

What Legal and Ethical Issues Should Primary Care Researchers Consider in the Development and Conduct of Research Involving Population Health Datasets: A Discussion Paper

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Introduction

Clinical records and information systems allow for extensive quantities of data to be collected and analysed to improve patient care—through improving our understanding of the epidemiology of disease—and facilitate the development and evaluation of new health interventions. This is an important resource in the development of health systems. Information and its transfer within health systems are key to health service reform, research, development, quality and safety for patients. In addition, biomedical research allows the identification of people at risk of diseases with a genetic basis.

The law surrounding privacy, confidentiality and data protection is very important and is a key factor in enabling the data that is collected to be used towards those positive ends. With the introduction of legislation in Ireland, such as the Health Information Bill, and the value of clinical data and population health datasets being increasingly recognised as a key tool to supporting research and innovation in clinical practice, this paper aims to review relevant legislation and legal principles and consider the implications of future legislation for practice.

Privacy and Confidentiality Law in Ireland

(i) Privacy Generally – Common and Constitutional Law

Privacy law in Ireland is long-recognised through common law principles and is given extra protection through its constitutional basis in Art.40.3 of the Constitution which promises to vindicate the personal rights of individuals. The courts have interpreted the right to privacy as one of these personal rights and, as a result, precedent has developed in Ireland protecting people's privacy.¹ The courts uphold the privacy and confidentiality inhering in the patient/doctor relationship unless:

- the patient consents to confidentiality being waived;
- the doctor is ordered by a court of law to reveal details of the patient/doctor relationship;
- there is a threat to a third party; or

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¹ See *Murphy v Attorney General* [1982] 1 I.R. 241.

- it is in the public interest to break confidentiality.²

Unless any of these criteria are met, the doctor must abide by the Hippocratic Oath which states: “To whatever in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not be spoken of abroad, I will not divulge, as reckoning that all should be kept secret.”

(ii) European Convention on Human Rights

The European Convention on Human Rights (ECHR) guarantees Irish citizens a right to privacy under art.8. Article 8 guarantees that:

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

The patient has a right to privacy under art.8 of the ECHR and, as a result, the doctor and hospital have a duty of confidentiality to ensure the information remains private. The patient/doctor relationship is known as a fiduciary relationship and the doctor owes a duty of care in respect of the patient’s personal information and health information. The common law and constitutional principles of privacy, along with the pre-existing duties of care and confidentiality, are further buttressed by the ECHR.

(iii) Data Protection

The law surrounding personal data in Ireland is governed by the Data Protection Acts 1988 and 2003 (the “DP Acts”). Patient medical data in Ireland must be protected in accordance with the DP Acts—the Data Protection (Amendment) Act 2003 amended the Data Protection Act 1988 in order to transpose the EU data protection directive.³ The EU data protection directive was an important landmark in regulating the way personal data was processed within the EU in the mid-nineties. The DP Acts are very important in protecting patients’ information in Ireland and in ensuring third parties cannot have access to patients’ information without their express consent. The DP Acts differentiate between “personal data” and “sensitive personal data”. Personal data is defined as data “relating to a living individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller”.⁴ Sensitive personal data, on the other hand, includes personal data in relation to the “physical or mental health condition or sexual life of the data subject”.⁵

While the DP Acts contain certain protections for “personal data”, they go further where sensitive personal data is concerned. The latter is governed by s.2B of the Data Protection Act 1998 which provides significant safeguards for handling sensitive personal data. A loss of control over an individual’s personal data, especially sensitive personal data such as medical data, is seen as a loss of autonomy and has led the courts and the Data Protection Commissioner (DPC) to prevent or minimise such a loss of control. For example, in Case 11/2012, the DPC opposed a Department of Education circular which required that a teacher’s medical

² Medical Protection Society of Ireland, *Medical Records in Ireland: An MPS Guide* (2012), pp.12–14.

³ Directive 95/46 of October 24, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31 (hereinafter the “EU data protection directive”).

⁴ Data Protection Acts 1988 and 2003 s.1.

⁵ Data Protection Acts 1988 and 2003 s.1.

certificate, explaining an absence from school, confirm the nature of the teacher's illness. The DPC stated that "an employer would not normally have a legitimate interest in knowing the precise nature of an illness and it would therefore be at risk of breaching the Data Protection Acts if it sought such information".⁶

Explicit consent is required for the processing of sensitive personal data of a patient/data subject. The GP is known as the "data controller" of the information and, as data controller, he is responsible for ensuring that the information is protected and safeguarded from others. It is the responsibility of the data controller to ensure the confidentiality of patient data and to obtain consent for its future use in research.⁷

There is an "opt in" and an "opt out" approach in medical research and it is important for patients to be aware of the approach in operation in order for them to know whether their information will be used for research or not. The "opt in" approach for patients means that they must actively consent to the research in order for their data to be included, and the "opt out" approach means they will automatically be included in the research unless they tell their GP or the research body that they wish to be excluded.⁸

The GP as the data controller can "process" the information, which includes collecting, organising, obtaining, recording, controlling and destroying the data. Explicit consent is needed in advance from the patient if the GP is to use the patient's data for research purposes without de-identifying the data. The GP, as the data controller, may anonymise the data, and once the data subject (human being) is unidentifiable, the information can be used for research as it is no longer "sensitive personal data" according to the DP Acts. In addition, if the GP processes and anonymises the data, a third party may use the information for research purposes without explicit consent. If a patient believes that his data is not being protected or treated correctly, the individual may apply to the DPC for an investigation. If the patient does so apply, then, pursuant to s.12 of the DP Acts, a "notice requirement" will be served on the data controller (GP) and this requires him to furnish all the information he has regarding the patient to the DPC. He must comply and provide the DPC with the information required, as a failure to do so is an offence.

In order to avoid any investigations by the DPC, GPs should therefore obtain "express consent" from their patients to using their data (which has not been de-identified or anonymised) for research purposes. For consent to be valid, it must be "freely given, specific, and [an] informed indication of [the data subject's] wishes".⁹ The DP Acts do not define express consent, but according to the English Mental Capacity Act 2005, this means that the data subject/patient must:

- have received sufficient information and been able to understand the information;
- not be acting under duress;
- be able to retain the information; and
- have the ability to weigh up the information and then communicate the decision.¹⁰

The circumstances in which consent ceases to be required are where the health data is anonymised and the patient is unidentifiable.¹¹

⁶ See <http://www.dataprotection.ie/docs/Case-Studies-2012/1354.htm#11> [last accessed April 14, 2014].

⁷ B. Hawkes, *Data Protection Guidelines on Research in the Health Sector* (Office of the Data Protection Commissioner, 2007), p.7.

⁸ The recent Irish case of the Guthrie cards in Temple Street Children's Hospital highlights the opt-out method verses the opt-in method. See J. Allen et al, "Irish public would prefer legislation to protect Guthrie card archive rather than destroy it" (2013) 347 B.M.J. 5232.

⁹ Directive 95/46 art.2(h).

¹⁰ Mental Capacity Act 2005 s.3 (1).

¹¹ National Consent Advisory Group HSE, *National Consent Policy* (2013), p.89.

Research and Children

Consent is more difficult to ascertain when it comes to children and adults lacking decision-making capacity. Children are allowed to participate in research on matters that affect them. One parent's/guardian's consent is sufficient for a child's participation unless the Research Ethics Committee involved has found the risks to be high, and then both parents'/guardians' consent is needed. Any child over the age of 16 can consent on his or her own behalf to partake in a clinical trial.¹² It is important to explain to the child taking part what will be involved and to obtain his or her assent to the research also.¹³

Healthy children can also be involved in research and may act as a control group; they should be treated in the same way as the other participants and risks should be minimal in the absence of any direct benefits to them.

Adults Lacking Decision-making Capacity

The participation of this group requires Research Ethics Committee approval and the research should only occur if the information cannot be acquired from research on adults with decision-making capacity. The research must be expected to give a direct benefit to, or help with the treatment of, the participants. Consent must be obtained from the legal representative of the participant, and the wishes of the participant must at all times be respected according to the English Mental Capacity Act 2005.¹⁴

Epidemiological Research

This is an important way of monitoring the prevalence of conditions in an area. This type of research involves huge numbers of patients and it is usually impractical to obtain consent from everyone. Usually, patient-identifiable data is not needed for epidemiological research, and so consent is waived by a Research Ethics Committee and the access must be supervised by someone who is very aware of confidentiality requirements. Where patient information is anonymised but the nature of the illness is very unique (i.e. an unusual health condition such as HIV,) and the patient may still be identified from the data, special care and consideration needs to be taken to remove the information that renders the patient identifiable.¹⁵

Archived Material

A lot of research can be carried out on material being kept in archives. The contentious nature of this issue was recently highlighted in Ireland with the debate surrounding the PKU heel prick test cards that are being stored without the consent of parents/guardians of patients in Temple Street Children's Hospital, Dublin. These tests provide considerable information to researchers with regard to the epidemiology and natural history of disease. After much debate, it was decided that this information could not be destroyed, and the "opt in" approach was changed to an "opt out" approach.¹⁶ The Health Service Executive's *National Consent Policy*¹⁷ states that in certain circumstances, biological data from individuals can be used for research without consent. These circumstances include where the information is anonymised or if no potential harm can come to the individual from whom the biological data was obtained. The Irish Government, as a result of the "PKU case", has established a committee to decide what should be done with

¹² See *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All E.R. 402.

¹³ National Consent Advisory Group HSE, fn.11 above, p.70.

¹⁴ Mental Capacity Act 2005 s.4(1).

¹⁵ B. Hawkes, fn.7 above, p.9.

¹⁶ J. Allen et al, fn.8 above.

¹⁷ National Consent Advisory Group HSE, fn.11 above, p.83.

the test cards in the future.¹⁸ The test cards are very important for research because they provide a snap-shot of conditions of the recent decades and can provide researchers with a lot of information as to trends in Irish people's health during that time.

In other circumstances, if consent has been obtained for a primary research investigation, then consent will be required for a second, separate research project to be undertaken, unless the researchers can get a Research Ethics Committee waiver of consent.¹⁹ It is still questionable on what legal authority a Research Ethics Committee can waive consent which may be otherwise be legally required, and this particular area is one of uncertainty.

Deceased Persons

The DP Acts do not cover information in relation to deceased persons. As a result, in the absence of prior consent, the decision whether to donate material for research when someone dies falls to the next-of-kin. In the case of a married adult, this would be the spouse; in the case of a child, it would be a parent; and in the case of an unmarried adult, the next-of-kin would be a sibling. Guidelines issued by the Irish Medical Council have also suggested executors' consent. Medical data relating to a deceased individual that can be linked to a living person may enjoy the protection of the DP Acts. An example of this would be that of a deceased female haemophiliac, as that information would indicate that any surviving sons suffered from the disease, as it is X-linked.²⁰

Anonymised Data

Consent is not required under the DP Acts if the information is anonymised. "Irrevocable anonymisation of personal data puts it outside data protection requirements as the data can no longer be linked to an individual and therefore cannot be considered to be personal data."²¹ The responsibility and process of anonymising and de-identifying data falls on the data controller. Once the data has been anonymised, it can be transferred to a third party for research without the consent of the data subject. "Where research can be conducted on anonymous data, this is the most desirable option as such data is unidentifiable and the Acts do not apply to it. Researchers should attempt to ascertain whether it is possible to receive data in this anonymous format."²²

No Consent Needed

In certain circumstances, consent is not needed for research, especially if there is a public health emergency and the health teams need research done immediately on certain strains of a flu or virus that is spreading throughout the population.²³ Gaining consent prior to research would be too time-consuming and would slow down the process.

Audits

An audit does not require explicit consent to be obtained, if the audit being carried out is by the clinical audit staff which is comprised of those involved in the patient's care or their support staff.

¹⁸ J. Allen et al, fn.8 above.

¹⁹ National Consent Advisory Group HSE, fn.11 above, p.83.

²⁰ A. Sheikh, *The Data Protection Acts 1988 and 2003: Some Implications for Public Health and Medical Research* (Dublin: Health Research Board, 2008) p.82.

²¹ B. Hawkes, fn.7 above, p.9.

²² A. Sheikh, fn.20 above, p.43.

²³ National Consent Advisory Group HSE, fn.11 above, p.82.

“Clinical audit is designed to improve the quality of care provided to patients generally. Given the fundamental role played by clinical audit in patient care, implied consent is normally all that is required when the audit could likely be of benefit to that patient.”²⁴

If the audit is to be carried out by third parties external to the data controller, informed consent will be needed. However, informed consent may be considered sufficient if the patient simply has access to a brochure or information sheet informing him that his personal data may be used for an external clinical audit, and that he has the opportunity to opt out of the audit if he wishes.²⁵

Establishing a National Register in Ireland

The National Cancer Registry was set up in 1991 by the Department of Health and has been registering cancers since 1994. It is exempt from the application of the consent requirements under the DP Acts, and this exemption is contained in legislation.²⁶ It allows for all cancer diagnoses in Ireland to be recorded on the register, and for the epidemiology and statistical trends in different cancers to be researched, analysed, reported and published. Patients diagnosed with cancer will be recorded on the register unless they opt out of their records being used. Their information is processed and de-identified by the National Cancer Registry which acts as the data controller. Information can be released to the patient’s treating physician, but all other research purposes must be consented to by the patient before the information is released. The data is collected from laboratories, death certificates, medical records in hospitals, and other registries. National Disease Registers are important research opportunities; they affect the public interest as they concern the following huge demographic groups:

- “1. Those currently with the disease
2. Those who have suffered with the disease
3. Those who may suffer with the disease in the future.”²⁷

A study was done recently on Irish attitudes towards using their medical information for research and it was found that “overall participants across demographic groups were positively inclined to medical records being used in health research”.²⁸ The male participants were more worried about insurance companies and employers learning about their medical issues, and the female participants were concerned about information being disclosed to others in the community. The study highlighted that most people would like to be informed of the use of their data and have an element of control over their data being used, such as a periodic requirement of consent. The consensus from the study was that the majority of Irish people would be in favour of the idea of their medical data being used for research for the “greater good” of society in general.²⁹ This is a very positive attitude towards medical research at the moment, and it shows that the majority of Irish people understand and accept the importance of access to patients’ medical records in the development of treatments for cancer and chronic illnesses.

Law and Future Research in Ireland

²⁴ B. Hawkes, fn.7 above, p.12.

²⁵ B. Hawkes, fn.7 above, p.13.

²⁶ National Cancer Registry Board (Establishment) Order 1991 (S.I. No. 19 of 1991).

²⁷ A. Sheikh, fn.20 above, p.56.

²⁸ P. Clerkin et al, “Patients’ views about the use of their personal information from general practice medical records in health research: a qualitative study in Ireland” (2013) 30 *Family Practice* 105.

²⁹ P. Clerkin et al, fn.28 above.

The EU data protection directive, implemented by the Data Protection (Amendment) Act 2003 in Ireland, was drafted and designed prior to globalisation, cloud computing and social networking, and it is now widely accepted that new standards of protection are required. The EU Commission wants to harmonise data protection within the European Union by means of the proposed General Data Protection Regulation (GDPR),³⁰ and it is expected that this will be adopted in 2014, to be effective from 2016.

While the draft includes medical information as personal data, the primary aim of the GDPR is to extend the application of EU data protection provisions to situations where either the data processor, the data controller or the data subject is based in the EU. It would therefore apply to organisations outside the EU if they processed the personal data of an EU resident. The notice requirements are expanded and must include retention time for personal data and contact information for the data controller and the data protection officer.

Privacy by design and by default are also included in art.23—it requires that data protection is designed into the development of business processes for products and that services' privacy settings are set at a high level by default. Data protection officers will be obliged to ensure compliance by organisations and all public authorities must appoint data protection officers, as must organisations with more than 250 employees. Consent to data collection and to the purposes for which it will be used must be explicit ("opt in" now) and the consent of minors under 13 must be obtained from their parents. Data controllers must be able to prove consent, and consent must be capable of being withdrawn (unless the data is irreversibly anonymised, in which case this will not be necessary or possible). Article 17 incorporates a "right to be forgotten" where an individual withdraws consent or the data is no longer necessary and there is no legitimate reason for an organisation to keep it.

In Ireland, the Health Information Bill³¹ is due to be enacted in 2014 and will provide the legislation needed to allow for patient information to be transferred between public and private sectors in a safe manner and in line with the best interests of the patient. It will play a significant role in the health information management process, including the collection, use, storage, transfer, disclosure and privacy of personal health information. It will remove information-flow obstacles and will assist in new technologies needed for patient treatment. It will be the root of a national and system-wide information governance framework for the health service in Ireland. The Health Reform Programme in Ireland is the initiative behind the Health Information Bill. The Reform Programme wishes to have a health service created whereby patient records can be accessed wherever the patient is in the country. There will be a national database, and patients' health summaries will be accessible through this. The Health Information Bill is required for this reform to succeed, as the national database will require robust governance. In light of the supremacy of EU law, however, the Bill cannot be enacted if it contains any provision conflicting with any adopted EU legislative instrument.

General Practices and Future Research

Explicit consent will be required from patients in order for the data controller to be able to process identifiable patient information for a purpose other than patient treatment. An opt-in approach will be applicable. Consent to future use of the information must be explained to the patient. Any subsequent conditions the patient develops will require new consent before the information can be used for research. In order for a third party to research the information, the data controller must anonymise the data and protect

Comment [U1]: Re the footnote below, is this a document of the Department of Health? See <http://www.dohc.ie/consultations/closed/hib/>. Also, do you want to refer to the fact that it is listed in Section B of the Government's legislative programme for Spring/Summer 2014? See http://www.taoiseach.gov.ie/eng/Taoiseach_and_Government/Government_Legislation_Programme/

Comment [U2]: In this article, are you using "explicit consent" and "informed consent" interchangeably?

³⁰ 2012/0011 (COD), available at: http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf [last accessed April 14, 2014].

³¹ B. Hawkes, *Discussion Paper on Proposed Health Information Bill* (2008).

the privacy of the patient; otherwise, express consent must be obtained from the patient allowing the third party access to the information. Internal clinical audits do not require explicit consent; however, the patient must have access to information about external clinical audits in the form of a brochure, and the patient must know that he can opt out of the audit.³²

Law and Practice in England—A Precedent to Follow?

Patient privacy and confidentiality in England is governed by the Human Rights Act 1998 and the Data Protection Act 1998.

Patient Privacy: ECHR Law

The Human Rights Act 1998 guarantees everyone a right to respect for their private life, and this includes confidentiality regarding medical records.³³ The Human Rights Act 1998 became applicable in England in 2000 and implemented the ECHR in England. Article 8 of the ECHR applies in England as in Ireland, and it “guarantees a right to respect for private and family life”.³⁴ The patient’s right to privacy over his medical records is protected by art.8 of the ECHR and the National Health Service (NHS) acknowledges this protection for patients and their medical records.³⁵

Data Protection

The Data Protection Act 1998 implemented the EU data protection directive in England and it defines “personal data” in s.1 and “sensitive personal data” in s.2.

Personal data means “data which relates to a living individual who can be identified—(a) from [that] data, or (b) from [that] data and other information which is in the possession of, or is likely to come into the possession of, the data controller ...”.³⁶

Whereas “sensitive personal data” concerns the subject’s race, ethnicity, politics, religion, trade union status, health, sex life or criminal record.³⁷ Patient’s health information therefore comes under the definition of “sensitive personal data” and is awarded greater protection. Informed consent from patients is required before patient records can be disclosed for research.³⁸ The terms “data controller”, “processor” and “data subject” all have the same interpretation in England as they do in Ireland. If there is any breach in a patient’s data protection, the Information Commissioner’s office will investigate the complaint for the patient.³⁹

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Common Law

Previous court judgments in England have allowed patient information to remain private and confidential in the majority of cases. The case of *X v Y*⁴⁰ highlighted the importance of patient confidentiality; in that case, the court held that the health records of two doctors who had contracted AIDs should not be disclosed in a newspaper, despite the public interest in knowing this information.

³² National Consent Advisory Group HSE, fn.11 above, p.91.

³³ See *X v Y* [1988] 2 All E.R. 648.

³⁴ See *S and Marper v UK* [2008] ECHR 1581.

³⁵ NHS Chief Information Officer, *NHS Direct Confidentiality Policy* (2010), p.7.

³⁶ Data Protection Act 1998 s.1.

³⁷ Data Protection Act 1998 s.2.

³⁸ Data Protection Act 1998 s.2.

³⁹ See the UK Information Commissioner’s Office website, www.ico.org.uk.

⁴⁰ [1988] 2 All E.R. 648.

“It is in the public interest that actual or potential AIDS sufferers should be able to resort to hospitals without fear of this being revealed, that those owing duties of confidence in their employment should be loyal and should not disclose confidential matters and that, prima facie, no one should be allowed to use information extracted in breach of confidence from hospital records even if disclosure of the particular information may not give rise to immediately apparent harm.”⁴¹

There will be times when a public interest issue, or threat to the life of another individual, require a breach of patient confidentiality.⁴² The general principle, however, is that patient information between doctor and patient is confidential and should remain so.⁴³ However, in the past few years, the NHS has made huge changes in its storage and use of patient records. The Prime Minister, David Cameron, stated in 2011 that he wished for every NHS patient to be “a research patient with their medical details opened up to private health care firms”.⁴⁴

Electronic Records

The NHS is in the process of changing from written records to electronic records, and they are proving to be a very effective means of communication in England. Electronic records have allowed the NHS to considerably develop its health research databases and, as a result, its overall health system. “The rapid digitization of medical records and administrative databases coupled with advances in statistics and computing capabilities promise to make epidemiological studies for improving health care more fruitful than ever.”⁴⁵

Summary Cards

The NHS, with the help of the Health and Social Care Information Centre (HSCIC), is developing a modern information system which will allow for all medical information (from general practices and hospitals) regarding a patient to be linked and saved in a secure central system which is managed by the HSCIC (data controller). It will provide a summary of patients’ records and will provide medical staff anywhere in England access to basic medical details of the patient in order to treat the patient in an emergency. A summary card is therefore an electronic record of patients’ medical details and it will improve the quality and safety of patient care.⁴⁶ Patients will be asked before medical staff access the information, and if a patient wishes to opt out of the summary card, he can tell his GP. This will ensure that records regarding that patient do not leave the patient’s GP practice and the patient will not have a summary card; however, records regarding that patient in a hospital or other NHS service may still flow into the HSCIC system.⁴⁷ The HSCIC, as the data controller, has the responsibility of ensuring the information remains confidential, and the identifiable information can only be shared with others where:

1. there is a court order;
2. there is a threat to the life of a third party;
3. there is a public interest⁴⁸; or

⁴¹ [1988] 2 All E.R. 648 at 660 .

⁴² See *W v Egdell* [1990] 1 All E.R. 835.

⁴³ NHS Chief Information Officer, fn.35 above, p.8.

⁴⁴ BBC News, “Everyone ‘to be research patient’, says David Cameron” (December 5, 2011), available at: www.bbc.co.uk/news/uk-16026827 [last accessed April 14, 2014].

⁴⁵ R. Krishna, K. Kelleher & E. Stahlberg, “Patient confidentiality in the research use of clinical medical databases” (2007) 97(4) *American Journal of Public Health* 654.

⁴⁶ NHS, “Introduction to summary care records”, available at:

www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Pages/servicedescription.aspx [last accessed April 14, 2014].

⁴⁷ NHS, fn.46 above.

⁴⁸ *W v Egdell* [1990] 1 All E.R. 835.

4. where the patient has consented.⁴⁹

If there is a breach of the Data Protection Act 1998, the Information Commissioner will impose heavy fines and penalties.⁵⁰ Researchers can carry out studies on summary card data; however, the information will be anonymised and unidentifiable. The Confidentiality Advisory Group can allow special approval to researchers who require identifiable information if it believes the research is in the public interest and will benefit the health service, e.g. research on cancer waiting times and the effect on patient survival.⁵¹

Research Networks

The National Institute for Health Research (NIHR) was set up by the NHS in 2006 by the Department of Health. The Clinical Research Network is part of this and its aim is to “create a world class health system within the NHS”.⁵² It provides the resources for clinical studies to be set up quickly and efficiently through the provision of funding, informative staff and help in identifying and recruiting suitable patients to volunteer their medical information for research purposes. The NIHR distributes £280 million research funding per year to primary and secondary care in England.

Future Research in England

As previously noted, the Prime Minister hopes to evolve every NHS patient into a “research patient”.⁵³ It is hoped that all anonymous data generated within the NHS will be used to make medical breakthroughs and to attract extra pharmaceutical companies into England and further develop medical research in England.⁵⁴

Like Ireland, however, England must comply with the EU GDPR which will be in effect from 2016 and will provide tight controls over data protection throughout Europe. All research that occurs in the NHS will have to comply with the GDPR’s guidelines, and it will impose strict regulations on access to patient records for medical research. Consent to data collection and to the purposes for which it will be used must be explicit (opt in) and the consent of minors under 13 must be obtained from their parents. Data controllers must be able to prove consent and it must be capable of being withdrawn. As previously stated, art.17 incorporates a “right to be forgotten” where an individual withdraws consent or the data is no longer necessary and there is no legitimate reason for the organisation to keep it.

Conclusion

Consent is the key to research and patient records in Ireland and England; however, if the information is de-identified and anonymised by the data controller, consent is not needed. Currently the DP Acts, the Constitution, the ECHR and common law provide the bases for privacy and confidentiality in Ireland. The DPC is a source of refuge for any patient who believes that his data has been used inappropriately.

The National Cancer Registry, which is a national research network, has been set up by the Irish Government and is exempt from the DP Acts. The advent of national research networks in Ireland and England allows for huge amounts of research to be undertaken which is integral to medical advances and the development of new information, technology and health services reform. The changeover to electronic medical records has been made in England, and with the introduction of the Health Information Bill in Ireland, the same transition is expected to occur. The majority of patients in Ireland understand the

⁴⁹ NHS, “How sharing information in your medical records can help the NHS to provide better care”, available at: <http://www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Pages/care-data.aspx> [last accessed April 14, 2014].

⁵⁰ NHS, fn.49 above.

⁵¹ NHS, fn.49 above.

⁵² NHS, National Institute for Health Research, *Five year strategic plan for research delivery 2012–2017* (2012).

⁵³ See fn.44 above.

⁵⁴ See fn.44 above.

importance of research and the use of population health datasets in the development of medicine for the greater good.⁵⁵

The future surrounding medical records, datasets and research in Ireland and England are, however, subject to the implementation and transposition of the GDPR. The GDPR will be in effect from 2016, and will govern the use and protection of medical records and population health datasets in Ireland, England and the rest of Europe.

⁵⁵ P. Clerkin et al, fn.28 above.