HRDPN REPORT

Enabling a Brighter Future for Data Protection in Clinical Research in ROI. Create an effective and streamlined ecosystem to deliver data protection while enabling health research in Ireland.

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ABOUT HRDPN

The Health Research Data Protection Network (HRDPN) is a network of professionals from Universities, the HSE, Hospitals, NCTO, and not-for-profit Research Organisation/Networks, who play a role in data protection compliance.

The HRDPN was established in 2018 to facilitate and promote a coordinated and collaborative approach to data protection for health research in Ireland. Since its inception, the Network has been working to achieve harmonisation of interpretation of data protection regulatory requirements, consistency of approaches, systems, processes and procedures. The Network has also delivered a guidance document and data protection training tailored for health researchers.

ABOUT THE CONFERENCE

On November 4th, 2024 the HRDPN held a day-long conference at the RCSI, Dublin. A diverse group of health research stakeholders—comprising researchers, clinicians, patient advocates, research administrators, health agencies, and regulatory experts—convened to discuss data protection challenges in the sector and devise strategies for improving efficiency and streamlining our national approach to these issues.

KEY DATA PROTECTION CHALLENGES FOR HEALTH RESEARCH IN IRELAND

Health research and clinical trials advance our ability to prevent, diagnose, manage and treat diseases, and clinical trials often offer patients access to new and potentially life-saving interventions.

However, the health research ecosystem in Ireland is complex and can be difficult to navigate for health researchers and clinical trial sponsors seeking to set up research studies and clinical trials.

In particular, health research data protection requirements can be unclear, complex and onerous. This can lead to frustration and delays for sponsors and researchers, especially where projects are run across multiple institutions, with issues such as inconsistent interpretation of requirements causing challenges.

In light of this, the HRDPN Conference aimed to address the following data protection challenges:

- **System unpredictability / inefficiencies**, which, in comparison with other countries, may deter sponsors from conducting clinical trials in Ireland. The system unpredictability / inefficiencies are associated with the challenges below:
- **Consent issues:** onerous requirements and a rigid interpretation of Irish law pertaining to consent, which does not necessarily reflect data subjects' point of view. This in turn can generate significant barriers to, for example, research relying on retrospective data or age of consent

- **GDPR/HRR process variation:** Inconsistency (between organisations) of (a) interpretation of the regulations and (b) institutional Data Protection Impact Assessment requirements. With significant operational differences being evident for GDPR and HRR interpretations between institutions, researchers/sponsors can experience challenges in undertaking multisite projects
- **Data Protection Impact Assessment (DPIA) inefficiencies:** Lack of clarity on responsibilities and the process and information required in preparation and review of DPIAs (which can result in duplication and inefficiencies)
- **Inefficient institutional approval processes for study set up (ethics, data protection and legal)**: onerous and time-consuming approval processes (duplication, delay, lack of coordination between functions within and among institutions) with trials and studies across multiple institutions being particularly impacted by these issues
- **Ethics oversight of data protection:** undefined role of research ethics committees with regard to confidentiality and privacy, which can overlap and conflict with the Data Protection Officer's (DPO's) review
- **Data protection contracts (legal aspects and workload):** differences in approaches to contracts, high volume, slow turnaround, researchers deterred by contract delays to engage with contract/legal teams
- **Human resources shortages:** Lack of sufficient staffing with which to deliver demands for research DPO and contract/legal roles.

HRDPN CONFERENCE RECOMMENDATIONS

At the HRDPN conference, participants discussed challenges and solutions for the Irish health research system in the area of data protection.

Consistent finding across many speakers and contributors included:

- the paucity of national policy guidance, which can result in variation in the interpretation of data protection requirements
- the under-resourcing of health research sectoral needs in data protection.

Having considered the stakeholders' perspectives, the HRDPN conference recommendations, which should be prioritised, are as follows:

To the DPC:

- Assist in the development of data protection guidance materials for health researchers, with a focus on the risk-based approach
- For multisite clinical trials and studies, in instances where one organisation is the sole Data Controller of the Research Study/Clinical Trial and the others are Data Processors, develop policy/guidance which clarifies that it is the lead Data Controller's responsibility to conduct the Data Protection Impact Assessment in accordance with its own standards

- To communicate with organisations involved in health research in relation to their Article 38(2) obligations regarding adequate resourcing of data protection roles and define what adequate resourcing is
- Create a designated information page on the DPC website for health research, including advice on DPO's responsibilities, interpretations for specific scenarios and send notification on updates to HRDPN/ DPOs
- Support HRDPN and other relevant stakeholders in developing a code of conduct for data protection in health research including an open access repository with resources and tools.

To the Department of Health:

- Undertake public engagement with Patients and Patient Advocacy Groups to review the Health Research Regulations (HRR) and the HRR amendments in particular in relation to explicit consent, with a view to reflecting on explicit consent and the interpretation of broad consent within the Regulation and balance GDPR/HRR with access to clinical trials, novel treatment and associated health research
- Support the HRDPN in the development and delivery of standardised national data protection training, resources and support for health research data protection professionals (DPOs and data protection support staff).

To all health research organisations (hospitals, universities and other Research Preforming Organisations):

- Work together and foster a more collaborative culture in health research to fulfil regulatory, legal and data protection requirements
- Develop a more integrated support system for health researchers and sponsors of clinical trials to help them efficiently fulfil data protection requirements.

To this end:

- Develop a transparent and easy to understand/implement process map which guides researchers through the hospital's and university's approval process(es)
- Enable researchers/organisations easily monitor the progress of submissions through the approval process
- Remove duplication of data protection review processes at DPO and ethics committee levels.
- Reconsider the current practice whereby DPIAs are reviewed by clinical sites who are acting as data processors
- Agree and adopt standard template contracts/agreements governing data protection in health research
- Clarify the roles and division of responsibilities in data protection for those involved in health research (DPOs, legal, researchers) taking into consideration the complexity of data protection requirements for researchers.
- Ensure that health research data protection roles are adequately resourced in line with statutory requirements. Specifically, support:
  - The creation of a designated research support role to help researchers navigate data protection requirements and approval processes (data protection and legal)
  - Where appropriate, the appointment of research-specific Data Protection/support personnel to deal with health research.

NEXT STEP

- Seek stakeholders' (including DPC, DOH, Health Research Organisations and patient representation bodies) organisations consensus on recommendations
- Set up a working group involving a representation of the HRDPN members with other health research stakeholders to put in place a plan that addresses the recommendation above and supports Cabinet-approved efforts to grow national clinical research and trials activity.

Mary Kirwan, Barrister and Lecturer in ethics at RCSI University of Medicine and Health Sciences

WELCOME ADDRESSES AND SCENE SETTING

Working together for solutions

Mary Kirwan, the chair of the event, welcomed attendees and set the scene for the day's discussions. "We have representation from across the board in the room and we are trying to make constructive recommendations on how to create a more efficient data-protection system to enable health research in Ireland," she said. "The goal of the day is to be collaborative and to be solution-oriented."

Professor Gianpiero Cavalleri, Deputy director RCSI's Office of Research and Innovation and Deputy director of FutureNeuro Research Ireland Centre for Translational Brain Science

Pipework for an efficient research ecosystem

Professor Gianpiero Cavalleri, a scientist studying genetic causes of rare diseases, emphasised the value of research involving personal patient data, which can be amplified when data are shared across institutes in Ireland and with international partners. He described how GDPR rightly protects personal data but how differences in interpretation of GDPR can hinder otherwise appropriate data sharing, slowing discovery. He spoke of these challenges in the context of the 'complex plumbing' of the research ecosystem in which we operate.

"When I think of a research ecosystem, I picture it in the form of pipe work, with multiple different entities, research institutes, hospitals, patients who provide their data, funders who provide the money to do the research, ethics committees who facilitate consent protocols, with whom we wish to share the data," he said. "I believe our role is to shape that pipe work for impact. If you leave it to evolve naturally, there's a risk that it's inefficient, and inefficiency in a research ecosystem ultimately costs the taxpayer and it impacts people's health in the long term."

The challenge is how do we maintain the critical privacy and protective elements of GDPR which are excellent and necessary, he noted, but also enable safe and impactful research to happen in Ireland.

"The safest research is no research, but I don't think that's in anyone's interest. The reward of doing this is impactful, trustworthy, efficient, critically sustainable research in Ireland."

Dr Suzanne Bracken, Chair of the National Biobank Working Group

HRDPN: A network for consensus

Dr Suzanne Bracken, first chair of the Health Research Data Protection Network (HRDPN), spoke about how the network aims to harmonise data-protection practices and regulatory interpretations within Ireland's health research sector and facilitate communication among data protection officers (DPOs) across universities, hospitals, and other health research organisations.

"The network started in 2018, the year when the Health Research Regulations came out," she said. "There was a lot of confusion and concern at the time, and we really felt that bringing everybody together to have a group consensus would be helpful for everyone."

The HRDPN has grown from 12 initial members to more than 50 today, and as volunteers they work together to standardise data protection, improve efficiency, and provide guidance. Major accomplishments include a data protection guide for researchers and training workshops. Dr Bracken particularly noted the positive engagement of the HRDPN with the Data Protection Commissioner, and highlighted how funding the network could enable more initiatives.

Health data – the changing European landscape

Barrister and lecturer in ethics Mary Kirwan outlined recent developments in GDPR's application to health data across the EU, highlighting fragmentation issues and inconsistencies in data sharing due to varied national interpretations, particularly around the use of secondary data. "Uneven implementation creates legal uncertainties, and GDPR has not achieved its goal for health data across Europe," she said. "The experience that we're having in Ireland were not unique."

Kirwan explained how the European Health Data Space (EHDS) regulation – expected to be implemented in 2025 - now aims to standardise health data usage, enabling secure access for research, innovation, and policy-making while ensuring data privacy. Key goals include empowering individuals with access to their health data, fostering a digital health market, and creating opt-out mechanisms for secondary data use and building in specific safeguards for data use and to prevent bias.

"Electronic health data holders will be required to make data available to health data access bodies, it will be a mandatory requirement" she explained, adding that opt-out was another major change. "In Ireland, we have an opt-in system where you have to specifically consent for your data to be used in a research setting. This legislation will introduce an opt-out mechanism, so you're included unless you opt out."

Stakeholders from across the health-research spectrum offered their perspectives on data-sharing and outlined challenges that need to be addressed.

STAKEHOLDER PERSPECTIVES AND CHALLENGES

Red tape is slowing Ireland's clinical trial opportunities

Consultant oncologist Professor Donal Brennan discussed how clinical research is directly linked to improved patient outcomes, improving services, generating revenue and attracting and retaining clinical staff. But he also described how Ireland is considered a "hostile environment" for clinical trials due to a range of issues, including a fragmented healthcare system, the perception of medico-legal risk and bureaucratic delays in starting trials – sometimes taking months or years instead of weeks.

Yet Ireland has many positives, noted Professor Brennan, such as pharmaceutical activity, good CROs and a respected regulatory framework, and we could improve the clinical trials landscape in Ireland through streamlined processes and improved data handling to ensure equitable trial access.

Establishing clinical trials as a standard of care would enhance access to advanced therapies and drive funding. Ultimately, reducing red tape and promoting transparency are essential to advancing patient care, and we need to prioritise clinical research as a matter of course.

"In the health system, clinical research should be considered just as important as the number of patients waiting in the emergency department," he said. "Because if it isn't, we can have the best EU legislation but we're going to be stuck in the same position in 10, 20 years' time."

Gwynne Morley, General Manager IQVIA Ireland

Ireland should act as a single site for clinical trials

Gwynne Morley from IQVIA provided an industry perspective. She stressed the growth opportunity for clinical research in Ireland if barriers can be addressed, and she highlighted the need to strive for clinical research as a care option.

Patients overwhelmingly want to be involved in research, she noted, but clinical trials face delays in Ireland, and this can stop patients from getting access and cause reluctance among trial sponsors.

Ms Morley identified barriers in Ireland such as the need for multiple DPIAs, and explained how a broader consent model could unlock potential, allowing more trials, and how federated data platforms could support the generation of real-world evidence by enabling the analysis of real-world data from various healthcare settings, which is crucial for understanding the effectiveness of treatments in everyday practice.

"Ireland needs to work as a network, so it doesn't matter where the trial takes part, we manage that internally, but to the external world, we're a single site," she said. "I think that is the real opportunity."

Resource and engage with DPOs, and be aware of their roles

DPO Ronan O'Halloran Data Protection Officer and Information Governance Manager at the Mater Misericordiae University Hospital outlined the key challenges faced by DPOs in Ireland. They include inadequate resourcing, diverging interpretations of GDPR leading to uncertainty, duplication of paperwork in the research application process (particularly DPIAs) and an increasingly complex data-protection landscape in Europe.

Mr O'Halloran said that organisations need to recognise that the role of DPOs is to inform, advise and monitor compliance, as set out in Article 39 of the GDPR, and ultimately the Controller is responsible for signing off on projects, not the DPO. He also noted that health research makes up only one part of a DPO's broad workload, which includes training, data-protection impact assessments, contracts, complaints and subject access requests.

"I would say to researchers to engage with your DPO at an early stage. We will guide you in the right direction to get GDPR and data protection right for your project," he said.

The complex landscape of research contracts

Yvonne Czajkowski, Solicitor, Head of Research Contracts, University of Limerick and is member of the Higher Education Research Contracts Working Group. This group is composed of a wide range of personnel from HEIs including contract managers, legal, financial, technology transfer and research support, whose objective is to promote and facilitate interaction between those working on research contracts in Higher Education in Ireland. Their remit is to discuss issues encountered ensuring a common understanding with the view to making the ecosystem more efficient by promoting harmonisation.

Ms.Czajkowski discussed the role of research contracts operating in parallel with data protection agreements and the importance of aligning data protection agreements with ethics approvals and consent forms. She highlighted the complexities involved in navigating the various requirements for health research projects, particularly when they are not directly funded under a State-funded call or application process. She emphasised how such projects still require the same level of governance and compliance with the ensuing paperwork.

"Ideally, we want early collaboration between researchers, legal teams and DPOs, so we can assist the clinicians, the scientists, to put the agreements in place as fast as possible, and then get out of the way and let the researchers get on with their work," she said.

Patrick Kivlehan, Chair of Patient Consultants Committee of Cancer Trials Ireland

Make clinical trials more accessible and timely for patients

Patient representative Patrick Kivlehan emphasised the general willingness of patients to share data for research purposes, once the data and privacy aspects are well handled. He spoke about how patients being delayed from starting on clinical trials or even precluded from those trials underscores the urgent need to make clinical trials more rapidly accessible for patients in Ireland. Kivlehan himself experienced a delay being recruited onto a clinical trial for treatment that put the cancer he had into remission.

Mr Kivlehan recommended that consent in Ireland be broadened to facilitate sharing with researchers for current and future studies, including easier sharing of data post-mortem, and that patients should have simplified access to their own medical records. "There shouldn't be any delays to any trials, whether it be GDPR or any other issue," he said.

Deputy Commissioner at the Data Protection Commission, with responsibility for Supervision of the Public, Health and Voluntary Sectors

Get the balance right for patients and research

David Murphy from the Data Protection Commission highlighted the DPC's approach of engagement over enforcement, and the need for guidance and education to address the administrative burden and harmonise data-protection practices across the health research sector. He stated that working with the HRDPN is valuable for the regulator to learn about practices and barriers.

We need to mitigate the risk created to individuals through the processing of their data, according to Mr Murphy, but he noted that the ethics and confidentiality that underpin clinical research already offer some safeguards in health research.

"From a regulatory perspective, the DPC considers health research to be a relatively low risk area as it does not give rise to complaints or data breaches to any great extent. Of course, working with health data and with vulnerable data subjects increases the risk profile of any processing operation, including in the research context, and the assessment and management of this risk is important. We would not be advocating a relaxed approach to data protection in this area, rather a more well-informed approach to balancing the data protection risks with the risks to patients of not getting access to research," he said.

"It's not to the benefit of individuals to overly protect their data in a way that in fact disadvantages them as patients and citizens. We know that patients want to access clinical trials and research projects. Let's balance their data-protection rights with their desire to become involved in health research and clinical trials."

Dr Robert O'Connor, Director of the HRB National Clinical Trials Office, led a panel discussion with the speakers, inviting audience questions.

PANEL DISCUSSION

Key points emerging from the discussion:

Key points emerging from the discussion:

- It is crucial that patients understand the implications of sharing their data for future research, even post-mortem
- If it is reasonably likely that a person can be re-identified from an anonymous dataset, then the data is not anonymous, rather pseudonymised but safeguards and measures can be put in place to drive down that likelihood of identification
- A harmonised approach across organisations is beneficial because it makes things repeatable – people can apply learnings from other organisations and essentially copy other people's homework, saving time and resources and reducing conflicts of interpretation
- International data sharing is challenging, particularly between Ireland and the UK post-Brexit. Harmonised policies and shared best practices could help to ease cross-border research
- Ireland can execute clinical trials well, but the problem is the length of time it takes to open a clinical trial to patients here .

BREAKOUT GROUPS AND FINDINGS

Conference participants assembled into breakout groups across eight topics. Each group brainstormed and explored solutions for their topic, with a goal to generate achievable, realistic steps. Facilitators and transcribers guided and documented the discussions for each group, and facilitators presented the findings.

System unpredictability/inefficiencies, which, in comparison with other countries, deter Sponsors from conducting clinical trials in Ireland.
Facilitator: Dr Robert O'Connor

Proposed solutions:

- A transparent framework or decision tree for the research approval processes
- A single review across institutions, for multi-site trials and non-trials
- A national policy to support standardisation
- Agreed risk libraries in plain English
- More training for DPOs and researchers.

Consent: onerous requirements, which do not necessarily reflect data subjects' point of view, barrier to research relying on retrospective data, age of consent (clinical trial versus biomedical research versus digital consent)

Facilitator: Dr Andrias Cullen

Proposed solutions:

- Research nurses to be resourced to have dedicated time to commit to informed consent - sitting with the patient, communicating about the trial/research
- The creation of a Forum/Working Group/Steering Committee with patients to identify what patient information leaflets (PILs) and Consent forms should look like
- Guidelines and templates on PILs and consent forms that should address private, public entities and broad consent
- A citizen-assembly style model to engage the public
- Examination of the research environment to identify best practices and useful solutions.

GDPR/HRR: Inconsistency (among organisations) of (a) interpretation of the regulations and (b) institutional requirement. The regulations are too complex and therefore poorly understood by researchers

Facilitator: Evelyn Fox

Proposed Solutions:

- HRR requires a review in consultation with the research community, to align it better to the GDPR
- We need guidance on secondary use of data from DOH, HSE and DPC to include when research data can be considered anonymous in hands of a third party. This guidance should be founded on a risk- based approach and include the context that research is low risk
- We need clearer guidance from DOH, DPC and HSE on who is responsible for the DPIA (i.e. the Controller and not the site)
- We could follow the UK example of Health Research Authority (HRA) and Information Commissioners Office (ICO), where the hospital can do a DPIA for clinical trials more generally at a site, but the Sponsor is responsible for the trial or project.

DPIA: Lack of clarity on requirements/process (duplication, inefficiencies), too complex for researchers

Facilitator: Ian Knight

Proposed Solutions:

- We need guidance from DPC to help dispel the mystique around requirements and processes for data protection
- A standard set of questions that can be agreed upon and used nationally would help to reduce the complexity of the DPIAs for researchers
- A national DPIA perhaps?
- Interventions that have a greater impact on people's well-being and future life could be prioritised for processing.

Institutional approval processes for study set up (ethics, DP and legal): onerous and time-consuming approval processes (duplications, inefficiencies, lack of coordination between functions). Added complexity and inefficiencies for collaborative projects, which require multiple approvals

Facilitator: Dr Suzanne Bracken

Proposed Solutions:

- Concierge roles could be introduced and resourced in research support offices in universities and hospitals. These concierges, who have expertise in data protection, regulatory and ethics requirements, could help facilitate the researcher in the research journey
- A resource hub would be useful, with sign-posting, templates with dropdown menus and case studies or worked examples of DPIAs for set scenarios with explanatory comments. The HRDPN could help to develop the resource hub
- A planning and study requirement checklist to establish the sequence and timing of events
- Key information should be given out to PIs as early as possible.

Ethics: undefined role of ethics committees' role in DP review, which can lead to the duplication of the DPO's review

Facilitator: Mary Kirwan

Proposed Solutions:

- National guidelines, including templates, to more clearly define the scope of research ethics committees and to differentiate between data privacy and ethical review of wider privacy and confidentiality issues
- A designated DPC page for research with advice on interpretation, to avoid interpretation happening in isolation. This would help Research Ethics Committees (RECs) at the pre-review validation stage of studies
- Streamlining and alignment of the Standard Application Form and DPIA to reduce duplication of work
- For multi-site studies, the possible acceptance of single REC review or sharing of review, depending on the expertise available on each REC. This would need trust between collaborating institutions and clarity around indemnity.

Data protection contracts (legal aspects and workload): inconsistently of approaches, high volume, slow turnaround, researchers deterred by contract delays to engage with contract/ legal teams

Facilitator: Derval Howlett

Proposed Solutions:

- Signposting for researchers for early engagement
- DP experts (regardless of location in organisation) to engage directly with researchers at an early stage
- Agreement with local and national ethics committees that the data protection review should be completed before submission of ethics applications
- For multi-site studies, early collaboration by DP experts across all research partners to agree approach
- Use of agreed template DP agreements.

Human resources: Lack of resources to deliver DPO and contract/legal roles.

Facilitator: Dr Fionnuala Keane

Solutions:

- Clear guidance and clarity from the DPC on best practice for GDPR compliance and the role of the DPO
- Dedicated research-specific DPO and data protection compliance expert teams need to be established and resourced, possibly through project funding
- One DPO is not enough - a suite of DP personnel (adequately remunerated so that people with relevant expertise apply) is needed to deliver all functions
- Closer engagement between legal personnel and DPOs on data protection issues in organisations would be beneficial (this is happening in some organisations but not in all)
- Ongoing availability of formal, targeted and relevant training courses in data protection for research purposes to be made available to researchers and people interested in working in the area
- DPOs to report on GDPR to Organisational Board on an annual basis at a minimum, with the recognition that failure to comply is against the law.

Dr Claire O'Connell, moderator

PANEL DISCUSSION AND Q&A

Science Journalist Dr Claire O'Connell facilitated a panel discussion and audience Q&A to reflect on the breakout groups' findings.

The panel featured David Murphy (Deputy Commissioner at the Data Protection Commission, with responsibility for Supervision of the Public, Health, and Voluntary Sectors), Professor Martina Hennessy (clinical pharmacologist and consultant physician in St James's Hospital Dublin), Patrick Kivlehan (Chair of Patient Consultants Committee of Cancer Trials Ireland), Gwynne Morley (General Manager, IQVIA Ireland) and Evelyn Fox (Data Protection Officer, Trinity College Dublin Research).

Key takeaways:

- Ireland's regulatory environment is viewed as making clinical trials unattractive, despite being safe
- Positive engagement and a solution-oriented mindset are a must to improve data protection in health research
- We need clarity on the data protection responsibilities for those involved in health research (DPOs, legal, researchers) ; and more generally on the distinction between ethics and data protection
- Consent needs attention, particularly informed consent and simplifying the process for patients to engage
- Trusted actors in health research in Ireland contribute to a culture with many built-in safeguards. We need to take the realistic risk of a piece of health research into account, and align it with appropriate data-protection measures
- We need clear interpretation of regulations and targeted education efforts, but education alone may not suffice, structural changes and clearer guidance are essential.

ABBREVIATIONS

CRO - Contract Research Organisation
DP - Data Protection
DPC - Data Protection Commissioner
DPIA - Data Protection Impact Assessment
DPO - Data Protection Officer
DOH - Department of Health
European Health Data Space - EHDS
EU - European Union
GDPR - General Data Protection Regulation
HEI - Higher Education Institution
HRA - Health Research Authority
HRB - Health Research Board
HRDPN - Health Research Data Protection Network
HRR - Health Research Regulations
HSE - Health Service Executive
ICO - Information Commissioner's Office
NCTO - National Clinical Trials Office
PIL - Patient Information Leaflet
RCSI - Royal College of Surgeons in Ireland
REC - Research Ethics Committee
UK - United Kingdom

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