IRISH HEALTH RESEARCH *forum*

HRCI Health Research Charities Ireland

A single voice ***to improve health research***

Irish Health Research Forum Recommendations and Event Report

Research ethics in Ireland: how do we strengthen and harmonise the system?

11th May 2023

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About the Irish Health Research Forum

The Irish Health Research Forum, which is run by Health Research Charities Ireland (HRCI), brings together all stakeholders nationally to positively influence health research. The Forum considers key health research issues at two events every year and produces widely used reports and recommendations. The events are constructive and inclusive, with benefit to patients and the public being at the heart of all activities.

As an independent organisation, representing over 40 charities and with a strong patient-focus, HRCI is ideally placed to bring people together to tackle the big issues in health research and to bring about change. We are supported in all Irish Health Research Forum activities by an exceptional and diverse Steering Group of leaders. For more information, see ***https://hrci.ie/irish-health-research-forum/***

About Health Research Charities Ireland (HRCI)

Health Research Charities Ireland (HRCI) is the national umbrella organisation of charities active in health, medical and social care research, together representing over 1 million people in Ireland. Through support and advocacy, we represent their joint interests, to achieve our vision of improved lives through a united community of health research charities.

In addition to running the Irish Health Research Forum, we offer our members the potential for matched research funding through the Joint Funding Scheme, run in partnership with the Health Research Board (HRB). We are also a national leader in patient and public involvement (PPI) and run a PPI Shared Learning Group for our members. ***www.hrci.ie***

Irish Health Research Forum recommendations on strengthening and harmonising the Irish research ethics system

Recommendations to help research ethics committees (RECs) be more effective

1. Research active institutions should integrate serving on RECs as a **core aspect of research roles**, rewarding its significance in career progression.
2. Institutions hosting RECs should ensure **sufficient funding and resources** for their operations, in order to enhance and sustain their effectiveness.
3. All RECs must prioritise the inclusion and support of **patient and public involvement** (PPI) which can significantly strengthen ethics decisions, especially in relation to research risk and benefit considerations.
4. The Department of Health should enable a **national coordinated approach, to developing training modules** for members of RECs, involving the National Office for Research Ethics Committees, the HSE, IPPOSI, the Irish Universities Association and other stakeholders.

Recommendations to improve the environment that research ethics committees (RECs) operate in

5. Research active institutions should strengthen their capacity to provide **dedicated data protection support for research**, ensuring that researchers are assisted in achieving data protection compliance, and that RECs are equipped to ethically assess data protection.
6. Key stakeholders, such as the Department of Health and the Data Protection Commission, should **refine the data governance responsibilities between RECs and research institutions**, to provide clarity and avoid duplication of effort.
7. The Department of Health should enable through legislation a coordinated approach to **providing single ethics opinions for multi-site research studies**, which are not currently covered by the National Research Ethics Committees.

For more detail on the recommendations, and the discussions which formed them, see the remainder of this report.

Key themes which emerged at the event

Some high-level challenges to and opportunities for strengthening and harmonising the Irish research ethics system emerged from the in-depth discussions at this event.

Challenges

- The distinction between **data protection and research ethics** and the relationship between them is not always clear.
- Data protection often ends up in the remit of Research Ethics Committees (RECs) even though it is a separate process. **Data protection officers** (DPOs) are often **overwhelmed** due to the requirements of GDPR and the Health Research Regulations.
- Existing RECs are experiencing high demands but are **under-resourced and volunteer based.**
- The research ethics system is **fragmented and lacking in cohesion**, with large areas of community services not having access to a REC.
- It is challenging to have to obtain approvals from many different RECs when conducting **multi-site studies.**

Opportunities

- The **National Office of Research Ethics Committees (NREC)** is leading the transformation of the research ethics system in Ireland, which will ultimately offer a co-ordinated single national ethics opinion.
- This is supported by an **EU regulatory environment** which supports and facilitates innovation, transparency and access to a harmonised system across member states.
- The **HSE National Framework for the Governance, Management and Support of Health Research (RGMS)** is driving reform of HSE RECs that are not covered by NREC.
- Within the RGMS, the **HSE Roadmap for the Reform of Health and Social Care RECs** sets out a new model for research ethics in the HSE which promises cohesion and equity of access.
- **PPI representation on RECs** has the potential to inspire patients' confidence in health research and brings together different perspectives on research ethics. It can drive researchers to question their decision making, reducing research waste and enhancing the accessibility of research to patients and the public.

Acknowledgements

Thank you to the chairs, speakers, panellists, facilitators and attendees at this event, who gave generously of their time and knowledge. We wish to acknowledge the support of the excellent Irish Health Research Forum Steering Group in shaping the agenda for the day and in developing the recommendations. We would also like to thank the HRCI staff and Board for their continued management and support of the Forum. Finally, we would like to thank Roche Products (Ireland) Limited who funded this Irish Health Research Forum event through an independent grant. Roche Products (Ireland) Limited have had no editorial influence over the content of the event or this report.

This report was compiled by Dr Sarah Delaney, HRCI Research Support Co-ordinator and Dr Avril Kennan, HRCI CEO.

Abbreviations used:

CPD: Continuing Professional Development

DPIA: Data Protection Impact Assessment

DPOs: Data Protection Officers

EU: European Union

FAIR: Findable, Accessible, Interoperable, and Reusable

GDPR: General Data Protection Regulation

HEIs: Higher Education Institutions

HRB: Health Research Board

HRCI: Health Research Charities Ireland

HSE: Health Service Executive

NICB: National Irish Covid-19 Biobank

NREC: National Office of Research Ethics Committees

PILs: Patient Information Leaflets

PPI: Patient and public involvement in research

R&D: Research and development

RECs: Research Ethics Committees

RGMS: HSE National Framework for the Governance, Management and Support of Health Research

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Welcome address

Prof Mark White;
Executive Dean, RCSI University of Medicine and Health Sciences & Chair, Irish Health Research Forum

Mark welcomed the group and thanked HRCI for their work in preparing for the event and all the contributors who agreed to speak on the day. He noted the opportunity offered by this event to reflect on the recent journey and the maturing of research ethics in the Irish health system, to highlight the positive developments, and to highlight some of the things that needed to be improved. Mark discussed the increasing intricacy of our social system, reflected on the complex ethical issues we need to address in Ireland. He noted the increasing demands that this places on our research ethics system to respond to the rapid change in societal expectations, the difficult balance meeting those expectations, adhering to fundamental values and principles, whilst avoiding becoming an overly legalistic and compliance-driven system.

> ***What we've done traditionally is no longer fit for purpose for the new world that we find ourselves in. There is a lot happening in the space of involving multiple stakeholders and disciplines in the research ecosystem, particularly health service research. Such a dynamic time of change in research provides us with a great opportunity to achieve excellence in many elements of what is becoming a very complex and complicated aspect of undertaking research. Research ethics is becoming as important as the research itself.***

Scene setting

Dr Ana Terres;
Head of Research and Evidence,
Assistant National Director, HSE

Ana introduced the health system and policy context underpinning reform of the HSE research ethics system. She referred to the HSE National Framework for the Governance, Management, and Support of Health Research (RGMS), which underpins a process of reform of research within the HSE. This includes reform of Research Ethics Committees (RECs), comprising HSE and hospital RECs., HSE and hospital RECs cover health research that is hosted by the HSE or HSE services – either research that takes place physically within services, or that involves participants that have been recruited through those services, their data or their samples. It excludes clinical audits, standard service evaluations and other activities taking place within the health care system for providing basic care and the management and planning of services. Ana described how the REC system for clinical trials, once spread across 12 RECs across the country, has now come under the remit of the National Research Ethics Committee (NREC). However, this still leaves the ethics system for non-regulated research split across 32 RECs, working independently. The system is inefficient and does not address the needs of all healthcare services, and it is this situation that the HSE wishes to reform. Ana then handed over to Dr Olga Cleary to describe the reform process in more detail.

> ***The last couple of years there was a transition with the establishment of the NREC, responsible for regulated clinical trials and medical devices and ... for setting up the national COVID Biobank. But this leaves a lot of studies still under the health service and that includes about 32 different committees working independently with different operational standards. So, we set out to reform this system.***

Dr Olga Cleary;
Senior Research & Development Manager, HSE

Olga started by outlining the role of the national HSE Research and Development (R&D) Office in transforming the HSE REC system, which is a key priority for 2023. Currently the HSE REC system faces a number of challenges: a fragmented system lacking in cohesion, large areas of community services that don't have access to a REC, high demands on existing RECs in the absence of other governance and management structures, and the necessity to obtain approvals from many different RECs when conducting multi-site studies – all of this in the context of additional pressures arising from the Covid-19 pandemic.

To address this, the HSE Roadmap for the Reform of Health and Social Care Research Ethics Committees[1] sets out a new model underpinned by equity of access. The aim is to achieve an effective, efficient and sustainable REC system where REC processes are integrated with overall research governance processes within the HSE. Olga stated that the HSE REC Reform aims to increase the capacity of the REC system to ensure all projects that fall within its remit are reviewed by a HSE Reference REC[2], and to increase the consistency and quality of Reference REC review processes. The REC reform process also aims to develop supports to enable a best practice REC system, and to enhance transparency, communication and co-operation.

Olga described four phases of implementation of the HSE REC Reform Roadmap:

Phase 1	Phase 2	Phases 3 and 4
• Establishing a Standard Code of Governance and Management for HSE Reference RECs (July 2022). • Establishing HSE Reference RECs to cover all HSE services (2023). • Establishing Reference REC structures for the HSE REC system (2022 – 2023).	• Establishing minimum standards for hospital RECs. • HSE Reference RECs authorised to provide single approval for multi-site studies.	• Engagement with RECs in third- level institutions to simplify and formalise ways of working. • Maintain institutional governance processes.

1 *https://hseresearch.ie/wp-content/uploads/2022/05/HSE-Reform-Roadmap-D3.pdf*
2 *https://hseresearch.ie/members-of-hse-reference-recs/*

Olga noted that a Standard Code of Practice has been developed which explains the remit of the HSE Reference RECs as opposed to those of NREC, hospital-based RECs and academic RECs. It sets out the governance and management of HSE Reference RECs, membership and recruitment, financial considerations, how HSE REC review is integrated with research governance, management and support, what activities fall under the remit of HSE Reference RECs, and the standard operating procedures for HSE Reference RECs. She emphasised the governance and support provided by the National Committee for the Governance, Management and Support of Research[3] by HSE R&D and referred to plans to set up a system of HSE research communities, with the intention that anyone involved in research ethics will benefit from peer support.

The HSE National Committee for the Governance, Management and Support of Research (National RGMS Committee), with responsibility for implementation of the RGMS framework, has been established as the Reference REC appointing authority. While it has oversight of the Reference RECs, it plays no role in ethical decision making. The HSE Reference REC Support and Co-ordination Office will be established as part of National HSE R&D and will oversee the implementation of Reference RECs according to the Roadmap for the Reform of Health and Social Care Research Ethics Committees. It will support recruitment, training of REC members and implementation of all the relevant operational protocols. This office will also develop and implement a quality assurance programme and will manage the REC aspects of the Electronic Research Management system. Olga noted that PPI collaboration is an inherent part of R&D activities and finished by highlighting HSE R&D's Twitter account (@HSEResearch) and the wide range of guidance, documents and support available on the website ***https://hseresearch.ie//***.

> ***We are looking towards a vision of an enabling and efficient HSE REC model, underpinned by equity of access across the full health care system.***

3 ***https://hseresearch.ie/research-ethics/hse-research-ethics-committees-support-and-co-ordination-office/***

Dr Emily Vereker;
Head of Office, National Office of Research Ethics Committees

Emily opened her presentation by setting out the main strategic objective of NREC, which is to lead the transformation of the national research ethics system in Ireland, and to become a leader in research ethics. This is achieved by partnering with various stakeholders such as the local research ethics community, the HSE and the Department of Health. Emily described the role of the National Office – an independent office with a statutory function – as including support for the National Research Ethics Committees (NRECs), and to establish NRECs in specific areas of health research, both regulated and unregulated. She emphasised how the EU regulatory environment supported the launch of the NRECs, and aims to facilitate cross border innovation, along with greater transparency and access to clinical research. It also created a harmonised system for the ethical assessment of clinical trials in Ireland and across European Member States.

Emily described how, since its launch in 2020, the National Office has gone on to establish three NRECs, and worked to increase NREC membership, as well as setting up a REC for the National COVID-19 bio bank. Currently, there are four NRECs and one COVID-19 sub-committee in place, comprising over 80 members across Ireland with a range of diverse backgrounds of expertise and experiences. Ultimately the aim of the National Office is to allow a co-ordinated single national ethics opinion. Emily presented the NRECs in the context of a mixed model system operating in Ireland, where the NRECs operate alongside recognised RECs covering studies involving ionising radiation, and local institutional RECs (including HSE Reference RECs currently undergoing reform). She outlined the NREC review process, from submission of applications, through review, and NREC meetings, to the final decision. Emily also described how the NREC process and delivery of a single national ethics opinion is underpinned by a range of international cornerstone resources for ethical research practice, such as for example, the Declaration of Helsinki. She emphasised the importance of a participant -centred approach to ethical considerations founded on the principles of value, scientific validity, justice, beneficence, informed consent, respect and dignity, and independent review.

With over 60 meetings convened, 120 new study applications submitted and over 500 opinions delivered, the National Office and NRECs strive for excellence, participant benefit, public trust, stakeholder confidence, national cohesion, and a strong reputation. Emily presented the National Office's work plans for 2023-24. These include enabling and improving the effectiveness of NRECs, strengthening engagement and collaboration with other local RECs and stakeholders, instilling international best practice, supporting research initiatives of national and international importance, advocating a patient, public and carer-centred approach, and operating with agility and precision.

Emily concluded by stressing the importance of co-operation and collaboration across key actors in the research ethics arena. She highlighted the advantage of our connection and harmonisation with the European regulatory environment. Finally, she praised the valuable work of the team in the National Office.

> ***The more we talk together, the more we work with each other, we can actually achieve national cohesion. We're right in the middle of this change at the moment.***

Discussion groups

Attendees at the event were asked to consider four themes through discussion groups of 8-10 people (two groups per theme), with an assigned facilitator. The main recommendations to address each theme, as reported in feedback at the event by the facilitators, are outlined below.

1 Research Ethics Committee membership, supports and training

Feedback was provided by table facilitators Mairead Murray, Senior Research and Development Manager, Strategy and Research, HSE, and Dr Frances Drummond, Research Manager, Breakthrough Cancer Research.

The main recommendations from two multi-stakeholder discussion groups who addressed this theme are:

- **Developing and delivering training for all REC members is key** – both basic training and more specific training in specialised topics (such as PPI or clinical research). Looking at national and international best practice in REC training is the best way to do this. We should develop a national training model and standard similar to the research integrity training currently utilised by higher education institutions.
- We need to move away from a volunteer-based REC system to a **valued and formally recognised model**. This should involve crediting academic and clinical members for their work on RECs in formal appraisals/scoring for recruitment and promotion and protecting time for clinicians to join RECs. Being a member of a Research Ethics Committee should not be an add-on but integrated into professional roles.
- **The membership of RECs should be expanded.** Making it part of everyone's role in an institution and rotating the role around research staff, as well as adequately reimbursing non-researcher members such as PPI contributors, would ensure that there is a national pool of expertise that can be drawn on when necessary.
- Related to the above point, research ethics should not be a chore. **An ethical attitude to doing research** should be fostered, integrating ethics as a fundamental part of research practice.
- We need to **adequately resource PPI members of RECs** by streamlining reimbursement and paying them for their participation. We should recognise PPI contributors as inherently important members of RECS and their role, input and expertise must be fundamentally valued.

2 The interplay between ethics and data protection

Feedback was provided by table facilitators Dr Anne Costello, National Office of Research Ethics Committees, and Dr Derick Mitchell, CEO, IPPOSI

The main recommendations from two multi-stakeholder discussion groups who addressed this theme are:

- There is a need for **greater consistency in how research is assessed by DPOs**, because DPO assessment is key to re-assuring REC members regarding data protection compliance.
- This could be achieved through **training for DPOs** to ensure that they understand what is and is not a research study and the different types of research studies.
- This interplay between RECs and data protection and the confusion between the different roles at play could be addressed by the **introduction of a national Data Protection Impact Assessment (DPIA) template** that should be recognised across research studies and settings.
- In order to expedite REC processes, full DPIAs could be replaced with a **DPO statement of compliance** to accompany REC applications. A full DPIA which would still need to be submitted to the DPO.
- We are faced with complex and disparate interpretations of GDPR and the Health Research Regulations. This could be addressed by **developing a standardised interpretation across all stakeholders**
- In order to facilitate research which is data protection compliant but remains as open as possible, **a patient identifier** could help standardise the availability of data and make sure it is FAIR (Findable, Accessible, Interoperable, and Reusable).

3 Balancing risk-benefit in research ethics decisions

Feedback was provided by table facilitators Dr Susan Quinn, National Office of Research Ethics Committees, and Dr Derek Stewart, PPI Contributor.

The main recommendations from two multi-stakeholder discussion groups who addressed this theme are:

- **Patient and public involvement** is extremely important in research ethics. Diverse PPI contributors should be engaged with throughout the research lifecycle.
- **Equality, diversity and inclusion** should be fundamentally interwoven throughout the research ethics process, ensuring that research is inclusive of diverse cohorts of participants, and that PPI reflects the complexity and diversity of human lives and experiences.
- Related to this, the questions of **who has ownership of the research**, who is the research relevant to, and why it is needed should be fundamental for RECs.

- The **scientific and ethical rigour of a research study** is essential to allow participants know that what they are signing up for has been thoroughly assessed and reviewed.
- RECs should also give greater attention to the **potential benefits of a proposed research study for participants**, as well as checking the risks. The essential relevance and value of the research should be examined.
- **Education and training** on the research lifecycle, different types of research, and the ethical questions at play in research should be delivered to researchers, PPI contributors, and the public.
- It is important to avoid **over-researching** the same cohort of people repeatedly, to reduce the risk of research fatigue. To this end, better future use should be made of data collected during a study.

4 Streamlining research ethics processes

Feedback was provided by table facilitators Mary Clare O'Hara, Strategy and Research, HSE, and Lucy Murphy, Cancer Trials Ireland.

The main recommendations from two multi-stakeholder discussion groups who addressed this theme are:

- We need to provide a **single, cohesive training programme** for REC members, research administrative support, and DPOs. Teaching the same processes across the board will ensure that the same knowledge is shared throughout the research ethics process, leading to consistent decisions. This could be linked to CPD points to motivate attendees.
- It is important to develop a **standardised approach to data protection** and streamline the process across RECs, hospitals, and higher education institutions (HEIs).
- It is also important to **integrate** data protection assessment into a REC's opinion rather than having a separate institutional data protection review.
- We need to have **one standard research ethics opinion and national approval** for all research, supported by training, data protection, streamlined processes, and facilitated by a research office.
- A national REC for the use of **secondary data** should be set up, to encompass activities such as patient registries.
- **National standards** should be established for RECs to provide clarity and consistency. This could be linked to a community of practice which can ensure that these national standards are achieved by researchers.
- Finally, RECs need to be **better funded and resourced** so that they are no longer staffed and supported on a voluntary basis.

Panel discussion and audience Q&A

Chair – Dr Conor O'Carroll;
Founder/Director SciPol Services & Independent Consultant on Research and Higher Education Policy

Dr Conor O'Carroll introduced the panel discussion by stressing that while it is not possible to solve all the problems associated with strengthening the Irish research ethics system in a day, it is possible to use the expertise of the people in the room to find solutions. He then welcomed the panellists to this discussion, representing applicant, PPI, and regulatory perspectives.

> ***We won't solve all the problems today, but what can be done is to find solutions.***

Dr Suzanne Bracken;
National Irish Covid-19 Biobank Co-ordinator,
Trinity College Dublin

Dr Suzanne Bracken described the National Irish Covid-19 Biobank's (NICB) experience of applying for ethical approval in Ireland as both lucky and unlucky. They were lucky to be the first Irish government-funded national Biobank, and to be granted a dedicated NREC. Suzanne said that this could be a gold standard for all other forms of non-interventionist research Biobanks.

As the NICB-NREC was not in place when the project began, they had to apply to eight local ethics committees while waiting for the NREC. Suzanne emphasised the high administrative burden of applying to local RECs and the NREC which caused significant delays to recruitment and the research. Nonetheless, she praised the setting up of the NREC NICB, which offers a clear pathway to a single national ethical opinion for future biobanking studies. Suzanne stated that some of the delays to recruitment were due to other elements in the hospital approval process including data protection and legal sign-off.

> ***We are delighted to have the NREC...it is the way forward for that single opinion... hopefully we'll be setting the scene for many other biobanking studies to come.***

Billy McCann;
PPI Member, National Research Ethics Committee for Medical Devices

Billy described how PPI representation on RECs has a number of benefits. From the patient's perspective it inspires confidence in health research. It encourages the use of clear and accessible language. It also brings together different experiences and perspectives on research ethics. He emphasised how he works on behalf of research participants by encouraging the use of plain English in applications, pointing out that an inability to use plain English in an application often raises the question of whether researchers would be able to effectively communicate with participants later on.

He described how PPI contributors on an ethics committee can question research practices that may otherwise be taken for granted and ensure that the rationale for decisions is made explicit and justified in evidence. This can lead researchers to rethink their decision making, minimising unnecessary data collection, reducing the burden on participants, and avoiding research waste.

Billy discussed the importance of actively seeking people to become PPI members of RECs. Recognising that people may feel intimidated at first by facing a room full of specialist professionals, he recommended that they should be supported and assured that their voice matters. He found it helpful to realise that decisions are made by the committee as a whole, and the onus for the REC's opinion does not rest on his shoulders. Allowing time for PPI contributors to get comfortable with being part of a REC is also important. Finally, Billy said that being part of a REC has been really positive and a wonderful learning experience, while acknowledging that being retired was a critical factor in being able to participate.

> ***Sometimes people... have to be helped to get involved. It's quite intimidating at the beginning. You're in a room with people who are very specialised in what they're doing... but I would encourage you to seek out people, to assure them also.***

Dr Clíona McGovern, Chair,
NREC Clinical Trials (B) & Head of Subject,
Legal Medicine, UCD

Clíona started by identifying the three main challenges Research Ethics Committee members repeatedly face: 1) patient information leaflets, 2) data protection and the interface with RECs, and 3) burying plans for retention of bio samples in long patient information and consent documents.

Regarding patient information leaflets (PILs), Clíona criticised some clinical trial PILs for being too long, using inaccessible technical language (even when the authors claim to be using Plain English). She pointed out that the best PILs received by RECs are those that have PPI involvement at the start. These tend to be clear, logical, well set-out, and legible.

The second issue Clíona raised was the relationship between data protection and RECs. She described a situation where, prior to GDPR, data protection did not have an obvious "home", so it ended up in the ambit of RECs by default. However, once GDPR was enacted along with the Health Research Regulations, every research applicant had access to a DPO, while the data protection system remained under-resourced. DPOs are working at capacity, which means it can take months for researchers to complete a Data Protection Impact Assessment (DPIA) and to get clearance from a DPO. This puts the onus back on RECs even though data protection is different to and distinct from research ethics. Clíona said she would prefer to see a situation where all that RECs need is a statement of compliance from a DPO, stating that the applicants have conducted a DPIA and have met their regulatory requirements. Otherwise, RECs have to try to manage data protection and yet have no regulatory remit to do so.

> ***I remember hearing a conversation, thinking 'I've listened to a conversation about a patient information leaflet for 15 minutes and I don't think I understood one word and I'm the Chair.' So, we have a problem.***

Finally, Clíona discussed the third issue faced by many RECs, which relates to researchers planning to retain samples but not making this explicit and clear to potential participants. The practice of referring to retaining samples for use in unspecified future research in complex and lengthy PILs means that patients who are unwell may not be able to clearly understand that this is being proposed, how samples are going to be retained, and what the researchers are going to use them for. She reported that applications are being rejected by RECs due to this practice and said that it is not acceptable simply to change the language used to describe what is essentially a biobank.

Panel questions and answers session

A number of questions were put to the panel, and the following points were made in response:

- When considering how to make **biobanking more explicit** in patient documentation for a proposed research project, it is good to remember that research participants are often less risk averse than REC members might be. While RECs have to ensure that the information about biobanking is clear and explicit, on the whole participants trust the researchers and the process.
- A good example of a **Patient Information Leaflet (PIL) specifically for biobanking**[4] has been developed that could be used and adapted as a template for research studies that include an element of biobanking.
- **NRECs are not against biobanking per se**. Rather, they are critical of the practice of not making researchers' intentions to retain and reuse participants' bio samples clear and explicit in participant information and consent documents. Provisions for biobanking should form a separate and distinct aspect of the consent process. Participants should be given the option to participate in a trial but not in the biobank if that is what they wish.
- **The voices of people in residential settings such as nursing homes, prisons, and hospitals must be heard.** This is especially the case for people who rely on others to distribute medication, to interpret for them, or to have access to a trial in the first place. The legislative environment has become much more conducive to this, thanks to the enactment of the Assisted Decision Making Capacity Act.
- However, this can be undermined by **risk aversion on the part of DPOs** which can delay research and even discourage researchers from recruiting from these populations. This is due to the perceived complexity of assessing capacity or recruiting those who lack capacity. A way of streamlining and facilitating research with these groups of people would be very helpful.
- **Assessing and reporting risk in clinical trials** can be difficult, especially in Phase 1 trails where side effects may not yet be known. In this case, highlighting any known priority risks is important as well as being explicit about the possibility of unknown side effects.
- The **data protection system for multi-site clinical trials needs to be streamlined.** At the moment it is not clear who should be lead DPO in this case, and this may lead to researchers having to complete DPIAs and apply to DPOs for each site in a trial. One way of doing this is to dedicate funding to buying out the time of a research DPO to facilitate them to act as lead DPO for a multi-site study.

4 *https://hrbopenresearch.org/articles/4-96*

Conference close

Prof Mark White;
Executive Dean, RCSI University of Medicine and Health Sciences & Chair, Irish Health Research Forum

Professor White thanked the speakers and emphasised that the report of the event will be extremely important in setting the scene for discussions around strengthening and harmonising the Irish research ethics system. Not just at the research ecosystem level but at the policy making, and government levels too. He praised the obvious commitment of all the stakeholders in attendance to keep innovating and progressing change. Finally, he introduced Suzanne McCormack, Chair of HRCI, to deliver the closing words.

Suzanne McCormack;
Chair, Health Research Charities Ireland & CEO, Irish Thoracic Society

Closing the event, Suzanne thanked Professor Mark White for his eloquent opening words. She also thanked Dr Ana Terres, Dr Olga Cleary, and Dr Emily Vereker for providing such an insight into the challenges and complexity involved in strengthening and harmonising the Irish research ethics system. She appreciated the contribution of the panel members: Dr Suzanne Bracken, Billy McCann, and Dr Clíona McGovern; and thanked all those who took part in the discussions, as well as the discussion group facilitators for their succinct feedback.

Suzanne noted the diversity of the event attendees, comprising charities, individual PPI contributors, researchers, REC members, policy makers,

funders and industry representatives. She was particularly heartened to see key change makers in the room such as the HSE, NREC, the Department of Health, and the Data Protection Commission. She highlighted the fundamentally important role of the patient voice at the front and centre of all these discussions, and thanked Billy McCann and Kevin Quaid (an audience member) for bringing home to everyone exactly what that means in practice.

Suzanne highlighted the Irish Health Research Forum's track record of achieving impact and output and said that this event would be no different. She said that it had become evident during the event that a shared commitment exists towards achieving a robust, coherent, streamlined and patient-focused research ethics system as an essential building block for a world-class research landscape. She expressed the hope that this will support an onward journey of collaboration, energy, and optimism. Finally, Suzanne closed the event by thanking the Irish Health Research Forum Steering Group and the HRCI team for their planning and support for the event.

> ***For me, it has become crystal clear from today's discussion, the unity of purpose towards achieving a robust, coherent and streamlined and patient focused ethics system as an essential building block for a world class research landscape.***

For further information

For further information on the activities of the Irish Health Research Forum please see our website:

https://hrci.ie/irish-health-research-forum/

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