An Roinn Sláinte
Department of Health

# National Office for Research Ethics Committees webinar: learnings, insights and next steps

National Research Ethics Committee's Stakeholder Event

Thursday 27th October 2022

Via Video Conference

An Roinn Sláinte
Department of Health

# Welcome & Recognition of Achievements to Date

- Office established in 2020.
- Ongoing commitment to building infrastructure supporting robust, safe and ethical health research in Ireland.

An Roinn Sláinte
Department of Health

# Role of NRECs in the National Health Research Infrastructure to date

- Need for centralisation and coordination of research ethics opinion.
- Introduction of new EU Regulations – Clinical Trials Regulations, Medical Device Regulations and In-Vitro Diagnostic Device Regulations
  - Meeting national obligations
  - Ensuring Ireland has required infrastructure to support and enable health research.
  - Attracting and encouraging the conduct of health research.
- Single national committee.
- Efficiency, reproducibility, clarity for stakeholders, governance.

An Roinn Sláinte
Department of Health

# Legislative basis for NRECs work: an overview

- **New EU primary legislation – Clinical Trials Regulations, the Medical Devices Regulations and the In-Vitro Diagnostic Medical Devices Regulation**
- CTR replaced CT Directive (2001/20/EC), MDR replaced MDD (93/42/EEC) and AIMD (90/385/EEC), IVDR replaced Directives 98/79/EC and 2010/227/EU
- **Irish primary legislation gives Minister of Health powers to enact EU legislation**
    - European Communities Act 1972 (No. 27 of 1972)
- **Committees established via secondary legislation**
    - European Union (Clinical Trials on Medicinal Products For Human Use) (Principal) Regulations, 2022
    - European Union (Clinical Trials on Medicinal Products For Human Use) (National Research Ethics Committees) Regulations, 2022
    - European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004. SI No. 190/2004 (to be revoked when studies can no longer be completed under the Directive).
    - European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021.
    - European Union (National Research Ethics Committee for Performance Studies of In Vitro Diagnostic Medical Devices Regulations 2022.

An Roinn Sláinte
Department of Health

# NRECs position as a decision-making entity

- Change from existing system
    - Clinical Trials – recognised REC system
    - Clinical Investigations – local REC system
- Legislation – NREC committee/s empowered to provide ethics opinions under the CT Directive (final applications January 2023), CTR, MDR and IVDR.
- Functions described in above legislation, informed by EU and existing national legislation.

An Roinn Sláinte
Department of Health

# Importance of the individual member and their contributions to the Irish public service

- Role of REC – to provide an independent opinion on the ethics of proposed heath research, representative of society.
    - Members are independent of the researchers involved in the study
    - Have a variety of backgrounds, including medical and scientific, and be representative of patients and wider society.
- Following public EoI and rigorous selection process, committee members were selected based on expertise, backgrounds, and representative capacity.
- Aim to provide robust and representative ethics opinions to support ethically sound heath research in Ireland.

An Roinn Sláinte
Department of Health

# Legislative basis for NRECs work:
## Emerging Legislative Changes

- Ionising Radiation – to be completed by January 2023

- NREC Bill

An Roinn Sláinte
Department of Health

# Other Priority Work Streams within the National Office for Research Ethics

- National Covid Biobank

An Roinn Sláinte
Department of Health

# Other Ongoing National Work on Health Research

- National Genetics and Genomics Strategy
  - Currently being develop
  - DOH is working with the HSE on Steering Group tasked with the delivery of this strategy
- Electronic Health Records
- HSE
  - Roadmap for reform 2022 – RECs moving to align with Regional Health Areas (RHAs)
  - Standard Code of Governance for HSE RECs (published 2022)
- Assessment of gaps in areas of health research
- Health Information Bill
- Human Tissue Bill – at advanced stage

An Roinn Sláinte
Department of Health

# What is the future for NREC?

- To date:
  - Regulated areas of health research
  - Responding to Covid-19 pandemic – covid REC and national covid biobank
- Assessment of learnings and refining system
- Greater role in strategic direction for health research infrastructure
- Supporting DOH in completing ongoing legislative work
- Consideration to expanding to other priority areas of health research

An Roinn Sláinte
Department of Health

# Thank you for your time and attention