

# Best Research for Best Health: A New National Health Research Strategy

## Consultation Questions

The Patient Information Advisory Group (PIAG) was established to advise the Secretary of State for Health about issues relating to the use of patient information. PIAG's role is to provide legal support for essential NHS activity and research to continue whilst also acting as a catalyst to improve practice. This legal support is provided under Section 60 of the Health and Social Care Act 2001 and is granted through an application process.

The purpose of Section 60 of the Health and Social Care Act is to allow organisations to obtain patient identifiable information, for medical purposes, in circumstances where it is impracticable to obtain informed consent from the patients concerned. Section 60 is intended to be transitional, allowing the NHS time to develop procedures for obtaining consent from patients or find ways of working with pseudonymised/anonymised information. PIAG is responsible for reviewing successful applications annually to ensure the use of patient identifiable information can still be justified and that these arrangements are not used inappropriately.

The focus of our response is therefore in relation to the use of patient information for research and its regulation. Consequently we have only responded to the two questions that are pertinent to our remit.

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### **Question 1- Challenges**

A major challenge facing research to which the consultation has not given due regard, is the fact that research not directly involving participation by patients, in general, has not sought to obtain the consent of patients, where identifiable information is required.

People come to the NHS to receive care and treatment and not to become the objects of research. Lawful, ethical research needs to move either towards consent or effective pseudonymisation /anonymisation of patient data. Whilst most patients would readily accept some analysis of their confidential personal information, this does not obviate the need to ask for their approval. If the NHS is to become an effective, ethical national research system, we need to ask and record the wishes of patients in relation to their attitude to involvement in research. The electronic health record should be able to store such information and provide that information, without compromising confidentiality in respect of other parts of the health record, to those with a legitimate need to know. There is much rhetoric about the importance of 'patient choice', but in the main, it is not apparent that this is being put into practice. There is a need therefore for the NHS to clarify the 'rules of engagement' for patients and for the NHS to develop a genuine consent-based culture built on informed choice.

A further challenge relates to research involving patients whose decision-making capacity may be limited through immaturity, or disorder of brain or mind. Whilst the Mental Capacity Act has provided some clarification on this, the challenge will be to implement it, so that where patients have some capacity to make their own decisions they are supported effectively to exercise it. This needs further public debate and a NHS research strategy to provide guidance.

### **Question 3 - National Institute for Health Research**

The Patient Information Advisory Group has no comment about the relative benefits of a virtual organisation. It is concerned that whatever structure is used that there are appropriate lines of accountability. Is it envisaged that this body would still be a legal

body? If not, how can it be held accountable? As it is proposed, it would seem that the sole line of accountability would be through the Director of Research & Development rather than through a board. This puts a huge onus on the Director in terms of governance.

That said, having one body could mean that there is a central resource of expertise to advise researchers and ensure compliance with legal requirements and best practice which would be of benefit both in terms of research and information governance.

### Question 13 – Bureaucracy ‘busting’

a	Do you agree with our guiding principle that procedures and data input should occur once and once only and that where duplication exists, we will seek to streamline it? <b>YES/NO</b>	
b	Are the proposals for bureaucracy ‘busting’ appropriate ? <b>YES/NO</b>	
c	If not, what would achieve the aims better?	
<p>The Patient Information Advisory Group has begun working with a number of agencies including COREC to facilitate the streamlining of application processes, so to this extent PIAG is supportive of reducing the administrative burden. The Advisory Group welcomes the acknowledgement that public confidence in the research community has been damaged by failures in research governance and the steps that have been taken to remedy these. However, there are still significant failures and risks in relation to the use of patient information in research. This is evident in the applications the Advisory Group receives for research groups seeking Section 60 support. Some researchers do not understand why they need to seek patient consent for the use of confidential, personal health information and seem to feel they have a right to information because it is for research purposes and therefore that this automatically constitutes a public interest</p>		

justification. Even though the Advisory Group only considers applications once approved by a Research Ethics Committee, we have nevertheless seen examples of poor practice and some scientifically questionable projects. Phrases such as 'bureaucracy busting' are unhelpful in this regard. The bureaucracy that exists, in general, has been developed in response to failures. Regulation is there to protect vulnerable patients from others who may not always have their interests at heart. Some bureaucracy is therefore valuable and necessary. What is important is to ensure that there is proportionality and fitness for purpose in regulation.

Additionally, whilst the proposal that information should be entered only once seems reasonable, there is an issue where different regulatory bodies may appear to be seeking similar information but where in fact their different remits mean that in reality they are looking for related but different information. There is therefore a risk in 'entering data once only' that what will be entered will not be quite relevant or appropriate to the purpose.

For further information about these issues please see our response to the call for evidence to the Academy of Medical Sciences study into the Use of patient information in research which is available on our website [www.advisorybodies.doh.gov.uk/PIAG](http://www.advisorybodies.doh.gov.uk/PIAG).

**Question 15 – Overall**

a	By what criteria will you judge us on the impact of this strategy?
<p>By the quality and number of applications to the PIAG.</p> <p>By the extent to which the new body works with organisations such as PIAG to ensure that the right advice is given to researchers in relation to the use of patient information.</p>	
b	Do you have any other comments?

We have two key comments to make in relation to the overall consultation:

1) There has been considerable effort put into pro-actively seeking the views of professional and research bodies but apparently no direct engagement with patient bodies. The Association of Medical Research Charities and Cancer Research UK (CRUK) are the only bodies you have sought to engage. The former is an umbrella body of charities that are actively engaged in medical research, many of which, including CRUK, do not have a patient membership. Neither of these can be said to reflect the views of ordinary patients or the public. This is wholly inadequate in terms of engaging the public, patients or patient/public representative groups in line with user involvement as conceived by Section 11 of the Health and Social Care Act 2001.

What steps do you plan to take to remedy this ?

2) The consultation document states that *'we intend to create a system in which NHS organisations have the necessary support and infrastructure to enable them to conduct and support first class research as an **integral element** of high-quality patient care'*. On the surface this seems a very laudable aim, however, caution needs to be exercised in relation to integrating research into clinical care. Patients go to clinicians to seek treatment and care and not to become research subjects. Many are willing to participate in research but it is clear that people have an expectation that they will be invited to participate and have the right to refuse without this affecting the care they receive. It is essential that the central focus remains on providing care appropriate to the individual and that the needs of research do not usurp this.

Thank you for completing this questionnaire. Please save this document and email it as an attachment to [RDconsultation@dh.gsi.gov.uk](mailto:RDconsultation@dh.gsi.gov.uk). For any queries or information, please contact this email address or telephone 020 7972 4113.

Further copies can be downloaded from

<http://www.dh.gov.uk/Consultations/LiveConsultations/>.

DH will report on the outcome of this consultation at the end of November 2005 at [www.dh.gov.uk](http://www.dh.gov.uk).