

GDPR was always going to be a challenging piece of legislation for researchers

Gillian Vale, 22 October 2020

(plus addendum, 8 August 2021 – pages 9 - 16)

GDPR was always going to be a challenging piece of legislation for researchers. Protracted negotiations and differing positions prior to its enactment meant its content forms a compromise. GDPR is a long regulation, and a difficult read for a non-expert in data protection. The articles / recitals which relate to scientific research need to be identified, and then interpreted, and this is difficult to do, as a strong understanding of the legislation in its entirety is required, to see where scientific research sits, and fits in. The challenges of interpreting and implementing GDPR have been felt by researchers in all EU Member States.¹ Gaining an understanding of GDPR and condensing that in to a series of simple take home messages, and action points is not an easy task. The legislation itself is an exercise in complexity, and highly nuanced². **In hindsight and well in to the third year post GDPR, the take home messages for researchers perhaps should have been: -**

A. Review and Assess: -

1. Review what data / datasets you hold;
2. Assess if the data relates, or could possibly relate, to a human being who is alive and in the EU³;
3. Assess if the data is personal data. You need to be aware that the definition of personal data changes on the 25th May 2018, and now includes pseudonymised data;
4. Assess if the data is sensitive data, now called 'special category' data. Take it as a given that if you hold healthcare data that this is 'special category'.

B. Identify: -

1. Identify who or what organisation is the data controller of the personal data you hold. Far from easy to do. There may be joint data controllers, and there may be data controllers and data processors;⁴
2. Identify your legal basis for processing the personal data you hold. (Remember processing is a by-word for doing absolutely anything with data – if you have it, you are processing!)

¹ The Application of GDPR to Biomedical Research Stakeholder Advisory Opinions to Assist Regulators (November 2019) http://iscintelligence.com/archivos_subidos/input_paper_on_gdpr_challenges_for_research-77623379-v15.pdf

² Clarke N et al (2019) GDPR: an impediment to research? Ir J Med Sci 188:1129–1135. <https://link.springer.com/article/10.1007/s11845-019-01980-2>

³ GDPR also applies to data of non-EU citizens, not living in the EU but whose personal data is being processed in the EU – Footnote written by Mary Kirwan

⁴ Latest European Data Protection Board Guidelines available here: https://edpb.europa.eu/system/files/2021-07/edpb_guidelines_202007_controllerprocessor_final_en.pdf (footnote updated August 2021)

Some comments on legal bases: Identifying your legal basis for processing is far from easy. There is a selection of legal bases for processing personal data in Article 6 of GDPR, and further conditions for processing special category personal data in Article 9. Only choose ‘consent’ as a Article 6 legal basis as a last resort, or when you are not permitted to use any of the other bases. (You will need a lawyer to tell you when you must use consent as your legal basis!) To add to the difficulty, you may be using the personal data you hold for several purposes, and have different legal bases for each purpose.⁵ On the subject of legal bases for processing, you will need to get your head around the fact that a ‘legal basis’ for processing is just a term for ‘something in law which allows you to process’, a justification if you will. And just because you do not use ‘consent’ as your legal basis, this does not mean you will not be getting consent. Consent continues to be important for research, as it has been since the Declaration of Helsinki was signed. Getting consent is the default position of all research and just as much embedded in a researcher’s world order as is applying for research ethics approval.

Back to ‘consent’ as a Article 6 legal basis though, if you decide on ‘consent’ as your legal basis for processing, or have no choice but to do so, you will have some challenges specific to you which other researchers who do not opt for this particular legal basis do not have. See table below -

When consent is used as a legal basis:	When any other legal basis is chosen:
<p>You, as the researcher, must then proceed to get ‘consent’ when conducting research. This does not mean getting ‘consent’ as you know it i.e. consent to take part / Declaration of Helsinki consent / the consent you traditionally get. (although you still need to get this as well!!)</p> <p>The type of ‘consent’ needed is GDPR consent for data processing.</p> <p>You need to get this ‘consent’, and to get it you need to meet a number of criteria (your lawyer can explain) and you need to prove you got it (i.e. keep a record).</p> <p>You will need a lawyer to review your information leaflets and consent forms to assess if you meet the criteria for GDPR consent for data processing.</p>	<p>You, as the researcher, should proceed to get consent as you know it i.e. consent to take part / Declaration of Helsinki consent / the consent you traditionally get. (sometimes referred to in the Republic of Ireland as ‘common law’ consent⁶ and sometimes just as ‘informed consent’)</p> <p>For this consent to be fully informed, you will of course, as always, be letting your participants know what you are doing with their data etc. etc.</p> <p>The ‘consent’ you get doesn’t need to meet all the criteria that GDPR consent for data processing needs to meet, but, that said, when you are processing personal data, GDPR in the broad sense does apply, so it is still a good idea to get a lawyer to look at your information leaflets / consent forms – this time, just to check if you meet the requirements of GDPR in a broad sense – GDPR in a broad sense is based on principles, e.g. transparency etc. And there is prescribed content which must be provided under GDPR.</p>
<p>If your research participant (also called the ‘data subject’) withdraws consent for data processing, you need to honour this, and this means</p>	<p>If your research participant / ‘data subject’ withdraws consent <u>to take part</u>, their <u>participation</u> in your research study will cease.</p>

⁵and to make it even more complicated again you may have several lawful basis for the same processing activity – Footnote written by Mary Kirwan

⁶ Mary Kirwan – presentation – Public Meeting - Irish Academy of Medical Science – April 2019

destroying the data you hold on them. (double-check with your lawyer before destruction)	
If your research participant / 'data subject' does not have capacity to give GDPR 'consent' for data processing, you could run into difficulties (as GDPR does not allow for this scenario)	Capacity shouldn't be an issue (in most EU member states)
<p>GDPR permits 'broad consent' for scientific research</p> <ul style="list-style-type: none"> - Just be careful that when getting broad consent that you fulfil of all of the criteria for a valid GDPR 'consent' for processing. - You will need to give your participants options, as one of the criteria for GDPR 'consent' is 'granulated' ('granulated means a series of graded options) 	Issues around 'broad consent' shouldn't arise
If you have already gotten consent from your data subjects under the old Data Protection Directive (basic consent for processing) you will need to review all your information leaflets and consent forms to check if they meet the criteria for GDPR consent for processing (your lawyer can explain), and if not, you will need to re-contact, and re-consent your research participants to obtain fresh consent.	<p>If you have already gotten consent from your data subjects (i.e. consent to take part, Declaration of Helsinki consent, the consent you traditionally get), or even consent for data processing under the old Data Protection Directive (basic consent for processing) you might need to re-contact your research participants to advise them generally that you hold personal data on them, who the data controller is, what their rights are, and how they can contact the data protection officer. (i.e. provide the prescribed content under GDPR)</p> <p>Re-consent shouldn't apply.</p>
<p>If you need to re-contact, or re-consent, and are unsuccessful in doing this, then you need to make decisions about the personal data you hold.</p> <p>If consent is your legal basis for processing you cannot continue to hold it without GDPR 'consent.'</p>	There is no requirement for re-consent.
If one of your data subjects makes contact, they can exercise their rights e.g. to request a copy of the data you hold of them etc. etc.	If one of your data subjects makes contact, they can exercise their rights e.g. to request a copy of the data you hold of them etc. etc.

C. Act:

1. Get really good legal advice on your legal basis for processing personal data and proceed accordingly;

(Reviewing information leaflets / consent forms is not easy. Re-contacting participants and re-consenting participants is not easy. To re-iterate, it is not recommended to use consent as a legal basis.)

2. Conduct a Data Protection Impact Assessment for your research study. Your data protection officer will help you with this.
3. Ensure your contracts are in place. Generally speaking, if there are joint data controllers, there needs to be a contract; and if there is a data controller and data processor, there needs to be a contract. The focus in GDPR is identifying who the parties are, and defining their responsibilities clearly via a contract.

In summary, GDPR is not for the faint-hearted, and there is a lot to grapple with, understand, and a lot of decisions for researchers to make. If you are not au-fait with data protection, GDPR will force you to become so, and to learn quickly.

Not discussed above are some of the derogations which are allowed under GDPR when processing data for scientific research purposes, and the option for Member States to implement national legislation.

The Irish situation is discussed overleaf.

The Irish Situation

Several papers have been published on the situation in the Republic of Ireland in respect of GDPR and scientific research, and the challenges specific to this jurisdiction. The Minister availed of the option to implement national legislation, and introduced the Health Research Regulations (HRRs) on the 8th August 2018.

There are some positive aspects to the regulations, and they were an attempt to provide clarity in an extremely complex area. They succeeded in doing this by: -

- 1) providing a definition of health research;

The lack of a definition for scientific research in GDPR had been problematic.

- 2) Listing all the safeguards which should be in place in respect of processing of data for health research;

The safeguards for scientific research in GDPR are listed in different articles, and recitals, and it is useful to have them all listed in one place for ease of access, reference, and clarity.

- 3) Adding some safeguards, or perhaps just clearly stating some obvious matters i.e. research needs research ethics approval, and researchers should receive data protection training;
- 4) Stating clearly that a form of broad consent is permitted when processing personal data for health research in the Republic of Ireland, and defining what that is, as follows: -

"for the purpose of the specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof"

Broad consent was permitted under GDPR but was the subject of debate.

Where the HRRs went astray, as has become clear in hindsight, and based on the analysis of legal commentators (Mary Kirwan et al)⁷, was to add this safeguard: -

"(e) explicit consent.....from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof."

It was the above sentence in the HRRs which was to throw Irish research into a state of confusion and disarray, as evidenced by researchers themselves (Blanaid Mee et al)⁸. Although it was not clearly

⁷ Kirwan M et al - What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent"-a legal analysis. Ir J Med Sci. 2021 May;190(2):515-521 <https://link.springer.com/article/10.1007/s11845-020-02331-2>

⁸ Mee B et al - What GDPR and the Health Research Regulations (HRRs) mean for Ireland: a research perspective. Ir J Med Sci. 2021 May;190(2):505-514. <https://link.springer.com/article/10.1007/s11845-020-02330-3>

understood in the chaotic period which followed enactment of the HRRs, it is clearer now that the adding 'explicit consent' as a safeguard meant that all Irish researchers needed to grapple with GDPR consent for data processing. The question of which legal basis to choose for data processing was still an important one, but irrespective of the decision to use consent as a legal basis, 'explicit consent' was now a mandatory safeguard in national legislation. Irish researchers who held personal data for health research, *irrespective of legal basis*, were catapulted en masse into a 're-contact and re-consent' conundrum, which they may have otherwise avoided.

This was an unexpected development. Irish researchers had not yet gotten to grips with GDPR itself, when the Department of Health (DoH) effectively took a policy position that GDPR 'explicit consent' for data processing was to be the default position for all health research taking place in the jurisdiction. Where this was not possible, a mechanism was put in place whereby 'data controllers' could apply for an exemption or 'health research consent declaration' from a Health Research Consent Declaration Committee (HRCDC).

The HRCDC was not a research ethics committee, and applications would take place after research ethics approval. It was to be used by researchers conducting research where they could not obtain GDPR 'explicit consent' for data processing, for any reason, for example – in the case of a cluster randomised trial, or a trial in an emergency setting where research participants lacked capacity, or a study on personal data where obtaining GDPR explicit consent was impracticable. Only the data controller could apply to the HRCDC. They needed input from their data protection officer, and they needed to satisfy the HRCDC of the public interest in conducting the research. In principle, the HRCDC seemed a good idea.

The HRCDC were also to have a second remit, and this would be to help researchers who already held personal data who needed to re-contact, and re-consent their participants. The help, per se, was written in to the HRRs. These researchers had been given a transition period to obtain GDPR explicit consent, and in cases where they were unsuccessful in these attempts, they could apply to the HRCDC. These researchers did not have to fulfil the public interest test. The data controller would apply to the HRCDC to state that consent for data processing under the old Data Protection Directive (basic processing consent) had been obtained, and that consent had not been withdrawn. A 'declaration' could then be granted by the HRCDC, and this would mean that the data could continue to be processed for health research purposes without GDPR 'explicit consent.'

While the above would seem like a good idea to assist researchers caught in the re-contact, and re-consent mire, there was a level of understanding though from the research community that the need for GDPR explicit consent wasn't mandatory in GDPR, and that the 'mire' many found themselves in was one created by national legislation, and one which GDPR didn't automatically place them in. Irish researchers lost more than a year post-GDPR (May 2018) and approximately 11 months post the HRRs (August 2018) to a re-contact, re-consent and/or apply to the HRCDC process. It was an unnecessary waste of time and resources, an expensive exercise, and very frustrating for all involved. And this was on top of GDPR. The system largely caved under the pressure. By early 2019, the Irish Academy of Medical Science was flagging the difficulties being faced (Niamh Clarke et al)⁹ while subsequent

⁹ Clarke N et al (2019) GDPR: an impediment to research? *Ir J Med Sci* 188:1129–1135. <https://link.springer.com/article/10.1007/s11845-019-01980-2>

publications from the Royal College of Physicians in Ireland¹⁰, and the National Office of Clinical Audit¹¹ sought to re-iterate that the HRRs did not apply to clinical audit; clinical audit had been an accidental casualty, caught up in the general confusion arising from the HRRs.

From the perspective of the DoHⁱ, the task at hand had been to draft national legislation on foot of a complex, and unwieldy European Regulation, which would provide 'consistency, clarity and certainty'¹²ⁱⁱ to a variety of stakeholders, and promote a culture of 'transparency, confidence and trust'¹³ in Irish research. During that process, it was probably realised that it would not be clear-cut to identify legal bases for processing, and that consent would not be the legal basis of choice for Irish researchers. Perhaps there were fears about what not choosing consent as a legal basis would mean, especially in scenarios where a researcher was neither getting consent to take part in a research study nor using consent as a GDPR legal basis (This scenario was classed as a waiver of consent).ⁱⁱⁱ Whatever the reasons^{iv}, the decision was made to place all Irish researchers in one shared space, to give them one shared issue to address, and one shared method of addressing it. While one can speculate as to context^v and motivation, the approach taken was not without consequences^{vi} - the scale of the challenge, coupled with the tight timeframe, and an ultra-steep learning curve in double data-protection laws was daunting, as neither the infrastructure, funding, resources nor expertise was in place for such a 'root and branch' endeavour. In addition to this, the HRRs created problems for Irish research in new areas^{vii} where there had been none previously. It can be argued that the HRRs were a distraction from the already complex and difficult GDPR, and that they have had a significant and lasting impact on the environment, ecosystem and atmosphere for research in Ireland.

Going forward, Irish researchers can continue to choose the most appropriate legal bases with which to process personal data for research. Notwithstanding this, they must always get GDPR 'explicit consent', or else a declaration from the HRCDC using a 'public interest' test. There are still concerns that GDPR explicit consent is difficult to get due the number of criteria which need to cumulatively be met to achieve it. (-Mary Kirwan et al)¹⁴

There are some moves from the DoH to formally remove the requirement for explicit consent for retrospective chart reviews; an informal concession type arrangement already exists. There is also some suggestion an amendment will be introduced to allow authorised personnel to pre-screen healthcare records to assess for eligibility for inclusion in a trial; one of the accidental casualties of the HRRs was that Irish research nurses could no longer access healthcare records for pre-screening. Both amendments would be welcomed. The DoH is hoping to address the issue of situations where lack of capacity exists (e.g. emergency research, research in patients with intellectual disability) via separate legislation, which is hoped will allow for proxy consent.

Only when a case is brought in the Irish courts, or perhaps a complaint made by a data subject to the Irish Data Protection Commission in respect of failure to meet the cumulative criteria for GDPR 'explicit

¹⁰ RCPI 'General Data Protection Regulation and Medical Practice' first issue March 2019, revision 1 December 2019 <https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2019/12/GDPR-Guidance-Doc-updated-December-2019.pdf>

¹¹ NOCA 'GDPR Guidance for Clinical Audit' v1, May 2019 http://s3-eu-west-1.amazonaws.com/noca-uploads/general/NOCA_GDPR_Guidance_for_Clinical_Audit_May_2019.pdf v2, June 2019 http://s3-eu-west-1.amazonaws.com/noca-uploads/general/NOCA_GDPR_Guidance_for_Clinical_Audit_version_2_Updated_June_2019.pdf

¹² As per Health Research Board website <https://www.hrb.ie/news/events/archives/health-research-regulations-seminar/>

¹³ As per HRCDC website <https://hrcdc.ie/>

¹⁴ Kirwan M et al - What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent"-a legal analysis. Ir J Med Sci. 2021 May;190(2):515-521 <https://link.springer.com/article/10.1007/s11845-020-02331-2>

consent' will the effect of the Irish Health Research Regulations be fully known. GDPR can be described as fear-based legislation, from fear of hefty fines to fear of lawsuits. It is also rights-based with a view to strengthening the rights of data subjects. Irish researchers need, perhaps more so than researchers in other Member States, to ensure their legal team has reviewed their information leaflets and consent forms. They most definitely have had a rockier introduction to GDPR than their counterparts in other Member States ^{viii}.

More than 2 years on, the situation is that:

- a) Data Protection Impact Assessments are regularly conducted as per GDPR itself.
- b) Data Protection Officers are in place in most hospitals / third level institutions, and advise on data protection impact assessments, again as per GDPR.
- c) Contracts between parties are put in place as per GDPR itself.
- d) Information leaflets and consent forms must be GDPR compliant as per GDPR itself.
- e) Information leaflets and consent forms must be HRRs compliant as per the HRRs i.e. 'explicit consent'.
- f) Where the data subject lacks capacity to give explicit consent, an application to the HRCDC applies.
- g) Where the researcher does not propose to obtain explicit consent (e.g. a cluster randomised trial) an application to the HRCDC applies.
- h) An informal concession with conditions applies in respect of 'retrospective chart reviews'

Above Content valid as of 22 October 2020

Addendum - Amendments to the Health Research Regulations - What happened next?

Gillian Vale, 8 August 2021

Promised amendments to the Health Research Regulations (HRRs) were signed into law on the 21st January 2021. The amendments had been unavoidably delayed due to the COVID pandemic.

The amendments continued to require 'explicit consent' for data processing as a safeguard for the processing of personal data for health research in the Republic of Ireland, but introduced the option of availing of a number of exceptions to this requirement.

This was welcome as it was the 'undifferentiated or blanket' (Mary Kirwan et al)¹⁵ application of the requirement for 'explicit consent' which had been particularly problematic in the original iteration of the HRRs.

Although there are lots of conditions attached in order to avail of the exceptions / exemptions meaning that they have not been resource-neutral, the amendments have largely been successful in addressing a number of the difficulties created by the original HRRs.

The planned amendments in relation to **pre-screening**, and **retrospective chart reviews** came into effect, and also an amendment to allow 'explicit consent' to be deferred until such time as an adult regains capacity (applicable to **emergency research** only) and can give 'explicit consent' himself/herself.

1. Pre-screening amendment

Prior to this amendment and as a consequence of the HRRs, only members of the direct care team could pre-screen records (to assess for eligibility to take part in health research) and research ethics committee (REC) approval was required for pre-screening.

After the amendment, a healthcare practitioner employed by the data controller, or a person studying to be a healthcare practitioner under the direction and control of the data controller, or an employee of the data controller who would ordinarily have access to personal data of individuals held by the data controller for the provision of healthcare, or an 'authorised person' could engage in pre-screening.

An important point however is that the pre-screening within the context of this amendment was to be exempt from the requirement for 'explicit consent' for data processing; and from the requirement for REC approval.

Posters and Notices with prescribed text needed to be put in place by data controllers to avail of this amendment.

Additional requirements, contractual and procedural in nature, applied in order to allow 'authorised persons' to engage pre-screening. As these have not been put in place in many

¹⁵ Kirwan M et al - What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent"-a legal analysis. Ir J Med Sci. 2021 May;190(2):515-521 <https://link.springer.com/article/10.1007/s11845-020-02331-2>

institutions, clinical research nurses employed in clinical research facilities / centres whose employer is an academic institution as opposed to a hospital no longer engage in pre-screening in many hospitals.

2. Retrospective chart review amendment

This amendment introduced the term 'retrospective chart review study' which it defined as a *"health research study carried out by a controller on personal data only for the purposes of health research that has already been obtained by that controller for the purposes of the provision of health care to an individual by the controller."*

The term was useful in distinguishing retrospective chart reviews conducted for purposes other than health research (e.g. clinical audit, service evaluation, provision of care) from retrospective chart reviews conducted for health research purposes.

Following on from the amendment, retrospective chart review studies would also be exempt from the requirement for explicit consent for data processing.

The exemption would be subject to the display of posters and notices with prescribed text.

A similar group of persons could conduct retrospective chart review studies without explicit consent for data processing as could conduct pre-screening, with one exception however – 'authorised persons' could not conduct retrospective chart review studies.

Retrospective chart review studies were not exempt from research ethics approval – the REC was required, as part of that approval, to be satisfied and state *"in writing that the assessment under Regulation 3(1)(c)(i) of the data protection implications of the processing of personal data being carried out by the controller indicates a low risk to the rights and freedoms of individuals."*

Most hospitals and healthcare institutions have put the necessary posters and notices on display to avail of this amendment.

From the researcher's perspective, the amendment not only allows for an exemption to the requirement for explicit consent for data processing, but also an exemption to the requirement for a health research consent declaration from the Health Research Consent Declaration Committee (HRCDC).

From a REC perspective, if the REC is not satisfied that the assessment of the data protection implications of the processing of personal data being carried out by the controller indicates a low risk to the rights and freedoms of individuals, then either an application to the HRCDC for a health research consent declaration or explicit consent from each individual data subject will apply. This would also be the case if it was proposed that any person other than those

permitted to conduct retrospective chart review studies under the amendment were to be involved in processing of personal data as part of the retrospective chart review study.

3. Emergency research amendment

This amendment introduced the concept of explicit consent for processing of personal data being deferred in time: -

“ In exceptional circumstances, where the principal purpose of the processing or further processing of the personal data by a controller is necessary for the provision of health care to an individual and necessary to protect the vital interests of the individual, and where the individual is, by reason of his or her physical or mental incapacity, incapable of giving consent at that time, the personal data may also be processed by that controller for a related health research purpose, where that health research has been approved by a research ethics committee, and the requirement for explicit consent under Regulation 3(1)(e) will be deferred until such time as the individual concerned has the capacity to give such consent.”

This amendment was helpful in respect of emergency research scenarios, and meant that emergency researchers could proceed with their research studies on the basis of REC approval, and explicit consent for data processing which could be deferred in time until the patient regained capacity.

It meant that emergency researchers no longer needed to apply for a health research consent declaration. In some cases, it also meant that where a health research consent declaration had already been obtained, it could be withdrawn.

4. Consent for processing of personal data prior to the 8 August 2018 amendment

The following amendment was also introduced:

“ A controller who is carrying out health research that commenced prior to 8 August 2018 shall not be required to have explicit consent in accordance with Regulation 6 where -

(a) that controller has obtained the consent of the data subject, before that date, to his or her personal data being processed or further processed for the purpose of the specified health research, either in relation to a particular area or more generally in that area or a related area of health research or part thereof, in accordance with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 and the Data Protection Acts 1988 and 2003 and that consent has not been withdrawn, and

(b) that controller has a valid and lawful basis in Article 6 for the processing of the personal data, and the processing of that data meets one of the conditions specified in Article 9(2).”

This amendment constituted another exception/exemption vis-à-vis the need for explicit consent and was aimed at researchers who had acquired consent for data processing under the old Data Protection Directive (i.e. basic processing consent) in that they no longer needed to re-contact/re-consent data subjects and/or apply to the HRDCD.

Unfortunately, this amendment was too late for the many research teams who had already done this (the deadline to do this had been July 2019). It did however facilitate some of these research teams in that some applications for consent declarations were no longer necessary, and could be withdrawn. It was also of help to any research teams who had not applied for health research consent declaration due to uncertainty or confusion.

Those research teams who had not obtained consent for data processing under the old Data Protection Directive (i.e. basic processing consent) continued to rely on health research consent declarations obtained.

5. Copy and Context Amendment

A final amendment was introduced to state that ‘explicit consent’ must be

“recorded and retained by the controller, and a copy of which is provided to the data subject prior to the commencement of the health research in accordance with international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight) for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof.”

This was a new requirement in law that a copy of the ‘explicit consent’ be provided to the data subject prior to the commencement of the research.

Secondly and importantly, the point of note here is that the amended HRRs acknowledge that explicit consent for data processing of personal data for health research as introduced as a safeguard in the HRRs exists alongside and in addition to *“international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight)”* (i.e. Declaration of Helsinki consent)

There is an understanding that in the Republic of Ireland the default position is for ‘explicit consent’ for processing of personal data in addition to informed consent to take part in research.

Hence, there is a recognition of the double-consent requirement in the Republic of Ireland as flagged by Mary Kirwan et al.¹⁶

¹⁶ Kirwan M et al - What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent"-a legal analysis. Ir J Med Sci. 2021 May;190(2):515-521 <https://link.springer.com/article/10.1007/s11845-020-02331-2>

Furthermore, the amendment took effect on the 21st January 2021, and the following month, the European Data Protection Board (EDPB) went on to state:

“when relying on another legal basis in Article 6 other than consent and one of the other exemptions in Article 9 (2) GDPR, the ‘ethical’ requirement of informed consent for participation in the medical research project will still have to be met. In the GDPR-framework, this can be perceived as one of such additional safeguards as foreseen in Article 89(1) GDPR that should be in place when processing personal data for scientific research purposes.”¹⁷

The EDPB phrase *“the ‘ethical’ requirement of informed consent for participation in the medical research project”* equates to informed consent to take part in research.

It is clear that the EDPB favours the use of consent to take part (Declaration of Helsinki consent) as a safeguard as opposed to the Irish dual consent approach, with the add-on of ‘explicit consent’ for processing of personal data.

The EDPB also stated that:

“The requirement of informed consent for participation in a scientific research project can and must be distinguished from explicit consent as a possibility to legitimise the processing of personal data for scientific research purposes.”¹⁸

There are differing views on this however across the various Member States¹⁹ - the EDPB notes that the current situation where a different legal basis for processing may be used in each of the Member States for the same project is not ideal.²⁰

¹⁷ European Data Protection Board Guidelines in reply to questions posed by European Commission here: https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

¹⁸ European Data Protection Board Guidelines in reply to questions posed by European Commission here: https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

¹⁹ DG Health and Food Safety Assessment of EU Member States Rules on Health Data in light of GDPR, https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_en.pdf

²⁰ European Data Protection Board Guidelines in reply to questions posed by European Commission here: https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

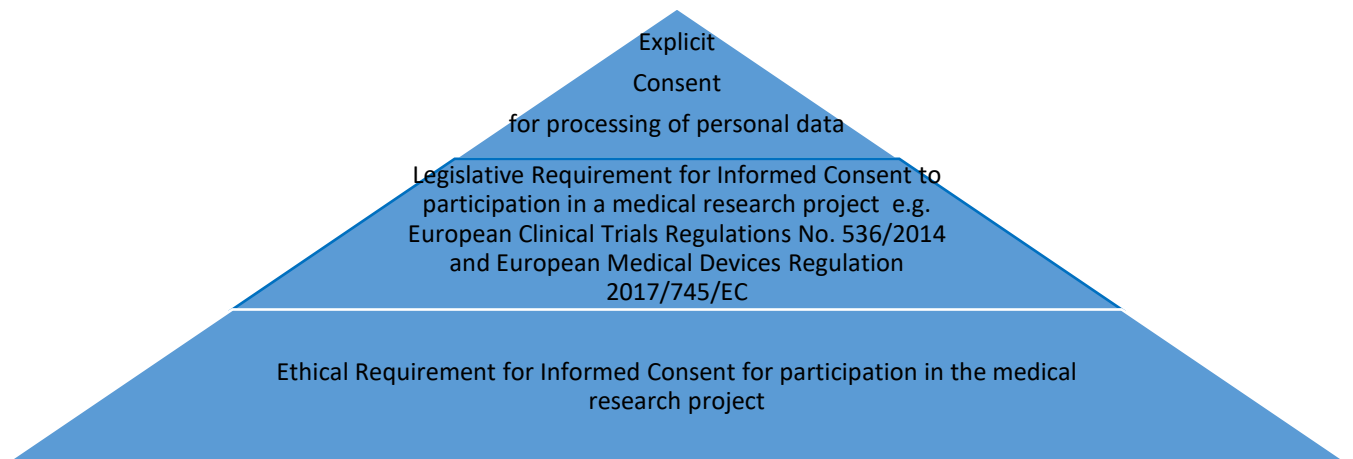
Conclusion:

What occurred in the Republic of Ireland was the introduction of ‘explicit consent’ as a safeguard when processing personal data for health research purposes. The HRRs did not introduce a requirement for ‘consent’ to be used a legal basis for processing personal data under Article 6. Neither did they introduce a requirement for ‘explicit consent’ to be used as a condition for processing special category data under Article 9.

The Regulations specified suitable and specific measures to safeguard the fundamental rights and freedoms of data subjects, and sought to place ‘explicit consent’ for processing personal data as the primary safeguard, and where this was not possible, for a ‘health research consent declaration’ to be the secondary safeguard.

The amendments to the HRRs in January 2021 sought to explain the rationale for the Irish approach, and also to provide for some pragmatic exemptions to the requirement for explicit consent or a health research consent declaration.

The HRRs place ‘explicit consent’ for processing of personal data at the top of the consent pyramid.



While Informed consent to take part may also constitute a legislative requirement in some study types taking place in the Republic of Ireland e.g. European Clinical Trials Regulations No536/2014 and the European Medical Devices - Regulation 2017/745/EC, the ethical requirement for informed consent to take part (i.e. Declaration of Helsinki consent) is not privileged to the same extent as ‘explicit consent’ (Edward Dove et al)²¹

²¹ Edward S Dove, Jiahong Chen, Should consent for data processing be privileged in health research? A comparative legal analysis, *International Data Privacy Law*, Volume 10, Issue 2, May 2020, Pages 117–131, <https://doi.org/10.1093/idpl/izp023>

On the third anniversary on the HRRs, the three options available to Irish researchers are:

1. Obtain explicit consent for processing of personal data , and provide a copy to the participant (data subject) prior to the commencement of the health research;
2. Obtain a health research consent declaration from the HRCDC;
3. Avail of one of the exemptions to the requirement for explicit consent or a health research consent declaration introduced in January 2021.

The residual difficulties for Irish researchers are equivalent to those of researchers across Europe who opt for consent as an article 6 legal basis, or an article 9 condition. Consent for processing of personal data is a high standard of consent to reach and higher than informed consent to take part in research (Mary Kirwan et al)²². It needs to be interpreted in light of any relevant publications from the EDPB.

At the present time, the most recent publication²³ states in respect of **broad consent** -

“26.....when research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset.

27. In addition, adequate safeguards should be in place to enhance the transparency of the processing during the research project and to ensure that the requirements on specificity of consent are met as best and as soon as reasonably possible. This also implies that for instance adequate procedures should be in place that data subjects can use to withdraw or further specify their consent for the use of their health data for scientific research purposes.....

28. It should also be noted that, considering the strict conditions stated by Article 9 GDPR regarding the processing of special categories of data..... when research purposes cannot be fully specified, a controller would be expected to do more to ensure the essence of the data subject's rights to valid consent are served, including through as much transparency as possible and through other safeguards pursuant to Article 89(1) GDPR .

29. Even though Recital 33 GDPR offers some room for flexibility in describing the research purposes for which consent is obtained from the data subject, the requirements in Article 5 GDPR still have to be met in order for the processing to be lawful, fair and transparent.....Adopted research areas are narrowed down, there is an obvious link to the context in which the personal data are collected and reasonable expectations of the data subjects are taken into account.

30. It will also be necessary to take into account any provisions in MS law as allowed for in Article 9(4) GDPR containing further conditions pertaining to processing of health data, since those

²² Kirwan M et al - What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "explicit consent"-a legal analysis. Ir J Med Sci. 2021 May;190(2):515-521 <https://link.springer.com/article/10.1007/s11845-020-02331-2>

²³ European Data Protection Board Guidelines in reply to questions posed by European Commission here: https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaire_research_final.pdf

provisions in MS law could also impact (enable, facilitate or impede) the usability of 'broad consent' in that MS. Q13.

31. Since Recital 33 GDPR requires that the scope of the research purposes for which the health data will be used is narrowed down (e.g. by areas and types of research questions). Therefore 'broad consent' cannot be asked and relied on for processing health data for 'any kind of - unspecified - future research purposes'. However the concept of broad consent could be relied on for different research projects that fall within the scope of that broad consent and that meet certain additional safeguards that will be elaborated on in the EDPB guidelines on processing personal data for scientific research purposes (currently in preparation and due in 2021)."

The EDPB Guidelines on processing personal data for scientific research purposes are currently awaited by the Irish and European research community.

Addendum Content valid as of 31 December 2021

ENDNOTES:

ⁱ An insight into the Department of Health's (DoH) thinking process can be garnered from a published presentation given by officials at a meeting of the Irish Academy of Medical Sciences in November 2019 (Peter Lennon et al) - https://hrcdc.ie/wp-content/uploads/2019/11/IAMS-Presentation_Nov2019_Dept-Health.pdf It would appear that officials in the Department were of the view that: -

1. consent to take part in a study (Declaration of Helsinki consent) was insufficient, and needed to be supplemented by GDPR explicit consent for data processing;
2. consent to take part in a clinical trial (EU Clinical Trials Regulation) was insufficient, and needed to be supplemented by GDPR explicit consent for processing;
3. consent under the old data protection directive (basic processing consent) did not materially differ from GDPR explicit consent;
4. GDPR explicit consent was attainable for Irish researchers (in terms of meeting its cumulative criteria);
5. A power imbalance between the data controller and the data subject would not invalidate GDPR explicit consent.

It seems that the existing model in England/Wales was partially relied upon, but not exactly, in part due to the decision of the UK to leave the EU.

England/Wales emphasizes consent to take part in a study (Declaration of Helsinki consent, also called 'common law consent' in the UK) and where researchers cannot get consent to take part in a research study, they can apply to a Confidentiality Advisory Group (CAG) – the DoH have been open that the aim was to replicate the English/Welsh consent to take part in research study / or application to the CAG, but to do so under the umbrella of GDPR i.e. explicit consent for data processing / or application to the HRCDC.

The DoH view the HRRs as a legislative success, as they succeeded in regulating an area which had previously been unregulated in Irish law, and introduced an innovation (the HRCDC); and stand by their decision to make explicit consent the default position for health research in Ireland. (Peter Lennon et al)

ⁱⁱ It is not without irony that in an attempt to bring clarity, the HRRs caused mass confusion. In pursuit of certainty, they caused the opposite. In an effort to ensure trust and confidence in research, the trust and confidence of those involved in undertaking and facilitating research was lost.

ⁱⁱⁱ Indeed, there had been a previous attempt to regulate waivers via the Health Information Bill, which had been unsuccessful. The HRRs were a success in this regard.

^{iv} At the time the regulations were being drafted, there was an absence of legislation governing research in the Republic of Ireland - the EU Clinical Trials Regulation was the main piece of legislation, and there was no national legislation dealing with research, consent or capacity outside of this. Notably, there was no legislation regulating the use of human tissue in research, or of biobanks. This legislative lacuna for research was one of several considerations, the second being a general lack of confidence in the health system among the Irish public, the most recent scandal at that time related to a decision not to inform patients of false-negative results during cervical smear tests. A third factor which in hindsight might have been in play was the fact that the another government department (enterprise and employment) had plans for further investment in a private company called Genomics Medicine Ireland which specialized in genetic and genomic research - the DoH would have been acutely aware that there was no legislation in place governing genetic and genomic research, and Ireland was heavily reliant on policy

documents and guidelines in the absence of legislation. A final factor for the DoH was time frame - the intention was to have regulations implementing the national derogations for scientific research under GDPR, on the same date as GDPR took effect (25 May 2018) and for there to be no gap in which GDPR only would apply - thus there was significant time pressure in which to interpret GDPR, decide on policy approach, negotiate with the Health Research Board, with Data Protection Commission, the Attorney General, and other government departments, draft legislation, and have it ready for signature by this deadline, or as soon as possible thereafter. The time constraints allowed no time to consult more widely in advance, only to inform select groupings that legislation was imminent, and of its likely content. The final date of signing was 8 August 2018.

^{vi} The HRRs sent research in the Republic of Ireland into a tailspin for approximately 12 - 18 months post the regulations. It placed immense pressure on data protection officers, research ethics committees, academic researchers, and the institutions in which they operated. It galvanised stakeholders in Irish research, but unfortunately, this was against the DoH and the Health Research Board, and resulted in a significant loss of trust in policy makers.

^{vii} While the most pressing problem was re-contact, re-consent, and/or apply to the HRCDC, additional questions were raised by the legislation in terms of who could access records, approach participants, and obtain consent; whether retrospective chart reviews were permissible, whether clinical audit required consent, and whether consent was required to anonymise data already collected.

^{viii} Broadly speaking the approach taken in the UK in relation to the GDPR was: -

1. To advise researchers not to use consent as their legal basis for processing under GDPR / or explicit consent as a condition for processing special category data.
2. To recommend to researchers which alternative legal bases / conditions should be relied upon.
3. To use the mechanism under GDPR for member states to introduce their own legislation, and in particular, to use the UK Data Protection Act to adjust the rights of data subjects whose personal data was processed for scientific research purposes (subject to the scientific research being in the public interest)

The result was that UK-based researchers did not experience the same jolt as Irish researchers, in terms of a scramble to re-contact and re-consent research participants to GDPR explicit consent standards.