



The National Office for Research Ethics Committees

Dr Emily Vereker, Head of Office



Strategic objective

Lead the transformation of the national research ethics system in Ireland to deliver a robust, efficient and transparent review framework that engenders the trust of key stakeholders, including the public

VISION

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

MISSION

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

STRATEGIC PRIORITIES

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

01

02

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

To engage with the research ethics committees community, researchers and the wider public to facilitate education on ethical decision-making.

03

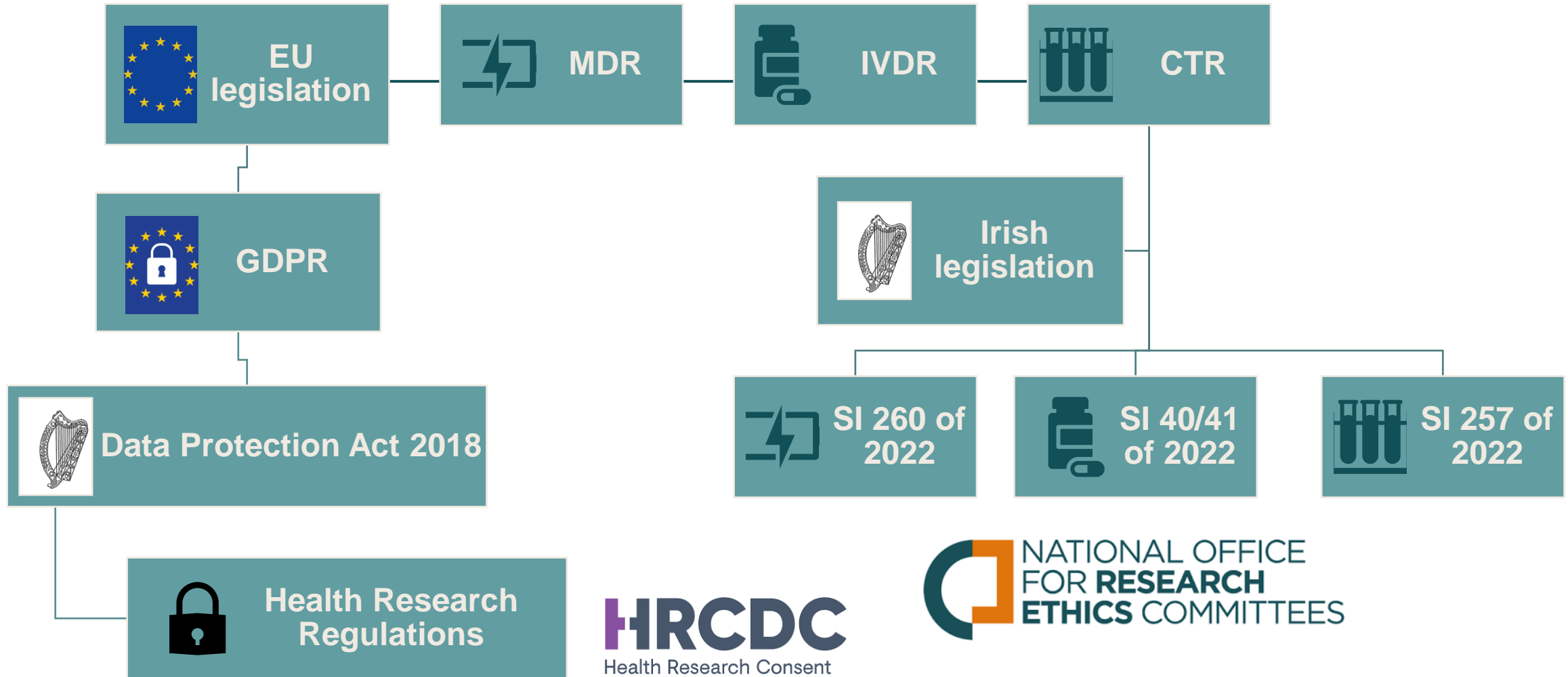
04

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

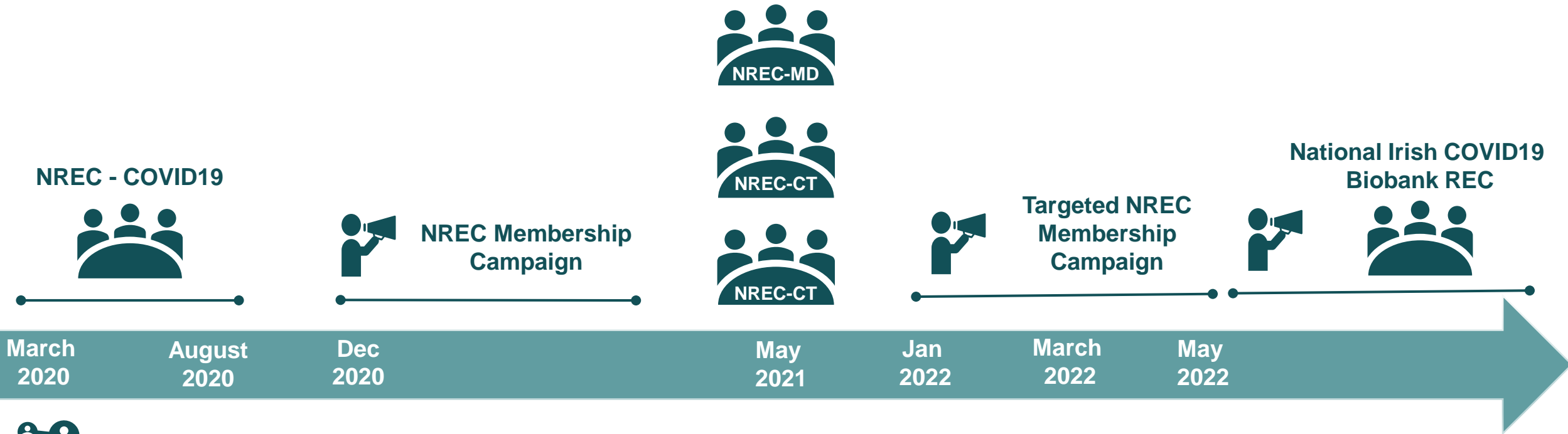
To be an agile and trusted office in national public service.

05

Irish health research regulatory landscape



National Office journey



March 2020 August 2020 Dec 2020 May 2021 Jan 2022 March 2022 May 2022



National Office Est.



EU MDR
May 2021

EU CTR
Jan 2022

EU IVDR
May 2022



S.I.260
May 2021

S.I.40/41
May 2022

S.I.257
May 2022

Core functions of the National Office



Committees at a glance

3 committees
68 members

Representing diverse backgrounds, including:



ethics



Lay,
public,
patient



Law



medical



sciences /
health care
professionals



public
health



industry



statistics



social
sciences


From all
over Ireland



Cornerstone resources for trusted research ethics review guidance



WORLD MEDICAL ASSOCIATION
WHAT WE DO POLICY PUBLICATIONS NEWS & PRESS WHO
Policy / Current Policies / WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
WMA DECLARATION OF HELSINKI



eurec
Position of the
European Network of Research Ethics Committees (EUREC)
on the
Responsibility of Research Ethics Committees
during the COVID-19 Pandemic



Standards and Operational
Guidance for Ethics Review
of Health-Related Research
with Human Participants
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
1 December 2016
EMA/CHMP/ICH/135/1995
Committee for Human Medicinal Products
Guideline for good clinical practice E6(R2)
Step 5



NUFFIELD COUNCIL ON BIOETHICS
Research in global health emergencies: ethical issues



Ethical principles instilled by the NRECs



Value → enhancements of health or knowledge



Scientific validity → rigorous methodology



Justice → fair participant selection, inclusivity



Beneficence → maximising potential benefits, minimising risks



Informed consent → communication, privacy & protection



Respect, dignity, well-being → participant-centered approach, assisted decision-making



Independent review → no conflicts or affiliation

The Committee's work

2021 snapshot

27
meetings

68
applications

44
decisions*

43
favourable decisions

1
unfavourable decision

36 days
average time to decision

150+
studies overseen**

13 therapeutic areas covered

- eye
- cancer and neoplasms
- blood
- respiratory
- infection
- inflammatory and immune system
- oral and gastrointestinal
- skin
- neurological
- congenital disorders
- metabolic and endocrine
- cardiovascular
- renal and urogenital

705
decisions

Total to date

80
meetings

Forward looking 2023



- Enable the NREC members to deliver national opinions under new legislative frameworks → operational effectiveness, NREC forum



- Strengthen our engagement & collaborate with local RECs for alignment & harmonisation → REC community of practice
- Build further on collaborations with our stakeholders → HPRA, DOH, HSE, HRB



- Instil international best practice - engagement with international experts, bioethics councils, EU counterparts, EMA working groups



- Support research initiatives of national importance, supporting excellence in innovative health and social service → COVID19

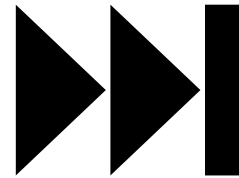


- Advocate for patient, public and carer entered approach

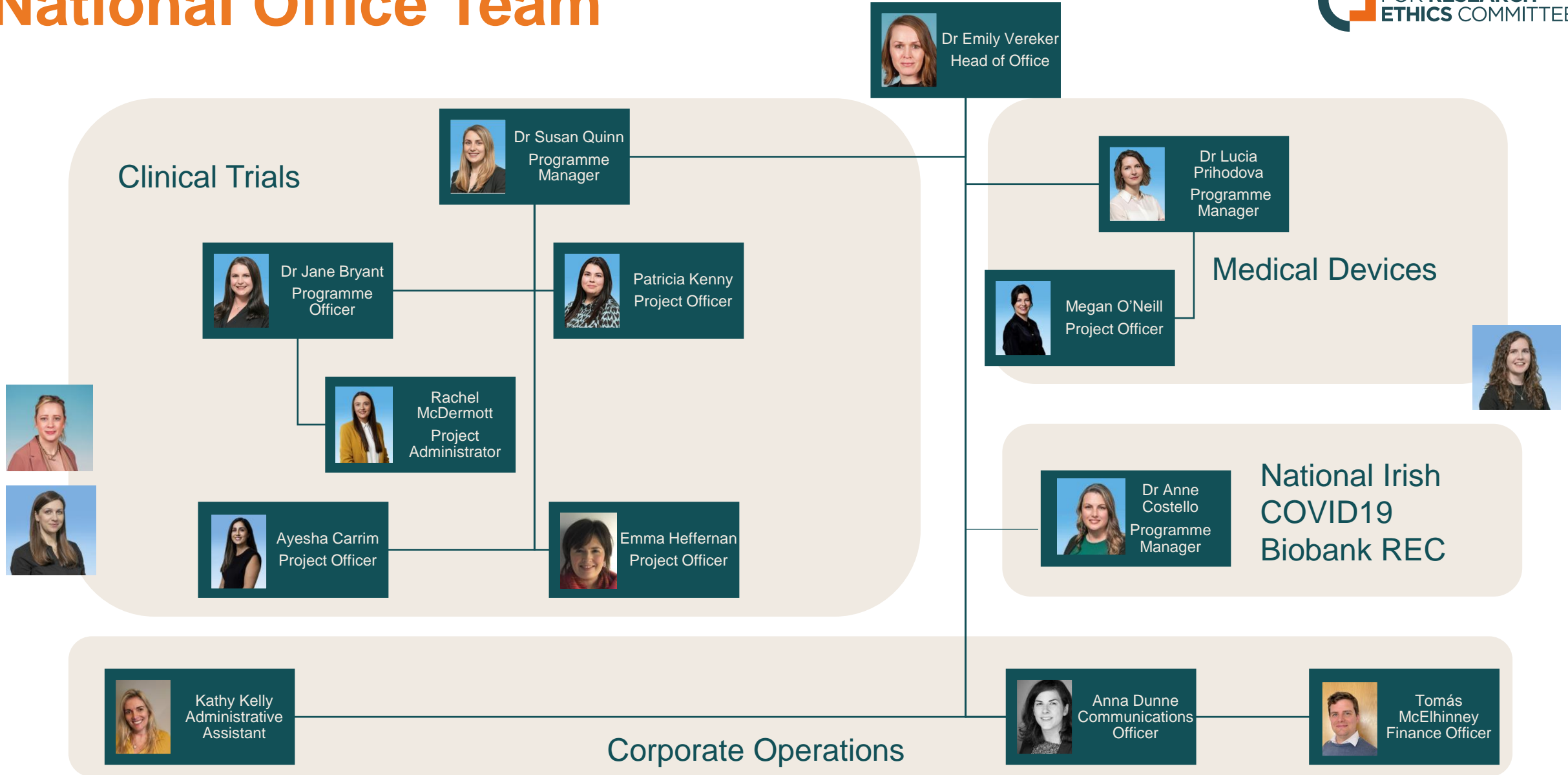


- Operate with agility & pragmatism

A national research ethics system



National Office Team





THANK YOU

Visit us and subscribe for updates at www.nrecoffice.ie

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Enabling a trusted national ethics opinion

