NATIONAL OFFICE FOR **RESEARCH ETHICS** COMMITTEES

Annual Report 2022

Enabling a trusted national ethics opinion

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The 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. In partnership with the Department of Health and the national regulatory authority, the Health Products Regulatory Authority (HPRA), we are implementing a road map of transition to a national system of research ethics review for regulated areas of health research, and other areas of research as mandated.

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 regulated health research in Ireland. We are tasked with establishing and supporting National Research Ethics Committees (NRECs) in prescribed areas of health research.

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 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 (NREC-CTs)
- 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, and
- The National Irish COVID-19 Biobank (NICB); assessed by the National Irish COVID-19 Biobank Research Ethics Committee (NICB-REC).

The NRECs are mandated under legislation, or by ministerial instruction, to return ethics decisions that are respected nationally ('single national ethics opinion'). Working alongside local research ethics committees (RECs) and supported by the National Office team, NRECs work in a mixed-model system to support research ethics across the spectrum of health research in Ireland.

The fundamental duties of the National Office include:

- Establishing NRECs in specific areas of health research
- Constituting the membership of the NRECs
- Supporting national initiatives of strategic importance
- Providing operational support to NRECs
- Monitoring and overseeing NRECs
- Issuing guidelines for NREC work, and
- Delivering education and outreach on research ethics more broadly.

OUR VISION

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

OUR MISSION

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

With a steadfast commitment to our vision and mission, we work to ensure that the dignity, safety, and well-being of research participants is front and centre of an NREC system that positions Ireland as the first-choice location for developing new medicines and technologies – all with the goal of improving access to emerging new treatments, cures, and preventions for Irish patients and the wider public.

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 third annual report, for the year 2022, highlighting the achievements and milestones of the National Research Ethics Committees (NRECs) and the National Office throughout that year. The report demonstrates the breadth of work achieved by the National Office and NRECs, reflecting the vibrant health research activity in Ireland.

In 2022, the National Office worked closely with the NRECs to advance, strengthen, and embed the national research ethics system in Ireland, which supports ethical health research practices aimed at safeguarding the rights, dignity, and welfare of research participants. We developed and adopted new processes, improved guidance, ensured preparedness for the entry into force of relevant European Union (EU) regulations, expanded the NREC membership, and delivered a comprehensive education and learning series to all Committee members.

A strong focus for the National Office in 2022 was strengthening connections and collaboration with our principal stakeholders, and proactively seeking feedback from sponsors, researchers, and national organisations such as the Health Products Regulatory Authority (HPRA), Clinical Trials Ireland, and the Health Service Executive (HSE), to name but some.

This critical engagement has allowed us to better identify the needs of those we support and to tailor our business operations accordingly, with the ultimate aim of effecting efficiency and consistency in ethical practices. An extension of this stakeholder work saw the National Office team representing Ireland as an EU Member State through participation in the Clinical Trials Coordination Group, a Europe-wide working group of experts in the classification, assessment, and oversight of clinical trials from national agencies.

In 2022, the National Office and NRECs for Clinical Trials (NREC-CTs A and B) experienced the full application of the EU Clinical Trials Regulation (CTR) and implementation of the associated Clinical Trials Information System (CTIS), which serve to harmonise and improve efficiency and transparency for this regulated research area across Europe.

The transition to the CTIS application procedure under the CTR introduced new processes for ethics review, which have been seamlessly and expertly navigated by the National Office and NREC-CTs. We greatly appreciated the collaborative support provided by the national regulatory authority, the HPRA, during this transition period, in helping to streamline processes to safeguard patient and public safety while enabling innovative research.

> **The National Office remains committed to its mission of promoting and maintaining the highest ethical standards in health research in Ireland, through the national ethics systems it supports.**
>
> **Dr Emily Vereker,**
> Head, National Office for Research Ethics Committees

Moreover, the application of the EU *In Vitro* Diagnostic Regulation (IVDR) in May 2022 added a further workstream of ethics review to the NREC for Medical Devices (NREC-MD), by delivering a national ethical opinion for analytical and clinical performance studies.

In response to the complexity and intensity of work necessary to deliver a national ethics opinion for all regulated areas of research, the National Office commenced a second recruitment campaign to bolster the NREC membership in 2022. In May, we warmly welcomed an additional 15 ministerially appointed members across the NREC-CT A, NREC-CT B, and NREC-MD, bringing with them complementary expertise and perspectives, including competencies to support ethical considerations for *in vitro* diagnostic medical devices.

As COVID-19 continues to be an area of strategic importance at the forefront of health research in Ireland, the National Office supported the Department of Health's investment in the National Irish COVID-19 Biobank (NICB) in 2022 through the establishment of a 15-member-strong dedicated NICB Research Ethics Committee (NICB-REC) in December. This Committee will provide national ethical oversight of this critical biorepository in order to ensure that use of the NICB for health research is underpinned by the highest standards in ethics, governance, and codes of practice. The establishment of the NICB-REC further complements the valuable work of the standing subcommittee of the first NREC for COVID-19, which, throughout 2022, continued its oversight of studies approved under the NREC's original tenure.

The year 2022 was exceptionally busy for the National Office and NRECs, beginning with an unprecedented volume of substantial modification applications submitted under the transitioning legislation of the Clinical Trials Directive. The National Office team enabled a high-throughput approach to support the NREC-CT members in delivering national ethics opinions over an intensive 8-week period. This tour de force illustrates the will and commitment of NREC members in driving the national ethics system in the interest of trial participants and the research community. The enormity of the workload and responsibility of the members cannot be overstated and is evident in their expert ethical assessment of applications, their constructive and well-considered deliberations, and their balanced, consensus-based decision-making. It is a pleasure and privilege for the National Office team to support NREC members in this vital work, and we thank them for the valuable contribution they make to the ethical conduct of research in Ireland.

I would like to take this opportunity to also thank and acknowledge the National Office team for their dedication, energy, and professionalism in supporting the NREC members and wider national ethics system. Their engagement with the research community and national and international stakeholders has helped position the National Office as a recognised and trusted body within the Irish regulatory research environment.

On behalf of the NREC members and the entire team at the National Office, I would like to express my sincere gratitude to all our stakeholders, particularly our colleagues in the Department of Health, for their ongoing support and collaboration. We are especially grateful for the invaluable operational and strategic support provided by our colleagues in our host organisation, the Health Research Board (HRB).

As we look ahead, the important role that research plays in advancing knowledge and improving healthcare outcomes must be balanced with the need to safeguard participant dignity, autonomy, and self-determination. The National Office remains committed to its mission of promoting and maintaining the highest ethical standards in health research in Ireland, through the national ethics systems it supports.

Dr Emily Vereker

Head, National Office for Research Ethics Committees

2022 snapshot

Committees' work at a glance

590 applications submitted

- **120** new studies
- **470** substantial modifications

60 meetings

513 opinions delivered*

- **98** new studies
- **415** substantial modifications

Health research areas covered 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

Committee membership

86 committee members in 2022**

48% male
52% female

From all over Ireland

Representing diverse backgrounds, including:

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

*Difference between applications submitted and opinions delivered reflects applications which were invalid or withdrawn before a decision was made

**Includes members who stepped down before the end of 2022

Highlights from the National Office in 2022

An agile response to an evolving legislative environment

The year 2022 was one of significant change in the legislative environment within which the National Research Ethics Committees (NRECs) operate, driven by regulatory developments at the European level.

The National Office team worked to deliver an agile response to these changes, in order to effectively support a seamless transition for NREC members and those applying to the NRECs.

Clinical trials: from CTD to CTR

The conduct of clinical trials for medicinal products in the European Union (EU) has undergone a major change with the Clinical Trials Regulation (CTR) entering into application on 31 January 2022 and being transposed into Irish law in May 2022. Replacing the Clinical Trials Directive (CTD), the CTR harmonises the submission, assessment, and supervision processes for clinical trials in the EU through the launch of a new, unified online portal known as the Clinical Trials Information System (CTIS). The CTR is designed to drive health research towards innovative new treatments for the benefit of patients and the public in Europe by streamlining the approval of clinical trials across EU Member States. It brings greater regulatory convergence and efficiency to the clinical trial application process, and places a renewed emphasis on clinical trial safety and public transparency.

The National Office had been laying the groundwork for the CTR since the office's establishment in 2020, engaging in training and development to ensure that our team was ready to master the change. The members of the NRECs for Clinical Trials (NREC-CTs) expertly balanced operating across two distinct legislative frameworks throughout the transition phase during 2022. In Ireland, a coordinated procedure for the scientific and ethical assessment of clinical trials has been developed by the National Office, the NREC-CTs, and the Health Products Regulatory Authority (HPRA), in conjunction with the Department of Health. As the new system involves a single national decision for Ireland, this means even greater harmonisation between the National Office and the HPRA, while maintaining independence of function. We further deepened our engagement with the HPRA in 2022, which has been hugely positive for streamlining review processes for clinical trials under the new framework. This coordinated procedure will lead to a timely single national decision for Ireland on the scientific and ethical aspects of an initial clinical trial application. This is a positive and welcome development for the National Office, NRECs, sponsors conducting research in Ireland, and clinical trial participants.

Crucially, the National Office team has continued to provide extensive support to the NREC-CTs, the research community, and sponsors as they navigate the new system. We support the NREC-CTs in navigating the new legislative environment and assessment procedures under strict timelines, providing comprehensive information on our website, answering queries, and engaging closely with sponsors and applicants as they familiarise themselves with the new framework. Through our active engagement in European working groups, we are continuously gathering best practices to inform our support for researchers based in Ireland working under the CTR and with the CTIS.

Expanding the scope of medical device ethics review

When the EU *In Vitro* Medical Devices Regulation (IVDR) came into effect on 26 May 2022 after a 5-year transition period, the remit of the National Research Ethics Committee for Medical Devices (NREC-MD) was expanded, from clinical investigations for medical devices, to include the review of applications seeking ethical approval for performance studies of *in vitro* diagnostic medical devices. Similar to the EU Medical Device Regulation (MDR), the IVDR aims to harmonise standards throughout the EU for the development and commercialisation of these devices, and for the management and surveillance processes that apply across their lifetime. Its application marked a key milestone in strengthening safety standards for research participants and patients and in supporting research and innovation in new diagnostic devices.

The National Office team worked to effectively facilitate the NREC-MD in adapting to this new scope of review once the NREC review of ethics applications submitted under the IVDR was transposed into Irish law. A targeted membership recruitment drive was conducted, seeking expressions of interest from experts in *in vitro* diagnostics, which resulted in additional members being appointed to the NREC-MD in June 2022. These new members have been contributing their specialist skills to the evaluation of applications falling under the NREC-MD's expanded remit, ensuring that timely and robust ethics review can support research in this important field.

Highlights from the National Office in 2022

Engaging, informing, collaborating: outreach activity in 2022

As the National Office and NRECs entered their second year of operation, a strategic priority for the team was to enhance our presence and strengthen collaboration within our community of stakeholders.

The National Office has gained considerable insights and learnings from NREC deliberations on ethics across regulated areas of health research, as well as from our colleagues in the HPRA and key opinion leaders within the European Medicines Agency (EMA). These engagements inform the trusted guidance and support we offer to the research community and national bodies that more broadly support and underpin health and social care research in Ireland.

Supporting stakeholders across the national ethics system

The mixed-model ethics system in Ireland requires sponsor organisations, researchers, and local institutional research ethics committees (RECs) to have clarity and certainty as to the role of the national ethics system and how to navigate it. In 2022, the National Office made concerted efforts towards direct and meaningful engagement with those requiring support in working with the NREC system and the new legislative framework under which it operates.

During 2022, the National Office team consulted and collaborated with a number of important groups that work across the research network in Ireland, providing NREC perspectives, facilitating candid discussions, and sharing trustworthy guidance and information on ethical research practices and operational changes informed by EU legislation. These included, for example, local institutional REC managers, the HRB National Clinical Trials Office, Cancer Trials Ireland, national clinical research facilities, and the Health Service Executive (HSE) research and development division.

In parallel, the National Office continued to collaborate with the Department of Health throughout 2022 on strategic, operational, and legislative matters pertaining to the national research ethics systems.

Sharing knowledge and shaping strategies

In order to shape and inform national and international policy, best practices, and strategic initiatives, the National Office team contributed its expertise and perspectives to a range of panels and groups in 2022, including:

- The HSE RECs Reform Working Group, in order to support the development of standard practices, management, and governance for HSE RECs
- The Irish Platform for Patient Organisations, Science & Industry (IPPOSI) citizens' jury on genomics – oversight panel, in order to advise on each of the steps throughout the jury preparation and implementation process
- The HSE Consent Policy Working Group, in order to revise and develop the now published *HSE National Policy for Consent in Health and Social Care Research* (2022)
- The Irish Health Research Forum steering group, in order to guide on themes and outputs of strategic areas of national importance for health research
- The European Clinical Trials Coordination and Advisory Group, in order to represent Ireland in the exchange of knowledge regarding the implementation of the CTR, and
- The European Expert Group on Clinical Trials, in order to represent Ireland in discussions on technical regulatory issues related to clinical trials of medicinal products for human use.

Consulting with the public

In 2022, the National Office carried out a public consultation exercise proposing a change in the submission fee structure for 2023, for all ethics applications. The National Office invited stakeholders to share their views on the proposed fee structure, with contributions submitted to the National Office for consideration. The final outcome of the consultative process and related changes to fees were implemented in 2023.

Advancing discussion through events

In October 2022, the National Office held a webinar for our stakeholder community and those with an interest in health and social care research ethics. Over 400 people registered to join us in reviewing the journey of the National Office and NRECs to date and sharing our learnings and insights with attendees. The keynote speaker, Emeritus Professor of Philosophy and Chair of the Nuffield Council on Bioethics David Archard, joined the NREC Chairs to discuss the evolution of the research landscape in Ireland and emerging trends in research ethics more broadly.

Our team also contributed to a number of events in the wider research community: for example, by participating in a panel discussion on Ireland's clinical research ecosystem at the leading industry event 'Medtech Rising 2022', and by making a presentation on the NRECs and National Office to the Irish Research Nurses and Midwives 14th Annual Conference, 2022.

Expanding education and sharing insights

The National Office hosted a series of 'lunch & learn' educational presentations for the benefit of NREC members on topics of significant relevance to the work of the NRECs, such as consent and capacity; the new CTR; data protection and research ethics; insurance and indemnity; and emerging legislation.

Moreover, and building on 2021's engagement with third-level students, the National Office and the Secretariat for the Health Research Consent Declaration Committee (HRCDC) continued their collaboration with Maynooth University in order to deliver the Project Live initiative. This collaborative educational programme between external stakeholders, academics, and students aims to enhance teaching and learning through applied principles and practices. Students worked on an assessment project on the topic of 'informed consent' as a component of their postgraduate module, the outputs of which proved beneficial to the work of both the National Office and the HRCDC Secretariat.

Highlights from the National Office in 2022

Patient, public, and carer involvement: an essential perspective for ethics review

Research plays a critical role in driving innovation to deliver improved and novel therapies and medical products.

At some point in our lives, we are all health and social care service users, patients, or carers for patients, who contribute to, and can benefit from, research-driven innovations. As such, ethical oversight of health research must be inclusive and representative of contemporary Irish society.

Across our work, the National Office and the NRECs we support are committed to understanding and bringing perspectives representative of Irish society that affect us all to the fore of ethical decision-making. We want to ensure that the ethics review carried out by our committees is shaped by a broad range of viewpoints and can benefit from the lived experiences of individuals with diverse backgrounds. This is the essence of public and patient involvement (PPI): the contribution that members of the public make to the research process across the research lifecycle, including patients, their families, and/or patients' carers.

All committees supported by the National Office include a number of PPI members whose expertise lies outside the medical or regulatory areas traditionally associated with health research ethics and, rather, in their lived experience as patients or members of the general public.

The opinions of these committee members are given equal weight in the decision-making process to those of members with medical or other professional expertise in ethics. Their unique insights and perspectives are invaluable during an NREC study application review, as they ground the process in individual experience and bring a personal perspective on advocating for patients' rights, safety, and well-being. PPI committee members are integral to the ethics review process and help to engender trust of the research community and wider public in the national ethics review system.

When establishing a new national committee, the National Office invites expressions of interest for membership from PPI applicants, specifically designed to be inclusive of race, religion, ethnicity, gender, sexual orientation, responsibilities for dependents, age, disability, civil status, and geographic location. PPI committee members are chosen based on their interests, backgrounds, and experiences, which will support ethics decisions on NREC applications.

Appointed members receive training, access to the electronic tools necessary to conduct committee work, and administrative support from the National Office team. Membership of an NREC is an important and valued public service role.

The National Office truly values the time and commitment shown by all our members, and appreciates the specific contribution made by our PPI members in ensuring that our NRECs' reviews are well rounded and reflective of Irish society as a whole.

We asked some of our PPI members to share insights from their committee work, why they chose to get involved, and how they would describe their contribution.

Sarah McLoughlin,
PPI member of NREC-MD:

An essential component of clinical research is the trust and confidence of the public and participants, which can only be fostered through a strong and competent ethical approval process that is consistent across all sites. Central to that trust is the inclusion of public and participant voices in the ethics process. In my experience, the PPI members of NREC-MD are supported, respected and heard.

Gerard Eastwood,
PPI member of NREC-CT A:

I have found my work on the National Research Ethics Committee to be very challenging but rewarding. My motivation for being a member of this committee is to help improve patient involvement in research to create an active and meaningful partnership between the people living with a condition and those researching it. By taking part in this forum, I hope to support the achievement of the goal of ensuring that the real-life experiences of people are considered in the decision-making processes around health research and healthcare.

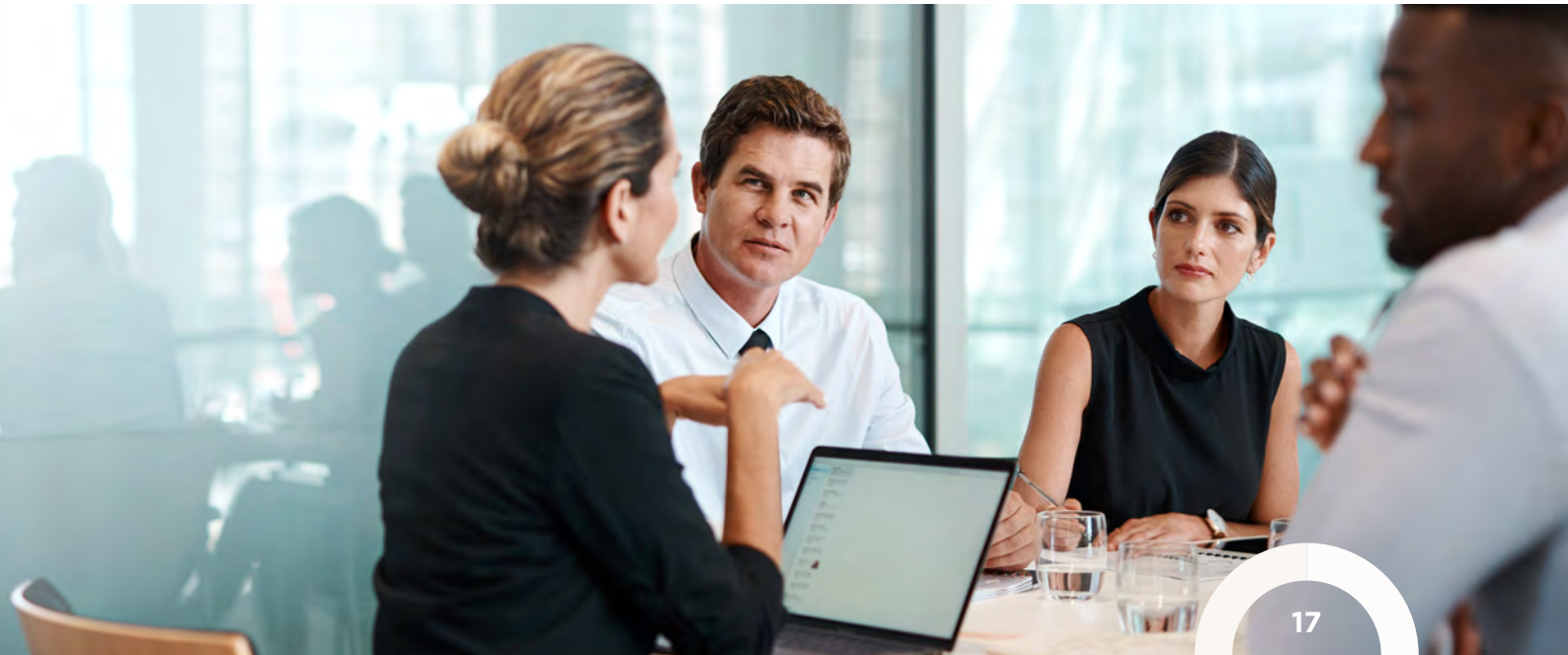
Highlights from the National Office in 2022

Assembling the right expertise for an emerging area in research ethics

As the world emerges from the COVID-19 pandemic, research into the virus remains essential, not only for developing treatment pathways for a disease that is still very much present in society, but also for unlocking learnings to help fight future pandemics.

Biobanks – repositories of biological samples and related data that are collected and stored for research purposes – are an invaluable resource in furthering these aims. With the ethical and legal frameworks around biobanking still evolving in Ireland, however, RECs will play an essential role in providing ethical oversight as work in this area progresses.

Against this background, the Department of Health mandated the National Office in 2022 to establish and support the operations of a single, dedicated REC for the National Irish COVID-19 Biobank (NICB), which will act as a national, integrated biorepository of human biological samples with linked data provided by individuals with COVID-19. The NICB-REC will oversee how biobank participants' dignity, autonomy, and well-being are upheld, and that their data protection and privacy rights are safeguarded, by carrying out an ethical assessment of the governance structure and operating procedures of the NICB and any future modifications to these.



Due to the new and highly specific nature of the NICB-REC's mandate, the National Office engaged in a dedicated recruitment process in order to ensure that the NICB-REC can draw on the necessary expertise and lived experiences to support a fully rounded ethical review of the NICB. Our targeted approach identified a range of members who, together, encompass the broad spectrum of expertise and experiences required, including:

- Biobanking, ethics, and biostatistics: to review ethical aspects specifically related to biobanking processes
- Bioinformatics and data protection: to ensure that data are appropriately used and adequately safeguarded
- Legal and regulatory: to review compliance with the legislative and regulatory framework
- Clinical, respiratory, and infectious disease medicine; and geriatric and paediatric medicine: to inform the ethical review of clinically related aspects
- Genetics and genomics, immunology, pathology, virology, and vaccine development: to inform the ethical review as it relates to pertinent areas of research and science
- Epidemiology, population and public health: to assess the NICB's potential impact on public health and pandemic preparedness, and
- A number of PPI members who will contribute their insights from the perspective of patients or members of the public, ensuring that diverse viewpoints and life experiences feed into the review process.

Fifteen new members of the NICB-REC were appointed by the Minister for Health in December 2022. By establishing and supporting the NICB-REC, the National Office demonstrates its commitment to supporting strategic areas of national importance and operating in the public interest.

Highlights from the National Office in 2022

Growing our team to support a national infrastructure

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 2022 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 in order 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 continuous 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 team members in 2022 included:

Dr Emily Vereker
Head, National Office

Dr Jane Bryant
Programme Officer

Ayesha Carrim
Project Officer (interim)

Dr Anne Costello
Programme Manager

Dr Emma Heffernan
Project Officer

Dr Louise Houston
Project Officer

Kathy Kelly
Administrative Assistant

Patricia Kenny
Project Officer

Dr Laura Mackey
Programme Officer

Rachel McDermott
Project Administrator

Megan O'Neill
Project Officer (interim)

Dr Lucia Prihodova
Programme Manager

Dr Susan Quinn
Programme Manager (interim)

Aileen Sheehy
Programme Manager

National Research Ethics Committees for Clinical Trials

Overview of activity in 2022

National Research Ethics Committees for Clinical Trials (NREC-CTs)

Two NREC-CT committees were established in May 2021 by ministerial appointment and are recognised under Irish law through S.I. No. 41/2022.

The NREC-CTs 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-CT A is chaired by Professor Alistair Nichol, and the NREC-CT B is chaired by Dr Cliona McGovern. Members hail from all over Ireland and represent a wide variety of professional backgrounds and lived experiences, bringing a diverse range of expertise to the ethical review decision-making process. A further 10 members were appointed across the NREC-CTs in 2022, expanding the committees' expertise and capacity to review a growing volume of applications.

In 2022, the two committees met a combined 23 times for main meetings and for a further 17 subcommittee meetings. In addition, a series of 8 additional 'bootcamp' meetings were held in order to review a backlog of 134 substantial modification applications. Over these 48 meetings, 62 new applications were reviewed, while a further 386 substantial modification applications received final decisions over this time period.

A major change for the NREC-CTs in 2022 was the launch and assessment of the first applications under the EU CTR, submitted through the CTIS portal. The transition from the former EU Clinical Trials Directive to the CTR has been a highly positive experience for the National Office and the NREC-CTs to date, who managed the balance of operating across two distinct legislations throughout 2022. Overall, 8 new studies and 1 substantial modification was submitted under the new framework of the CTR.

The National Office has benefitted from a highly positive engagement with the HPRA during this transition period, and has participated in multiple EMA working groups and training and development programmes for our team. With the transition to CTR completed in early 2023, the foundations are set for the NREC-CTs to fully embrace this new system.

At a glance: NREC-CTs' work in 2022

Application status:

	New studies	Substantial modifications
Submissions (CTD/CTR)*	**75/8**	**443/1**
Deemed invalid	**21**	**47**
Received favourable opinion	**63**	**386**
Received unfavourable opinion	**3**	**4**
Withdrawn by applicant**	**2**	

* Applications received up to December 2021 and pending an NREC decision were subsequently reviewed in 2022

** Withdrawn after request for further information decision issued

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

NRECs in action: ensuring ethical research

The studies that received a favourable ethics opinion from the NREC-CTs in 2022 aim to enhance medical treatment and patient care across a wide range of healthcare areas. Here are just two examples:

Delivering national ethical oversight for research in the context of a global outbreak

Mpox (formerly monkeypox) is an uncommon viral infection caused by the monkeypox virus that may lead to a range of medical complications. After the World Health Organization (WHO) declared the global mpox outbreak a Public Health Emergency of International Concern (PHEIC) in July 2022, a multi-country study commenced across Europe, aiming to observe clinical and virological outcomes in both treated and untreated patients with confirmed mpox. A primary outcome for the study was to generate safety and efficacy data for the antiviral drug tecovirimat, licensed for mpox treatment by the EMA. The Irish arm of this study, entitled 'Cohort study of treatment outcomes in human monkeypox virus disease', is led by Associate Professor Aoife Cotter of the Mater Misericordiae University Hospital and University College Dublin (UCD).

Given the context of a global outbreak, and the need to rapidly establish effective treatment outcomes, an expedited, Europe-wide, ethics review process was supported by the National Office and the NREC-CT. Ethics approval was granted by the NREC-CT in September 2022, less than 2 months after the initial PHEIC declaration by the WHO.

Delivering national ethical oversight for groundbreaking cancer research

Ireland's first ever clinical trial for a cell therapy to treat multiple myeloma commenced in early 2023 using groundbreaking chimeric antigen receptor T-cell (CAR-T) therapy. Multiple myeloma is a type of rare, incurable blood cancer diagnosed in approximately 350 people in Ireland annually. The 'CARTITUDE-5' study seeks to evaluate the safety and efficacy of a type of CAR-T therapy called Ciltacabtagene Autoleucel (cilta-cel) in people newly diagnosed with multiple myeloma. The Irish arm of the CARTITUDE-5 clinical trial is led by Professor Christopher (Larry) Bacon at St James's Hospital and received a favourable ethical opinion from the NREC-CT in 2022, paving the way for the CARTITUDE-5 trials to commence. These will contribute significant new information in the areas of cancer research and personalised medicine, which can help improve outcomes and sustained remission rates for patients in Ireland with multiple myeloma.

NREC CT-A – committee members

The following members served on the NREC-CT A in 2022:

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
Member
Bon Secours Radiotherapy/UPMC Hillman Cancer Centre

Prof. David Brayden
Member
UCD

Prof. Donal Brennan
Member
UCD/Mater Misericordiae University Hospital

Mr Gerard Daly
Member
Retired civil servant

Dr Darren Dahly
Member
HRB Clinical Research Facility

Prof. Eugene Dempsey
Member
UCC/Cork University Maternity Hospital

Dr Jimmy Devins
Member
Retired general practitioner

Prof. Patrick Dillon
Member
University Hospital Limerick

Mr Gerard Eastwood
Member
Retired engineer/ academic lecturer

Dr Geraldine Foley
Member
Trinity College Dublin (TCD)

Prof. Catherine Hayes
Member
TCD

Dr Tina Hickey
Member
UCD/patient advocate

Dr Dervla Kelly
Member
University of Limerick (UL)

Ms Muireann O'Briain
Member
Retired barrister

Dr John O'Loughlin
Member
Retired medical scientist

Ms Evelyn O'Shea
Member
Naas General Hospital

Mrs Ann Twomey
Member
The Alzheimer Society of Ireland

Prof. John Wells
Member
South East Technological University

> **2022 brought many new experiences and learnings to the NREC-CT A, most importantly through the implementation of the CTR. Through a close partnership with the HPRA, the NREC-CTs have ensured that the rights and safety of research participants continue to be protected under the new legislation. We look forward to 2023, and the full implementation of the CTR, fostering harmonisation across Europe. NREC-CT A, alongside our sister committee NREC-CT B, continues to focus on our key role of protecting people taking part in clinical trials and ensuring that participant well-being is placed at the centre of clinical research in Ireland.**

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

NREC CT-B – committee members

2022 was a landmark year for NREC-CT, with the implementation of the CTR and the first submissions for review by our Committees through the CTIS system. The NREC-CTs have responded with agility and flexibility to come up to speed on the new system and regulation, while keeping the participant at the heart of the process. The diversity of expertise across the membership provides excellent insight across critical areas including consent, data protection, and vulnerable populations.

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

The following members served on the NREC-CT B in 2022:

Dr Cliona McGovern
Chair
UCD

Dr Jean Saunders
Deputy
CSCS Statistical Consulting

Prof. John Faul
Deputy
Connolly Hospital

Dr Enda Dooley
Member
Mental Health Commission

Prof. David Smith
Member
Royal College of Surgeons in Ireland (RCSI)

Dr Mary McDonnell Naughton
Member
Athlone Institute of Technology

Dr Eimear McGlinchey
Member
TCD

Ms Paula Prendeville
Member
Senior educational psychologist

Dr John Hayden
Member
RCSI

Mr Gavin Lawler
Member
Beacon Hospital

Dr Mark Robinson
Member
Maynooth University

Prof. Abhay Pandit
Member
CÚRAM SFI Centre for Medical Devices

Dr Lorna Fanning
Member
Career break (pharmaceutical industry)

Ms Serena Bennett
Member
Barrister

Ms Mandy Daly
Member
Irish Neonatal Health Alliance

Mr Philip Berman
Member
Retired, hospital services policy and management

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

Prof. Colm O'Donnell
Member
National Maternity Hospital

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

Ms Susan Kelly
Member
HSE

Ms Deirdre Mac Loughlin
Member
Retired IT manager/PPI advocate

Prof. Seamus O'Reilly
Member
Cork University Hospital

Dr Christina Skourou
Member
St Luke's Radiation Oncology Network

National Research Ethics Committee for Medical Devices

Overview of activity in 2022

National Research Ethics Committee for Medical Devices (NREC-MD)

The NREC-MD was established in May 2021 in order to meet Ireland's requirements under the Medical Devices Regulation (MDR) (EU) 2017/745.

In May 2022, the NREC-MD expanded its remit to review applications seeking ethical approval for performance studies of *in vitro* diagnostic medical devices submitted under the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) (EU) 2017/746.

The NREC-MD is a ministerially appointed committee recognised by the Department of Health under S.I. No. 260/2021 European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021 and S.I. No. 257/2022 European Union (National Research Ethics Committees for Performance Studies of *In Vitro* Diagnostic Medical Devices) Regulations 2022 and provides a single national ethics opinion for clinical investigations of medical devices as defined in the MDR and for performance studies of *in vitro* diagnostic medical devices as set out in the IVDR.

The Committee is chaired by Barry O'Sullivan, Professor of Artificial Intelligence at the School of Computer Science and Information Technology, UCC. Committee members bring to bear lived experiences and professional expertise in medicine, engineering, nursing, immunochemistry, legal and regulatory affairs, medical device development, statistics, and ethics. Thanks to this diverse spectrum of knowledge, each application to the NREC-MD benefits from a comprehensive, robust, and efficient review.

In 2022, members convened for a total of 12 NREC meetings, dedicating significant time and effort to reviewing ethics applications. By providing ethical oversight of medical devices and diagnostics, and by delivering robust and trustworthy ethics opinions, the NREC-MD supports the safety and performance of devices, paving the way for medical innovations for Irish patients and the public.

At a glance: NREC-MD's work in 2022

Application status:

Received	New studies **37**	Substantial modifications **18**
Deemed invalid	New studies **31**	Substantial modifications **3**
Favourable opinion	New studies **24**	Substantial modifications **15**
Unfavourable opinion	New studies **8**	Substantial modifications **2**
Withdrawn by applicant	New studies **1**	Substantial modifications **1**

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

NRECs in action: ensuring ethical research

The studies that received a favourable ethical opinion from the NREC-MD in 2022 aim to positively impact patient care and clinical outcomes across a wide range of medical conditions. Here are just two examples:

Exploring new pathways for treating tinnitus

Irish company Neuromod Devices has developed a device to support adults living with chronic tinnitus. Lenire® is a non-invasive medical device with combined acoustic and electrical stimulation capabilities designed to sit comfortably in the closed mouth (intraoral). The addition of intraoral stimulation to Lenire® was evaluated for safety and efficacy in the Treatment Evaluation of Neuromodulation for Tinnitus – Stage A3 (TENT-A3) multi-country clinical trial. The Irish arm of TENT-A3 took place at St James's Hospital, led by Mr Seng Guan Khoo, Consultant Otolaryngologist. Overall study results demonstrated that patients who were at least moderately bothered by tinnitus achieved a clinically meaningful improvement in tinnitus symptoms after using Lenire® with intraoral stimulation, in comparison with acoustic stimulation alone.

A new investigational stent designed for patients with moderate to severe iliocaval venous disease

Venous disease, or blocked vessels, is a common condition worldwide. Patients may have debilitating symptoms due to scarring from deep vein thrombosis, or from compression of veins from surrounding tissue. The current standard of care involves conservative medical management. The inferior vena cava is a blood vessel that transports blood from the legs and abdomen back to the heart, and it can become obstructed. There are limited surgical options indicated for this condition, and they can be associated with significant patient morbidity and poor long-term efficacy. The GORE® VIAFORT Vascular Stent is a stent (a tube that expands the vein walls) intended for treatment of the entire spectrum of iliocaval venous disease. This global investigational clinical trial, led in Ireland by Professor Gerry O'Sullivan of University Hospital Galway, will explore the safety and efficacy of the GORE® VIAFORT Vascular Stent in patients with moderate to severe iliocaval venous disease, and represents a significant step forward in this area of research.

NREC-MD – committee members

The following members served on the NREC-MD in 2022:

Prof. Barry O'Sullivan
Chair
UCC

Prof. Mary Sharp
Deputy
TCD

Prof. Declan Patton
Deputy
RCSI

Dr Caitriona Cahir
Member
RCSI

Dr Mireille Crampe
Member
HSE

Ms Ruth Davis
Member
Barrister

Dr Owen Doody
Member
UL

Dr Frank Houghton
Member
Limerick Institute of Technology

Dr Gloria Kirwan
Member
RCSI

Ms Orla Lane
Member
Economist

Mr Billy McCann
Member
Retired/patient advocate

Dr Sarah McLoughlin
Member
UCD

2022 marked an important milestone for the NREC-MD, as we augmented the expertise of our committee members in response to the IVDR – and we are now lucky to have within our ranks individuals with a specific skillset in this area. Looking to the year ahead, the committee will continue to engage with the complex ethical issues around emerging technologies such as artificial intelligence, which is increasingly a feature of medical device development.

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

Prof. Tom Melvin
Member
TCD

Prof. Thérèse Murphy
Member
Queen's University Belfast

Dr Declan O'Callaghan
Member
Retired cardiologist

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

Dr Clare O'Connor
Member
UCD

Dr Paul O'Connor
Member
University of Galway

Prof. Cathal O'Donnell
Member
National Ambulance Service

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

Mr Damien Owens
Member
Engineers Ireland

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

Ms Riona Tumelty
Member
Beacon Hospital

Prof. Mahandra Varma
Member
Retired cardiologist

Mr Peter Woulfe
Member
Galway Clinic

Committees supporting COVID-19 research

Overview of the National Irish COVID-19 Biobank Research Ethics Committee and the standing subcommittee of the NREC for COVID-19

Committees supporting COVID-19 research

The emergence of the COVID-19 pandemic triggered the establishment of the first Irish NREC in 2020. The then Minister for Health asked the nascent National Office to form an NREC that could deliver an expedited national ethics opinion for COVID-19-related health research in Ireland.

This resulted in the NREC COVID-19 playing an essential role in providing ethical oversight for internationally relevant research at a critical time for public health. Following the end of this NREC's tenure in August 2020, a standing subcommittee continues to review modifications to studies it has approved. In 2022, on foot of instruction from the Department of Health, the National Office built on its strong foundation of supporting Ireland's research response to COVID-19 by establishing a dedicated REC to provide ethical oversight of the establishment and operations of the NICB.

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

The NICB-REC was appointed in December 2022 at the request of the Minister for Health, as an essential component of Ireland's response to the ongoing challenge of COVID-19. Its remit is to provide a national ethical opinion for the NICB as a multisite, national biobanking infrastructure, in order to ensure that it is established, governed, maintained, and accessed in accordance with best national and international ethical practice and in compliance with data protection legislative frameworks.

The NICB-REC will carry out its ethical assessments on the application submitted by the NICB directors, plus subsequent applications for ethics approval for any modifications to the NICB governance structures and operating procedures. The Committee will review compliance of the NICB with relevant international declarations and conventions on ethical principles. It will also assess, from an ethical perspective, all data protection and governance safeguards, with the aim of ensuring that the fundamental rights and freedoms of individuals participating in the NICB can be exercised and are protected.

The NICB-REC is chaired by Dr Georgina Flood, Consultant Anaesthetist at the Mater Misericordiae University Hospital, and its membership encompasses a broad range of expertise in topics ranging from biobanking and bioethics to data protection, and from respiratory medicine and genetic research to lived experience as patients.

The creation of the NICB and the establishment of a dedicated REC to underpin it, is a huge development for Ireland. While the NICB offers unprecedented scientific potential, it is absolutely imperative that the ethical issues surrounding it are carefully considered and managed – not least as the legal and ethical frameworks around biobanking are still evolving. Internationally, the legal and ethical frameworks to support the research and scientific advances offered by biobanking are still developing. The establishment of this new committee will lead the way, utilising the highest level of national expertise to protect patient safety and safeguard the rights and autonomy of participants. In this manner, the committee will support this significant national infrastructure development, securing the future of the NICB as a valuable and important national resource.

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

The following members were appointed to the NICB-REC in 2022:

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

Dr Anne Moore
Deputy Chair
UCC

Prof. Kathleen Bennet
Member
RCSI

Dr Brian Clarke
Member
Ferring Pharmaceuticals

Mr John Culliney
Member
Retired businessperson

Dr Aisling de Paor
Member
DCU

Prof. Sean Hynes
Member
University of Galway

Mrs Joan Jordan
Member
European Patients' Academy on Therapeutic Innovation (EUPATI) patient advocate

Dr Sonja Khan
Member
University of Galway

Dr Patrick Manning
Member
Ballinderry Clinic/RCSI

Dr Kevin May
Member
General practitioner

Prof. Shaun O'Keefe
Member
University Hospital Galway/University of Galway

Prof. Cathal Seoighe
Member
University of Galway

Prof. Anthony Staines
Member
DCU

Dr Ciara Staunton
Member
European Academy Bozen/Bolzano (EURAC)

NREC COVID-19 standing subcommittee

Since the end of the NREC COVID-19 tenure in August 2020, a standing subcommittee has continued to meet for oversight and related responsibilities regarding modifications to studies approved by the NREC COVID-19, with the support of the National Office team. This standing subcommittee comprises the Chair, Professor Mary Horgan, and the two Deputy Chairs, Professor Hannah McGee and Professor Anthony Staines.

A key role of this standing subcommittee is to review substantial modifications of ongoing studies: it reviewed and approved eight substantial modifications in 2022.

NREC COVID-19: at a glance

The following key figures represent the work of the NREC COVID-19 and the standing subcommittee between 2020–2022:

	New studies	Substantial modifications
Applications received	**87**	**51**
Favourable opinion	**78**	**48**
Unfavourable opinion	**4**	**2**
Withdrawn by applicant	**5**	**1**

Of the 78 studies ethically approved by the NREC COVID-19, 59 have been completed and 17 are ongoing (2 did not commence). The approved studies have contributed significant new information in COVID-19 patient care and health policy, with national and international impact on public health, diagnosis, treatment, and prognosis.

NRECs in action: ensuring ethical research

The following case studies showcase a small sample of the outputs from research programmes that received ethical approval from the NREC COVID-19 during its tenure.

An app to support rapid triage and assessment of COVID-19 patients

As part of a multidisciplinary group including collaborators in UCD and industry partner S3 Connected Health, Professor Richard Costello, RCSI, developed a web-based clinical support tool, Enodatis for COVID-19, to enable healthcare professionals in hospitals to quickly triage and assess COVID-19 patients using an app on their smartphones. The Enodatis for COVID-19 app is available for use in Irish hospitals by approved clinicians. It was CE marked and registered as a Class 1 medical device in the EU in May 2020, just 7 weeks after the research project commenced. By April 2021, over 4,000 patients were registered on the system. The Enodatis for COVID-19 app has received three awards to date: the 2020 PM360 innovative product award, the 2020 Irish MedTech innovation of the year award, and the 2021 RCSI clinician innovation award.

Data to inform national testing guidelines

In 2021, Dr Mary Keogan, a member of the HSE COVID-19 Antigen Testing Working Group, produced the *Antigen Test Validation Summary Report*, which informed the National Pandemic Health Emergency Team (NPHET) COVID-19 testing guidelines. In addition to confirming that reverse transcriptase polymerise chain reaction (RT-PCR) was more sensitive for detecting SARS-CoV-2, the report highlighted differences in sensitivity between different antigen tests, and the limited sensitivity of antigen testing in asymptomatic individuals. While antigen diagnostic tests (ADTs) are not as sensitive, they are useful in situations where the availability of RT-PCR tests is inadequate. In this instance, the lower sensitivity of the ADT could be compensated for by more frequent testing. The Working Group report advised on these and other COVID-19 testing items, and was published in June 2021.

National Office strategic priorities

Achievements to date and priorities for 2023

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 whose goal is 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.

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

We have identified five strategic priorities for guiding the NREC system, which we were able to further advance in 2022 and into 2023.

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 importance** by sharing and driving best ethical practices

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

The following summary sets out key actions taken in 2022 under each strategic priority, and provides a snapshot of how the National Office plans to continue to address each focus area in 2023.

1. To establish the National Office as an agile and trusted office in national public service, we:

- Developed the skills and knowledge of the dynamic and dedicated National Office team in order to meet the demands of its core objectives, and to provide an agile and trustworthy source of guidance for the research community
- Recruited additional, key team members to resource the National Office in the strategic and operational elements of its remit
- Launched a second public expression of interest campaign for membership, with a robust assessment process, in order to complement and strengthen the NREC-CTs and NREC-MD
- Made a recommendation to the Minister for Health to appoint an additional 15 NREC members across the NREC-CTs and NREC-MD. These appointments further ensured expertise within the NREC-MD to meet the mandate of delivering a national opinion for performance studies for *in vitro* diagnostic medical devices
- Commenced a significant IT project that brought in specialist expertise to assist with characterising the business requirements for a bespoke application management system
- Developed processes and procedures to improve operational effectiveness and preparedness for the implementation of the CTR and the CTIS portal, and
- Improved the National Office for Research Ethics Committees website for content and accessibility, in order to ensure that it remains an important tool for trusted information and transparency in NREC work.

2. To partner with health research stakeholders such as the HPRA and the Department of Health, with the mutual objective of implementing best practice across Ireland's ethics review system and adopting change under EU legislative frameworks, we:

- Collaborated and consulted with the HPRA in order to ensure that a streamlined and harmonised approach was taken to delivering a national opinion under the CTR, while efficiently meeting legislative timelines

- Participated in regular meetings with the HPRA regarding regulatory changes or cross-cutting areas of relevance for clinical investigation and performance studies for medical devices
- Participated in the European Clinical Trials Coordination and Advisory Group and European Expert Group on Clinical Trials, representing Ireland in the exchange of knowledge regarding CTR implementation of, and regulatory issues in, clinical trials of medicinal products for human use
- Engaged with key stakeholders in the Irish health research environment, including the Irish Health Research Forum; the HSE REC Reform Working Group; the Data Protection Commission; Cancer Trials Ireland; the Irish Pharmaceutical Healthcare Association (IPHA); the Irish Platform for Patient Organisations, Science & Industry (IPPOSI); and the HRB National Clinical Trials Office
- Represented Ireland's interests at the European level on the European Network of Research Ethics Committees (EUREC), and
- Commenced development of a memorandum of understanding with the Department of Health in order to underpin a collaborative framework setting out the role of the National Office to support strategic areas of research importance.

3. 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, we:

- Ensured that the committees' membership includes the expertise and perspectives necessary to enable robust research ethics review for the expanding remits of the NRECs
- Supported operations and decision-making across the NRECs in order to ensure rigour, consistency, and transparency in research ethics review and the delivery of national ethics opinions
- Operationalised an intensive, rapid-response, 8-week series of subcommittee meetings in order to address the backlog of substantial modifications that emerged as studies transitioned from the local recognised REC system to the NRECs, and
- Provided NREC members with education and training in order to ensure that they are as informed as possible about pertinent, complex subject areas across legislation, regulation, policy, and scientific advancements.

4. To support and advance research initiatives of national importance, such as the COVID-19 national response, by sharing and driving best ethical practices, we:

- Supported the NREC COVID-19 standing subcommittee as an enduring component of the national, coordinated research response to the pandemic, helping Irish health research to rapidly address the questions posed by COVID-19, and
- Established a bespoke, ministerially appointed national committee to provide ethical oversight of the NICB.

5. To establish the National Office as a thought leader in the area of research ethics by providing trusted information, seeding discussion, advancing debate, and facilitating education and training, we:

- Hosted the National Office webinar 'Learnings, insights and next steps', with presentations from the National Office team, a keynote address from Emeritus Professor of Philosophy David Archard of the Nuffield Council on Bioethics, and a panel discussion with the NREC Chairs
- Co-hosted a HRB postdoctoral intern in providing first-hand experience of working in a health research regulation agency, alongside the experienced National Office team
- Partnered with Maynooth University through the Project Live initiative to collaborate with a Master of Science class in order to develop education and outreach materials on the topic of informed consent
- Developed applicant guidance on improving research ethics applications, informed by NREC discussions and review outcomes
- Operated an efficient 'help desk' function and met occasionally with prospective applicants in order to assist researchers, where appropriate, with their applications, informed by the practical guidance and experience of the National Office team
- Represented the National Office and the NRECs at conferences such as the HRB National Conference and the Irish Research Nurses & Midwives Annual Conference, and other events, in order to foster understanding of the role of the NREC system, and
- Consulted with the local REC community on various operational and procedural matters in order to ensure harmonisation and consistency of practices where possible.

Next steps for 2023

As we look forward to the rest of 2023, the National Office will strive to deliver strategic and operational actions to enable the success of the Irish national research ethics review system.

This is essential to embedding the national research ethics system within Ireland's wider health and social care research infrastructure. In 2023, we will:

- Stay abreast of regulations and guidelines relevant to research ethics and developments in the health research environment, so as to establish ourselves as a trusted resource for information for the research community.
- Host a national research ethics symposium in collaboration with our host organisation, the HRB.
- Constitute the committees' membership with the expertise and perspectives necessary to enable robust research ethics review and to deliver national opinions with rigour, consistency, and transparency.
- Provide NREC members with education and training, in order to ensure that they are as informed as possible about pertinent, complex subject areas across legislation, regulation, policy, and scientific advancements.
- Characterise the business and technical requirements for a bespoke IT system to support the efficient receipt and management of applications for NREC review.
- Represent Ireland's interest in key European working groups in order to ensure that timely and accurate knowledge informs the national implementation of EU health research regulations and application of best practice.
- Connect with patient advocacy organisations, including the IPPOSI and Health Research Charities Ireland, in order to ensure that the NREC system is centred on the research participant and the patient, and ensuring appropriate PPI representation on the NRECs.
- Support strategic initiatives of national and international importance that are driven by the Department of Health, and share intelligence to inform best practice and shape policy development.
- As important components of Ireland's response to the COVID-19 pandemic, continue to support the NREC COVID-19 standing subcommittee and further operationalise and support the work of the NICB-REC.
- Strengthen our transparent communications with the research community and wider public, as the NREC system responds to the needs of the research environment.
- Develop and provide tailored resources for researchers, research participants, students, and the wider public, in order to improve understanding of research ethics throughout society.

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