



Changes in the Clinical Research Environment: National Research Ethics Committees (NRECs)

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National Office for Research Ethics Committees

A significant change in the clinical research environment

- Established in March 2020
- Independent office with statutory role
- Key player in the regulation of health research
- Office provides operational support to National Research Ethics Committees (NRECs)
- NRECs will provide a 'single national ethics opinion' on applications
- NRECs assembled in prescribed areas of health research over time by Head of National Office and appointed by Minister for Health



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.

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



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.



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.



STRATEGIC PRIORITIES



NREC COVID-19

SUMMARY INFO

GENERAL Applications & Decisions*

April to August 2020



93
TOTAL APPLICATIONS CONSIDERED



83
PROVISIONAL APPROVALS



71
FINAL APPROVALS



04
DECLINES

*Data to be updated as decisions are finalised

RESEARCH CATEGORISATION

according to the Health Research Classification System standard



HEALTH CATEGORIES

	#
Cancer	05
Cardiovascular	05
Generic Health Relevance	19
Infection	49
Neurological	02
Respiratory	13
Inflammatory & Immune System	05
Mental Health	14
Metabolic	01
Skin	02



RESEARCH ACTIVITY

	#
Aetiology	44
Detection & Diagnosis	09
Disease management	05
Health Services	17
Prevention	05
Treatment Evaluation	12
Underpinning	04

*Some studies are counted across multiple categories and activities

GENDER BREAKDOWN of lead researcher on each application



44
MALE



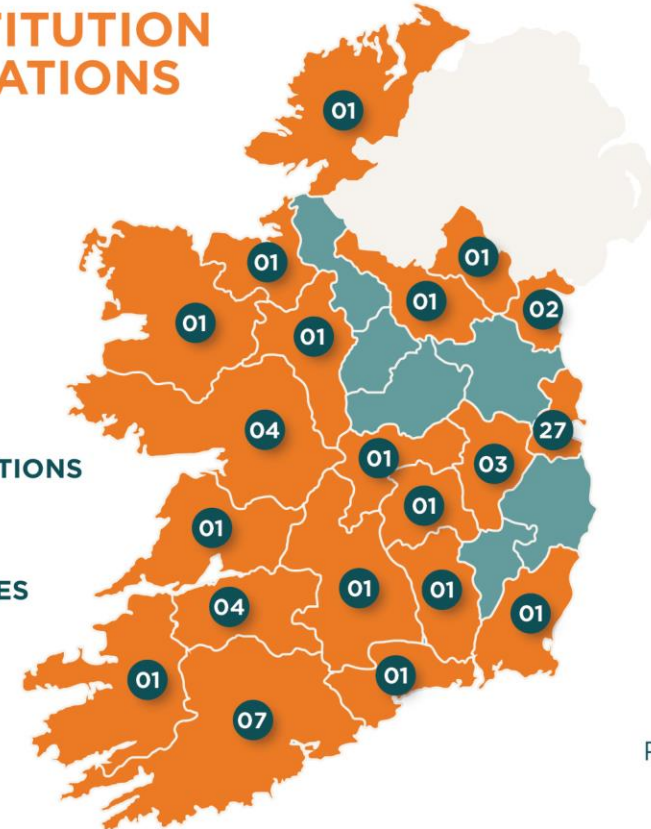
49
FEMALE

*Gender data was not collected; this is an assumption based on researcher name

INSTITUTION LOCATIONS

61
INSTITUTIONS

20
COUNTIES



- Dublin 27
- Cork 07
- Limerick 04
- Galway 04
- Kildare 03
- Louth 02
- Offaly 01
- Kilkenny 01
- Kerry 01
- Waterford 01
- Wexford 01
- Donegal 01
- Sligo 01
- Tipperary 01
- Cavan 01
- Mayo 01
- Monaghan 01
- Clare 01
- Laois 01
- Roscommon 01



European regulatory developments driving changes to clinical research in Ireland

EU Medical Device Regulation (No. 2017/745)



Coordinated national opinion
within 55 days



Implemented
May 2021



Harmonise rules for conducting research in these important areas throughout the EU

- Improve consistency
- Increase collaboration
- Increase transparency
- Increase safety standard stringency
- Electronic submission & assessment

EU Clinical Trial Regulation (No. 536/2014)



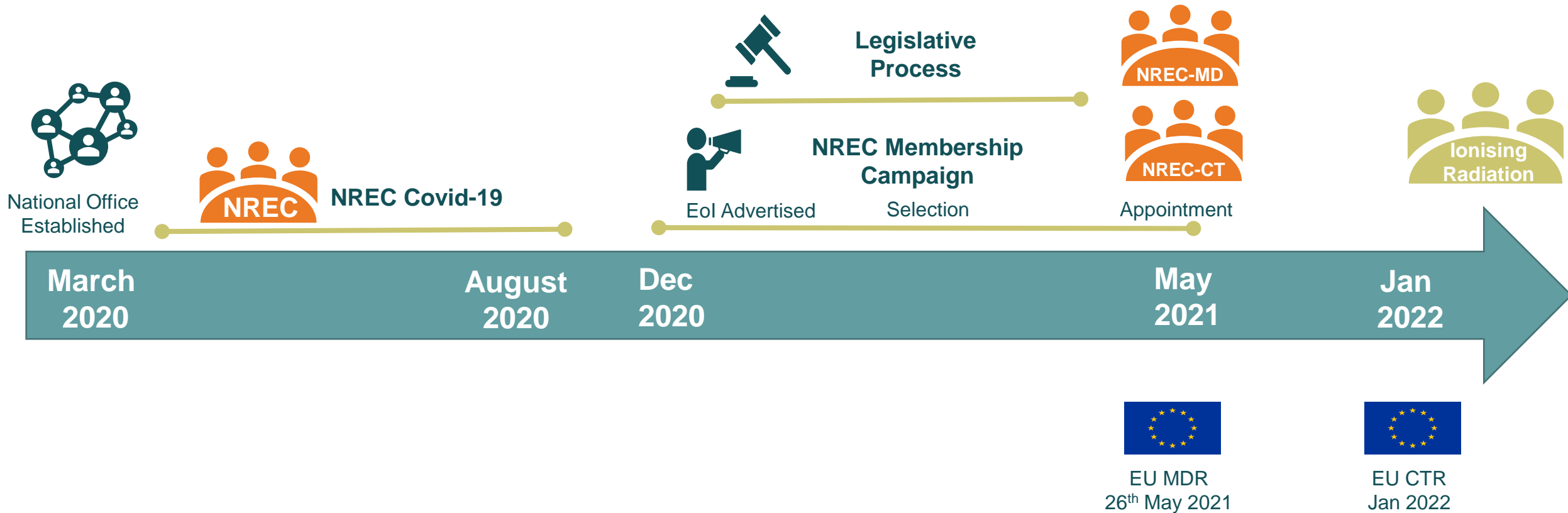
Single national opinion
within 60 days



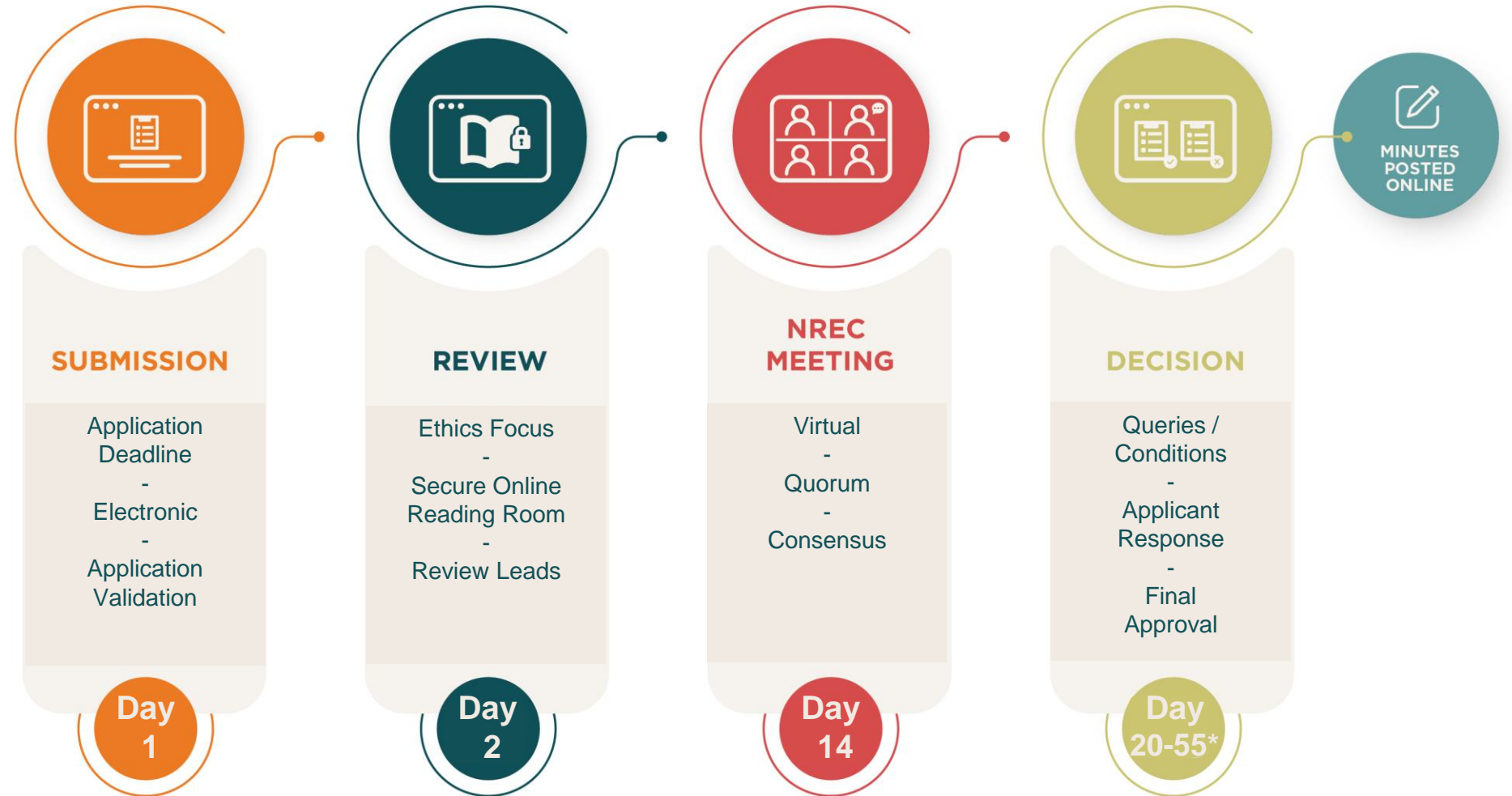
Scheduled
Jan 2022



Demonstrating best practice in establishing of NRECs



National Research Ethics Committee – Review Process



- Similar review format across NRECs
- Timeframe for responses stipulated by European Regulations

Indicative timing by way of example, *20-60 for NREC-CT



Mixed-model system - Supporting research ethics across the spectrum of health research



National Research Ethics Committees

- All Clinical Trials of Investigational Medicinal Products - **NREC-CT**
- All Clinical Investigations of Medical Devices - **NREC-MD**
- Independent
- Single national ethics opinion
- Monitored
- Appeals mechanism



Local Research Ethics Committees

- Including 32 public health service RECs
- All remits beyond that prescribed for NRECs
- Local jurisdiction, locally applicable opinions
- Reform pending - HSE Reference RECs with potential for multisite decisions



Nationally Endorsed REC

- Ionising radiation
- Working relationship between St Luke's REC & National Office
- Single national ethics opinion
- Model best practice



Adding a key piece to Ireland's landscape for health research



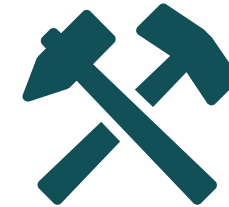
Engaged & proactive PPI



International visibility & strong networks



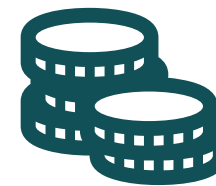
Skilled & educated workforce in healthcare & research



Supporting infrastructures for health research



Strong industry footprint



Healthy R&D investment





THANK YOU

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Enabling a trusted national ethics opinion

