The **Academy** *of* **Medical Sciences**

UNIVERSITY OF CAMBRIDGE
Faculty of Law

Public Health Genetics

Personal data for public good: using health information in medical research

Report by the Academy of Medical Sciences (January 2006)

Report of proceedings at the legal symposium 24 June 2006

February 2007

Contents

Introduction

This report provides a summary of the legal symposium on the Academy of Medical Sciences report *'Personal data for public good: using health information in medical research'* [1], which took place at the Faculty of Law, University of Cambridge on 24 June 2006. The symposium was jointly hosted by the Academy of Medical Sciences, the University of Cambridge Faculty of Law and the Public Health Genetics Unit, and was generously supported by Mills & Reeve.

The aims of the symposium were as follows:

1. To facilitate discussion on the legal arguments in the Academy's report by senior members of the legal profession, including solicitors, barristers, academics and the judiciary;
2. To draw out the strengths and limits of the arguments presented by the Academy;
3. To establish areas of certainty around the legal arguments and highlight areas of ambiguity; and
4. To anticipate future legal and medical developments and problems, so as to identify areas where legislative or regulatory change may be required.

This report is split into three sections. Section 1 is a record of the presentations and discussions at the meeting, with contributions approved by each speaker. Section 2 is a summary of the issues raised at the symposium in the context of both the Academy's report and wider developments in the area. Section 3, 'conclusions', draws together proposals that received broad support from the symposium delegates.

The organisers are most grateful to the speakers and discussants for their thoughtful presentations and stimulating remarks. We also thank Dr Isabella Alexander (University of Cambridge) and Dr Kathy Liddell (University of Cambridge) for acting as rapporteurs for the meeting.

1 See www.acmedsci.ac.uk/images/project/personal.pdf

Part 1 Report of proceedings

Session 1: Welcome

The Symposium delegates were welcomed by **Professor David Feldman FBA** of the University of Cambridge, **Sir Keith Peters FRS FMedSci** of the Academy of Medical Sciences and **Dr Ron Zimmern**, Director of the Public Health Genetics Unit. Delegates were reminded that the focus of the day would be on the Academy of Medical Science's Report, *'Personal data for public good: using health information in medical research'*, and the legal problems identified within it. The Chair of the Symposium, **Mr Justice Munby**, of the Royal Courts of Justice, Family Division, reiterated the 4 aims of the meeting:

1. To facilitate discussion on the legal arguments in the Academy's report by senior members of the legal profession, including solicitors, barristers, academics and the judiciary;
2. To draw out the strengths and limits of the arguments presented by the Academy;
3. To establish areas of certainty around the legal arguments and highlight areas of ambiguity; and
4. To anticipate future legal and medical developments and problems, so as to identify areas where legislative or regulatory change may be required.

Session 2: The strengths and limits of the argument

Mr Philip Havers QC (Crown Office Row) opened the first session, stating that he thoroughly supported the conclusions reached in the Academy's Report. There is a tendency in recent regulation to put too great an emphasis on confidentiality and privacy, at the expense of the exceptions set out at Article 8, paragraph 2, of the European Human Rights Convention and the public interest in general. This emphasis on rights obscures the fact that with rights come responsibilities to assist and support fellow citizens, and those who wish to shift the balance of the debate in favour of rights and away from the public interest would do well to consider this.

One of the vital questions prompted by the Report is: how would the courts respond to a challenge to the use of patient information in secondary medical research without the consent of the patient (or patients) involved? There is currently a paucity of case law in this area but researchers could be even bolder than the Report suggests. The courts are likely to be highly receptive to arguments that the law justifies breaches of confidence and privacy with regard to secondary data research, provided that the infringements are no more than is necessary. The word "necessary", which appears in many places in the Data Protection Act 1998, should have the same meaning as it does in the European Convention of Human Rights, i.e. the interference should fulfil a pressing social need and be no greater than is proportionate to the legitimate aim pursued.

Previous cases that have considered the issue of medical records should be looked at in their own particular contexts and should not necessarily be seen by researchers as raising the bar for establishing a countervailing public interest. The case of *Z v Finland* is frequently cited as a leading decision in the area and, in this case, the European Court of Human Rights (ECHR) was prepared to accept the special importance of medical records. However, the Strasbourg Court also noted that the privacy interests of patients and the community might be outweighed by the interests in Article 8, paragraph 2, of the ECHR. In this case, very little in the way of a public interest argument was advanced by the Finnish government, given the facts of the case. Had a better and more compelling public interest argument been applicable, there is no reason to think that it might not have been successful. In addition, the public interest argument relied on in the case of *Campbell v MGN* is very different to that

on which researchers would rely. The success of researchers' arguments would depend on putting forward cogent and compelling evidence to demonstrate the strength of the public interest in using health information for a particular research protocol, as well as on demonstrating that it was simply not practicable to obtain the consent of the patient, or to provide the patient with information about the research. Medical researchers should be encouraged to "be bold", as they are likely to be supported by the courts both in the UK and in Strasbourg.

Finally, if the problems are indeed as serious as the Academy suggests, a radical solution may be required. Noting that in France there is a general presumption in favour of organ donation, a similar general presumption in favour of permission to use medical information could be introduced in the UK. This would require revisiting both the Data Protection Act 1998 and the Data Protection Directive.

Professor Vivienne Harpwood (University of Cardiff) described the broader background of developments in the NHS and society as a whole. The central argument in the Academy's Report is that research using secondary patient data is being inappropriately restricted by misunderstandings of the legal position, confused professional advice, assumptions about public attitudes and unnecessary bureaucracy. A rigid "consent or anonymisation" policy is impractical in secondary research. However, it should be possible to find a fair balance between the interests of individual patients and the public interest in medical research.

It seems that there is considerable confusion in the healthcare sector regarding data protection, and that data controllers generally respond very cautiously to requests for data. This confusion results from:

- The emphasis in codes of ethics on privacy and autonomy and an over-cautious approach by regulatory bodies when giving guidance.
- The complexities of the law.
- Confusion about the concept of consent in the light of the developing common law and new statutory provisions in the Human Tissue Act and the Metal Capacity Act.
- Fear of litigation and adverse publicity.

Confidentiality and consent have a long-standing and important ethical basis. However, there is also moral worth in making data available, and this is where proportionality and justifiability are relevant. In the real world, privacy and confidentiality of medical information are imperfect, and neither can be treated as an absolute – one only has to think of the unavoidable limits on privacy in hospital wards.

The medical and social context around health care is changing, and our consumer society is leading to a growing "consent culture". Access to the internet has made personal information more accessible to more people, but at the same time there are widely held concerns over a "big brother" society. The cause of medical research is also not helped by medical scandals and perceptions of a climate for medical litigation. Furthermore, a growing culture of consent, linked to notions of privacy and autonomy, has been developed by the courts in the media context, such as the case of *Douglas v Hello!*. In the context of medical *treatment*, the courts are also developing the notion that patients must give informed consent and this is further reflected in recent legislation.

There are a number of situations in which patient privacy might give way to the public interest. In the case of large-scale public health initiatives, it is impractical to seek consent from individuals and in such cases individual privacy should yield to the public good, as long as the overall value of the research outweighs individual concerns. Although the perceived wisdom is that the public considers consent for, or anonymisation of, medical data to be essential, surveys show that the majority of people are actually less concerned than might be expected about the use of their medical

records. Patients are generally willing for information to be used for research, provided certain safeguards are met. Interestingly, there is a perception that electronic data are less secure than traditional paper-based records. Demonstrating high standards of data security will therefore be important for public support of the new NHS IT system, including its use for large-scale secondary data research. Since there is evidence that the public is more supportive of the research enterprise than regulatory bodies seem to believe, an approach in the healthcare sector that puts greater emphasis on security mechanisms and the public interest is likely to be broadly acceptable. There is a pressing need for national, coordinated and standardised guidance on this issue.

Session 3: The principle of proportionality

Professor David Feldman FBA (University of Cambridge) argued that there is a tension between confidentiality and the public interest, and that "proportionality" is the line drawn between the two. Focussing on the issue of proportionality, he disagreed with some of the statements in the Executive Summary of the Academy's Report, arguing that the subtleties warrant close examination. First, literary shorthand that could be read to suggest that all kinds of research are the same and of similar value should be avoided. It is also important to distinguish between different kinds of personal health data. It is disingenuous to state summarily that there has been an "undue emphasis on privacy and autonomy", given that the dignity and privacy of the individual are fundamentally important human rights; such a statement requires more detailed explanation. Finally, the question should not be whether there are disproportionate interferences with the capacity to conduct research, but whether research disproportionately interferes with the right to private life.

The legal test of proportionality becomes relevant, in the context of Article 8, when there is an act, or the threat of an act, which would interfere with the respect for family or private life, which is at least potentially made lawful by a legal rule which covers the case and which can be shown to further a legitimate aim. In Article 8, paragraph 2, the relevant legitimate aim would be "the protection of health". However, this could cover a broad spectrum of activities. It will not, therefore, be enough for researchers to state merely that research is good and often produces benefits. The proportionality assessment will require the researcher to demonstrate that the research in question fulfils a pressing social need and interferes with rights no more than is necessary to achieve this goal. The inquiry must be specific as to the benefit likely to be produced by the research in question: What will it be? How many people will be helped? How much will they be helped? Researchers should have good answers to these questions before arguing that any unauthorised use of patient data is a proportionate interference for the protection of health.

There are several implications of asserting that medical information can be made available if there is a sufficient public benefit with as minimal an interference with rights as is possible. First, the rule should be put in place on the basis of case-by case-analysis if one is serious about protecting the rights of individuals. This will not lead to less regulation but, on the contrary, to *more* regulation. Second, it is clear from Strasbourg jurisprudence that the requirements of Article 8 are not limited to the stage of deciding whether the information will be made available, but also to the storage, processing, use and publication of data. Very tight controls will be required, backed up with severe criminal and civil penalties. In this way, the loss of protection offered by consent and anonymisation may be offset, so as to create a system for using data that *could* be proportionate to the need for respect of the family and private life. Notably, the word 'could' is used in place of the word 'would', to emphasise that there is no bright line for the application of proportionality, which

ought to be assessed on a case-by-case basis. Third, with regard to public attitudes, in many ways it is irrelevant whether or not there is public support for research. The question of whether the treatment of data meets the minimal requirements of the rights of privacy and dignity is an issue of human rights law and not a matter of public opinion.

Session 4: Panel discussion

Mr David Smith (Deputy Information Commissioner) addressed issues of consent in the Data Protection Act 1998, noting that the Act itself does not necessarily require consent for the use of health information in medical research. The key is to ensure that people know what is happening with their information. Reliance on consent is a problem because it can impose disproportionate obligations in some contexts and there are risks involved in getting it wrong. The Commission takes the same view as that expressed by Mr Havers – namely, that researchers could be bolder. The statute sets out broad principles for handling personal information. It is not about enforcing absolutes. Whatever interpretation is placed on the principles, they can be open to challenge. The holders of information can legitimately risk challenge so long as they can defend their position. However, there is a need for the development of codes of practice, which would assist researchers and the holders of health records in staying within the law; the symposium delegates would do well to work together to develop such a code. Finally, there is a need for greater penalties, not for those who are well intentioned yet make errors, but for those who deliberately sell on information to insurers, private investigators and other bodies.

Dr Mark Walport FMedSci (Director of The Wellcome Trust) noted that, while privacy is important to each of us individually, society as a whole cannot function without involving people in activities which they may not support, for instance tax collection. Quite often this involves identifying people, or having the capacity to identify them where necessary. The irony for researchers is that the identity of individual data subjects does not really concern them; the power of secondary data research comes in aggregating large datasets to reveal characteristics on a group or population, rather than individual, level. Identity is used solely to ensure the veracity of the dataset, for example to avoid double counting or to update information about an individual's outcome etc. A great deal of personal health information is currently available for public purposes, such as disease surveillance and clinical audit, so why should research be treated differently? Another question is what should be done when some people wish their medical information to be available and others do not - whose interests should win out? We are in danger of moving towards a society where the interests of a sensitive minority trump those of the majority.

Mr Gavin Phillipson (King's College, London) noted that, on reading the Academy's Report, he was struck by the emphasis in contemporary regulation on privacy in the face of a strong countervailing public interest. The common law of confidentiality should easily encompass the issue of medical research, despite the lack of legal authority on the subject. Given that the public interest has prevailed in media cases, such as the publication of Naomi Campbell's drug addiction in *Campbell v MGN*, it would be inconsistent if the more pressing purpose of medical research were not treated in the same way. The public interest in medical research can only be seen as more weighty than the media's right to publish information about celebrities, as it has the laudable goal of alleviating human suffering. It is also possible that medical researchers may be able to take advantage of their own countervailing human right to freedom of expression. This approach would require the two rights – privacy and free expression - to be balanced and would mean that researchers would not solely be seen as potential infringers of rights, but as rights-holders themselves.

Mr Andrew Caldecott QC (One Brick Court) noted that the decision of *Campbell v MGN* heralded a re-drawing in the taxonomy of law. Where we once used to start by focussing on the doctor's equitable duty of care to his patient, we now start from the patient's point of view. Does the patient have a reasonable expectation of privacy? It is arguable, albeit rarely discussed, that secondary research in the public interest would not get past this question, i.e. secondary data research should not be limited because Article 8 might not even be engaged. But supposing it is, the focus is then on the issue of proportionality. While researchers would like certain specific rules to follow, the proportionality exercise requires intense scrutiny of the facts. One way to establish more leeway for secondary research is for researchers to rely on Article 10 (the right to free expression) to make out their side of the argument. There is a case for a very high level of freedom of expression for the limited disclosure of medical data, which would counterbalance the strong Article 8 right to privacy.

General discussion returned to point that researchers need to show good evidence of the benefits of secondary research (to establish proportionality). While researchers often do not know what answers they will get to their research, they should consider gathering information about its *potential* benefits. A further question is how a patient can consent to the use of data if the researcher, at the time of seeking consent, does not know all the future issues that might be investigated. The proposal that an independent regulatory authority should specifically examine the proportionality of interference for secondary research on a case-by-case basis was challenged, on the grounds that such a system would quickly collapse under its own weight. The arbitrariness of imposing this approach on secondary research (but not on clinical auditors, medical educators, tax collectors or media organisations etc) was reiterated, as was the need for codes of practice at national and international levels.

Session 5: Section 60 of the Health and Social Care Act 2001

Dr Gill Thomas (Mills & Reeve) examined the background to section 60 of the Health and Social Care Act 2001, noting that it was introduced in the wake of the Human Rights Act 2000, the Data Protection Act 1998 and recent confidential information cases. In particular, it was a response to the General Medical Council's 2000 guidelines, which jeopardised the reporting of cancer incidence to cancer registries. It was also prompted by the government's concern at losing the *Ex p Source Informatics* case in the Court of Appeal. Section 60 allows the Secretary of State to make regulations that would allow the use of patient information without consent. Section 61 of the same Act set up the Patient Information Advisory Group (PIAG) to advise the Secretary of State on section 60 applications.

In 2002, the Health Service (Control of Patient Information) Regulations were introduced to provide relief from the duty of confidentiality when processing patient information for certain purposes, including medical research (Regulation 5). However, this regulation contains certain parameters, including the removal of personal identifiers where they are not required, restrictions on who can process the information, a requirement for technical and organisational measures to prevent unauthorised processing and an annual review of the on-going need to process. In addition, information can only be processed for the enumerated purposes in the Regulations, including to anonymise records, to process information with reference to geographic locations, to seek consent for medical research, to validate or link information, to conduct medical research and to audit or monitor health services. Processing must be approved by the Secretary of State, who is required to have regard to the recommendations of PIAG.

Sections 60 and 61 were introduced into a confusing legal and regulatory situation

and the complex jigsaw of law in this area persists. In this environment, it is perhaps unsurprising that PIAG has been criticised by both sides of the debate. Groups seeking to strengthen privacy protection argue that its very existence delays the move to a more rigorous culture of consent. On the other hand, groups representing medical research interests have argued that it is overly cautious in its approval of research projects. Sections 60 and 61 were never intended to establish a separate framework for the use of patient records for medical research, so the mechanism should be treated as a last resort. Despite being introduced as a transitional measure, five years on there have been no proposals for replacement of section 60 and more rigorous public debate is needed on this issue.

Professor John Bell (University of Cambridge) did not disagree with Dr Thomas' perspective on section 60. The Academy's Report presents section 60 as a wide-ranging measure, but the government had no lofty ideals when passing the legislation. Its main concern was to reverse the effects of the High Court decision in *Source Informatics* and to control patient information. The current remit of PIAG is quite different to that envisaged by Parliament. It was introduced late in the passage of the Bill (the third reading stage), and was not intended to be a body giving case-by-case approval to applications.

In relation to principles of statutory interpretation, if the common law sets out a broad principle, and legislation is passed to deal with a particular point within that principle, the rest of the law not relating to that principle will remain untouched, unless the legislation introduces a new scheme of regulation. Clearly, section 60 was intended to address only a narrow point of law, and not to set up a legislative scheme. Therefore, it cannot deliver to researchers their desired goal of avoiding the need for patient consent, as this was never its intent. Nor was it intended that PIAG would approve every piece of research individually as it has incrementally come to do.

Session 6: Principle of fair processing in the Data Protection Act 1998

Ms Rosemary Jay (Pinsent Masons) looked at the concept of "fairness" in the Data Protection Act 1998, in particular the obligations it sets out and the derogations allowed to researchers. Data protection has a longer history than many people think and, to some extent, the difficulties experienced by researchers are a consequence of health services failing to implement the regulation in a timely way. Data protection dates back to the OECD Guidelines of 1980 (Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data) which set out that the collection of personal data should be carried out by "lawful and fair means" and that the consent of the data subject is *usually* required for disclosure. Derogation was allowed in the public interest, and for uses which were so minimal that they presented no threat to the privacy of the individual. Another early instrument, the Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Treaty 108), to which the UK has long been a signatory, also required that personal data be obtained and processed "fairly and lawfully" and introduced a special category of "sensitive personal data", including medical data, that requires a higher level of protection.

Although the law has moved on, Treaty 108 remains relevant as an international treaty adopted by the UK. It is important to remember its existence, since it puts constraints on the legislative changes that signatory countries can introduce. Under the Treaty, exemptions for medical research are permitted only to obligations of transparency, and the rights of access by data subjects. There is no scope for exemptions when storing and collecting data for medical research. The UK first ratified Treaty 108 via the Data Protection Act 1984. The research exemption mirrored that set out in Treaty 108.

Subsequently, the EC Data Protection Directive of 1995 was passed to harmonise the very different levels of protection applied to personal data throughout EU member states. The UK implemented the Directive through the Data Protection Act 1998. The Directive and the 1998 Act permit wider derogations, relating not just to subject access but also to disclosure and the requirement to give data subjects notice of processing, for instance where giving notice would require disproportionate effort.

In 1983 the Council of Europe gave guidance on the operation of Treaty 108, recommending that the use of personal data for research be based on the principle of "functional separation". This requires that derogations from the privacy standards are acceptable as long as the data are not used to make decisions, or to take actions, that may affect the individual. This concept made its way into the Directive and the Data Protection Act 1998.

Researchers are given some leeway in the Data Protection Act 1998 to process data without consent when doing so for 'medical purposes', which include medical research. This was fortuitous for researchers, but differs from Treaty 108 and the 1995 Directive, which treat research as a separate purpose. It should be noted that, even if there is an exemption from the consent requirement, there is still a requirement to inform the data subject that their data are being used, and section 10 of the Act gives them the right to object to processing.

With regard to the principle of fair processing contained in Data Protection Principle 1 of the Data Protection Act 1998, the legislation does not define the concepts of "fairness" and "lawfulness". Fairness is always a nuanced question and a recurring thread is transparency. The core requirements for processing to be fair are that the person must be informed as to:

- The identity of data controller;
- The purpose of the processing; and
- Any further information that is necessary in the circumstances.

This poses several hurdles for research. First is the common situation where the research is being conducted by someone other than the person who originally obtained the data. Individuals need to be made aware that information will be disclosed to a third party where that party is a different legal entity with a different data controller. A second issue arises when the use to which the information is put (e.g. research) is different to the use for which the information was disclosed by the individual (e.g. medical treatment).

To address these issues, the Act qualifies the requirement to give fair processing information when it would involve disproportionate steps. The most difficult questions for researchers are to determine what information is needed to ensure that the processing is fair, and what constitutes proportionate and disproportionate steps. Researchers should remember that, when the statute says that the information must be given to the person to ensure that the processing is fair, it means fair with respect to that *particular* person. Individuals should not be presumed to have the same concerns; some types of research may be unacceptable to certain people but not others. It can be argued that Section 33 does not relieve researchers from the requirement to give notice any more than the exemption that applies when data subjects cannot be contacted without "disproportionate effort". The question of what constitutes "disproportionate effort" is unclear, but must be determined on a case-by-case basis, and by reference to the key concept of "fairness" to the subject. Thus it will need to take into account such factors as the purposes of the research, whether it is historical or statistical, and the circumstances in which the data has been gathered.

Obtaining consent from data subjects need not be as onerous as researchers sometimes claim. In order to obtain treatment it is necessary to be interviewed by a health professional, who could be more involved in both giving notice to patients that their medical data will

be used for research, and in obtaining their consent. If medical research is as important as the Academy's Report argues, clinical health services should work harder to inform patients about the uses and benefits of research using personal information and to ask patients for their consent to use their data for such purposes.

Session 7: Requirements for valid consent to use patient information

Mr Justice Tugendhat (Royal Courts of Justice) prefaced his comments with a reminder that, in addition to medical research, personal autonomy and trust in the medical system are also "public goods". When these are difficult to reconcile, the starting point, as Baroness Hale pointed out in the *Campbell* decision, should be the protection of the confidentiality of medical information, not just to protect individual autonomy, but also to retain confidence in the healthcare system. Medical data incorporate information that can cost a person their job, their mortgage or their marriage. Two questions then emerge: What sort of consent is valid to permit the use of medical data? Under what circumstances does an activity constitute a public interest that outweighs the importance of confidentiality?

While the law should uphold strict standards for valid consent, this can make it very difficult to obtain consent in the context of secondary research. His Honour proceeded to explain in more detail the sorts of strict standards that govern the legal concept of consent, and why consent should not be seen as the primary regulatory concept in secondary data research.

Lawyers are familiar with the concept of consent as a defence to an act that would otherwise be an interference with another person's rights. Valid consent will more readily be found to exist by a court in circumstances where there is a benefit conferred on the person alleged to have consented. Where the benefit is less apparent, the courts will infer consent less readily. Secondary medical research falls under the second category since it primarily benefits the population, rather than the individual.

Another critical aspect of the legal concept of consent is that it may be withdrawn at any time. Irrevocable consent is rare, and must be contained in a formal document, such as a deed or a written contract. Thus, a researcher who needs to know with certainty that an act of data processing is lawful may face problems, because she will have no way of knowing whether the consent previously provided by the data subject is still valid or has been revoked.

Another important factor to be considered is that certain people, such as children and the mentally ill, are not considered to have the capacity to consent to research. When an individual's level of capacity changes or fluctuates, it is difficult for medical researchers working with tissue or health records to know when or who they should re-consult, because they generally do not keep in regular contact with the research subjects. In addition, it is an unavoidable fact that, in secondary research, consent is only very rarely sought by the researcher. In most cases, this duty falls on the doctor or other health care professional providing treatment, which raises complex questions about their appropriateness to seek consent for research as well. The treating doctor's main concern should be the interests of the patient. Courts could be sceptical of the validity of consent to research where it is obtained by the treating doctor, since their special relationship with patients could give rise to undue influence or misapprehension by the patient that they will benefit directly from the research. For these reasons, consent should be viewed as a non-starter for medical researchers as it is too hedged with uncertainties and legal pitfalls.

Mr Michael Harrison (Human Genetics Commission and 2 Temple Gardens) agreed with Mr Justice Tugendhat's points. He emphasised that consent is not simply a

signature on a piece of paper, but a process of agreement between the giver and receiver of the consent. At most, a signature on a piece of paper can be evidence of consent, but it cannot be consent itself or absolute proof of consent.

Three different ways in which consent could operate are described in the Academy's Report: implied consent; opt-out consent; and broad consent. The problem with implied consent is that it is not really consent at all. If it is necessary to imply consent, then it is unlikely that there has been voluntary positive assent by the data subject. Hence Kennedy and Grubb drew a distinction between inferred and imputed consent in their well-known textbook, stating that the latter is a false concept of consent. Inferred consent has not even been upheld in certain banking contexts, on the grounds that the customer had no notion that his information was being shared. A related problem with implied consent is the question of whether it covers the ability to withdraw consent, which is another key element of valid consent. While statistics may show that the public supports the use of medical data for research, it is also necessary to remember that different people have different sensibilities, and that what they consent to at one time, in certain circumstances, might not be what they would consent to at a different time, in different circumstances.

Opt-out consent is problematic because it is merely an extension of inferred consent, i.e. consent is inferred by those who have not actively opted out. The practical advantage of opt-out consent for research is that fewer people will take the active steps required to opt out, leaving researchers with bigger data sets. However, opt-out consent runs counter to the current flow of legislative initiatives, which increasingly require explicit consent, and subjects the interests of the individual to those of science and society in general.

Seeking broad consent might therefore be the best approach for researchers. Data could be given as an absolute gift to researchers, perhaps subject to the condition that the research is examined and approved by an ethics committee. Once the patient donates the data, she has no further interest that could be protected by consent. This might work in the context of prospective collection of data, although it would not be practical for historical collections. There are still problems, however, as it is questionable whether it is possible to consent effectively without detailed information as to what will be done with the data. Moreover, if the researcher never intends to go back to the subject, it may be difficult for them to withdraw their consent. Thus, broad consent is probably not consent *per se*, but is something more akin to a waiver of any future rights in that data. Based on the well-known case of *R v Brown*, the courts might not recognise such a waiver. It is also worth noting that tissue samples might give rise to valuable commercial rights, as in the recent dispute at the University of California regarding research on a cell line derived from an individual's spleen.

However, it should be emphasised that researchers would in many situations be able to justify their research on public interest grounds, rather than consent. A code of practice to assist researchers in knowing what steps to follow would be highly desirable in this respect. The public has sympathy with the aims of medical researchers, who should indeed "be bold".

Session 8: Panel discussion

Professor Lionel Bently (University of Cambridge) drew out the similarities between the discussions on the use of personal information in secondary data research and the general law of intellectual property, suggesting that some of the solutions proposed in the context of intellectual property might prove useful in furthering the debate. Intellectual property law is familiar with the problems that stem from the proliferation of people having rights to, or interests in, the thing under

question (in this case data; in other cases a piece of music). Another complex issue is the mechanism of exceptions introduced in an attempt to avoid the problems surrounding consent. Exemptions in copyright and patent law in favour of research, private study, criticism and review are also based around concepts of "fairness", which makes them unpredictable for those who seek to rely on them. Some of the solutions proposed, which can also be seen in intellectual property, are:

- try it and keep your fingers crossed;
- develop a code (e.g. in the context of copyright and libraries);
- develop legislation which gives a broad exemption, expressed in reasonably certain terms;
- establish a body that can provide consent in the absence of locating those people whose consent is required (e.g. the Copyright Tribunal);
- buttress risk-taking with litigation insurance;
- establish a tribunal or equivalent which can tell you *ex ante* whether you will be infringing the law by acting in the way proposed.

Intellectual property law is also familiar with the difficulty of finding solutions compatible with European law and the other international regimes to which the United Kingdom is committed.

The second main problem that arises both in the context of medical research and intellectual property is the proliferation of regimes. In medical research this includes the Data Protection Act 1998, the Health and Social Care Act 2001, the European Convention on Human Rights and the common law of confidentiality and privacy. The complexity and differences between the regimes makes it very difficult for users. Two solutions have been implicitly proposed. First is to interpret the regimes so that they are consistent. This has been discussed with reference to the definition of "necessary" in the Data Protection Act 1998 and the Human Rights Act 1998. Second, where there is a *sui generis* regime that is inconsistent with the common law, the position could be simplified by legislation that sets out the relationship between the regimes more clearly.

Finally, it may be worth considering a solution that is currently fashionable in intellectual property law, although some speakers have suggested that it might be problematic. This is the notion of the "creative commons", whereby creators can place works in the public domain for certain purposes. Although there are real concerns about people giving up their fundamental rights of autonomy and dignity, it is arguable that they should have the right to say that they would like all their medical data to be available for medical researchers if they wish to do so.

Professor Robert Souhami FMedSci (University College, London), who chaired the Academy's Report, noted that the points that were made over the course of the day were similar to the points that had preoccupied the working group during the Report's preparation. It is reassuring that the same issues surfaced amongst the leading legal minds in the field. However, there does seem to be some confusion about the type of research in question. The kind of research addressed in the Report involves huge databases of information that have *already* been collected from hundreds of thousands of subjects, and involves no human contact between the data subjects and the researchers. The question is whether researchers are encountering real legal difficulties relating to the use of such information in medical research and the consultation that formed part of the Report confirmed this to be the case. These are not trivial issues, because this research cannot proceed with small numbers of individuals and is highly significant for good quality medial care.

The Report supported the existence of PIAG, because it provides some sort of statutory authority for medical researchers. However, it is impractical for every research project that encounters difficulties with fully informed

consent or absolute anonymisation to be considered by a single body.

Introducing a system of obtaining patients' implied and generic consent for secondary data research in hospitals and other health care settings should be considered in the same way that teaching hospitals obtain consent from patients for medical students to be involved in their treatment. A climate where consent to research is discussed in primary health care settings would be a significant advance on the current situation. Surveys with more rigorous methodologies (e.g. those that ask specific and targeted questions) would be of assistance both to legislators and other policy-makers, and work by Cancer Research UK, the Medical Research Council and Wellcome Trust is extremely welcome. Likewise, good standards in this field call for the development of practical guidance on consent, anonymisation and security of data. The public, researchers, regulators and lawyers all have a role to play in this process.

The **floor discussion** that followed was wide-ranging but addressed in particular the issue of consent. It was noted that there is a difference between obtaining consent for future research and consent in the context of existing databases. The notion of hospitals becoming more closely involved in obtaining general consents was welcomed, but it was noted that even when they do, the regulatory regime is so complex and consent such an uncertain notion that data subjects who are happy to participate are compelled to sign a frustrating number of consent forms pertaining to the same piece of research. Attention was drawn to the difficulties faced by patients who wish to provide data for research, but who are not given the option; this relates to the question of who trumps who, i.e. do the interests of a sensitive minority trump those of a willing majority? It was noted that PIAG might not mirror the body envisaged by Parliament but it has tried to follow the remit described to it by government departments and is trying to find a balance between the protection of privacy and the facilitation of research.

Consent is a notoriously difficult issue, and it was reiterated that it should not be pursued as the fundamental regulatory solution. While it is important to develop a culture of consent in the healthcare system, a strong line of argument lies in the notion that secondary research is an activity, similar to the collection of tax, which is justified on public interest grounds. Some thought that the tensions between the public interest and private rights might need to be solved by legislation, rather than waiting for questions to be settled by the common law. Most supported the recommendation of further work on a code of practice for the use of personal data in secondary research.

Part 2 Summary of issues raised

Areas covered in this summary include:

1. Terminology
2. The public interest defence in the common law of confidentiality
3. Public attitudes to the use of personal data by medical researchers
4. PIAG and the Health and Social Care Act 2001
5. The distinction between medical research and clinical audit
6. Data Protection Act 1998
7. Legally valid consent

1.Terminology

It is important to be clear about the type of medical research under discussion. The Academy's report was primarily concerned with secondary data research, which involves large repositories of existing information and no contact between the data subjects and the researchers. At times, speakers and delegates referred to other types of research, for example clinical trials, information-based research where the researcher has easy contact with the research subjects, or pre-implantation embryo screening. Although analogous in some ways, secondary data research involves less serious implications for physical and informational privacy.

Confusion also arises if researchers speak generally of 'the need to recognise a public interest defence for medical research' since it sounds as if they are seeking an outright defence covering all 'medical research' or all 'secondary data research'. A blanket rule of this kind would over-generalise the benefits of research, and would be struck down by Strasbourg courts. Medical research is not all of the same quality and some projects affect privacy more than others. To avoid confusion, statements should make clear that the research community is arguing that: the public interest defence covers situations where seeking individual consent or full anonymisation would render secondary data research highly impracticable, *and* the benefits of research are such that the putative privacy interference is proportionate to the protection of health. In these cases, it should be lawful to proceed provided the interference is no more than necessary and strict data security standards are observed. The conditions and qualifications that apply to this position mean that only some research would be covered. In future, where succinct statements are required, it might be better to speak of 'the need to recognise a public interest defence for *eligible* medical research'.

2. The public interest defence in the common law of confidentiality

There is a tension between confidentiality of medical information and the public interest in research. In general, data controllers respond very cautiously to requests for data and are increasingly insistent on evidence that individuals have given, and have not revoked, informed consent. This is not a strange aberration, but rather a positive development stretching back some 50-60 years, reflecting the fact that confidentiality of data protects individual autonomy and helps retain confidence in the healthcare system. However, it is perhaps less widely appreciated that secondary medical research using personal health data can identify unsafe medical treatments and is often the basis for medical progress. This can lead to difficulties, since confidentiality protects individuals' personal preferences about how their data are used, whereas medical research (like taxation) cannot function unless individuals participate in certain ways, sometimes against their personal preferences. This is not an irreconcilable tension and 'proportionality' is the line drawn between the two.

Rightly or wrongly, the law considers privacy to be the fundamental human right, and activities to protect human health are considered less

important. Stronger or weaker degrees of privacy are recognised, but the protection of health is the responding variable, rather than the other way round. If privacy is under serious threat, the protection of health must give way. Thus one speaker emphasised that, as a matter of law, the question is not whether regulation poses a disproportionate interference with the capacity to conduct research, but whether research disproportionately interferes with the right to privacy. There was general but not complete unanimity on this point. Some speakers argued that the right to 'investigate' (i.e. conduct research) also formed part of the framework of protected rights. Researchers acting in the public interest, they said, have a fundamental, albeit qualified, human right to receive and impart information. This is protected by the right to free expression in Article 10 of the Human Rights Act 1998. If correct, the work of researchers is protected in the same way as the work of investigative journalists.[2] If this is the case, laws restricting investigative research (e.g. privacy laws) should also be limited, and it would be legally accurate to query whether rules about consent and anonymisation are a disproportionate interference with the liberty to conduct medical research.

The assessment of proportionality is crucial. Most speakers agreed with the Academy's primary argument that researchers and health services could be bolder in their use of personal data for medical research. They argued that, despite the lack of authority, the English and European courts are likely to be highly receptive to the use of personal data for secondary medical research, provided the research has the potential to significantly benefit the public and reasonably practical efforts had been made to anonymise the data (or to ensure a minimum interference with privacy). Speakers cited *Campbell v MGN* [2004] 2 All ER 995*, Z v Finland (1998) 25 E.H.R.R.371* and a case concerning the medical records of the French President, Francois Mitterand.[3] They also noted the Court of Appeal's general acceptance of the Medical Research Council's argument in *ex p Source Informatics*, asserting that such use of information would not be considered 'misuse of private information' (a phrase used by Lord Nicholls in the *Campbell* case).

Some speakers argued that medical researchers have a particularly strong case, given that tabloid newspapers have mounted successful defences when publishing health information and subjects' identities to the entire world. The public interest in the use of data for better medical care is substantially stronger than the public interest in the disclosure of celebrities' weaknesses and indiscretions. Moreover, researchers also ensure that patients' identities are protected, not only for the purposes of publication, but also during the research. Identity is used solely to ensure the veracity of the dataset, for example to avoid double counting or to update information about an individual's outcome etc.

There was wide agreement, however, that researchers should compile cogent and compelling evidence of the need to process personal health data without consent or anonymisation. Such evidence should be as concrete and specific as possible and compiled on a project-by-project (i.e. case-by-case) basis. Researchers should also note that the right to privacy is a right owed to *individuals*; while most people might be sanguine about researchers using their health information, some might not. The implications of this point split the speakers. Some averred that researchers should be permitted to proceed, even if the attitude of some individuals is unknown, provided they (or their employer) accept legal liability if an individual subsequently alleges an interference with their right to privacy and the researcher is unable to prove that the interference was necessary and proportionate. This avoids what might be

2 In this case, it would be legally correct to query whether rules about consent and anonymisation are a disproportionate interference with the liberty to conduct medical research.

3 Dr Claude Grubler, who was President Mitterand's doctor, was sentenced to four months (suspended) imprisonment for breach of professional secrecy. Dr Gubler was the author of 'Le Grand Secret', a book recounting the late president's fight against metastatic cancer of the prostate. See News Article (1996) 'Mitterand book provokes storm in France'. BMJ 1996;312:201 (27 January) and News Headlines (1996) BMJ 1996;313:70 (13 July).

called 'tyranny of the minority'. Other speakers thought that a more rigorous system of review should be established, whereby researchers apply to a court or statutory authority before proceeding.

Legal decisions interpreting the word 'necessary' (see Article 8(2), European Convention on Human Rights and the Human Rights Act 1998) have sometimes stipulated that there must be a 'pressing social need' before an interference in privacy can be said to be justified. Given that the very purpose of research is to find answers to the unknown, this translates into a requirement that researchers should prove that a research question is sufficiently important. Some speakers observed that this threshold had been interpreted in a relatively non-demanding way; courts appear to be more concerned with the test of proportionality. For example, the House of Lords in *Campbell v MGN* did not question whether the public had a *pressing social need* to know that Naomi Campbell was a drug user (contrary to prior denials) and receiving treatment. It was more concerned with the question of whether the disclosure of this information was a proportionate action for the protection of free speech, given the implications for her privacy. The majority concluded that publication of photographs and some treatment information *did* constitute a disproportionate interference in this case.

3. Public attitudes to the use of personal data by medical researchers

While the received wisdom is that either consent or anonymisation of data is essential for fair use of health information, some speakers pointed to surveys demonstrating that most people support the use of their health data for research, provided that high security levels are observed. Indeed, many are surprised that data are not used routinely for research. Speakers observed that survey design is important. Less well-designed surveys can ask leading questions such as *"should people be asked for their consent or data anonymised as a condition for secondary research?"* For a more balanced picture, follow-up questions should be asked about what the respondent means by consent or anonymisation (it appears that few have the legal definition in mind), what they think secondary research achieves, and what policy should apply if researchers cannot meet these standards. Without this sort of specific and targeted research, there is a danger of creating a society where the interests of a sensitive minority trump those of a compassionate majority.

One speaker demurred on the above point, arguing that surveys of public attitudes are beside the point. Our society, at the European and national level, has enacted a legal framework to protect individuals' rights against the 'tyranny of the majority'. The correct interpretation (including the concept of proportionate interference) is a matter of law and not one of public opinion. Others doubted whether improved surveys would in fact show that the public supports the use of health information for medical research. There may be less trust of medical researchers and health services than researchers realise, and more scepticism about the translation of medical research into clinical benefits.

One speaker noted the diversity of attitudes on this issue across European Member States. For instance, the history of abusive medical experimentation and euthanasia in Germany, in which the medical profession was complicit, has left a lasting distrust. This will be a particularly significant factor when research extends across nation-state borders.

Another speaker pointed out that it should not be assumed that patients are naive 'know-nothings'. Many patients have an extensive knowledge of their health condition because it is a long-term illness or a condition that

has affected other members of their family. They do not approach the research encounter fearfully or ignorantly, but rather in a partnership with the researcher, hoping that improved treatments will become available. Regulators should not assume that all patients share the view that strict privacy is of greater fundamental importance than improved health.

4. PIAG and the Health and Social Care Act 2001

New powers for the Secretary of State for Health and the Patient Intformation Advisory Group (PIAG) were intended to provide a framework for greater certainty on the question of whether processing of confidential health information for research- and audit-related purposes is reasonable and proportionate. However, the relevant legal instruments use imprecise terms and have a complex relationship with obligations of confidentiality at common law and the Data Protection Act 1998. There is nevertheless a need to see if the system can be improved. PIAG was proposed by Parliament in the third reading of the Health and Social Care Bill as a body to give *general* guidance. Speakers observed that PIAG works in this way in relation to the use of data for clinical audit, but where medical research is concerned, it is set up as a body that examines applications on a case-by-case basis. This adds a layer of bureaucracy to the research process that some speakers argued was unintended by Parliament. It was also observed that the legislative history supports the idea that researchers are not legally obliged to obtain PIAG approval before proceeding with research, if they believe the research is covered by the common law public interest defence. However, in practice researchers will need the cooperation of health services in possession of the relevant data. They may find that health services insist on approval from PIAG if they perceive it to reduce legal risk.

5. The distinction between medical research and clinical audit

A number of speakers challenged the distinction drawn by regulators and others, either wittingly or unwittingly, between research and clinical audit. The regulatory framework takes a less heavy-handed approach to the use of personal data for clinical audit than it does for research. Yet both involve the same sort of interference in privacy, and both aim to benefit health service users in general (rather than a particular individual patient). The speakers suggested that the current distinction is the result of regulatory convention rather than legal requirement, and that research should not be presented as any more invasive or risky than clinical audit.

6. Data Protection Act 1998

Several important points were made in relation to the Data Protection Act 1998. For instance, data protection has a longer history than is generally assumed and, to some extent, the difficulties experienced by researchers are a consequence of health services failing to implement the regulation in a timely way. The European Data Protection Directive and the Data Protection Act 1998 are now the more obvious and direct sources of law in England, but some earlier instruments (e.g. OECD Guidelines of 1980 and Treaty 108) remain relevant as international legal standards binding on signatory countries.

Treaty 108 and the 1995 Directive refer to research and medical purposes as separate activities. This arguably has implications for notifying individuals of how their data might be processed (e.g. the processor should specify medical purposes and research, if both were intended). The 1998 Act does not observe the same distinction. It permits processing of sensitive personal data without consent where necessary for medical purposes, and

defines medical research as a type of medical purpose (Condition 8 of Schedule 3). One speaker argued that the UK thus falls short of European standards. In response it was argued that the recitals of the Directive state that Member States may allow the processing of personal data for scientific research, provided specific and suitable safeguards are imposed. Condition 8 of Schedule 3 coupled with section 10 appears suitable.

In accordance with the statutory duty to process data fairly, researchers should generally provide information about the identity of the data controller, the purpose of the processing and any further information necessary in the circumstances ('fair processing information'). When assessing what is 'fair', it is good practice to consider the situation from the perspective of an individual patient, rather than a hypothetical perspective. The researcher's perspective is not determinative. Researchers should bear in mind that the proposed processing for research may not be contentious to the majority, but may be unacceptable to certain individuals.

Researchers are not required to provide 'fair processing information' if they obtain the data from another legal entity (governed by a different data controller) and the individual cannot be contacted without 'disproportionate effort'. The question of what constitutes 'disproportionate effort' is unclear, but must be determined on a case-by-case basis, and with reference to what would be fair to a particular subject. An assessment of fairness should thus consider the purposes of the research, the sensitivity of the data, whether the research is historical or statistical, and the circumstances in which the data have been gathered.

One speaker asserted that section 33(2) permits no exception from the requirement to notify individuals that data are to be used for the purposes of research. This contrasts with the interpretation put forward by the Academy of Medical Sciences. Further research might resolve the doubt.

The Data Protection Act 1998 is not about enforcing absolutes. It recognizes that there are occasions when it is acceptable to use data about other people without their knowledge or consent. This is inevitable in modern society, and ethically responsible. The Office of the Information Commissioner will permit a robust, though not reckless approach, to the use of medical data by researchers. Researchers will be expected to institute arrangements to prevent onward disclosures and to stop processing the data if it is causing harm or distress.

7. Legally valid consent

In the legal system, consent is typically regarded as a defence to an act that would otherwise be an interference with another person's rights. It is regarded as a mark of the 'consent–giver' having reached agreement with a proposed course of action by the 'consent–receiver'. The standards that govern the validity of consent are strict to ensure that individuals are not held to have agreed when they have not. These standards can be difficult to observe in the context of secondary data research, which involves data from large numbers of individuals (most of whom have no contact with the researcher). A number of speakers thus took the view that consent should not be seen as the primary regulatory concept in secondary data research.

Speakers and delegates raised several points:

- Since people have different sensibilities, the law requires the terms of agreement to be determined subjectively for each individual. This is highly resource intensive where research involves hundreds or thousands of individuals.
- Inferred consent, also known as implied or imputed consent, is rarely, if ever, valid consent. Opt-out consent also has doubtful legal credentials. Both lack a process of subjective agreement formation, which is the essence of 'consent', and it is difficult to

see how consent can be withdrawn if it has simply been presumed.

- So-called 'blanket consent' might be valid if it were understood not as consent *per se*, but as the giving of a legal 'gift' or waiver to any future rights over the data. Whether the courts would recognise such a waiver as valid may depend on whether there are good reasons for the research (see R v Brown [1994] 1 A C 212).
- In the event of ambiguous evidence, courts will hesitate to conclude that the individual consented to secondary research because research (unlike treatment) does not confer a direct benefit on the person alleged to have consented.
- Ordinarily, consent may be withdrawn at any time. An argument based on estoppel, if it exists in this context, is limited. Irrevocable consent is rare, and must be contained in a formal document, such as a deed or a written contract. Thus, a researcher who needs to know with certainty that an act of data processing is lawful may face problems, because she will have no way of knowing whether the consent provided previously by the data subject is still valid or has been revoked.
- Certain people, such as children and the mentally ill, lack the capacity to consent to research. When an individual's level of capacity changes or fluctuates, it is difficult for medical researchers to know when (or who) they should consult to update their records, since they generally do not keep in regular contact with research subjects.
- In secondary data research, consent is rarely sought by the researcher. It is accordingly difficult for them to ascertain whether the individual was properly informed or had the capacity to consent.
- In most cases, the duty to seek informed consent falls on the doctor or other health care professional providing treatment. The patient usually expects the professional to provide advice to improve his health (rather than generalisable knowledge). They might be influenced by the doctor's position or mistakenly assume that the research would have some therapeutic benefit for them personally. Courts will therefore be sceptical about the genuineness of consent to research when obtained by someone other than the researcher. This makes it even more difficult for a researcher to obtain valid consent.

The speakers making these points emphasised that the conclusion to draw from their remarks was not that secondary data research should be considered wrong or illegal, but that consent should not be thought of as a strict principle for its regulation. It was asserted that such an approach is unworkable and one of two things will happen: secondary data researchers will be left in an untenable position or the requirements for valid consent will gradually relax. Neither outcome is recommended. The better approach is to be less rigid about the requirement for consent, and to improve the way that public interest considerations are assessed.

Part 3 Conclusions

The discussion at the symposium ranged broadly. It highlighted ways in which the Academy's report could have been clearer, raised new issues, and pointed to some conclusions and proposals for future work. Although differences of opinion were aired, the spirited debate helped to bridge the gaps and map more carefully the residual points of divergence.

Unanimous decision could not be reached on all the legal issues, although a number of points were generally agreed. One reason for the enduring disagreement was the absence of case authority. Another was the different ethical judgments underpinning the speakers' presentations. For instance, they weighed the evidence about the difficulties facing secondary research differently, they were not agreed on whether the importance of privacy should be ranked ahead of improvements in medical care (or on a par), they drew on different experiences of health, illness and health services, and they had different tolerance levels for bureaucratic process.

There was broad support for several proposals:

- There is a pressing need for national, coordinated and more standardised guidance on the use of personal data in medical research. One speaker remarked: *"If we wait for a court to pronounce, we'll all be dead"*. A single code of practice, covering consent, anonymisation and security, would be of considerable assistance researchers. Ultimately though, researchers, health service providers and regulators will have to accept that there is no 'bright line'. Evidence must be weighed and there will be uncertainties about potential benefits. Accordingly, the regulatory framework will always be open to a degree of reasonable disagreement and legal uncertainty. The goal should be to secure as much clarity and balance as possible. Procedures for data sharing that sensibly manage legal risk (rather than avoid it at all costs) should be implemented to support research.
- Stricter penalties should be implemented, not for bona fide researchers who make well-intentioned errors, but for those who deliberately make onward disclosures or worse, sell information to organisations such as insurers or private investigators. Other onward disclosures that might be subject to stricter penalties are those made without legal authority to organisations that plan to take action or to make decisions affecting the individual, for example schools, direct marketers, employers, welfare or tax departments, the police or legal representatives.
- A proposal to revisit the structure and powers of PIAG was raised. For example it might provide advice on general rules and principles (e.g. Bar Council), be set up as a body that can provide authorisation in the absence of being able to locate the people whose consent is required (e.g. the Copyright Tribunal) or alternatively operate as a tribunal that tells researchers *ex ante* whether they will be infringing the law by acting in the way proposed. It might record the basis of its reasoning in particular cases to build up a system of case precedent.
- Secondary research should be buttressed by insurance to ensure that participants are recompensed in the event of information being used and causing them physical, financial or emotional damage. This might help public sector health services move beyond their fear of legal uncertainty and adverse publicity. Privacy and confidentiality laws should be respected, but the lack of legal precedents should not lead to system-paralysis.
- The various laws could be codified to counteract the proliferation of legal instruments, or amended so that the manner in which they interact is clearer.

- Researchers should be bolder about relying upon the argument that some secondary research is justified on public interest grounds. English and European courts would support the use of personal data for secondary medical research if it has the potential to significantly benefit the public, and reasonably practical efforts had been made to anonymise the data or to act in accordance with the data subjects' wishes.
- Health services should be encouraged to put better systems in place to make patients aware that health services use data in research as well as teaching, clinical audit and service monitoring. For example, it could more routinely be explained on signs at health services and as information accompanying electronic health records.
- While it is important to develop a culture of consent in the healthcare system, it cannot be seen as the fundamental solution for secondary research activities.
- The framework surrounding electronic NHS health records IT programme should be reviewed to ensure it takes adequate account of the legal circumstances surrounding the use of health data in research.
- Further consideration could be given to the law on gifting health records to medical researchers and 'creative commons' reforms in intellectual property law, whereby creators can place works in the public domain for certain purposes.
- If the research community feels strongly about this issue, it should enter a dialogue with research ethics committees and health services. If the medical profession *in toto* argue that research is important, it will have a more persuasive impact on regulators than an argument made by researchers who, after all, have a clear vested interest.

Appendix I Symposium programme

Saturday 24 June 2006
Faculty of Law, University of Cambridge, 10 West Rd, Cambridge, CB3 9DZ

9:30	Registration & Coffee	
10:00	Welcome	Professor David Feldman, Faculty of Law Sir Keith Peters, Academy of Medical Sciences Dr Ron Zimmern, Public Health Genetics Unit
10:10	Chair's welcome	Mr Justice Munby, Royal Courts of Justice
10:15 10:45	The Strength and Limits of the Argument	Mr Philip Havers QC, 1 Crown Office Row Professor Vivienne Harpwood, University of Cardiff
11:15	The Principle of Proportionality	Professor David Feldman, University of Cambridge
11:45	Tea/ Coffee	
12:00	Panel Discussion	• Mr David Smith, Deputy Information Commissioner • Dr Mark Walport, Wellcome Trust • Mr Gavin Phillipson, King's College London • Mr Andrew Caldecott QC, One Brick Court
13:00	Lunch	
14:20	Section 60 of the Health and Social Care Act 2001	Dr Gill Thomas, Mills & Reeve Comment: Professor John Bell, University of Cambridge
14:50	Principle of Fair Processing in the Data Protection Act 1998	Ms Rosemary Jay, Pinsent Masons
15:20	Tea/ Coffee	
15:40	Requirements for Valid Consent to Use Patient Information	Mr Justice Tugendhat, Royal Courts of Justice Comment: Mr Michael Harrison, Human Genetics Commission and 2 Temple Gardens
16:30	Panel Discussion	Led by contributions from: • Professor Robert Souhami, University College London (replacing Professor John Harris, University of Manchester) • Professor Lionel Bently, University of Cambridge
17:30	Drinks reception	

The organisers are grateful to **Mills & Reeve** for their generous support of this event.

Appendix II Symposium delegates

Dr Isabella Alexander, Centre for Intellectual Property and Information Law, University of Cambridge
Professor John Bell, University of Cambridge
Professor Lionel Bently, Herchel Smith Professor of Intellectual Property Law, University of Cambridge
Dr Peter Brook, Secretary, Council for Science and Technology
Mr Nigel Brooksby, President, Association of British Pharmaceutical Industries
Mr Jason Brown, NHS Information Centre
Professor Wylie Burke, Department of Medical History and Ethics, University of Washington
Mr Andrew Caldecott QC, One Brick Court
Professor Mike Catchpole, Head of Information and Knowledge Management, Health Protection Agency
Dr Sandy Chalmers, Director, Data Privacy Policy, GlaxoSmith Kline
Dr Peter Dukes, Research Management Group, Medical Research Council
Professor Peter Elias, ESRC National Datasets Strategy Co-ordinator, University of Warwick
Dr Catherine Eliot, Clinical Ethics and Research Liaison Manager, Medical Research Council
Professor David Feldman FBA, Faculty of Law, University of Cambridge
Mr Jon Fistein, Connecting for Health
Dr Julian Flowers, Consultant in Public Health Medicine, Eastern Region Public Health Observatory
Dr Sue Gibbons, Researcher in Law, Oxford Genetics Knowledge Park
Mr Wally Gowing, Connecting for Health
Ms Alison Hall, Research Associate, Cambridge Genetics Knowledge Park
Ms Anureet Hara, Legal Department, Wellcome Trust
Professor Vivienne Harpwood, University of Cardiff
Dr Evan Harris MP
Ms Caroline Harrison, British Medical Association
Mr Michael Harrison, Human Genetics Commission and 2 Temple Gardens
Mr Philip Havers QC, 1 Crown Office Row
Dame Professor Joan Higgins, Chair, Patient Information Advisory Group
Ms Rosemary Jay, Pinsent Masons
Mr Alistair Kent, Director, Genetics Interest Group
Dr Kathy Liddell, Faculty of Law, University of Cambridge
Sir John Lilleyman, Director, National Patient Safety Agency
Dr William Lowrance, Consultant in Health Policy & Ethics, Geneva
Professor Robyn Martin, Research Professor in Public Health Law, Centre for Research in Primary and Community Care, University of Hertfordshire
Ms Ann McAllister, NHS Information Centre
Mr Charles Meyer, Oxford Intellectual Property Research Centre
Mr Justice Munby, Royal Courts of Justice
Dr Helen Munn, Policy Manager, Academy of Medical Sciences
Ms Hilary Newiss, Solicitor
Dr Jane O'Brien, Head of Standards and Ethics, General Medical Council
Ms Ngozi Okwundili-Ince, Programme Manager, UK Clinical Research Collaboration
Professor Rosemary Pattenden, Professor of Law, University of East Anglia
Sir Keith Peters FRS FMedSci, President, Academy of Medical Sciences (until November 2006)
Mr Gavin Phillipson, King's College London
Mr Timothy Pitt-Payne, 11 King's Bench Walk
Dr Chris Pounder, Pinsent Masons

Mr Dominic Povey, NHS Information Centre
Ms April Shropshire, Senior Legal Adviser, Cancer Research UK
Mr Peter Singleton, Director, Cambridge Health Informatics
Mr David Smith, Deputy Information Commissioner
Ms Wendy Smith, Mills & Reeve
Professor Robert Souhami FMedSci, Professor Emeritus of Medicine, University College London
Dr Gill Thomas, Mills & Reeve
Ms Karen Thomson, Head of Operations, Patient Information Advisory Group
Mr David Townend, Senior Lecturer, University of Sheffield
Mr Justice Tugendhat, Royal Courts of Justice
Ms Louise Turner, NHS Information Centre
Dr Mark Walport, Director, Wellcome Trust
Dr Mark Watts, Bristows
Professor Simon Wessely FMedSci, Professor of Epidemiological and Liaison Psychiatry, King's College London
Ms Jan Wilkinson, Care Record Development Board
Ms Jane Williams
Dr Ron Zimmern, Director, Public Health Genetics Unit