Health Research, Consent and the GDPR Exemption

This is a pre-edited version of M.Donnelly and M.McDonagh 'Health Research, Consent and the GDPR Exemption' (2019) 26(2) *European Journal of Health Law* 97-119

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1. Introduction

For health researchers, the General Data Protection Regulation (GDPR)[1] is a mixed blessing. On the one hand, the GDPR allows for a limited exemption from certain obligations, including the requirement to obtain the data subject's consent to processing, in respect of scientific research (which includes health research). On the other, because the GDPR leaves delivery on the research exemption to Member States, it perpetuates the fragmented approach to data protection in health research which had been a problem with the Data Protection Directive (DPD).[2] This, in turn, increases the difficulties for EU cross-border health research projects[3] and impedes the policy goal of a harmonised regulatory framework for health research.[4] If this problem is to be addressed, Member States will have to develop overlapping frameworks for the operation of the health research consent exemption . This is no easy task. However, a better understanding of the legal and normative foundations for the GDPR requirement for consent and for the health research exemption will help Member States in formulating and applying legal standards in this regard. The aim of this article is to advance this understanding.

The operation of the GDPR must be considered against the background of the fundamental rights protected by the Charter of Fundamental Rights of the EU (CFEU).[5] The fundamental rights to respect for private life[6] and data protection[7] are clearly relevant to the processing of personal data in the context of health research. The protection of these rights must however be weighed against the need to protect other rights that are relevant

[1] Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, [2016] OJ L 119/1.
[2] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, [1995] OJ L 281/31.
[3] See M. Timmers, E. Van Veen, A.Maas and E. Kompanje, 'Will the EU Data Protection Regulation 2016/679 Inhibit Critical Care Research', *Medical Law Review,*27(1) (2019) 59-78.
[4] This is an underpinning goal of Regulation (EU) 2014/536 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, [2014] OJ L 158/1.
[5] [2012] OJ C 326/391; see M. Mostert, A. Bredenoord, M. Biesaart and J. van Delden, 'Big Data in medical research and EU data protection law: challenges to the consent or anonymise approach' *European Journal of Human Genetics* 24(7) (2016) 956-960, 957.
[6] CFEU, art. 7.
[7] CFEU, art. 8.

to the conduct of health research, such as the right to health care[8] and freedom of the arts and sciences.[9]

The article begins with a close analysis of the legal requirement for consent in the GDPR and then moves to a normative analysis of the role of consent to data processing in respect of health research. Drawing on Daniel Solove's argument that data protection law and policy should address the substance of data usage rather than taking 'refuge in consent',[10] it shows that the normative weight of the consent requirement differs depending on the context for the health research in question.[11] This more substantive approach to the consent requirement is reflected in the research exemption, which allows for a more nuanced balancing of societal interests in data protection with societal interests in facilitating research. However, because the GDPR articulation of the exemption is set out at an abstract and principled level, in order to understand what the exemption means in practice, it is necessary to identify the ways in which it is given effect in Member States. The final part of the article uses the example of Ireland, which gives effect to the research exemption through the Health Research Regulations 2018,[12] to facilitate a more indepth analysis of delivery on the research exemption.

2. The GDPR Requirement for Consent to Data Processing for Health Research

The traditional approach to data protection in health research tended towards a simple binary: anonymise or obtain consent.[13] Although both concepts remain central under the GDPR, as health researchers have long pointed out, in some areas of health research, anonymisation cannot be achieved without fundamentally undermining the quality and contribution of the research. The discussion here begins by identifying the understanding of anonymisation in the GDPR and explaining the challenges that this poses for health research.

2.1 Health Research and Data Anonymisation

The GDPR applies to the processing of 'personal data'. This is defined as 'information relating to an identified or identifiable natural person'.[14] Thus, as recital 26 makes clear, the GDPR has no application to the processing of anonymous data, including for research

[8] CFEU, art. 35.
[9] CFEU, art. 13.
[10] D. Solove, 'Introduction: Privacy Self-Management and the Consent Dilemma', *Harv L Rev* 126 (2013) 1880-1903, 1880.
[11] See also M.C. Ploem 'Towards an Appropriate Privacy Regime for Medical Data Research'*European Journal of Health Law* 13 (2006) 41-64, 60 who argues that that when developing privacy standards, 'the specific characteristics of the data processing activity concerned should be taken into account'.
[12] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).
[13] See E. Dove and G. Laurie, 'Consent and Anonymisation: Beware Binary Constructions', *British Medical Journal* 350 (2015) h 1139-; M. Mostert *et al* above n. 5.
[14] GDPR, Art. 4(1).

purposes. Recital 26 describes data as anonymous where it does 'not relate to an identified or identifiable natural person' or is 'rendered anonymous in such a manner that the data subject is not or no longer identifiable.'

The Article 29 Data Protection Working Party (WP29) has described anonymisation as a 'technique applied to personal data in order to achieve irreversible de-identification'.[15] Thus, personal data which has undergone pseudonymisation[16] and which could be attributed to a natural person by the use of additional information, cannot be described as anonymised for GDPR purposes.[17] This means that many of the pseudonymisation techniques commonly used in health research, e.g. key coding of data, may not be sufficient to take the processing outside of the ambit of the GDPR requirements.[18] There is inevitably a degree of ambiguity as regards the borderline between pseudonymisation and anonymisation for GDPR purposes. Recital 26 states that, in deciding whether personal data is attributable to a natural person, account must be taken of 'all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person, directly or indirectly.' In ascertaining whether means are reasonably likely to be used, account should be taken of all objective factors, including costs, time and the availability of technology.[19]

As several commentators have identified, the constraints of this understanding of anonymisation mean that the possibility of avoiding GDPR requirements through anonymisaton is not possible for some categories of health research.[20] These include research on rare or unusual conditions; research involving long-term follow up of participants; and research which takes account of social/environmental/economic factors. As Paul Quinn describes, '[w]hilst it may be possible to anonymise such data … doing so may render it devoid of usefulness in terms of potential research value'.[21]

2.2 Consent to Data Processing in Health Research

The requirement for consent to processing in respect of data concerning health derives from two aspects of the GDPR. First, one of the core data protection principles set out in

[15] Opinion, 05/2014 on Anonymisation Techniques, adopted 10 April 2014, 0829/14/EN, 7.
[16] This process is defined in GDPR, Art. 4(5) as 'the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributable to an identified or identifiable natural person'.
[17] GDPR, recital 26.
[18] See P. Quinn, 'The Anonymisation of Research Data - A Pyric Victory for Privacy that Should Not be Pushed Too Hard by the EU Data Protection Framework?', *European Journal of Health Law* 24 (2017) 1-21, 16-17; although note the argument by M. Mourby et al., 'Are 'Pseudonymised' Data Always Personal Data? Implications of the GDPR for Administrative Data Research in the UK' *Computer Law and Security Review* 34(2) (2018) 222-233, 227 that is should be possible for data which has been pseudononymised to be rendered anonymous in some circumstances eg. if pseudononymised data held by a research centre is shared with an external researcher without sharing the key, this data will not necessarily be personal data within the GDPR from the perspective of the external researcher.
[19] See Case C-582/14 *Patrick Breyer v Bundesrepublick Deutschland* [2016] ECLI: EU: C:2016: 779.
[20] See eg R. Fears et al, 'Data Protection Regulation and the Promotion of Health Research: Getting the Balance Right', *Quarterly Journal of Medicine* 107 (2014) 3-5; Quinn above n. 18, 15-16..
[21] Ibid, 16.

art. 5 is that personal data must be processed lawfully, fairly and in a transparent manner. Article 6(1) sets out a list of conditions, at least one of which must be satisfied in order for processing to be considered lawful within the meaning of art. 5. One of these is that the consent of the data subject has been obtained to the processing of the data.[22] Secondly, heightened data protection requirements apply to designated 'special categories of data', which category includes data concerning health.[23] This is defined as meaning 'personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status'.[24] Article 9(1) prohibits the processing of these categories of personal data except in certain limited circumstances, one of which is that the data subject has given explicit consent to the processing.[25] The WP29 has underlined that in the case of special categories of data, meeting the requirements of art. 9 is not necessarily sufficient to ensure lawfulness under art. 6: analysis has to be undertaken on a case-by-case basis as to whether art. 9 'in itself provides for stricter and sufficient conditions, or whether a cumulative application of both Article [6] and [9] is required to ensure full protection of data subjects'.[26]

2.2.1 The Nature of Consent in the GDPR

The GDPR defines consent as 'any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.'[27] This means that, as described by the WP29 Guidelines on Consent ('WP29 Consent Guidelines'),[28] 'if the data subject has no real choice, feels compelled to consent or will enduring negative consequences if they do not consent, then consent will not be valid.'[29] A component of this is that the data subject must also have the right to withdraw consent to processing at any time and it must be as easy to withdraw as to give consent.[30] The difficulty which this poses for some researchers is acknowledged by the WP29 Consent Guidelines.[31] However, unlike some other GDPR rights, for which a derogation is permitted

[22] GDPR, art.6(1)(a).
[23] GDPR, art. 9(1).
[24] GDPR, art. 4(15). Recital 35 states that this 'should include all data pertaining to the person's health status which reveals information relating to his or her past, current or future physical or mental health status'. This comprises information collected in registering for a health care service; any identifying number or symbol; information derived from testing or examining a body part or bodily substance, including from genetic data and biological samples; as well as any information on a disease, disability, disease risk, medical history, clinical treatment, or the physiological or biomedical state of the data subject.
[25] GDPR, art. 9(2)(a).
[26] Article 29 Data Protection Working Party, Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, European Commission, 9 April 2014, 15. The articles referenced in Opinion 06/2014 are arts 7 and 8 of the Data Protection Directive which are the forerunners of arts 6 and 9 respectively of the GDPR.
[27] GDPR, art. 4(11).
[28] Guidelines on Consent under Regulation 2016/679, adopted on 28 November 2017, rev'd and adopted 10 April 2018, WP257 rev.01.
[29] WP29 Consent Guidelines, 5.
[30] Article 7(3).
[31] Above n. 28, 28–29.

in the context of processing for research purposes,[32] there is no provision for derogation from the right to withdraw. Thus, as described by the WP29 Consent Guidelines, 'if a controller receives a withdrawal request, it must in principle delete the personal data straight away if it wishes to continue to use the data for the purposes of the research.'[33]

The GDPR requirement for informed consent to data processing aligns with the standard for informed consent to health research as set out in international ethics standards[34] and in EU legislation.[35] This means that the GDPR conception of consent is one with which all health researchers should be familiar. Informed consent requires the provision of sufficient information to enable the recipient of the information to make an informed choice about whether to participate in the research. The WP29 Consent Guidelines set out the minimum amount of information which should be provided to ensure that consent to data processing is informed. This consists of: the data controller's name (and those of any parties to whom the data will be transferred); the purpose of each of the processing operations for which the consent is sought; what (type of) data will be collected and used; the existence of the right to withdraw consent; information about the use of data for automated decision-making (where relevant); and, the possible risks of data transfers due to absence of an adequacy decision or of appropriate safeguards.[36] Other information may also be required, with the core question being whether the information provided is sufficient in order to 'allow the data subject to genuinely understand the processing operations at hand'.[37]

The procedural conditions for consent to data processing are set out in art.7 of the GDPR. This article places the obligation to demonstrate consent on the data controller.[38] It also requires that where the consent is given in a written declaration that concerns other matters, the request for consent must be presented in a way which is clearly distinguishable from the other matters and in an intelligible and clearly accessible form, using plain and clear language.[39] Thus, in a health research context, consent to data processing must be clearly distinguished from the consent to the research itself.[40] The data subject must be informed of his or her right to withdraw consent prior to giving the consent.[41] S/he must also be informed as to how to exercise the withdrawal right.[42] Again, this resonates with the requirements in respect of withdrawal from the research itself and should not be unfamiliar to health researchers.

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[32] For example, arts 14 (Information to be provided where personal data have not been obtained from the data subject), 17 (right to erasure) and 21 (right to object).

[33] Above n. 28,.29.

[34] The requirement for informed consent to participation in health research is a 'settled ethical and legal principle': D. Brock, 'Philosophical Justifications of Informed Consent in Research' in E. Ėmanuel et al, *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press, 2008): see eg Guideline 9 of the *International Guidelines of Health Related Research involving Humans* (Geneva, 2016) prepared by the Council for International Organizations of Medical Sciences (CIOMHS) in collaboration with the World Health Organisation (WHO).

[35] See eg. Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, [2014] OJ L 158/1.

[36] WP29 Consent Guidelines, 13.

[37] WP29 Consent Guidelines, 13.

[38] GDPR art. 7(1).

[39] GDPR, art. 7(2).

[40] WP29 Consent Guidelines, 28.

[41] Art. 7(3).

[42] WP29 Consent Guidelines, 22 (drawing on GDPR, recital 39).

For data concerning health, there is the additional requirement that the consent be 'explicit'.[43] The WP29 Consent Guidelines state that the term 'explicit' refers to the way consent is expressed by the data subject and requires that the data subject have given an express statement of consent.[44] One obvious way to ensure this is to have the data subject expressly confirm their consent in a written statement. [45] However, the WP29 Consent Guidelines are clear that a signed statement is not the only way to obtain explicit consent. Thus, in the online context, explicit consent could be given by filling in an electronic form, by sending an email or by uploading a scanned document with a signature.[46] The WP29 also states that 'in theory' an oral consent could be sufficient to meet that explicit consent requirement although it acknowledges the difficulties for a data controller in demonstrating explicit consent where that consent is oral only[47] and it is difficult to envisage many circumstances in which a health researcher could safely rely on oral consent to data processing.

2.2.2 Consent to Further Use

One of the fundamental data protection principles provided for in art.5 is that of 'purpose limitation'. This states that personal data shall be collected for specified, explicit and legitimate purposes and may not be further processed in a way that is incompatible with those purposes. The effect of this is to prohibit further or 'secondary' processing of data which arises where data collected for one purpose are then used for another purpose without the data subject's consent (unless the research exemption applies). This prohibition is of particular relevance to health research where further use of data is increasingly common, in particular in epidemiological research, including through retrospective cohort studies and through the combination of existing datasets in the context of big data analytics.[48] As Quinn identifies, the use of data in this way reduces costs in conducting health research and also opens new research possibilities which, given the increases in processing power, may not have been even thought about at the time the data was originally collected.[49]

Two of the recitals to the GDPR provide further detail on the consent requirements in respect of further use. Recital 32 states that consent should cover all processing activities

[43] GDPR, art. 9(2)(a). This enhanced requirement also applies to other forms of 'special' or 'sensitive' data: data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as genetic and biometric data for the purpose of uniquely identifying a natural person and data concerning a natural person's sex life and sexual orientation.
[44] WP29 Consent Guidelines, 18.
[45] Ibid.
[46] Ibid.
[47] Ibid.
[48] See eg M. Paterson and N. Witzleb, 'The Privacy-Related Challenges Facing Medical Research in an Era of Big Data Analytics: A Critical Analysis of Australian Legal and Regulatory Frameworks' *Journal of Law and Medicine* 26(1) (2018) 188-203, 197; P. Quinn and L. Quinn, 'Big Genetic Data and its Big Data Protection Challenges' *Computer Law and Security Review* 34(5) (2018) 1000-1018; B. Huang, W. Mulyasasmita and G. Ragagolol, 'The Path from Big Data to Precision Medicine', *Expert Review of Precision Medicine and Drug Development* 1(2) (2016) 129-143.
[49] Above n. 18, 2.

carried out for the same purpose or purposes and that where the processing has multiple purposes, consent should be given for all of them. However, recital 33, which is concerned with consent to certain areas of scientific research, recognises that it is often not possible to fully identify the purpose of data collection at the time of collection. It therefore stipulates that data subjects should be able to give their consent to the use of their data for certain areas of scientific research when this is in keeping with recognised ethical standards for scientific research. This recital also states that data subjects should be afforded the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

Further elaboration on the scope of this broader consent is provided by the WP29 Consent Guidelines.[50] These make it clear that recital 33 does not disapply the obligations with regard to the requirement for specific consent to the processing of data for scientific research purposes. The Guidelines state that, when regarded as a whole, the GDPR cannot be interpreted to allow a controller to 'navigate around the key principle of specifying purposes for which the consent of the data subject is asked.'[51] This means that where research purposes cannot be fully specified, the controller must seek other ways to ensure that the 'essence of the consent requirements' are met.[52] The WP29 gives the example of allowing a data subject to consent for a research purpose in general terms and for the specific stages of the research project that are known at this time. Then, as research advances, consent for subsequent stages can be obtained before the next stage begins.[53] This resonates with the view of informed consent in contemporary ethical guidance on health research whereby consent is conceptualised as an ongoing process rather than a single, once-off event.[54]

The WP29 Consent Guidelines also identify other ways in which the deficiencies arising from lack of purpose specification at the outset of the research can be mitigated. These include increased transparency, such as the regular provision of updates as the research project progresses, thus placing the research subject in a position to use his or her right to withdraw; and having a comprehensive research plan in place and available to data subjects, which could compensate for a lack of purpose specification.[55]

2.2.3 Consent and Capacity

Although the GDPR does not explicitly require that the data subject must have the capacity (or competence) to provide the required consent to data processing, this would seem to be implicit in the requirement that consent must be an 'informed … indication of the data subject's wishes'.[56] The issue of capacity to consent arises in respect of two categories of

[50] WP29 Consent Guidelines, 28-9.
[51] Ibid, 28.
[52] Ibid, 29.
[53] Ibid, 29.
[54] See eg. Guideline 9 of the CIOMHS Guidelines above n. 34.
[55] WP29 Consent Guidelines, 29.
[56] GDPR, art. 4(11).

data subjects: children and adults with impaired capacity. The first of these categories is catered for in the GDPR although not in respect of research; the second is not addressed at all.

The GDPR recognises that children merit special protection in respect of their personal data[57] because 'they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data'.[58] However, the issue of children's consent to data processing is addressed only in the context of the provision of 'information society services'.[59] The age of consent to data processing in this context is set at 16 years although Member States are permitted to provide for a lower age, subject to a limit of 13 years.[60] The general rules relating to consent provided for in the GDPR also apply to consent given by children. The WP29 Consent Guidelines recognise the need for special care to be taken in ensuring that sufficient information is supplied to children to render their consent informed. It states that where the targeted audience includes data subjects who are underage, data controllers are expected to make sure that such information is understandable for minors.[61] The GDPR makes specific reference to children in terms of the transparency. Art 12 requires data controllers to take appropriate measures to meet their transparency obligations 'in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child'. This provision is supported by recital 58 which states that, where appropriate, a controller should make sure the information provided is understandable for children.

Beyond these limited measures, the matter of children's consent to data processing is not specifically addressed in the GDPR but is left to be dealt with by Member States. In the UK context, for example, the Information Commissioner has expressed the view that 'the general rule in the UK is that you should consider whether the individual child has the competence to understand and consent for themselves (the '*Gillick* competence test')'.[62] The matter of adults who lack capacity to consent to data processing is not addressed at all in the GDPR. Given the wide range of approaches to consent and capacity across the EU member states, it is easy to understand the lack of engagement with the issue by the GDPR. Nonetheless, as discussed below this creates significant problems for certain kinds of health research.

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[57] See recitals 38 and 75.
[58] GDPR, recital 38.
[59] GDPR, art. 8(1). As summarised by WP29 Consent Guidelines, 24 this covers contracts and other services that are concluded and transmitted online.
[60] GDPR, art. 8(1). For children below this age, consent to processing is lawful only if given by the holder of parental responsibility over the child.
[61] WP29 Consent Guidelines 13.
[62] UK Information Commissioner, Guide to the General Data Protection Regulation: Consent: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/consent/what-is-valid-consent/#what9; see further M. Taylor, E. Dove, G. Laurie, D. Townend, 'When Can the Child Speak for Herself?: The Limits of Parental Consent in Data Protection Law for Health Research', *Medical Law Review* 26(3) (2017) 369-391.

2.3 The (Varying) Normative Case for the Consent Requirement to Data Processing in Health Research

As Daniel Solove identifies, since the 1970s, the basic components of the legal framework for data protection have remained largely unchanged.[63] Solove describes this approach as 'privacy self-management'.[64] The approach 'attempts to be neutral about substance - whether certain forms of collecting, using or disclosing personal data are good or bad - and instead focuses on whether people consent to various privacy practices.'[65] However, Solove argues that for a range of reasons,[66] '[p]rivacy self-management cannot achieve the goals demanded of it, and it has been pushed beyond its limits'.[67] This does not mean that the requirement for consent to data processing should be abandoned but rather indicates the need for a more reflective approach to consent. Part of this, Solove argues, should encompass a move towards evaluating the substance of the data usage in question when making policy decisions about data protection rather than relying on consent to do all the normative work.[68]

If we adopt this more substantive approach to data processing in health research, it becomes clear that there are differences in the ways in which consent works to strike a balance between societal interests in protecting personal data and societal interests in facilitating research. Separating these out is a first step in evaluating the way in which Member States approach the health research exemption. We can begin with the 'normal' situation of an adult with capacity where data is being collected for use in the future. Most of the time, in this situation a strong normative case may be made that a requirement for consent to data processing should operate alongside the requirement for consent to research. It is true that requirement to obtain consent to data processing (and to carry out the necessary steps in respect of further processing) adds to researchers' administrative burdens. However, the mere fact of administrative inconvenience is not sufficient to outweigh the benefits of informed consent, which include showing respect for the contribution of the research participants whose data is used and without whom the research would be impossible.[69] Possibly the most persuasive case for an exemption from the consent requirement is where, because of the nature of the data in question, the withdrawal of consent would fundamentally undermine a research project which is of

[63] Above n. 10, 1880.
[64] Ibid.
[65] Ibid.
[66] These include the difficulties caused by individuals' cognitive biases and bounded rationality and by the structural problems in contemporary data usage: see Solove ibid., 1881.
[67] Ibid., 1903. For similar assessments, see eg. A.Mantelero, 'The Future of Consumer Data Protection in the EU: Rethinking the 'Notice and Consent' Paradigm in the New Era of Predictive Analytics', *Computer Law and Security Review* 30 (2014) 643-660; F. Cate and V. Mayer-Schönberger, 'Notice and Consent in the World of Big Data', *International Data Privacy Law* 3(2) (2013) 67-73; E. Gratton, 'Beyond Consent-Based Privacy Protection' available at https://eloisegratton.openum.ca/files/sites/4/2016/07/Gratton_Beyond-Consent-based-Privacy-Protection_-July2016.pdf.
[68] Ibid. 1902-1903.
[69] As described by Alan Wertheimer, '(Why) Should we Require Consent to Participation in Research?', *Journal of Law and the Biosciences* 1(2) (2014) 137-182, 181-182, 'as a general ethical principle, we are not entitled to ask others to spend time on our projects - whatever they are - without their undeceived consent.'

significant public interest. There may be other justifications depending on the specific feature of the research in question.[70]

The issue becomes more complex in respect of historic data sets collected prior to the coming into force of the GDPR. While the DPD required explicit consent to data processing (and made no provision for an exemption for research), Member States gave effect to this requirement in very different ways.[71] Moreover, in some cases, the possibilities for further use of data in health research were not even contemplated at the time when consent was obtained. A retrospective strict application of the consent requirement could result in valuable data being 'wasted'. This has an ethical dimension arising from a failure to maximise existing data. The normative balance is therefore shifted. Again there is a case to be made for the requirement for informed consent to data processing. However the ethical principle of maximising data and avoiding waste must be part of the analysis. This approach is supported by the need to take account of the right to health care (including 'preventive healthcare'[72]) and freedom of the sciences. It can be argued that a retrospective strict application of the consent requirement in the health research context could hinder preventive approaches to health care. Freedom of the sciences and in particular freedom of research has been described as creating 'optimal conditions for our collective search for knowledge'[73] and the imposition of a retrospective consent requirement would clearly stand in the way of such a search for knowledge.

The consent issue become even more complex where the data subjects do not have capacity to give personal consent to data processing. As identified above, the GDPR is largely silent on how the consent requirement should operate in respect of data processing for health research for two categories of data subjects for whom capacity to consent to data processing is an issue: children and adults who lack capacity to make decisions about consent. Most European jurisdictions operate on the basis of proxy consent to health research in these situations and this is also the approach taken in applicable European legislation. The Clinical Trials Directive;[74] the Clinical Trials Regulation[75] and the Medical Devices Regulation[76] all require that consent to participation in a clinical trial by a 'minor'[77]

[70] See analysis of possible justifications for non-consensual research in L. Gelinas et al, 'When and Why is Research without Consent Permissible?', *Hastings Center Report* 46(2016) 1-9.
[71] For a (rather outdated) overview, see D. Beyleveld et al, *The Data Protection Directive and Medical Research Across Europe* (Ashgate, 2004); see also summary in Timmers et al, above n. 3, 63-70.
[72] CFEU, art. 35.
[73] T. Wilholt, 'Scientific Freedom: Its Grounds and Their Limitations' *Studies in History and Philosophy of Science Part A*, 42(10) (2010) 174-181, 175.
[74] Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, [2001] OJ L 121.
[75] Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, [2014] OJ L 158/1.
[76] Regulation (EU) No 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, [2017] L 117/1.
[77] This is defined as a 'subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent: see Reg (EU) No 536/2014, art. 2(18).

or an 'incapacitated subject'[78] must be given by his or her legally designated representative (i.e. proxy consent).[79] In both the Clinical Trials Regulation and the Medical Devices Regulation, the proxy consent is supplemented by the requirement that the researcher provide information to the minor/incapacitated subject in a manner which facilitates his or her understanding;[80] and the requirement that the minor/incapacitated subject's express wish not to participate in or to withdraw from the trial should be respected where s/he 'is capable of forming an opinion and assessing the [relevant] information'.[81] There are also other protective/balancing measures relating to risk and benefit specific to the clinical trials/clinical investigations context.

Proxy consent (whether to participate in research or to data processing in the context of the research) does not carry the same normative force as personal consent. Instead, it 'imitate[s] the checks and balances normally provided by the subject'[82] while leaving unresolved the fundamental (and ethically complex) question of the basis on which a proxy decision-maker can make the decision to consent to health research (or to accompanying data processing).[83] This is one reason why the contemporary legal measures which utilise proxy consent to health research include a broader range of protective/balancing measures. There are conceptual questions to be asked around the legitimacy of proxy consent to data processing in all events (although these are not within the scope of this article).[84] For present purposes, the relevant point is that there may be better ways of protecting the privacy rights of data subjects who cannot give personal consent than relying on proxy consent.

In addition to the normative issues around proxy consent, there are also practical matters which make the operation of the consent requirement more difficult especially in respect of consent to further use of data. The WP29 has posited that where proxy consent has been given in respect of a minor, the minor may revoke this consent on reaching the age of majority and that if processing of health data is to continue after the age of majority, the fresh consent of the data subject must be obtained.[85] The WP29 also appears to envisage a period of parallel consent whereby as the child advances in maturity, the consent of both

[78] This is defined as a 'subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving informed consent according to the law of the Member State concerned: Reg (EU) No 536/2014, art. 2(19).

[79] Reg (EU) No 536/2014, art. 31(1)(a) (incapacitated subjects); art. 32(1)(a) (minors).

[80] Reg (EU) No 536/2014, art. 31(1)(b) requires that the incapacitated subject have received relevant information 'in a way that is adequate in view of their capacity to understand it' while art. 32(1)(b) requires that information must be provided in a way adapted to the minor's 'age and mental maturity'. See also Regulation (EU) No 2017/745, art. 64 (b) and art.65(b)

[81] Reg (EU) No 536/2014, art. 31(1)(c) (incapacitated subjects); art. 32(1)(c) (minors); Regulation (EU) No 2017/745, art. 64 (c) and art.65(c).

[82] K. Liddell et al, 'Medical Research Concerning Incapacitated Adults: Implications of the EU Clinical Trials Directive 2001/20/EC', *Medical Law Review* 14 (2006) 367-417.

[83] See R. Berg, 'An Ethical Analysis of Proxy and Waiver of Consent in Critical Care Research', *Acta Anaesthesiologica Scandinavica*, 57 (2013) 408-416.

[84] It is difficult to see that proxy consent to data processing (or indeed to research) is compatible with Art. 12 of the United Nations Convention on the Rights of Persons with Disabilities, A/RES/61/106 Annex 1, at least as interpreted by by the Committee on the Rights of Persons with Disabilities in General Comment No 1: Art. 12 Equal Recognition before the Law, CRPD/C/GC/1.

[85] Article 29 Data Protection Working Party, Opinion 2/2009 on the Protection of Children's Personal Data (General Guidelines and the Special Case of Schools) 398/09/EN, WP 160, 5.

child and parents is obtained. While this is consistent with the Convention on the Rights of the Child, as Mark Taylor and colleagues identify, it leaves researchers in a difficult position in determining the scope of their obligations.[86] Similar practical issues arise in respect of adults lacking capacity. Contemporary legal approaches reject the view of incapacity as a fixed or immutable state but instead recognise that capacity/incapacity are time and task specific.[87] Thus, even if proxy consent is legally recognised, its status persists only so long as the 'incapacitated subject' lacks capacity. This then opens up the question of what steps a researcher must take to ensure the ongoing status of proxy consent.

These practical problems make research involving participants who cannot give personal consent to data processing very difficult and run the risk that this kind of research would become so administratively difficult that it would effectively cease. This in turn raises an issue of distributive justice. Children and adults with impaired capacity should have an equal entitlement to the benefits of health research as other members of society who can give personal consent. Their exclusion from participation would mean that their specific needs would not be met. Thus, the situation of children and adults lacking capacity provides a strong normative argument in favour of an approach to data processing for health research purposes in these situations which is not reliant on (proxy) consent.

3. Consent and the (Health) Research Exemption

The express recognition of a research exemption is one of the defining features of the GDPR. While research is not defined in the body of the GDPR, recital 159 states that research should be interpreted broadly and outlines a range of examples of activities coming within the scope of scientific research.[88] These clearly are sufficiently broad to encompass both publicly and privately/commercially funded health research.[89]

3.1 The Operation of the Research Exemption

The GDPR's research exemption is set out in art. 9(2)(j). This states that the prohibition on the processing of special categories of personal data (which includes health data) does not apply where the processing is necessary for inter alia scientific research purposes and is

> 'in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.'

[86] Above n. 62, 377.
[87] This approach is generally given effect through the functional approach to capacity assessment: see eg. the Mental Capacity Act 2005 (EW).
[88] There include technological development and demonstration, fundamental research, applied research and privately funded research, and studies conducted in the public interest in the area of public health.
[89] See K. Pormeister 'Genetic data and the research exemption: is the GDPR going too far?', *International Data Privacy Law*' 7(2) (2017) 137-146, 138.

Thus, this serves as an alternative to the explicit consent requirement, as set out in art. 9(2)(a).[90]

Article 9(2)(j) must be read in conjunction with the standards for lawful processing under art. 6(1). The WP29 has indicated that unless art. 9 'in itself provides for stricter and sufficient conditions' for the processing of personal data than art. 6,[91] a cumulative application of both articles is required to ensure full protection of data subjects. As there are substantive differences between the research exemption in art. 9(2)(j) and the lawful processing grounds in art. 6, and art. 9(2)(j) is not simply a more demanding version of any of the grounds for lawful processing provided for in art. 6, it is clear that the processing of personal data for research purposes must also meet the lawful processing requirements of art. 6. [92]

Two bases (besides consent) for lawful processing are potentially relevant to health research. The first is where the processing is necessary for the performance of a task carried out in the public interest.[93] Unsurprisingly, the WP29 has confirmed that health research can be viewed as task carried out in the public interest[94] and that this may be the case even where the research is carried out by a private sector body or commercial entity.[95] However, this is not inevitably the case; it is possible to conceive of health research which has an entirely commercial purpose and cannot be regarded as being in the public interest. The UK Medical Research Council has identified this basis as the one that UK public bodies such as universities, the NHS and research council institutes are most likely to rely on for the processing of personal data for research purposes, on the grounds that such authorities are funded by the public purse in order to conduct tasks that are considered to be in the public interest.[96]

The second lawful processing ground is where processing is necessary for the purposes of the legitimate interests pursued by the data controller or by a third party.[97] Reliance on the legitimate interests condition is restricted to the extent that art.6(1)(f) states that any such interests can be overridden by 'the interests or fundamental rights and freedoms of the data subject'. The WP29 has taken the view that application of the legitimate interests condition calls for a balancing test in which the legitimate interests of the controller (or third parties) must be balanced against the interests or fundamental rights

[90] As a further element of the research exemption, the GDPR allows the EU or Member States to adopt laws which allow for derogations from certain of rights of the data subject where personal data is processed for scientific research purposes. Such derogations may only be granted where the rights derogated from are likely to render impossible or seriously impair the achievement of the scientific research purposes and only as are necessary for the fulfilment of these purposes. These derogations must also be subject to the safeguarding requirements of art.89(1).

[91] Above n. 26, 15.

[92]This is supported by the UK Medical Research Council, General Data Protection Regulation (GDPR): Consent in Research and Confidentiality: Guidance Note 3 (March 2018, updated May 2018).

[93] GDPR, art. 6(1)(e).

[94] Many of the developments in contemporary healthcare are derived from the efforts by researchers, especially in the latter half of the 20th century: see eg J. Le Fanu, *The Rise and Fall of Modern Medicine* (London: Abacus, 1999).

[95] WP29 above n. 26, 22 recognises the increasing tendency to outsource processing in health research to the private sector.

[96] Guidance Note 3, above n. 92, 2.

[97] GDPR, art. 6(1)(f).

and freedoms of the data subject.[98] Guidance as to the meaning of 'legitimate interests' can be found in recital 47 which states that controllers should take into account 'the reasonable expectations of data subjects based on their relationship with the controller'. The legitimate interests ground does not apply to processing carried out by public authorities in the performance of their tasks.[99] It could, however, be relied upon by private and/or commercial entities that carry out health research. This ground is identified by the UK Medical Research Council as being likely to provide the most appropriate basis for the processing of personal data for health research purposes by charitable research institutes that are not public authorities, and by commercial companies.[100]

In addition to the lawful processing requirement, in order to avail of the research exemption, the research must also comply with the framework developed by the Member State in which it is conducted in accordance with the requirements of art. 89(1). Article 89(1) requires that the framework must be proportionate to the aim pursued and must respect 'the essence of the right to data protection' and provide for 'suitable and specific measures' to protect the rights of the data subject. Article 89(1) also requires that processing for scientific research purposes must be subject to appropriate safeguards for the rights and freedoms of the data subject, including that technical and organisational measures are in place, in particular to ensure the principle of data minimisation.

While setting out general parameters, art. 89(1) leaves the detail of the framework to be developed by Member States. As identified in the Introduction, the result is continued fragmentation in data protection standards for health research across the EU. The final part of this article presents a flavour of this fragmentation by focussing on the approach taken in one Member State, namely Ireland. Viewing the matter through a jurisdiction-specific lens allows for a better understanding of the challenges faced in establishing an appropriate balance between data protection/privacy and right to health/scientific freedom norms.

4. Delivering on the Health Research Exemption: The Irish Experience

In Ireland, those elements of the GDPR which are left to the discretion of Member States, including the research exemption, are given effect in the Data Protection Act 2018 (DPA 2018) and, in the case of health research, in the Health Research Regulations 2018 (HRR). The HRR came into force on 8 August 2018.[101] In addition to setting out the required

[98] Guidance Note 2, above n. 92, **Error! Bookmark not defined.**23.

[99] In theory, the ground could apply to public authorities processing personal data otherwise than in the performance of their tasks, although it is not clear when this would arise; see E. Dove, 'The EU General Data Protection Regulation: Implications for International Scientific Research in the Digital Era' (University of Edinburgh School of Law, Research paper Series No. 2018/28), 19.

[100] Guidance Note 3, above n.92, 3.

[101] The DPA 2018, s. 54 permits the processing of data concerning health where this is necessary and proportionate for scientific research purposes subject to 'suitable and specific measures being taken to safeguard the fundamental rights and freedoms of data subjects' and respect for the principle of data minimisation. The DPA 2018 sets out some 'suitable and specific measures' and allows for secondary legislation (or regulations) to be made to identify additional 'suitable and specific measures' in designated contexts: DPA 2018, s. 36(2). This provides the statutory basis for the HRR.

'suitable and specific measures' under art.89(1), the HRR also provide a mechanism for researchers to apply for an exemption from the consent requirement.[102]

Health research is broadly defined in the HRR as covering scientific research for the purposes of human health. It encompasses research regarding innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury; research with the goal of improving the diagnosis and treatment of human disease and injury and of improving the quality of life of individuals; research with the goal of understanding normal and abnormal functioning at molecular, cellular, organ and whole body levels, research with the goal of improving the efficiency and effectiveness of health professionals and the health care system; and, research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.[103]

4.1 'Suitable and Specific Measures'

The HRR set out the 'suitable and specific measures' with which data controllers must comply. These obligations are cumulative and therefore the other obligations all continue to apply notwithstanding the consent exemption.

First, arrangements must be in place to ensure that personal data is processed 'as is necessary to achieve the objective of the health research' and not in such a way that damage or distress is or is likely to be caused to the data subject.[104] Secondly, appropriate governance structures must be in place. These include ethical approval of the research by a research ethics committee (REC);[105] specification of the controller/joint controllers of the data; specification of any data processers involved; specification of anyone who provides funding for, or otherwise supports, the research project; specification of any person other than a joint controller/data processer with whom it is intended to share any of the data collected (including where this data has been anonymised/pseudonymised); and, the provision of training in data protection law and practice for the individuals involved in carrying out the health research.[106] Thirdly, designated processes and procedures relating to the management and conduct of the health research must be in place. This requires that there must be an assessment of the data protection implications of the research and where this indicates a high risk to the rights and freedoms of individuals, a data protection impact assessment (DPIA) must be carried out.[107] Measures must also be in place that demonstrate

[102] HRR, reg. 5(1). On the HRR, see M. Donnelly and M. McDonagh, 'Health Research and Data Protection: Researchers' Obligations under the GDPR Framework' *Medico-Legal Journal of Ireland* 24(2) (2018) 80-92.
[103] HRR, reg.3(2).
[104] HRR, reg.3(1)(a).
[105] HRR reg.4(2) sets out a range of issues which must be consider ethical issues (and therefore part of the review process by the REC).
[106] HRR, reg.3(1)(b).
[107] The Irish Data Protection Commission provides a List of Types of Data Processing Operations with require a DPIA: see https://www.dataprotection.ie/sites/default/files/uploads/2018-11/Data-Protection-Impact-Assessment.pdf, accessed 12 March 2019.

compliance with the data minimisation principle and to protect the security of the personal data, as must arrangements to anonymise, archive or destroy personal data once the health research has been completed. There must also be in place technical and organisational measures designed to ensure that processing is carried out in accordance with the GDPR, as well as processes for testing and evaluating the effectiveness of these measures.[108] Fourthly, there must be arrangements to ensure that personal data is processed in a transparent manner.[109]

Finally, there is a requirement that the explicit consent of the data subject have been obtained (unless the exemption applies) prior to the commencement of the health research.[110] The consent in question may be in relation to a particular area of the research or can be more general in relation to research 'in that area or a related area of health research, or part thereof'.[111] A question arises as to whether this is sufficiently precise to be consistent with the WP29 Consent Guidelines as regards purpose specification.[112] The consent requirement is retrospective, in that it applies also to any further processing of data collected prior to the coming into force of the HRR. However, data controllers were afforded a period (up to 30 April 2019) to get the required explicit consent in place.[113] There is no reference in the HRR to how consent should be addressed in situations involving minors or adults who lack the capacity to consent.

4.2 The Public Interest Exemption from Consent

The HRR allow health researchers to apply to the Health Research Consent Declaration Committee for a declaration of exemption from the consent requirement. The Committee, which was established under the HRR, must comprise between 15 and 21 members who, in the view of the Minister for Health, are suitably qualified, including having knowledge of data protection, research ethics and statistics.[114] Decisions of the Committee may be appealed to an Appeal Panel which must be specially constituted by the Minister for Health[115] within 40 working days of the receipt of the request.[116]

4.2.1 Basis for the Exemption

The HRR reflect the normative difference regarding the timing of the data collection identified above. Thus, they distinguish between the requirements for a declaration in respect of research commenced before the HRR came into force (8 August 2018) and research commenced after this time. For research commenced after 8 August 2018, the

[108] HRR, reg.3(1)(c).
[109] HRR, reg.3(1)(d).
[110] HRR, reg. 3(1)(e).
[111] HRR, reg.3(1)(e).
[112] See text following n. 50 above.
[113] HRR, reg.6(1).
[114] HRR, reg.7. See Schedule to the HRR.
[115] HRR, reg.11(1). The Appeal Panel consists of three persons, none of whom is a member of the Committee, and may determine its own procedure: reg.11(3).
[116] HRR, reg.11(2).

application made is for a declaration that the public interest in carrying out the research *significantly* outweighs the public interest in requiring the consent of the data subject.[117] Prior to making the application, the data controller must carry out a DPIA; obtain the approval of the research by an REC[118] and appoint a data protection officer.[119] There is also a lengthy set of procedural requirements.[120] Written information must also be provided which demonstrates that the public interest in the research significantly outweighs the public interest in obtaining explicit consent and sets out why it is proposed not to seek consent.[121] The Committee may only make the declaration that consent is not required where all of the requirements under the HRR are met *and* it is satisfied that the public interest in carrying out the research significantly outweighs the public interest in obtaining consent.[122]

For research already commenced by 8 August 2018, the controller may apply for a declaration that explicit consent is not required for processing or further processing of the data after 8 August 2018 on one of two grounds.[123] The first is the significant public interest ground, as outlined above. The second is that the controller obtained the consent of the data subject to the processing of the data under the Data Protection Acts 1988 and 2003 (DPA 1988 and 2003) and that this consent has not been withdrawn. Unlike the GDPR, the right to withdraw consent is not explicitly stated in the DPA 1988 and 2003 and there is no requirement to inform data subjects of the existence of this right. It might therefore be presumed that few data subjects were, in fact, aware of their right to withdraw. The procedural requirements are the same as those for post-8 August 2018 applications, with one difference: if the data controller applies on the basis of having obtained the consent of the data subject under the DPA 1988 and 2003, he or she must demonstrate that he or she has made reasonable efforts to contact the data subject for the purpose of reobtaining consent from that data subject.[124] The Committee may only make the declaration that explicit consent is not required where all of the requirements under the HRR are met *and* it is satisfied that the public interest in carrying out the research significantly outweighs the public interest in obtaining consent *or* that the data subject had consented under the DPA 1988 and 2003 and this consent has not been withdrawn.[125]

4.3 The Irish Approach in Perspective

Although the HRR give effect to the research exemption, they do so rather begrudgingly. The underlying policy message is that consent is always the ideal. This is reflected in several aspects of the HRR. First, the standard which the Committee must apply is that the public interest in the research *significantly* outweighs the public interest in obtaining explicit

[117] HRR, reg. 5(1).
[118] HRR, reg.5(3).
[119] HRR, reg.5(4)(c)(vi). The functions of a "data protection officer" are outlined in DPA 2018 s.88(5).
[120] HRR, reg.5(4)(a).
[121] HRR, reg.5(4)(e).
[122] HRR, reg.5(5).
[123] HRR, reg.6(4).
[124] HRR, reg.6(7)(e)(ii).
[125] HRR, reg.6(8)(b).

consent. This wording, which goes beyond what is required by the GDPR,[126] restricts the scope of the Committee in granting applications for a declaration. The normative balance is struck in favour of obtaining consent, even in those situations where, for the reasons identified above, consent lacks normative force because the data subject lacks capacity to give consent. Secondly, the procedures and requirements which the HRR require are likely to quell the enthusiasm of even the most enthusiastic researcher. Every research project in which a consent exemption is sought (no matter how small) will require REC approval; a DPIA; the appointment of a data protection officer and compliance with substantial procedural requirements. Taken together, these requirements are likely to have a chilling effect on health research, especially in respect of participants for whom personal consent is not an option.

The Irish position is in striking contrast with that adopted in the UK. The Medical Research Council (UK) advises that "consent is not likely to be … the condition to process special categories of personal data, for research"[127] and that the 'GDPR's consent requirements don't often apply to research.'[128] Thus, we see two neighbouring jurisdictions, both in the common law tradition, with entirely different approaches to the role of consent and the application of the research exemption.

5. Conclusion

This article reflects the ongoing tension between two important social values: protecting personal health data on the one hand and facilitating health research, with its attendant benefits, on the other. In a contemporary context, this tension is played out against a backdrop of data commodification, market pressures and monetary incentives.[129] In addressing this tension, the GDPR reiterates the importance of consent and elevates the requirement for consent to processing for certain categories of data, including health data. In this, the GDPR position is largely consistent with the universally accepted legal and ethical requirement for informed consent to health research. However, the GDPR also recognises that in some circumstances, the requirement for consent should be made subordinate to other requirements (provided there are suitable and sufficient safeguards for the data subject's rights).

The article has argued that the subordination of the consent requirement is most likely to be justified where a data subject's withdrawal of consent would fatally undermine health research of significant public interest; where data collected pre-GDPR, in accordance with the relevant Member State's consent requirements of that time, would be wasted;

[126] The approach is, in fact, reminiscent of that taken by the European Parliament in the debates preceding the GDPR: see O. Nyrén et al., "The European Parliament Proposal for the New General Data Protection Regulation May Severely Restrict European Epidemiological Research" (2014) 29 *European Journal of Epidemiology* 227

[127] Guidance Note 3, above n. 92, 4.

[128] UK Medical Research Council, GDPR and Data Protection Act 2018: Key Facts for Research (13 June 2018), available at https://mrc.ukri.org/documents/pdf/gdpr-key-facts-for-research/ retrieved 13 March 2019.

[129] BIS Research, *Global Big Data in Healthcare Market: Analysis and Forecast, 2017–2025* (2018) estimated that in 2017, the global market for big data in health care was worth $14.25 billion and that it was expected to grow to $68.75 billion by 2025.

and, where a data subject is unable (because s/he is a child or lacks the required capacity) to provide personal consent. Consent to further data processing in the context of big data also poses problems for contemporary researchers but it is difficult to see that these should provide a basis for an exemption from the consent requirement in the absence of a strong public interest argument.

The main difficulty with the GDPR health research exemption is its lack of detailed guidance for Member States. The need for a nuanced compromise is recognised at a policy level only and it is left to Member States to operationalise this. As this article has shown, for a jurisdiction, like Ireland, which adopt a demanding (and undifferentiated) approach to the consent requirement, the consequences may well be exclusion from European-wide health research projects and an overall reduction in research projects involving research participants/data subjects who are unable to provide personal consent. Other jurisdictions may take quite a different approach to the research exemption, using it to diminish the consent requirement across the board and rendering the important principle of consent essentially meaningless. Inconsistencies in Member State approaches to the health research exemption need to be addressed at a European level. The most obvious way to do this is through guidance from the European Data Protection Board.[130] A careful analysis by the Board of the norms at stake would provide Member States with the tools to develop appropriate and consistent legal frameworks around consent to data processing in health research.

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[130] The Board, established under art. 68 may 'examine, on its own initiative, on request of one of its members or on request of the Commission, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation': art. 70(1)(e).