Genetic Interest Group

Working to benefit all those affected by genetic disorders

HUMAN RIGHTS, PRIVACY AND MEDICAL RESEARCH

ANALYSING UK POLICY ON TISSUE AND DATA

REPORT BY

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CONTENTS

Preface and Acknowledgements

This report is one outcome of a study into privacy and human genetics initiated by John Gillott and staff and trustees of the Genetic Interest Group.

The initial focus was on genetics and human rights, with an emphasis on legal aspects and policy decisions informed by law and rights ideology. Article 8 of the Human Rights Act 1998, the right to respect for private and family life,[1] is of most relevance to this study, though other Articles are considered.

The study as a whole comprises two broad strands of inquiry, reflecting those areas in which privacy rights are most relevant and have had the greatest impact: the effect of law and ideology on research and clinical practice, with a focus on genetics; and human reproduction, again with a particular focus on genetic aspects. These two areas present contrasting analytical challenges. While there is recent law indirectly or directly relevant to research and clinical practice (notably the Human Tissue Act 2004), there is little or no case law on the subject. In contrast, as regards reproduction and genetics, there have, over the past five years or so, been a number of court decisions, at all levels up to the House of Lords and the European Court of Human Rights. We therefore decided to publish the results of our study into the two areas separately, the better to highlight the key issues in each subject area. This report is on the first strand: the right to privacy in the context of medical research using tissue and data.

Research for this report involved both textual study and active participation in a number of policy developments considered in the text. Throughout the project, Dr Kathy Liddell, University of Cambridge and Cambridge Genetics Knowledge Park acted as our Legal Advisor, contributing in a variety of ways. We are also grateful to the following people who attended a half-day workshop that provided us with valuable insights and feedback: Celia Brazell; John Crolla; Peter Dukes; Chris Friend; Laura Gilbert; Alison Hall; Jenny Hewison; Dipak Kalra; Jane Kaye; Alastair Kent; Justin Lambert; Philip Lord; Catherine Moody; Rosemary Pattenden; Maggie Ponder; Peter Singleton; David Widdowson; and Andrew Wilkie.

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[1] For the sake of brevity we will refer to ‘the right to privacy’ rather than ‘the right to respect for private life’.

Overview

This report traces the impact that the right to privacy is having on the regulation of medical research and clinical practice, with a particular focus on implications for human genetics. Less than 15 years ago, English law categorically rejected the right to privacy,[2] and professional guidelines encouraged researchers to see research using health data as their moral duty (without necessarily seeking consent or research ethics committee approval).[3] However, in the five years since the implementation of the Human Rights Act 1998 and the Data Protection Act, the situation has changed beyond recognition, and this shift has shaken the medical and scientific establishment to its very core. Some wonder whether conducting research is now too difficult (and insufficiently appreciated) to be worth the effort. Others pity the poor patients who, in the absence of rigorous research, are diagnosed and treated with products and skills of uncertain efficacy and accuracy. Most are wondering what the future holds.

This report addresses the latter point by analysing the directions that government policy has been taking, and suggesting some responses. We argue that the right to privacy is being given too much weight in the context of medical research and clinical genetics, with insufficient reference to wider rights law and court decisions. This is creating political, legal and social turmoil that is disruptive for the public, regulators and the research community. We outline a set of proposals for a more reasonable and stable future, most notably, a future that emphasises the importance of cooperation and solidarity, as well as individualism and choice.

In **Section 1** we begin by examining the most recent legislative implementation of the right to privacy—the Human Tissue Act 2004 (HT Act). In particular, we highlight some of the Parliamentary debates that convey the government's spirited and sometimes perplexing defence of an individual's right to privacy regarding the analysis and use of their tissue, cells and DNA. This demonstrates that the government has taken its program of patient-centred consent-based practice to extraordinary lengths. It also explains why clinicians and researchers have become increasingly concerned that the public interest in medical research and genetic testing for a family member's benefit is being overlooked, or not given adequate weight. Although the government amended its original Bill after comments from the medical and scientific communities, concessions to research were piecemeal, diffident and on occasion, virtually secret.

Section 2 shows that the increasingly powerful impact of the right to privacy is applauded by some academics, who argue it is just and fair that privacy rights should be broadly construed. In particular, they interpret existing laws on the use of data analogously to the legislative scheme implemented for tissue in the HT Act. Some want to go further still, questioning the reality and utility of anonymisation in the context of privacy rights. These

[2] *Kaye v Robertson* [1991] F.S.R. 62 (CA).

[3] Michael P. Coleman, Barry G. Evans and Geraldine Barrett, Confidentiality and the public interest in medical research—will we ever get it right?, *Clinical Medicine*, 2003, 3(3): 219-228.

interpretations have gained wide currency and have had a significant impact on research and clinical practice, leading some scientists and institutions to adapt practice to privacy-centric interpretations of data laws. Specifically, automated extraction of data, independent scrutiny of data analysis during research, the manipulation of data to obscure the identity of research subjects and patient participation in governance arrangements have all been put forward as measures to address the perceived failings of existing approaches.

In the conclusions to Section 2, where we note that many patients are willing to accept current practices if they can be shown to be necessary, then on through the remainder of the report, we outline the legal and political basis for a different approach.

Section 3 compares the recent legislative developments on tissue with those in earlier years in relation to data. Legislative changes regarding data occurred around the time the Human Rights Act 1998 was passed and the right to privacy first entered the English regulatory field. The differences between the law on data and tissue demonstrate that the right to privacy, at least in the government's mind, has been growing more, rather than less, important. The differences also demonstrate, contrary to some of the recent interpretation of the data laws considered in Section 2, that the earlier data protection laws contained a balance between the right to privacy on the one hand, and the public interest in research and the health needs of other individuals on the other. This balance has been lost sight of, in part due to confusions embodied in recommendations and guidance from a number of governing bodies, in particular the General Medical Council and the Patient Information Advisory Group (PIAG).

In **Section 4** we show that the legal basis for developing a less privacy-centric approach is reinforced once the views of the judiciary are taken into account. The judicial system is the social institution that has the power to decide ultimately whether any activity unlawfully interferes with fundamental human rights embodied in the Human Rights Act 1998. The views of judges are thus a useful means of assessing whether the government's implementation of the right to privacy and the emphasis given to consent are excessive. This part of the analysis is not straightforward, since the courts have not yet been asked to decide a case concerning clinical genetics or information-based medical research. That said, much can be gleaned from two recent decisions by the House of Lords about health and genetic information. It is clear that the courts consider that the right to privacy protected by the Human Rights Act 1998 shifted the law in some significant respects. Most notably, it crystallised the value of autonomy and dignity in the law of confidentiality, thereby expanding individuals' right to protect 'private' information. However, the judiciary was equally careful to point out that the right to privacy is qualified by certain public interests, including the protection of health, the investigation of crime, and the rights of others (including the right to free

expression). The important message from the courts is that the right to privacy is extensive, but also extensively qualified. Interferences in privacy, even if substantial, are considered just if they are necessary and proportionate to protect public interests. From this, we argue that recent developments in tissue law and the interpretation of data laws unduly emphasise the right to privacy. We conclude, however, with a cautionary point on the importance of political and cultural factors: the value society attaches to an activity has an influence on legal decisions, although this has yet to be tested regarding issues in research and clinical practice.

Section 5, the concluding section, summarises the predicament facing researchers. It is plain, we argue, that the government has been pushing the boundaries of a balanced interpretation of the right to privacy. It wishes to cement support for some of its flagship policies, including the electronic health care record,[4] using the rhetoric of consumer choice and patient-centred care. Like many others, it has drawn tenuous conclusions from the Alder Hey organ retention controversy, to the effect that researchers are not trusted and that research (unlike audit) is an optional frill in evidence-based care. The key question for the research and genetics communities is how to react. We discuss several proposals that have been put forward, including a model of implied consent, and a comprehensive programme for reform from the Academy of Medical Sciences. We conclude on a political note. Professionals critical of the government's policy are aware that they have a powerful and important story to tell, and a degree of public support for their case, but they remain uncomfortable with the position in which they find themselves—out of favour with sections of the government and their values questioned—and wary of presenting their own concerns too forcefully in public. Difficult though it may be, there is a pressing need to take the issues into political and public arenas; to make the case for the value of research and to explain the means as well as the ends of research to a wider audience.

1 The Human Tissue Act 2004

1.1 Background[5]

For many years, the Human Tissue Act 1961 governed the taking of tissue from deceased persons. It stated that a person lawfully in possession of a deceased person was authorised to remove tissue for medical education or research if 'having made such reasonable enquiry as may be practicable, he has no reason to believe' that the deceased person had previously objected or that any surviving relative objects.[6] Consent was not an absolute requirement, and no particular penalty was stipulated for breaching the 1961 Act.[7] A survey by England's Chief Medical Officer in the wake of the Alder Hey and Bristol inquiries in 2001 found

4 This is the most expensive public IT program of its generation.

5 This section draws on Kathleen Liddell and Alison Hall, Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue, *Medical Law Review*, 2005, 13: 170-223.

6 Human Tissue Act 1961, s 1(2).

7 Ian Kennedy and Andrew Grubb, *Medical Law: Text with Materials*, Butterworths, London, 3rd Edition, 2000.

that more than 54,000 organs, body parts, stillborn children, or fetuses had been retained since 1970. A significant proportion of this collection was compiled without specific consent. Against this background the 1961 Act was declared to be too vague, 'complex and obscure', and 'outmoded and paternalistic' for the modern biotechnological era.[8] Or as the medical lawyer and chair of the Retained Organs Commission, Professor Margaret Brazier, stated: '*it was a toothless tiger imposing fuzzy rules with no provision for sanctions or redress*'.[9]

Accordingly, the Human Tissue Act 1961 was repealed for England and Wales and replaced by the HT Act 2004.[10] The latter Act indicates more clearly the situations in which consent is required before taking, storing or using a deceased person's body or tissue from their body after a hospital post-mortem, and identifies those who may give consent on behalf of a deceased person.[11] However, it goes much further than this; the government took the opportunity to regulate the use and storage of tissue acquired from living as well as deceased persons, the 'trafficking' of certain bodily materials, and non-consensual DNA analysis.

The medical research community vigorously resisted several of the government's proposals, but not all of their criticisms were heeded. In the end, the pivotal rule for biomedical research is that a researcher must have the individual's consent before using or storing tissue obtained from a living adult for medical research, and before analysing the DNA within the tissue. An exception applies if a research ethics committee (REC) has approved the study, the researcher is not able to identify the individual and is not likely to be able to identify them in the future.

The requirements for valid consent—which is called appropriate consent in the case of use and storage of tissue and 'qualifying consent' for situations where DNA is analysed—are not set out in the legislation. This is left to the common law and guidance from the Human Tissue Authority (HTA, a regulatory authority set up under the Act). Failure to obtain appropriate consent before using or storing tissue for medical research is an unlawful act that is punishable as a criminal offence subject to three years' imprisonment, a fine, or both. Strangely, the Act does not impose civil liability, which would give the wronged individual the right to compensation. Whilst consent is needed for research, it is not required for public health monitoring, clinical audit, quality assurance, performance assessment or medical training. The government took the (contentious) view that research is categorically different and not intrinsically related to medical treatment or the maintenance of public health. The soundness of this view was disputed during the passage of the Bill through Parliament, with critics pointing to the importance of research for evidence-based medicine and the blurred

[8] Chief Medical Officer, *Report of a Census of Organs and Tissues Retained by Pathology Services in England*, The Stationery Office, 2001; Mavis McLean, Letting Go… Parents, Professionals and the Law in the Retention of Human Material after Post Mortem, in Andrew Bainham, Shelley Day Sclater, Martin Richards (ed.), *Body Lore and Laws*, Hart Publishing, Oxford, 2002: 79-89; Bristol Royal Infirmary Interim Report, *Removal and retention of human material*, para. 64.

[9] Margaret Brazier, Organ retention and return: problems of consent, *Journal of Medical Ethics*, 2003, 29: 30-33.

[10] Expected to commence in 2006.

[11] Rules applying after a Coroner's post mortem will be dealt with under a revised Coroners Rules.

distinctions between research, clinical audit, quality assurance and performance monitoring.

The underlying philosophy of the original Bill was somewhat reminiscent of Graeme Laurie's concept of spatial privacy, which we discuss later in Section 2, and the broad concept of privacy defined by Beyleveld *et al*[12]. Lawmakers brought forward a proposal based on the idea that people have a tight moral and emotional connection with their tissue even after it is removed from their body and even when they cannot be identified from it; and as such, it ought to be unlawful to use their tissue without their authorisation. Medical researchers, particularly pathologists, argued that it is not practical for them to obtain appropriate consent. For clinical geneticists, the Bill would have prohibited them from analysing DNA to assist a relative in the absence of consent from the original individual. Both groups were aghast that they stood to be found guilty of a criminal offence if they slipped up. Lord May was quoted as saying the proposals were '*like using a sledgehammer to crack a nut*'.[13]

1.2 The Parliamentary debate

More detail, and a sense of the background issues, can be gained from the Parliamentary debates on the Bill, especially those in the Lords. These bring out the government's spirited and sometimes perplexing defence of an individual's right to privacy regarding analysis and use of their tissue, cells and DNA. They also explain why clinicians and researchers have become increasingly concerned that the public interest in medical research and genetic testing for a family member's benefit is being overlooked, or not given sufficient weight. Discussion of these issues helps to develop an understanding of current government and Parliamentary thinking relevant to the research and genetic communities.

For the government, Lord Warner set out the background to the Human Tissue Bill during the first House of Lords debate in the following terms:

'*the Bill is brought forward as a response to the scandals revealed by the Alder Hey and Bristol inquiries. There can be no doubt that many people suffered when they discovered that the organs of their loved ones had been kept without their knowledge. We must not underestimate the pain endured by those who came to realise—often many years later—that the body of the child, husband or mother whom they had buried was incomplete. We must ensure that that does not happen again, and this legislation is key to ensuring just that. However, it does much more than that. This Bill will provide the comprehensive statutory framework needed to ensure the appropriate use of human organs and tissue. It will make consent the clear controlling mechanism for the retention and use of organs and tissue and it will establish a regulatory body to oversee a range of related activity in this area such as post-mortems, tissue banking and the public display of human bodies.*'[14]

12 http://www.privireal.org

13 Pincock, S., Human Tissue Bill could jeopardise research, scientists warn, *British Medical Journal*, 2004, 328: 1034.

14 *Lords Hansard*, 22 July 2004, column 366.

In this section we focus on two areas: research, and analysis of tissue to benefit a relative. This brings out the background assumptions relevant to the concrete proposals and changes, and the general tone of the debates.

1.2.1 Research

The original Bill proposed that all research required consent. However, before entering the Lords, changes were made and clarifications given in response to severe criticism from what Lord Warner later called the 'medical-scientific establishment':

'*Following extensive discussion with a range of medical research interests, including many eminent people in that sphere, amendments were also made in another place to provide for the use, without consent, of residual tissue from living patients in research, provided that the tissue is effectively anonymised and the research approved by a research ethics committee.*'[15]

The HT Act lists, in Schedule 1, Part 1, purposes requiring consent. Included in the list is: '*6. Research in connection with disorders, or the functioning, of the human body*.' This is an extension and elucidation of general principles outlined at the very beginning of the Act, in Part 1. However, in Part 1 of the Act we also find that sub-sections 1(7)-(9) provide:

'(7) Subsection (1)(d) does not apply to the storage of relevant material for use for the purpose of research in connection with disorders, or the functioning, of the human body if-

(a) the material has come from the body of a living person, and
(b) the research falls within subsection (9).

(8) Subsection (1)(f) does not apply to the use of relevant material for the purpose of research in connection with disorders, or the functioning, of the human body if-

(a) the material has come from the body of a living person, and
(b) the research falls within subsection (9).

(9) Research falls within this subsection if-

(a) it is ethically approved in accordance with regulations made by the Secretary of State, and
(b) it is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified.'

A similar couplet—stating the general principle of consent then excluding anonymised samples—governs genetic analysis (Part 3, 45 & Schedule 4, Part 2: 10). Uncertainty remains as to the circumstances in which it is expected that consent should be sought rather than relying on anonymisation. Lord Warner's statement in the first Lords debate—on the possibility of research without consent using anonymised samples—was repeated several times by the government in response to probing by Peers. However, save reiterating that RECs would consider the issue, statements in the debates on this question always contained an element of ambiguity as to the circumstances in

[15] *Lords Hansard*, 22 July 2004, columns 369-70.

which consent should be sought.[16]

Having made the concession prior to debate in the Lords to allow research on anonymised samples without consent, the government refused to move any further, sticking to the principle that research *could only* take place if there was consent or anonymisation (or both). At every opportunity, amendments were presented to make possible, in defined circumstances, the confidential handling of identifiable tissue in research when consent might be absent or unclear. These were firmly rejected. The following quote taken from Lord Warner's response during the Grand Committee stage of the House of Lords debate gives some background to the government's thinking:

'*As a number of Members of the Committee have said, the amendment seeks to remove the requirement for anonymisation of residual tissue when it is used without consent and with ethical approval… As I set off along the path of arguing against the amendment, I am very conscious that I shall probably be told later how cautious I am being by the noble Lord, Lord Clement-Jones. However, I have something to say gently to him. In one of his rhetorical flights, he said that there was a huge barrier to consent. However, there is quite a simple solution—it is called asking the patient, and I shall come back to it in a while…*

…There is also some misunderstanding about the issue of confidentiality. The requirement in the Bill that the researcher should not know the identity of the patient if he or she is using the tissue without the patient's consent is really about fairness and balance. If the researcher is to use tissue without the consent or knowledge of the person from whom it came, then in fairness he should not know the identity of that person. It is inappropriate for doctors or researchers to be in a position where they hold tissue and names, and potentially discover relevant new clinical information through a research project, when the patient has no knowledge that research might be conducted using their tissue.

That is the principle we are seeking to enforce in this legislation. We believe that researchers need to respect it as part of—I repeat—the balance that the Bill seeks to strike in what has been an extremely contentious area.

Furthermore, this provision is in keeping with the data protection principles which require patients to be provided with information on the uses to which data they provide will be put. It also reflects the principles identified by the Patient Information Advisory Group, as the noble Earl, Lord Howe, said in an earlier debate, which include the "ask or anonymise" principle.'[17]

PIAG does indeed promote the 'ask or anonymise' principle. However, there is

16 In Grand Committee, Lord Warner said: 'if the researcher really needs to know the identity of the patient in order to access his identifiable clinical records, for example, he should ask for the patient's consent. We accept that there is a need for linkage, and we have done nothing in the Bill to prevent linkage. It would be surprising if ethical committees did not require a researcher to ask for consent in these circumstances, and a number of noble Lords have hinted that they believe that that would be the case.' (*Lords Hansard*, 15 September 2004, column 426). In the final Lords debate he said: 'Most typically, if consent has not been sought or given, then REC-approved research with anonymisation will be the norm.' (*Lords Hansard*, 03 November 2004, column 404).

17 *Lords Hansard*, 15 September 2004, columns 425-6.

(currently at least) the possibility of using identifiable data without consent. We return to examine the analogy with data protection rules in Section 5.[18]

One further comparison between the use of data and tissue made by government in debate bears recording: although organisations are, subject to ethical approval, allowed to process anonymised patient data without consent, this should not, according to PIAG, override a refusal of consent. During the Grand Committee stage in the Lords on the Human Tissue Bill, an amendment was tabled that would have placed such a restriction on the use of tissue into the Act itself. The government agreed with the principle, but resisted the amendment. The reasons presented by Lord Warner bring out further some of the underlying thinking on the working of consent under the Act:

'*I would not wish to give the impression that the government think that the views of patients should be ignored. On the contrary, we wish to enlist the support of patients in medical research for the good of us all. That is why we have made a requirement for consent the default position for using tissue for research. Ministers have made it quite clear that, notwithstanding the fact that it may be lawful to use it without consent if it is anonymised, if an individual particularly does not wish his tissue to be used in research, then it would not be good practice to do so. We would not expect tissue to be used in those circumstances. Code of practice guidance on this will be issued by the Human Tissue Authority and tissue storage facilities and their records will be licensed and inspected accordingly.*

However, the practical effect of the amendment would be to bring about a situation whereby patients may have to be invited to give or withhold their consent. It would also entail an onerous process of having to check the records of all patients from whom potential research samples have come, in case they had withheld consent. That would be a considerable bureaucratic problem. I am sure that it is not what the noble Lord had in mind when he tabled this amendment, but I would ask him to reconsider the position in the light of what I have said because I think that it will add to the concerns and demands on the medical research community.'[19]

1.2.2 Analysis of tissue to benefit a relative

We now consider the second issue highlighted earlier: analysis of tissue to benefit a relative. As with the rules governing research, the government's position softened as the Bill passed through its various Parliamentary stages. But once more a line was drawn beyond which no further changes were entertained.

Initially, explicit consent was required from the proband (the initial or index case in the genetic investigation of a family) for their tissue to be analysed for the benefit of a relative. The problems this would present in those cases where contact had been lost with such a person, or when they

[18] A similar role to that played by PIAG for England and Wales, is that carried out by the Privacy Advisory Committee for Scotland which was set up to provide advice to NHS Scotland and the General Register Office of Scotland on the release of patient-identifiable data for research purposes.

[19] *Lords Hansard*, 15 September 2004, column GC419.

refused to answer requests, led the government to propose a mechanism for making applications to the court, which might deem consent to be given. This was later amended so that the HTA had powers to consider these applications instead of the courts. However, the government rejected the proposal to allow the use of tissue for the benefit of another individual against a refusal. Under the HT Act, such a refusal cannot be examined or challenged, whether or not a living individual can be contacted to discuss it further. Such a refusal holds absolutely even if the individual is now dead.[20]

The case made by professional and genetic patient groups began from the common practice of analysing samples from a family in order to give the most accurate diagnosis possible to the individual. Two related examples circulated to Peers were assessing risk for familial breast cancer and hereditary non-polyposis colon cancer. The significance of a genetic variation for an individual can, in some cases, *only* be assessed by determining whether an affected relative carries the same mutation, and through studying the cancerous cells of that person.

Whilst it was agreed that the need to consider acting against a refusal would arise infrequently—the vast majority of patients consent to help family members—it was generally acknowledged that problems did arise occasionally. However, amendments to create a mechanism to allow the courts to consider the competing interests at stake in such cases were roundly rejected by government. Speaking in the Grand Committee, Baroness Andrews was emphatic:

'*Without wanting to use language that is too emotive, I should say that the amendment, though sincerely meant, would drive a stake through the heart of the Bill because it goes against its basic principle; namely, that people should be able to decide what happens to their bodily material*.'[21]

Pressed to justify such a resounding rejection of the interests of others, the government, in this debate and others (and also in a letter to Peers), developed the argument that people have an interest in their tissue, in this context at least, that is similar in strength to a right to prevent battery. The analysis of tissue retained in a laboratory against consent was compared with forcing someone to submit to medical examination,[22] and support was claimed from court judgements that have upheld the right of the individual to refuse medical treatment, however irrational others might

[20] We should declare an interest in this. On behalf of the Genetic Interest Group John Gillott lobbied the Lords on this question, while Kathy Liddell helped to prepare briefings with members of the Cambridge Genetics Knowledge Park.

[21] *Lords Hansard*, 15 September 2004, column 480.

[22] *Lords Hansard*, 15 September 2004, column 482.

consider that choice to be.[23]

We have highlighted research and the analysis of tissue to benefit a relative because it is around these issues that the HT Act has indicated the direction of travel most clearly. As the quote from Lord Warner given at the beginning of this section indicates, on these questions the government had the perspective that consent should be the 'clear controlling mechanism'. For better or worse, some clarity has undoubtedly been created on the question of analysing tissue to benefit a relative[24], but more needs to be said regarding research, especially about consent—on the ambiguities inherent in the idea, and on the political background to the contemporary debate.

1.3 The researcher's dilemma

For the government Lord Warner, in the first Lords debate, upheld the validity of generic and enduring consent in the following terms:

'*The Bill does not set out the form consent should take in any particular situation. Let me state clearly that the Bill does not require consent to be specific to each research project for which tissue might be used. Consent can be broad. Consent to research can be generic and enduring*.'[25]

This same point had been made by the government in the Commons debate and was repeated several times subsequently. In the Lords debate at Report stage, Baroness Onora O'Neill, along with many other knowledgeable members of the Lords, welcomed such Ministerial comments. She supported (unsuccessful) attempts to have this inserted into the Bill. Earl Howe explained why researchers were keen to see the statements written into law:

'….*many scientists in the research community are anxious to ensure that some kind of generic and enduring consent will be legal when the Bill becomes law*.

At Second Reading, the Minister gave reassurances on that point. However, worries persist. They persist principally because of the requirement for specificity of consent laid down by many research ethics committees. They also stem from the fact that the Bill is silent on the whole matter. If we are serious about the need to maintain the momentum of medical

[23] *Lords Hansard*, 3 November 2004, column 419. The court judgement thought to have the most force was *Re MB*, in which Lady Justice Butler-Sloss said that: 'a competent woman, who has the capacity to decide, may, for religious reasons, other reasons, for rational or irrational reasons or for no reason at all, choose not to have medical intervention, even though the consequence may be the death or serious handicap of the child she bears, or her own death. In that event the courts do not have the jurisdiction to declare medical intervention lawful.' The government acknowledged that the cases were far from identical, but we would suggest that it was an exceedingly long stretch to compare a case that examined the mother's rights (where third parties propose surgical intervention) against those claimed for an unborn fetus, with cases which require a balance to be drawn between the rights of an adult (where third parties propose to use information or tissue) and another adult.

[24] This point requires a caveat, which will be discussed in more detail later in this section. The Act covers the analysis of tissue (containing cellular material), including the analysis of DNA contained within tissue. It does not cover DNA extracted from tissue. From the strong statements made by Baroness Andrews and other members of the government, it might seem reasonable to assume that the intention was to forbid analysis of DNA to help a relative in the face of a refusal in all circumstances. However, there is evidence to suggest that despite such public statements, the government knew of this loophole when it crafted the legislation.

[25] *Lords Hansard*, 22 July 2004, columns 369-70.

research in this country, and about imposing on it the least possible administrative burden, there is a case for ensuring on the face of the Bill that obtaining generic and enduring consent will be one option open to medical researchers when presenting their proposals to research ethics committees for approval. A signal of that kind would be important for the HTA.'[26]

This illustrates the sometimes perplexing character of the regulatory regime facing researchers at the moment. The government argues that generic and enduring consent is valid. The government also states that they cannot second-guess the decisions of Research Ethics Committees (RECs), to whom they are looking to make the decisions in practice. At the same time RECs often insist on specific and time-limited consent. They in turn look for guidance, but receive little from the government beyond general statements. Researchers find themselves caught in the middle, and increasingly feel themselves to be knocked from pillar to post.[27]

In addition to pressing for amendments to legitimise generic and enduring consent, Baroness O'Neill and Earl Howe also pressed the government to accept amendments that would have allowed research using identifiable tissue without consent subject to appropriate ethical approval.

The attempt to amend the Bill in ways that might appear to be contradictory—reinforcing the legitimacy of general consent and simultaneously seeking a mechanism for the confidential handling of identifiable tissue without consent—further illustrates the complexity of the issue. At the heart of the problem is the tension between the pressures of clinical practice and the complexity and open-ended character of research on the one hand, and the ideal of express and informed consent on the other. No matter how often the government states that generic consent is valid, the concern remains that in specific circumstances it might be thought insufficient.

The response of many scientists to the difficulty of obtaining meaningful informed and specific consent, and the perceived deficiencies of general consent, is to seek to legitimise, or re-legitimise, implicit consent, or else to advocate a public interest defence to the use of identifiable material without consent. This reflects a pragmatic concern that only in this way can they be sure that their actions are ethically and legally permissible. More positively, it also expresses a belief that beyond the formal aspect of general consent, the real content remains a confidential relationship between patient and scientist, based on trust that scientists are behaving ethically and in the public interest. Part of that trust is an understanding that scientists will handle sensitive information and tissue in

[26] *Lords Hansard*, 15 September 2004, column GC 517.

[27] At the time of writing, the Regulations to be made under the HT Act and the Codes of Practice for the HTA had not been finalised. However, drafts issued for consultation did, implicitly, grant a greater validity to specific over general consent in that they contained the proposal that a researcher did not need a licence to store tissue if this was for a specific research project with specific consent, but did need a licence if a general consent had been given to enable the material to be stored and used for future projects. Our own view is that this distinction is misguided both in the specific situation of licensing under the HT Act, and as a general principle. General consent can be just as valid as specific consent. The important thing is that it be informed.

confidence. Approaching the issue from the perspective of anonymisation, scientists wonder why they should invest a lot of time and effort, and maybe lose important information in the process, for little gain, when a system of qualified confidentiality has served them and the public well for many years.

1.4 The politics of the HT Act

This brings us to the politics of the HT Act. Lord Warner, at Report stage in the House of Lords debate, stated:

'*I know that the use of residual samples is not the same as what happened at Alder Hey. But, first, it was not just at Alder Hey, as we saw from Bristol and the Isaacs report. Unconsented removal and the use of tissue and organs was widespread. But the impact of the whole episode went far wider. It has affected the use of tissue in research, as we have seen, since pathology laboratories, RECs and tissue banks have been uncertain about whether and when they can release samples. Under the Bill, this will become clear and confidence can return. But that must be accompanied by a change in the way in which some parts of the research and clinical professions regard these questions. It is not just a question of post-mortem tissue, but of all elements of professional medical and research practice. To say, "Trust me because I am a doctor", is not good enough in today's world*.'[28]

Lord Jenkin undoubtedly spoke for many, inside and outside the chamber, when he disagreed with Lord Warner's presentation of the background to the Bill:

'*When the reports [into Bristol and Alder Hey] were published and the matter became a matter of public comment, the then Ministers at the Department of Health, by using some very unrestrained language, managed to turn the whole affair into a national horror story. I believe that this was quite unnecessary. I also believe that events subsequent to that have been coloured by those comments. The first comment on the report by the right honourable Alan Milburn, the then Secretary of State for Health, was that it was "gruesome". One wonders whether he had the slightest idea of what happens in a post-mortem examination. Perhaps modern television programmes could have shown him. The fact is that this got off on the wrong foot from the beginning.*

I do not doubt that many of the relatives, particularly of children who had died and whose tissues had been removed and retained without consent, were very distressed indeed to learn what had happened. I believe that in their distraught reactions, as graphically recorded in the Kennedy and Redfern reports and also in the minutes of the Chief Medical Officer's summit meeting held on 11 January 2001, these people deserve our profound sympathy. There is no doubt that they suffered grievously.

[28] *Lords Hansard*, 25 October 2004, column 1072. Of course, measures to curtail or remove the autonomy previously enjoyed by the medical profession predate Alder Hey and Bristol, as does the argument that such measures are necessary because the old adage 'Trust me because I am a doctor' is inadequate in today's accountability-conscious world. For a (partially sympathetic) analysis of how this attitude is embedded in the Health Act 1999 see A. C. L. Davies, Don't Trust Me, I'm a Doctor, Medical Regulation and the 1999 NHS Reforms, *Oxford Journal of Legal Studies*, 2000, 20(3): 437-456.

Equally, I have little doubt that it was Ministers' desire to fall over backwards to respond to that distress that led to the Bill, as originally introduced, to being seriously out of balance.'[29]

During Grand Committee in the Lords, Lord Jenkin put the matter in stronger terms:

'*For a former Minister of Health [Alan Milburn, at the time] to describe it as the worst disaster that ever happened to the National Health Service seems to me to be a most extraordinary statement. It should never have been made because it is not that at all*.'[30]

In today's world of research there is much to be gained by linking multiple data and tissue collections. Anonymisation is possible, but to link the different sets, someone needs to be able to return the data and samples to a non-anonymised form, even if only temporarily. The idea that 'Trusted Third Parties', perhaps collected together as a formal or quasi-government agency, should handle the necessary anonymisation and de-anonymisation required carries with it the obvious message that such parties are trust-worthier than researchers.

This message reinforced the irritation, and even hostility, of many scientists.[31] In debate Lord Winston made the pointed observation that: *'People are more worried about political statements and about those scientists who advise government. There is a deep mistrust of politicians rather than a mistrust of the medical profession. As every review reports, scientists and doctors are much more trusted than politicians. Noble Lords ought to bear that in mind when we consider these matters and seek to put them in some kind of focus.*'[32] It would be interesting to know what the public would make of, for example, what would amount to a government run, centralised system of non-consented anonymisation and de-anonymisation of tissue and data collections, if this were to emerge, in contrast to a system in which professionals shared data confidentially on a localised basis.[33]

In summary, the idea that individuals, even knowledgeable ones, have the background information, time or inclination to give detailed consent to the range of possible future uses of their tissue is widely recognised to be seriously flawed. And yet, as an ideal or an aspiration (with unclear legal aspects), it is also widely upheld. The role of RECs in relation to anonymised tissue (and data), or the proposed role of representative research participants when a general consent has been sought and given, can be seen as a response to the gap between rhetoric or aspiration and reality. Existing regulatory frameworks and proposals are also premised upon something else, however: a lack of trust, or a perceived general loss of trust, in clinicians and researchers, who

29 *Lords Hansard*, 22 July 2004, columns 389-90.

30 *Lords Hansard*, 15 September 2004, column 456.

31 Of a piece with the messages transmitted by the Act is the fact that the Bill was introduced into Parliament without, contrary to what was anticipated, a draft being circulated to professional bodies for comment and discussion.

32 *Lords Hansard*, 22 July 2004, column 385.

33 In what must be the acknowledged to be a highly self-selecting group, John Gillott found that when it was put like this, all (approximately 30) participants at a workshop at the Genetic Interest Group's 2004 AGM preferred confidential exchange of information between professionals to the suggested alternative.

in the past had greater latitude to use their own judgement to fill the inevitable gap between public and specialist knowledge and interest. This constellation of legal, sociological and political factors underpins contemporary confusion and dissatisfaction.

1.5 Privacy after the HT Act

Where does the HT Act leave the issue of privacy? Informational privacy is, to a first approximation, strengthened, in that research using identifiable samples will need consent. However, this needs to be qualified by considering the fact that linkage of anonymised samples with medical records will be possible and, crucially, de-anonymisation and linkage to other tissue or data collections will also be possible. It might be more accurate to say that the right to informational privacy will be upheld against scientists but not 'trusted third parties'—the individuals and bodies entrusted with the initial anonymisation process and the subsequent de-anonymisation needed to link sets of data and / or tissue.

The precise degree to which spatial privacy is protected in the context of medical research is unclear. A spatial privacy right embodies the idea that an individual should be able veto some or all uses of their tissue or health information, whether or not it is identified as originating from them as a named individual or is anonymised in some way. As we have shown, the government rejected an amendment that would have made it illegal to use anonymised tissue in research if a patient had expressly refused to give consent to this. In the Act itself, no distinction is drawn between absence of consent and refusal to give consent in the clauses governing research using anonymised tissue, but the government stated that if an individual particularly does not wish his tissue to be used in research, then it would not be good practice to do so. This point remains a little unclear. However, it might be that even if licensing arrangements enforce a distinction, it would require an individual to be aware of the subtleties involved and to be motivated enough to force the issue for the distinction to become meaningful, especially if anonymised samples are used and consent therefore is not sought.[34]

By establishing that a clinician must ask for consent before using tissue to benefit a relative, and stating clearly that it is illegal to use the tissue in the face of a refusal, the Act strengthens a spatial privacy claim within the family (clearly, in this context, the analysis cannot be performed meaningfully on an anonymised sample). There is, however, an important caveat to this that has not been widely commented on. The Act as a whole covers tissue containing cells, and the DNA offence in particular covers the analysis of DNA within a cell or the holding of material containing cells with the intention of analysing DNA contained within; but it

[34] Our purpose in highlighting the limitations placed upon a spatial privacy right in the research context is not to suggest that such a right should be enacted or strengthened. In fact, our own preference would be for a clearer, more transparent system in which the limitations placed on privacy claims were honestly acknowledged and reasons given for such limitations. We consider interferences in spatial privacy to be a relatively minor incursion and one that would almost always amount to a necessary and proportionate interference where the motivation was medical research.

explicitly does *not* cover analysis of what is often called Extracted DNA. Extracted DNA, as the name suggests, is DNA that has been extracted from a cell and stored in a form that is stable in a non-cellular environment. Within clinical genetics it is becoming routine to store DNA in this form, and there is a trend to do the same in other areas of specialist practice. Clearly, the provisions of the Act will cover the material before the DNA is extracted and indeed the extraction process itself. However, in the clinical context these actions will be covered by the consent given during the initial clinical encounter for the original clinical purposes.

The Human Genetics Commission, in its report *Inside Information* (2002), recommended that the government create a criminal offence of the non-consensual or deceitful obtaining and/or analysis of personal genetic information. This was put forward primarily in response to the idea that people might try to establish, for example, paternity in the case of well-known individuals by surreptitiously collecting cellular material from discarded items (such as a toothbrush or a beer glass).

One reading of the relevant clauses in the Act is that the government has acted upon this concern in crafting a law that makes this kind of activity illegal, while allowing clinical genetics in particular to use and store DNA in a manner which falls outside the Act. This may be true, and there is evidence that professionals are operating on the assumption that it is true.[35] It does however run counter to public statements by government about the spirit and ideology of the Act in Parliamentary debates. In recommending its Bill to Parliament and the public, the government repeatedly emphasised the importance of upholding the individual's right to refuse that their tissue be used by medical professionals, as well as in non-medical contexts.

Whether this legislative sleight of hand will form the basis of a significant exception or simply a curiosity of drafting will depend on the extent to which DNA is stored in a non-cellular form, and whether medical professionals are comfortable conducting non-consensual analysis of tissue on the imprimatur of a legislative technicality. Certainly, civil servants have sought to reassure medical professionals that it would indeed be lawful to analyse DNA without consent in certain circumstances if they use Extracted DNA. It thus seems that the loophole will be significant.

2 Legal Policy and Proposals for Research Using Data

We have shown that, in drafting the Human Tissue Bill in the way that it did, the government wanted to strengthen individual privacy rights, and that it has achieved this to some degree in the Act. A number of influential academics and writers recommend a similar regime for the handling of data; a structure that they believe is, or might be, consistent with a number of international legal and policy instruments.

35 See Joint Committee on Medical Genetics, *Consent and confidentiality in genetic practice: guidance on genetic testing and sharing genetic information*, 2006.

In considering views on the legal standards relevant to and interpretations given to the principles of confidentiality, data protection and privacy, a useful starting point is an article by Jean McHale, Professor of Law, University of Leicester[36], in which she argues that overlapping legal problems are rife. Her focus is genetic databases, but many of her points have broader relevance. There is, she argues, some uncertainty surrounding the legality of various research practices. In particular, rights-based European and international statements emphasise free and informed consent for the taking and analysis of genetic material, and it is far from clear that this is always gained in practice, depending on how the term 'informed' is interpreted, and on whether it is accepted that anonymisation removes the need for detailed consent to future uses.

To elaborate briefly on McHale's concerns about informed consent and anonymisation: a common response to the difficulty of obtaining consent to many possible specific uses of samples and data is to seek a generic or general consent. Additionally, the giving of generic consent is often viewed as expressing a wider commitment to medical research: *'Generic consent may also be seen to cohere with notions of social solidarity.'*[37] But for McHale this merely serves to re-highlight the significance given to *informed* and *freely given* consent in rights-based statements and data protection legislation. Furthermore, related to concerns about whether it can be truly informed, she argues that generic or general consent is flawed, as it relies on a 'gift' model that runs into trouble since it in turn is connected with ideas of ownership that are not accepted or acknowledged. McHale believes that anonymisation can be a solution, but she doubts it can remove entirely data protection (and duty of care) obligations. She is also concerned that anonymisation is rarely complete (irreversible); much genetic research and clinical practice requires linkage of genotypic and phenotypic data.

It is not our intention to endorse these legal arguments, but to draw attention to this significant legal opinion, which demonstrates why data protection laws are currently so controversial amongst bioethicists and scientists. One way of viewing these proposals is as an argument for data to be governed by a regime similar to that governing tissue under the new Act, or perhaps by a still tighter regime. Within this framework, further issues and problems are raised.

2.1 Privacy and anonymisation

The significance of and limitations on anonymisation are particularly relevant today. The Icelandic Health Sector Database was set up by an Act of Parliament of December 1998 to investigate the relationship between genetic and environmental factors in common diseases. Initially, controversy centred on the security of data storage and the 'opt out' basis on which the project was established. This discussion has not ceased, but more recently a different aspect has come to the fore, spurred by a decision of the Icelandic Supreme Court in 2003, which considered whether data

[36] J. V. McHale, Regulating Genetic Databases: Some Legal and Ethical Issues, *Medical Law Review*, 2004, 12: 70-96.
[37] McHale: 82.

could be legally deposited in the database if it provides identifiable information about others who have refused consent for their data to be entered. Related to this are controversies about the meaning of anonymisation and its practical limitations when multiple data sets are linked. While the detailed character of the Icelandic data sets combined with the relatively small size of the Icelandic population have thrown these issues into sharp relief, these points are considered by some to be relevant in other countries. In a number of articles, in particularly in commentary on the Supreme Court ruling, Renate Gertz argues that anonymisation will always be incomplete:

'*One of the facts that the Icelandic Supreme Court criticised most harshly regarding the Health Sector Database was the fact that through combining three different databases—the Health Sector Database consisting of the medical records, the Book of Icelanders containing Icelandic genealogy and the genetic samples database—the database could no longer be considered anonymous. In fact, the combination of the three databases would enable scientists operating the combined database to identify Icelandic citizens, as the database would contain all other information except for names and addresses, namely marital status, education, profession, municipality of residence and age of the person as well as specific diseases. In fact, in data protection law, it is stipulated that, if a data controller has access to several different databases and an individual can be identified from linking the information contained in both, then the relevant content of each single database is to be considered personal data. It does not matter in this connection whether the information from each individual databank would not suffice to identify the person. Also if the information is contained in an encrypted database, to which the data controller has the key or is likely to obtain the key in the future, the information in the database will be considered personal data. Directive 95/46 goes even further: if a key to the encrypted database exists anywhere in the world, the data controller is deemed to have access to the key, however unlikely this event may be, resulting in encrypted information being personal data*.'[38]

The legal academic Graeme Laurie makes a more fundamental criticism of current practice in one of the few book-length treatments of genetic privacy. He argues that: *'the avoidance of harm is not the only reason that we respect individual privacy. We also respect privacy in order to respect individuals themselves. It is not clear, however, that this particular goal is currently being met. It indicates that something is missing from our perspective on privacy.*'[39]

For Laurie, this missing privacy right is captured by the notion of 'spatial privacy', which we touched on in Section 1 above. Spatial privacy is the interest individuals have in a certain zone of solitude and separateness from others, including what they know and do not know about themselves, and in the manner in which information about them is used. In his

38 Renate Gertz, Is it 'Me' or 'We'? Genetic Relations and the Meaning of 'Personal Data' under the Data Protection Directive, *European Journal of Health Law*, 2004, 11: 235-6.

39 Graeme Laurie, *Genetic Privacy*, Cambridge University Press, 2002: 255.

book, Laurie devotes more attention to the former question, 'the right not to know', and indeed in the first instance he defines and develops the notion of spatial privacy in relation to this: *'we have examined the nature of privacy interests that individuals have in genetic information and identified those as being of two kinds: informational privacy interests which concern issues of security of existing information, and spatial privacy interests which relate to the protection of the self from unwarranted intrusion, including intrusion with information about one's own self.'*[40]

However, he develops the point further by arguing that there should be constraints on the way information leaves the zone notwithstanding the possibility that it may be anonymised. This means that consent should be sought and given, but more besides: he argues that consent is an insufficient reference point for deciding when information is fairly used or communicated, in the light of spatial privacy interests. His concern is that when information leaves the zone, individuals are typically asked to give consent on a one-off basis, which does not enable them to mediate the ways in which the information is subsequently used. He believes that this has contributed to public distrust of research, which must be addressed by offering the public and patients meaningful participation in research projects: *'it is precisely because people feel disenfranchised from, and disempowered by, the modern machinery of research that we face the current public crisis of confidence in research in general and genetic research in particular. Individuals who provide samples for research purposes are not, and do not feel like, stakeholders in the enterprise.'*[41] To give effect to control and participation, he concludes with the radical suggestion that a property right in the body may need to be considered.[42]

2.2 Automating analysis, scrutinising scientists and manipulating data

The pressure to move towards the use of data on the basis of specific consent to all uses or at least clear consent or strict anonymisation, set against a background of real or perceived distrust of scientists in general, and researchers in particular, has generated support for several adaptations

40 Laurie: 243.

41 Laurie: 311.

42 More recently, Laurie has argued: 'Property is a powerful control device for the bundle of rights that it confers. It also carries a particular message—one of the potential for commerce and trade; of market advantage and disadvantage. To recognise a "quasi-property" claim to material is to support a normatively strong connection to that material and, accordingly, to establish a strong, justiciable legal interest; by the same token, these examples indicate that "full" property rights will only be recognised where there is little or no prospect of exploitation or other harm, which can include the "harm" of disrespect for the dignity of the human organism. We see, then, a widespread ambivalence about property in human material. Other devices, such as consent or contract, are often used instead of property to establish rights and resolve conflicts. Moreover, there is arguably nothing inherently valuable in an appeal to property itself save when such an appeal can furnish rights or solutions to disputes which escape other legal concepts. It is with just such a critical eye that we should consider the entire gamut of legal mechanisms that are employed in the medico-legal sphere, from which, we contend, *property* should not be excluded without careful consideration of its own utility and limits.' J. K. Mason and G. T. Laurie, *Mason and McCall-Smith's Law and Medical Ethics*, Seventh Edition, Oxford University Press, 2006, para. 15.4.

Our own view is that the public interest in research will overwhelm any residual interests the individual might have in the data after it has been anonymised. Furthermore the burdens that would be placed on researchers by mechanisms that attempted to record all individual preferences on the use of anonymised data would be excessive. If the issue is one of controversial research uses of data, this should be addressed at the level of public debate and policy rather than via individual veto.

to current practice highlighted in this section.

Computerised systems are being developed to anonymise data while at the same time extracting the maximum amount of information useful to a project. This includes the ability to extract information from clinical notes in which personal and medical information are mixed freely together. This could be seen as a mechanism to make 'ask or anonymise' work. Alternatively, it could be seen as demonstrating that researchers are going the extra mile in an attempt to meet the ideal, thus providing a defence in limited circumstance of the practice of using identifiable data without clear consent.

A different if related idea is for scientists to submit to greater levels of scrutiny and control through audit mechanisms. This was the conclusion of a fascinating and telling Policy Forum piece in *Science*. Zhen Lin and colleagues[43] at Stanford pondered the limitations of anonymisation in the genetic age, and what conclusions should be drawn from this.

Their starting point was that the growing amount of anonymised data in numerous collections available to research scientists, combining both phenotypic and genotypic data (that is, data relating to both bodily and genetic characteristics), can, when sufficiently rich, be matched to a sample obtained from an individual. This makes it possible for the researcher to use the genetic match (aided by other clues) to access phenotypic information, which was originally given on the understanding that the dataset would be anonymised:

'*Single nucleotide polymorphisms (SNPs) contain information that can be used to identify individuals. If someone has access to individual genetic data and performs matches to public SNP data, a small set of SNPs could lead to successful matching and identification of the individual. In such a case, the rest of the genotypic, phenotypic, and other information linked to that information in public records would also become available*.'

In the UK it has been suggested that data (such as date of birth or addresses) in anonymised sets might be modified slightly, made deliberately false or less precise in other words, to make the job of identification harder. Lin *et al* considered the merits of doing something similar with SNP data, but rejected it, though regrettably not primarily on the grounds that it would reduce the quality and effectiveness of the research:

'*Tension between the desire to protect privacy and the need to ensure access to scientific data has led to a search for new technologies. However, the hurdles may be greater than had been suspected. For example, one approach to protecting privacy is to limit the amount of high quality data released and randomly to change a small percentage of SNPs for each subject in the database. Suppose that 10% of SNPs are randomly changed in a sequence of DNA, a fairly major obfuscation that would not please many genetic researchers. Our estimates show that measuring as few as 75 statistically independent SNPs would define a small*

[43] Zhen Lin, Art B. Owen, Russ B. Altman, Genetic Research and Human Subject Privacy, *Science*, 2004, 305: 183.

group that contained the real owners of the DNA. Disclosure control methods such as data suppression, data swapping and adding noise would be unacceptable by similar arguments.'

This led them to the conclusion that audit and monitoring is required, something they plan to implement as a condition of access to the data they are collecting:

'*Until technological innovations appear, solutions in policy and regulations must be found. We are building the Pharmacogenomics Knowledge Base, which contains individual genotype data and associated phenotype information. No genetic data will be provided unless a user can demonstrate that he or she is associated with a bona fide academic, industrial, or government research unit and agrees to our usage policies (including audit of data access). Although this does not prevent data abuse, it provides a way to monitor usage*.'

The argument that in the genetic age true anonymisation is impossible is, analogously, advanced by some commentators in the UK as a reason for tightening up the rules governing the use of anonymised data. What is perplexing and irritating about this discussion for many practising scientists is the assumption that they need to be prevented from surreptitiously trawling databases to make links with biological samples they have access to from, for example, clinical work. It is a form of organised distrust, even if it is not always presented as such, and support for it from some scientists can only be read as a defensive reaction to a critical climate.

2.3 Patients' views

A similar defensiveness lies behind another proposal that enjoys varying levels of support within the policy and scientific community: patient participation in bodies overseeing research.

Some social scientists feel that the use of patient information (particularly genetic information) is an unsettling form of instrumentalisation and commodification. Some are perturbed by departures from fully informed, specific, explicit consent; others seem to suggest that even when individuals have given their consent, the extent of health-data banking and the motivations that drive it constitute a worrying affront to human dignity.

Schematically, we can break the argument down in the following way:

- An argument based on rights (a spatial privacy right): individuals must be allowed to have an influence even if their data is anonymised.
- An argument based on rights with a sociological aspect: there is pressure to conform / to participate, such that consent is expected. Protections need to be put in place to counteract this.
- A sociological argument: people do not pay attention or consider things in detail; therefore the rights and wrongs of handling data and tissue have to be considered separately from the views of individual

participants—the family and society have an interest. More pejoratively, this latter argument is phrased as: genetic science and biomedicine objectify and commodify life and individuals; controls are needed because individual participants offer limited protection against this.

A recent edited collection, *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA*[44], provides some reflections on these themes, focusing on a range of European countries. Klaus Hoeyer's chapter captures some key features of the real-life interactions between researchers and participants in the kinds of studies under discussion. In the background he identifies contrasting views of the state—not only the traditional welfare model, but also a more recent notion of the 'facilitating' state, which offers choices rather than providing universal services. In this context, informed consent gives people a sense of responsibility for the research conducted, but it also creates a *'diffuse arrangement of donors who can be only semi-accountable agents. This network of agents is linked by a notion of public oversight'*.[45]

As for consent forms—the mechanism through which informed consent is supposed to operate—Hoeyer argues that few people remember or even read them. This does not mean that people do not have concerns about genetic research. However, typically their concerns are about high level and somewhat nebulous questions—such as cloning and eugenics—that are essentially unconnected to the research in question. Furthermore, he continues, the 'they' who might do these things are not seen as the scientists working on the study. The lack of interest in the details of consent reflects that fact that most participants choose to resolve feelings of uncertainty and ambiguity by placing trust in the medical authorities they interact with.

The central argument in Jane Kaye's chapter is that it is not possible to apply either informed consent or public interest exemptions to population collections as a clear mechanism to ensure that legal and ethical standards are met. Such collections, she argues, carry the risk of harm, especially when multiple (including genetic) data sources are combined. Individuals' moral rights to control the use of personal information should accordingly increase over time. Beyond the interests of the individual, *'the nature of genetic information means that there is an obligation to accommodate the interests of the family as well as other groups in society and that of the population as a whole'*.[46] For Kaye, informed consent is the *'threshold requirement for the use of identifiable medical data in medical research practice and the privacy law of the European Union'*[47] (specifically European Directive 95/46/EC), but this needs to be supplemented with other mechanisms. One suggestion is to regularly seek renewed consent from the

[44] Richard Tutton and Oonagh Corrigan (eds), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA*, Routledge, London, 2004.
[45] Tutton et al: 102-3.
[46] Tutton et al: 131.
[47] Tutton et al: 118.

individuals involved. Another is to have some participants sit on bodies with decision-making powers regarding research using the collections.

Hoeyer is undoubtedly right in many of his sociological observations about the real world interactions between doctors, scientists and patients. Kaye's points about the wider family and societal interests at stake are also well made. However, these observations and points do not support conclusions regarding patient participation in governance arrangements.

Certainly, if the claimed role for participants is based on what patients themselves want, some evidence runs in the opposite direction. Richard Tutton, one of the editors of *Genetic Databases*, and a proponent of greater patient and public involvement in oversight of research, recognises in his chapter that the claimed crisis of patient and public trust in medical research—a key background assumption—may not be true, or at least not so true as is commonly claimed,[48] while Helen Busby discusses the fact that in a fairly typical study participants did not see genetic data as especially significant. Indeed, for many, the photographs taken of a skin condition they had were seen as far more worrying and invasive. Busby goes on to make the interesting observation that the contemporary vogue for emphasising lay knowledge (which shares a similar root to the idea that participant involvement in 'governance' arrangements is necessary to address defects in current practices) has obscured the problem of participants having unreal expectations of what research projects will do for them, which is a product of the imbalance of expertise in the knowledge that matters—the science.

It is possible that most participants really do not share the concerns raised or indeed have the desire to 'participate', a situation supported by work conducted for UK Biobank by the School of Health and Related Research at the University of Sheffield: '*individuals who are most likely to be interested in UK Biobank are more likely to want individual feedback, consent just at the start, and for information to continue to be used after withdrawal (with or without the DNA being destroyed)*.'[49] Crudely put, they are happy to be passive and altruistic, but may want information and feedback at the start.

To generalise and move the focus away from the particulars of genetic databases, 'participation' is a poor mechanism to register patients' and the wider public's interest in research. Some patients would like to be involved more, and many would like some idea of what is being or might be done with data and tissue. But most people are simply uninterested in the fine detail and would like professionals to get on with the job without troubling them too much. Unlike some other areas of their lives, people have little knowledge or

48 Tutton et al: 31-2.

49 *ScHARR*, *Public attitudes to participating in UK Biobank*: 113.

interest in research use of data or tissue and would not appreciate what participation might mean. The desired relationship is far better characterised as one based on trust in professionals to use data and tissue for research purposes in an ethically sound manner.[50]

3 The Law Governing Use of Patient Data

In this section we show that some or indeed many of the policy proposals discussed in Section 2, while often presented as established legal principles, have in fact run ahead of, or are really attempts to develop, the law on data protection. This is not (solely) an academic question. One of the biggest problems of the present governance system is the uneven weight given to commentary surrounding the importance of individual privacy relative to its limits. The government, civil servants, regulators, professional guidelines and academic commentators repeatedly emphasise the importance of confidentiality, privacy and consent. In contrast, they give very little attention to the importance of medical research, its similarities with clinical audit and its connections with evidence-based care. Nor is much scrutiny given to the finely balanced exemptions that were purposively included in data protection legislation and have been developed by the courts in common law decisions about confidentiality. As a result, the regulatory burdens imposed on research are crudely interpreted to be more demanding than the higher courts would likely have held if the questions had been litigated in court. These burdens are severely hampering scientific investigation, especially epidemiological research.

A further problem is that strict interpretation of the right to privacy protection can be self-reinforcing. If called upon to decide a dispute, the courts would ordinarily give deep consideration to guidelines published by the Department of Health, the NHS, the Office of the Information Commissioner, the Patient Information Advisory Group, the Medical Research Council, the General Medical Council or a combination of these. If a large number of these bodies suggest that there is a strict requirement to obtain explicit consent or to anonymise data fully, judicial assessments of what is 'reasonable', 'unconscionable', 'proportionate' or 'good practice' may be affected.[51]

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[50] Of concern to researchers is that public feeling following the revelations about practices at Alder Hey looms large in much of the political discussion of these issues (see Section 1 above), and yet in reality little is known, of a comprehensive nature, about public attitudes towards the use of tissue in research. More is known about attitudes towards research use of data. A study by ScHARR found that: '*the public are generally happy for their personal health information to be used when this is in the public interest. People are concerned about who has access to their information rather than what it is used for. The public are content for information to be used by NHS staff, although their responsibilities to maintain confidentiality should be made clearer, potentially with a requirement to sign a contract acknowledging their obligations. Transfer of anonymised data causes least concern, but the use of identifiable data is acceptable if necessary*.' ScHAAR, *Patient Electronic Record: Information and Consent (PERIC); Public attitudes to protection and use of personal health information*, 2002: 6.

Overall, more could and should be done to test the opinions of groups of patients and selected members of the public who have been informed about research methods and the difficulty of working, in some cases, with anonymised tissue and data or with tissue and data with appropriate consents.

[51] A particularly striking example is the confusion caused by the GMC's advice on the duties of confidentiality owed by doctors to patients, issued in 2000. For a discussion of this see Michael P. Coleman, Barry G. Evans and Geraldine Barrett, Confidentiality and the public interest in medical research—will we ever get it right?, *Clinical Medicine*, 2003, 3(3): 219-228.

3.1 The Human Rights Act 1998

The laws we discuss below have been shaped at a semi-constitutional level since 2000 by the Human Rights Act 1998. One of the human rights protected by the Human Rights Act 1998 is, adopting the language of the European Convention on Human Rights, the person's *'right to respect for private and family life... home and ... correspondence'*. As with many of the other rights in the Act, the right to private life is not absolute; interference is permitted where it is '*necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'*.[52] While the language may appear straightforward, significant complexities exist. The scope of the exception is vague and left open to interpretation. It is well accepted that the scope of the right applies to confidential and sensitive information (which helped fuel the Data Protection Act 1998), but questions have been raised as to whether it applies to human tissue excised from the body, or to anonymised information. Other rights that impact on biotechnology are the rights to life and liberty, and the prohibitions against torture, slavery and discrimination. The right to freedom of expression might also be highly pertinent for researchers if it is held to encompass a right to impart and receive scientific knowledge. In addition, there has been some degree of debate about *who* is accountable for respecting the rights of *whom*. In particular does the Human Rights Act 1998 give citizens rights that they can enforce against other private persons, or merely against the State and other public authorities?

We discuss the likely impact of the Human Rights Act 1998 further in Section 4. But whatever ambiguities and difficulties of interpretation it has given rise to, there is no doubt that the legal framework governing the use of data, including use of identifiable data without clear consent, allows a balance to be struck between privacy and other interests, including those of relatives and the wider public. Nor is there any doubt that the Human Rights Act 1998 reinforces the possibility of striking such a balance. We make some suggestions below (Section 3.3) on the factors that might be involved in this process.

3.2 The Data Protection Act 1998

Although relatively recent, the Data Protection Act 1998 has already dramatically influenced the acquisition, processing and sharing of health information for medical research and other purposes. The central demand of the Act is that personal data must be processed in accordance with eight data protection principles, if the data relate to an individual who can be identified from that data or from that data and other information which is in the possession of, or likely to come into the possession of, the data controller.

A key consideration is to determine whether information used by a researcher constitutes 'personal data'. The Court of Appeal recently gave this term a narrow

[52] See Schedule 1 Article 8(1) and 8(2).

definition in *Durant v Financial Services Authority*.[53] Data that is merely held in conjunction with an individual's name or other information that identifies him does not necessarily qualify as personal data; the data must 'relate to' the individual, meaning it affects the person's privacy. To elaborate further, the judgement highlighted two considerations:

'*The first is whether the information is biographical in a significant sense, that is, going beyond the recording of the putative data subject's involvement in the matter or an event that has no personal connotations…. The second is one of focus. The information should have the putative data subject as its focus rather than some other person with whom he may have been involved or some transaction or event in which he may have figured or have had an interest*.'[54]

In the main, health records clearly satisfy these tests. However, once data has been extracted from the files and aggregated with health data from other people, it may be argued that the data is not 'personal', particularly if the data has been reversibly anonymised or is compiled and used in a way that does not affect the individual or cause them serious damage or distress. Accordingly, researchers might argue according to *Durant* that collations of research data are not subject to the data protection principles.[55] However it might not be prudent for them to act on this argument.[56] The safer view for the time being is that, if the data is sensitive, the definition of 'personal data' in section 1(1) of the DPA covers reversibly anonymised data wherever the encryption key is held by a member of the research team, or another person under the control of the same 'data controller' (*e.g*. the same NHS Trust or University for whom the researcher works).

The first data protection principle stipulates that personal data must only be processed 'fairly and lawfully'. The data controller must also meet a condition of Schedule 2 and 3.[57] Where possible the data controller should ask the data subject for their explicit consent before processing their personal data. Where consent has not been given, it is permissible to process health data if the processing meets another relevant condition in Schedule 2

53 *Durant v Financial Services Authority* [2004] FSR 28 (CA).

54 *Durant* para. 28.

55 Correspondence from Dr Chris Pounder, editor of *Data Protection and Privacy Practice* (23/01/06).

56 It is unclear how the Information Commissioner will apply the *Durant* judgement in relation to health information. Guidance on the Information Commissioner's website states that provided the information in question can be linked to an identifiable individual, information about the medical history of an individual is an example of personal data. It is also unclear whether the decision will stand. Although the House of Lords declined leave to appeal, commentators have criticised the reasoning (see e.g. the special issue of *Data Protection and Privacy Practice*, 2004) and the European Commission has commenced negotiations with the UK government voicing its concern that UK law now falls short of the protection required by the European Data Protection Directive (see e.g. http://www.out-law.com/page-4717). Proceedings might be commenced in the European Court of Justice if the government fails to allay the concerns. Furthermore, medical research data is usually at *some point* personal data in the sense of being biographical and focussed on the individual.

57 There is some dispute whether the requirement under the Act that data is processed 'fairly and lawfully' in and of itself requires compliance with laws external to the Data Protection Act, most notably the law of confidentiality. Our view is that meeting a condition of Schedule 2 and 3 ensures that data is processed 'lawfully' and compliance with Part II of Schedule 1 ensures it is processed 'fairly'. Nevertheless laws external to the Data Protection Act apply as separate causes of action. We also take the view that the balance struck in the common law of confidentiality between the value of privacy and the public interest in medical research is similar in many ways to that allowed under the Data Protection Act. For a discussion see K. Liddell, The Mythical Connection Between Data Protection Law and Confidentiality: Processing Data 'Lawfully', *Bio-science Law Review*, 2005, 6(6): 215-222.

and 3. The qualifying conditions are infamously unclear and the subject of much debate. One of the most controversial points is whether a medical researcher who claims justification from a condition other than consent is obliged to notify the data subject that their information is being used for research purposes. Some argue that this forms part of the requirement to process data fairly, whereas others point out that the obligation to process data fairly is to make efforts 'so far as practicable' to notify the individual and that the obligation may be set aside further if the research fits under the section 33(2) exemption for statistical and historical research.[58] Our own view is that the latter interpretation is correct, provided the conditions of section 33 are observed. These include that the research involves a secondary use of data (that is the research is based on clinical records and involves no fresh collection of data from the subject), will not cause substantial harm or distress, and the data will not be used to make decisions that affect the individual. A further condition is that the information should have been collected in accordance with the first data protection principle for another legitimate purpose (*e.g.* clinical treatment).

3.3 The law of confidentiality

Personal information of a private or confidential kind is also regulated by the common law of confidentiality. Unlike the Data Protection Act 1998, there is no special government regulator to monitor and enforce confidentiality, and there have been few court cases dealing with health information or medical research. Nevertheless the common law has a significant impact because it influences guidelines produced by professional bodies and the Office of the Information Commissioner, and decisions by RECs. The effect of the law of confidentiality is that one must not use or disclose information that the law considers confidential, except if authorised by the person to whom confidentiality is owed, a provision of statute, the common law public interest defence, or in accordance with the procedures established under section 60 of the Health and Social Care Act 2001. Confidential information includes information that is imparted on the understanding that a special relationship of confidence exists between the parties, and information that is obviously private. The courts have interpreted this to include information that a reasonable defendant would realise is confidential, information which is not generally available or which is obtained on private property, or which a reasonable person in the place of the complainant would consider offensive, embarrassing or humiliating to disclose. Unlike actions brought under the Data Protection Act 1998, a successful complainant in common law probably has rights to compensation for emotional distress as well as physical and psychological injury and financial loss. That being said, costs associated with legal representation would generally deter plaintiffs who claimed compensation for emotional distress only.

[58] Section 33 relieves a researcher from the requirements of the second data principle, which ordinarily requires *'that personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes'*. In other words, provided the researcher observes the boundaries of section 33, secondary historical and statistical research may be carried out as if it was a component of the clinical reason for processing data.

Several elements in the action for breach of confidence have been the subject of considerable debate, particularly by newspaper editors and celebrities. The most controversial issues in the medical arena are:

- 'does the public interest defence stretch to cover medical research?'; and
- 'is explicit and specific consent necessary before a research subject can be said to have authorised the use of confidential information for medical research?'

Although we agree that medical research activities are not in and of themselves sufficient to trigger the public interest defence, in our view the defence applies to medical research in some situations. The key determinant is whether a breach of confidentiality could be said to be a necessary and proportionate response for the protection of health. The principle of proportionality is not an easy one to apply in practice, particularly as the courts have not had an opportunity to offer guidance in the context of medical research. If the researchers can demonstrate several of the following points, research without full anonymisation or consent is more likely to be considered a proportionate interference[59]:

- researchers are dealing with data from a large number of data subjects;
- a large proportion of data subjects are untraceable;
- there is a serious risk of introducing bias that will jeopardise the validity of the results or a risk that people may be harmed through being contacted;
- there is a serious cost burden in seeking consent;
- the research does not involve direct contact with the data subjects (*i.e.* it is secondary research);
- information is anonymised as soon as possible and to the extent possible;
- highly sensitive information is segregated and not used;
- people with access to the data have signed contracts which subject them to discipline or penalty for mishandling information;
- approval is obtained from an appropriate research ethics committee;
- the data is protected by strong security systems; and
- strong efforts are made to respect the choices of the patients who specifically indicate that they do not wish their information to be used in research.

3.4 Concluding remarks

In recent years, some of the nuances of the central principles of data protection and confidentiality have been overlooked. This has proven particularly problematic in the recruitment of research subjects, and the anonymisation of data. For instance, a rule of thumb has emerged which holds that it is unlawful for researchers to examine patient records in order to select

[59] It is not essential to meet each of these conditions for the public interest defence to apply. The list is indicative. And equally, meeting all would not guarantee that the public interest defence applies (this depends on the nature of the information and the context in which it is obtained).

the patients to be contacted about participation in research. This is sometimes termed 'consent to consent'. It is suggested that the health professional who first prepared the records (*e.g.* their GP) should be engaged for this work. There is a certain ethical appeal in this view, but as a matter of practice a GP's practice assistant or nurse often carries out the work. It seems arbitrary that a practice assistant or nurse should be entrusted to peruse patient records, yet researchers are not. It has also been argued that, strictly speaking, an individual's consent is needed before identifying details are removed from a patient's information in preparation for researchers' analysis. This might be termed 'consent to anonymisation'. This view is based on a particular reading of the definition of 'processing' and the ethical assumption that patients have a legitimate right to choose whether or not information originally sourced from them (but subsequently anonymised) is used in research. To follow this assumption would be crippling for epidemiological research.

Despite the ambiguities inherent in the law, the analysis presented above suggests that the reinforcement of biomedical privacy is not coming directly from the Human Rights Act 1998, the Data Protection Act or indeed the common law of confidentiality, or at least that it is not coming directly *and primarily* from these sources. The explanation for the privacy-centric discourse lies, at least in part, elsewhere. This point is reinforced if we examine the thinking behind decisions taken by the courts in these areas, to which we now turn.

4 Insights from Court Judgements

To this point, we have sketched the legal patchwork that governs the use of DNA, tissue and data, and studied some of the emphases in recent academic commentary and human tissue policy. This section compares and contrasts judicial views about privacy in recent years with the attitudes of academics and policymakers. The comparison cannot be made directly; judges' comments are anchored to existing law, rather than being statements about ideal positions. Within these constraints we turn to two sources. We examine recent decisions for ideologies of privacy and confidentiality that can be identified in judicial reasoning. In addition, we consider what judges have said about the extent to which the law has changed since the introduction of the Human Rights Act 1998. Based on this, we observe that judges have gradually strengthened the right to privacy protected by the law. However, they have been far less ready than academics and policymakers to find extended privacy rights —for example rights of spatial privacy—or to enforce strictly a right to privacy where information sharing advances a competing public interest.

4.1 Two important cases

The most telling case, and a case to which we refer to several times below, is *Ex p S and Marper*.[60] It concerned two appellants—a boy who was acquitted after facing trial for an attempted robbery, and an adult man whose trial for harassment

[60] *R (S and Marper) v Chief Constable of South Yorkshire Police* [2004] 1 W.L.R. 2196 (HL).

was discontinued after he was reconciled with his partner. These individuals requested that their DNA samples and fingerprints, which had been collected and stored without their consent in accordance with section 64(1A) of the Police and Criminal Evidence Act 1984, be removed from the National Forensic DNA Database. The men argued that the statutory power to retain DNA fingerprints and samples after acquittal and discontinuation was contrary to the right to privacy in Article 8 of the Human Rights Act 1998. To establish their case, the men argued that the retention of DNA samples and fingerprints without consent contravened their right to privacy, and that the interference was not justified as being necessary and proportionate in a democratic society. Four of five House of Lords judges held that the retention of DNA did not constitute an interference in privacy, adding that even if it did, the interference could be justified as being proportionate. In their view, the retention policy enabled the database to expand, conferring substantial advantages in the fight against serious crime. They also noted that the retained information would not be made public, and a person was not identifiable to the untutored eye from the profile on the database. The decision is a clear indication that senior judges do not regard genetic information or the right to control it as a quintessentially private matter. Although Baroness Hale took a broader view of the privacy right, deriving some of her arguments from the Canadian Privacy Commissioner, she also refused the appeal. She took the view that while article 8(1) rights were engaged, the interference was proportionate under 8(2).

A second indicative case is *Campbell v MGN*.[61] In this case, the former supermodel Naomi Campbell claimed damages for breach of confidence and compensation under the Data Protection Act 1998 following the publication of a photograph of her emerging onto a public street from a Narcotics Anonymous meeting. The photograph was accompanied by text asserting she was a drug addict, that she was receiving treatment from NA and detailing the frequency of her attendance. The information was surreptitiously acquired without her consent. Nevertheless Campbell conceded it was legitimate for the newspaper to inform the public that she took drugs, had a serious problem with addiction and was receiving treatment. She had previously lied about this to the public and hence the parties agreed that the press was entitled to put the record straight. As a result the case turned on whether it was legitimate for the press to disclose the additional information, in particular the photograph and the nature and frequency of her treatment.

Their Lordships accepted that the additional information included private information that engaged the Article 8 right to privacy. However they were more closely divided about whether the interference was proportionate given the importance of free expression in a democratic society. Two judges[62] took the view that the interference was comparatively minor relative to the information that could legitimately be disclosed to the public, and that some latitude of journalistic freedom is

61 *Campbell v Mirror Group Newspapers* [2004] 2 A.C. 457 (HL).

62 Lords Nicholls and Hoffmann.

necessary in order to explain news stories with credibility. They also held that the photograph added nothing of a private nature. However, the majority reached a different view of the balance between the unauthorised disclosure and the public interest in free expression. They concluded that the photograph represented the fruits of covert surveillance and hence was a significant interference, even though the picture was taken in a public street and did not of itself reveal embarrassing information. The majority also held that the additional information about Campbell's treatment was a significant disclosure since it could affect addicts' willingness to seek therapy, and that there were no compelling political or democratic reasons for the public to know the details of her treatment.

Although the appeal was ultimately decided in Campbell's favour, the decision illustrates the preparedness of judges to find a disclosure of health information to be justified in the light of competing public interests. All the judges in this case clearly found it a closely balanced issue.

4.2 Judicial approaches to confidentiality and privacy

Another point we can draw from the cases is that judges have different ideas about the value of privacy and confidentiality.[63] This is apparent from the statements the judges made about whether anodyne photographs taken by covert surveillance constitute a breach of privacy and the manner in which *retention* of genetic information was distinguished from its use and disclosure. Roughly analysed at least four reasons have been advanced for protecting privacy and confidentiality.

4.2.1 Privacy and confidentiality engenders trust

Traditionally the judiciary has protected confidentiality because it supports relationships of good faith, and full and frank disclosure within such relationships. The relationship between a doctor providing health care and a patient is a quintessential example. In several cases, for example *X v Y*[64] and *W v Egdell*[65], the judiciary has noted that strong rights to confidentiality help secure the trust of patients in their doctors, which means they do not hesitate to seek treatment when they need it. *X v Y* concerned a newspaper story about doctors who were believed to be continuing to practice despite having contracted AIDS. *Egdell*

[63] A note on 'confidentiality and privacy': Ethicists and doctors typically draw a distinction between confidentiality and privacy. The concept of confidentiality is perceived to protect information imparted within a relationship of trust, ensuring that the information is not disclosed without authorisation. This is rationalised on the ground that it would jeopardise the future placing of trust. Privacy, on the other hand, is perceived to have greater connection with an individual's right to control their personal matters and identity. It is a right connected with self-determination, separateness from others (particularly the State), autonomy and dignity. Informational privacy, unlike confidentiality, protects the information from unauthorised *use* as well as disclosure, and protects the information whether or not it has been imparted in a relationship of confidence. In the past, this distinction had practical significance because English law recognised a legal right of confidentiality, but not privacy. Whilst the conceptual distinction can still be made, its practical significance has been diluted by recent developments in the common law of confidentiality. The law of confidentiality is now recognised as one of the primary means for giving effect to the right to privacy. The courts' conflation of privacy and confidentiality has been criticised, but we copy it here because our purpose is to describe how the courts understand the concepts.

[64] *X v Y* [1988] 2 All ER 648.

[65] *W v Egdell* [1990] Ch 359.

involved a consultant psychiatrist, who was asked by W's solicitors to prepare a report on his mental state ten years after he had shot seven people, killing five, throwing hand-made bombs as he did so. The report was buried after it disapproved transfer to a less secure regional unit. At the next periodic review, Dr Egdell forwarded his report to W's current hospital and pushed the medical director to send a copy to the Home Office. Sir Stephen Brown of the Court of Appeal said there is a public interest in maintaining confidence. Quoting Rose J in *X v Y*, he explained:

'*In the long run, preservation of confidentiality is the only way of securing public health; otherwise doctors will be discredited as a source of education, for individual patients "will not come forward if doctors are going to squeal on them." Consequently, confidentiality is vital to secure public as well as private health, for unless those infected come forward they cannot be counseled and self-treatment does not provide the best care*.'[66]

The same view has continued to underscore judicial reasoning since the commencement of the Human Rights Act 1998. For example in *Campbell v MGN*, Baroness Hale and Lord Hope indicated that a critical question was whether disclosure of information about Campbell's drug rehabilitation by the newspaper would disrupt drug treatment services.[67]

4.2.2 Privacy and confidentiality preserves an important realm of autonomous decision-making

Since the European Convention on Human Rights and the Human Rights Act 1998, judges have more commonly described privacy as a right drawn from personal autonomy. The right to privacy is engaged when a person's opportunity to determine (*i.e.* choose) how their information is used is compromised.[68] This may be because the information is used without their authorisation, or because the information is passed on to a third party without them choosing that this should occur. Lord Hoffmann lent support to this theory in *Campbell v MGN*: *'[since the Human Rights Act 1998] [the breach of confidence action] focuses upon the protection of human autonomy and dignity—the right to control the dissemination of information about one's private life…*'[69] And later: '*I should have thought that the extent to which information about one's state of health, including drug dependency, should be communicated to other people was plainly something which an individual was entitled to decide for herself.*'[70] Baroness Hale was influenced by similar thinking about privacy in her dissenting speech in *ex p S and Marper*. She cited approvingly the following words from the Canadian Privacy Commissioner, as a basis for explaining the importance of decisional freedom:[71] '*[w]e are all entitled to expect enough control over what is known about us to live with dignity and to be free to experience*

66 *W v Egdell* [1990] Ch 359, 389-90.
67 *Campbell v MGN* paras 81 (Lord Hope), 165 (Lord Carswell).
68 *Douglas v Hello! Ltd* [2001] QB 967 (CA), 1001 (Sedley LJ).
69 *Campbell v MGN* para 51 (Lord Hoffman).
70 *Campbell v MGN* para 53 (Lord Hoffman).
71 *ex p S and Marper* para. 69.

our individuality. Our fundamental rights and freedoms—of thought, belief, expression and association—depend in part upon a meaningful measure of individual privacy. Unless we each retain the power to decide who should know our political allegiances, our sexual preferences, our confidences, our fears and aspirations, then the very basis of a civilised, free and democratic society could be undermined.'[72]

It is significant, however, that both Lord Hoffmann in *Campbell v MGN* and Baroness Hale in *ex p S and Marper* concluded that the interference was necessary and proportionate, ultimately dismissing the appellants' complaints.

4.2.3 Privacy and confidentiality preserves the patient's right to the esteem and respect of other people

The idea that privacy and confidentiality preserves the patient's right to the esteem and respect of other people is evident in passages where judges focus on the need to protect the way in which an individual is perceived by other people. For example, Lord Hoffmann said in *Campbell v MGN*: *'in my opinion, therefore, the widespread publication of a photograph of someone which reveals him to be in a situation of humiliation or severe embarrassment, even if taken in a public place, may be an infringement of the privacy of his personal information.'*[73] This approach to privacy also explains why the courts have held that there is no breach of confidentiality where a newspaper publishes information to correct untrue statements or false images that a public figure circulates about themselves. The underlying rationale is that the individual forfeits their right to esteem and respect of other people through their deceit; the public is entitled to know that their esteem is misplaced. It also explains why judges are concerned only to protect sensitive information. For example, Lord Nicholls indicated there is little significance in a disclosure that a person who has fractured a limb has his limb in plaster or that a person suffering from cancer is undergoing a course of chemotherapy, or (as in *Campbell v MGN*) that a person with a serious drug problem is attending Narcotics Anonymous meetings.[74] Innocuous information of a predictable kind does not affect the esteem and respect of other people.[75]

4.2.4 Privacy protects a zone of inviolate personal space

Occasionally judges equate the value of privacy with inviolate personal space. This approach is exemplified by Lord Hoffmann's approving reference in *Campbell v MGN* to Lord Mustill's statement: '*An infringement of privacy is an affront to the personality, which is damaged both by the violation and by the demonstration that the personal space is not inviolate*.'[76] Based on this, several of their Lordships, including Lords Hoffmann and Hope, were prepared to find that covert surveillance interfered with the right to privacy.[77] It also seems that this

72 Canadian Privacy Commissioner, *Genetic Testing and Privacy*, 1995: 2.

73 *Campbell v MGN* para. 75 (Lord Hoffmann).

74 *Campbell v MGN* para. 26 (Lord Nicholls). Note that the wording suggests Lord Nicholls' comment was premised on the idea that one already knew that the limb was fractured and that the person suffered from cancer.

75 See also *Theakston v MGN Ltd* [2002] E.M.L.R. 22 for another instance where this approach was adopted.

76 As Lord Mustill said in *R v Broadcasting Standards Commission, ex p BBC* [2000] 3 All ER 989 at 1002, [2001] QB 885 at 900 (para. 48).

77 *Campbell v MGN* paras 74, 121-122.

approach was an undercurrent in the majority's reasoning in *ex p S and Marper,* in so far as their Lordships held that unauthorised *retention* was not interference in privacy or at most a minor interference. Their Lordships seemed implicitly to interpret the right to privacy to be a right to be inaccessible rather than a right to control information about oneself. Since the DNA samples were not stored in a publicly accessible form and individuals were not identifiable to the untutored eye simply from the profile on the database, their Lordships felt that non-consensual retention did not raise an issue of privacy.[78]

4.3 Protection of privacy since the Human Rights Act 1998

In each of these approaches, judges have identified a different way in which people can be harmed when their information is handled without their consent. Many judges make reference to more than one of the four ideological approaches, and very often judges on the same Bench disagree with one another about the interests at stake in a particular context. Further research is necessary to ascertain if there is a clear trend towards a dominant view. However, even without this analysis, an interesting dynamic emerges.

Despite their multiple understandings, all judges are committed to the view that whatever the justification for privacy and confidentiality, it is not an absolute value and interference with it is lawful provided it is proportionate and necessary for a legitimate aim. The primary explanation for judges adopting this approach is that it comports with human rights legislation and the common law. However a subsidiary reason, which explains why the judges have so *readily* adapted their reasoning to these principles, is that it sets up a framework that achieves an overlapping consensus between competing ideologies of privacy.[79] Thus, whatever their differences when it comes to explaining the moral value of privacy, judges find the idea that breaches of privacy are acceptable where they are necessary and proportionate to be one that they can willingly accept when it comes to setting legally binding standards of behaviour. Even judges who believe that an individual is harmed by being denied the choice to decide how their information is used (irrespective of any pecuniary, physical or psychological harm) have agreed with other judges in cases concerning DNA and health information that use and disclosure of that information did not, in the circumstances, amount to a breach of the law because it was a necessary and proportionate interference.

[78] *Ex p S and Marper* paras 31, 38.

[79] The significance of an overlapping consensus between competing moral ideologies for law and legal policy-making is explained in more detail in: K. Liddell, *Biolaw and Deliberative Democracy* (DPhil thesis, University of Oxford, 2003).

Prior to the introduction of the Human Rights Act 1998, two peculiar legal dynamics affected the use of health information. On the one hand, the law courts had ruled that English law did not protect privacy. Accordingly, when a newspaper published an unauthorised interview and photos of a media personality recovering from a motor vehicle accident, the Court of Appeal said there was no basis on which it could award compensation.[80] On the other hand, commentators seemed to conclude from other cases (*e.g. W v Egdell*[81]) that medical professionals owed a duty of confidentiality of the strictest kind such that they were not permitted to disclose medical information without consent, except where non-disclosure posed a serious and imminent risk to another person's health or safety. In part influenced by these interpretations of a doctor's duty of confidence and in part by concerns about the implications of the Data Protection Act 1998 the GMC advised doctors that they should not disclose cancer diagnoses or other non-reportable diseases to public health registries without the consent of patients.

Against this background the commencement of the Human Rights Act 1998 in 2000 was an interesting development. Would it broaden patients' rights to privacy and confirm the strength of that right in the face of public health monitoring and research? Early indications suggested that the Human Rights Act 1998 might indeed be a watershed for broadening legal rights of privacy. In *Douglas v Hello!*, Sedley LJ said:

'*The courts have done what they can, using such legal tools as were to hand, to stop the more outrageous invasions of individuals' privacy; but they have felt unable to articulate their measures as a discrete principle of law. Nevertheless, we have reached a point at which it can be said with confidence that the law recognises and will appropriately protect a right of personal privacy. The reasons are twofold. First, equity and the common law are today in a position to respond to an increasingly invasive social environment by affirming that everybody has a right to some private space. Secondly, and in any event, the Human Rights Act 1998 requires the courts of this country to give appropriate effect to the right to respect for private and family life set out in article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms. …. What a*

[80] Mr Kaye's Counsel did not however expressly ask the court to consider whether there had been a breach of confidence.

[81] This would seem however to be based on an overly strict reading of *W v. Egdell*. *Egdell* was a case where the information was highly sensitive information about the patient's mental state and the disclosure carried serious consequences for his liberty. The confidentiality interest was thus very strong. To justify his disclosure without consent, Dr Egdell needed to show strong countervailing factors. Imminent risk to public safety might have helped establish this. It was not however an essential criterion. All three appeal judges agreed that Dr Egdell was clearly justified in making the disclosure. Only Lord Justice Bingham (as he was then) commented on the imminence of risk, and he found it was not immediately pressing but nevertheless of sufficient concern and, contrary to submissions from W's counsel, an important opportunity to take action: 'it appeared to be only a matter of time, and probably not a very long time, before W [might journey back into the community]'. Of greater salience to future cases was the unanimous conclusion that the case called for a 'balancing operation' that took account of 'the special facts of the case'. If the information in *Egdell* had been less sensitive and the consequences of disclosure less damaging for the patient, it is reasonable to speculate that the court would not have required such a serious threat to public safety to justify disclosure. Indeed in *obiter dicta* their Lordships countenanced the disclosure of medical information for research. Brown LJ noted that GMC guidance permitted information to be disclosed without consent for the purpose of an ethically approved medical research project, and Bingham LJ indicated that a doctor might discuss a case in a learned article if he took appropriate steps (i.e. practical and reasonable) to conceal the identity of W.

concept of privacy does, however, is accord recognition to the fact that the law has to protect not only those people whose trust has been abused but also those who simply find themselves subjected to an unwanted intrusion into their personal lives. The law no longer needs to construct an artificial relationship of confidentiality between intruder and victim: it can recognise privacy itself as a legal principle drawn from the fundamental value of personal autonomy.'[82]

However, the courts quickly drew back from the suggestion that English law might recognise a specific tort of privacy.[83] Rather than take the view that the 1998 Act creates a new cause of action between private persons,[84] judges argued that the impact of the Human Rights Act 1998 was principally to clarify that the breach of confidence action enshrined the *values* of the Human Rights Act 1998. Most significantly, this meant that a duty to keep information confidential could be owed in the absence of a pre-existing relationship between the plaintiff and defendant (*e.g.* between a newspaper and the subject of its scoop). It also meant that the courts would be more inclined to view information as confidential if it were sensitive or offensive (putting less emphasis on the question of whether the information was already known to a few members of the public). This shift had already begun through the influence of the European Convention on Human Rights, but it became stronger and more definitive. Lord Hoffmann put it thus:

'*What human rights law has done is to identify private information as something worth protecting as an aspect of human autonomy and dignity. And this recognition has raised inescapably the question of why it should be worth protecting against the state but not against a private person. …The result of these developments has been a shift in the centre of gravity of the action for breach of confidence when it is used as a remedy for the unjustified publication of personal information. It recognises that the incremental changes to which I have referred do not merely extend the duties arising traditionally from a relationship of trust and confidence to a wider range of people. As Sedley LJ observed in a perceptive passage in his judgment in Douglas v Hello! Ltd …, the new approach takes a different view of the underlying value which the law protects. Instead of the cause of action being based upon the duty of good faith applicable to confidential personal information and trade secrets alike, it focuses upon the protection of human autonomy and dignity—the right to control the dissemination of information about one's private life and the right to the esteem and respect of other people. These changes have implications for the future development of the law. They must influence the approach of the courts to the kind of information which is regarded as entitled to protection, the extent and form of publication which attracts a remedy and the circumstances in which publication can be justified*.'[85]

82 *Douglas v Hello! Ltd* [2001] QB 967 (CA), 997 (emphasis added).

83 For example *Wainwright v Home Office* [2004] 2 A.C. 406 (HL) explained that privacy is a 'principle only in the broadest sense', which directs the development of the recently expanded law of breach of confidence rather than a distinct tort.

84 Such development would have raised many complex questions about the boundaries of the action—*e.g.* what remedies and defences apply, and how does the new action overlap with confidentiality and defamation?

85 *Campbell v MGN* paras 50-52 (Lord Hoffmann) (emphasis added).

These passages show that the Human Rights Act 1998 expanded the protection of personal information, though in a more subtle and indirect manner than anticipated. And what of the circumstances in which non-consensual use and disclosure might be permitted? Interestingly, and perhaps ironically, the implementation of the Human Rights Act 1998 has at the same time extended and tamed the duty of confidentiality by clarifying the principle that confidential information may be disclosed to support the public interest. In decisions under the Human Rights Act 1998, judges are strongly responsive to the public interest in sharing information, even sensitive information. This is because the Human Rights Act 1998 makes clear that the right to privacy is subject to a number of exceptions where interference is important for social purposes (see Article 8(2)), and furthermore that the right to privacy must operate in conjunction with other fundamental rights including the right of free expression (see Article 10). Imminent harm is no longer, if it ever was, a necessary requirement.

Lord Hope and Baroness Hale's speeches in *Campbell v MGN* draw attention to the conditioning that has become clearer since the implementation of the Human Rights Act 1998. Lord Hope said:

'*The language has changed following the coming into operation of the Human Rights Act 1998 and the incorporation into domestic law of article 8 and article 10 of the Convention. We now talk about the right to respect for private life and the countervailing right to freedom of expression. The jurisprudence of the European Court offers important guidance as to how these competing rights ought to be approached and analysed. …It seems to me that the balancing exercise to which that guidance is directed is essentially the same exercise, although it is plainly now more carefully focussed and more penetrating*.'[86]

Baroness Hale said:

'*[Articles 8 and 10] have provided new parameters within which the court will decide, in an action for breach of confidence, whether a person is entitled to have his privacy protected by the court or whether the restriction of freedom of expression which such protection involves cannot be justified*.'[87]

She described the circumstances in which interference in fundamental rights was permitted in the following way:

'*[Art 8 and 10 rights] may respectively be interfered with or restricted provided that three conditions are fulfilled. (a) The interference or restriction must be "in accordance with the law"; it must have a basis in national law which conforms to the convention standards of legality. (b) It must pursue one of the legitimate aims set out in each article. Article 8(2) provides for "the protection of the rights and freedoms of others". Article 10(2) provides for "the protection of the reputation or rights of others" and for "preventing the disclosure of information received in confidence". The rights referred to may either be rights protected under the national law or, as in this case, other convention rights. (c)*

86 *Campbell v MGN* para. 86 (Lord Hope) (emphasis added).

87 *Campbell v MGN* para. 132 (Baroness Hale) (emphasis added).

Above all, the interference or restriction must be "necessary in a democratic society"; it must meet a "pressing social need" and be no greater than is proportionate to the legitimate aim pursued; the reasons given for it must be both "relevant" and "sufficient" for this purpose. The application of the proportionality test is more straightforward when only one convention right is in play: the question then is whether the private right claimed offers sufficient justification for the degree of interference with the fundamental right.'[88]

Thus, from a legal perspective, the Human Rights Act 1998 has in fact done as much to limit the rights to confidentiality and privacy as to extend them. Non-consensual disclosure of private or confidential information is permitted provided the disclosure is necessary and proportionate for the protection of public health. Accordingly, the disclosure of health information to public health registries is likely to be permitted and the use of personal information by medical researchers might well be permitted in a broad range of circumstances.

4.4 Court judgements and the value of research

The phrases 'likely' and 'might well' used above reflect an unavoidable element of uncertainty. In this section we explore this question a little further, examining a factor that might influence court decisions: the value society and government attaches to medical research.

The approach of the courts in the two cases discussed in 4.1—concerning retention of DNA samples and treatment for drug addiction—was to place society's interest in investigating crime and free expression, respectively, in the balance against privacy interests. The courts then decided how to weigh that balance to reach a decision. Michael Coleman, Barry Evans and Geraldine Barrett thought that medical research should be considered of sufficient value to be weighed similarly in any balancing act, but they also recognised, indeed were deeply troubled by, the fact that the media and some other sections of society did not see it that way:

'*Expecting the police to protect society against crime without a database of identifiable information would be considered absurd. Equally, asking the Inland Revenue to ensure that we all pay the right amount of income tax to the state without an identifiable database would be unthinkable. When the security of such systems is breached, society does not demand that they are closed down, or even that the perpetrators are fired. In 2003, Inland Revenue staff were caught trawling confidential tax databases both maliciously (for information about ex-spouses) and for profit, selling juicy snippets about the tax affairs of celebrities to tabloid newspapers. The press calmly reported that new rules would be brought in shortly. The contrast between press criticism of legislation designed to tighten the control of confidentiality in research and the lenient reporting of repeated, deliberate breaches of confidentiality for*

88 *Campbell v MGN* paras 139- 140 (Baroness Hale) (emphasis added). See also para. 131 (Lord Hope).

malice or profit in the Inland Revenue could hardly be more striking. The press clearly applies double standards when reporting on confidentiality and the public interest. Media treatment of a breach of confidentiality by medical researchers, whether accidental or deliberate, would probably be very severe.'[89]

Therein lies the problem. The value society attaches to research is important in many ways. Perhaps less obviously, it affects the decisions courts might make. There is an inescapable political and cultural dimension to the issue. 'Society' might seem too abstract a notion, and the possibility of values directly affecting a court decision too unmediated. However, as we noted earlier, an obvious mediation is the fact that the courts would seek guidance from recent legislation and professional guidance, among other sources. If professional guidance is infused with a defensive spirit and makes suggestions and proposals that effectively shift the balance away from research interests towards privacy interests, this, whilst not necessarily a decisive factor, could nevertheless be important.

5 Conclusions: Directions, Conflicts and Proposals

By contrasting the law on tissue and the legal policy discussion of data on the one side, with existing law and court judgements on the other, we have established that it is not the law that is the primary driver towards a strict privacy regime governing data. We have also drawn attention to the large degree of choice in the government's decision to move in the direction they did regarding the law on human tissue.

In this concluding section we focus on the direction of change indicated by government policy, and attempts to modify this by researchers and others. The dominant trend is to reinforce informational privacy interests (and move towards the modification of data protection laws in line with the schema laid down for tissue in the HT Act). Professionals critical of the government's policy are aware that they have a powerful and important story to tell, and a degree of public support for their case, but they remain uncomfortable with the position in which they find themselves—out of favour with sections of the government and their values questioned—and wary of presenting their own concerns too forcefully in public.

5.1 Tissue and data: differences and similarities

In discussions on the Human Tissue Bill, the government highlighted some differences between re-analysis of tissue and use of existing data, with the implication that this might lead to different emphases in policy. Regarding research, Lord Warner argued:

'*Many noble Lords have mentioned the issue of research using residual samples where the Bill allows for research without consent, provided ethical approval is given to the use of anonymised samples. The questions are twofold. First, does anonymised mean permanently unlinked?*

89 Michael P. Coleman, Barry G. Evans and Geraldine Barrett, Confidentiality and the public interest in medical research—will we ever get it right?, *Clinical Medicine*, 2003, 3(3): 223-4.

I have already tried to indicate that it does not. The Bill allows samples that are anonymised in ways that will retain their linkage to the clinical record. Secondly, is it in fact necessary for such samples to be anonymised in the first place? We maintain that it is. While we recognise that it is part of the duty of professionals to maintain confidentiality in their handling of patient information, we believe that the use of tissue samples is not an identical issue, especially the use of those samples for research when the patient has not given consent.'[90]

Baroness Andrews was more specific: '*That is where the analogy made by the noble Earl with the PIAG and the use of data seems to fall down because data protection concerns the use of existing information, but the use of tissue concerns the effort to derive new information. I suggest, therefore, that different criteria would apply.*'[91] Similarly, in relation to comparing re-analysis of tissue to benefit a relative with use of existing data for the same purpose, Lord Warner argued in a letter to Peers that: '*In the debate, analogies were drawn with data protection, but using tissue is not the same as using data. Data already exists, it may be held by several people, and considerations of its confidentiality are dealt with elsewhere in legislation. The issue here is the use of tissue to undergo a process that would generate new information which the person concerned might not want to have, let alone want other people to have.*'[92]

While there is a distinction to be made between gaining new information and using existing information, the government's attempt to equate this with a distinction between analysing tissue and using data is ultimately unconvincing. Re-analysis of tissue may reveal nothing particularly sensitive for the original donor. In the context of examples given in Section 1.2.2, it is hard to see how it is obvious that an individual would have more concern about analysis of tissue to test for the expression of a gene, say, than the release of existing, potentially sensitive data.

5.1.1 Ask or anoymise

More straightforward is the overarching approach to future developments taken by the government and PIAG, despite statements emphasising the potential differences and their possible policy implications. Many professional bodies are working on the assumption that government wants to move towards an 'ask or anonymise' system (and the abolition of PIAG), and this is certainly the impression we have gained in talking with officials. Following the HT Act, and bearing in mind the tight connection between tissue and data in research, pressure will be exerted in this direction.

Indeed, for the government, the HT Act is part of a reconfiguration of research and clinical practice, which is advanced as being all of a piece with the agenda of placing the patient at the centre of the healthcare system, and covering both tissue analysis and data handling. The government argues that this is entirely consistent with effective research and

90 *Lords Hansard*, 22 July 2004, column 426.
91 *Lords Hansard*, 25 October 2004, column 1112.
92 Letter dated 1 November 2004. A copy has been placed in the House of Lords library.

professional education. As Lord Warner put it at Report Stage during the Lords' consideration of the Human Tissue Bill:

'*This Bill is not just a reaction to Alder Hey. We are not positing a false divide between patients, doctors and researchers. It is part of a whole process of developing a patient-focused approach to health, research and education. But as my right honourable friend Alan Milburn said four years ago, patient-centred consent-based practice is not at odds with research and education. On the contrary, it will be to our advantage that we develop and encourage the engagement of patients with these vital activities that support our healthcare system*.'[93]

This contrasts with the view of many researchers that the cumulative effect of the government's reforms, whilst not actually blocking research (with some exceptions), has been to hinder rather than facilitate scientific and clinical investigation.

5.2 The professionals' perspective

Aware of the resilience of underlying public sympathy, even support, for medical research and practice, some philosophers, policy makers and scientists would like, tentatively perhaps, to put the case for the scientists' perspective rather than accept and adapt to the contemporary drift in policy.

5.2.1 Implied consent or a public interest exception to consent?

Professor O'Neill has pressed the legal and bioethical communities to reconsider the issue from a philosophical perspective. She argues that strict requirements for explicit consent cannot and should not substitute for relationships of trust between individuals and institutions.[94] Implicit in her argument is the notion that recent legal policy has missed the point and should seek to promote relationships of trust without being fixated on the idea of explicit consent.

Policy expert William Lowrance shares these concerns and in 2002 he asked: *'is an updated version of implied consent then the solution? Probably. With the section 60 mechanism in place, the NHS is proceeding as though this will become the case. But evolution in this direction will require a lot of driving, and ultimately the decisions will be political…. Section 60 is both a solution and a restatement of the problem.'*[95]

The legitimacy of the notion of implied consent to research might be bolstered if notices were more frequently posted in hospitals to inform the public that tissue taken and data gathered is routinely used in research. But for ethical and legal reasons we are not attracted to the idea that implied consent *simpliciter* is the solution. While the measures might be practical, consent is properly valid only where it is a true expression of agreement (*e.g*. offering an arm for blood to be taken). In our view it is better to acknowledge that consent has not been

93 *Lords Hansard*, 25 October 2004, column 1073.

94 For example in *Autonomy and Trust in Bioethics*, Cambridge University Press, 2002.

95 William Lowrance, *Learning from Experience*, The Nuffield Trust, 2002: 24; 41

given, and that research is justified because it serves the public interest and involves no more than a proportionate interference in the individual's right to privacy.

As we outlined in section 3.3, in our view research without full anonymisation or consent is more likely to be justified where:

- researchers are dealing with data from a large number of data subjects;
- a large proportion of data subjects are untraceable;
- there is a serious risk of introducing bias that will jeopardise the validity of the results or a risk that people may be harmed through being contacted;
- there is a serious cost burden in seeking consent;
- the research does not involve direct contact with the data subjects (*i.e.* it is secondary research);
- information is anonymised as soon as possible and to the extent possible;
- highly sensitive information is segregated and not used;
- people with access to the data have signed contracts which subject them to discipline or penalty for mishandling information;
- approval is obtained from an appropriate research ethics committee;
- the data is protected by strong security systems; and
- strong efforts are made to respect the choices of the patients who specifically indicate that they do not wish their information to be used in research.

5.2.2 Key studies

Two important studies by the Medical Research Council (MRC) and The Academy of Medical Sciences[96] have examined the use of patient data in research, in particular the secondary use of data, against the background of contemporary concerns. Together they have highlighted, among other points:

- the importance of and varied types of research using existing data;
- the conflict between stringent regulation and the desire to facilitate cost effective secondary research;
- that full anonymisation is often not possible and if achieved it can undermine, even destroy, the value of the data collection concerned.
- that many of the most promising research opportunities involve comparing and integrating data from different sources (such as different databases and / or clinical records), and between different disciplines and organisations;
- that it is often necessary to handle identifiable data when bringing different data sets together to avoid errors, and that this is a difficult job, often better done by researchers than by third parties less familiar with the issues and pitfalls;
- that the insistence or strong preference of RECs that in seeking consent to research contact be

[96] Publications resulting from the MRC study are in preparation at the time of writing. Academy of Medical Sciences, *Personal data for public good: using health information in medical research*, 2006. Available in hard copy and online at: http://www.acmedsci.ac.uk/images/project/Personal.pdf. For a case study highlighting issues raised in the report see: Iversen, A., Liddell, K., Fear, N., Hotopf, M. and Wessely, S., Consent, confidentiality, and the Data Protection Act, *British Medical Journal*, 2006, 332: 165-169. The same issue of the *BMJ* contains response and comment from Peter Goldblatt, chief medical statistician, Office for National Statistics and Tom Walley, chair, Research Governance Group, Royal Liverpool and Broadgreen University Hospitals.

made by clinicians or a GP known to the patient rather than the researcher is creating a barrier to effective research using identifiable data; and

- that in turn this encourages the use of anonymised data, which may have costs in terms of the effectiveness of the research, since it can often lead to the loss of useful information.

The Academy's recent report in particular provides a detailed and clear analysis (aided by many examples) of the issues from the professional perspective. Of particular note is a thorough examination of the laws covering the use of data in the UK (Chapter two) and a powerful defence of the need for researchers to access identifiable data without clear consent in certain circumstances (Chapter three). In summary, on this latter point, they write:

'*Most types of research using personal data require access to identifiable data at some point for some purposes. If researchers are not allowed access to the key to coded data, those that do hold the key (i.e. GP practices and hospital trusts) will need to undertake many tasks on behalf of the research teams. This includes many of the processes described in the previous section, including linkage to eliminate double-counting, addition of follow up data on a regular basis, amalgamation of data sets from different sources, as well as validation both internally and against external standards such as paper records. Experience shows that these are not straightforward tasks and the quality with which they are undertaken determines the quality of the subsequent research.*

The additional level of security gained from pseudonymisation (where researchers do not have access to the key codifying the data set) is extremely small compared with the use of coded identifiable data sets by academic research groups operating under a strict security policy.'[97]

5.3 Medical research and the public interest

The government is, in a broad sense, in favour of medical research. Indeed it wishes to promote it. Sections of the government and some regulators are also sympathetic to some of the researchers' concerns. The tension arises from the conflict between the needs of research and the government's promotion of consumer choice and patient-centred care and research. Indeed, catalysed by the publication of the Human Tissue Bill, the past few years have witnessed a partial breakdown in the usual channels of communication between the medical establishment and the government.

In addition to feeling the cool wind of disapproval, clinicians and researchers were presented with a Bill (the initial draft of the Human Tissue Bill as introduced into the House of Commons) into which they had had minimal input, forcing them into a process of semi-public lobbying,

[97] *Personal data for public good: using health information in medical research*: 54.

with which they were uncomfortable. Some ground was clawed back, especially during the debate in the Lords. However, reluctant publicly to challenge the rhetoric of patient-centred care and research in the post Alder Hey world, the medical and research community remained to a large extent on the back foot.

In 2003, Coleman *et al* called on government to '*consider carrying out a careful survey of public opinion, large enough to be statistically robust, and with suitable background information to enable adequate responses.*' The results, they added, '*should be the basis of wider debate aimed at reaching a settled public consensus.*'[98] Similarly, the Academy of Medical Sciences calls on the Department of Health to '*undertake a programme of public engagement around these issues.*'[99]

It would undoubtedly help the medical profession in its negotiations with the government if it were able to show that patients and the wider public are supportive of the means as well as the ends of medical research, based on an appreciation of the reality of research practice. There is every chance that such a detailed survey of a representative sample of the population would make manifest what many believe is still there waiting to be revealed: broad public support for medical research carried out in the public interest, even if consent cannot be gathered in all cases.

But whether or not such surveys are undertaken, the case for medical research and its methods, carried out in the public interest, needs to be made in a clear and public way. The direction taken by the government's thinking, most clearly expressed in the HT Act, suggests to us that professionals and others of a similar mind (including some or many patients) need to take a lead on this themselves, rather than hoping the government will do it for them.

98 Michael P. Coleman, Barry G. Evans and Geraldine Barrett, Confidentiality and the public interest in medical research—will we ever get it right?, *Clinical Medicine*, 2003, 3(3): 225.

99 *Personal data for public good: using health information in medical research:* 72.

The Genetic Interest Group (GIG) is a national alliance of patient organisations with a membership of over 130 charities which support children, families and individuals affected by genetic disorders.

GIG's primary goals are:

- To promote awareness and understanding of genetic disorders so that high quality services for people affected by genetic conditions are developed and made available to all who need them.
- GIG seeks to educate and raise awareness amongst opinion formers, people of influence and the public about human genetics and genetic disorders.
- GIG provides a common platform from which effective programmes can be launched to raise awareness, inform the media and influence government, industry and the NHS
- GIG focuses on issues of policy and practice keeping an active watch on developments within the UK and Europe that will influence the effective transfer of knowledge and understanding into products and services for families that are supported by our member groups

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