'Big data analytics' and processing of health data for scientific research purposes : The Irish legal framework

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1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018)

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.

There is no overarching legislation governing the conduct of scientific and/or health research in Ireland.

Legislative provisions relating to the processing of health data in Ireland:

Data Protection Acts 1988 - 2003

These Acts govern the collection and the processing of personal data. The Data Protection Act was adopted in 1988, and it was amended in 2003 to transpose Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[1] The Acts will undergo further changes with the implementation of the GDPR.

Health Identifiers Act 2014

The Health Identifiers Act 2014 provides for the assignment of unique health service identifiers to individuals to whom a health service is being, has been, or may be provided and for the assignment of unique identifiers to health services providers. Section 11 of the Act permits health service providers and other entities including the Health Research Board and the National Cancer Registry Board to provide an individual's health service identifier or other identifying particulars to an authorised disclosee in order to enable the processing of such information for a 'secondary purpose'. Authorised discloses include the Central Statistics Office and health profession regulatory bodies. The definition of 'secondary purposes' in the 2014 Act is quite narrowly cast: it includes '(d) the carrying out of health research that is the subject of a research ethics approval (or any cognate expression) under an enactment or European act prescribed for the purposes of this paragraph'.

Health (Provision of Information) Act 1997

The Health (Provision of Information) Act 1997 provides a general exception to the data protection Acts rules by allowing the National Cancer Registry Board, the Minister for Health, a health board, hospital or other body or agency participating in any cancer screening programme authorised by the Minister for Health to request from any person information held by or in the possession of that person. That person may provide any personal information to the National Cancer Registry Board for the purpose of any of its functions; or to the Minister for Health or any other body or agency for the purpose of compiling a list of people who may be invited to participate in a cancer screening

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

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programme authorised by the Minister. Under the amendment to the Health (Provision of Information) Act 1997 by the Data Protection Act 2018, compliance with the request for the provision of information to the National Cancer Register is made mandatory.

European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004

Pending the coming into operation of EU Regulation 536/2014 on clinical trials on medicinal products for human use, clinical trials involving medicinal products are covered in Ireland by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004)[2] as amended, which implement the EU Clinical Trials Directive (2001/20/EC). These regulations set out a number of conditions and principles applicable to all clinical trials. They include the following 'The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with the Data Protection Acts 1988 and 2003, are safeguarded'.[3] An authorised officer appointed by the Board may, for the purpose of ensuring that the Regulations are being complied with, inspect and copy or extract information from any data (including personal data) within the meaning of the Data Protection Acts 1988 and 2003.

National Archives Act 1986

The National Archives Act 1986 does not apply to health records so the transfer of any health records to the National Archives is voluntary and is conducted on an ad hoc basis.

Electronic Health Record

An electronic health record is under development in Ireland. The eHealth Strategy of 2013 established the agency known as eHealth Ireland (www.ehealthireland.ie), which has responsibility for overall governance around eHealth implementation including funding, legal enabling, public awareness, stakeholder engagement and building the 'eHealth Ecosystem', including the Electronic Health Record. The electronic health record was identified in the second interim report of the Houses of the Oireachtas Committee on the Future of Healthcare as 'a critical enabler for integrated care'.[4] The final report of the committee (the Sláintecare Report[5]) was published in December 2017 but no legislation relating to the electronic health record has, as yet, been introduced. The National Development Plan 2018 – 2027 which was published on February 16, 2018 expresses support for the provision of digital health services, including 'the development of electronic health records in many health care settings such as the New Children's Hospital over the 10-year implementation timescale'.[6]

[2] S.I. 190 of 2004.

[3] European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004), S.I. 190 of 2004, Part 2, Principle 5.

[4] Houses of the Oireachtas Committee on the Future of Healthcare, Second Interim Report, December 2017: http://www.oireachtas.ie/parliament/media/committees/futureofhealthcare/Second-Interim-Report-of-the-Committee-on-the-Future-of-Healthcare-200117.pdf, 11.

[5] Houses of the Oireachtas Committee on the Future of Healthcare: Sláintecare Report, May 2017: https://www.oireachtas.ie/parliament/media/committees/futureofhealthcare/Oireachtas-Committee-on-the-Future-of-Healthcare-Slaintecare-Report-300517.pdf

[6] National Development Plan 2018 – 2027 <http://www.per.gov.ie/en/national-development-plan-2018-2027/> p.91.

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In the absence of specific legislation, in practice, there is significant reliance on the Data Protection Commissioner's *Data Protection Guidelines on research in the Health Sector* (2007) (the *Guidelines)*. In the introduction to the *Guidelines*, the Data Protection Commissioner states that the aim is to provide 'a comprehensive overview of the data protection considerations which need to be taken into account in advance of undertaking research which involves the use of personal data' (p. 3). The Commissioner states that the *Guidelines* will be used as a framework for investigating any complaints brought in respect of health research projects (p. 3).

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach?

The Data Protection Bill 2018 was introduced in the Irish parliament (Seanad i.e. Upper House) on January 30, 2018. It was passed by the Oireachtas (Parliament) on May 18, 2018 and was signed into law by the President on May 24, 2018.

As well as giving effect to the Regulation in the areas in which Member State flexibility is permitted, the Act transposes the Law Enforcement Directive (Directive 2016/680/EU) into national law. The Act also establishes the Data Protection Commission as the State's data protection authority with the means to supervise and enforce the protection standards enshrined in the Regulation and Directive and it enacts consequential amendments to various Acts that contain references to the Data Protection Acts 1988 and 2003. The Act repeals some, but not all, of the provisions of the Data Protection Acts 1988 – 2003. Section 7 of the 2018 Act repeals the sections of the Data Protection Acts 1988 – 2003 that are replaced by the directly effective provisions of the GDPR while section 8 provides that the remaining provisions in the 1988 Act apply only to the processing of personal data for the purposes of national security, defence and the international relations of the State

This analysis relies on the Act, its Explanatory Memorandum and the debates relating to the passage of the Bill through the Oireachtas (Parliament).

In addition, secondary legislation to be made by the Minister for Health which is expected to be titled the Data Protection Act 2018 (Suitable and Specific Safeguards for the Processing of Personal Data for Health Research) Regulations 2018 (hereafter the 'proposed 2018 Regulations') is expected to come into force within a short time. This secondary legislation has not yet been published and the discussion here relates to the proposed contents insofar as this information has been available. The Report will be further updated following the coming into force of the proposed 2018 Regulations.

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

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The office of Data Protection Commissioner was established in 1988 as an independent office and the relevant provisions of the Data Protection Acts 1988 – 2003 are ss. 9 – 15 inclusive and the Second Schedule to the Act.

Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

Part II of the Data Protection Act 2018 establishes the Data Protection Commission (DPC) which will replace the office of the Data Protection Commissioner. Section 11 of the Act designates the Data Protection Commission as the independent supervisory authority for the purposes of the GDPR and of Directive 2006/680/EU /EU.

The Act modifies the provisions of the 1988-2003 Acts regarding the authority and its powers. The most significant change is the replacement of the single Data Protection Commissioner with a DPC consisting of up to three members (s.15).

The Act confers on the DPC the power to impose an administrative fine (s.115). A limit of €1,000,000 is placed on the magnitude of administrative fine that may be levied on a public authority (other than a public authority or a public body that acts as an undertaking within the meaning of the Competition Act 2002) (s.141(4)).

A decision of the DPC to exercise its corrective powers or to impose an administrative fine may be appealed to the Circuit Court (if the fine does not exceed €75,000) or to the High Court within 28 days of notice of the decision. On hearing the appeal, the Court may confirm the decision, replace it with another decision, or annul the decision (section 142). Where a controller or processor does not appeal against a decision by the Commission to impose an administrative fine on the controller or processor, the Commission shall, as soon as is practicable after the expiration of the period referred to in that subsection, and on notice to the controller or processor concerned, make an application in a summary manner to the Circuit Court for confirmation of the decision. The Circuit Court shall, on the hearing of the application, confirm the decision the subject of the application unless the Court sees good reason not to do so.

Additional investigative tools are introduced by the Act such as enhanced powers to obtain and seek access to documents, including electronic records, and an obligation for persons under investigation to co-operate and to answer questions under oath.

The Act also contains provisions regarding cooperation between the DPC and other European data protection authorities (section 103).

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

Art. 8.4 of Directive 95/46 provides: 'Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.'

a. Transposition of Article 8.4 of Directive 95/46

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In Ireland, personal data as to the physical or mental health or condition of a data subject constitutes sensitive personal data (section 1(1)) and as such its processing is prohibited by section 2B(1) of the 1988 – 2003 Acts. However, the prohibition does not apply if, among other grounds, the data subject has given his/her explicit consent (section 2B(1)(b)(i)), or if the processing is necessary to protect the vital interests of the data subject or of another person (section 2B(1)(b)(iii)).

Processing of health data necessary for medical purposes: section 2B(1)(b)(viii)

In addition to these exceptions and as permitted by Article 8(4), a public interest exception is provided for in respect of the processing of health data for research purposes. Specifically section 2B)1)(b)(viii) permits the processing of personal data as to the physical or mental health or condition of a data subject where it is necessary for medical purposes and is undertaken by a health professional, or a person who in the circumstances owes a duty of confidentiality to the data subject that is equivalent to that which would exist if that person were a health professional.

Health professional is defined as including a registered medical practitioner, within the meaning of the Medical Practitioners Act 1978, a registered dentist, within the meaning of the Dentists Act 1985 or a member of any other class of health worker or social worker standing specified by regulations made by the Minister after consultation with the Minister for Health and Children and with any other Minister who ought, in the opinion of the Minister, be consulted (s.2B(4)). No regulations have, as yet, been made which specify other classes of health or social workers as health professionals for the purposes of the Data Protection Acts.

Guidelines

The *Guidelines* state that the definition of the term 'health professional' in the Data Protection Acts is intentionally broad to ensure all appropriate health professionals can access patient data for medical purposes which also include research.[7] The *Guidelines* advise that questions as to whether a staff member, who is not a health professional and is to access patient identifiable information without consent, can be considered to owe an equivalent duty of confidentiality to the patient, need to be assessed on a case by case basis. As a general guide, such persons, in the Commissioner's view, would need to have a contractual duty of confidentiality that would carry an appropriate penalty should there be a breach of confidentiality.[8] The *Guidelines* specifically refer to a 'medical scientist' as an example of a person who owes a duty of confidentiality to the patient that is equivalent to that which would exist if that person were a health professional. The *Guidelines* further state that strict confidentiality obligations on the data processors must be set out in writing before they are granted access to patient data.[9]

Medical purposes is defined as including 'the purposes of preventive medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services' (section 2B(4)).

[7] Data Protection Commissioner, *Data Protection Guidelines on research in the Health Sector*, (2007), 12.

[8] Ibid.

[9] Data Protection Commissioner, *Data Protection Guidelines on research in the Health Sector*, (2007), 12.

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b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes?

Not at present.

From which generally applicable data protection provisions are researchers exempted and under what conditions?

The Irish Data Protection Acts do not establish a separate regime for medical or other scientific research but they do include some provisions relevant to the conduct of such research.

Section 2(5)(a) comprises an exception to the following two data protection principles: that data obtained for a specified, explicit and legitimate purpose shall not be further processed in a manner incompatible with that purpose (as provided for in section 2(1)(c)(ii)); and that data shall not be kept for longer than is necessary for that purpose or those purposes (as provided for in section 2(1)(c)(iv)).

The effect of section 2(5)(a) is that these principles do not apply to 'personal data kept for statistical or research or other scientific purposes, and the keeping of which complies with such requirements (if any) as may be prescribed for the purpose of safeguarding the fundamental rights and freedoms of data subjects', if the data are not used in such a way that damage or distress is, or is likely to be, caused to any data subject. No such requirements for the purpose of safeguarding the fundamental rights and freedoms of data subjects have been prescribed in Irish law.

The further processing exception provision provided for in section 2(5)(a) is further elaborated upon below in the context of the discussion of specific conditions relating to the further processing of personal data for scientific research.[10]

Section 2(5)(b) comprises an exception to the principle that data shall have been obtained, and shall be processed, fairly (as provided for in section 2(1)(a)). It states that personal data kept for statistical or research or other scientific purposes shall not be regarded as having been obtained unfairly by reason only that its use for any such purpose was not disclosed when it was obtained, if the data are not used in such a way that damage or distress is, or is likely to be, caused to any data subject.

Section 2D of the Data Protection Acts 1988 – 2003 transposes Article 11 of the Directive which provides for the provision of information to a data subject where personal data relating to him or her have not been obtained from the data subject (for example, where a medical researcher receives the subject's medical data from the treating physician). Article 11(2) states that the requirements with respect to the provision of information shall not apply 'where, in particular for processing for statistical purposes or for the purposes of historical or scientific research, the provision of such information proves impossible or would involve a disproportionate effort'. This provision is transposed into Irish law by section 2D(4)(a) of the Data Protection Acts which states that the requirements concerning the provision of information to data subjects do not apply 'where, in particular for processing for statistical purposes or for the purposes of historical or scientific research, the provision of the information specified

[10] See p.

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therein proves impossible or would involve a disproportionate effort' where such conditions as may be specified in regulations made by the Minister after consultation with the Commissioner are complied with. No relevant regulations have been made.

In pursuance of Article 13 of the Directive which permits Member States to restrict the right of access to personal data provided for in Article 12 where data are processed solely for purposes of scientific research (provided that 'there is clearly no risk of breaching the privacy of the data subject'), section 5(1)(h) of the Data Protection Acts provides for an exception to the access right in the case of personal data 'kept only for the purpose of preparing statistics or carrying out research if the data are not used or disclosed … for any other purpose and the resulting statistics or the results of the research are not made available in a form that identifies any of the data subjects'. Note that disclosures of personal data permitted by exceptions provided for in section 8 of the Acts do not qualify as disclosures under this provision. Thus section 5(1)(h) provides for an exception to the right of access for data kept for the purpose of preparing statistics or carrying out research even if it such data is disclosed for one of the purposes permitted by section 8.

c. Are there additional specific conditions governing the processing of data for scientific research purposes?

What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

Article 8 (4) of the Directive requires that the processing of sensitive data, when authorised by the Member States for reasons of significant public interest, is subject to suitable safeguards. The safeguards provided for in section 2B(1)(b)(viii) of the Data Protection Acts which permits the processing of personal data as to the physical or mental health or condition of a data subject consist of a requirement that the processing be 'necessary' for medical purposes and that it be undertaken by a health professional, or a person who in the circumstances owes a duty of confidentiality to the data subject that is equivalent to that which would exist if that person were a health professional.

Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

(i) professional secrecy

Personal data concerning health is protected by the common law duty of confidentiality. The importance of this duty in the context of health data was recently affirmed by the High Court of Ireland in *The Child and Family Agency v AA and Another* [2018] IEHC 112. The Court here held (para 7) that 'the public interest in ensuring that patients can have absolute confidence in revealing their most private medical and personal information to doctors, without fear of disclosure to third parties' superseded the right of a young man's sexual partner to be warned if she engaged in unprotected sex, she risked contracting HIV. The Court affirmed also exemptions to this duty arising in situations of a risk to life or a risk of very serious harm short of death. The question of whether, where confidential information

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is provided on the basis of one of these exemptions, a duty of confidentiality applies also the person to whom the information is transferred was not addressed in this case. However, in *National Irish Bank v RTE* [1998] 2 IR 465 (which involved the transfer of confidential financial information), the Supreme Court held that anyone obtaining confidential information was also bound by the duty of confidentiality.

Confidentiality regarding personal data is also a professional obligation. In respect of medical professionals, this obligation is set out in the *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (8th edn, 2016), para 29. This expressly incorporates the eight rules of data protection from the website of the Data Protection Commission. It also states the confidentiality is central to the trust between doctor and patient and that before sharing or disclosing any identifiable information about patients, the medical professional should be clear about the purpose of disclosure and that s/he has the patient's consent or other legal basis for the disclosure. Medical professionals must also be satisfied that: they have considered using anonymised information and are certain that it is necessary to use identifiable information; they are disclosing the minimum information to the minimum number of people necessary; and, that the person to whom the medical professional is disclosing the information knows that it is confidential and that they have their own duty of confidentiality in respect of this information.

A medical professional who fails to comply with the obligations set out in the *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (8th edn, 2016) is subject to sanction (up to and including removal from the Register of Medical Practitioners) under the Medical Practitioners Act 2007.

(ii) express consent for specific data

There are no specific provisions as to the obtaining of express consent for the processing of specific health data.

(iii) deceased data subjects

The definition of personal data in the Irish Data Protection Acts (section 1(1)) is confined to data relating to a living individual and therefore research involving personal data relating to deceased persons is outside the scope of the Acts.

The *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (8th edn, 2016), para 32.1 states however that patient information remains confidential even after the patient's death.

(iv) specific provisions for minors or persons subject to guardianship?

No such provisions are included in the Data Protection Acts. The *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (8th edn, 2016), para 30. 2 states that if a patient lacks capacity to give consent to disclosure of information and is unlikely to regain capacity, the medical professional should consider making the disclosure if it is in the patient's best interests.

Are there specific requirements about the data subject's information or about the person from whom the data was collected?

Section 2D(4)(a) of the Data Protection Acts states that the requirements concerning the provision of information to data subjects that derive from Article 11 of the Directive do not apply 'where, in particular for processing for statistical purposes or for the purposes of historical or scientific research, the provision of the information specified therein proves impossible or would involve a disproportionate effort'.

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Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

Separate penalties for breach of the conditions for processing of scientific research in the field of health are not provided for.

d. Formalities prior to processing: the general regime under the current framework

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

Section 12A of the Data Protection Acts implements Article 20 of the Directive which established a regime for prior checking for the processing of personal data. Section 12A applies to processing 'that is of a prescribed description' and which appears to the Commissioner to be particularly likely to either cause substantial damage or substantial distress to data subjects, or otherwise significantly to prejudice the rights and freedoms of data subjects. The first and so far only set of regulations that prescribe processing for the purposes of section 12A were introduced in 2007. They concern the processing of genetic data in relation to employment.[11]

The mechanics of prior checking are provided for in section 12A(2) – 12A(11). The Commissioner will undertake prior checking either in response either to an application for registration, or to a request from a data controller. The Commissioner is required to consider and determine whether the processing is processing to which section 12A applies and, if it is, to determine whether the processing is likely to comply with the provisions of the Acts. Section 12A(3) requires the Commissioner to serve a notice on the data controller within 90 days of receiving the application for registration or request from the data controller, stating the extent to which in his or her opinion, the proposed processing is likely or unlikely to comply with the provisions of the Acts. Section 12A makes provision for the extension of the period of 90 days to allow for the serving of an Information Notice by the Commissioner on the data controller. Processing of the data can be carried on only where the data controller has a received a notice under section 12A(3) to the effect that the processing can go ahead, or where the 90 day period has expired without a notice under section 12A(3) being received by the data controller or where the notice issued under section 12A(3) has set out conditions for the carrying on of the processing and these have been complied with. Breach of this provision is an offence and the Acts provide for the bringing of an appeal against such a notice to the Circuit Court.

3. Further processing of health data (for research purposes): the current regime

How is the notion of further processing regulated in your national framework?

[11] Data Protection (Processing of Genetic Data) Regulations 2007, S.I. No. 687 of 2007.

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Section 2(1)(c)(ii) of the Data Protection Acts provides that data obtained for a specified, explicit and legitimate purpose shall not be further processed in a manner incompatible with that purpose.

Are there specific conditions to the further processing for scientific research in the field of health purposes?

Section 2(5)(a) of the Data Protection Acts establishes an exception to the principle (provided for in (section 2(1)(c)(ii))) that data obtained for a specified, explicit and legitimate purpose shall not be further processed in a manner incompatible with that purpose. The exception applies in respect of 'personal data kept for statistical or research or other scientific purposes, and the keeping of which complies with such requirements (if any) as may be prescribed for the purpose of safeguarding the fundamental rights and freedoms of data subjects' if the data are not used in such a way that damage or distress is, or is likely to be, caused to any data subject.

No requirements have been prescribed in Irish law for the purpose of safeguarding the fundamental rights and freedoms of data subjects in the context of the further processing of personal data kept for statistical or research or other scientific purposes as permitted section 2(5)(a).

The *Guidelines* state that in all situations, the optimal approach is to ensure that the explicit and informed consent of the patient is obtained for further processing of health data (p. 13).

Where this has not happened, the *Guidelines* distinguish between the further use of personal data for research purposes by the treating health professional and its disclosure to third party researchers.

In respect of further use by the treating professional (the data controller), the *Guidelines* advise that, in very limited circumstances, where personal information is deemed integral to the success of a research project and where capture of consent is not possible for specific reasons, the research can [only] be undertaken by the data controller itself with appropriate safeguards for the confidentiality of patient information in place (pp. 13-14). Moreover in such circumstances, it is necessary that no damage or distress is, or is likely to be, caused to the individual (p. 6).

On the other hand, the *Guidelines* limit the circumstances in which personal data may be disclosed to third party researchers where consent to this has not been obtained.

The *Guidelines* state that personal data may be disclosed to third party researchers only where it consists of anonymised or aggregate data or pseudonymised data (subject to safeguards) from which individual patients cannot be identified The *Guidelines* provide further guidance as to the process of anonymization and pseudonymisation. In respect of anonymization, it states that irrevocable anonymization of data puts the data outside of the data protection requirements as it can no longer be linked to an individual (p. 9). However, the *Guidelines* also note that care must be taken when rendering data anonymous as depending on the nature of the illness and the profile of the patient, there may be instances in which the data is still identifiable (p. 9).

In respect of pseudonymisation, the *Guidelines* state that where sufficient measures are put in place to ensure that data is not accessible or likely to be identifiable by parties external to the data controller, the requirement to capture consent to use the data for research purposes will no longer apply (p. 10). Appropriate pseudonymisation is described as including the use of initials or coding although the *Guidelines* also note that where data relates to rare conditions, pseudonymisation methods beyond the use of initials must be incorporated (p. 10).

The *Guidelines* also include specific provision for 'historical data' in patient files in respect of which consent for further use has not been obtained. (p. 11-12). They describe as 'good practice' an approach (adopted by a private medical data compilation company in the UK) which attempts to capture consent by having the hospital write twice

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to the data subject seeking a response, then telephoning once, and finally submitting the case for ethics approval. The *Guidelines* however also acknowledge that secured patient consent in these cases may not be practical due to passage of time or numbers involved. They therefore provide that in limited circumstances, which the *Guidelines* emphasise should be the exception rather than the rule, the *Guidelines* envisage that access can be provided by the data controller. In allowing such access, the data controller must satisfy itself that the legislative position would allow for such access, with appropriate safeguards incorporated, for research purposes. Every effort should be made to establish contact with the patient and if this is not possible or feasible, consideration needs to be given to the use of media notices (p. 11). In addition, the patient files must be anonymised either by the data controller prior to release or by a data processer subject to an appropriate data protection contract so as to allow any future research to be conducted on anonymised data (p. 11).

What are the rights of the data subject when it comes to further processing?

Section 2D of the Data Protection Acts provides that where personal data is collected otherwise than from the data subject, the data controller must ensure, so far as practicable, that the data subject is informed of the identity of the data controller, the identity of any representative of the data controller nominated for the purposes of the Acts, the purpose for which the data are intended to be processed and any other information necessary to render the processing of the data fair to the data subject.[12] The data controller must also inform the data subject of the categories of data concerned and the name of the original data controller. Such information must be supplied no later than the first processing of the data by the data controller, or in the case of disclosure to a third party, when such disclosure takes place.[13]

If the data was initially collected for a purpose different from that of the further processing there is an exception to the obligation to inform the data subject. This exception applies in the case of personal data kept for statistical or research or other scientific purposes, the keeping of which complies with such requirements (if any) as may be prescribed for the purpose of safeguarding the fundamental rights and freedoms of data subjects'. No such requirements for the purpose of safeguarding the fundamental rights and freedoms of data subjects have been prescribed in Irish law.

Section 6A transposes the right to object provided for in article 14 of the Directive. Section 6A gives data subjects the right to request a data controller at any time to cease or not to begin the processing of personal data relating to them. The right to request a data controller to cease processing personal data can be availed of where the the processing of the data is causing or is likely to cause substantial damage or distress to the data subject or to another person, and the damage or distress is or would be unwarranted. This right does not however apply in relation to the processing of personal data for medical research purposes.

What about the data subject's rights and further processing for scientific research purposes?

[12] Examples of 'other information necessary to render the processing of the data fair' set out in s.2D are: information as to the recipients of the data, whether replies to questions are obligatory, the consequences of failure to reply, the existence of the right of access and the right to rectify data: 2D(2)(d).

[13] s.2D(1)(b).

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No additional requirements are provided for in the Acts with respect to the rights of a data subject in the context of further processing of personal data for research purposes nor have any regulations been introduced for the purposes of safeguarding the fundamental rights and freedoms of data subjects as envisaged by section 2(5)(a).

However, the *Guidelines* recognise the relevance of consent (as set out above) and restrict further use of data (unless it is anonymised or appropriately pseudonymised. The *Guidelines* also identify further safeguarding obligations (beyond consent) relating to security and access.

4. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

In the context of this study, only sections 42, 54 and 36 of the Data Protection Act 2018 are particularly relevant. They deal respectively with: processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes; processing of special categories of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes; and suitable and specific measures for processing; A further relevant provision is section 61(2) which deals with restrictions on exercise of data subjects' rights in the context of processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. This provision is discussed further below at p. 15.

Section 42 makes provision for the processing of personal data for the purposes of archiving in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89 of the GDPR. It provides that personal data may be processed for such purposes subject to suitable and specific measures being taken to safeguard the fundamental rights and freedoms of data subjects. Section 42 also requires that the processing of personal data for such purposes must respect the data minimisation principle and that where identification of individuals is not required for such purposes, the processing should be carried out in a manner that does not permit such identification.

Section 54 provides for the processing of special categories of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. It states that subject to compliance with section 42, the processing of special categories of personal data is lawful where it is necessary and proportionate for: (a) archiving purposes in the public interest, (b) scientific or historical research purposes, or (c) statistical purposes.

Section 36 sets out the suitable and specific measures to safeguard the fundamental rights and freedoms of data subjects required in connection with the processing of personal data under both section 42 and section 54. It provides that such measures may be identified in regulations and may include any of the following: explicit consent,

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limitations on access to the data within a workplace, time limits for the erasure of the data, targeted training, and, having regard to the state of the art, the context, nature, scope and purposes of data processing and the likelihood and severity of risk to the rights and freedoms of data subjects: logging mechanisms; designation of a data protection officer; where the processing involves data relating to the health of a data subject, a requirement that the processing is undertaken by a health practitioner, or a person owing an equivalent duty of confidentiality to the data subject; pseudonymisation; or encryption.. In addition to requiring the putting in place of any such measures, regulations made under section 36 may also require that governance structures, processes or procedures for risk assessment and for the management and conduct of research projects and other technical and organisational measures designed to ensure that the processing is carried out in accordance with the GDPR together with processes for testing and evaluating their effectiveness be put into effect.

The proposed 2018 Regulations will be made under section 36. The Minister for Justice said on Report Stage of the Bill in the Seanad (22 March, 2018), that the 'toolbox' of safeguards [in section 36] is 'in addition to, and not a substitute for, the technical organisational measures required under a risk-based approach in Article 24'.

We understand that the Regulations will provide a broad definition of health research and that this will include 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 or of defined sub-populations through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status. The definition is also expected to include a necessary action taken to establish whether an individual is suitable for inclusion in the research.

It is expected that the 2018 Regulations will make the safeguard of explicit consent the default option in respect of all health research. However, it is expected that they will also include a mechanism for a consent exemption in certain limited situations. It is expected that the decision as to whether a consent exemption will apply in an individual situation will be made by an independent broadly-based committee appointed by the Minister for Health. It is also expected that the proposed 2018 Regulations will include specific treatment for research which is already underway on 25 May 2018 where that research is based on explicit consent that was in line with the requirements of the EU Data Protection Directive and the Data Protection Acts when it was obtained. If the consent in respect of this research does not meet the more stringent requirements of the GDPR, re-consenting will be the ideal. However, it is expected that provision will be made in circumstances in which re-consenting is not possible for practical reasons, to allow an application to be made to the independent committee for an exemption.

Further detail on data processing in the context of health research will be provided by the proposed 2018 Regulations.

b. Modification to the processing authorisation procedure applying to research in the field of health

As provided for under the GDPR, once the controller has made a data protection impact assessment, and the results indicate high risks in the absence of measures taken to limit such risks, then the controller will consult the competent supervisory authority.[14] The Authority can take action within an eight week time period. The Irish Data Protection Act 2018 does not take up the opportunity provided for in article 36 (5) of the GDPR for Member States to require

[14] Article 35 and 36 GDPR.

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controllers to consult with, and obtain prior authorisation from, the supervisory authority in relation to processing by a controller for the performance of a task carried out by the controller in the public interest, including processing in relation to social protection and public health. The Act does however state that the processing of personal data which is necessary for the performance of a task carried out in the public interest by a controller or which is necessary in the exercise of official authority vested in a controller may be specified in regulations made by a Minister who is required to consult with the Commission before making such regulations.[15]

Further detail on data processing in the context of health research will be provided by the proposed 2018 Regulations.

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

As explained above (at pp. 9-10) the Data Protection Acts 1988 – 2003 establish a system of prior checking for processing of a prescribed description which appears to the Commissioner to be particularly likely to either cause substantial damage or substantial distress to data subjects, or to otherwise significantly prejudice the rights and freedoms of data subjects. By virtue of the fact that only one set of regulations has been introduced under this provision, this system only applies to the processing of genetic data in relation to employment.[16]

Under the GDPR, data controllers are required to consult the supervisory authority prior to processing in all cases where a data protection impact assessment under Article 35 indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk. Where the supervisory authority is of the opinion that the intended processing would infringe the GDPR, in particular where the controller has insufficiently identified or mitigated the risk, the supervisory authority must provide written advice to the controller and, where applicable to the processor, within eight weeks of receipt of the request for consultation. As already noted, the Irish Data Protection Act 2018 does not take up the opportunity provided for in article 36 (5) to require controllers to consult with, and obtain prior authorisation from, the supervisory authority in relation to processing by a controller for the performance of a task carried out by the controller in the public interest, including processing in relation to social protection and public health.

Further detail on data processing in the context of health research will be provided by the proposed 2018 Regulations.

What about the right of the data subject and the obligations of the controller?

Article 89 (2) GDPR provides the opportunity of derogations to: the right to access the data by the data subject, the right to rectify, the right to restrict the processing and the right to object. However, these derogations are only available if those rights would seriously impair or make impossible the scientific purpose of the processing.

Section 61(2) of the Data Protection Act 2018 imposes restrictions on the exercise by data subjects of certain rights conferred by the GDPR in respect of personal data processed for archiving purposes in the public interest, scientific or historical research purposes or for scientific purposes. In the case of the processing of data for scientific research purposes, the rights of a data subject set out in Articles 15 (right of access), 16 (right to rectification), 18 (right to

[15] Section 38(4).
[16] Data Protection (Processing of Genetic Data) Regulations 2007, S.I. No. 687 of 2007.

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restriction of processing) and 21 (right to object) of the GDPR are restricted to the extent that the exercise of any of those rights would be likely to render impossible, or seriously impair, the achievement of those purposes, and such restriction is necessary for the fulfilment of those purposes.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing can be defined as 'the processing of personal data for purposes other than those for which the personal data has been initially collected'. Further processing is allowed only when its purpose is compatible with the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. For example, if personal data is initially processed based on the data subject's consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorising the further processing of the same data.

How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by Article 6 (4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the further processing is 'compatible'. This is particularly relevant to big data analytics. Article 6 (4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject's consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing's purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under Article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller, and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under Article 5 (1) (b) of the GDPR the compatibility of the processing purpose of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily imagined. Scientific research is very often

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based on existing data, this is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This assumption made for the benefit of scientific research is linked to the derogation of the principle of data minimisation for scientific research purposes. However, this presumption is limited by some requirements, which are set out in Article 89(1) of the GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organisational measures, such as pseudonymisation. Although a different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: 'The further processing of personal data for (…) scientific (…) research purposes (…) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data).'

Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, 'personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject'.

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

The rules set out by the GDPR will be directly applicable. The provisions of the Data Protection Acts 1988 – 2003 relating to further processing, including further processing of personal data kept for statistical or research or other scientific purposes, are repealed by the Data Protection Act 2018.[17]

Further detail on data processing in the context of health research will be provided by the proposed 2018 Regulations.

6. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

There are no specific provisions regarding anonymised data. The Data Protection Act references pseudonymisation of personal data only in the context of identifying it as a 'suitable and specific measure to safeguard the fundamental

[17] The 1988 Act shall however continue to apply only to the processing of personal data for the purposes of national security, defence and the international relations of the State.

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rights and freedoms of data subjects'[18] in connection with the processing of personal data for archival and scientific and other research purposes.[19]

What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

Health data or data concerning health is sensitive data and so in principle its processing is prohibited. However, this prohibition does not apply to processing which is necessary for medical purposes provided that it is undertaken by a health professional, or a person who in the circumstances owes a duty of confidentiality to the data subject that is equivalent to that which would exist if that person were a health professional as set out in section 2B(1)(b)(viii) of the Data Protection Acts 1988 - 2003. Such collection and processing must also comply with section 2D of the Acts provides that in the case of data obtained from the data subject, the data controller must ensure that the data subject is informed of the identity of the data controller, the identity of any representative of the data controller nominated for the purposes of the Acts, the purpose for which the data are intended to be processed and any other information necessary to render the processing of the data fair to the data subject. Where the data is collected otherwise than from the data subject, the data controller must, in addition to supplying the information set out above, inform the data subject of the categories of data concerned and the name of the original data controller.

Section 2D(4)(a) of the Data Protection Acts states that the requirements concerning the provision of information to data subjects do not apply 'where, in particular for processing for statistical purposes or for the purposes of historical or scientific research, the provision of the information specified therein proves impossible or would involve a disproportionate effort' where such conditions as may be specified in regulations made by the Minister after consultation with the Commissioner are complied with. No relevant regulations have been made.

However, the *Guidelines* set out the procedures which a researcher should follow in obtaining consent to the use of health data from a patient (pp. 10-11). These are based on the Working Papers of the EU Data Commissioners working through the Article 29 Working Party. To be valid, a consent must be a 'freely given, specific and informed indication of the data subject's wishes'. Based on European practice (at that time), the *Guidelines* strongly advocate that, insofar as is practically possible, an informed and explicit consent, should be sought as soon as possible after a patient presents at a health facility. The precise method for collection is a matter for each health facility to determine with the health facility setting out in a fully transparent manner to the patient what it considers to be the permissible and desired uses of patient data. Each health facility should set out, based on past experience or known future plans, the specific purposes unrelated to the patient's treatment for which patient data may be used. These purposes must be captured in an appropriate consent form and supported by an informative patient leaflet. Although the manner of consent may vary, the *Guidelines* state that consent would be by way of an 'opt in' and that patients should be informed of their right to revoke their consent at a later date.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

[18] Section 36, Data Protection Act 2018.

[19] As provided for under sections 42 and 54 of the Data Protection Act2018.

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Under the revised legal framework, data processing of personal data for research purposes by health professionals falls under the data processing general regime set by the GDPR.

Further detail will be provided by the proposed 2018 Regulations. It is highly likely that these will lead to changes in procedure: see pp. 16-17.

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

It is presumed that this question relates to the collection of patient health data from medical staff etc.

As noted above (p.12), section 2(5)(a) of the Data Protection Acts establishes an exception to the principle that data obtained for a specified, explicit and legitimate purpose shall not be further processed in a manner incompatible with that purpose. The exception applies in respect of 'personal data kept for statistical or research or other scientific purposes, and the keeping of which complies with such requirements (if any) as may be prescribed for the purpose of safeguarding the fundamental rights and freedoms of data subjects' if the data are not used in such a way that damage or distress is, or is likely to be, caused to any data subject.

In the absence of explicit legislative provisions, collection of patient health data from medical staff/hospitals etc is provided for in the *Guidelines*. As described above (p.11), the *Guidelines* set out obligations in respect of consent of the data subject to the processing of their data and limited circumstances in which anonymised and pseudonymised data may be processed in this way.

Under the revised legal framework will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The Act does not substantially modify the conditions of access to data gathered by health professionals and health care establishments. However, further detail will be set out in the proposed 2018 Regulations.

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

While creating a private database containing health data is not explicitly prohibited, its legal basis must be carefully applied. Indeed, while the processing of health data is in principle prohibited, it is possible to do so if the data subject has given his/her explicit consent.[20]

In respect of population databases, the *Guidelines* acknowledge that in order to compile this resource and achieve 100% coverage, the personal information of individuals may need to be accessed. They state that where a database or registry is being established or maintained for the benefit of the health or wellbeing of the population or a sector of the population, an exemption to data protection must be made in legislation. The *Guidelines* cite the example of the National Cancer Registry, which is provided for under the Health (Provision of Information) Act 1997, as perhaps

[20] s.2B(1)(b)(i).

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the best example of such an approach (p. 12). The *Guidelines* do not make a distinction between a private or public registry in this respect.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

This may be provided for in the proposed 2018 Regulations.

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

Health data may be provided to the Health Research Board which is established under the Health Research Board (Establishment) Order 1986, SI 279/1986 as amended. This is the leading funder of health research in Ireland and it maintains four national health information systems; produces evidence reviews for the Department of Health to inform health policy. The Health Research Board must comply with the Data Protection Acts.

Health data in respect of cancer may be provided under the exemption to the Data Protection Acts by the Health (Provision of Information) Act 1997. This allows information to be provided (on their request) to the National Cancer Registry for the purposes of any of its functions; and to the Minister for Health, a health board, hospital or other body or agency participating in any cancer screening (including any breast or cervical cancer screening) programme authorised by the Minister for Health for the purposes of compiling and maintaining a record of the names, addresses and dates of birth of persons who, for public health reasons, may be invited to participate in that programme.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The Health Research Board is currently in the process of revising its data protection policies and the amended policy will be published shortly.

Further details may be included in the proposed 2018 Regulations.

b. Application of the national framework to the AEGLE cases

In the AEGLE project, the 'research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphotic Leukemia (CLL), Intensive Care Units and type 2 diabetes for the

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prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models'. [21]

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

Current position:

The use of pseudonymised data in this instance is permissible. However, the following steps must be taken:

- The data subject's consent must be reviewed to ensure that it covers the specific instance of data processing involved in the research in question and meets the standards for a 'freely given, specific and informed indication of the data subject's wishes' as set out in the *Guidelines*.
- If the transfer of the data in this specific instance is fully covered by this consent, there is no requirement for further consent. Unless there is a specific commitment to this effect in the original consent, there is no requirement under Irish law that the data subject must be informed of the further processing of the data as concerns them.
- If the transfer of the data in the specific instance is not fully covered by the consent, then the consent of the data subject to the further processing of the data must be obtained. If this is not possible, the data must be fully anonymised or the requirements in respect of pseudonymisation must be reviewed to ensure that the meet the standards set out in the *Guidelines.*

Once the GDPR has been implemented:

Until the proposed 2018 Regulations are published, it is not possible to provide a comprehensive indication of how the legal requirements will operate. However, it is highly likely that a review of consent will be required and it may then be the case that re-consent or an application to the independent committee may be required.

2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

Current position:

The *Guidelines* limit the circumstances in which personal data may be disclosed to third party researchers where consent to this has not been obtained from the data subject.

[21] AEGLE Grant Agreement, Annex 1, p. 83.

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The *Guidelines* state that personal data may be disclosed to third party researchers only where it consists of anonymised or aggregate data or pseudonymised data (subject to safeguards) from which individual patients cannot be identified. Under the *Guidelines*, appropriate pseudonymisation requires that sufficient measures are put in place to ensure that data is not accessible or likely to be identifiable by parties external to the data controller

Once the GDPR has been implemented:

In light of the expectation that consent will be a core element of the proposed 2018 Regulations, given the absence of consent in this instance, it is highly likely that either a consent process will be required or an application to the independent committee for an exemption.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

Current position:

Under the *Guidelines*, a consent must meet the standard to be a 'freely given, specific and informed indication of the data subject's wishes'. A general consent would not meet this standard.

Therefore the legality of the transfer of information in this instance turns on the effectiveness of the pseudonymisation. The *Guidelines* require that sufficient measures are put in place to ensure that data is not accessible or likely to be identifiable by parties external to the data controller.

Once the GDPR has been implemented:

Until the proposed 2018 Regulations are published, it is not possible to provide a comprehensive indication of how the legal requirements will operate. However, it is highly likely that a review of consent will be required and that re-consent or an application to the independent committee may be required.

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