An Roinn Sláinte
Department of Health

GDPR and Health Research Regulations

Where we are and why we're there

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IAMS commissioned two papers this year on the Health Research Regulations.

- The first made 5 recommendations for changes in the Regulations.
- The second was about informed consent under GDPR versus informed consent under the common law.

This presentation will describe:

1. How the Department had already publicly stated that it is taking action in a number of areas covered by the recommendations – so an update will be provided and will show how we have even gone beyond the recommendations, where possible
2. What GDPR consent means and why the common law proposal is not appropriate and would, in fact, have negative consequences for health research in Ireland.
3. How the Regulations are really just about formalising international best practice in health research
4. How Ireland is actively engaged in Europe regarding GDPR and health research

Let’s start with what we all agree on!

- Health research is an important freedom with positive benefit for individuals, the health system and society generally.
- Health research needs public confidence and support.
- Privacy and self-determination are very important legal and ethical rights and are particularly important where personal health information is involved.
- Informed consent is important for researchers, participants and public trust.
- Sometimes consent is not feasible.
- Properly constituted, limited and clearly specified consent exceptions should be provided for in law (and they require primary and secondary legislation).
- The best way to support health research is to promote public confidence in health research through transparency, consent and patient empowerment.

The GDPR and health research

- Good things in the GDPR for scientific/historical research.
- Scientific/historical research subject to Article 89(1)
- Must be appropriate safeguards in place –Article 9 –and consent is an appropriate legal, ethical and best practice safeguard.
- Research involving health, genetic or biometric data can be subject to further safeguards Article 9(4).

Implementation of GDPR in EU Member States

Implementation of GDPR has varied in Member States - shaped by health systems, legal systems, health related law, REC frameworks and cultural considerations. However, EU Commission who pioneered the GDPR in 2012 have stated:

"Informed consent is the cornerstone of research ethics. It requires you to explain to research participants what your research is about, what their participation in your project will entail and any risks that may be involved. Only after you have conveyed this information to the participants – and they have fully understood it – can you seek and obtain their express permission to include them in your project (Articles 4(11) and 7 GDPR)."

(Ethics and Data Protection November 2018)

GDPR sets out several elements for consent to be valid

- It defines consent as “any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”.

The GDPR is clear that consent should not be bundled up as a condition of service

- Article 7(4) says: “When assessing whether consent is freely given, utmost account shall be taken of whether… the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.”
- Recital 43 says: “Consent is presumed not to be freely given… if the performance of a contract, including the provision of a service, is dependent on the consent despite such consent not being necessary for such performance.”

The GDPR is also clear that people must be able to refuse and withdraw consent without being penalized

- Explicit consent is not defined in the GDPR, but there is absolute consensus across Europe that the use of the word “explicit” refers to the fact that consent must be affirmed in a clear statement (whether oral or written).

EU DP Directive

"any freely given, specific and informed indication of a data subject's wishes by which he or she signifies his or her agreement to personal data relating to him or her being processed which must be 'unambiguously given' in order to make the processing of personal data legitimate"

GDPR

"consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her"

Helpful Elaborations on Informed Consent

Article 7 –conditions for informed consent , in particular what is meant by “freely given”.

Article 29 Working Group Guidance on Consent teases out Article 7.

Key Steps to validity –granular, specific, non-conditionality and revocability

While explicit consent is not defined, it must be informed consent that is properly captured and recorded.

The preference is in favour of specific, informed and written consent, where possible.

- The **Declaration of Helsinki (2013)** requires that participants be **informed** of the aims of the research, methods, sources of funding, any possible conflict of interests, benefits and risks, institutional affiliations of the researchers and any other relevant information (Principle 26).

- The **2016 Council of Europe Recommendation** requires that participants be **informed** of the conditions applicable to the storage of the materials, including access and possible transfer policies and any relevant conditions governing the use of the materials, including re-contact and feedback (Article 10).

- **The WMA Taipei Declaration (2016)** seeks to regulate health databases and biobanks and provides more details on the requirements for consent: participants have to be informed about the purpose, the risks and burdens, storage and use of data and material, the nature of the data or material to be collected, the procedures for return of results including incidental findings, the rules of access to the health database or biobank, the protection of privacy, the governance arrangements, procedures to inform participants about the impact of anonymisation of data, their fundamental rights and safeguards as established in the Declaration, and when applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries (Article 12).

- Most instruments recognise the limits on the withdrawal of consent- and state that the limits on the withdrawal of consent should be communicated to the participants and that procedures in place to accommodate withdrawal of consent.

Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo)	1997	Council of Europe	47 Member States of the Council of Europe
Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research	2006	Council of Europe	47 Member States of the Council of Europe
Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes	2008	Council of Europe	47 Member States of the Council of Europe
Report of the European Commission Expert Group on biobanks	2012	European Commission	
International Ethical Guidelines for Health-related Research Involving Humans	2016	Council for International Organizations of Medical Sciences	Health-related researchers
Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin	2016	Council of Europe	47 Member States of the Council of Europe
Declaration of Helsinki	2013 Edition	World Medical Association	Doctors (but persuasive for all health researchers)
Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks	2016 Edition	World Medical Association	Doctors (but persuasive for all health researchers)
Recommendation on Health Data Governance	2017	OECD	35 Member States
OECD Guidelines on Human Biobanks and Genetic Research Databases	2009	OECD	35 Member States

All of these instruments provided guidance on the importance of informed consent and other possible safeguards

- Throughout the definitions, three constructs underpin the notion of '**informed consent**':
  - ✓Study information
  - ✓Subject's comprehension and understanding
  - ✓Voluntary participation

- The importance of strong and clear **governance procedures** (and by implication, **transparency**), **oversight by RECs**, better technical and secure solutions and a move towards **consent as an ongoing process** rather than a once-off event

The safeguards must respond to a multitude of legal, ethical and social risks which are not static and change over time. Thus, any safeguards must be dynamic and responsive to an evolving science.

- **Traditional consent** was designed to deal with a single study, having a specific purpose, and a pre-defined timespan.

- **Blanket consent** authorises all future and unforeseeable data uses with no limitation - That is, participants consent to the broad usage of their data, without any specific information about any future research, nor any possibility for further oversight. This is not considered best practice in the EU since 2012.

- **Broad consent** also authorises future and unforeseeable data but within broadly specified research areas, and gives subjects the ability to exercise restrictions in some of these areas. Proponents of broad consent argue for its ethicality if certain restrictions (safeguards) are imposed, for example, if personal information is handled safely, if subjects are given the right of withdrawal and if all studies are subject to transparent governance arrangements and projects are overseen by an ethics board.

- **Tiered consent** is a minor upgrade from broad consent. It allows participants to choose general research areas they wish to participate in, and exclude others. Subjects can also request to be re-consented for future uses of their data.

- **Dynamic consents** are personalized online consent and communication platforms, and use modern IT to provide a communication channel between researchers and participants of a project.

The Health Research Regulations

- Government and Minister committed to health research (for example, we have invested through the HRB over €150m in the clinical trials area in the last decade as this improves the standard of care and delivers better outcomes for patients.

- Purpose of the Regulations
  - *consistency, clarity and certainty into an area that was essentially unregulated*

- There is nothing in the Regulations that is not consistent with international best practice.

- The Regulations changed very little in terms of good governance and best practice –just formalised it

- Introduced an innovation –a consent declaration process

“Nothing written in stone.”

- When the Regulations were launched we publicly identified certain matters that we would examine further.
- We also engaged with, listened to and have responded to genuine and meaningful challenges and concerns (and continue to do so…….)
- The scope for action is not unlimited (policy wise or by reference to law) –for example, capacity to consent and biobanks.

HRR Amendments

- Pre-screening
- Retrospective chart review
- Emergency Care Intervention Studies
- Personal data obtained for health research before the Regulations came into effect

Why the common law proposal is not appropriate and would, in fact, have negative consequences for health research in Ireland.

common law consent

- IAMS has proposed that consent for the processing of personal data for health research purposes should be on the basis of the common law.
- IAMS seem to be saying that the common law standard of consent is less demanding than GDPR standard of consent (and the longstanding ethical standard of consent–notably in that GDPR/Informed consent requires consideration of the power imbalance while the common law does not.
- Not clear that is the case (and no evidence presented by IAMS to show it is) but even if it is the case, it is something that doctors should be/ are already positively addressing.
- Case suggested by IAMS - *Re T (Adult: Refusal of Treatment) [1993] Fam 95(CA)*
- The EDPB Opinion on Clinical Trials and GDPR recognised that “depending on the circumstances of the clinical trial, situations of imbalance of power between the sponsor/investigator and participants may occur”.
- That challenge can be met through the informed consent process and that is evident from a neutral and careful read of the EDPB Opinion on Clinical Trials and GDPR (February 2019).

Implications of common law consent

- A common law approach to informed consent would only bring uncertainty and perhaps an outcome that would “demonise doctors and infantalise patients”. That is surely in no one’s interest.
- It seems strange to be proposing that health professionals/researchers (and data subjects) should have to grasp with both common law and data protection principles when processing personal data for research.
- Consent under the common law can be implied which is really not very useful if there is a dispute as to what was actually consented to in research. It is also inconsistent with a core general data protection principle of demonstrable data controller accountability where any processing of personal data is carried out.
- The common law duty of confidentiality remains after death.

Implications of common law consent

- The HRA statement as quoted by IAMS seems most definitely to indicate that health practitioners involved in the care of a patient would not need consent for using that patient's information for research, thereby hugely disempowering patients.

- Where disclosures occurred that breached the consent given, the data subject could be forced into bringing a civil action to court for a breach of confidentiality with all the costs involved.

- No consent declaration process.

- Post-Brexit realities and common law –aligning with UK would isolate us.

Concluding Comments

- GDPR and the Health Research Regulations have not so much changed the rules or standards for health research as changed the environment.
- Hope that we have helped to re-assure on certain concerns and debunked certain claims.
- The Department will continue to engage, listen and act.
- However, as the Minister has said, the Regulations are there to promote clear, certain and consistent best practice governance in health research through transparency and consent arrangements that will ensure public support and trust.

GDPR/HRR are only one key step on a journey

- **Legislation on National RECs**
  - *Amending SI 190 of 2004 (clinical trials on medicinal products)*
  - *National REC Bill (other human health research)*

- **R&D and research governance in health provider organisations**
  - *HSE National Service Plan (2019) - national framework for research governance*
  - *HSE launching first Action Plan for Research in December*

- Clear that Ireland needs clarity and legal certainty for the collection, storage, use and re-use of **human tissues/biospecimens** (a register and accreditation system for biobanks)

- DoH participating in an **EU Joint Action on a Code of Practice** for health and social care data (including for Health Research)

- Important to influence discussions regarding the Health Information Systems Strategy (to optimise **data use for secondary purposes-** DASSL model)

Thank you

common law consent

- IAMS has proposed that consent for the processing of personal data for health research purposes should be on the basis of the common law.
- The common law is judge made law. In other words it is not set out or codified in EU or national legislation.
- Ireland, UK (and Cyprus) are common law countries. All the other EU Member States are not. They rely on codified legislation.
- Consent for medical interventions evolved in UK and Ireland in the absence of principles set out in legislation.
- Two aspects of that consent -permission to physical interference (tort of battery), consent which gives permission to run personal physical risks is governed by the tort of negligence.
- IAMS seem to be saying that the common law standard of consent is less demanding than GDPR standard of consent (and the longstanding ethical standard of consent–notably in that GDPR/Informed consent requires consideration of the power imbalance while the common law does not.
- Not clear that is the case (and no evidence presented by IAMS to show it is) but even if it is the case, it is something that doctors should be/ are already positively addressing.

common law consent

Case suggested by IAMS - *Re T (Adult: Refusal of Treatment) [1993] Fam 95(CA)*

So what is the present “common law” position on informed consent for medical treatment?

-(Ireland) Fitzpatrick v K (2009)

-(UK) Montgomery v Lanarkshire Health Board (2015)

-(Ire) *Healey v. Buckley* [2015] “*latest decisions in the UK Supreme Court, including Montgomery, reflect enhanced status of the patient …the law on consent in this jurisdiction may require to be re-considered in the light of developments.*

Chairman of the Health Research Authority wrote an article on informed consent: “infantalises patients and demonises doctors”. an inexpert decision?”

Consent and the Power Dynamic

- Informed consent must always be voluntary/ freely given –under any area of law.
- Article 29 WG Guidance on Consent states that “inappropriate pressure or influence upon the data subject “…….. which prevents a data subject from exercising their free will shall render the consent invalid.”
- Guidance refers to power imbalance as something that must be taken into account.
- Is there a power imbalance in the doctor-patient relationship? -Yes
- Is it one that doctors should already be/are addressing irrespective of GDPR? -Yes
- Does Article 29 Guidance say that the power imbalance renders consent invalid –No.
- What the GDPR (and related Guidance) did was simply to formally identify the power imbalance and set the challenge to address it.
- That challenge can be met through the informed consent process and that is evident from a neutral and careful read of the EDPB Opinion on Clinical Trials and GDPR (February 2019).

EDPB on Power Imbalance

- The EDPB Opinion on Clinical Trials and GDPR recognised that “depending on the circumstances of the clinical trial, situations of imbalance of power between the sponsor/investigator and participants may occur”.
- It adds that a clear situation of imbalance of powers between the participant and the sponsor/investigator will imply that the consent is not freely given in the meaning of the GDPR.
- Note: the term is “imply”. It is not a definitive fact as some have represented.
- How is that situation properly addressed?
- The EDPB states that it “considers that data controllers should conduct a particularly thorough assessment of the circumstances of the clinical trial before relying on individuals’ consent as a legal basis for the processing of personal data for the purposes of the research activities of that trial.”
- That is something that doctors and researchers are/should be already doing where patients are involved(as the next two slides show).

A view from the medical side

"*In a clinical setting, voluntariness may be fragile because of the vulnerability of the patient, the imbalance in knowledge and power between professional and patient and, for some patients, a measure of dependency on the professional……..*
Voluntariness is of even greater concern in other consent situations, such as participation in research and organ or tissue donation. For example, a dependent relationship between patient and professional might lead some patients to feel obliged to volunteer for a research project, or to fear mistakenly that their medical care will be adversely affected if they refuse.
Consent procedures and patient information resources need to be carefully scrutinised to ensure, as far as possible, that patients understand that their decision is voluntary, will not influence their medical care, and that their consent can be withdrawn at any time."

N G Messer Professional-patient relationships and informed consent (University of Wales) BMJ Journals (2004)

Another view from the medical side

"*Unless it is made explicit to them, they [patients] may feel that the extent to which they receive proper care depends on them being cooperative in agreeing to take part in research. To avoid this, the professional must go an extra mile to point out that the quality of care they will deliver is not contingent on the patient agreeing to take part in a research programme; that refusal to participate in research will not lead to victimisation, but that the professional will continue to do their very best for the patient*."

Professor Martin Bobrow CBE, DSc, FRCP, FRCPath, FRCPCH, FMedSci Head, Department of Medical Genetics, University of Cambridge, UK (2003)

HRA Comment (Quoted by IAMS)

- “For the purposes of the GDPR, the legal basis for processing data for health and social care research should NOT be consent. This means that requirements in the GDPR relating to consent do NOT apply to health and care research.”
- HRA states “common law duty of confidentiality is not changing, so consent is still needed for people outside the care team to access and use confidential patient information for research, unless you have support under the Health Service (Control of Patient Information Regulations) 2002 via the Confidentiality Advisory Group in England and Wales or similar arrangements elsewhere in the UK.”
- Is that statement factually correct? No and the response in other EU countries is to view the statement as unhelpful and reflective of a common law mentality.
- Irish Legal experts say (common law) Ireland could be ‘isolated’ within EU after Brexit. Paul Gallagher, a former Attorney General stated in April 2019 that “differences between the two legal traditions of common and civil law have come to a head in the EU.“ He added EU lawmakers have demonstrated “an impatience with the common law”.
- More immediately, if we were to go down the common law consent route we will have no lawful basis for consent declaration process.