

# Genetic Research and Human Biological Samples

## The Legal and Ethical Considerations

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# Contents

Foreword by Dr Michael Murphy, Chairman, Health Research Board	1
<b>1 Introduction</b>	<b>5</b>
<b>2 The Doctrine of ‘Informed Consent’</b>	<b>11</b>
2.1 The Principle of Informed Consent as Applied in Standard Healthcare Provision and Treatment	13
2.2 The Healthcare Provider’s Duty of Disclosure of Facts for the Purposes of a Valid Consent	13
2.2.1 Pre-treatment disclosure	13
(a) Material risks	17
(b) The therapeutic privilege	20
2.2.2 Post-treatment disclosure	22
(a) The general duty to disclose	22
(b) The nature and scope of the duty to disclose	24
2.3 The Principle of Informed Consent within the Parameters of Research	25
2.3.1 Types of research – Therapeutic and Non-therapeutic	25
2.3.2 Informed consent:	27
(a) Competent adults	27
(b) Minors	27
(c) The mentally incompetent	28

<b>3</b>	<b>The Participation of Individuals in Genetic Research</b>	<b>31</b>
3.1	The Law	33
3.2	Ethical Guidelines and International Jurisprudence	34
3.2.1	Council of Europe, <i>Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine</i> , Convention on Human Rights and Biomedicine (1997)	34
3.2.2	Irish Medical Council, <i>A Guide to Ethical Conduct and Behaviour</i> , 5th Ed. (1998)	35
3.2.3	Nuffield Council on Bioethics (UK), <i>Human Tissue: Ethical and Legal Issues</i> , (April 1995)	35
3.2.4	Nuffield Council on Bioethics (UK), <i>Mental Disorders and Genetics: The Ethical Context</i> , (September 1998)	36
3.2.5	National Bioethics Advisory Commission (NBAC) (US), <i>Research Involving Persons with Mental Disorders that may affect Decisionmaking Capacity</i> , (December 1998)	41
3.2.6	National Bioethics Advisory Commission (NBAC) (US), <i>Research Involving Human Biological Material: Ethical Issues and Policy Guidance</i> , (August 1999)	41
3.2.7	Medical Research Council (MRC) (UK), <i>Human Tissue and Biological Samples for Use in Research</i> , (November 1999)	44
<b>4</b>	<b>Confidentiality and Security of Information</b>	<b>49</b>
<b>5</b>	<b>Summary and Conclusions</b>	<b>59</b>
5.1	Research Proposals and Genetic Research: Points of Concern	65
5.2	Requirements of an Informed Consent	?
<b>Appendix I</b>	<b>Sample Consent Form</b>	<b>67</b>
<b>Appendix II</b>	<b>The 'Safe Harbor' Principle</b>	<b>69</b>
	<b>List of Cases and Statutes Cited</b>	<b>71</b>
	<b>Bibliography</b>	<b>73</b>

# Foreword



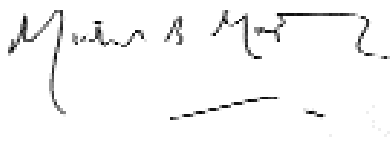


# Foreword

The mapping of the human genome, completed last year, is a major landmark in the history of science. The genome is the set of instructions by which every human being develops and which makes every human being unique. The deeper investigation of this set of instructions through research offers unprecedented opportunities to prevent disease and enhance health. This research requires the skills of scientists and clinicians from a variety of disciplines. Crucially, it requires the co-operation of individuals who are prepared to donate bodily samples such as saliva or blood that can be analysed for genetic markers for certain diseases. Major advances in understanding the genetic origins of diseases such as breast cancer, spina bifida and schizophrenia have been made in this country through the close co-operation of scientists, clinicians and patients and their families.

Important ethical issues arise about the conditions under which patients and their families are invited to donate bodily samples. What information should be provided to patients and families so that they can make an informed decision to donate a sample? What steps should be taken to protect the privacy of the information collected? What, if anything, should donors be told about the examination of samples they have donated? Do donors have rights to any intellectual property that may arise as a result of the research involving their sample? What protections, if any, are required if samples are transferred for analysis to another country?

The Health Research Board, which is involved in genetic studies to identify the genes associated with schizophrenia and alcoholism and to research the link between folic acid and neural tube defects (spina bifida) and orofacial clefts, has had to consider these issues to ensure that these studies conform to the highest ethical standards. In reviewing its procedures, the Board was fortunate to have the assistance of Asim Sheikh BL, of the Division of Legal Medicine, University College Dublin. The Board has decided to put Mr Sheikh's report in the public domain to encourage discussion on the ethics of genetic research. The report should also be of assistance to those engaging in such research, to prospective participants in genetic research and to members of research ethics committees charged with responsibility for reviewing the protocols and procedures of research proposals for genetic research. The Board is publishing this report as the first in what it hopes will be a series on research ethics and research governance.



Michael B Murphy  
Chairman  
Health Research Board  
January 2002





# Introduction





# 1. Introduction

Even before the announcement of the partial completion of the Human Genome Project (HGP), research into the genetic basis of disease was being undertaken in many countries, Ireland among them. Thus, for example, the Health Research Board (HRB) is currently involved in three important studies relating to the exploration of the genetic basis of schizophrenia, alcoholism, neural tube defects and orofacial clefts. The importance of such research cannot be over emphasised. With the completion of the HGP, it is hoped that the link between the estimated 31,000 genes in the human genome and the causes of disease can now begin to be established. The US Department of Energy and the National Institutes of Health give an overview of post-HGP possibilities in relation to predicting disease and disease intervention, stating:

*All diseases have a genetic component, whether inherited or resulting from the body's response to environmental stresses like viruses or toxins. The successes of the Human Genome Project (HGP) have even enabled researchers to pinpoint errors in genes, the smallest units of heredity, that cause or contribute to disease.*

*The ultimate goal is to use this information to develop new ways to treat, cure, or even prevent the thousands of diseases that afflict humankind. But the road from gene identification to effective treatments is long and fraught with challenges...*

*Within the next decade, researchers will find most human genes. Explorations into the function of each one, a major challenge extending far into the 21st century, will shed light on how faulty genes play a role in disease causation. With this knowledge, commercial efforts will shift away from diagnostics and toward developing a new generation of therapeutics based on genes. Drug design will be revolutionized as researchers create new classes of medicines based on a reasoned approach, using gene sequence and protein structure function information rather than the traditional trial-and-error method. The drugs, targeted to specific sites in the body, promise to have fewer side effects than many of today's medicines.*

*The potential for using genes themselves to treat disease, known as gene therapy, is the most exciting application of DNA science. It has captured the imaginations of the public and the biomedical community for good reason. This rapidly developing field holds great potential for treating or even curing genetic and acquired diseases, using normal genes to replace or supplement a defective gene or to bolster immunity to disease (e.g., by adding a gene that suppresses tumor growth).<sup>1</sup>*

The purpose of this paper is to examine the legal and ethical issues that should be considered before researchers commence genetic research which entails the study of the genetic basis of disease. The paper deals mainly with the legal and ethical concerns regarding the nature of the consent that should be obtained from biological/bodily sample/DNA donors who donate biological/bodily/DNA

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<sup>1</sup> At: <http://www.ornl.gov/hgmis/medicine/medicine.html>. See also: Jimenez-Sanchez *et al.* 'Human Disease Genes' *Nature*, 409, 15 February, 2001: 853.

samples that will be utilised as 'coded samples'<sup>2</sup> by researchers for the purposes of discovering the genetic basis of disease. Such donors are 'donor participants' (where research subjects donate biological/bodily sample/DNA for the purposes of non-therapeutic research in which the donors do not receive treatment) in genetic research, as opposed to 'patient participants' (where research subjects actually receive treatment of some kind, for example, gene therapy).

For the above future possibilities to become a reality, there is no doubt that the donation of biological/bodily/DNA samples is imperative in order that such research flourishes, continues and progresses. However, there are many ethical and medico-legal questions regarding the issue of what can and will be done with such samples and these questions must be discussed and analysed in some depth once researchers contemplate this type of genetic research. Such approach is an essential aspect of any research protocol and will ultimately benefit all involved by ensuring that the research is carried out within an ambience of candour, trust and safety, such that participants will be safe, feel comfortable and secure and thereby more willing to participate in research that, it is hoped, will provide better prognosis, therapy, treatment and maybe even a cure for the condition which participants suffer from.

The following illustrates the context in which the legal and ethical issues relating to consent to participate in genetic research arise:

Patient X is asked to donate a blood sample for the purposes of genetic research which is being carried out in Ireland and in conjunction with a Non-EU State into the causes of a disease that is a major cause of disability in the population. He/she is told that some minimal payment will be involved and that the sample will be used for purpose A and in the future might or might not be used for purpose B. He/she is not told whether anyone else might have access to the sample. He/she is not sure if there is any direct benefit in terms of treatment to him/her. He/she is then told that if he wishes to participate he/she should take the consent form home, have a read of it then sign and return it...

#### CASE STUDY

It is clear that a plethora of questions of a medico-legal/ethical nature arise, for example: What information should researchers give to donors of bodily samples before such samples can be obtained? Can samples be used for only one type of genetic study or might they be used for other future genetic studies and, if so, should consent be re-obtained at a later stage or when the initial sample is obtained? Who will have access to the samples given? Can confidentiality/privacy rights of subjects be properly protected? Does the donor have the right to request that such sample be destroyed? Should there be a financial incentive for the donor? These are some of the complex issues that will be discussed in this paper. In order to explore properly all of the important and difficult legal

2 Here, the phrase 'coded sample' is taken from the US National Bioethics Advisory Commission (NBAC). The NBAC describes such a research sample as follows: 'Sometimes termed "linked" or "identifiable", these samples are supplied by repositories to investigators from identified specimens with a code rather than with personally identifying information, such as a name or Social Security Number.' NBAC. *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance: Executive Summary* (NBAC, Rockville, Maryland, 1999) at 1.

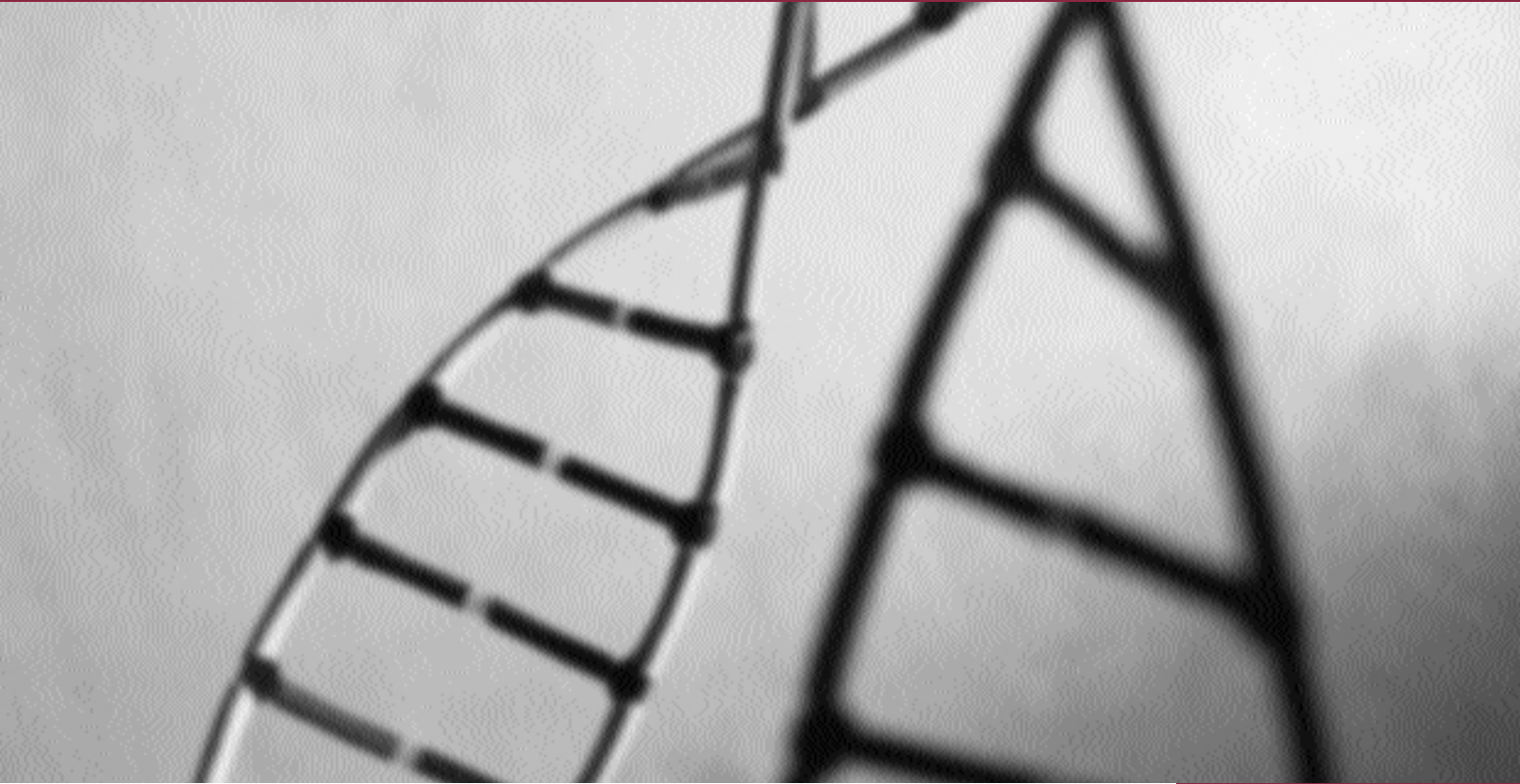
and ethical issues pertaining to the topic of participation in genetic research, the paper will discuss in some depth:

- (i) the law in relation to informed consent in the everyday standard healthcare setting and what information is required to be normally disclosed in order for a consent to be properly informed and valid;
- (ii) the requirements that are necessary for consent to be properly informed and valid in the case of non-therapeutic genetic research;
- (iii) the issue of confidentiality that will take into account the requirements of EC Directive 95/46/EC, *Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of Such Data*;
- (iv) the international ethical consensus on the issue of consent to genetic research.

A sample Consent Form, reflecting the status of current legal thinking and international ethical guidelines, is included as an Appendix to this report.



# The Doctrine of 'Informed Consent'







## 2. The Doctrine of 'Informed Consent'

It is axiomatic that the observance of the doctrine of consent marks the starting point and is the primary essence of both medical treatment and ethical research. Kennedy and Grubb state that the doctrine of consent is 'better expressed as respect for a person's bodily integrity stemming from a right of self-determination'.<sup>3</sup> In Ireland, the Supreme Court has observed:

*The requirement of consent to medical treatment is an aspect of a person's right to bodily integrity under Article 40, s. 3 of the Constitution.*<sup>4</sup>

The Court has also made it clear that:

*If medical treatment is given without consent it may be trespass against the person in civil law, a battery in criminal law and a breach of the individual's constitutional rights.*<sup>5</sup>

By virtue of the importance of the doctrine as a pre-requisite to healthcare and as a fundamental human right, it is imperative that healthcare providers and researchers have an in-depth understanding of it as it works in everyday healthcare and then in the context of research.

Mason & McCall Smith<sup>6</sup> indicate that, depending on the situation, the informed consent and the nature of the information to be disclosed to a patient will vary. This will depend on whether the situation is one of everyday standard healthcare or of research. Thus, informed consent can be divided up into informed consent with regard to *everyday standard healthcare*, and informed consent with regard to *research*. Due to the importance of the doctrine, it is important to examine its significance and operation in standard healthcare in order to evaluate the manner in which the doctrine will apply in research. It will then be seen that the doctrine has special significance when applied to genetic research.

### 2.1 The Principle of Informed Consent as applied in Standard Healthcare Provision and Treatment

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law...

EU CHARTER OF FUNDAMENTAL RIGHTS, 2000

3 Kennedy & Grubb. Eds. *Principles of Medical Law* (Oxford University Press, UK, 1998) at 110.

4 *In re a Ward of Court (withholding medical treatment) (No. 2)* [1996] 2 IR 79 at 156, per Denham J.

5 *ibid.*

6 Mason & McCall Smith. *Law & Medical Ethics* 5th Ed. (Butterworths, Great Britain, 1999) at 278-279.

It is now a well-established tenet of law that, before a patient embarks on any course of medical treatment, his/her consent must be obtained. The reason for this necessity is that it is meant to best protect the autonomy of the patient. A patient expresses his/her autonomy or right to self-determination in law by giving his/her consent to medical treatment. Consent can be implied, verbal or written. It is accepted without a doubt that:

*The patient has the right to chart his own destiny, and the doctor must supply the patient with the material facts the patient will need in order to intelligently chart that destiny with dignity.<sup>7</sup>*

Consent must be valid consent. A valid consent is one that: (i) is made by a person with capacity<sup>8</sup> (ii) is voluntarily given, without any element of duress and (iii) is given with the requisite information of risks, side-effects and alternatives such that the patient is able to make an *informed* decision as to whether or not to proceed with treatment.

Such consent given by a patient is known as an 'informed consent' since the patient is in the knowledge of and understands the full 'material facts' before he/she gives the required consent to the procedure.<sup>9</sup> The doctrine of 'informed consent' is explained by Lord Scarman in the following terms:

*...where there is a 'real' or 'material' risk inherent in the proposed operation (however competently and skilfully performed) the question whether and to what extent a patient should be warned before he gives his consent is to be answered not by reference to medical practice but by accepting as a matter of law that, subject to all proper exceptions (of which the court, not the profession is the judge), a patient has the right to be informed of the risks inherent in the treatment which is proposed.<sup>10</sup>*

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7 *Miller v. Kennedy* 85 Wash. 2d 151, 530P. 2d 334 (1975) aff'g 11 Wash. App. 272, 522P. 2d 852 (1974).

8 The British Medical Association (BMA) states: 'To demonstrate capacity individuals should be able to: understand in simple language what the medical treatment is, its purpose and nature and why it is being proposed; understand its principal benefits, risks and alternatives; understand in broad terms what will be the consequences of not receiving the proposed treatment; retain the information for long enough to make an effective decision; and make a free choice (i.e. free from pressure).' BMA. *Consent Tool Kit* (BMA, London, 2001) at 18.

9 The term 'informed consent' was first used in the American case of *Salgo v. Leland Stanford Junior University Board of Trustees* (317 P 2d 170 (Cal, 1957)) where Judge Bray, at p. 181, stated that the doctor had a duty to disclose to the patient 'any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment... in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent'.

10 *infra*, n13., per Lord Scarman at 649. It should be noted that Lord Scarman's was the dissenting judgment.

## 2.2 The Healthcare Provider's Duty of Disclosure of Facts for the Purposes of a Valid Consent

### 2.2.1 Pre-Treatment Disclosure

Although in theory the concept of informed consent is relatively well understood, the issue of what is to be regarded as a 'material fact' to be disclosed by the healthcare provider to a patient, is somewhat more difficult to answer: (i) Is the healthcare provider obliged to disclose every risk to the patient, regardless of its minimality or medical insignificance? (ii) Is the issue of disclosure purely a matter of clinical discretion, whereby the degree of disclosure is decided in accordance with what would be disclosed by 'a responsible body of medical men' (the *Bolam* test/approach)?<sup>11</sup>

The former 'prudent/reasonable-patient' approach (or the patient standard) reflects the move in some jurisdictions toward full patient self-autonomy, whereby the patient is sovereign and has full command over what is to be done to his/her body and thus requires disclosure by the doctor to the patient of *all* material facts to enable the patient to make a fully informed choice as to whether he/she wishes to proceed with the treatment. The latter 'paternalistic' approach (or the professional standard) leaves the issue of disclosure of facts very much to the discretion and control of the healthcare provider, such that it is the healthcare provider who, in his/her clinical judgment, decides what information should be disclosed to the patient.

The difference in the two approaches is explained in the following manner by Davies:

*In the USA and other common law jurisdictions, the question for the law has come from the perspective of the patient; the law will ask: How much does the patient need to know? In English medical law, the question comes from the medical profession; the law will ask: How much does the doctor think the patient needs to know? The difference is between the rights-based medical law of these other countries and the paternalism and medical protectionism of medical law in England.*<sup>12</sup>

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11 The '*Bolam* Test' is that whereby, traditionally, a doctor will not have acted negligently where he acted 'in accordance with the practice accepted by a responsible body of medical men skilled in that particular art': *Bolam v. Friern Hospital* [1957] 2 All ER 118 (QB). Such a test is used in two contexts: (i) to decide the question of whether a particular instance of diagnosis or treatment met a requisite standard of care and (ii) to decide the question of whether the proper amount of information was given to a patient, such that the patient's consent could be deemed to be a valid one. It should however, be noted that this paternalistic test that seemed to completely vest the standard of care with the medical profession has been eroded certainly in Ireland by virtue of the Supreme Court decision in *Dunne v. National Maternity Hospital* [1989] IR 91 and now also in the UK by virtue of the House of Lords' decision in *Bolitho v. City & Hackney HA* [1998] Lloyd's LR Med. 28; both decisions are authority for the proposition that in certain cases, where there are 'inherent defects' in the medical processes supported by the medical experts as being the standard procedure, then where those processes cannot withstand logical analysis by the law, the law may not support such processes. For further analysis on this point, see: Sheikh, A.A. & Cusack, D.A. 'Collins v. Mid-Western Health Board and O'Connor: GPs, Hospital Doctors, Hospitals and their Duty of Care' *Medico-Legal Journal of Ireland* 6 (2000) 1: 4 at 10-12.

12 Davies, M. *Textbook on Medical Law* 2nd Ed. (Blackstone Press, London, 1998) at 162.

Many countries of the common law world have moved or seem to be moving towards the 'prudent/reasonable-patient' approach. Until very recently, both Ireland and England seemed to adopt an approach that lay between the two, whereby the disclosure of facts was a matter of clinical discretion except where the disclosure of a particular risk

*was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it.*<sup>13</sup>

In the UK, although the courts may not have entirely embraced the 'prudent/reasonable-patient' approach, it seems that they may be moving towards something similar or certainly somewhat more towards a 'pro-patient' approach. The Court of Appeal in the recent case of *Pearce v. United Bristol Healthcare NHS Trust*<sup>14</sup> has, whilst adopting the *Bolam* approach to the disclosure of risks, nevertheless stated:

*In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law... that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt... Obviously, the doctor, in determining what to tell a patient, has to take into account all the relevant considerations, which include the ability of the patient to comprehend what he has to say to him or her and the state of the patient at the particular time, both from the physical point of view and an emotional point of view. There can often be situations where a course different from the normal has to be employed. However, where there is what can realistically be called a 'significant risk', then, in the ordinary event, as I have already indicated, the patient is entitled to be informed of that risk.*<sup>15</sup>

Lord Woolf's emphasis on the patient and the 'reasonable patient' may indicate a certain change in attitude from a practitioner/professional-based test to a more patient-based one.

Very recently, the Irish High Court has also commented on the issue of informed consent. In *Geoghegan v. Harris*,<sup>16</sup> a case concerning dental negligence, the plaintiff's case concerned the alleged failure of the defendant dentist to warn the plaintiff of a risk of chronic neuropathic pain which might result after a bone graft in the course of an implant procedure. The procedure was elective, but involved both a 'cosmetic and functional component'.<sup>17</sup> The court found against the plaintiff, however, following a detailed commentary on the law of informed consent, the High Court concluded by favouring the 'reasonable patient' test which requires full disclosure of all material risks.

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13 *Sidaway v. Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643 at 663 and [1985] AC 871 (HL) at 900, per Lord Bridge. Almost identical words were used by Finlay CJ in the Irish case of *Walsh v. Family Planning Services Ltd* [1992] 1 IR 496, where he stated, at p. 521, that in relation to elective surgery, 'in determining whether or not to have an operation in which sexual capacity is concerned, it seems to me to supply the patient with the material facts is so obviously necessary to an informed choice on the part of the patient that no reasonably prudent doctor would fail to make it'. McMahon & Binchy describe this as the 'third approach': *Law of Torts* (Butterworths, Dublin, 2000) at 381.

14 20th May, 1998: [1999] PIQR P53. The facts are discussed in section 2.2.1 (a) of this paper.

15 *ibid.*, per Lord Woolf MR, at P59.

16 High Court, Unreported: 21st June, 2000. Kearns J.

17 *ibid.*, at 48.

If one were to take the *Bolam* approach, then the issue of what risks are to be disclosed is assessed by examining what a responsible body of medicine would do. Whatever such body decides is to be disclosed is the standard the law will adopt.<sup>18</sup> If however, the seemingly more popular prudent/reasonable-patient approach is adopted, the questions to be asked by a healthcare provider are: What would a patient regard as a material risk, such that it would be necessary to disclose for the purposes of an informed choice by patient? Should all and every fact be disclosed to the patient or are there certain facts and risks that the doctor ought to and can withhold from the patient in order to protect the patient's health. If such facts and risks do exist, then what are they?

#### (a) Material risks

There is no definite manner in which to define a material risk for the purposes of disclosure to a patient. An examination of some case law in various jurisdictions can give some insight into how the courts have tried to deal with the concept of a material risk.

The leading US case is that of *Canterbury v. Spence*,<sup>19</sup> in which the doctor failed to mention a one per cent risk of paralysis, which did in fact occur. The court severely criticised the *Bolam* rationale and stated that it was for the law to prescribe the relevant standard of care regarding what is to be disclosed and not for the medical profession. The court stated that all material risks were to be disclosed to the patient, and what were material risks was a question decided by the 'prudent patient' test which states that:

*a risk is... material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy.*<sup>20</sup>

The court was therefore stating that, for the purposes of a doctor's duty of disclosure, it was not what was regarded as adequate by the medical profession that was the test to be used, but rather what the 'reasonable patient' would regard as adequate. The question therefore to be asked is: Would the reasonable patient attach a significance to this risk, such that he/she would not go ahead with the treatment if the risk were disclosed to him/her? If the patient would attach significance to the risk, then regardless of its insignificance to the healthcare provider, it would have to be disclosed.

In the Canadian case of *Reibl v. Hughes*,<sup>21</sup> there was a four per cent risk of death and a ten per cent risk of stroke if the patient had surgery done to correct the narrowing of the carotid artery, which was causing high blood pressure. Neither of these risks was communicated to the patient and he consented to the operation. Although the operation was performed competently, the patient did in fact have a stroke resulting in serious paralysis and impotence. He sued the doctor claiming that his consent was not an 'informed consent'.

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18 The *Bolam* test/approach as applied to the disclosure of information has been the test that the UK courts have used to decide the degree of information that a patient was entitled to be told. In the *Sidaway* case, this was the test endorsed subject to the dicta of Lord Bridge who said that the disclosure of facts was a matter of clinical discretion save where the disclosure of a particular risk 'was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it' (*supra*, n13). The *Bolam* test/approach in relation to the disclosure of information has also been endorsed in Scotland: *Moyes v. Lothian Health Board* (1990) SLT 444, at 449, per Lord Caplan. However, it seems that the UK courts may also be shifting towards the prudent patient rationale. A definitive English judicial stance cannot be said to currently exist on the issue of the disclosure of information regarding risks to patients: see further: Brazier, M. & Miola, J. 'Bye-Bye Bolam: A Medical Litigation Revolution?' *Med. L. Rev.* (2000) 8, 1: 85 at 107-110.

19 (1972) 464 F 2d 772.

20 *ibid.*, at 787.

21 (1980) 114 DLR (3d) 1.

The Canadian Supreme Court, followed the rationale of the court in *Canterbury*, stating that a surgeon, without being questioned by the patient, should disclose to him the nature of the proposed operation, its gravity and any material, special or unusual risks. Even if a certain risk was a mere possibility, which ordinarily need not be disclosed, if its occurrence carried serious consequences, for example, paralysis or even death, it was to be regarded as a material risk requiring disclosure.<sup>22</sup>

Again, the test to be used was whether the procedure was one which 'the average prudent person, the reasonable person in the plaintiff's particular position, would agree to or would not agree to, if all material and special risks of going ahead with the surgery or forgoing it were made known to him'.<sup>23</sup>

The Canadian case of *Videto v. Kennedy*<sup>24</sup> summed up the issue of risk materiality stating the following as noted by Jones:<sup>25</sup>

- (i) The question of whether a risk is material and whether there has been a breach of duty of disclosure should not be solely determined by the standards of the profession. Medical professional standards are merely a factor to be considered.
- (ii) A risk which is a mere possibility does not ordinarily have to be disclosed, but if its occurrence would have serious consequences it should be regarded as a material risk.
- (iii) The question of whether a particular risk is a material risk and whether there has been a breach of duty is a matter to be decided by the trier of fact.
- (iv) The doctor does have a 'therapeutic privilege', whereby the emotional condition of the patient may in certain cases justify the doctor in withholding or generalising information which otherwise should be more specific.

In the case of *Rogers v. Whitaker*,<sup>26</sup> the patient was almost blind in her right eye, but her left eye was normal. The defendant doctor advised her that an operation could improve her sight. The plaintiff asked many questions concerning the consequences of the operation, but did not ask if there was a risk to her left eye. There was a 1 in 14,000 chance of sympathetic ophthalmia developing in the left eye, but the doctor did not mention this to the patient and the condition did in fact develop. The Australian High Court rejected the *Bolam* test with regard to the disclosure of information to the patient and adopted the prudent patient material risk test, stating that, although the risk was extremely small, it was a material risk requiring disclosure since the reasonable person in the patient's position would be likely to attach significance to the risk. By virtue of recent judicial dicta, this stance is now also the one favoured by both the UK and Irish courts.

In *Pearce v. United Bristol Healthcare NHS Trust*,<sup>27</sup> the plaintiff suffered a stillbirth. The birth was overdue, however, the examining doctor considered that intervention was not appropriate. The risks involved with induction and the disadvantages of a Caesarean section had been discussed with the plaintiff. However, the risks of a stillbirth associated with non-intervention were not discussed. The question therefore arose: Had the plaintiff been informed of the risk of a stillbirth, would she have

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22 Here, the court was repeating its own dicta laid down in the case of *Hopp v. Lepp* (1980) 112 DLR (3d) 67, 81 (SCC).

23 *supra*, n21, at 16.

24 (1981) 1254 DLR (3d) 127, 133-134 (Ont. CA).

25 Jones, M.A. *Medical Negligence* 2nd Ed. (Sweet & Maxwell, London, 1996) at 344.

26 (1992) 109 ALR 625.

27 May 20th, 1998: (CA) PIQR [1999] P53. See section 2.2.1 of this paper for analysis of legal points of this case.

opted for a Caesarean? The risk of a stillbirth was noted to be very small, in the scale of 0.1 to 0.2 per cent. This risk, was not considered to be a 'significant risk', such that there was any duty on the part of the examining doctor to inform the patient of this 'very, very small additional risk',<sup>28</sup> especially since she was in a distressed state. It was found as a fact that, even if the plaintiff had been told of the risk, she would still not have agreed to intervention. The Court therefore found against the plaintiff.

The facts of a recent Irish High Court decision in *Geoghegan v. Harris* have already been examined. The status of Irish law in relation to the disclosure of risks is unambiguously expounded by Kearns J, who states:

*The application of the reasonable patient test seems more logical in respect of disclosure. This would establish the proposition that, as a general principle, the patient has the right to know and the practitioner a duty to advise of all material risks associated with a proposed form of treatment. The Court must ultimately decide what is material. 'Materiality' includes consideration of both (a) severity of the consequence and (b) statistical frequency of the risk... The reasonable man, entitled as he must be to full information of material risks, does not have impossible expectations nor does he seek to impose impossible standards.*<sup>29</sup>

He goes on to state:

*It is the view of this Court that current Irish law imposes the following obligations on a medical practitioner in relation to disclosure of risks as follows-*

- (a) The requirement on a medical practitioner is to give a warning of any material risk which is a known or foreseeable complication of an operative procedure properly carried out.*
- (b) The test of materiality in elective surgery is to inquire only if there is any risk, however exceptional or remote, of grave consequences involving severe pain stretching for an appreciable time into the future.*<sup>30</sup>

And continues by observing:

*This Court is of the view that the 'reasonable patient' test, which requires full disclosure of all material risks incident to proposed treatment, is the preferable test to adopt, so that the patient, thus informed, rather than the doctor, makes the real choice as to whether treatment is to be carried out. It is the view of this Court that assessment of the duty of disclosure on this basis is more logical than the professional standard test, whereby the Court adopts the standard of the medical profession, yet reserves the right to override the views of the medical experts as and when it sees fit...*<sup>31</sup>

Thus, by virtue of this decision, it is clear that Irish law has now adopted the prudent/reasonable patient test whereby a material risk is one which involves the consideration of the following questions: (i) Would a patient attach a significance to the risk? (ii) Is there a reasonably foreseeable risk that is attached to the proposed treatment? (iii) Would its occurrence have serious consequences into the future? Where the answers are in the affirmative, then such risk is material and must be disclosed to a patient. Such an approach respects patient autonomy to a much higher degree by placing the

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28 *ibid.*, per Lord Woolf MR, at P60.

29 High Court, Unreported: 21st June, 2000, at 31-32 (Main Section).

30 *ibid.*, per Kearns J, at 1-2 (Summary Section).

31 *ibid.*, at 3-4.



decision-making process regarding medical treatment firmly in the hands of a patient. The patient, thus possessed with such mechanism and information, is in the most appropriate mindset within which to be able to make a decision with regard to medical treatment that concerns him/her.

Consent should be considered as a process, not an event, and it is important that there is continuing discussion to reflect the evolving nature of treatment.

BMA - CONSENT TOOL KIT, 2001<sup>32</sup>

#### (b) The therapeutic privilege

Despite the test to be adopted in disclosing information to a patient within the ambit of everyday standard healthcare, there is no doubt that there does exist a 'therapeutic privilege', whereby the healthcare provider is allowed to withhold some information from a patient. This is accepted in most jurisdictions, not as a complete defence for the doctor to withhold information from a patient, but on the basis that:

*Even if the risk be material, the doctor will not be liable if on a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health.*<sup>33</sup>

Lord Scarman in the same case explained what was meant by the privilege, stating:

*...this exception enables a doctor to withhold from his patient information as to risk if it can be shown that a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a serious threat of psychological detriment to the patient.*<sup>34</sup>

It is difficult to pinpoint what exactly may be regarded as disclosure that is of psychological detriment to a patient, but it must consist of such information that would cause the patient more harm than good. The onus of establishing the justification of the privilege lies with the doctor. The justification will be based necessarily on a clinical judgement which must be on reasonable grounds.

The US President's Commission in its report, *Making Health Care Decisions*, attempts to lay down the parameters of the therapeutic privilege, stating

*...the privilege should not apply in situations when the potential harm to the patient from full disclosure would result not from the disclosure itself, but from a treatment decision the practitioner fears the patient might make as a result of the information disclosed. More plausible claims of therapeutic privilege might involve certain disclosures to patients previously known to be suicidal or those susceptible to serious psychological effects of stress, and in situations where there is strong reason to believe that a particular disclosure is likely to result in serious self-destructive behaviour that could not be justified in terms of the patient's own long-term values and goals... there is much to suggest that the therapeutic privilege has been vastly overused as an excuse for not informing patients of facts they are entitled to know. In the light of the values at stake, the burdens of justification should fall*

32 British Medical Association. *Consent Tool Kit* (BMA, London, 2001) at 9.

33 *Sidaway Case*, *supra*, n13, per Lord Scarman, at 655.

34 *ibid.*, at 653, repeating the principles that were enunciated by the court in the case of *Canterbury v. Spence* (1972) *supra*, n20.



*upon those who allege that the informing process is dangerous to patient health, and information should be withheld on therapeutic grounds only when the harm of its disclosure is both highly probably and seriously disproportionate to the affront to self-determination.<sup>35</sup>*

An examination of some cases shows a somewhat dubious application of the therapeutic privilege. An example of the privilege was seen in the Australian case of *Battersby v. Tottman*<sup>36</sup> where the doctor had prescribed high doses of a drug to treat a patient with mental illness. The doctor was aware of the risk of eye damage to the patient as a result of the treatment but was of the opinion that any disclosure of either the risks or monitoring by an eye specialist would have a detrimental effect on the patient. The patient did subsequently develop permanent eye damage and sued the doctor. The court decided that the patient would have reacted hysterically and irrationally as a result of her mental condition and thus the doctor was entitled to act for her and not to disclose the risks to her. Although this may seem to be a valid use of the privilege defence, it is interesting to note the dissenting judgment of Zelling J, who stated that, in his opinion, no doctor was ever entitled to give a patient such treatment as would blind her or seriously damage her eyesight without first discussing it with her, regardless of the possible reaction of the patient. He stated in rather stark terms

*...a doctor could hardly chop off a patient's leg without discussing it with the patient first. I see no reason why a doctor should be able to send a patient blind and be excused by saying 'I thought it was in your best interests to be blinded rather than have your treatment hampered.'*<sup>37</sup>

In the Irish case of *Daniels v. Heskin*,<sup>38</sup> the doctor, while repairing the torn perineum of the plaintiff who had given birth to a baby while at home, broke the needle and left a portion of it in the plaintiff's flesh. The defendant doctor did not tell the patient on the basis that it would damage her health, but merely told the midwife to monitor for any unusual occurrences. The plaintiff eventually discovered her predicament and the needle was removed by another doctor. The plaintiff sued the doctor. Lavery J, in the Supreme Court, stated that no damage had been caused by the non-disclosure since the needle was successfully removed. Her action therefore failed on the issue of causation.<sup>39</sup> Kingsmill Moore J's rationale was that the therapeutic privilege was justified on the basis that whether or not to disclose something to the patient depended, *inter alia*, on the patient's

*...health, social position, intelligence, nature of the tissue in which the needle is embedded... the needle was not in any place where any immediate damage was to be anticipated; husband and wife were of a class and standard of education which would incline them to exaggerate the seriousness of the occurrence and to suffer needless harm...<sup>40</sup>*

It is submitted that Kingsmill Moore J's position, with respect, can no longer represent the law in this or in any other jurisdiction, and has been criticised by leading academics and by the Supreme Court itself.<sup>41</sup>

35 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Making Health Care Decisions* (US, 1983): as noted by Kennedy & Grubb. *Medical Law: Text with Materials* 2nd Ed. (Butterworths, UK, 1994) at 212-213.

36 (1985) 37 SASR 524 (SC of S. Aus).

37 *ibid.*, at 527.

38 [1954] IR 73.

39 *ibid.*, at 81.

40 *ibid.*, at 87.

41 Jones has stated of this dicta that 'It may be that this approach reflects the attitudes of an earlier age, when medical paternalism was more widely accepted than it is today', Jones, M.A., *op. cit.*, at 185. In *Walsh v. Family Planning Clinic* [1992] 1 IR 496, McCarthy J, at 520, commenting on the *Daniels* case, stated 'The learned trial judge may well have been offending against the very principle that he was seeking to uphold.'

These cases do reflect the fact that the therapeutic privilege ought to be used only in the most extreme of cases and where there is a high probability of danger to the patient's health if the information in question is revealed to the patient. It is not and never should be utilised as a licence to withhold material information from a patient.

### 2.2.2 Post-Treatment Disclosure

In the cases discussed above, the situation referred to pre-treatment disclosure and the amount and nature of information to be given to the patient for the purposes of enabling the patient to make an informed decision with regard to whether or not to go ahead with any medical procedure. But what of 'post-treatment disclosure', i.e., where, subsequent to a medical procedure, a mishap occurs? What continuing duty, if any, is there on a doctor such that he/she may have a duty to 're-contact' the patient where he/she thinks that there may be (a) a danger from the initial treatment rendered or (b) a new danger from the initial treatment that has just come to the knowledge of the doctor?

McMahon & Binchy state:

*the answer will depend on the degree of risk which has been discovered about the former treatment; but where the former patient is continuing to act on the advice given, it seems clear that there should be a stringent duty to go to some lengths to communicate urgently with the former patient.<sup>42</sup>*

It is submitted here that, regardless of the degree of risk, the courts would look towards the seriousness of the consequences in the occurrence of the risk. It is the future serious consequences of ignoring the risk that should be a determining factor in contemplating a duty to re-contact, as was seen above when the concept of a 'material risk' was examined.

#### (a) The general duty to disclose post-treatment

That there exists such a duty does not seem to be in doubt. In *Lee v. South West Thames Regional Health Authority*,<sup>43</sup> Sir John Donaldson MR asked the question:

*Suppose that, by accident, he [the patient] is given a quantity of air as well as blood and suffers serious ill effects. Is he not entitled to ask what treatment he in fact received, and are the doctor and hospital authority not obliged to tell him... Why is the duty different before the treatment from what it is afterwards? If the duty is the same, then if the patient is refused information to which he is entitled, it must be for consideration whether he could bring an action for breach of contract claiming specific performance for the duty to inform.<sup>44</sup>*

The same judge, in the subsequent case of *Naylor v. Preston Area Health Authority*,<sup>45</sup> reiterated this line of thought, stating that:

*...there is a duty of candour resting on the professional man... This also appears to be recognised by the Medical Defence Union, whose view is that 'the patient is entitled to a*

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42 McMahon & Binchy. *Law of Torts* 3rd Ed. (Butterworths, Dublin, 2000) at 399.

43 [1985] 2 All ER 385 (CA).

44 *ibid.*, at 390.

45 [1987] 2 All ER 353, [1987] 1 WLR 985 (CA).

*prompt, sympathetic and above all truthful account of what has occurred' (Journal of the MDU (1986) Vol. 2, No. 2, p. 2)<sup>46</sup>*

The question, however, is *how far* this duty extends and what is its scope? Thus, where the doctor becomes aware of a further risk or of a new risk or danger from the initial treatment, what is the nature of the duty to *re-contact* a patient?

If there is a failure to inform whereby this 'may cause further injury if, for example, the patient takes a risk that he would otherwise have avoided, or if the patient's ignorance leads to a delay in diagnosis (resulting in additional harm) if an emergency should subsequently arise as a result of the injury of which he is unaware',<sup>47</sup> then an action can sound in negligence. However, a plaintiff will have difficulty establishing negligence as a result of the failure to disclose information, unless the harm caused resulted from the lack of disclosure.

#### **(b) The nature and scope of the duty to disclose post-treatment**

The situation in the future and especially in the case of genetic research will depend on the nature of the consent form and the consent that the patient specifically gives. Consent forms will have to ask:

- (i) the types of tests that the patient would like done on the sample given by him/her; and
- (ii) whether or not the patient will want to be re-contacted if new information comes forward about the initial test.

In order for this to take place, the patient or research participant will have to know the full nature and extent of the research project and whether the results will be conveyed to them. If the results are to be conveyed to them, then their very specific consent, in relation to the results/information they wish to receive and any other results over and above the initial purposes of the research project, will have to be obtained.

When, however, does this duty end, if in fact it ever does? Does the doctor have a duty to warn that patient in the future of a potential change or further threat to his health that results from the same initial test?

Most cases concerning a duty to warn entail situations where the doctor has not adequately warned the patient about either a pre- or post-operative risk. In both situations the individual is still under the care of the doctor and therefore the doctor has a duty of care to disclose any risks that may exist. In such cases, the doctor has caused the initial harm either by making a mistake in an operative procedure or by failing to inform the patient of a subsequent side effect of the procedure. In either case, it is that same initial harm that has caused the later damage.<sup>48</sup> There are certain US cases where the courts have created duties for doctors to disclose subsequently discovered risks of treatments. In *Schwartz v. United States*,<sup>49</sup> the plaintiff, while in the US Navy, had a special dye ('umbrathor') inserted into his sinuses so that physicians could take an x-ray. Several years later he learned that the dye had caused a tumour. The court noted that the dangers of dye had been known for a long time before the plaintiff's illness and that therefore the Government had a duty to review the records of all the

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46 *ibid.*, at 360.

47 Jones, M.A., *op. cit.*, at 186.

48 Jones, M.A. *Medical Negligence* (Sweet & Maxwell, London, 1991) at 128-132.

49 230 F. Supp. 536 (E.D. Pa. 1964), as cited by Andrews: Andrews, L.B. 'Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks' *Houston Law Review* Vol. 29:1 [1992] at 171.

patients who had been treated with the dye and to warn them of the danger. The court noted that 'even if [Schwartz] had never returned to a Government physician after his discharge from military service, there was a duty resting on the Government to follow up those cases in which the umbrathor had been installed'.<sup>50</sup>

The case of *Tresemmer v. Barke*<sup>51</sup> involved the insertion of a 'Dalkon Shield IUD' (a contraceptive intra-uterine device) where the doctor neglected to mention to the patient that the device should be removed. The device was inserted six years before the action was brought. The defence claimed that the plaintiff should be barred from bringing the action since it was beyond the time limit by virtue of the Statute of Limitations. The court, however, disagreed since it found that the doctor's failure to re-contact the patient to disclose the fact that the device should be removed was a 'continuing omission' and that the statute therefore did not begin to run until the patient learned that the device had been recalled.

Andrews also describes the doctor's continuous duty to a patient as a situation analogous to a doctor's duty not to abandon a patient. She states that:

*A person who engages a physician for diagnosis and treatment implicitly engages the physician to attend throughout the illness or until the services are no longer needed.*<sup>52</sup>

She cites the case of *Ricks v. Budge*,<sup>53</sup> where the court stated that a physician's employment continues as long as the patient requires attention, in the absence of a contrary agreement, and that, if the doctor were to end the relationship while the patient still needed treatment, the doctor will have abandoned his patient and is in breach of his duty towards that patient.

It is therefore clear that, in the absence of an agreement between doctor and patient ending the treatment or limiting the relationship in such a way that the patient knows that the doctor-patient relationship has ended, then there exists a continuing duty on behalf of the doctor to act to treat the patient.

It should be noted, however, that in a situation where a non-therapeutic study is being carried out to discover the genetic basis of disease and where it has been decided that participants will not receive the results of such study, there will be no duty of post-treatment disclosure since there has been no 'treatment' of any sort. In therapeutic research or in a genetic counselling situation, an obligation may arise to inform the donor patient subsequently, if new information through the genetic research or genetic testing becomes available that would affect his or her condition or reveals some other condition.

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50 *ibid.*, at 540, as cited by Andrews, *op. cit.*, at 171.

51 150 Cal. Rptr. 384, 394 (Ct. App. 1978).

52 Andrews, *op. cit.*, at 172.

53 64 P, 2d 208, 211-12 (Utah) (1937), as cited by Andrews, *op. cit.*, at 172.

## 2.3 The Principle of Informed Consent within the Parameters of Research

Genetic research is subject to the same standards as any other branch of medical research in that informed consent is required from the donor at the time a sample is obtained. There are, however, certain features of genetic research which give rise to special ethical issues...

UK HUMAN GENETICS COMMISSION, 2001<sup>54</sup>

The necessity of 'Informed Consent' within the context of research is an absolute imperative. As Moreno notes:

*As the field of medical ethics has grown, some distinguished commentators have continued to defend the view that no research is permissible without the subject's informed consent. They point out that scientific progress is morally optional, while respect for human beings and their self-determination is not.*<sup>55</sup>

Thus, from the outset, the obtaining of informed consent from a research participant is to be regarded as part and parcel of the research project itself and not a concept that exists apart. Any default from this absolute rule will invalidate any research project by virtue of the fact that (i) the absence of a valid informed consent from a research participant makes the research unlawful and (ii) any ethics committee considering a research proposal would not approve any such project without this most vital ingredient.

### 2.3.1 Types of Research

There are two main categories of medical research: Therapeutic and Non-therapeutic.

**Therapeutic research:** The primary aim of therapeutic research is essentially diagnostic, that is, to treat and/or cure a disease or illness. The research participant will usually be a patient, in other words, he/she will actually receive treatment, albeit new or experimental, which it is hoped will have a therapeutic benefit on the patient/research participant. The desired benefit is therefore direct in terms of treatment.

Kennedy & Grubb<sup>56</sup> illustrate three situations where therapeutic research may be carried out:

- (a) a doctor tests the efficacy of a new treatment where none had previously been available and the patient would have received ordinary nursing care, symptomatic relief but nothing else;
- (b) a doctor tests the efficacy of a new treatment as against other established forms of treatment;
- (c) a doctor tests treatments A, B, and C (all of which are established) because it has not been established which is the most efficacious.

54 UK Human Genetics Commission. *Whose Hands on your Genes? - A discussion document on the storage, protection and use of personal genetic information* (2001) at 23.

55 Moreno, J.D. 'Critical Issues Concerning Research Involving Decisionally Impaired Persons' in: *Research Involving Persons with Mental Disorders that may Affect Decisionmaking Capacity* Volume II (US National Bioethics Advisory Commission, Rockville, Maryland, May 1999) at 52.

56 Kennedy & Grubb, *op. cit.*, *Medical Law: Text with Materials*, at 1042.

**Non-Therapeutic research** is where the primary aim is not immediate therapy but, through testing a hypothesis or through the collection of data, a contribution to general knowledge is made or a discovery of knowledge is made. Thus, although the research may benefit the subject in the future or in the longer term, it is not directed intentionally as therapy to the subject. Non-therapeutic research does therefore not usually involve patients who receive treatment and a desired direct benefit in terms of treatment, but involves research participants from whom information/bodily samples are collected and as a result of which there may be a future or long-term benefit for the participants in terms of increased knowledge of the condition from which they suffer and/or new or improved treatment.

The main and simplest distinction between the two types of research, therefore, lies in the intention of the researcher.

In therapeutic research, there exists the *dual* intention and aim of:

- (i) seeking to benefit the patient who is the research subject by means of treatment,
- and
- (ii) gathering data of a generalised/specific nature.

In non-therapeutic research, the primary intention is that of gathering data and increasing knowledge and *not* immediate treatment.

<b>Therapeutic Research</b>	<b>Example: GENE THERAPY</b> <b>Primary Intention:</b> <b>Other Intention:</b> <b>Benefit:</b>	<b>Immediate treatment/therapy/cure</b> <b>Gathering data</b> <b>Direct/immediate in relation to treatment</b>
<b>Non-Therapeutic Research</b>	<b>Example: RESEARCH ON GENETIC BASIS OF ALCOHOLISM</b> <b>Primary Intention:</b> <b>Other Intention:</b> <b>Benefit:</b>	<b>Identification of genetic basis of disease/gathering data</b> <b>Long-term/future treatment/therapy/cure</b> <b>Long-term/future in relation to treatment</b>

#### TYPES OF RESEARCH

Thus, research which seeks to identify the genetic basis of disease by collecting biological/bodily/DNA samples from research participants is non-therapeutic. The collection of such samples may identify the genetic basis of the disease by locating the gene/s possibly responsible for certain conditions and diseases and may offer the benefit of insights into the disease, but such research will not usually offer the present and direct benefit of treatment. Those such benefits are in the long term.

In research of any class, a high standard of disclosure is necessary. Within the parameters of non-therapeutic genetic research, the very highest standard of disclosure is required. The requirement is stated in the Canadian decision of *Halushka v. University of Saskatchewan*.<sup>57</sup>

<sup>57</sup> 53 D.L.R. (2d) 436 (Sask. C. A. 1965).

*There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself. The example of risks being properly hidden from a patient where it is important that he should not worry can have no application in the field of research. The subject of medical experimentation is entitled to full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.<sup>58</sup>*

The *Patient Standard* is the correct standard to be applied with regard to any type of genetic research and requires full and complete disclosure of all facts. Being research, there seems to exist no reason to withhold any information whatsoever from the patient and the normal 'therapeutic privilege' clearly does not apply in such situations. The same full disclosure should apply in cases where the patient has an advanced stage of illness and would be more willing to volunteer than a patient who had the illness to a lesser degree. Care should clearly be taken not only in relation to the information given, but also to the way in which it is conveyed. It should be conveyed clearly in a manner in which the reasonable patient at such a stage of the illness would be able to understand the nature of the procedure and the risks involved and then be able to consent.

### 2.3.2 Informed Consent

#### (a) Competent adults

##### Therapeutic and Non-Therapeutic Research

In the case of the competent adult, in cases of both therapeutic and non-therapeutic research, once there is full disclosure of *all* facts (in relation to the objectives of the research, the personnel involved, the procedure involved, existence of alternatives, the side-effects if any, benefits and risks, advantages and disadvantages) to the adult, it will be the adult who will consent by means of a written informed consent.

#### (b) Minors

##### Therapeutic Research

It seems that the consent of an incompetent minor to participation in therapeutic research can be given by a proxy (an individual who can lawfully make a decision for another). This must be without unlawful pressure. Kennedy & Grubb<sup>59</sup> indicate that the doctor must give full disclosure to the proxy, including the disclosure of any risks involved. The proxy must also be satisfied that on a reasonable assessment of a risk-benefit ratio, the treatment is in the best interests of the child.

It should be noted that, before 1997, for the purposes of normal medical treatment, a minor was an individual below the age of 18 years. Since 1997, the provisions of section 23 of the Non-Fatal Offences against the Person Act 1997 should be noted. This section states that:

*(1) The consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his or her person, shall be as effective as it would be if he or she were of full age; and where*

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58 *ibid.*, at 442-443.

59 Kennedy & Grubb, *op. cit.*, *Medical Law: Text with Materials* at 1052.



*a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his or her parent or guardian.*

*(2) In this section "surgical, medical or dental treatment" includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment.*

*(3) Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted.*

Thus, a minor aged between 16 and 18 years can now consent to surgical, medical or dental treatment, which includes any procedure undertaken for the purposes of diagnosis, and any procedure including the administration of an anaesthetic, which is ancillary to any treatment as it applies to that treatment.

An incompetent minor, for the purposes of 'surgical, medical or dental treatment', is one who is below the age of 16 years. The Act may be of relevance to therapeutic research since diagnosis and treatment may be part of such research. However, due to the fact that such diagnosis and treatment is still in the form of research, as a matter of good practice and prudence the consent of a guardian should still be required along with consultation and serious consideration of the views of the minor.

#### Non-Therapeutic Research

As regards non-therapeutic research, where the benefit to the individual is not direct in terms of treatment, Tomkin & Hanafin<sup>60</sup> suggest the test laid down in *S v. McC; W v. W*,<sup>61</sup> where a parent or a guardian can give a legally effective consent to any procedure to which a 'reasonable parent' would consent. This assumes that a 'reasonable parent' would not normally put the child's interests in jeopardy. This consent could only be valid after full disclosure. Section 23 of the Non-Fatal Offences against the Person Act, 1997, is not relevant for the purposes of non-therapeutic research since such research does not involve diagnosis or treatment but only the ascertainment of knowledge.<sup>62</sup> Thus, for the purposes of non-therapeutic research, a minor is an individual who is below the age of 18 years. In such cases, again, parental consent or the consent of a next of kin would be required along with the consultation and consideration of the views of the minor.

#### (c) The mentally incompetent

##### Therapeutic Research

As regards the mentally incompetent adult, the situation is not clearly defined and depends on whether the research will be therapeutic or non-therapeutic. With regard to therapeutic research, Kennedy & Grubb observe that:

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60 *Irish Medical Law* (Round Hall Sweet & Maxwell, Dublin, 1995) at 38.

61 [1972] AC 24 at 57 per Lord Hodson: This was a case where the paternity of a child needed to be determined. The issue before the Court of Appeal was whether a blood test from the child was in his best interests. Here, such blood test was not 'therapeutic' but the information gained from it would provide an indirect benefit to the child. Lord Hodson stated: 'Here the court is occupying the position of the parent and must act as the judicial reasonable parent. The parent is not guilty of assault if he physically interferes with his child by way of reasonable restraint or chastisement or for therapeutic reasons.'

62 Kennedy & Grubb also make this point in relation to an almost identical provision of the UK Family Reform Act, 1969: *op. cit.*, at 1055.



*...consent, in the case of an incompetent adult, is no longer the relevant consideration. Instead, the doctor stands as a proxy and is entitled in law to treat if such treatment is in the patient's best interest... By this reasoning, the doctor may involve the incompetent adult in therapeutic research if what is to be undertaken is in the patient's best interests. Clearly, if the treatment holds out a prospect of benefit and is not available other than in a research project, or if the prospects of benefit outweigh both any risks that may be involved and the consequences of not being exposed to the procedure, the involvement of the incompetent adult would seem to be prima facie lawful.<sup>63</sup>*

## Non-Therapeutic Research

With regard to non-therapeutic research, the legal status quo of such research is currently uncertain. Generally, the rule at law is that no one can consent to any treatment on behalf of an adult patient. When the adult is unable to express consent by virtue of mental incapacity, then, in normal cases, a doctor can only act out of necessity when the treatment is in the patient's best interest, for example, in a life-threatening emergency.

With regard to therapeutic research, again the doctor must act in the best interests of the patient and only if those best interests can be served by the therapeutic research and the benefit outweighs the risks.

Such necessity could not exist in terms of non-therapeutic research since its aim is not treatment. Since there is no necessity, the healthcare provider cannot act. Since the adult is incompetent, then in normal circumstances, he/she cannot consent nor can anyone else on their behalf. Commenting on this general rule, Kennedy & Grubb state:

*From this would follow the inevitable conclusion that non-therapeutic research on an incompetent adult is unlawful.<sup>64</sup>*

The reason for such rationale is that, in the light of a lack of consent and an absence of direct benefit in terms of treatment, there can be no good reason to involve an incompetent adult in non-therapeutic research. However, such rationale is based on the general reasoning that non-therapeutic research has no 'benefit' to a research participant. While this may be accurate in terms of direct benefit in relation to treatment (since treatment is not the aim of non-therapeutic research), to say that non-therapeutic research holds no 'benefit' at all to the participant is not entirely accurate. This is especially so in relation to research into the genetic basis of disease, since the findings of such research, while not immediately aimed at treatment, therapy or cure, may give invaluable insights into disease which may hold indirect benefits to research participants. Above and beyond this, the mentally incompetent and minors are primary target groups for such research since it is those very groups that suffer from certain serious diseases that will be the target of genetic research. Thus, not allowing non-therapeutic research on these groups may entirely exclude the hopes of any medical or scientific progress, therapy, treatment or cure at any future time. Notwithstanding the lack of legal clarity on the matter,<sup>65</sup> several schools of thought abound and it has been stated that:

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63 Kennedy & Grubb, *op. cit.*, *Principles of Medical Law*, at 725-726.

64 *ibid.*, at 731.

65 *ibid.* Kennedy & Grubb state that the inevitable conclusion is that such research is unlawful. Whilst this may be completely accurate, perhaps it is more prudent to say that the matter lacks legal clarity in light of the fact that the matter remains untested by the courts or commented on by way of legislation.

*The prevailing ethical standpoint is that volunteers in non-therapeutic research should never be exposed to a risk greater than that which can be described as minimal... In addition to setting the limit to non-therapeutic research at minimal risk, two further limits are recognised as ethically appropriate in the case of research on those incompetent to consent, where such research is permissible. The first is that the case for carrying out the research on the incompetent should be compelling. It is not enough merely to wish to know. What is required is strong evidence that the information which is sought will be gained and that, once gained, it is likely to have significant practical consequences. The second additional limitation is that the researcher must clearly demonstrate that the research must be carried out on the incompetent, or, put another way, no other group of researcher subjects would be suitable to generate the desired data. There is no doubt that these two ethical concerns would be recognised as a legally relevant part of the process of determining whether the proposed research is or is not against the interests of the incompetent child or adult.<sup>66</sup>*

The situation pertaining to *donor participation* in genetic research (as opposed to treatment) such as where an individual donates a biological/bodily/DNA sample for the purposes of research aimed at discovering the genetic basis of disease and where physical intervention is minimal, as is any risk, has not been examined by the courts or commented on by way of legislation. However, in the light of current ethical thinking, it cannot be said authoritatively or at all (as will be examined later by ethical guidelines) that such participation is illegal/unlawful.

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<sup>66</sup> Kennedy & Grubb, *op. cit.*, at 736-737.

# The Participation of Individuals in Genetic Research





# 3. The Participation of Individuals in Genetic Research

## 3.1 The Law

Neither legislation nor judicial dicta have commented on the issue of the participation in genetic research where that research is non-therapeutic. However, the principles of law in relation to informed consent will apply and additional caution to protect the incompetent adult will have to be exercised as commented on in the previous section.

As a pre-requisite to these medico-legal requirements, from the outset, the objectives of the proposed research must be absolutely clear and unambiguous in the minds of researchers and this is ever more so the case in a genetic study where the results may have very important present and future ramifications for a DNA sample donor and his/her family. At the commencement of a genetic study, several points must be clear:

Are incompetent individuals (children or adults) to be participants in the study?

If so, what procedures in relation to consent are to be utilised?

Do the proposed participants understand the nature of the study, how it is relevant to them and all of its ramifications?

Will the research subjects be given the results of the study individually, by way of publication, or at all?

If research subjects are to be given results, have follow-up procedures for genetic counselling been considered and/or arranged?

If research subjects have been offered any financial reward, what is the nature of such reward and is there any possibility that it might be construed as an inducement such that it might negatively affect the nature of the consent given?

What assurances are in place to protect DNA samples and the information derived from the DNA?

These are some considerations of vital importance that any ethics committee considering a research proposal will have concern about.

In the absence of national law and guidelines, there does now exist a corpus of International Ethical guidelines and some European jurisprudence on some of the issues concerning participation in genetic research that will now be considered.

## 3.2 Ethical Guidelines and International Jurisprudence

### 3.2.1 Council of Europe. *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Convention on Human Rights and Biomedicine (1997)*

The aim of the Convention is to protect the dignity and human rights of human beings by virtue of the advances in biomedicine. It should be noted, however, that the Convention (i) has not been signed by Ireland and (ii) even if it were, it would then have to be ratified and transposed into National Law for it to carry any substantive legal effect.

Chapter V of the Convention deals with 'Scientific Research' and states:

#### **Article 15 - General rule**

*Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.*

#### **Article 16 - Protection of persons undergoing research**

*Research on a person may only be undertaken if all the following conditions are met:*

- (i) there is no alternative of comparable effectiveness to research on humans,*
- (ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,*
- (iii) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability,*
- (iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,*
- (v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.*

#### **Article 17 - Protection of persons not able to consent to research**

*Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:*

- (i) the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;*
- (ii) the results of the research have the potential to produce real and direct benefit to his or her health;*
- (iii) research of comparable effectiveness cannot be carried out on individuals capable of giving consent;*
- (iv) the necessary authorisation provided for under Article 6 has been given specifically and in writing, and*

(v) *the person concerned does not object.*

*Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, subparagraphs i, iii, iv and v above, and to the following additional conditions:*

- (i) *the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.*
- (ii) *the research entails only minimal risk and minimal burden for the individual concerned.*

### 3.2.2 Irish Medical Council. *A Guide to Ethical Conduct and Behaviour*, 5th Ed. (1998)

The guidelines do not specifically separate research into therapeutic and non-therapeutic. They deal with the issue of consent, albeit within the context of clinical trials,<sup>67</sup> at paragraph 22.1, stating that:

*It is essential that written consent be obtained if patients are to be involved in clinical trials. The aims and methods of the proposed research, together with any potential hazards or discomfort, should be explained to the patient.*

Paragraph 22.4, entitled 'Special Circumstances', states:

*In those who are too young or too incapacitated, as well as the mentally ill or unconscious person, consent to take part in research may be unobtainable. Research is best avoided unless it can be shown to be relevant and potentially beneficial to the patient and there is no objection from parents or relatives.*

### 3.2.3 Nuffield Council on Bioethics (UK). *Human Tissue: Ethical and Legal Issues*, (April, 1995)

The Council's report states at paragraph 13.16 in relation to tissue samples from competent donors:

*We recommend that those involved in the removal of tissue from donors should ensure that the explanation given to the donor is explicit about the range of intended uses of the tissue and about any risks the donor may incur either in having the tissue removed or as a consequence of its removal. Only on these conditions can the consent of the donor, and hence the procedure itself, be valid.*

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67 In Ireland, clinical trials are governed by the Control of Clinical Trials Act 1987 and the Control of Clinical Trials and Drugs Act 1990. They, however, are not relevant to the conduct of non-therapeutic research where an individual is a 'donor participant' (e.g., an individual who donates a biological/bodily/DNA sample for the purposes of research, but is not a patient receiving treatment) in genetic research. This is because the 1987 Act at Section 6 states that the conducting of a clinical trial is 'the conducting of systematic investigation or series of investigations for the purpose of ascertaining the effects (including kinetic effects) of the administration of one or more substances or preparations on persons where such administration may have a pharmacological or harmful effect'. The donation of a DNA sample by a research participant is clearly not an administration of a substance or preparation nor an administration. 'Administered' is defined in the Act as meaning 'the administration either directly or indirectly to a person of one or more substances or preparations by introduction into the body (whether orally, by injection or in any other way) or by external application (whether by direct contact with the body or not)'.

With regard to the incompetent, the Council notes the legal uncertainty in current law and notes the UK Law Commission's observation in their 1995 paper on Mental Capacity<sup>68</sup> that, without a change to the law, non-therapeutic research on the incompetent adult unable to give consent would actually be unlawful. At paragraph 13.17 the report states: 'Removal of tissue from living persons who are deemed legally incompetent, where this is not part of their treatment, but is for the treatment of others or for medical research, raises complex issues. This is because the safeguard normally provided by the requirement for consent is not available. Procedures which provide equivalent protection have to be devised and followed...' The Council concludes at paragraph 13.20:

*We consider that non-therapeutic removal of tissue from living incompetent adults would be ethically acceptable only if the procedures were of negligible risk and minimal burden. The person should not object, or appear to object, to the procedures... Additional safeguards include recommendations that such persons should be included in research only if the relevant knowledge could not be obtained otherwise and if the research is approved by a research ethics committee...*

Two of the most relevant and important works that have recently been produced are the Nuffield Council on Bioethics *Report on Mental Disorders and Genetics: the Ethical Context* (September, 1998) and, more recently, the Medical Research Council's excellent *Guidelines on Human Tissue and Biological Samples for Use in Research* (interim guidelines, November, 1999 and 2001). Both reports are the first properly to address the issues of consent within the context of genetic research where a sample donor is only a participant in the research. The reports make important suggestions and will be considered in some depth.

### 3.2.4 Nuffield Council on Bioethics (UK): *Mental Disorders and Genetics: the Ethical Context*, (September, 1998)

#### (a) Capacity to Consent

The Nuffield Council's report is detailed and thorough and discusses in great depth all of the relevant ethical, social and legal aspects of genetic research in the context of mental disorders. The report is important in the context of genetic research, such as studies relating to schizophrenia or alcoholism and other mental illnesses, in that the participants may not always have full capacity (or may have diminished capacity or varying degrees of capacity at different times) to consent to the research. This is a factor of the utmost importance in non-genetic research but becomes even more significant when genetic research is involved. This is because it may have far-reaching implications on both research participants and members of their families, whether or not the test results are released individually to the participants or if they discover the results through other means by virtue of subsequent publications once the results of the study are obtained and compiled. With this clearly in the forefront of the Council's thoughts, their report sets out at paragraph 5.23 the necessary ingredients of 'capacity':

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68 The Report is in agreement with the new legislative scheme proposed by the UK Law Commission which recommends that 'research which is unlikely to benefit a participant, or whose benefit is likely to be long delayed, should be lawful in relation to a person without capacity to consent...' subject to strict safeguards. A new statutory Mental Incapacity Research Committee is proposed that would be required to approve non-therapeutic research procedures. In addition, procedures for approving the participation of each individual in the research project are recommended. The Nuffield Council states 'We endorse the view of the Law Commission, noting that it would not contemplate the removal of tissue save in circumstances where the procedure is of negligible risk and is not unduly invasive; where the research would add to the knowledge of the incapacitating condition with which any participant is affected; and where the knowledge could not be obtained without involving such persons.'



*Because of the significance attached to consent, the ethical principles have been developed in some detail in law. The law requires that, in determining if a patient has the necessary capacity to decide whether or not to consent to a procedure, the psychiatrist or other responsible medical officer must be satisfied that the patient:*

- possesses the capacity to make a choice;*
- understands what the procedure is, that somebody has said that he, or she, should have it;*
- and why it is being proposed;*
- understands in broad terms the nature of the procedure;*
- understands the principal benefits and risks of the procedure;*
- understands the consequences of not receiving the procedure.*

The report also describes very well the fact that, although many participants will have the requisite capacity to consent, researchers must be cognisant of other problems:

*7.4 ...an individual's capacity to make a particular decision will depend partly on the complexity of the issues and partly on its risks and benefits. In considering the risks and benefits of participating in genetic research, a person with a mental disorder will face similar issues to those with any other kind of disorder. In most cases the personal benefits are likely to be small, at least in the short term, and advantage is most likely to be conferred on sufferers as a group. Physical procedures involved in genetics research are generally not hazardous, involving perhaps the withdrawal of a small sample of blood from a vein. It is now feasible, although less common, to take a sample from the lining of the mouth (a sample of so-called buccal mucosa), which may be obtained with a mouthwash or a gentle scrape of the inside of the cheek. For those with a mental disorder, and indeed for some with a physical disorder, the attendant structured interview and family study may, however, be psychosocially intrusive and even hold the potential for creating difficulties and tensions within the family.*

Careful to ensure that consent is properly obtained by those with requisite capacity, the report states at paragraph 7.7: 'The Working Party recommends that individuals who are intermittently competent should only be approached about participation in research when competent.'

#### **(b) The Issue of Payment to Donors**

The Nuffield Council's report also comments on the issue of payment to donors of samples. These observations are important and, as has been stated earlier, are of great significance due to the fact that if payment is seen to be a primary factor in research, it may be an inducement to participants to become involved in research. This is ever more so the case with more vulnerable individuals and it therefore may be the case that payment may erode the nature of the consent given or even vitiate that consent. The report at paragraph 7.9 states:

*Particular circumstances may impede the process of obtaining genuine consent. There may be some grounds, for example, for believing that in the past, prisoners have been overtly or covertly coerced into taking part in research. It is particularly important in circumstances where potential participants in research may be confined in an institution, or may be detained patients, to be clear that participation cannot and will not be used for bargaining. Another concern in relation to freely given consent is the issue of personal reward. Small fixed, or individually calculated, sums of money for time spent are sometimes offered to individuals participating in projects. With respect to each funded project, it must be a matter for careful ethical consideration. The assumption, for which there is no evidence, is that people with a mental disorder may be indirectly coerced into participation by the offer of payment. (It is arguable that a more pernicious practice was their attempted recruitment or retention by supplying cigarettes.) The Working Party recommends that any proposed payment for participation in research should always be carefully considered by research ethics committees and by grant-giving bodies. Researchers who make no explicit comment on this point should be asked to do so.*

It may be prudent that the words 'payment' and 'reward' for example, are best omitted in research material and proposals. Words such as 'expenses', 'compensation' or 'reimbursement' are more suitable. A further step in ensuring that participants are neither induced nor perceived to be induced would be to place the issue of expenses, compensation or reimbursement at the end or towards the end of any literature explaining the research project.

In relation to the mentally incompetent, the Council reiterated its previous opinion:

*The Working Party recommends, therefore, that non-therapeutic research involving people lacking the capacity to consent to participation on their own behalf should be considered ethically acceptable, subject to strict safeguards. Whether or not some additional, statutory body is created... the expertise of existing Research Ethics Committees (RECs) to consider such research may need to be broadened, and a mechanism established by the Department of Health, which provides guidance in such matters, by which consistency can be ensured... The Working Party recommends that every research ethics committee should include at least one member who has experience in the area of competence in decision making about research participation. Where necessary, committees should seek to co-opt such a person on occasions when such research is to be considered. (7.17)*

### **(c) The Disclosure of Clinical Implications to Sample Donors**

Whether or not information on the clinical implications of non-therapeutic research ought to be disclosed subsequently to donors is a matter of defining the objectives of the research and establishing whether or not the consent obtained from the donors (i) informs them that there may be clinical implications of the research at a later stage and (ii) includes their specific consent to receiving such information. It may be the case that they express their desire not to know and exercise what is also called in law an 'informed dissent'. Thus, in order for a dissent to be informed, such information as the fact that, notwithstanding the clinical ramifications of the findings there may still be no better therapy or cure, must be made clear to the research participant.

The Nuffield Council felt very concerned in relation to this aspect of genetic research and examined the problem, stating:

7.19: In a rapidly evolving field such as human genetics, it is probably inevitable that research and clinical work will be closely entwined. Research aimed at identifying genes related to particular disorders may depend on assembling the largest possible collection of families with the disorder. Contact with family members develops as they may be asked to contribute DNA samples and information about themselves and other family members. Many will have questions about the disorder which runs in their family and researchers at the forefront of their field may be better placed than other clinicians to answer these (but see paragraph 7.24 below). In some areas of genetics (for example, cancer genetics) researchers have set up special clinics to which family members at risk may be referred for genetic counselling.

7.20: Provided that appropriate guidelines are followed and patients are not pressurised to be involved in research, such arrangements should not raise any particular ethical problems. Indeed, such clinics may be a very effective way of providing well-informed genetic counselling and other clinical support to members of families that carry some of the rarer genetic disorders. Difficulties over financing may arise, however, as such clinics are often initially financed by research funding but research bodies may be reluctant to continue to support clinics that provide a routine clinical service. As the discovery rate of rare disease genes is accelerating rapidly, this difficulty is likely to increase.

7.21: More complicated ethically are situations where DNA samples have been collected for research purposes and researchers later discover information which is of clinical significance to the donor of the sample. This is quite a common situation in research aimed at identifying disease-related genes. When such a gene is identified and its location and sequence published, most research groups working in the area will screen DNA samples in their possession for relevant mutations. Correlating the presence or absence of particular mutations with information about the development of the disease in individuals can provide important insights into the disease process. Such research should be covered by the general consent that individuals will have given when they provided DNA samples and information about themselves and other family members.

7.22: When such a disease-linked gene has been identified and significant mutations found, the question arises as to how to deal with any clinical implications for individuals who have contributed DNA and information to a research project. For those who have been found to have the condition and a relevant mutation, there could be implications for relatives (who may or may not have consented to take part in the research), in terms of their risk and also possibilities of direct testing. For those in the research sample who do not have the condition, the presence of a mutation may indicate a risk of developing it in the future, while its absence may suggest that the individual will be free of the condition that runs in their family.

7.23: The ethical difficulty arises because the process of obtaining the informed consent required for research does not usually include consent for disclosure of identifiable data to clinics outside the strict environs of the research. Nor is the kind of genetic counselling included that would be required for an individual seeking a genetic test for clinical purposes. To provide an individual with information from a research study about gene mutations which they might or might not carry and which, at the time samples and information were collected, could not have been foreseen, could be to give them information they would choose not to have, and/or information for which they or other members of the family are not prepared or cannot understand in terms of its implications.

7.24: A further difficulty is that quality controls and procedures used for clinical testing may be different and sometimes more rigorous than those used in research studies. For example, in some protocols for direct predictive testing in Huntington's disease, DNA samples are collected on two separate occasions from an individual who chooses to undergo testing. These are tested independently and only if these yield identical results is the result regarded as valid. Such checking procedures are unlikely to be used in a research study. For these reasons **the Working Party recommends that, as a general rule, those who consent to take part in research should be told that individual information derived from analysis of their DNA will not be given to them.** This principle should certainly apply in all situations where the genetic loci under study would, at best, identify only weak susceptibility to a disorder. A summary of the overall findings of the research can be provided if the participant wishes.

7.25: **The Working Party further recommends that, in any research study that could yield genetic information which is clinically relevant to a research participant and/or their relatives, consent to that research should make it clear whether or not such information will be made available.** If it is to be made available then, before consenting to the research an individual should receive genetic counselling, and give written consent to make it clear whether or not they wish their designated medical adviser to receive information of clinical relevance derived from analysis of his or her own DNA, and/or to receive such information personally. Where information is to be given to research participants (or, with their consent, to their medical adviser), the procedures used for collecting and processing samples should be of the same standard as those used in clinical services, and accompanied by further appropriate advice

#### **(d) The Use of Samples for Testing beyond the Initial Use**

Here the Council divides the issue into the ethical position that pertains to those with competence and those without, stating:

*The Working Party recommends that, when a person is considered to be incompetent to make his or her own decision about participation in research, data collected for non-therapeutic research purposes should not be used for any other purpose.*

*When an individual participant is regarded as competent, the Working Party recommends that any possible further use of data in the longer term should be discussed with him or her as part of the consent procedure; new research should, as a minimum, be submitted for approval to a research ethics committee before proceeding. (7.27)*

#### **(e) The Use of Samples by Outside Agencies**

The Council report was more concerned by the possibility of abuse by a third-party agency such as insurance companies or finance agencies. It states simply that:

*As with clinical information... access to research data, without permission, needs strong justification. The European Human Rights Convention and recent EU initiatives on data protection address the protection of privacy. If anything, research data are likely to be safer because they are kept under entirely separate records systems and because, by their nature as research databases, they tend to be seen as likely to be less meaningful than routinely*

*collected clinical data. Potential problems around confidentiality should not be exaggerated. We know of no instance in which raw research data have been used for non-research purposes without the knowledge or consent of the researchers, nor of any where the latter may have been forthcoming inappropriately. Researchers do have a responsibility to take all reasonable steps to ensure that their raw, individualised data will not be used for any other purpose.*

The law in relation to the EU initiatives as mentioned above will be discussed later in this paper in addressing the obligations that are placed on researchers who are exporting data to a non-EU State to ensure that the third-party country has adequate data protection laws or practices in place to protect the relevant data.

### **3.2.5 National Bioethics Advisory Commission (NBAC) (US). *Research Involving Persons with Mental Disorders that may affect Decisionmaking Capacity*, (December, 1998)**

In examining the possible ‘promise of research on mental disorders’, the NBAC notes:

*Of the ten leading causes of disability in the world, according to a recent World Health Organization report, five are psychiatric conditions: unipolar depression, alcohol use, bipolar affective disorder, schizophrenia and obsessive compulsive disorder.<sup>69</sup>*

With a greater understanding of how genetic factors may be partly or wholly causative of such conditions, projects to understand the genetic basis of such conditions will be vital and on the increase. The issue of consent within the context of research where participants may have varying degrees of capacity becomes more complex, since it is not the case that mental disability vitiates or diminishes the necessity for consent, but merely that mental disability may diminish the means by which an individual can express consent. It is clear that additional protection is required for such participants to ensure that the right of self-determination is equally respected in such cases as in those where there is no mental disability.

Many of the concerns of the NBAC, although not exclusive to genetic research, were nevertheless similar to the concerns expressed by the Nuffield Council on Bioethics. However, the recommendations of the NBAC are not examined in detail here since the Nuffield Conclusions are more appropriate in their structure and applicability within the Irish context, especially with regard to non-therapeutic research.

### **3.2.6 National Bioethics Advisory Commission (NBAC) (US). *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, (August, 1999)**

This Report outlines its objectives in its summary, stating:

*To advance human health, it is critical that human biological materials continue to be available to the biomedical research community. Increasingly, it will be essential for investigators to collect human biological materials from individuals who are willing to share important clinical information about themselves... The growing availability to third parties of genetic and other medical information about individuals has fueled the current debate about medical privacy and discrimination, and NBAC is sensitive to the possibility that the*

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<sup>69</sup> *Research Involving Persons with Mental Disorders that may Affect Decisionmaking Capacity*: Volume I (US National Bioethics Advisory Commission, Rockville, Maryland, May 1999) at 4.

*use of information obtained from human biological samples can lead to harms as well as benefits. These concerns require that those who agree to provide their DNA, cells, tissues, or organs for research purposes not be placed at risk. Measures to provide appropriate protections for individual privacy and for the confidentiality of clinical and research data are important if significant research is to continue. The recommendations provided in this report are intended to promote the goals of improving health through biomedical research while protecting the rights and welfare of those individuals who contribute to human knowledge through the gift of their biological materials.<sup>70</sup>*

In making its recommendations, the NBAC used the following framework:

*First, research use of human biological materials is essential to the advancement of science and human health; therefore, it is crucial that there be permissible and clearly defined conditions under which such materials can be used.*

*Second, the people who provide human biological materials for research should be protected and respected.*

*Third, the rapidly advancing Human Genome Project and associated technologies, as well as the application of a molecular-based approach to understanding human disease, have raised issues of autonomy and medical privacy. These issues are relevant to all areas of medical research using human biological materials, not merely genetic research.*

*Fourth, there is disagreement within the scientific community about the nature of risks to individuals and about the levels and types of protections that are needed to ensure that biological samples can be used in research with minimal risks to those whose materials are used.<sup>71</sup>*

The Report concentrates heavily on the issue of informed consent and on the issue of confidentiality<sup>72</sup> and makes several recommendations following a very thorough discussion of the relevant issues. In relation to the issue of consent, the NBAC states:

*Whether obtaining consent to the research use of human biological materials in a research or clinical setting, and whether the consent is new or renewed, efforts should be made to be as explicit as possible about the uses to which the material might be put and whether it is possible that the research might be conducted in such a way that the individual could be identified.<sup>73</sup>*

It then makes the following recommendations:

*Recommendation 6:*

*When informed consent to the research use of human biological materials is required, it should be obtained separately from informed consent to clinical procedures.*

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70 *ibid.*, at viii.

71 *ibid.*, at 9.

72 The issue of confidentiality is discussed in section 4 of this paper.

73 NBAC. *Research Involving Persons with Mental Disorders*, at iv.



*Recommendation 7:*

*The person who obtains informed consent in clinical settings should make clear to potential subjects that their refusal to consent to the research use of biological materials will in no way affect the quality of their clinical care.<sup>74</sup>*

An essential ingredient of informed consent, as was earlier discussed, is the healthcare provider's/ researcher's duty to provide the maximum amount of necessary information to the healthcare receiver/research participant to enable him/her to come to a decision. In the context of the collection of biological material, the NBAC recommends the type of information that might be provided:

*Recommendation 9:*

*To facilitate collection, storage, and appropriate use of human biological materials in the future, consent forms should be developed to provide potential subjects with a sufficient number of options to help them understand clearly the nature of the decision they are about to make. Such options might include, for example:*

- a) refusing use of their biological materials in research,*
- b) permitting only unidentified or unlinked use of their biological materials in research,*
- c) permitting coded or identified use of their biological materials for one particular study only, with no further contact permitted to ask for permission to do further studies,*
- d) permitting coded or identified use of their biological materials for one particular study only, with further contact permitted to ask for permission to do further studies,*
- e) permitting coded or identified use of their biological materials for any study relating to the condition for which the sample was originally collected, with further contact allowed to seek permission for other types of studies, or*
- f) permitting coded use of their biological materials for any kind of future study.<sup>75</sup>*

The NBAC also ventures further than the mere intricacies of research protocol, and states:

*Public and professional education plays an essential role in developing and implementing effective public policy regarding use of human biological materials for research. By education, NBAC is referring not simply to the provision of information with the aim of adding to the net store of knowledge by any one person or group; rather, education refers to the ongoing effort to inform, challenge, and engage. Widespread and continuing deliberation on the subject of this report must occur to inform and educate the public about developments in the field of genetics and other areas in the biomedical sciences, especially when they affect important cultural practices, values, and beliefs.<sup>76</sup>*

On foot of this admirable goal, the NBAC makes the following recommendations:

*Recommendation 21:*

*The National Institutes of Health, professional societies and health care organizations should continue and expand their efforts to train investigators about the ethical issues and regulations regarding research on human biological materials and to develop exemplary practices for resolving such issues.*

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74 *ibid.*

75 *ibid.*, at v.

76 *ibid.*, at vii-viii.

*Recommendation 22:*

*Compliance with the recommendations set forth in this report will require additional resources. All research sponsors (government, private sector enterprises and academic institutions) should work together to make these resources available.<sup>77</sup>*

This is a recommendation that ought to be incorporated within the Irish research context, where, by virtue of geographic and population convenience, the existing educational structures and means will make the achievement of this important goal easier. In the longer term, a better educated community (scientific and medical and non-scientific and non-medical) will mean a greater understanding by healthcare providers of healthcare receivers' rights and a greater understanding by healthcare receivers of the 'good' that is likely to benefit the community as a whole by their continuing efforts in participating in research. The mechanism by which to foster this almost symbiotic relationship is a continuing, imaginative and pro-active educational effort.

**3.2.7 Medical Research Council (MRC) (UK). *Human Tissue and Biological Samples for Use in Research: Interim Operational and Ethical Guidelines, (November, 1999)***

The objectives of this Report are set out in the introduction and are very clearly relevant to studies which involve the genetic basis of disease with donor DNA:

*These guidelines draw attention to the practical, ethical and legal issues that should be considered when making and using collections of human biological material for research, and recommend best practice to ensure that such collections can be used optimally to increase scientific understanding for the benefit of human health. These guidelines should be followed by:*

- *Those preparing research proposals for support by the Council that include the collection of samples of human biological material.*
- *Those planning, undertaking or collaborating in research funded by the MRC using existing collections, whether the collections were made by themselves or by others.*
- *Those managing collections of human materials made with MRC funding, or research using such collections.*

**(a) Commercial Exploitation**

The issue of commercial exploitation is sensitive. The duties of disclosure resting on a doctor/researcher in the case of a financial interest in a biological donation that is either a part of research or is a factor that is above and beyond the parameters of the research in question, are unclear and in Ireland and the UK remain judicially untested. Usually, the patenting of part of a sample will not be the primary objective, or any objective, of collecting a biological sample, but it may be the case that at some stage during research or after it, part of the cell may be the subject of a patent application. In this event, the question arises as to whether sample donors ought to be told, or ought to have been told, of this possibility at the time the sample was collected. The MRC makes the following observations and conclusions:

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<sup>77</sup> *ibid.*, at viii.



*One of the major concerns in allowing commercial access to sample collections is the potential to damage the gift relationship between scientists and research participants. Research participants may be particularly sensitive to the idea of a company or an individual making a profit out of the tissue that they have freely donated. It is important that research participants are made aware of the potential benefits of allowing commercial access, and that the role of any one individual's sample in the generation of future profits is likely to be minimal as well as impossible to quantify. Given the possible sensitivities, **it is essential that research participants are made aware that their sample or products derived from it may be used by the commercial sector, and that they will not be entitled to a share of any profits that might ensue.***

*Patenting of inventions based on, or using, biological material of human origin is covered by the EU Directive on the Legal Protection of Biotechnological Inventions. To comply with the Directive, a person from whose body the material used for an invention is taken must have had an opportunity of expressing free and informed consent (Recital 26). This should be borne in mind when there is a possibility that human material collected for research may be used directly in making a biotechnology product. However, since this is relatively rare, it should not be necessary routinely to seek consent to possible patenting from all donors of tissue for research.*

The last lines of the above paragraphs are difficult to reconcile but they seem to be suggesting that (i) information regarding the possibility of commercial exploitation must be revealed to donors, including the fact that they are not entitled to share in any profits, but that (ii) their consent to possible patenting is not routinely necessary since patenting in such cases is rare.<sup>78</sup>

Notwithstanding the fact that the legal position remains unclear, one can hypothesise the question that is likely to be asked by a court if a patient were to take an action claiming that his/her consent was not properly obtained. As has been discussed in the first part of this paper, the question of consent in Ireland and the UK has thus far hinged on the information that a patient should be given such that he is able to make an informed choice as to whether or not to consent to the medical treatment. In order to be able to do this properly, information regarding the material risks involved with that treatment must be disclosed. Applying this rationale to the present situation the question therefore that might be asked by a court is: Is the issue of a doctor/researcher's financial interest in donor's biological sample, material to that donor's decision to take part in the research? Putting it another way: Would the reasonable sample donor regard disclosure of a doctor's financial interest in a sample as a material fact that would affect his/her decision in both giving the sample and in being a participant in the research?

In the US case of *Moore v. Regents of the University of California*,<sup>79</sup> the facts were as follows: The plaintiff/patient, John Moore, was, in 1976, diagnosed as suffering from hairy-cell leukaemia. His doctor, Dr David Golde, realised that Moore's cells possessed unique properties which were commercially invaluable. This realisation, however, was at no stage communicated to Moore. Dr Golde recommended a removal of the spleen for the purposes of slowing down the disease for which Moore executed a consent form. Dr Golde and a research associate obtained a tissue sample of the

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<sup>78</sup> For a further discussion on the issue of gene patents and the EU Directive on the Legal Protection of Biotechnological Inventions generally and on the specific issue of informed consent within this context, see: Sheikh, A.A. 'Owning' Life: New Frontiers in Patent Law, Genetics and Biotechnology' *Medico-Legal Journal of Ireland* 5 (1999) 1: 23.

<sup>79</sup> *Moore v. Regents of the University of California* (1990) 793 P 2d 479 (Cal Sup Ct).

removed organ to replicate its DNA. On several post-operative visits, Dr Golde obtained additional and various tissue samples which were used to develop the eventual 'invention' for which a patent application would be filed, its inventors being named as Dr Golde and his associate and the invention being patented by the University. An agreement was then entered into with two biotechnology companies, Genetics Institute and Sandoz Pharmaceuticals. The estimated value of this agreement was thought to have exceeded several billion dollars. When Moore returned to Dr Golde, he was again presented with a consent form to sign and told it was a formality. After repeated inquiries as to whether there was a financial interest involved, he refused to sign the form and instituted proceedings against the doctor, the University and Sandoz and Genetics Institute. His claim was for a breach of fiduciary duty by the doctor for removing his cells without his informed consent, that the unauthorised removal amounted to a conversion (denial by another of the owner's right over his/her property) since he retained a proprietary interest in his cells even after their removal, and that he was entitled to share in the profits from the use of his cells. Although the plaintiff failed on the issue of having a proprietary interest in his cells, it was held by the California Supreme Court that the doctor had breached his duty to his patient by not disclosing to him his interests. The Court stated that:

*The possibility that an interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed treatment. It is material to the patient's decision, and thus a pre-requisite to informed consent.<sup>80</sup>*

In Ireland and the UK, there is no 'correct answer' to this issue, and, in fact, such disclosure may go beyond a doctor's current duty of disclosure. However, in light of the principles of maximum disclosure for the purposes of research, it may be prudent to inform participants of *all* possibilities coupled with the possible, if any, benefits for them in the longer term. Unless there is an agreement to the contrary, which in many cases will be unlikely, research participants ought to be told that their samples may be used by the commercial sector and they will not be entitled to any share or profit that ensue.

Although this paper will not discuss the issue of patenting it is important that, where there exist two or more parties to the research, especially where one is a non-EU member, then issues and agreements pertaining to the possible patenting of cell-lines and genes, or parts thereof, be very carefully discussed, drafted and scrutinised; this is especially important due to the fact that the patenting of such material is commonplace in such countries as the US and will become more common within the EU by virtue of the new Directive on the Legal Protection of Biotechnological Inventions which came into force in Irish law on the 30 July 2000.<sup>81</sup> It is prudent that a written agreement be in place between the parties subsequent to and subject to legal advice.

#### **(b) The MRC and the Issue of Consent in Research**

The MRC Guidelines state:

*When obtaining consent to take a tissue sample for research, it is important to allow for the fact that the sample might subsequently be useful for new experiments that cannot be foreseen. Therefore, unless a sample is to be used only for a single project, consent must be obtained for storage and for future use for other research. If consent is obtained to use a*

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80 *ibid.*, at 484.

81 S.I. No. 247 of 2000, European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000, brought the Directive into force in Ireland.

*newly collected sample for one specific study only, the only purpose for which it can be re-used is to verify the results of that study. When no longer required for that purpose it should be destroyed. When consent is sought for research that has not yet been planned in detail, it is important that participants clearly understand the type of research that may be done using their sample and the possible impact it might have on them. Where a sample is being collected for a specific project and will also be stored for future use, a two-part consent process is recommended, the donor being first asked to consent to the specific experiments that are already planned, and then to give broader consent for storage and future use for certain types of research. Consent should also be obtained to access participants' medical records if this is likely to be necessary for future research. It is the responsibility of the custodian to ensure that all uses of a sample are in accordance with the consent obtained from the donor.*

*The special sensitivity of the public with regard to genetics research should always be taken into account. There are certain types of genetics research which currently give rise to particular concern, for instance that relating to personality or intelligence. It is particularly important that specific consent is obtained to use samples in these or other areas of research likely to cause special concern. When seeking consent for research, information for potential participants must be presented in a form that they can understand.*

With regard to the feedback of information, at paragraph 2.7, the MRC states:

*Tests done on tissue samples in the course of research may reveal information that has implications for the donors' future health or healthcare, or otherwise impacts on their interests. It is important to decide before the start of a research project what will be done if this arises.*

This is important, as has been stated before, with regard to having clear objectives in the research protocol and in any information leaflets to be given to potential participants. It will, of course, have important implications for consent.

The MRC gives good practical advice regarding how to keep participants up-to-date about information pertaining to their samples:

*Often the clinical relevance or predictive value of a research result is unclear, at least initially, and there will be no individual data of value to be fed back. It will always be difficult to define the point at which a research hypothesis becomes a clinical fact. Where consent is being sought for a specific research project at the time a sample is collected, the potential relevance, if any, of the results for the participant should be explained and the opportunity to receive feedback of individual results should be offered where appropriate. There should be a mechanism in place for participants to change their minds (for instance, a contact telephone number) if this opportunity is declined initially. Researchers feeding back individual results must be prepared to explain their significance to the participant and advise on access to counselling where appropriate.*

It is good practice to offer research participants the opportunity to be kept informed about the general results of research projects done using the samples they have donated, though this may not be appropriate in all circumstances. Participants could be informed by posting information on research outcomes on a website, or by offering them the opportunity to receive a newsletter.

Where the clinical relevance of research results becomes clear some time after the sample was obtained, or where the results obtained from secondary research may impact on the donors' interests, such a mechanism should be used to inform donors that results of potential interest may be available and offer them the opportunity to receive individual feedback or advice if they wish.

Where samples may subsequently be used for secondary studies, a mechanism should be put in place to allow participants the opportunity to seek individual results that might impact on their interests, but it is acceptable for the onus to be on the participant to seek the information rather than on the researcher to be pro-active in providing it. The research protocols for secondary studies and the arrangements (if any) for feeding back results to participants must be approved by an ethics committee, preferably the committee that oversaw the making of the collection. If samples from a collection are shared with other researchers, the custodian of the collection is responsible for decisions on whether to feed back results.

### **(c) Consent and the Incompetent**

The MRC states at paragraph 5.4:

*The person must not object or appear to object, and an informed independent person acceptable to the Local Ethical Committee must agree that the individual's welfare and interests have been properly safeguarded. Risk of harm must be negligible (for non-therapeutic research) or must be outweighed by the likely benefits, and the research must not be against the individual's interests.*

*When seeking consent, it is important for the researcher to ascertain whether the potential participant has the capacity to consent. There will be individuals who, while not suffering from mental illness as such are, through grave illness or stress, in a state of altered consciousness or reduced comprehension when samples are obtained. The validity of consent obtained under these circumstances is questionable. If taking samples cannot be delayed until the capacity to give valid consent is regained, participants must be given the opportunity to opt out of the research at a later stage, and if they do so their sample must be destroyed.*

# Confidentiality and Security of Information





## 4. Confidentiality and Security of Information

An important issue within the context of genetic research is that of privacy and confidentiality of the biological sample and data derived therefrom. Any medical information to be stored within Ireland is subject to the Data Protection Act 1988, the Freedom of Information Act 1997, and the EC Directive on the Protection of Data: 95/46/EC. Confidentiality between the healthcare provider and healthcare receiver has always been protected by Common Law. These Acts and the common law ensure that third parties do not have access to the information save with the consent of the individuals to whom the information pertains. Thus, generally, if institution 'A' holds information about person 'B', then person 'C' cannot obtain that information in the normal course of events without the consent of person 'B'.

### Directive 95/46/EC on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of Such Data<sup>82</sup>

The Irish Acts protect information within Ireland. The new Directive aims to ensure that information that is conveyed to non-EU countries or 'third countries' is done so only when such a country also has satisfactory legislation or practices in place that will ensure data protection. Where that is not the case, the information, in the normal course of events, cannot be transferred.

Article 2 provides for important definitions that lay down the basis of the Directive:

- (a) *'personal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological mental, economic, cultural or social identity;*
- (b) *'processing of personal data' ('processing') shall mean any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction;*
- (c) *'personal data filing system' ('filing system') shall mean any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralized or dispersed on a functional or geographical basis.*

Recital 15 states that only data in the following format is the subject of the Directive:

*Whereas the processing of such data is covered by this Directive only if it is automated or if the data processed are contained or are intended to be contained in a filing system structured according to specific criteria relating to individuals, so as to permit easy access to the personal data in question.*

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82 The Department of Justice, Equality and Law Reform have also published a *Consultation Paper on Transposition into Irish Law*, November, 1997.



Recital 38 states that:

*Whereas, if the processing of data is to be fair, the data subject must be in a position to learn of the existence of a processing operation and, where data are collected from him, must be given accurate and full information, bearing in mind the circumstances of the collection.*

Article 8 deals with the processing of 'special categories of data' and 8(1) states:

*Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.*

However, this section does not apply where 'the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject's giving his consent'.

Article 8 (3) goes on to state:

*Paragraph 1 shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.*

Article 10 deals with information in cases of collection of data from the data subject and states:

*Member States shall provide that the controller or his representative must provide a data subject from whom data relating to himself are collected with at least the following information, except where he already has it:*

- (a) the identity of the controller and of his representative, if any;*
- (b) the purposes of the processing for which the data are intended;*
- (c) any further information such as
  - the recipients or categories of recipients of the data,*
  - whether replies to the questions are obligatory or voluntary, as well as the possible consequences of failure to reply,*
  - the existence of the right of access to and the right to rectify the data concerning him in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.**

Article 20 deals with 'prior checking' and states that:

*Member States shall determine the processing operations likely to present specific risks to the rights and freedoms of data subjects and shall check that these processing operations are examined prior to the start thereof.*



Chapter IV and Article 25 deal with the issue of the transfer of personal data to third countries, and state:

1. *The Member States shall provide that the transfer to a third country of personal data which are undergoing processing or are intended for processing after transfer may take place only if, without prejudice to compliance with the national provisions adopted pursuant to the other provisions of this Directive, the third country in question ensures an adequate level of protection.*
2. *The adequacy of the level of protection afforded by a third country shall be assessed in the light of all the circumstances surrounding a data transfer operation or set of data transfer operations; particular consideration shall be given to the nature of the data, the purpose and duration of the proposed processing operation or operations, the country of origin and country of final destination, the rules of law, both general and sectoral, in force in the third country in question and the professional rules and security measures which are complied with in that country.*
3. *The Member States and the Commission shall inform each other of cases where they consider that a third country does not ensure an adequate level of protection within the meaning of paragraph 2.*
4. *Where the Commission finds, under the procedure provided for in Article 31 (2), that a third country does not ensure an adequate level of protection within the meaning of paragraph 2 of this Article, Member States shall take the measures necessary to prevent any transfer of data of the same type to the third country in question.*
5. *At the appropriate time, the Commission shall enter into negotiations with a view to remedying the situation resulting from the finding made pursuant to paragraph 4.*
6. *The Commission may find, in accordance with the procedure referred to in Article 31 (2), that a third country ensures an adequate level of protection within the meaning of paragraph 2 of this Article, by reason of its domestic law or of the international commitments it has entered into, particularly upon conclusion of the negotiations referred to in paragraph 5, for the protection of the private lives and basic freedoms and rights of individuals. Member States shall take the measures necessary to comply with the Commission's decision.*

Article 26 deals with derogations to the above rule and states:

*By way of derogation from Article 25 and save where otherwise provided by domestic law governing particular cases, Member States shall provide that a transfer or a set of transfers of personal data to a third country which does not ensure an adequate level of protection within the meaning of Article 25 (2) may take place on condition that:*

- (a) the data subject has given his consent unambiguously to the proposed transfer; or*
- (b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of precontractual measures taken in response to the data subject's request; or*

- (c) *the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and a third party; or*
  - (d) *the transfer is necessary or legally required on important public interest grounds, or for the establishment, exercise or defence of legal claims; or*
  - (e) *the transfer is necessary in order to protect the vital interests of the data subject; or*
  - (f) *the transfer is made from a register which according to laws or regulations is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate legitimate interest, to the extent that the conditions laid down in law for consultation are fulfilled in the particular case.*
2. *Without prejudice to paragraph 1, a Member State may authorize a transfer or a set of transfers of personal data to a third country which does not ensure an adequate level of protection within the meaning of Article 25 (2), where the controller adduces adequate safeguards with respect to the protection of the privacy and fundamental rights and freedoms of individuals and as regards the exercise of the corresponding rights; such safeguards may in particular result from appropriate contractual clauses.*

With these obligations in mind, the MRC states at paragraph 2.4:

*Personal data should be stored, processed and analysed in a form that does not allow individuals to be identified, unless there is a strong ethical or scientific justification for not doing so. Identifiable data should only be accessible to staff who have a formal duty of confidence to the participants... When custodians of a collection provide samples to other researchers, transfer of identifiable data should be kept to a minimum.*

Further to the obligations of the Directive, its implications are that: (i) the relevant third country has legislation or practices in place that adequately protect personal data or (ii) assurances need to be gained by a 'third country' that the data received will be protected,<sup>83</sup> or when 'third country' protection is not adequate then the data can be transferred only if (iii) the data subject gives his consent unambiguously to transfer the data.

The meaning of the word 'unambiguously' is uncertain, but a consent could only be so if the person giving it was fully informed and in this case it must be presumed to mean that the data subject has been clearly told that the 'third country' does not have adequate protection measures in place and also told of the full ramifications or potential ramifications of this lack of protection.

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83 Opinion No. 13 of the European Group on Ethics in Science and New Technologies to the European Commission, of 30 July 1999, entitled *Ethical Issues of Healthcare in the Information Society*, reiterates the concerns of the EU Directive.

In the light of the uncertainty, it is advisable where 'third countries' are involved in joint research projects that a written assurance is given to the EU-member country stating that the absolute privacy of data subjects is protected and that any third party not a part of the research team will not have access to the information and samples and that the information and samples will be secured. This written assurance should be both explained to potential research participants and either shown to them or available for inspection.<sup>84</sup>

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84 It should be noted that as between the EU and US, there now exists an agreement in relation to the Directive and the transfer of personal data from EU States to the US. This is known as the 'Safe Harbor' Agreement and was agreed by the European Commission and the US Department of Commerce in July, 2000. The agreement allows for US organisations to join, on a voluntary basis, the 'safeharbor' public list (<http://web.ita.doc.gov/safeharbor/shlist.nsf/webPages/safe+harbor+list>.) To qualify for the safe harbor, a US organisation can either join a self-regulatory privacy programme that adheres to the safe harbor principles or develop its own scheme that adheres to the safe harbor principles. There are 7 Principles: (i) NOTICE: An organisation must inform individuals about the purposes for which it collects and uses information about them, how to contact the organisation with any inquiries or complaints, the types of third parties to which it discloses the information, and the choices and means the organisation offers individuals for limiting its use and disclosure. This notice must be provided in clear and conspicuous language when individuals are first asked to provide personal information to the organisation or as soon thereafter as is practicable, but in any event before the organisation uses such information for a purpose other than that for which it was originally collected or processed by the transferring organisation or discloses it for the first time to a third party\*. (ii) CHOICE: An organisation must offer individuals the opportunity to choose (opt out) whether their personal information is (a) to be disclosed to a third party\* or (b) to be used for a purpose that is incompatible with the purpose(s) for which it was originally collected or subsequently authorized by the individual. Individuals must be provided with clear and conspicuous, readily available, and affordable mechanisms to exercise choice. For sensitive information (i.e. personal information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), they must be given affirmative or explicit (opt in) choice if the information is to be disclosed to a third party or used for a purpose other than those for which it was originally collected or subsequently authorized by the individual through the exercise of opt in choice. In any case, an organisation should treat as sensitive any information received from a third party where the third party treats and identifies it as sensitive. (iii) ONWARD TRANSFER: To disclose information to a third party, organisations must apply the Notice and Choice Principles. Where an organisation wishes to transfer information to a third party that is acting as an agent, as described in the endnote, it may do so if it first either ascertains that the third party subscribes to the Principles or is subject to the Directive or another adequacy finding or enters into a written agreement with such third party requiring that the third party provide at least the same level of privacy protection as is required by the relevant Principles. If the organisation complies with these requirements, it shall not be held responsible (unless the organisation agrees otherwise) when a third party to which it transfers such information processes it in a way contrary to any restrictions or representations, unless the organisation knew or should have known the third party would process it in such a contrary way and the organisation has not taken reasonable steps to prevent or stop such processing. (iv) SECURITY: Organisations creating, maintaining, using or disseminating personal information must take reasonable precautions to protect it from loss, misuse and unauthorized access, disclosure, alteration and destruction. (v) DATA INTEGRITY: Consistent with the Principles, personal information must be relevant for the purposes for which it is to be used. An organisation may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual. To the extent necessary for those purposes, an organisation should take reasonable steps to ensure that data is reliable for its intended use, accurate, complete, and current. (vi) ACCESS: Individuals must have access to personal information about them that an organisation holds and be able to correct, amend, or delete that information where it is inaccurate, except where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question, or where the rights of persons other than the individual would be violated. (vii) ENFORCEMENT: Effective privacy protection must include mechanisms for assuring compliance with the Principles, recourse for individuals to whom the data relate affected by non-compliance with the Principles, and consequences for the organisation when the Principles are not followed. At a minimum, such mechanisms must include (a) readily available and affordable independent recourse mechanisms by which each individual's complaints and disputes are investigated and resolved by reference to the Principles and damages awarded where the applicable law or private sector initiatives so provide; (b) follow up procedures for verifying that the attestations and assertions businesses make about their privacy practices are true and that privacy practices have been implemented as presented; and (c) obligations to remedy problems arising out of failure to comply with the Principles by organisations announcing their adherence to them and consequences for such organisations. Sanctions must be sufficiently rigorous to ensure compliance by organisations. \* It is not necessary to provide notice or choice when disclosure is made to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of the organisation. The Onward Transfer Principle, on the other hand, does apply to such disclosures. (at: [http://www.export.gov/safeharbor/sh\\_overview.html](http://www.export.gov/safeharbor/sh_overview.html)). Once an organisation meets the principles and joins the list, it is deemed 'adequate' and can receive data from EU bodies.

This is also within the parameters of recent recommendations by the US NBAC which state that, when reviewing and approving protocols for research on human biological materials, Institutional Review Boards (IRBs) or Ethics Committees should require the investigator/researcher to set forth:

*a full description of the mechanisms that will be used to maximize the protection against inadvertent release of confidential information.*<sup>85</sup>

The Recommendation 10 goes on to state that:

*IRBs should operate on the presumption that research on coded samples is of minimal risk to the human subject if*

- a) the study adequately protects the confidentiality of personally identifiable information obtained in the course of research,*
- b) the study does not involve the inappropriate release of information to third parties, and*
- c) the study design incorporates an appropriate plan for whether and how to reveal findings to the sources or their physicians, should the findings merit such disclosure.*<sup>86</sup>

A recent decision of the English Court of Appeal in the case of *R v. Department of Health, ex parte Source Informatics Ltd*,<sup>87</sup> apart from confirming that the Common Law will protect confidentiality, also raises interesting and important issues with regard to confidential but anonymous information. In this case, Source Ltd (S) wished to collect data on the prescribing habits of GPs. S then planned to sell such data to pharmaceutical companies so that they could more effectively market their products. S therefore asked pharmacists, in return for a small fee, to provide them with certain information from the prescriptions they received, that being: (i) name of GP and (ii) quantity and identity of the drug prescribed. S did not want the name of the patient. The Department of Health issued a policy document stating that the anonymisation of such information would not remove the duty of confidence owed to patients. S sought a judicial review of the policy seeking a declaration that it was wrong in law and that the disclosure by doctors or pharmacists to a third party of anonymous information did not constitute a breach of confidentiality. The Court agreed with S, the defendant/respondent, and the head note describes the Court's decision given by Simon Brown LJ, stating that:

*In a case involving confidences, the disclosure of information by the confidant would not constitute a breach of confidence provided that the confider's identity was protected. In such a case, the law was concerned only to protect the confider's privacy...*<sup>88</sup>

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85 Recommendation 5(d), NBAC. *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance: Executive Summary* (NBAC, Rockville, Maryland, 1999) at 4. Also note the NBAC's most recent guidelines: *Ethical and Policy Issues in Research Involving Human Participants*, May 18, 2001, which states at Recommendation 4.7: 'Federal policy should be developed and mechanisms should be provided to enable investigators and institutions to reduce threats to privacy and breaches of confidentiality. The feasibility of additional mechanisms should be examined to strengthen confidentiality protections in research studies.'

86 *ibid.*, at 5.

87 [2000] 1 All ER 786.

88 *ibid.*, at 786.

Simon Brown LJ went on to state:

*...the confidant is placed under a duty of good faith to the confider and the touchstone by which to judge the scope of his duty and whether or not it has been fulfilled or breached is his own conscience, no more and no less... the concern of the law here is to protect the confider's personal privacy. That and that alone is the right at issue in this case... in a case involving personal confidences I would hold... that the confidence is not breached where the confider's identity is protected.<sup>89</sup>*

The other issue raised in the case was whether or not the anonymisation of such data was in breach of Directive 95/46/EC on the Protection of Individuals with regard to the processing of Personal Data. This was on the basis that Article 8.1 prohibits such 'processing'. The response to this was that the Directive is not applicable to anonymising data just as it would not be to anonymous data since such data is not 'personal data'. The Court of appeal agreed with this contention.<sup>90</sup>

Thus, it is only in the case of anonymous or anonymised samples<sup>91</sup> that the provisions of the Directive would not apply, since they would be unidentifiable and would therefore not come within the ambit of the definition of 'personal data' which is, according to Article 2 of the Directive, '...any information relating to an identified or identifiable natural person... an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number...'

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89 *ibid.*, at 796-797.

90 *ibid.*, at 799.

91 The NBAC labels such samples as 'Unidentified samples' (anonymous) and 'Unlinked samples' (anonymised): NBAC. *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance: Executive Summary* (NBAC, Rockville, Maryland, 1999) at 1.



# Summary and Conclusions







# 5. Summary and Conclusions

Annas states that:

*We have a tendency simply to let science take us where it will. But science has no will, and human judgement is almost always necessary for any successful exploration or experiment in the unknown.<sup>92</sup>*

The role of law and bioethics will be to provide such human judgement to the explorations that will be led and conducted through genetic research. Increasingly, the norms and tenets of law and bioethics cannot be divorced from science and thus 'progress' in genetics and research must be seen by the measurement of ultimate participant/patient benefit. That benefit is not merely in terms of scientific discovery per se but also in terms of respect for human dignity and autonomy. It can only be in an atmosphere of joint co-operation between law and science that the true advantages and potential of human genetics can be realised and maximised, with any disadvantages and dangers eliminated, controlled and minimised.

With regard to the law as it stands on research and informed consent and having taken into account all of the observations and recommendations of international ethical guidelines, the following points must be borne in mind where biological/bodily/DNA samples are to be taken from participants in a genetic study.

## 5.1 Research Proposals and Genetic Research: Points of Concern

- 1 Non-therapeutic research must have the objective of the ultimate attainment of some benefit to participants – it cannot be merely an exercise of 'a wish to obtain knowledge'.
- 2 The questions must be asked:
  - Will participants be competent to give consent?
  - If not, what safeguards are in place to ensure the protection of their dignity and autonomy?
- 3 Have the full extent and ramifications of the research been conveyed to the potential participants or those consenting on their behalf, and how has this been done?
- 4 Research participants should be provided with a proper and full but comprehensible information pack/leaflet; the pack could contain pictorial diagrams to explain the basics of genetics, the research in its various steps and the medical benefits, whatever they may be, that will or may result to the participant.
- 5 A presentation involving visual aids could be given to participants by the research/medical team.
- 6 Individual sessions with participants should also be held.

92 Annas G.J. 'The Man on the Moon, Immortality and other Millennial Myths: The Prospects and Perils of Human Genetic Engineering' 49 *Emory Law Journal* 3 (2000) at 11.

- 7 Will participants receive feedback of results directly or at all?
- 8 If so, will genetic counselling be provided?
- 9 If not, are there mechanisms in place, such as the posting of leaflets or a website whereby participants can follow the progress of the research if they so wish?
- 10 Are confidentiality agreements in place?
- 11 The research proposal entailing genetic research must have independent ethical committee approval.<sup>93</sup>

## 5.2 Requirements of an Informed Consent

- 1 In the competent adult, consent must be valid, full and written, and signed by an authorised member of the research team, the participant and preferably by a witness.
- 2 In the case of an incompetent minor participating in non-therapeutic research, a parent/next-of-kin/proxy can give consent after full disclosure of facts and if the research carries minimal burden and risk and cannot be achieved by other means.
- 3 In the case of an incompetent adult, no other person in law can consent on their behalf, therefore in non-therapeutic research:  
The opinion of a GP or other appropriate person ought to be sought to ensure capacity when or if capacity is in doubt and families or very close friends may be consulted;  
The procedure must involve minimal risk, invasion, burden and discomfort;  
The individual must agree to the procedure or it must be made sure that the person does not object or seem to object;  
The research must be such that it cannot be achieved by any other means.
- 4 Those potential participants where capacity is intermittent should only be approached during a 'lucid period' (when they have capacity).
- 5 Prior to the obtaining of consent to take a sample:  
individuals must be told of the purpose for which the sample will be used;  
and researchers must seek permission if samples are intended to be used for any other purpose whatsoever at any time (such 'further use' is inadvisable in the incompetent individual participating in non-therapeutic research).
- 6 Interviews and all explanations especially with a view to or prior to obtaining consent must be impartial, without force or inducement, and should be conducted in as sensitive a manner as possible and explained in language that the potential participant can understand.
- 7 Any indications that the benefits are monetary are not acceptable and should not be mentioned. Expenses for time, effort, expense and inconvenience are of course acceptable. At all times, the primary benefit is medical.

93 While this may not be a legislative obligation in every circumstance, approval by an independent and recognised ethics board is a matter of both good practice and protocol and validates the integrity of the proposed research. Above and beyond this, it may be a pre-requisite to the approval of financial support and grant funding that ethical approval be received. Such is the case with proposed research that is funded through the Health Research Board in Ireland: see Health Research Board, *Grants Regulations*, 1999 at paragraph 3 (a).

- 8 If results are to be fed back to individuals, their consent to a whole range of issues must be obtained:  
to the primary testing;  
to any other testing that will be done (having explained what those other tests may be).
- 9 Participants must be told if there may be a commercial exploitation of any nature of the samples taken and that they will not be entitled to any profits (unless there is an agreement to the contrary).
- 10 Participants must be told of privacy protective measures over samples and data:  
within Ireland and  
within any other host country: written assurances from the host country must exist, be shown or available for inspection.
- 11 The participants must have the option of withdrawing at any time.
- 12 The participants must be able to request that the samples be destroyed.

It is with these factors in mind that the consent forms, to fulfil the requirements of a fully informed consent within the ambit of genetic research, should be drafted.



Appendices  
List of Cases and Statutes Cited  
Bibliography





# Appendix I

## Sample Consent Form

### CONSENT FORM FOR PARTICIPATION IN GENETIC RESEARCH FOR ADULT WITH FULL CAPACITY<sup>1</sup>

Protocol Number: .....

Participant Identification Number: .....

Title of Protocol: .....

Name of Institution(s) leading the Research: .....

Research Director: .....

Phone Number and Contact Details: .....

**Please Initial Boxes**

1. I have read the attached information sheet on the above project, dated ..... | |  
and have been given a copy to keep. The information has been fully explained to me  
and I have had the opportunity to ask questions about the project and understand  
why the research is being done and any foreseeable risks or consequences  
involved. I also understand that no guarantee can be given about the possible results.

2. I AGREE TO GIVE A SAMPLE(S) OF

BLOOD/OTHER BODILY SAMPLE/DNA FOR RESEARCH IN THE ABOVE PROJECT.

I understand how the sample will be collected, that giving a sample for this research is  
Voluntary and that I am free to withdraw my approval for use of the sample at any  
time without giving a reason. If I withdraw my consent I understand that my  
sample will be destroyed unless I otherwise authorise. I understand that I may for ask my  
samples to be destroyed and that this will be without my medical treatment or legal rights  
being affected. I agree that the samples I have given and the information gathered by me  
can be stored and looked after by the (name of institution).

3. (a) I GIVE PERMISSION FOR MY MEDICAL RECORDS TO BE LOOKED AT and information taken | |

from them to be analysed in the strictest confidence by the relevant and responsible  
people from the (name of study team) or from organisations supervising the  
research. I have been told that all medical information/data pertaining to me will be  
protected by the principles of confidentiality and both national and  
EU data protection legislation. I have further been told of/shown assurances that this  
also applies to all medical information/data pertaining to me that are utilised in any non-EU state.

<sup>1</sup> This form is modelled on one published by the UK Medical Research Council (MRC) in their paper  
entitled, *Human Tissue and Biological Samples for Use in Research* (November 1999 and 2001).

3. (b) I understand that the confidentiality of the sample(s) I donate and information derived therefrom will be protected. I have been told that all medical information/data pertaining to me and derived from the sample(s) will be protected by the principles of confidentiality and both national and EU data protection legislation. I have further been told of/shown assurances that this also applies to all medical information/data pertaining to me and derived from the sample(s) that are utilised in any non-EU state.

#### 4. FOR OTHER GENETIC RESEARCH:

I UNDERSTAND THAT FUTURE RESEARCH USING THE SAMPLE I GIVE MAY INCLUDE GENETIC RESEARCH aimed at understanding the genetic influences in disease but that such test will not be of predictive / clinical value and that the results of these investigations are unlikely to have any implications for me personally.

5. I understand that I will not benefit financially in any way if this research leads to the development of a new treatment or medical test.

6. I understand that the sponsors and investigators have appropriate insurance so that compensation will be available in the event of injury resulting from this research.

7. I know how to contact the research team if I need to.

.....  
Name of participant (BLOCK CAPITALS)

.....  
Date

.....  
Signature

.....  
Name of researcher

.....  
Date

.....  
Signature

.....  
Name of witness

(or) GP for patient without capacity

.....  
Date

.....  
Signature

1 FOR PATIENT; 1 FOR RESEARCHER; 1 TO BE KEPT WITH HOSPITAL/GP'S NOTES



# Appendix II

## The 'Safe Harbor' Principle

These Frequently Asked Questions (FAQs) are taken from the US Department of Commerce web page (at: <http://www.export.gov/safeharbor/faq14pharmafinal.html>) but have been amended to reflect concerns that may be voiced in relation to non-therapeutic genetic research.

### Biological Samples, Pharmaceutical and Medical Products

1. **Q: If personal data are collected in the EU and transferred to the United States for pharmaceutical/medical/scientific research and/or other purposes, do Member State laws or the Safe Harbor Principles apply?**

1. A: Member State law applies to the collection of the personal data and to any processing that takes place prior to the transfer to the United States. The Safe Harbor Principles apply to the data once they have been transferred to the United States. Data used for pharmaceutical research and other purposes should be anonymised when appropriate.

2. **Q: Personal data developed in specific medical/scientific or pharmaceutical research studies often play a valuable role in future scientific research. Where personal data collected for one research study are transferred to a U.S. organisation in the safe harbor, may the organisation use the data for a new scientific research activity?**

2. A: Yes, if appropriate notice and choice have been provided in the first instance. Such a notice should provide information about any future specific uses of the data, such as periodic follow-up, related studies, or marketing. It is understood that not all future uses of the data can be specified, since a new research use could arise from new insights on the original data, new medical discoveries and advances, and public health and regulatory developments. Where appropriate, the notice should therefore include an explanation that personal data may be used in future medical and pharmaceutical research activities that are unanticipated. If the use is not consistent with the general research purpose(s) for which the data were originally collected, or to which the individual has consented subsequently, new consent must be obtained.

3. **Q: What happens to an individual's data if a participant decides voluntarily or at the request of the sponsor to withdraw from the research study?**

A: Participants may decide or be asked to withdraw from a research study at any time. Any data collected previous to withdrawal may still be processed along with other data collected as part of the research study, however, if this was made clear to the participant in the notice at the time he or she agreed to participate.

4. **Q: Pharmaceutical and medical/scientific organisations and companies are allowed to provide personal data from research studies conducted in the EU to regulators in the United States for regulatory and supervision purposes. Are similar transfers allowed to parties other than regulators, such as company locations and other researchers?**
4. **A: Yes, consistent with the Principles of Notice and Choice.**
5. **Q: Does a pharmaceutical or medical device firm have to apply the Safe Harbor Principles with respect to notice, choice, onward transfer, and access in its product safety and efficacy monitoring activities, including the reporting of adverse events and the tracking of patients/subjects using certain medicines or medical devices (for example, a pacemaker)?**
5. **A: No, to the extent that adherence to the Principles interferes with compliance with regulatory requirements. This is true both with respect to reports by, for example, health care providers, to pharmaceutical and medical device companies, and with respect to reports by pharmaceutical and medical device companies to government agencies like the Food and Drug Administration.**
6. **Q: Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects. Research Organisations sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he/she can identify the research subject under special circumstances (e.g. if follow-up medical attention is required). Does a transfer from the EU to the United States of data coded in this way constitute a transfer of personal data that is subject to the Safe Harbor Principles?**
6. **A: No. This would not constitute a transfer of personal data that would be subject to the Principles.**

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