



Meeting Minutes: Role of the NRECs in Ireland's health research agenda – an introduction to the Department of Health

Date and time: 11/11/2021, 12.30pm (convened via Zoom)

Attendees:

Department of Health: Mr Muiris O'Connor (MOC), Ms Anne-Marie Seymour, Mr Colm O'Loughlin, Mr Peter Lennon, Dr Karen McNamara, Mr Cody York.

HRB CEO: Dr Mairead O'Driscoll

NREC Chairpersons: Prof. Alistair Nichol (NREC-CT A); Dr Cliona McGovern (NREC-CT B); Prof. Barry O'Sullivan (NREC-MD).

NREC Members: Dr Caitriona Cahir, Dr Catherine O'Neill, Dr Owen Doody, Mr Billy McCann, Mr Damien Owens, Ms Orla Lane, Ms Riona Tumelty, Prof. Declan Patton, Prof. Mahandra Varma, Prof. Mary Sharp, Prof. Susan O'Connell, Dr Darren Dahly, Dr Dervla Kelly, Dr Geraldine Foley, Dr Heike Felzmann, Dr John O'Loughlin, Prof. Gene Dempsey, Mr Gerard Daly, Ms Ann Twomey, Prof. Catherine Hayes, Prof. David Brayden, Prof. Mary Donnelly, Dr Enda Dooley, Dr Jean Saunders, Dr Lorna Fanning, Dr Mark Robinson, Mr Gavin Lawler, Mr Philip Berman, Ms Caoimhe Gleeson, Ms Serena Bennett, Prof. Abhay Pandit, Prof. Colm O'Donnell.

National Office: Dr Jennifer Ralph James (JRJ), Ms Aileen Sheehy, Ms Kathy Kelly, Dr Laura Mackey, Dr Lucia Prihodova, Dr Melissa Jones.

Agenda item number	Agenda item	Discussion / Actions
1	Welcome: Dr Jennifer Ralph James, Head of the National Office (5min)	<ul style="list-style-type: none"> • JRJ opened the meeting and acknowledged the impact, quality and volume of work undertaken by the three committees since launch, the operational support for the National Office received by the HRB, collaboration from the Department of Health (DoH), and the hard work of the wider National Office team.
2	<p>Key introductions (10mins):</p> <ul style="list-style-type: none"> • Department of Health (DoH): <ul style="list-style-type: none"> Muiris O'Connor (Assistant Secretary, Research & Development and Health Analytics Division) Anne-Marie Seymour (Principal Officer, Medicines, Controlled Drugs & Pharmacy Legislation Unit) Colm O'Loughlin (Assistant Principal Officer, Medicines, Controlled Drugs & Pharmacy Legislation Unit), Peter Lennon (Data Protection Specialist, Research Services and Policy) 	<ul style="list-style-type: none"> • All those listed on the left introduced themselves and outlined their respective role including that in relation to the NREC system, and acknowledged the importance and work of the three NRECs and support from the National Office to date.

	<p>Dr Karen McNamara (Assistant Principal, Medicines, Controlled Drugs & Pharmacy Legislation Unit)</p> <p>Cody York (Administrative Officer, Medicines, Controlled Drugs & Pharmacy Legislation Unit)</p> <ul style="list-style-type: none"> • HRB: Dr Mairead O'Driscoll (CEO) • NREC Chairs: Prof. Alistair Nichol (Chair NREC-CT A) Dr Cliona McGovern (Chair NREC-CT B) Prof. Barry O'Sullivan (Chair NREC-MD) • National Office: Ms Aileen Sheehy (Programme Manager) Dr Lucia Prihodova (Programme Manager) 	
3	<p>Role of the NRECs in Ireland's health research agenda: Muiris O'Connor & colleagues (20mins)</p>	<p>MOC presented on the <i>Role of the NRECs in Ireland's health research agenda – an introduction to the Department of Health</i>, and commented on:</p> <ul style="list-style-type: none"> • DoH views on NRECs' role in the national research infrastructure:

		<ul style="list-style-type: none"> - MOC thanked the committee members on behalf of the Minister - NRECs recognised as having integral part in improving health research in Ireland • Overview of legislative basis for NREC work <ul style="list-style-type: none"> - NREC Bill likely to be enacted before the end of 2022 - Envisages continuation of mixed-model of local and national research ethics review • Position of NRECs as a decision-making entity <ul style="list-style-type: none"> - The Department relies on the work of the NRECs to enable Ireland to meet its Member State obligations to EU regulations • Importance of individual contributions to Irish public service <ul style="list-style-type: none"> - The commitment of members is appreciated by the Minister
4	<p>Chair reflections - Six months leading Ireland's first NRECs in regulated areas: Prof. Alistair Nichol; Dr Cliona McGovern; Prof. Barry O'Sullivan (15mins)</p>	<ul style="list-style-type: none"> • The Chairs agreed that the NRECs represent an important development for health research with impact in Ireland and internationally, and that their individual experiences have been positive overall.

		<ul style="list-style-type: none"> • The Chairs acknowledged the hard work of the deputy Chairs, the dedication and conscientiousness of NREC members, and the support received from the National Office. • The Chairs commented on the NREC deliberation and decision-making processes, and complimented the committees for informed discussions and consensus-based decisions. • The Chairs highlighted the learnings over the first six months of the NRECs and the potential role they can now play as guidance to the research community. • The Chairs also spoke about the three committees ‘hitting the ground running’ in terms of their crucial work, which is reliant upon volunteerism. • The Chairs voiced concerns about the rising volume of the workload (“tsunami of applications”) and the relative unknowns for expectations of the committees in an increasingly EU regulated-research environment, particularly for CTR implementation.
5	Q&A: facilitated by the Chairs (10mins)	The Chairs highlighted the unique position of the NRECs and raised the following matters on behalf of the committees:

		<ul style="list-style-type: none"> • The absence of official Terms of Reference and confirmation of the details of indemnification for the NRECs • Regarding the recent circulation of appointment letters to members, the Chairs queried why these were not signed by the Minister for Health as these are Ministerial appointments • The status of upcoming national legislation for the CTR • Noting the reliance on a volunteer system of NRECs, the Chairs queried whether a professionalised approach was ever considered • The Chairs raised concern as to the rising and unknown future committee workload, particularly in light of the provision for tacit approval of applications under the CTR; this is an important implication of both committee and National Office capacity issues, and will impact the sustainability of the NRECs, the retention of members, and potentially the quality of service that is possible to be delivered. • The Chairs queried the potential in principle for mutual recognition of ethics approvals of research approved in Northern Ireland and the Republic of Ireland, in future. • The Chairs queried the mechanism for an appeals process
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		<p>DoH response:</p> <ul style="list-style-type: none"> • Departmental colleagues confirmed that the Minister is briefed on NREC activity and apologised for the potential confusion with the appointment letters. The DoH agreed to ensure that the link to the Minister is improved for the committees. • Regarding the national legislation to give effect to the CTR, the DoH team agreed to brief the NRECs accordingly in advance of its implementation. Furthermore, in the immediate term, the DoH agreed to meet, share and discuss key points of the draft Statutory Instruments with the Chairs • The DoH acknowledged the significant concern in relation to volume of work and NREC capacity, and will continue to work closely with the National Office to stay abreast of such issues • The DoH agreed to meet with the Chairs to discuss Terms of Reference and the details pertaining to indemnification, and to provide written confirmation of same • The DoH confirmed that a professionalised system of NRECs was not considered, and added that public sector constraints are necessarily factored in
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