[1]

Committee membership

106 committee members in 2023[2]

51% male
49% female

From all over the island of Ireland

Other countries
Denmark **Italy**

Representing a breadth of backgrounds, including:

- ethics
- law
- lay
- medical
- sciences
- data protection
- public and patient involvement (PPI)
- healthcare professionals
- industry
- social sciences
- public health
- statistics
- biobanking

1 Based on the UKCRC Health Research Classification System.

2 Includes members who stepped down before the end of 2023.

Highlights from the National Office in 2023

Restructuring the NREC-CTs to deliver in an evolving legislative environment

The NREC-CTs were established in April 2021. Since their inception, the legislative landscape for the ethics assessment of clinical trials has changed significantly due to the initial implementation of the EU Clinical Trials Regulation (CTR) in January 2022.

Both the National Office and the NREC-CTs have rapidly garnered expertise in these new regulatory frameworks and, despite the complexity and operational challenges, the NREC-CTs have successfully delivered single national ethics opinions on clinical trials for medicinal products, in coordination with the HPRA.

Identifying challenges

However, future challenges were foreseen for 2024 and beyond that would compromise the sustainability and development of the system as well as the capacity of the NREC-CTs and National Office. These were:

- The impact of the CTR coming fully into force in 2024 and driving application volume
- The ability to deliver ethics opinions within strict EU legislative deadlines and risk ‘tacit approval’
- The retention of NREC members
- The complexity of regulated studies conducted under multi-EU legislative frameworks, and
- Participation in strategic European initiatives.

Mitigation and preparedness for these challenges was paramount in ensuring the current NREC operations could transition towards a more sustainable, predictable, and optimal model. As such, the National Office spent a significant amount of time in 2023 dedicated to designing and implementing a robust strategy to transform the current structural model of NREC-CT.

With the full transition to the CTR due in January 2025, the proposed restructure aimed to create a more agile environment for the ethics assessment of clinical trials under the CTR, while maintaining a sustainable workload for committee members and delivering robust and trusted single national ethical opinions.

Operational change for capacity and sustainability

A number of objectives were identified to achieve the fundamental goal of capacity building and sustainability:

- Consolidate the assessment of new study applications and substantial modification applications into one standard meeting type
- Increase the number of meetings convened on a monthly basis, to deliver ethics opinions within stringent legislative timelines, and to avoid the risk of 'tacit approval'
- Enable NREC-CT members to participate fluidly across NREC-CTs as required, creating flexibility, agility, and maximising their expertise
- Enable the National Office through delegated responsibilities to better support the NREC-CT members, and
- Prioritise retention of members and knowledge sharing of CTR and ethics considerations across members.

The key implementation actions to deliver on these objectives involved:

- Transition from a larger two-committee structure to a smaller four-committee structure
- Increase the number of members to ensure the requisite expertise and knowledge across each of the four NREC-CTs
- Provide the National Office with greater authority to support and manage various aspects of the ethics assessment process, and
- Provide the National Office with adequate resourcing to support the new model of NREC-CT operations, manage the legislative demands of the EU Regulations and participate in EU-critical implementation projects.

The design of the restructure was not only influenced by learnings garnered over the last number of years, but also by consultations with other European countries on the operations and management of their research ethics systems for regulated areas of research. The National Office consulted with its counterparts in Luxembourg, Finland, and Norway to inform changes to the system in Ireland. These European countries were selected as their national approaches to ethics assessment of clinical trials aligned with the centralised national approach taken for the NREC system.

Strengthening NREC-CT membership

To operationalise the restructure, the team launched a public expression-of-interest campaign in 2023 to bring complementary expertise to the existing knowledge base on the committees. The Minister for Health appointed 21 new members across the four NREC-CTs, ensuring the requisite breadth of expertise and knowledge was acquired. Some of the additional expertise brought to the NREC-CTs included bioinformatics, paediatrics, obstetrics, statistics, epidemiology, psychiatry, and clinical research.

Full implementation of the restructure has been achieved in 2024 and will strengthen the operational and advisory capacity of the National Office, as well as capacity of the NRECs, towards delivering a sustainable, robust ethics review system in Ireland, which is respected and trusted within Ireland and across EU Member States.

“I was motivated to join the NREC-CT to bring my expertise in clinical research and my institutional REC experience to enhance access to clinical trials for Irish patients. The proposed restructure should create an environment of speed and agility for the ethics assessment of clinical trials. Such improvements in the system enhance Ireland’s reputation as a destination to run important clinical trials.”

Dr Deborah Wallace
Assistant Professor in Clinical Research at University College Dublin (UCD) and new member of the NREC-CT

Highlights from the National Office in 2023

Ethical biobanking informed by international and human rights frameworks

A biobank or biorepository is the managed collection and storage of human biological samples with associated personal data. Biological samples and data donated by research participants to a biobank facilitates research that could not otherwise be easily undertaken.

Biobanks can coordinate and collaborate locally, nationally, and internationally to provide researchers with valuable biological samples and data required to perform truly impactful research for patient and public benefit.

First national research ethics committee for a national biobank

In response to the COVID-19 pandemic, the Department of Health invested in the establishment of Ireland's first national, multi-site, multi-legal entity biobanking infrastructure, known as the National Irish COVID-19 Biobank (NICB).

To ensure that the collection, storage and use of biological samples, and associated data for research are underpinned by the highest standards in ethics, governance, and codes of practice, the Minister for Health mandated the establishment of a dedicated, independent REC to ethically assess the governance and operations of the NICB and issue a single national ethics opinion for the biobank that spans across 19 sites.

Further to the establishment of the NICB-REC in 2022, the National Office performed a scoping review of best practices in ethical biobanking and human rights to inform the development of the national ethical application and assessment process.

Scoping best ethical practices to inform ethics committee assessment

The ethics application process was designed to gather information to support the ethics assessment and enable a single national ethics opinion. The standards of ethical practices for biobanking are grounded in the following trusted national and international instruments:

- The World Medical Association Declaration of Taipei[3] on ethical considerations regarding health databases and biobanks
- The Council of Europe Recommendation CM/Rec (2016)6 of the Committee of Ministers to Member States on research on biological material of human origin[4]
- The EU General Data Protection Regulation,[5] and
- The Irish Health Research Regulations 2018, as amended.[6]

The process was also informed by human rights frameworks and guidelines, such as the World Medical Association Declaration of Helsinki,[7] the Oviedo Convention,[8] the Council for International Organizations of Medical Sciences (CIOMS) 2016 Guidelines,[9] and the Belmont Report,[10] all of which cover the protection of human participants in research.

3 World Medical Association Declaration of Taipei.

4 The Council of Europe recommendation CM/Rec(2016)6.

5 General Data Protection Regulations.

6 Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018.

7 The WMA Declaration of Helsinki on ethical Principles for Medical Research Involving Human Subjects.

8 The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine 1997 is more commonly known as the Oviedo Convention.

9 The Council for International Organizations of Medical Sciences (CIOMS) 2016 International Ethical Guidelines for Health-related Research Involving Humans.

10 The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

A bespoke ethics application form was developed in consultation with a selection of NICB-REC members to ensure all information required for the ethical assessment of the NICB as a multi-site infrastructure was captured for ethical assessment, namely:

Operations	Protocol	Biobank participants	Public engagement	Ethics committee approvals from local sites predating the NICB-REC
Governance	Biological samples, associated data	Informed consent processes	Public and patient involvement	
Researcher access rights	Scope of use for research	Participant information leaflets and consent forms	Sustainability	
			Societal impact	

The prevailing role of the committee is to ensure the protection of the rights, safety, dignity, and well-being of biobank participants. Additionally, the committee has a responsibility to ensure that the biosamples and data gifted to the biobank by its participants will be managed ethically to generate impactful research evidence into the causes, progression, diagnosis, and treatment of COVID-19.

The ethical framework developed specifically for the NICB as a national, multi-site, biobanking infrastructure may serve as a reference for any future ethical assessments of biobanking infrastructures in Ireland and beyond.

Highlights from the National Office in 2023

Engaging with European agencies and networks

Throughout 2023, the National Office was a key contributor to a series of European working groups and forums, representing Ireland's interest on pertinent research ethics matters and building a reputation as a trustworthy EU Member State.

Strategic EU working groups and projects that require Member State representation are coordinated by the European Medicines Agency (EMA), the Heads of Medicines Agencies, and the European Commission. The coordinated and harmonised consensus-based interpretation of the EU Regulations by all Member States is core to these forums.

Ireland's participation is critical to ensure alignment with other Member State competent authorities and national ethics committees, regarding the implementation of the CTR, the Medical Devices Regulation (MDR), and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR), and preparedness for all regulated research as the EU Regulations come fully into force, including the transition period from 2024. This complex work is coordinated though our collaborative partners and Ireland's national competent authority, the HPRA.

The forums and projects that the National Office participated in during 2023 are as follows.

Accelerating Clinical Trials in the European Union

The Accelerating Clinical Trials in the European Union[11] (ACT EU) initiative strives to support impactful, high-quality and efficient clinical trials and to enhance the integration of clinical research with the European health system. This initiative aims to develop the EU further as a competitive hub for innovative clinical research in a patient-focused manner.

The National Office has a vested interest in a number of the priority action groups of ACT EU, such as the Clinical Trials in Public Health Emergencies; Good Clinical Practice Modernisation; and Clinical Trials Methodologies. We were represented by Dr Jane Bryant, as a panellist at the 2023 ACT EU annual matrix meeting, providing insights into the National Office and NREC-CT on-the-ground experiences with the CTR framework.

[11] Accelerating Clinical Trials in the EU.

CTR COLLABORATE Project

The CTR COLLABORATE Project aims to optimise how EU Member States, through their respective national competent authority and research ethics committee expert representatives, can collaborate to facilitate high-quality clinical trial activity in Europe, underpinned by operational effectiveness.

The project is dependent on all-Member State participation to align on optimal processes that enable the implementation of the CTR. The National Office, through its representatives, Dr Jane Bryant and Dr Laura Mackey, have actively participated and led on the coordination of key tracks under the initiative throughout 2023.

MedEthics EU

MedEthics EU – formally known as the Clinical Trials Coordination Group (CTCG) ethics advisory group – is dedicated to the shared knowledge, learnings, and harmonisation of the procedures of ethics committees across Europe, which work under the EU regulatory frameworks of the CTR, MDR and IVDR. The focus of this group is to align and harmonise operational procedures of medical research ethics committees among EU Member States while instilling the highest ethical standards.

The National Office, through Dr Susan Quinn and Ms Aileen Sheehy, represent Ireland's interests on this forum, sharing best-practice procedures for ethics committee operations and for ethics assessment matters.

It was an honour for the National Office to have Aileen Sheehy join as a board member of MedEthics EU in 2023, which will be critical in informing and effecting the necessary changes across Europe, and in anchoring ethics assessments and ethical practices within the EU regulatory frameworks.

"The enhanced integration of ethics into regulatory processes and decisions for clinical trial assessment has been a major sea change across Europe, which will have a positive impact for trial participants, sponsors, investigators, and Member States of the European Medicine Regulatory Network alike. We are at the beginning of an exciting journey to drive change, building trust, and harmonise and improve ethics practices across Europe. This collaborative approach to clinical trial assessment underpinned by robust ethical practice is one that has great potential for lasting impact."

Dr Monique Al

Special Adviser to the Central Committee on Research Involving Human Subjects (CCMO), Netherlands and Co-Chair of MedEthics EU

COMBINE Project

The objective of the EU-led COMBINE[12] Project is to rapidly determine the key issues faced by sponsors that are conducting studies, which may involve a combination of an investigational medicinal product together with a medical device or an *in vitro* diagnostic. As such, the respective EU Regulations may need to be applied together, resulting in legislative and procedural challenges that impact harmonisation and expediency of approvals for combined studies across EU Member States.

The National Office team, represented by Dr Laura Mackey and Ms Chita Murray, participated in track under the initiative in 2023, which has ambitious timelines for EU landscape mapping and identifying solutions to the challenges currently faced. This work will continue into 2024.

European Network for Research Ethics Committees

The European Network for Research Ethics Committees (EUREC)[13] is a network that brings together already existing national REC associations, networks or comparable initiatives at the European level. Among many of its key objectives is to provide a forum for shared learnings and insights into best ethical practices for current and emerging methodologies and technologies.

The National Office is a proud member of EUREC and values the ability to leverage this network in building new partnerships with European national ethics committees. The National Office, represented by Dr Emma Heffernan, has participated on working groups that drive EUREC projects, such as the development of a best ethics practice guidance paper on compensation for research participants.

International registration – the Office for Human Research Protections

The Office for Human Research Protections (OHRP)[14] in the United States (US) oversees the protection of the rights, welfare, and well-being of participants involved in research conducted or supported by the US Department of Health and Human Services (HHS). All RECs must be registered with the OHRP, where the research under ethics review is funded by the HHS.

A significant step for the National Office was to complete the registration of all the NRECs with the OHRP, which was done by Ms Patricia Kenny. Registration of the NRECs is critical for studies carried out in Ireland that are in receipt of US funding.

12 Combined studies and The COMBINE project presentation.

13 EUREC.

14 Office for Human Research Protections.

Highlights from the National Office in 2023

Fostering discussion and connecting community

National Conference on Research Ethics

A key strategic priority for the National Office is to promote thought leadership in the area of research ethics by providing trusted information, seeding discussion, and advancing debate. Events are a valuable opportunity to further this goal, by bringing together stakeholders from across health and social care, research, and society more broadly to explore and discuss topical issues. Building on the strong interest in online events in previous years, the National Office was inspired to organise the first in-person National Conference on Research Ethics in 2023, in partnership with the HRB.

A Programme Committee comprising internal and external members and including PPI representation was critical to the development of a programme designed to provide insights into the history and governance of research ethics in Ireland and abroad, together with an examination of how research ethics works in real-world scenarios.

The full-day conference attracted around 250 delegates, spanning health and social care researchers and practitioners, ethics committee members, patients, and members of the public. Attendees heard from an eclectic line-up of national and international keynote speakers, case study presenters, and panellists who contributed their insights across three key themes.

The history of research ethics and present-day governance in Ireland and internationally – from the dark episodes that informed current-day principles to answering the challenges posed for ethics governance in an increasingly cross-border research landscape.

The ethics of inclusion in research – examining the reasons why certain groups in society may traditionally have been excluded from studies and the practical steps researchers are taking to address these gaps. Case studies ranged from how to include pregnant women in research, a parent's perspective on the value of paediatric trials, to the importance of including marginalised groups in health research.

Ethical challenges surrounding the emergence of new healthcare technologies – a thought-provoking keynote address on the latest developments was followed by case studies highlighting the potential and limitations of today's artificial intelligence, rethinking data and privacy in the context of biobanking, and the conundrums presented by new forms of genomic testing.

In addition to creating a valuable forum for addressing these important issues, the conference also provided participants with the opportunity to meet with contacts old and new – reinforcing and expanding the community that has developed around research ethics in Ireland. The National Office looks forward to continuing to facilitate these platforms for debate, connection, and learning in 2024 and beyond.

Education and knowledge sharing

The National Office hosted seven Lunch & Learn educational presentations for the benefit of NREC members on topics of significant relevance to NREC work, namely:

Topic	Speaker
Development and clinical study design of investigational medicinal products and medical devices	Prof. David Brayden Prof. Tom Melvin
Genetic data in clinical research	Prof. Andrew Green
Involvement of pregnant participants in research	Prof. Jennifer Donnelly
PPI in clinical research	Prof. Mary McCarron Prof. Seán Dinneen Mr Michael Foley
Patient information leaflets and informed consent forms	Dr Lydia O'Sullivan
Involvement of children as participants in clinical research	Prof. Paul McNally
Good clinical practice in regulated studies	Mr Lorcan Gregorian

As part of its mission to develop an inclusive community of ethics practice and promote shared learnings, the National Office opened up the Lunch & Learn series to the wider research ethics community. We are very grateful to all our 2023 speakers for their time and valuable expert contributions on these topics that inform the conduct of health research.

Promoting the work of the National Office and NRECs

Notwithstanding the fundamental and critical work of the National Office in supporting the work of the NRECs, the National Office team had a very eventful year in 2023. We invested considerable time promoting the work of the ethics committees and informing stakeholders of the operational and legislative procedures that frame the work of the National Office and NRECs. The National Office team delivered presentations and were invited speakers at the following events:

- HRB Trials Methodology Research Network Spring School, discussing the ethics of randomised trials
- Irish Health Research Forum, hosted by Health Research Charities Ireland, speaking about the national research ethics system supported by the National Office
- The National Cancer Trials Office Stakeholder Day, speaking about the work of the National Office and NRECs
- BioBANC Symposium, hosted by the University of Galway, speaking about the ethics of informed consent and ethics review of a national biobank, and
- Clinical Investigations and Performance Studies in Ireland under the MDR/IVDR, providing insights into the submission of an ethics application to the NREC-MD.

Public consultations – contributing to advancements of international policy and practice

In addition to our participation at an EU level, the National Office contributed its views on public consultations, surveys, and benchmarking initiatives, set by the EMA and World Health Organization (WHO) in relation to ethical and clinical practices. We inputted to the modernisation of the Good Clinical Practice[15] guidelines; the WHO Best Practices for Clinical Trials;[16] and the WHO Global Benchmarking Tool for evaluation of national regulatory systems.[17]

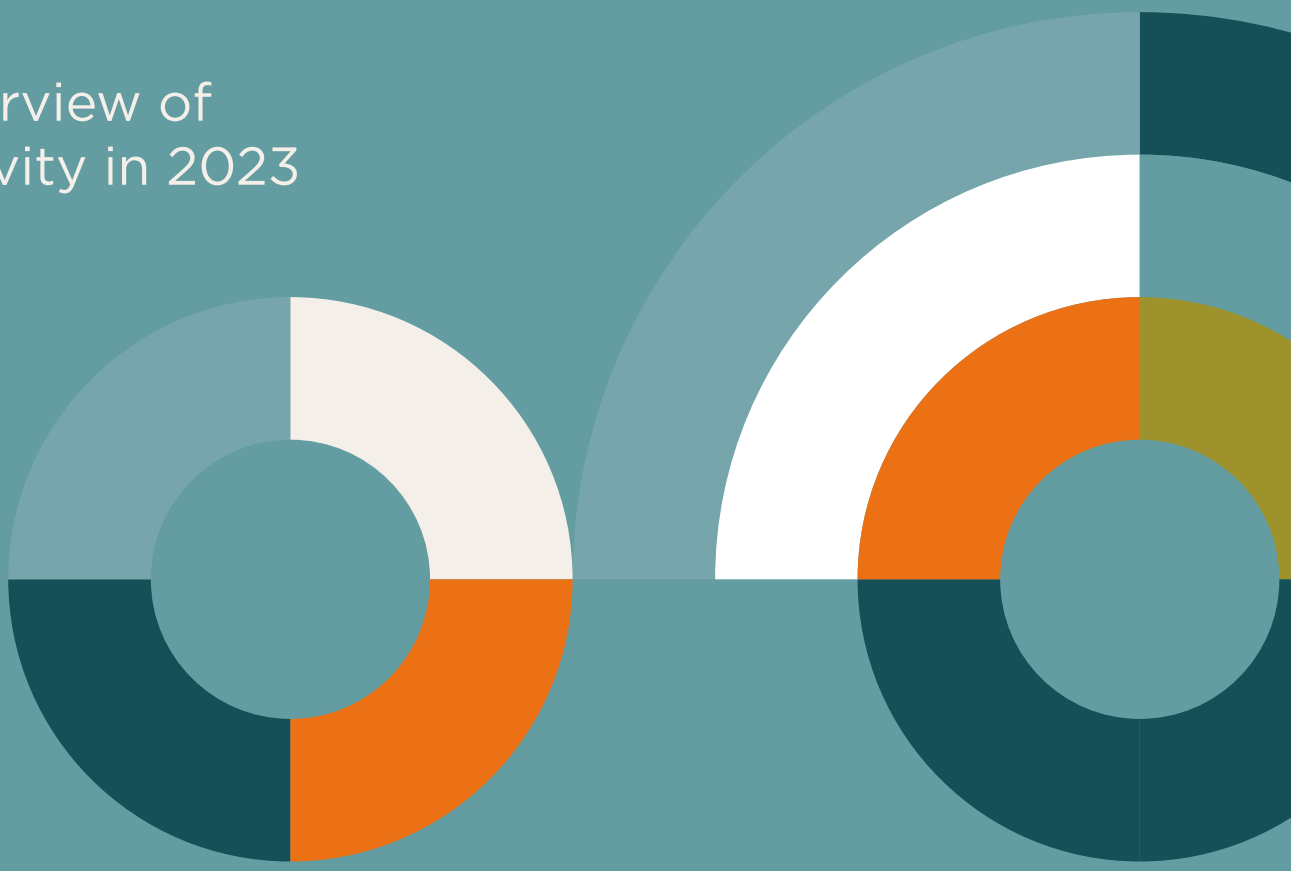
15 ICH-Good Clinical Practice e6(R3).

16 WHO Guidance for Best Practice for Clinical Trials.

17 WHO Global Benchmarking Tool (GBT).

National Research Ethics Committee for Clinical Trials on Medicinal Products

Overview of activity in 2023



National Research Ethics Committees for Clinical Trials on Medicinal Products for Human Use (NREC-CTs)

The two NREC-CTs (A and B) were established in May 2021 by ministerial appointment, which are recognised under Irish law through S.I. No. 41/2022.[18] NREC-CT A and NREC-CT B consider ethics applications submitted through the National Office and seek ethics approval for studies that are within the regulated remit of the CTR on clinical trials on medicinal products for human use.

The NREC-CTs bring a diverse range of expertise to the ethical review decision-making process, with members representing a wide variety of professional backgrounds and lived experiences. A further 21 members were appointed across the NREC-CTs in 2023, expanding the committees' expertise and capacity to review a growing volume of applications under the CTR. NREC-CT A is chaired by Professor Alistair Nichol, while NREC-CT B is chaired by Dr Cliona McGovern.

In 2023, the two committees convened 49 times. Over these 49 meetings, 98 new studies and 469 substantial amendments were reviewed by the NREC-CTs, with 86 new studies receiving a favourable ethics opinion to commence in Ireland in 2023. A small portion of new studies reviewed in late 2023 received a final opinion in 2024.

In 2023, the final date for submission of new study applications under the Clinical Trials Directive (CTD) was the end of January, with a full transition of all new applications submitted through the online Clinical Trials Information System (CTIS)[19] portal bringing a big change for the National Office and NREC-CTs. A high volume of CTD applications were submitted in advance of the deadline, with the NREC members responding rapidly to a call from the National Office for additional meetings. Twenty additional CTD applications were reviewed and approved across two additional meetings, bringing the CTD to a successful closure. The full transition from the former CTD to the CTR has been a very busy but highly positive experience for the National Office and the NREC-CTs to date; they continued to manage the balance of operating across two distinct legislations throughout 2023, as substantial amendments under the CTD will continue to be accepted until all studies have transitioned to the CTR in early 2025.

The National Office has benefitted from strong engagement with multiple European working groups throughout 2023. With the final transition of all CTD applications taking place throughout 2024, the foundations are set for the NREC-CTs to fully embrace the new system and wider EU engagement, while keeping participants at the heart of the process.

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18 European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022.

19 The Clinical Trials Information System.

At a glance: NREC-CTs' work in 2023

Application status

	New studies	Substantial modifications
Submissions*	**102**	**438**
Deemed invalid	**-**	**10**
Received favourable opinion	**86**	**469**
Received unfavourable opinion	**1**	**4**
Withdrawn by applicant**	**2**	**12**

* Due to CTIS evaluation timelines, applications received up to December 2023 and pending NREC decision received the outcome in 2024.

** Withdrawn after request for further information decision issued.

All decisions of the NREC-CTs can be viewed on the National Office website: https://www.nrecoffice.ie/committees/decisions/

NRECs in action: supporting ethical research

The studies that received a favourable ethics opinion from the NREC-CTs in 2023 strive to develop and advance innovative medical treatments across a wide range of healthcare areas. The following are sample studies that received a favourable single national ethics opinion by the NREC-CTs in 2023.

SHAMROCK Study

A new clinical trial, the SHAMROCK Study, explores how certain women respond to a new anti-HER2 drug. In approximately one in five breast cancers, the cancer cells have extra copies of the gene that makes the HER2 protein. In HER2-positive breast cancer, the cancer cell expresses the HER2 receptor, which is a protein that promotes the growth of cancer cells.

The goal of this study is to investigate how effective the treatment called trastuzumab deruxtecan is for patients with early stage locally advanced HER2-positive breast cancer. As patients enrolled in the study will receive only one drug as part of the treatment regime, the study will also investigate whether patients can potentially experience fewer side-effects, such as hair loss and nausea, than they would if they were receiving the standard course of treatment containing several chemotherapy drugs plus HER2 blockade.

The SHAMROCK multi-centre clinical trial is an investigator-initiated trial led by Consultant Medical Oncologist Professor Bryan Hennessy at Beaumont Hospital and sponsored by Cancer Trials Ireland. It is being conducted at several other cancer-treating hospitals in Dublin, Cork, and Limerick.[20]

The study was reviewed by the NREC-CT. Furthermore, a component of this study was also assessed by the NREC-MD, as the study included an investigational *in vitro* diagnostic test for use in treatment decision-making, along with imaging results. The aim of the diagnostic test is to understand whether the response to chemotherapy before surgery can be predicted from the tumour sample and therefore help doctors decide whether the patient needs a shorter or longer course of treatment.

The study received a favourable ethical opinion from both the NREC-CT and NREC-MD in 2023, paving the way for the SHAMROCK Study to commence. The study aims to contribute significant new information in this field, which can help improve outcomes for patients in Ireland with HER2-positive breast cancer.

[20] The SHAMROCK Study, Cancer Trials Ireland.

Supporting access to clinical trials for children and adolescents

Paediatric clinical trials are an essential requirement to develop age-specific, empirically verified therapies and interventions to determine and improve treatment outcomes for children and adolescents. Since their establishment, the NREC-CTs have been strong advocates of promoting the broad access to paediatric clinical trials in Ireland that are ethically designed and include the appropriate and necessary safeguards.

In 2023, the NREC-CTs delivered a favourable single national ethics opinion for 12 trials that included paediatric participants. The research areas for these trials included oncology, muscular dystrophy, achondroplasia, premature infants, kidney disease, pulmonary hypertension, dermatitis and other skin conditions, and blood disorders. This variety of research areas highlights the sheer breadth of trials being run in Ireland to improve outcomes for paediatric patients.

To support the improved access of paediatric populations to clinical trials, in 2023, the National Office responded to the public consultation on the WHO Best Practices for Clinical Trials. This guidance document promotes the wider inclusion of paediatric groups on clinical trials and specifies that paediatric participants should not be excluded from clinical trials by default. This inclusionary approach is supported by the National Office and NRECs.

NREC-CT A – committee members

The NREC-CTs continue to strengthen and develop their knowledge and expertise year on year, with 2023 being no different. The NREC-CTs responded with agility to a busy year of increased European and national collaboration and full implementation of the CTR, resulting in new ways of working and new legislative timelines. Our NREC welcomed new members in 2023 whose diversity, skillset, and experiential knowledge added to the success of the committees' outputs. The NREC-CTs continue to focus on our key role of ensuring that participant well-being is placed at the centre of clinical research in Ireland.

Professor Alistair Nichol
Chair of NREC-CT A and Consultant Anaesthetist and Intensivist at St Vincent's University Hospital

The following members served on the NREC-CT A in 2023.

Prof. Alistair Nichol
Chair
St Vincent's University Hospital

Prof. Mary Donnelly
Deputy
University College Cork (UCC)

Dr Heike Felzmann
Deputy
UCC

Mrs Erica Bennett
Bon Secours Radiotherapy Cork/ UPMC Hillman Cancer Centre

Dr Katherine Benson*
Royal College of Surgeons in Ireland (RCSI)

Prof. David Brayden
UCD

Prof. Fionnuala Breathnach*
Rotunda Hospital Dublin/RCSI

Prof. Donal Brennan**
UCD/Mater Misericordiae University Hospital

Mr Gerard Daly
Retired civil servant

Dr Darren Dahly
HRB Clinical Research Facility

Prof. Eugene Dempsey
UCC/Cork University Maternity Hospital

Ms Dympna Devenney*
Law Library/Children's Health Ireland at Temple Street

Dr Jimmy Devins**
Retired general practitioner

Prof. Patrick Dillon**
University Hospital Limerick

Mr Gerard Eastwood
Retired engineer/ academic lecturer

Dr Susan Finnerty*
Retired – Mental Health Services

Dr Geraldine Foley
Trinity College Dublin

Prof. Catherine Hayes
Trinity College Dublin (TCD)

Dr Tina Hickey
UCD/patient advocate

Dr Dervla Kelly
University of Limerick

Dr Maeve Kelleher*
Children's Health Ireland at Crumlin

Dr Seán Lacey*
Munster Technological University

Dr Andrew Lindsay*
UCC

Ms Muireann Ó Briain
Retired barrister

Dr John O'Loughlin**
Retired medical scientist

Ms Evelyn O'Shea
Health Service Executive (HSE)

Prof. Andrew Smyth*
University of Galway

Dr Dawn Swan*
Connolly Hospital Blanchardstown

Mrs Ann Twomey
The Alzheimer Society of Ireland

Prof. Cathal Walsh*
TCD

Prof. John Wells
South East Technological University Waterford

* New members appointed in 2023.

** Stepped down during 2023.

NREC-CT B committee members

The NREC-CTs have faced numerous challenges since their establishment, such as changing legal landscapes, stringent timelines, and high workload volumes. The year 2023 brought changes to the system that will ensure longevity in the NREC system. The integration with European working groups creates an avenue for shared learning and harmonisation across ethics committees, while the proposed restructure and additional membership leads the NREC-CTs on the road to success. I commend the ongoing commitment of my fellow committee members, without whom the system could not exist.

Dr Cliona McGovern
Chair of NREC-CT B and Head of Subject in Forensic and Legal Medicine, UCD

The following members served on the NREC-CT B in 2023.

Dr Cliona McGovern
Chair
UCD

Dr Jean Saunders
Deputy
CS CS Statistical Consulting

Prof. John Faul
Deputy
Connolly Hospital Blanchardstown

Ms Serena Bennett
Barrister

Mr Philip Berman
Retired – hospital services policy and management

Ms Mandy Daly
Irish Neonatal Health Alliance

Dr Enda Dooley
Retired – Mental Health Commission

Dr Lorna Fanning
Career break from pharmaceutical industry

Ms Caoimhe Gleeson
HSE National Office for Human Rights and Equality Policy

Prof. Andrew Green
Children's Health Ireland at Crumlin and Temple Street

Dr John Hayden
RCSI

Ms Jasmine Joseph*
Tallaght University Hospital

Ms Susan Kelly
HSE

Mr Gavin Lawler**
Beacon Hospital, Dublin

Dr Steve Meaney*
Technological University Dublin

Ms Deirdre Mac Loughlin
Retired IT manager/PPI advocate

Dr Mary McDonnell-Naughton
Technological University of the Shannon: Athlone

Dr Eimear McGlinchey**
TCD

Dr Niall McGuinness*
Self-employed clinical research scientist

Prof. Deirdre Murray*
National Cancer Registry Ireland

Dr Geraldine O'Dea*
Retired – HPRA

Prof. Colm O'Donnell
National Maternity Hospital

Prof. Seamus O'Reilly
Cork University Hospital (CUH)

Prof. Abhay Pandit
CÚRAM SFI Research Centre for Medical Devices

Dr Mark Robinson
Maynooth University

Dr Christina Skourou
St Luke's Radiation Oncology Network

Prof. David Smith
RCSI

Dr Deborah Wallace*
UCD

Dr Lina Zgaga*
TCD

* New members appointed in 2023.

** Stepped down during 2023.

National Research Ethics Committee for Medical Devices

Overview of activity in 2023

National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies of *In Vitro* Diagnostic Medical Devices (NREC-MD)

In May 2021, the NREC-MD was established to meet Ireland's requirements for the review of clinical investigations of medical devices as defined in the EU MDR 2017/745. The following year, the NREC-MD broadened its scope to receive applications seeking ethical approval for performance studies in *in vitro* diagnostic medical devices, as defined in the EU IVDR 2017/746.

NREC-MD members are appointed by the Minister for Health, while the activities of the committee are recognised by the Department of Health under S.I. No. 257/2022[21] and S.I. No. 671/2023.[22] A single national ethics opinion is provided on behalf of the Republic of Ireland for clinical investigations and performance studies which seek to enrol participants nationally and, in many cases, in other EU Member States.

In 2023, the NREC-MD welcomed five new members. Each committee member contributes significant and valuable lived experiences and professional expertise. Members are drawn from diverse fields which include medicine, engineering, pharmacy, nursing, immunochemistry, legal and regulatory affairs, medical device development, statistics, and ethics.

This wide spectrum of knowledge enables the NREC-MD to provide a comprehensive, robust, and efficient review of clinical investigations and performance studies. The committee is chaired by Professor Barry O'Sullivan of the UCC School of Computer Science and Information Technology.

In 2023, NREC-MD members convened a total of 12 meetings, dedicating significant effort and time to the ethical review of complex applications. Compared with 2022, the volume of applications submitted under the IVDR has greatly increased. The majority of these applications related to performance studies of companion diagnostic devices, which were carried out in combination with a clinical trial of an investigational medicinal product.

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.

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21 S.I. No. 257/2022 European Union (National Research Ethics Committees for Performance Studies of *In Vitro* Diagnostic Medical Devices) Regulations 2022.

22 S.I. No. 671/2023 European Union (National Research Ethics Committees for Clinical Investigations of Medical Devices) Regulations 2023.

At a glance: NREC-MD's work in 2023

Application status	Clinical investigations of medical devices	Performance studies of *in vitro* diagnostic medical devices
Submissions*	New studies **40** Substantial modifications **30**	New studies **18** Substantial modifications **5**
Deemed invalid	New studies **20** Substantial modifications **6**	New studies **9** Substantial modifications **2**
Received favourable opinion	New studies **18** Substantial modifications **27**	New studies **8** Substantial modifications **1**
Received unfavourable opinion	New studies **2** Substantial modifications **-**	New studies **-** Substantial modifications **-**
Withdrawn by applicant**	New studies **-** Substantial modifications **-**	New studies **1** Substantial modifications **1**

All decisions of the NREC-MD can be viewed on the National Office website:
https://www.nrecoffice.ie/committees/decisions/

NRECs in action: supporting ethical research

The studies assessed by the NREC-MD in 2023 strive to develop and advance innovative medical devices and diagnostic tests across a wide range of healthcare areas. The following are a sample of the diversity of studies that received a favourable single national ethics opinion by the NREC-MD in 2023.

Visualising the heart during surgery

Irish company LUMA Vision Ltd. has developed VERAFEYE,™ a highly innovative, four-dimensional (4D) digital imaging system that allows high-resolution 360-degree visualisation within the heart during cardiac surgery.[23] VERAFEYE™ is controlled by software which has been designed specifically to meet the needs of physicians while navigating cardiac anatomy and will allow access to real-time data when delivering treatment.

The usability and integration of the VERAFEYE™ system is being evaluated during a number of routine cardiac procedures. The study is taking place at the Mater Private Hospital, Dublin led by Professor Gábor Széplaki, Head of Cardiac Electrophysiology.

Wireless ultra-long-term EEG recordings in epilepsy

The standard diagnosis and treatment of epilepsy today is a long and time-consuming process for the patient, with many hospital visits and examinations supported by the patient's self-evaluated opinion, such as a seizure diary to monitor their epilepsy.

Danish company UNEEG Medical A/S aims to revolutionise this process by its novel device called UNEEG EpiSight Analyzer.[24] The device allows for continuous wireless monitoring and recording of brain activity; it consists of an implant, attachment piece, recorder, and a phone app.

The Irish arm of this international study is led by Professor Norman Delanty from Beaumont Hospital, Dublin and Professor Daniel Costello from CUH and will involve approximately 20 participants. The study will assess the safety and performance of the device, as well as other health-related outcomes and the participant's experience of using the device.

Novel wearable fetal movement monitor

A multidisciplinary team led by Professor Niamh Nowlan at UCD has developed a novel, wearable fetal movement monitoring system, called the FeMo device. It aims to address the urgent need to enable remote monitoring of fetal movements and thereby dramatically reduce stillbirth rates on a global scale. The pilot study is supported by the UCD Clinical Research Centre and will be carried out by Professor Fionnuala McAuliffe from the National Maternity Hospital in Dublin and will include at least 30 participants. Results from the study will lead to design refinement of the device, training of movement detection algorithms, and will provide crucial information for a future pivotal study of the device.

23 Luma Vision – VERAFEYE.

24 UNEEG EpiSight Analyzer™.

NREC-MD – committee members

In 2023, the members of the NREC-MD dedicated their time and expertise to the ethical review of complex and important health research studies, with a view to safeguarding the rights, dignity, and well-being of research participants in the Republic of Ireland. I am grateful for their thoughtful contemplation, their engagement, and dedication to participating in a process that illustrates the possibilities of effective collaboration. Following a successful expression-of-interest campaign in 2023, the committee membership has now grown to its full complement of 28, having welcomed five new members. Together, we look to the future and to fulfilling our obligations to the research participants of today and the patients of tomorrow.

Professor Barry O'Sullivan
Chair of NREC-MD and Professor of Constraint Programming, UCC School of Computer Science and Information Technology

The following members served on the NREC-MD in 2023.

Prof. Barry O'Sullivan
Chair
UCC

Prof. Mary Sharp
Deputy
TCD

Prof. Declan Patton
Deputy
RCSI

Dr Caitriona Cahir
RCSI

Dr Daniel Coakley*
CUH

Dr Mireille Crampe
HSE

Ms Ruth Davis
Barrister

Dr Owen Doody
University of Limerick

Dr James Gilroy*
HSE

Dr Frank Houghton
Technological University of the Shannon: Limerick

Dr Gloria Kirwan
RCSI

Ms Orla Lane
Economist

Prof. Cara Martin*
TCD

Mr Billy McCann
Retired/patient advocate

Dr Sarah McLoughlin
Patient Advocate, Cancer Trials Ireland

Prof. Tom Melvin
TCD

Prof. Thérèse Murphy
Queen's University Belfast

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

Prof. Susan O'Connell
Children's Health Ireland at Crumlin

Dr Clare O'Connor
UCD

Dr Paul O'Connor
University of Galway

Prof. Catherine O'Neill**
Retired senior lecturer/ researcher in nursing

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

Mr Damien Owens
Engineers Ireland

Prof. Anne Parle-McDermott
Dublin City University (DCU)

Ms Ríona Tumelty
Beacon Hospital, Dublin

Prof. Mahendra Varma
Retired cardiologist

Ms Simone Walsh*
RCSI

Mr Peter Woulfe
Blackrock Health Galway Clinic

* New members appointed in 2023.

** Stepped down during 2023.

National Irish COVID-19 Biobank Research Ethics Committee

Overview of activity in 2023

National Irish COVID-19 Biobank Research Ethics Committee (NICB-REC)

As mandated by the Minister for Health, a dedicated research ethics committee was established by the National Office and fully operational in 2023 to ethically assess and deliver a single national ethics opinion on the governance and operations of the National Irish COVID-19 Biobank (NICB).[25]

The NICB-REC[26] is chaired by Dr Georgina Flood, Consultant Anaesthetist at the Mater Misericordiae University Hospital. Its membership encompasses a broad range of expertise, knowledge, and lived experiences, in areas such as biobanking operations, bioethics, data protection, law and regulation, infectious diseases, respiratory medicine, and genetics, including patient advocate perspectives.

A consensus-based favourable single national ethics opinion was delivered by the NICB-REC, applicable to all 19 biobank sites and collaborative partners contributing to the NICB. This ensures standardisation and harmonisation of ethical biobank operations that were ethically assessed.

Ethics assessment procedures

The NICB-REC assessment process was informed by best national and international practices and applicable legislative frameworks.

All members contributed ethical assessment reports to facilitate deliberations at NICB-REC meetings. The assessments considered the information submitted by the NICB through the application form, which was structured in a section-by-section format to enable the members to ethically assess the operational and governance aspects of the biobank, such as:

- Informed consent and assent
- Withdrawal of consent/assent
- Vulnerable participants
- Regulatory compliance
- Research scope
- Governance and operations
- Standardisation and harmonisation of processes across sites
- Data protection safeguarding and risk mitigation
- Genetic data considerations
- Data integrity and usability
- Technical safeguarding of biosamples and data
- Access and transfer of data and biosamples
- Public and patient involvement
- Pathway to research translation towards improved public health, and
- Destruction plans for biosamples and data.

25 National Irish COVID-19 Biobank (covidbiobank.ie).

26 National Irish COVID-19 Biobank REC – NREC (nrecoffice.ie).

Phased and partitioned ethics opinion model

As the biobank is an evolving and progressive infrastructure, a phased and partitioned ethics opinion model was implemented by the NICB-REC. Such a model facilitates NICB operations by ensuring established and ethically robust procedures and operations, such as participant recruitment, are facilitated to commence.

NICB elements assessed	Ethics opinion delivered
Governance: governance and oversight	Favourable with conditions
Participant recruitment: identification of potential participants; participant-facing information and consent protocols	Favourable with conditions
Biological samples and data: collection storage, processing, cataloguing, general curation, and security aspects	Favourable with conditions
Researcher access and public health impact	Opinion reserved subject to new application for full ethics assessment

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.[27]

Operational framework

The establishment of the NICB-REC and the processes developed to ethically assess the NICB comprehensively encompass the requirements for the ethical assessment of the governance and operations of a multi-site, multi-legal entity biobanking infrastructure. The bespoke operational framework allows for biobank establishment milestones to be fulfilled, while ensuring the biobank is ethically robust. This enables the generation of research evidence and data that can benefit society, while also preserving the safety, autonomy, and well-being of research biobank participants. The operational framework established for the NICB-REC may be considered a blueprint for the ethical assessment of biobanks in Ireland and beyond.

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

NICB-REC – committee members

The calendar year 2023 was groundbreaking with the commencement of operation of the NICB-REC, a committee tasked with ethical oversight of the first ever national health research biobank in Ireland. To achieve its aim, a bespoke phased ethics opinion model was implemented, enabling the committee to assess and deliver an ethics opinion on each aspect of biobank function. The ethical framework developed for assessment of the NICB ensures the safeguarding of biobank participants, their data and biological samples, while also ensuring that the research generated will inform public health for the greater good of society as a whole into the future.

Dr Georgina Flood
Chair of the NICB-REC and Consultant Anaesthetist at the Mater Misericordiae University Hospital

The following members served on the NICB-REC in 2023.

Dr Georgina Flood
Chair
Mater Misericordiae University Hospital/ Mater Private Hospital

Dr Anne Moore
Deputy
UCC

Prof. Kathleen Bennet
RCSI

Dr Brian Clark
Ferring Pharmaceuticals

Mr John Culliney
Retired business person

Dr Aisling de Paor
DCU

Prof. Sean Hynes
University of Galway

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

Dr Sonja Khan
University of Galway

Prof. Patrick Manning
Ballinderry Clinic/RCSI

Dr Kevin May
General practitioner

Prof. Shaun O'Keeffe
University Hospital Galway/University of Galway

Prof. Cathal Seoighe
University of Galway

Prof. Anthony Staines
DCU

Dr Ciara Staunton
European Academy Bozen/Bolzano (EURAC)

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 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 it to provide guidance, insight, and constructive feedback at appropriate points in the review process to both applicants and NREC members.

The team expanded in 2023 in response to the significant growth in applications and the operational complexity of the work required to deliver a robust and trustworthy national ethics review system in accordance with the applicable EU legislation. Specifically, the new CTR has introduced nuanced and time-sensitive work that must be carefully coordinated operationally, scientifically, and collaboratively with the HPRA to deliver a national opinion within rigid legislative timelines.

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 host organisation, the HRB.

National Office for Research Ethics Committees team members in 2023 included:

Dr Emily Vereker
Head, National Office

Dr Jane Bryant
Programme*/
Project Officer

Ms Ayesha Carrim*
Project Officer

Dr Anne Costello
Programme Manager

Dr Emma Heffernan
Project Officer

Dr Louise Houston/
Ms Megan O'Neill*
Project Officer

Ms Kathy Kelly
Administrative Assistant

Ms Aisling Collins*
Administrative Assistant

Ms Patricia Kenny
Project Officer

Dr Laura Mackey
Programme Officer

Ms Rachel McDermott
Project Administrator

Dr Lucia Prihodova/
Ms Chita Murray*
Programme Manager

Dr Susan Quinn
Programme Manager

Ms Aileen Sheehy
Programme Manager

Ms Anna Dunne
Communications Officer

Mr Tomás McElhinney
Finance Officer

* Interim roles, covering leave.

National Office strategic objectives

2023 achievements and 2024 priorities

National Office strategic objectives

The ambitious brief of the National Office for Research Ethics Committees is underpinned by clear strategic objectives to ensure that a sharp focus on success is maintained and to bring cohesion and clarity to the evolving regulatory research environment in Ireland.

We remain committed to supporting and operating a national system for research ethics review to ensure that the safety, dignity, and well-being of research participants are ethically safeguarded and that they have the ability to exercise their autonomy, fundamental rights, and freedoms.

On balance, the National Office and NRECs strive to support the spectrum of health research through a rigorous and independent ethics review process, in a timely and transparent manner.

We identified five strategic priorities for guiding the NREC system that we were able to further advance in 2023 and into 2024.

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

Key achievements in 2023

The following summary sets out the National Office's key achievements in 2023, which are aligned with our strategic priorities.

- We continued to support the work and growth of the National Office for Research Ethics Committees, which is hosted by the HRB. The NREC-CTs delivered a single national opinion for 87 new clinical trial studies and 473 substantial modifications applications.
- The NREC-MD delivered a national opinion for 28 new medical device studies and 28 substantial modifications applications.
- The National Office supported 61 national research ethics committee meetings to deliver a total of 616 single national ethics opinions.
- In response to the EU CTR coming into force in January 2023 and in collaboration with the HPRA, the National Office and NREC-CTs transitioned from an application form process to the CTIS, a single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial information.
- The National Office supported the NICB-REC to deliver a single national ethics opinion for the NICB, underpinned by best international ethics practices for biobanks.
- The National Office launched an expression-of-interest call that resulted in a further 22 NREC members being appointed by the Minister of Health, strengthening capacity and building sustainability for the national research ethics system in Ireland.
- The National Office operationalised a critical restructure of the NREC-CTs, from two to four committees, enabling weekly NREC-CT meetings to ensure that EU regulatory timelines are met.
- All the NRECs were registered with the US Office for Human Research Protections, which is necessary where research under ethics review is funded by the US Department of Health and Human Services.
- The HRB and National Office co-hosted the National Conference on Research Ethics, which was attended by more than 250 delegates, and brought together stakeholders such as health and social care researchers and practitioners, ethics committee members, patients, and members of the public to address some of the most burning ethical issues currently facing the health research sector.
- The National Office represented Ireland's interests on ethics expert working groups and clinical trial programmes, such as the MedEthics EU forum and Accelerating Clinical Trials in the EU, to drive harmonisation of the implementation of EU Regulations and clinical trial research activity in Ireland.

- The National Office participated in three public consultations, surveys, and benchmarking initiatives set by the EMA and WHO: the EMA's guidance on Good Clinical Practice; the WHO's consultation on Best Practices for Clinical Trials; and the WHO's Global Benchmarking Tool for evaluation of national regulatory systems.
- The National Office hosted seven Lunch & Learn educational sessions for the benefit of the NRECs and the wider research ethics committee community, with topics such as genetics and genomics, children and pregnant participants in clinical trials, and good clinical practice.

Next steps for 2024

As we look forward to the rest of 2024, the National Office will strive to deliver strategic and operational actions 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 2024, we will:

- Ensure the committees are constituted with the requisite expert knowledge and lived experiences to bring the perspectives necessary to enable robust research ethics review and to deliver national ethics opinions with rigour, consistency, and transparency.

- Provide our committee members and the wider community with education and training to ensure that they are informed about pertinent, complex subject areas across legislation, regulation, policy, and scientific advancements.
- Continue to represent Ireland's interest in key European stakeholder expert groups (e.g. CTIS, CTCG, EUREC, ACT EU, Medical Device Coordination Group, MedEthics EU) to inform best practice and enable a harmonised and consistent approach to the delivery of a single national ethics opinion under the EU Regulations.
- Connect with patient and public advocacy organisations, including the Irish Platform for Patients' Organisations, Science and Industry (IPPOSI) and Health Research Charities Ireland, to ensure that the ethics system is centred on the research participant, with strong PPI engagement.
- Promote the role of the National Office and the committees it supports through education, outreach, and editorial content development to improve understanding of research ethics throughout society.
- Work in partnership with the Secretariat of the Health Research Consent Declaration Committee (HRCDC) in setting out a policy of seamless engagement for cross-cutting areas of research regulation.
- Support the work of the NICB-REC and COVID-19 Subcommittee, as an important component of Ireland's response to the COVID-19 pandemic and, in parallel, engage with international organisations for future pandemic preparedness.
- Collaborate with the Department of Health to support strategic initiatives, shape key legislative changes, and inform best-practice and policy developments that will impact the operational and strategic objectives of the National Office and its committees.
- Establish a National Community of Practice for Research Ethics that connects the research ethics community across the island of Ireland.
- Develop new relationships with international bodies, such as the US Office for Human Research Protections, the Health Research Authority, WHO, Science Europe, and the Council of Europe to understand and inform ethical best practices on a global level.
- Collaborate with national stakeholders to harmonise and align cross-cutting areas of health research and ethics, including collaboration on HRB cross-organisation initiatives.
- Develop a bespoke business system, in collaboration with the HRCDC Secretariat, to support the efficient receipt and management of applications for ethics review and consent declarations.

Notes

Notes

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

nationaloffice@nrec.ie

www.nrecoffice.ie

@NREC_Office