NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

The National Office for Research Ethics Committees

Dr Emily Vereker, Head of Office

Strategic objective

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

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

Irish health research regulatory landscape

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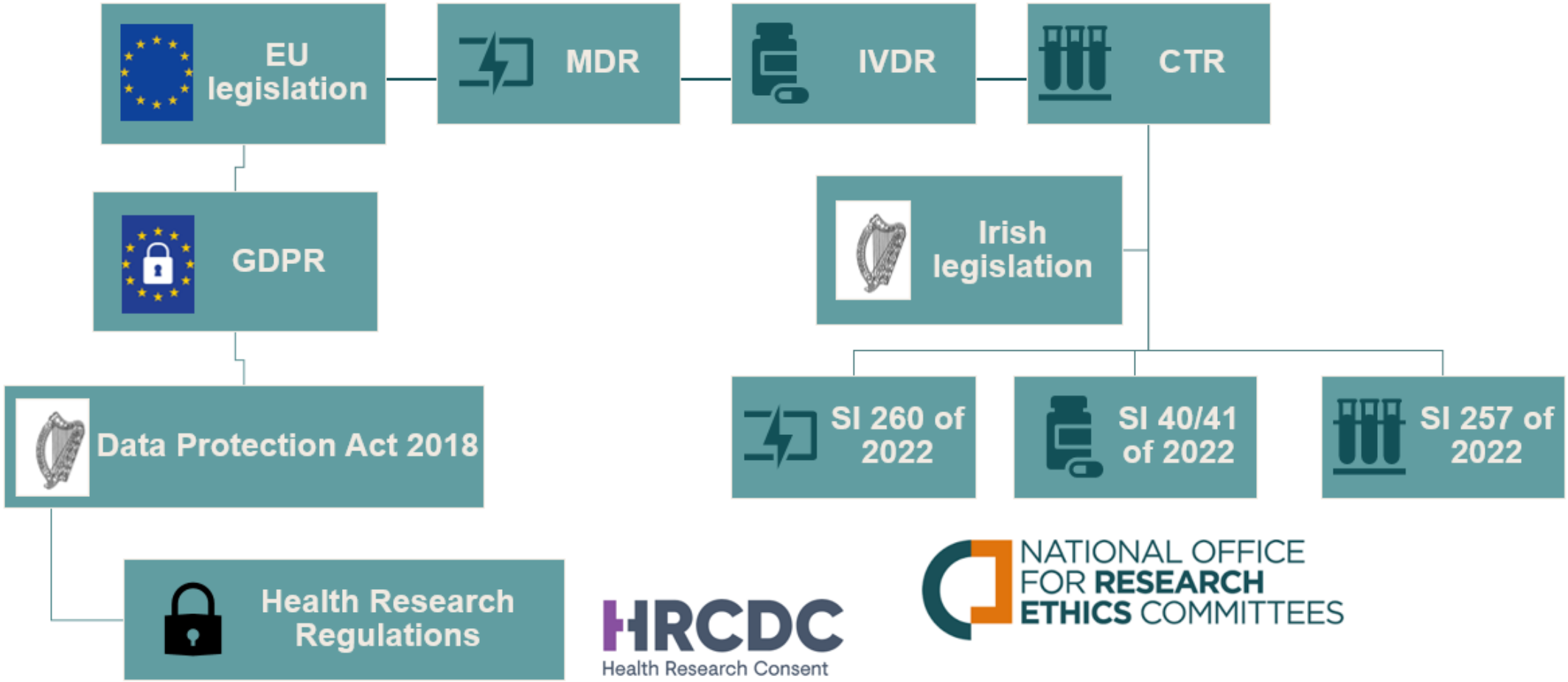

National Office journey

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

NREC - COVID19

NREC Membership Campaign

NREC-MD

NREC-CT

NREC-CT

Targeted NREC Membership Campaign

National Irish COVID19 Biobank REC

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

Committees at a glance

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3 committees

68 members

COVID19
Sub-committee (x3)

National Irish COVID19
Biobank REC (x ~15)

Representing diverse backgrounds, including:

- ethics
- Law
- sciences / health care professionals
- industry
- social sciences
- Lay, public, patient
- medical
- public health
- statistics

From all over Ireland

Core functions of the National Office

support NREC members

education & outreach

Guiding ethical practices

skills & capacity

establishing /oversight of NRECs

Stakeholder engagement

Cornerstone resources for trusted research ethics review guidance

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Ethical principles instilled by the NRECs

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- **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 dignity** → participant-centered approach, assisted decision-making
- **Independent review** → no conflicts or affiliation

Opinions delivered to date

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Year	New applications		Substantial amendments		Total	
	NREC-MD	NREC-CT	NREC-MD	NREC-CT	NREC-MD	NREC-CT
2021	10	49	7	216	17	265
2022	28	50	13	332	41	382
Total	38	99	20	548	58	647

80 meetings

705

opinions

Time to decision: approx. 39 days

Substantial Amendments - bootcamp

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		Decisions made		
	# Amendments considered	Request for further information	Favourable	Favourable with conditions
Week 1	20	1	13	6
Week 2	20	4	14	2
Week 3	20	5	9	6
Week 4	20	9	2	9
Week 5	20	8	9	3
Week 6	15	3	4	8
Week 7	12	0	7	5
Week 8	7	3	4	
Total	**134**	**33**	**62**	**39**

- Submissions greatly exceeded volume forecast –
- Backlog in early 2022
- 8 week Bootcamp
  - 14 members from CT-A/B came forward to help tackle the task
- Current process
  - 2 Subcommittees /month
  - Monitoring
  - Current average time from validation to decision: 25 days

CTD →CTR Transition 2023

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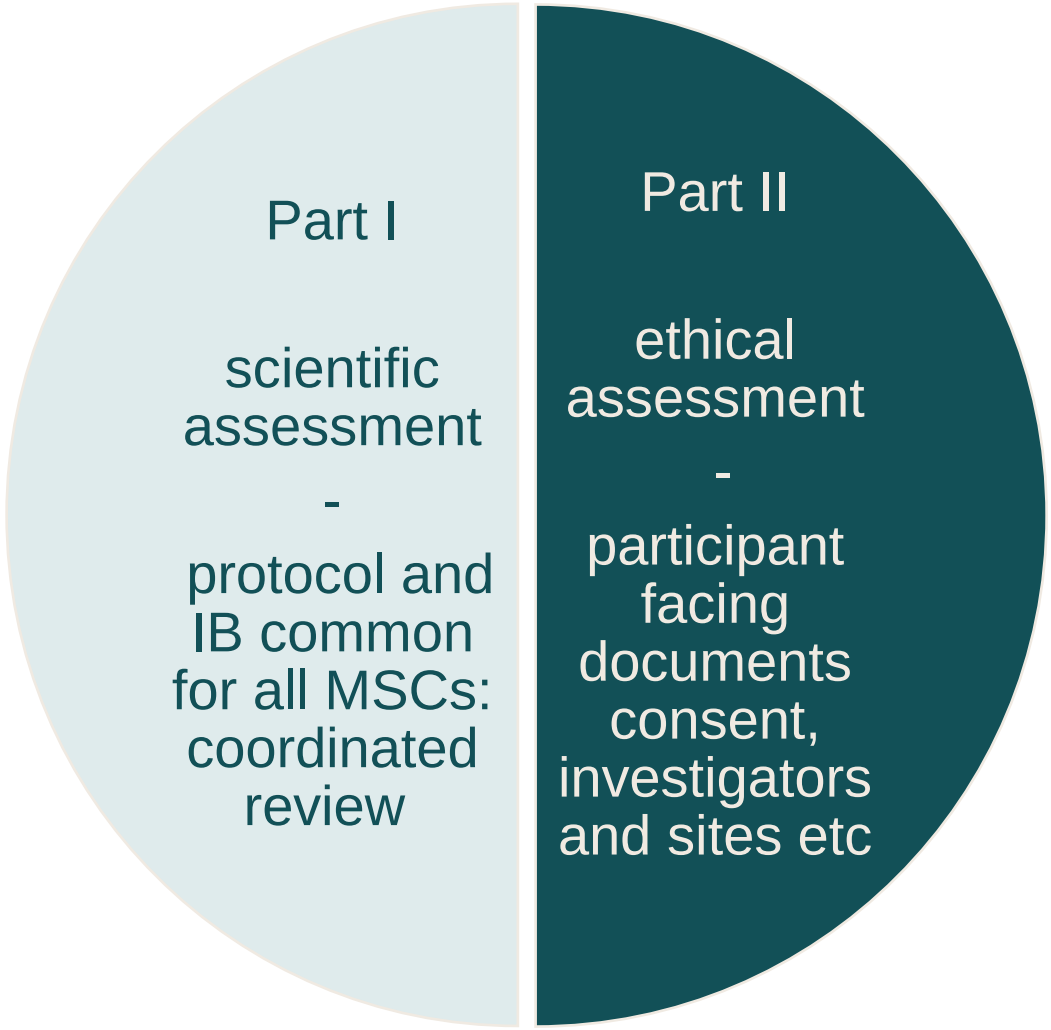
NREC	SUBMISSION CUT OFF DATES 2022/2023	MEETING DATE
NREC CT B	10 November 2022	23 November 2022
NREC CT A	24 November 2022	7 December 2022
NREC CT B	*Break*	*Break*
NREC-CT B	15 December 2022	11 January 2023
NREC-CT A	11 January 2023	25 January 2023
NREC-CT B	**25 January 2023 (last date for submission of valid new applications under the CTD*)**	8 February 2023
NREC-CT A	**8 February 2023 (all submissions must be through the CTIS system under the CTR)**	22 February 2023
NREC-CT B	1 March 2023	15 March 2023
NREC-CT A	15 March 2023	29 March 2023

Changes for the NREC-CTs



- Part I and Part II do not need to be submitted together:
  - NREC-CT may be reviewing Part I and Part II separately – potentially 2 years apart
  - No requirement for an applicant to submit a Part II
- NREC-CT will only have one opportunity to request changes or further information under an ‘RFI’ for both Part I and Part II
- Applicant can appeal an NREC-CT decision

6 new applications

1 substantial amendment

5 transition trials

Changes for the NREC-MD

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Clinical investigations of medical devices (MDR)

- Systematic investigation
- involving one or more human participants,
- undertaken to assess the safety or performance of a medical device.

- Remit defined by MDR & IVDR
- Oversight of studies under MDD

- Mandate for single national opinion
- Independent review by HPRA

Performance studies of in vitro diagnostic medical devices (IVDR):

- Study undertaken to establish or confirm the analytical or clinical performance of an in vitro device

Forward looking 2023

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

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

- 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

National Office Team

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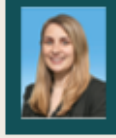
Clinical Trials



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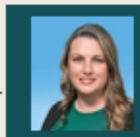
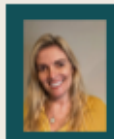


Dr Anne Costello
Programme Manager

National Irish COVID19 Biobank REC



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THANK YOU

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Enabling a trusted national ethics opinion