

# National Information Governance Board for Health and Social Care



## **Annual Report 2010**

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Rt. Hon. Andrew Lansley CBE MP  
Secretary of State for Health  
Department of Health  
Richmond House  
79 Whitehall  
London SW1A 2NS

01 November 2010

Dear Secretary of State,

I am pleased to attach a copy of our annual report for 2009/2010.

The National Information Governance Board for Health and Social Care (NIGB) was established under the Health and Social Care Act 2008 and took over its role by consolidation of activities previously performed by a range of other bodies. The purpose of the Board is to support improvements in information governance practice, to monitor information governance trends in the NHS and adult Social Care and to administer applications to use powers established under section 251 of the NHS Act 2006. The latter is important in supporting the legal use of patient identifiable information in medical research and in other secondary uses of patient information in improving care.

The NIGB meets every two months and reports annually to you.

This report outlines the role of the Board and how it works to fulfil its statutory functions. In addition to supporting the increased use of information technology the NIGB also supports the sharing of data whilst maintaining patient confidentiality.

It has been pointed out that NIGB forms a unique bridge between health and social care and that appropriate data sharing across agencies needs to be promoted more actively.\* We find increasingly that doubt and uncertainty over information governance issues can often lead to an avoidance of decision taking when it comes to the appropriate and desirable sharing of data. The NIGB Office has been actively engaged in developing advice and guidance on this point and it remains a strategically important target area for the Board's work.

The NIGB is the custodian of the Care Record Guarantees for both the NHS and Social Care. The NHS Care Record Guarantee was first published in 2005 and sets out for patients how their information should be used so that their rights are protected and their health and wellbeing promoted. In October 2009 NIGB launched an equivalent guarantee for social care records. We have consulted partners before recommending a series of amendments to the NHS Care Record Guarantee. The changes reflect the move towards more localised IT solutions within the NHS and act as a guide to patients on how their information is used to support effective healthcare delivery.

\*Care Quality Commission National Study 'The right information, in the right place, at the right time – a study of how healthcare organisations manage personal data', September 2009.

The NIGB provided evidence to the Academy of Medical Sciences Review of Medical Research Regulation in May. In addition we held very useful meetings with Professor Sir Michael Rawlins, Chairman of the review panel, in May and July and we look forward to the outcome of the review.

The Department of Health Advisory Non-Departmental Public Bodies Review has indicated that the functions of the NIGB will transfer in part to the Care Quality Commission and part to the proposed Research Regulator. We do not know the timetable of implementation, it is therefore an appropriate time to restate the principles of effective information governance which must continue to be the basis of any new arrangements which the Government puts in place.

We set out our principles in more detail on page 9 of this report. In summary, the oversight of information governance in health and social care must be:

- Committed to patient and public good;
- Independent of vested interests;
- Credible with partners and the wider public;
- Proportionate and practical;
- In accordance with law and best ethical practice.

I believe that the combination of public and professional representative membership within the NIGB has brought a wealth of expertise in balancing the rights of patients and the needs of professionals enabling the Board to give well-judged and useful advice.

In addition, the NIGB includes observers from both Scotland and Wales. This maintains a valued and consistent approach to information governance in the devolved administrations.

I would like to express my thanks to both Board and ECC members and the many stakeholders who have contributed to the work of the Board. I appreciate their commitment and support that has made an essential contribution to the success of our work.

Yours sincerely,



Harry Cayton  
Chair

# **ABOUT THE NATIONAL INFORMATION GOVERNANCE BOARD FOR HEALTH AND SOCIAL CARE (NIGB)**

## **Why is there a National Information Governance Board?**

The National Information Governance Board for Health and Social Care (NIGB) was established in order to advise on the promotion of safe and secure use of patient information to support good practice in both clinical services, health service management, delivery of social care and medical research; the role of its Ethics and Confidentiality Committee ensures a sound legal basis for secondary use of confidential patient information without consent.

## **Background**

The National Information Governance Board for Health and Social Care was established as a Statutory Advisory Non-Departmental Public Body by the Health and Social Care Act 2008 in order to support improvements in information governance practice and to monitor relevant information governance trends in health and social care.

A review of information governance in the Department of Health and the wider NHS conducted in 2005 ([www.nigb.nhs.uk/about/publications/igreview.pdf](http://www.nigb.nhs.uk/about/publications/igreview.pdf)) commented on the absence of a single co-ordinating body which, in the case of disagreements about interpretation of best practice or in the giving of advice, could provide a single authoritative voice. This recommendation was accepted by Ministers. Thus, the NIGB and its Ethics and Confidentiality Committee (ECC) replaced a range of different bodies that were previously engaged in patient information governance roles. These included the Patient Information Advisory Group (PIAG), the Care Record Development Board (CRDB), the Security and Confidentiality Advisory Group (SCAG), the Office of National Statistics Advisory Group on Medical Research and NHS Connecting for Health's Confidentiality Requirements Advisory Group (CRAG).

The NIGB therefore already represents an improvement and simplification of the advisory framework around information governance.

The NIGB reviews and publishes the Care Record Guarantees for both the NHS and social care.

The Terms of Reference for NIGB are given in Annexe 1.

## **Composition and Structure of the NIGB**

The NIGB consists of a main Board which has a total of 21 members, plus additional advisors and observers. The NIGB's Ethics and Confidentiality Committee has 16 members (three of whom are also NIGB members including the Chair).

The NIGB can appoint up to 11 public members, including the Chair. These are public appointments made by the Appointments Commission – biographies of public members are available in Annexe 3. The Chair of the ECC is a publically appointed NIGB member. Members are appointed for up to a period of 4 years and can be re-appointed for a further period at the discretion of the Chair.

**The representative members of NIGB** are appointed by the Department of Health to represent relevant stakeholder organisations in the work of the Board. Currently the organisations represented are:

Allied Health Professions Federation  
NHS Confederation  
British Medical Association  
Academy of Medical Sciences  
Royal College of Nursing  
UK Council of Caldicott Guardians  
Local Government Association  
Independent Healthcare Advisory Services  
Academy of Medical Royal Colleges  
Association of Directors of Adult Social Services

Biographies of representative members are available in Annexe 3.



**“The BMA and the NIGB are determined to ensure that confidential identifiable personal medical records are properly protected and that when the information contained within them is accessed without consent the process is legal and uses types of anonymisation to prevent individual identification. My role as BMA representative is to ensure that both organisations achieve their goal.”**

**Dr Tony Calland**  
BMA Representative Member

**“For me, the strength of the Board lies in the range of skills, knowledge, experience, and the personal and professional perspectives that its members bring to every discussion. The work we do is complex and challenging, and we don’t always agree – but we can, and do, reach genuinely informed decisions.”**

**Penny Hill**  
NIGB Public Member

Additionally the NIGB has a number of corresponding advisors from other stakeholder organisations. **Corresponding organisations are:**

Royal College of Midwives  
General Medical Council  
Ministry of Defence  
Strategic Health Authority Chief Information Officer’s Council  
Medical Protection Society  
Information Standards Board for Health and Social Care  
Department for Education

Biographies of corresponding advisors are available in Annexe 3.



## **How does the NIGB fulfil its remit?**

In summary the major supporting functions of the NIGB are:

**Providing advice and publishing guidance** - Stakeholder organisations represented at the NIGB are from both health and social care and in close consultation with these bodies, the NIGB provides leadership and promotes consistent and higher standards for information governance across both sectors. Recent published guidance includes:

- Requesting Amendments to Health and Social Care Records - 14 January 2010

**Giving patients and the public a voice** – Half of the membership of the NIGB is drawn from members of the public, appointed by the independent Appointments Commission after a public recruitment process. The public members ensure that the perspective of patients and the wider public is taken into account when the Board discusses or provides advice or guidance on governance matters.

**Providing advice to care professionals** - The NIGB provides advice on the interpretation of policies, guidelines and legislation relating to information governance. There are many policies, procedures, legislation and professional guidelines which relate to the use and sharing of patient and service user information. Whilst the general principles are consistent there can be differences in the detail which can sometimes make it difficult for those providing care to be sure that they are acting appropriately. NHS and social care organisations have Caldicott Guardians\*, in place to support staff to ensure that information is handled appropriately and most will also have information governance boards or committees. The NIGB provides guidance in particular situations where professionals feel unable to decide on the correct action.

\* A Caldicott Guardian is a senior person responsible for protecting the confidentiality of patient and service user information and enabling appropriate information sharing. The Guardian plays a key role in ensuring that the NHS, Councils with Social Services responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information.

**Providing advice to patients, service users and the public** - The NIGB reviews the NHS and Social Care Record Guarantees for England. The NHS Care Record Guarantee was first published in 2005 and sets out for patients how their information should be used so that their rights are protected and their health and wellbeing promoted. The NHS Care Record Guarantee is available at <http://www.nigb.nhs.uk/guarantee>. In October 2009 NIGB launched an equivalent guarantee for social care records, available at [www.nigb.nhs.uk/social](http://www.nigb.nhs.uk/social).

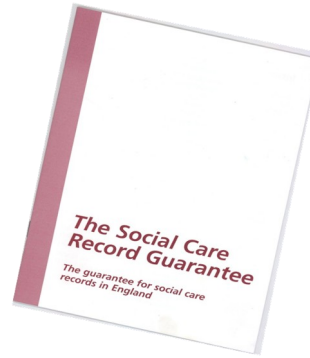
Both Guarantees set out a summary of the legal and policy requirements organisations should meet and the best practice standards for the ethical use of personal and confidential information. The Social Care Record Guarantee has been supported or endorsed by the following organisations:

- Association of Directors of Adult Social Services
- Association of Directors of Children's Services
- Department for Education
- Local Government Association
- UK Council of Caldicott Guardians
- CAFCASS Children and Families Court Advisory and Support Service
- Information Commissioner
- 11 Million (Children's Commissioner)
- General Social Care Council

The NHS Care Record Guarantee has been revised recently to take in to account the movement towards the implementation of more local information technology solutions. Non-compliance with the NHS Care Record Guarantee or the Social Care Record Guarantee could be used as the basis of a complaint; how patients can make a complaint about the use of their information is explained in the Guarantees. Patients and service users contact the NIGB seeking advice. Wherever appropriate NIGB provides general advice but is unable to investigate individual complaints.

“We have decided to adopt the Social Care Record Guarantee. It is a helpful reminder of some of the key principles on sharing we should be following, and provided us with a fresh opportunity to review how we are doing against them.”

Camden Council



**Providing monitoring and oversight - NHS** organisations are required to assess their information governance performance annually using the Information Governance Toolkit (available at <https://www.igt.connectingforhealth.nhs.uk/>). The NIGB advises on the content of the toolkit and has begun to use the annual returns to monitor information governance trends and issues more closely. The NIGB is also supporting work to increase the use of the toolkit within social care. New IT systems are continuing to be implemented in all NHS organisations in England either by individual organisations or through the NHS IT programme. The NIGB maintains an oversight, provides advice and guidance, and reviews access control frameworks.

Similarly, new IT systems or the upgrading of systems is also happening within social care and the NIGB has also provided advice when requested on the information governance implications of system changes.

**Providing links with other UK countries** - The devolution of government has led to differences in the way that healthcare and social care is delivered across the UK. The NIGB works closely with equivalent or similar bodies in Wales and Scotland and the devolved administrations send observers to NIGB meetings.

### **Engaging with partners through consultation and building strategic alliances –**

The Board has both formal and informal contact with a range of partners including patient groups, research organisations and professional bodies. The aim is to remain in touch on current and developing issues in information governance and feed these in to the Board and provide advice where appropriate. In particular NIGB has concluded Statements of Collaborative Working with National Voices, the Association of Medical Research Charities and the UK Council of Caldicott Guardians.

The Board's work has also received international attention and invited presentations have been made at the World Health Executive Forum, Montreal, Canada in November 2009 and at a Workshop sponsored by the Office of the National Coordinator for Health Information Technology, Washington DC USA in July 2010.

**Ensuring a consistent approach** - The Board has agreed a set of principles that it uses to promote a consistent approach to its decision making and the provision of advice and guidance.

“Attendance provides a valuable opportunity to share experience with counterparts in England, keep abreast of mutual areas of activity, and where possible provide consistency in the approach taken. The reciprocal arrangements that are in place for the NIGB to attend meetings of the NHS Wales National Information Governance Advisory Group (NIGAG) are found to be equally as valuable.”

Claire John  
NIGAG— NHS Wales

## ***Principles of the National Information Governance Board in decision-making and in the preparation of advice and guidance***

The following principles\* provide a framework that the NIGB uses to promote a consistent approach to decision-making and as a basis for advice and guidance. These are high level principles to which there are always exceptions either for legal or for practical reasons. In such cases we will resolve them in an ethical manner.

1. People have personal interests and responsibilities as patients, users of services, as carers and also as citizens.
2. Within health and social care services:
  - The interests of patients and service users come first;
  - Informed consent and personal autonomy should underpin the provision of health and social care; this involves an ongoing process of negotiation and not a single consent event;
  - With patient consent, the right information should be available to the right people at the right time to provide individual care whilst preserving confidentiality;
  - Secondary users should seek to use de-identified data;
  - The wishes of people who have withheld or withdrawn their consent for the use or disclosure of information should be respected.
3. It is in people's interests to have:
  - Appropriate and accessible care, which promotes health, social welfare and public safety;
  - A sound research base on which to build and improve effective services; and
  - Well managed and cost effective services.
4. The principles of good regulation should be followed. These are proportionality, accountability, consistency, transparency and fairness.

These principles will sometimes be in tension with each other. In seeking to resolve those tensions it should be noted that:

- a. Allowing service users appropriate control over and access to their own information, and its use, is central to the role of the NIGB and is a requirement of the Data Protection Act 1998;
- b. Trust and public confidence in health and social care services should be earned and maintained, and not assumed;
- c. Patients, service users and carers have a right to confidentiality;
- d. People's information should be stored and shared in a secure manner;
- e. All those processing personal information must comply with legal requirements and professional practice standards and guidance;
- f. An appropriate balance between individual and public interests must be maintained. In accordance with Article 8 of the Human Rights Act 1998, interference with people's privacy is only permissible where it is in accordance with the law and necessary for a number of specified purposes including public safety, the protection of health and the rights and freedoms of others and is proportionate to the purpose.
- g. Where decisions are made concerning the balance of individual and

professional or public interests, those making decisions should be accountable and, except where personal details are involved, the basis for such judgements should be made public.

## **Compliance**

Information Governance in health and social care must ensure compliance with legal and best practice requirements and encompasses in particular:

- a. The Data Protection Act 1998, including the requirements for personal data to be accurate and up to date, kept secure, 'adequate, relevant and not excessive' and only used for the purpose for which it was collected and compatible purposes in accordance with fair processing requirements;
- b. The Human Rights Act 1998, especially article 8 of the European Convention on Human Rights (respect for private and family life);
- c. The Common Law in relation to confidentiality;
- d. Requirements set out as conditions of approval where support has been given under The Health Service (Control of patient information) regulations 2002 [SI 1438];
- e. The NHS Care Record and Social Care Record Guarantees for England; and
- f. The Caldicott Principles need to be adhered to; namely to:
  - Justify the purpose;
  - Not to use personally identifiable information unless it is absolutely necessary;
  - Use the minimum personally identifiable information;
  - Restrict access to personally identifiable information on a need to know basis;
  - Ensure everyone is aware of their responsibilities;

- Understand and comply with the law.

This is further underpinned by commitments contained in the NHS Constitution and NHS standards as provided within the NHS Confidentiality, Information Security and Records Management Codes of Practice and the General Social Care Council's Code of Practice relating to confidentiality for Social Care Workers.

## **Objectives of decision-making**

The promotion of health and well-being, and the prevention of harm, are essential components of effective health and social care services.

In accordance with these principles, the National Information Governance Board should have the following objectives to aid the decisions it takes and the advice and guidance that it provides. Principles should:

- a. Be practicable and clearly expressed;
- b. Benefit everyone fairly;
- c. Promote trust and public confidence;
- d. Increase transparency;
- e. Support choice and control for individuals;
- f. Improve people's knowledge and understanding of the way in which their information is used within health and social care; and
- g. Not only support the care provided to people but also the efficient delivery of health and social care services, including governance, public health, health promotion, epidemiology, education and research.

\*These principles have been endorsed by the British Medical Association, Royal College of General Practitioners, UK Council of Caldicott Guardians, NHS Information Centre and the Research Capability Programme.

## ***Board Report***

In the last year the NIGB has continued to develop in providing a key service to a wide range of stakeholders. This has included NHS organisations, health and social care professionals, the public, patients and their advocates, service users and carers. It has also included national and local bodies with regulatory and advisory functions and the research and research governance communities. We have also given advice to the Department of Health, NHS Connecting for Health and the Information Centre for Health and Social Care.

There has been a period of significant change in the approaches concerning the secondary uses of patient information. The NHS Information Reporting Service is being established to enable the collection of data from operational systems to support training, management, research, audit and aspects of public health. The NIGB has been consulted throughout these changes and has provided advice across a range of projects including projects from the NHS Information Centre and the NHS Research Capability Programme. We have been able to respond to the challenge using the strength of expertise brought to the Board through public and representative members. This ensures that advice and guidance we give represent all shades of opinion and draws on our experience.

A particular focus this year has been the development of the Honest Broker concept into a series of practical proposals. Honest Broker\* services are designed to significantly reduce the number of organisations that need access to identifiable patient information and at the same time increase access to such information to support improvements in patient care. This will be rigorously controlled in secure settings with technical capability to ensure confidentiality. We see this development as a key opportunity to build public trust and confidence in the legitimate use of patient information for both audit and research. It has been recognised that the ability to utilise information in this way is a particular strength in the UK and one of several benefits to be gained from the major national investment in IT in health and social care.

We are actively working with our stakeholders to ensure that we recognise patient concerns over secondary uses of their information and these are fed in at the appropriate stage to influence but not impede project delivery and outcomes. To this end we have built up strategic alliances (via Statements of Collaborative Working in some cases) with the Association of Medical Research Charities, National Voices, INVOLVE and the Genetics Alliance. We find that this is a valuable mechanism for bringing issues to the Board leading to the generation of timely advice and guidance.

In the course of the last year NIGB has produced specific guidance to patients and professionals on 'Requesting amendments to health and social care records'. This is a prime example of how we can meet requests for advice from patients and the public. In this case we set up a time limited small working group which combined selected public members of the Board with external health professionals. We also conducted a three month consultation exercise on the guidance before it was published.

\*An honest broker is an organisation with specific legal powers to process (including where necessary viewing) identifiable patient information held in electronic and/or paper form without requiring explicit patient consent. This definition has been taken from the Information Centre's Honest Brokers Privacy Impact Assessment document Part I but there is no legal definition and as yet this definition has not been formally agreed.

## ***Board Report continued...***

In addition to this we have been active in three other areas where advice has been sought. Firstly, in the growing demand for the creation of research databases where there is increasing evidence of a lack of co-ordination and danger of duplication.

The second area of guidance is in consent for diagnostic tests and is presented both from the patient and professional perspectives. The introduction of 'consent to view' has raised questions over the access to data by appropriate members of the healthcare team engaged in diagnostic work. It is important to ensure that on the one hand patients know what to expect if they undergo diagnostic tests and that professionals are not impeded in their vital work.

The past twelve months has seen significant changes in the direction of informatics within the health system. With the emphasis on more localised solutions to IT requirements the challenges of information governance remain. Indeed a strong and consistent information governance framework is even more important if there are to be local solutions with very different capabilities. We are disappointed that one of the significant advances that an electronic record system promised to patients – a reliable and identifiable audit trail- seems unlikely to be delivered in practice. The NHS Care Record Guarantee has been revised this year in the light of these changes. We believe we can still make effective national commitments to patients that their records will be safe and secure and only used with consent but our revision of the Guarantee recognises that they will need to take more action on their own behalf to find out what safeguards are in place wherever and whenever they are receiving care.

We are pleased to report the positive impact of the Social Care Record Guarantee. Indeed many local authorities are incorporating the text in to local guidance in addition to widespread distribution of the original version. The commonality of the two guarantees and of shared information governance requirements, along with robust information sharing protocols and consent, forms the basis of a structured approach to information sharing across the two domains. The NIGB has a key position in facilitating the appropriate use and sharing of information across sector boundaries. This was recognised in a report from the Care Quality Commission that promoted the idea of the NIGB fulfilling an important role as a facilitator between these different professional communities.

Additionally, we have fulfilled our statutory requirement in providing the Care Quality Commission (CQC) with advice on their Code of Practice on Confidential Patient Information.

In considering what are sometimes complex issues of confidentiality and consent the NIGB and the ECC always endeavour to provide clarity. We have used this annual report as an opportunity to revisit our principles for decision making.

It is therefore disappointing that despite the NIGB providing advice at the consultation stage, the 'Guidance on Confidentiality 2009' published by the General Medical Council had two issues with which the NIGB is in disagreement.

## ***Board Report continued...***

Firstly, the guidance has indicated that 'public interest' may be used by individual clinicians as a reasonable alternative to the use of powers under section 251 to set aside the duty of confidentiality in using patient information for research or other secondary purposes without consent. The NIGB is given to understand that the guidance was written in this way to accommodate the differing arrangements for use of patient identifiable information in the four UK nations, as section 251 only applies to England and Wales. However, as it is presented in the guidance, it may lead to more confusion as to when an application for support under the Health Service (Control of Patient Information) Regulations is needed. The NIGB recognises that there are instances where specific individuals' information could be disclosed on public interest grounds such as where there was a serious risk to the health or wellbeing of another person. These situations are clearly established by statute or precedent. In relation to the disclosures of groups of patients and service users' information for secondary purposes such as health and social care services management, clinical audit and research then the public interest should not be relied upon where confidential information is needed. The powers under section 251 of the NHS Act 2006 provide a secure lawful mechanism for such consent. We believe Parliament in providing for this legal mechanism intended it to be used not by-passed by individuals.

Secondly, the guidance states that the task of anonymising, coding the information or seeking patients' consent to disclose it, can be delegated to someone incorporated into the healthcare team on a temporary basis and bound by the legal and contractual obligations of confidentiality. The NIGB is of the view that the temporary incorporation of a person who is not directly involved in patient care to carry out these functions without patient consent could be liable to a breach of confidence, and could undermine patient trust in the service. A securer basis in law can be provided in these circumstances through the class support provided under section 251 and it would appear that this was the intention of the Act and accompanying regulations, where it is not practicable to obtain prior consent for the disclosure.

The ECC continues to consider applications for section 251 support and the number of applications remains steady from last year. The Committee has also been busy assessing annual reviews of applications and other related proposals. The ECC and the Office are continuing important work to improve transparency and codify decision-making. I must thank the Chairman, Dr Andrew Harris and the committee members for their outstanding work. In July the Committee considered its first application under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Act 2010. The responsibility to consider these applications has been delegated to the NIGB by the Human Fertilisation and Embryology Authority.

Further issues which have been recurrent themes with the Board in the course of the last year were the use of Smartcards and use of the NHS number. Both issues have resonance in the overall need for a change in approach across the NHS towards the effective implementation and use of IT in healthcare. Universal use of the NHS number has made very significant progress but still has a long way to go and we understand that there are sometimes difficulties for trusts in fully implementing this (e.g. legacy systems). As a consequence many applicants for section 251 approval have to use other identifiers for verification purposes.

## *Board Report continued...*

We wish to re-emphasise the NIGB's support for the comprehensive use of the NHS number both for the correct identification of individual's records for the purposes of safe care and also because it is a key component for the effective pseudonymisation of patient information and underpins Connecting for Health's Pseudonymisation Implementation Project.

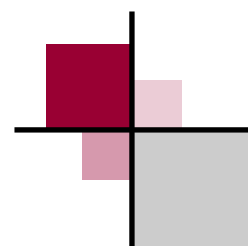
In relation to Smartcards, the NIGB is aware that in some clinical settings such as accident and emergency departments there have been technical and practical issues with systems which has necessitated the sharing of Smartcards to access patient records. We feel very strongly that these technical issues need to be addressed as a matter of priority as the sharing of smartcards undermines effective clinical information governance. The NIGB has also recommended to regulatory bodies that they emphasise the requirement not to share Smartcards within record-keeping standards and Codes of Practice.

It is pleasing to report that there continue to be steady improvement in results with the IG Toolkit across NHS and Social Care organisations overall. However, there are a number of requirements that organisations continue to find challenging, most notably:

- off-shore processing;
- information security of systems and external transfers of data;
- robust information governance measures in place to comply with the Operating Framework requirements;
- ensuring contractors comply with the necessary IG standards.

Whilst the NIGB acknowledges the usefulness of the toolkit as a self- assessment tool, it welcomes the move to a requirement that evidence is submitted to support the scoring and the use of audit to verify the results. This means that the toolkit results are becoming a more reliable measure of how well organisations are meeting information governance requirements.

One aspect of the Board's work which we wish to formally acknowledge is that of the Database Monitoring Subgroup (DMsG) which has been an additional part of ECC's activities since inception. We have agreed following discussion with the NHS Information Centre, that this role would sit more comfortably within their management structure so the responsibility for DMsG was transferred in October of this year. The Board would like to take this opportunity to thank Dr Patrick Coyle for his very able chairing of the group over many years and for the work that he and his colleagues have carried out under the ECC's auspices.



# **Ethics and Confidentiality Committee**

Section 251 of the NHS Act 2006 (previously section 60 of the Health and Social Care Act 2001) and its supporting regulations, the Health Service (Control of Patient Information) Regulations 2002, provide powers for the Secretary of State for Health to allow the common law duty of confidentiality to be set aside in specific circumstances so that information which identifies patients can be used for NHS activities and medical research without seeking patients' consent. The NIGB delegates these powers to its Ethics and Confidentiality Committee (ECC).

In addition, on 6 April 2010, under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 [SI 995/2010] the Human Fertilisation and Embryology Authority can permit HFE related data to be disclosed for research purposes without explicit patient consent or for the purposes of facilitating the seeking of consent and the NIGB was given authority to advise and assist the HFEA when requested. These powers are inclusive for all four UK nations. These powers reflect and sit alongside the powers under the Health Service (Control of patient information) regulations and the NIGB and HFEA have developed an integrated application process to streamline the application process for researchers.

The NIGB Ethics and Confidentiality Committee members are appointed by the NIGB except for the Chair who is a publically appointed member of the NIGB; there are 16 members in total (a list of ECC members is at Annexe 4).

Applications for approval under section 251 are normally received via Integrated Research Application System (IRAS) - [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk) for research and via a form on the NIGB website for other medical purposes.

These are considered by the ECC following an initial office appraisal. The ECC meets on a frequent basis (at least six times a year) and some applicants are invited to attend in person to discuss applications.

The ECC receives between 90-100 applications each year with an average time between application submission and decision of 40 working days for a standard application. There is also a 'fast track' approval process for applications which meet certain criteria to be considered outside of formal committee meetings. Fourteen such applications have been considered in this way in the last year and a decision via this route can take between 15 and 20 working days.

Each application for section 251 support is considered carefully and a judgment made on whether the benefits of the NHS activity or proposed research are significant enough to set aside the common law duty of confidentiality in favour of public interest.

Applicants need to demonstrate that their proposal is necessary or expedient either in the public interest or to improve patient care, and this is balanced against any detriments to the individuals whose records are being used. Secondly applicants need to show that seeking consent, or using anonymised or pseudonymised data, is not practicable or possible for their study. Effective patient and service user involvement in the study is also assessed, together with an exit strategy from the use of section 251 - for example that steps will be taken to adopt pseudonymisation techniques or seek consent in future.

To ensure appropriate governance arrangements, the Chair of the ECC is appointed by the Appointments Commission and is a full member of the NIGB. Two other members of the NIGB are also ECC members.

Applications to use section 251 come from a range of organisations, including the Department of Health, NHS organisations and research institutions. In the last 12 months the ECC received 93 applications.

Applications Approved	63
Declined	25
Section 251 not required	2
Partially approved	1
Pending	2
<b>Total</b>	<b>93</b>

Further details of section 251 applications can be found at Annexe 5, and the register of all approved applications is at <http://www.nigb.nhs.uk/ecc/reg>

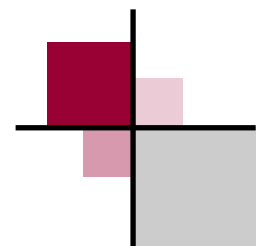
## ECC Report

In the course of considering applications for section 251 support a number of issues arose.

The first of these concerned the Department of Health who contacted the ECC concerning the GP Patient Experience Survey which consists of a postal questionnaire which is sent to 5 million patients to assess their experience of primary care. The patient's demographic data, NHS number and registered GP are used to send the patient the questionnaire via a third party. The Department of Health were of the view that section 251 application was not necessary. This was partly because they considered that the use of this information was not a breach of the common law duty of confidentiality as the information was largely already in the public domain. The ECC challenged this view as it did not consider that date of birth, registered GP and NHS number were generally in the public domain. Furthermore, the fact that some of the information may be partially in the public domain did not lessen the duty of confidence to protect those parts which were not. The ECC felt that there was a risk that identity may be discoverable by linking this group of disclosed data with other published data. It was considered that the use of this information in this way by the survey would almost certainly fall within the definition of confidential patient information in the NHS Act 2006. The ECC concluded that it would be in the Department of Health's interests to apply for section 251 support to ensure that an appropriate legal basis for the disclosure would protect PCTs which release the information, and the Department and Ministers from legal challenge.

**“In a complex landscape of legal and regulatory requirements for health and social care research, it is vital that governance bodies work closely together to minimise duplication and provide consistent, facilitative guidance for researchers. Working in partnership with the NIGB is important for NRES. We value the high quality of advice from the ECC on use of patient data in research, and look forward to further developing our existing collaboration in future.”**

National Research Ethics Services (NRES)



Last year's annual report noted applications were being received from researchers to set up databases or disease registers without there often being a clear basis on which these would be used and what specific scientific hypotheses would be addressed. This year this theme has continued with an increase in applications to establish research databases using patient identifiable information, and requests to local research committees to give secondary permissions to researchers to access these data. In response to this, on the ECC's recommendation, the NIGB has established a Working Group to assess the nature and scope of the problem and to make recommendations on good practice. The membership of the Group includes representatives from the National Research Ethics Service (NRES) and the National Cancer Intelligence Network (NCIN).

Another issue that has come to light following an application for an international cancer benchmarking project revealed the lack of commonality of data handling and analysis techniques between cancer registries. As a result, much of the data already collected by cancer registries cannot be readily combined. Members felt that as these registries were mainly publicly funded, possess legal powers to use identifiable data and are in a good position to act as an 'Honest Broker' that improvements in the capacity of registries and their methodology to improve data utility should be seen as a high priority for the future.

Finally, the ECC has received some applications from researchers who are under the impression that because they have an honorary research contract or 'research passport' they are able to access patient identifiable data without consent. This is not the case. Clinicians treating patients and their supporting staff have access to confidential patient information with patient consent (usually implied as part of consent to examination and treatment) for the purposes of providing or directly supporting care. Other clinicians, administrative staff and researchers should obtain legitimate access to records through explicit consent.

Honorary contracts and research passports therefore cannot be used to override or evade the legal requirements such as those of the common law duty of confidentiality, Data Protection Act 1998 or conditions set as requirements of approval under section 251.

## **Database Monitoring Subgroup**

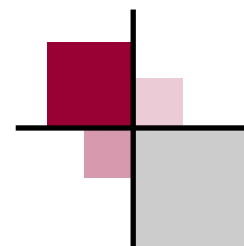
The DMsG was until recently a subgroup of the NIGB Ethics and Confidentiality Committee. The Group considers applications for extracts containing sensitive but not directly identifiable data from the Hospital Episode Statistics (HES) database. HES is a national database which records all hospital admissions and care provided by NHS hospitals and for NHS hospital patients treated in other settings. It does not contain people's names and addresses, but coded details of the care they received. Sensitive data items are those which the DMsG considers, should they be disclosed, may cause greater harm or distress to the patient. The DMsG recommends, where necessary, additional safeguards given the sensitive nature of the data and ensures that a combination of, or linked data items, do not result in identifying an individual.

The DMsG also reviews applications made via the Medical Research Information Service (MRIS) for access to records on the Central Register. The Central Register is a computerised record of every patient registered with a general practitioner in England, Wales and the Isle of Man. The DMsG checks that where consent has been sought from individuals participating in research cohorts, that the consent is valid for the purpose of the study.

From October 2010 the DMsG has been transferred to the management of the NHS Information Centre.

## HES Applications

Approved	15
Approved with conditions	1
Approved outside Committee	4
Declined	2
Referred to ECC	1
<b>Total</b>	<b>23</b>



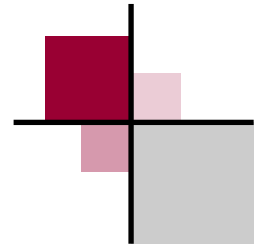
## Central Register Applications

Approved	19
Approved with conditions	3
<b>Total</b>	<b>22</b>

## Appeals

During 2009/10 the NIGB developed an Appeals and Complaints Procedure for applicants dissatisfied with the outcome of an application to the ECC. This is accessible via the NIGB website (<http://www.nigb.nhs.uk/ecc/applications/Complaints-and.pdf>). In the twelve months to which this report pertains the ECC has received two appeals. The purpose of an appeal is to assess whether the ECC has acted reasonably, according to due process and arrived at a reasonable decision on the basis of the information it was given. Appeals are reviewed by the NIGB Chair and a panel of selected NIGB members (who are not ECC members). In both appeals the original decision of the ECC was upheld. The substantive reasons for declining both applications for section 251 support was that the ECC and the appeal panel were both of the view that consent could be reasonably sought from the cohorts, and therefore use of powers under section 251, which may only be used where there is no reasonable alternative, could not be justified.

## *Our work in 2009/10*



### **Examples of NIGB consultations and guidance:**

Requesting Amendments to Health and Social Care Records - NIGB  
Guidance published January 2010

The guidance covers:

- The purpose of healthcare and social care records;
- How we believe problems develop in terms of content;
- What the law says;
- What should happen when requesting a change;
- How to complain, should the need arise.

### **The South London and Maudsley Mental Health Trust, which sought the advice of the NIGB's Ethics and Confidentiality Committee**

The South London and Maudsley NHS Foundation Trust (SLaM) is a mental health trust providing mental health and substance misuse services for people in South London and specialist services nationally. SLaM has established a pseudonymised research database which extracts data from its electronic patient records system. This research database is currently used to support non-contact research. SLaM is in the process of developing this, both in terms of the database and supporting human processes, to facilitate contact research.

As patients are seen at SLaM, members of the clinical care team will ask patients for their consent to be part of the case register, to allow approved researchers to have access to their contact details and limited clinical information i.e. that they fit the research criteria and to be contacted by these approved researchers directly in the future. This is therefore in keeping with the principle that the initial approach is made by the clinical care team and is aimed at addressing the consent for disclosure issue.

When it comes to a particular study, the approved researcher (employed by SLaM or one of the King's Health Partners) will access the pseudonymised data held in the research database and select patients according to their research criteria. Having completed their searches they will have a list of pseudonymised patient ID codes for the patients matching their criteria. The researcher will then give this list to the Research Database Project Manager, who will have access to separate linkage software which looks up on the patient record system whether the patients listed have given consent and then return the NHS numbers only for those that have given consent. This list of NHS numbers will then be given to the researcher who will then use the patient record system to contact each patient's clinical care team to check it is not inappropriate to contact the patient and will then contact the relevant patients directly to invite them to participate in the particular study for which they are recruiting and to ask for consent for the use of their medical records or tissue.

Whilst the NIGB's Ethics and Confidentiality Committee had a number of reservations and provided advice about additional safeguards, they felt that this offered potentially an elegant solution to a difficult issue and highlighted that the benefits included:

- The initial contact is made by a clinician that has a relationship with the patient;
- Researchers only gain access to identifiable information for patients who have given consent;
- Access is limited to researchers operating in SLaM and its partner organisations;
- For SLaM, patients would be aware that the data held in their medical records would include particularly sensitive data and therefore the consent given would have taken this into account.

As a result of discussions SLaM agreed to issue an annual newsletter to remind patients that they had provided this consent and how to withdraw their consent if they subsequently changed their mind about continuing to participate in research.



**“Recently appointed to represent the Academy of Medical Royal Colleges on the NIGB, I have been impressed by the Board's careful and deliberative approach to the safeguarding of personal medical information and by the determination to ensure that those using data for financial and managerial purposes are not allowed laxer standards than clinical researchers.”**

**Dr Iona Heath**  
AMRC Representative Member

## NHS West Kent sought advice from NIGB

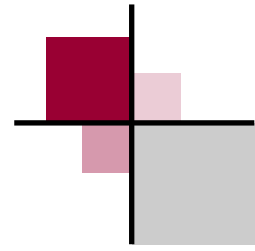
The West Kent Call Service has been established to provide support to patients with long-term health conditions. It is provided by BUPA on behalf of GPs in West Kent PCT and registered nurses give advice and information by telephone. The NIGB discussed the information governance arrangements and the methodology for collaborative care models.

The Board's response was to set out a number of principles that are generic for this type of service and they are worthy of elaborating here:

- There needs to be transparency so that patients and users know who is providing the service and who and under what conditions has access to their information.
- The initial approach to patients should be from an organisation with which the patient has a clinical relationship.
- The contract with the provider should include appropriate information governance and security standards including compliance with the NHS Care Record Guarantee.
- There needs to be clear consent from the patient or service user to process the information. This could be explicit or in some instances implicit provided there is a sufficient basis for implying consent.
- Where consent has been implied people must be given a reasonable time period in which to opt out prior to disclosure of confidential information.
- Where a service is provided for people with long-term conditions or belonging to particular risk groups, any cohort data processing should be done using pseudonymised data and links not held outside the NHS.
- If eligible patients do not opt to use the service then their data should be removed from the system after a reasonable period (typically four months).
- The information provided to those who may use the service should be clear and sufficiently detailed to inform them how the service will operate, including:
  - a. Who is providing the service;
  - b. The type of information which will be disclosed to the provider;
  - c. How consent will be obtained;
  - d. That the minimum information necessary will be held on the provider's systems, securely and confidentially and only for as long as they provide the service;
  - e. That the information can only be used for the purpose of providing this service and cannot be used for any other without agreement from the data controller;
  - f. Where they can obtain more information and with whom they can discuss concerns.

In response to the advice, Julia Ross, Director of Strategy and Communications for West Kent wrote:

***“Thank you for sharing your proposed guidelines with us. We feel that these are both appropriate and proportionate and will allow initiatives such as Care Call to go forward in future. They provide the right level of balance between properly protecting people’s information and being able to run a cost effective service that reaches the whole population.”***



## Information Sharing Workshops

Multi-agency information sharing is vital to achieving improved outcomes for service users and patients and to prevent the tragic deaths of both vulnerable adults and children.

In January 2010, with grateful permission from the County Durham and Tees Valley Information Governance Leads Group who had produced the original materials, our NHS and Social Care Leads adapted these and ran an information sharing workshop pilot at Stockton University. The audience were from social care and the event proved to be very successful.

In May this year, at St James’s Hospital, Portsmouth, and in partnership with Portsmouth Social Care Safeguarding Adults and Solent Healthcare NHS, we were able to run a further pilot specifically concentrating on the multi-agency setting and Safeguarding Adults. The audience consisted of 80 staff working within the police, social care, health, voluntary organisations and charities. The response was overwhelming, the event being over-subscribed by over 60 people. This highlighted the concerns and anxieties professionals continue to experience when making decisions on how, when and if to share information legally and appropriately with other agencies.

During the first session delegates heard presentations on the work of the NIGB, role of the

Caldicott Guardian, the legal basis for sharing information and issues around consent. The second part of the workshop, with the assistance of expert IG facilitators, gave the delegates the opportunity to discuss scenarios, to decide from the information given whether to share some or all of the information on their card and who they would share it with.

From the evaluation it was evident that professionals found it invaluable to discuss issues within a range of cross organisational staff. Comments include:

*‘Excellent diverse range of delegates and speakers good relevant content’*

*‘I enjoyed the course and the wide range of different agencies – this was particularly helpful.’*

*‘Very good session, good materials and a wealth of expertise present.’*

This workshop enabled us to finalise the materials which will be available on our website for any organisation who wish to run an information sharing workshop in their area. They can be adapted for specific audiences or used in their current format, however, the key here is multi-agency as there are obvious benefits to this approach. If you would like more information on running a workshop please contact the NIGB Office.



## **NIGB: The June 2010 Meeting as an example of how the Board conducts business**

The Board met on 23<sup>rd</sup> June 2010 at New Kings Beam House located on the South Bank in central London. The meeting was one of the six held each year that bring forward a range of topics for the Board to consider, comment and advise where appropriate. It also provides an opportunity for Board members to discuss a range of issues with invited guest presenters as in the example given here. All Board Meeting minutes are available on the NIGB website, <http://www.nigb.nhs.uk/about/meetings>

Selected topics at this particular meeting of the Board included a session on current ethical and governance issues in medical research, a discussion of the NIGB Strategic Plan 2010/2013 and an update from the team responsible for HealthSpace and the Summary Care Record.

### **Research**

This is one of several important areas of interest to the Board in regard to the secondary use of identifiable patient information. Dialogue on the issues from the research funder and research investigator perspective was seen as important for Board members to gain an insight in to the ways that information governance is viewed and managed in context. In particular, drawing upon specific examples stimulates discussion and debate.

Dr Catherine Elliott, Head of Clinical Research Support and Ethics at the Medical Research Council (MRC) provided an overview of the MRC and its research strategy given in their Strategic Plan 2009/2014 (<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC006090>)

The Board was informed that, in order to identify pathways of diseases, the MRC supported research with patient-based cohorts, tissue banks (e.g. Biobank) and population-based cohorts (e.g. birth cohorts). Researchers sometimes have to access patient records in order to identify potential research participants, to collect data for primary research projects, to follow up long-term research aims and to link data across datasets. The Board was assured that the MRC only supported research carried out within a strict legal and ethical framework, obtaining consent from research participants when feasible or applying for support under section 251. There was a channel of communication between researchers and cohort members which provided participants opportunities to discuss their participation in the study. Research programmes supported by MRC were subject to risk assessments in order to minimize breaches of confidentiality and ensure appropriate information governance.


Professor Carol Dezateux, NIGB representative member for the Academy of Medical Sciences and member of the NIGB Ethics and Confidentiality Committee gave a presentation on “Information governance - a research perspective”. Professor Dezateux provided an overview of her own research as an epidemiologist and paediatrician.



She discussed the need to take a broad view of the wider social and environmental determinants of children's health and, in doing so, to access and link to data outside the health care system, including, for example, data on educational outcomes or environmental pollutants. She outlined how research could enhance public health, improve public safety and improve knowledge of rare diseases. The importance of having accurate unbiased data sets of validated quality to prevent misleading conclusions in research was highlighted. Researchers usually required anonymised data but those data often had to be linked at the individual level first, posing information governance challenges. She highlighted some advantages of electronic records including the ability to employ common standards, structures and terminologies across different data sources. Professor Dezateux concluded her presentation by raising the need to resolve philosophical, regulatory and operational issues regarding information governance, including approaches to consent, definitions of the clinical care team; whether full anonymisation was achievable and consent for contacting patients for research.

Board members discussed potential issues involving access to patient identifiable information for research. It was suggested that the law was subject to different interpretations. This could affect the way the common law duty of confidentiality was applied when deciding whether patient identifiable information could be accessed for research. There were different ethical approaches that could be adopted when considering these issues. The need to raise public awareness on the use of patient records for research was discussed. There were misconceptions, amongst patients and professionals, of the legal framework which governed researchers access to patient identifiable information. General Practitioners in particular would benefit from initiatives which explained how they could seek patient consent for research without affecting their relationship of trust and confidentiality. Patients would also benefit from a broader campaign which explained the relevance of research for health purposes and provided assurances that their records were being accessed appropriately and within the legal framework.





It was agreed by the Board that having presentations from guest speakers followed by detailed discussion had been valuable in drawing out the priority areas in terms of communicating the benefits of research more positively to both patients and healthcare professionals.

### **NIGB Strategic Plan**

Dr Alan Doyle, NIGB Director discussed with Members the strategic objectives to further develop the role of the Board over the next three years. Priority areas and opportunities had been identified by the NIGB Executive and the Board. Opportunities to: improve the application processes for support under section 251; build partnerships with other stakeholder organisations; work more closely with the Department of Health, Connecting for Health and Information Standards Board in key areas; develop communications strategies on the role of the NIGB; develop its monitoring role and to proactively develop guidance on topical issues. It was also suggested that the Board should continue to promote public engagement with its activities, improving channels of communication and access to information available about the NIGB (e.g. improving the website) and developing the role of members as NIGB ambassadors. The Board agreed the objectives but wanted to see more actions explicitly focused on improving relations with the social care community.

### **HealthSpace and Summary Care Record**

The Board has periodic updates from members of the Connecting for Health team and each side see this as an important initiative so that the Board can have an opportunity to provide advice and guidance as projects develop. This also helps maintain a view on how the Care Record Guarantee impacts on IT projects in practice. There was an update presentation from Dr Gillian Braunold, Clinical Director for Summary Care Record and HealthSpace, NHS Connecting for Health and several of her colleagues.

HealthSpace provides: an online personal health organiser; a diary and an address book; access to Choose and Book; access to Summary Care Records for patients who had one created; and access to the HealthSpace Communicator service within pilot areas, allowing users and clinicians to send and receive secure electronic messages. These functionalities were developed following a patient survey conducted in July 2009 to identify desirable features for HealthSpace. It was outlined that HealthSpace had adopted strong single factor authentication (e.g. PinSafe) to ensure that the person accessing the system was the person to whom the data related, as suggested by the Board in September 2009.

The Board also received an update on the progress and usage of the Summary Care Record. Approximately 30 million people have been informed that they would have a SCR created, unless they opted out (0.81% of patients have opted out to date).



It was noted that the SCR was used in primary care out of hours services such as walk-in centres and polyclinics and for secondary care (emergency department, medical assessment units and hospital pharmacists). It was discussed that the use of SCR for secondary care faced some challenges. The SCR should comply with the Caldicott Guardians Principles without creating obstacles for access and layers of bureaucracy.

The Board discussed the challenge presented by the discontinuity between patient contact and the availability of the record itself. It was felt that this should be communicated more effectively to avoid any potentially damaging misconceptions amongst patients.

This snapshot report gives an insight in to the range of topics brought to the Board by a range of stakeholders who maintain a constructive dialogue and which also provides important background for NIGB in providing advice and guidance. Board meetings thus provide a valuable forum for horizon scanning on issues on the one hand and dealing with specific and often detailed information governance issues on the other. This combination is necessary and important for the Board to successfully fulfil its remit.



**“Collectively, we have a massive responsibility. Our work groups, analysis, focused questioning and back office follow-up work help us to be effective. I always remind myself that words on a page and numbers in tables can directly affect millions of real people from every walk of life in significant ways.”**

**Wayne Cleghorn**  
NIGB Public Member

## NIGB responses to Consultations

The following responses to consultations have been submitted by the NIGB:

### December 2009

The ['Big Care Debate: Shaping the Future of Care Together'](#) (PDF 34Kb) consultation.

The European Union Consultation on ['The legal framework for the fundamental right to protection of personal data'](#) (PDF, 36Kb)

The Department of Health consultation on the ['Draft Code of Practice for health and adult social care on the prevention and control of infections and related guidance'](#) (PDF, 24Kb)

### January 2010

The Department for Children, Schools and Families Consultation on the ['New Statutory Children's Trust Guidance and New Children and Young People's Plan Regulations'](#) (PDF, 31Kb)

The Ministry of Justice Consultation on ['Knowing or reckless misuse of personal data – introducing custodial sentences'](#) (PDF, 17Kb)

### February 2010

The Ministry of Justice Consultation on the ['Edited Electoral Register'](#) (PDF, 21Kb)

The Department for Children, Schools and Families Consultation on ['Working Together to Safeguard Children Guidance'](#) (PDF, 30Kb)

### May 2010

[The General Medical Council Consultation on Revalidation: the Way Ahead](#) (PDF, 21Kb)

### June 2010

[The Department of Health Consultation on Proposed Regulations – Duty of Co-operation](#) (PDF, 156Kb)

[Department of Health Draft Code of Practice for Health and Adult Social Care on the Prevention and Control of Infections and Related Guidance – consultation response](#) (PDF, 22Kb)

### September 2010

Honest Broker Privacy Impact Assessment Consultation.

### October 2010

Ministry of Justice Call for Evidence on the Current Data Protection Legislative Framework

“Really appreciate your very detailed and considered reply and associated documents. I only wish I could be so prompt when people ask me questions, you set the bar high!”

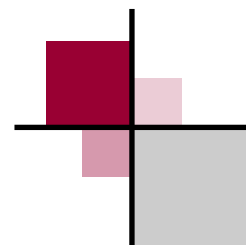
Information Governance Manager

**The NIGB Chair has spoken about information governance and the role of the NIGB at:**

- Demos Roundtable on Public Attitudes to the Use of Personal Medical Information, London.
- ‘Electronic Infrastructure for the Learning Healthcare System: the Road to Continuous improvement in Health and Health Care’, Institute of Medicine Workshop, Washington DC, USA.

**The NIGB Deputy Chair has spoken about information governance and the role of the NIGB at:**

- Intellect UK – Health and Social Care Group, London.



### **The ECC Chair has spoken about information governance and the role of the ECC at:**

- Information Governance: Enabling Research and Improving Quality of Patient Care Conference, London.
- Managing and Sharing Patient and Service User Identifiable Data; Confidentiality and Information Governance; Implementing the GMC and Care Quality Commission Recommendations in Health and Social Care – First and Second National Conference, London and Manchester.

### **NIGB Office staff have given presentations on information governance to:**

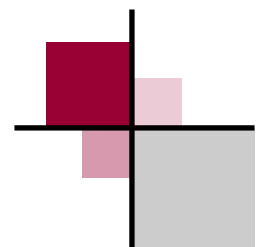
- Social Care Information Management Group, London Borough of Hillingdon;
- Information Sharing Workshop, Stockton University;
- South East Coast Information Sharing Workshop with Health and Social Care;
- Multi-agency Safeguarding Information Sharing Workshop - NIGB/PCC/Solent NHS;
- Social Care IMG London IG/Caldicott Guardian Subgroup;
- Bio-information Workshop, Sheffield University;
- NRES OnCore Training workshop- Ethical Principles for consent for tissue samples – London, Leeds and Manchester;
- BCS ISSG Seminar, 'Building information governance for personal health information';
- Capita NHS Data Sharing and IG Conference, Manchester;
- UK Biobank Ethics and Governance Council.

**“Your presentation was well received by our members, visitors and guests, it was extremely informative, and will have left those present with something to think about back in their workplace.”**

**Kim Bellis**  
National Chairman  
Institute of Health Records and Information Management

## *Annexe 1 - NIGB Terms of Reference*

- Provide leadership and promote consistent standards for information governance across health and social care, to enable ethical, legal and policy issues to be appropriately dealt with;
- Monitor information governance trends and issues through analysis of annual information governance returns from all bodies using or holding NHS or social care information;
- Arbitrate on the interpretation and application of information governance policy and give advice;
- Have oversight of and advise on the confidentiality management and access control frameworks implemented through the National Programme for IT;
- Own and review the NHS Care Record Guarantee and the Social Care Record Guarantee for England annually;
- Advise the Secretary of State on any matters of information governance that should be brought to their attention and to produce an annual report to the Secretary of State;
- Deal with other such matters as required by the Secretary of State and other appropriate bodies; and
- Work with appropriate bodies, including those in the home countries, on issues within its remit.



## *Annexe 2: ECC Terms of Reference*

The Ethics and Confidentiality Committee (ECC) is accountable to the National Information Governance Board for Health and Social Care (NIGB) and has delegated powers from the NIGB to:

- Undertake the responsibilities of the National Information Governance Board for Health and Social Care under section 251 of the NHS Act 2006 and section 33 D of the Human Fertilisation and Embryology Act 2008. These are to advise the Secretary of State on use of powers provided by section 251 of the NHS Act 2006, and the Human Fertilisation and Embryology Authority in relation to section 33D of the HFE Act 2008 and in particular on:
  - Applications and proposals for use of these powers;
  - Draft regulations made under section 251 of the Act;
  - Proposals to vary or revoke such regulations following the Secretary of State's required annual review of existing provisions; and
  - Inform the NIGB of the decisions it has taken.
  - Consider and advise on ethical issues referred to it by the NIGB and relating to the processing of health or social care information.
  - Bring to the attention of the NIGB any ethical issues which the ECC considers requires the Board's attention and which arise from the exercise of its functions under relevant Acts or otherwise.

The powers under section 251 of the NHS Act 2006 relate to health information in England and Wales. Powers under section 33 D of the Human Fertilization and Embryology Act 2008 relate to all four UK nations. The ECC will make regular reports to the NIGB and contribute to the NIGB Annual Report.

- The ECC will have 16 members.
- The ECC will be a quorum with 9 members including the Chair or Deputy Chair, or person designated Chair.
- The ECC currently meets bi-monthly, but will meet as necessary to deliver its functions.
- A Deputy Chair will be elected by the ECC.
- If the Chair is unavailable for a meeting then the Deputy Chair will act as Chair, or should the Deputy Chair be absent also the Chair will ask one of the members to act as Chair or, if necessary, the members present will agree one of their number to act as Chair for that meeting.
- Failure to attend three or more consecutive meetings without reasonable explanation may result in the removal of a member from the Committee by the NIGB.

## Annexe 3: NIGB Members

The NIGB was established to give assurance to service users and the public that their information is being shared and used appropriately. To emphasise this commitment to the public, more than half of the members of the NIGB who attend Board meetings are members of the public who have responded to a public recruitment campaign and been appointed by the Appointments Commission. The remaining members represent organisations which are stakeholders in information governance and have been invited to be represented on the Board.

### Chair



#### Harry Cayton

Harry Cayton OBE was appointed chair of the statutory NIGB by the Appointments Commission in 2008. He has been chief executive of the Council for Healthcare Regulatory Excellence (CHRE) since August 2007. He was formerly National Director for Patients and the Public at the Department of Health. From 1992 to 2003 he was chief executive of the Alzheimer's Society and from 1981-1992 Director of the National Deaf Children's Society. Harry was chair of the Care Record Development Board from 2004 until it closed in summer 2007 and also chaired a Ministerial Taskforce on the Summary Care Record in 2006. Harry is an advisor to both Macmillan Cancer Support and The Health Foundation and is a trustee of both Comic Relief and the Friends of Alzheimer's Disease International.

### Deputy Chair



#### Della Cannings

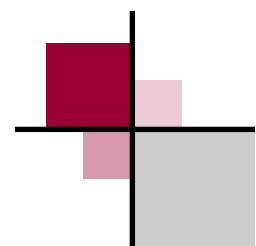
Della M Cannings QPM FRSA BSc MIOd is the Chairman of the Yorkshire Ambulance Service. Della was born in Exeter, Devon and is a graduate in Mathematical Studies from the University of Bath. Ms Cannings was Chief Constable of North Yorkshire Police 2002 – 2007. She currently undertakes consultancy work and is a trained assessor, and is also a keen gardener, traveller and photographer.

### Public Members



#### Edward Briffa

Edward Briffa is Head of Learning at BMJ Publishing and has a background in online medical education, online broadcasting and TV production.





### **Rodney Brooke**

Sir Rodney Brooke CBE DL is Chair of the Quality Assurance Agency for Higher Education and a former member of the General Medical Council. He was Chair of the General Social Care Council until October 2008. Rodney is a solicitor, a director of Capacitybuilders, a trustee of the Dolphin Square Charitable Foundation, the RNID, the Internet Watch Foundation and the Tavistock Institute. He has been Chief Executive of West Yorkshire County and Westminster City Councils and the Association of Metropolitan Authorities and Chair of the Bradford Health Authority.



### **Wayne Cleghorn**

Wayne Cleghorn, L.L.M., is a Solicitor and the Data Protection Officer for South Gloucestershire Council. He specialises in data protection, privacy, information law, information technology law and aspects of intellectual property law. He also has a professional interest in corporate governance, public law and human rights. His experience includes public and private sector legal services. He is a member of the British Computer Society.



### **Andrew Harris**

Dr Andrew Harris began his NHS career as a paediatrician, and has a wide range of NHS appointments including being a GP, medical director, Director of Clinical Governance, and Consultant in Public Health. Andrew was admitted as a barrister and more recently transferred to practice as a consulting solicitor with an interest in health law, on which he writes. He runs his own consultancy business, specialising in NHS governance, mediation and legal research. Andrew is also currently an Assistant Deputy Coroner for London Inner South. Andrew is the Chair of the Ethics and Confidentiality Committee.



### **Penny Hill**

Penny Hill is currently on secondment with the National Information Centre for Health and Social Care, supporting the work of the National Strategic Improving Information Programme for Social Care. This includes the development of information standards for social care, the revision of social care record guidance, and the co-ordination information developments across a range of policy initiatives, such as personalisation, common assessment, and closer integration with health. Her previous post was that of Information Strategy Manager for Social Care in Warwickshire. She has a wealth of experience in Information Governance and Information Management for Social Care, and has a particular interest in Information Sharing.



### **Nadeem Khan**

Dr Nadeem Khan is Divisional Manager/Associate Director (Research and Development) at UCLH Foundation Trust and is a trustee for a learning disabilities charity. He has previously worked in primary care (strategy and service development), as a consultant with the National Screening Committee (NSC) and in academia. Nadeem has led collaborative projects with neuropathology centres as part of Brain Net Europe and currently lectures in neurosciences at London University with continuing research interests in adult-onset dementias.



### **Hilary Newiss**

Hilary Newiss qualified as a solicitor and was a Partner in Denton Hall until 1999 specialising in intellectual property, including confidential information and data protection. She is a former member of the Human Genetics Commission, the Royal Society Working Party Report on Intellectual Property ("Open Science"), the Intellectual Property Advisory Committee and the Ethics and Governance Council of Biobank UK. She is currently a Trustee of the Roslin Foundation, a member of the Advisory panel on Public Sector Information and Deputy Chair of the Appeals Committee of the Human Fertilisation and Embryology Authority.



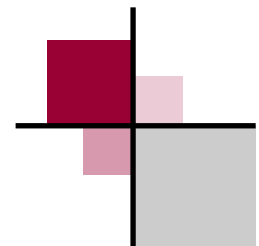
### **Sylvia Rothschild**

Rabbi Sylvia Rothschild took a degree in psychology at Manchester University and worked for a mental health charity in a therapeutic community, and for a London Borough in adult psychiatric care. She was ordained as a Rabbi in 1987 by the Leo Baeck College and has worked as a community Rabbi ever since. Rabbi Rothschild has continued her interest in medical and community ethics, sitting on a Research Ethics Committee and a local standards committee. She was Chair of the Assembly of Rabbis, and has edited and contributed to books and periodicals on subjects ranging from theology to prayer to ethical matters.



### **Michael Wilks**

Dr Michael Wilks is a forensic physician working in London. He worked as a GP in London between 1977 and 1992. He chaired the BMA's Medical Ethics Committee from 1997 to 2006, and its Representative Body from 2004 to 2007. He is currently President of the Standing Committee of European Doctors (CPME). He is Chairman of the Trustees of the Rehabilitation of Addicted Prisoners Trust (RAPt), a leading provider of addiction treatment in UK prisons.



## **Members Representing Organisations**



### **Allied Health Professions Federation - Gareth Beatty**

Gareth Beatty qualified as a Podiatrist in 1984 and has worked for the NHS ever since, in a range of posts from domestic porter and nursing auxiliary to his current role as the Clinical Governance facilitator at NHS Richmond. His first professional post was at Guy's Hospital before moving to NHS Richmond. He has been the accredited staff side representative for the Society of Chiropodists & Podiatrists, and is the chair for the Partnership Forum for Industrial Relations at NHS Richmond.



### **NHS Confederation - Frances Blunden**

Frances Blunden is senior policy manager at the NHS Confederation, leading work on informatics (including the National Programme for IT and information governance), regulation, and patient and public engagement. The NHS Confederation is the only independent membership body for the full range of organisations that make up today's NHS, representing over 95 per cent of NHS organisations and a number of independent healthcare providers. Frances has a background in policy and research in health and related areas, and was previously principal policy adviser on health issues at Which?.



### **British Medical Association - Tony Calland**

Dr Tony Calland is a retired general practitioner who worked on the Welsh border for 34 years. He has been a non executive director of Gwent Health Authority and also Chairman of three major BMA committees including currently the Medical Ethics committee. He was part of the BMA GP team which negotiated the new GP contract in 2003. He has an interest in information governance and is involved in these matters in England and in Wales.



### **Local Government Association - Andrew Cozens**

Andrew Cozens CBE is Strategic Adviser (Children, Adults and Health Services) for the Improvement and Development Agency for local government and a member of its Executive Leadership Team. In this role he advises central and local government and partner agencies in relation to children's services, adult social care, public health and local government's relationship with the NHS. He also is the LGA Group's Strategic Lead for Adult Social Care, managing the whole Group's activity in this area. He also oversees the Agency's work on culture and sport, and its relationship with the Centre for Public Scrutiny. Before joining IDeA in 2006, he spent ten years as director of social services in Gloucestershire and Leicester City. He also was Deputy Chief Executive for Leicester City Council from 2001-5. He was President of the Association of Directors of Social Services (ADSS) in 2003/4.



### **Academy of Medical Sciences - Carol Dezateux**

Professor Carol Dezateux is a clinical professor of paediatric epidemiology and directs the MRC Centre of Epidemiology for Child Health at the UCL Institute of Child Health, London. She is an honorary consultant paediatrician at Great Ormond Street Hospital for Sick Children NHS Trust. Her research addresses early life influences on child health and the effectiveness of clinical and public health strategies to improve the health and well-being of children and the adults they will become. Carol was elected Fellow of the Academy of Medical Sciences in 2006 and in 2010 was awarded a CBE for services to science.



### **Royal College of Nursing - Liz Fradd**

Elizabeth is an independent health service adviser and a fellow of the Royal College of Nursing. Until April 2004 she was the Nurse Director and lead Director for the Review and Inspection Programme in the Commission for Health Improvement (CHI). Prior to this appointment she was Assistant Chief Nurse in the Department of Health. Her current portfolio of work includes commissioned independent reviews, the delivery of innovative development programmes and the mentoring of senior personnel.



### **Academy of Medical Royal Colleges - Iona Heath**

Iona Heath worked as an inner city general practitioner at the Caversham Group Practice in Kentish Town in London from 1975 until 2010. She has been a nationally elected member of the Council of the Royal College of General Practitioners since 1989 and chaired the College's Committee on Medical Ethics from 1998 to 2004 and the International Committee from 2006 to 2009. She is currently President of the Royal College of General Practitioners having been elected for a three year term from November 2009. She has been a member of the WONCA (the world organisation of family doctors) world executive since 2007.



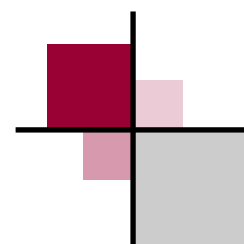
### **UK Council of Caldicott Guardians - Stephen Hinde**

Stephen is the Head of Information Governance and the Group Caldicott Guardian for the Bupa Group and is a member of the Board's Information Governance Executive Committee. Stephen is the past Chairman of the UK Council of Caldicott Guardians, and of the Data Protection Panel of the Association of British Insurers, Chairman of the Confidentiality Working Group of the Independent Healthcare Advisory Services, and Chairman of the Private Medical Insurance Companies Confidentiality Forum. Stephen also represents the Independent Sector on the NHS Scotland Information Governance Network.



### **Independent Healthcare Advisory Services - Sally Taber**

Sally Taber has worked in the independent sector for 20 years. She has been the Director of Nursing at the Independent London Bridge Hospital, and an advisor to the Royal College of Nursing. She originally qualified as a Registered General Nurse in London and is also a qualified midwife. After a period working abroad, she specialised in renal nursing and pioneered the role of transplant co-ordinator in the renal field. She became the Secretary of the European Dialysis and Transplant Nurses Association and is currently the Director of Independent Healthcare Advisory Services Ltd (IHAS).



## Corresponding Advisors



### **General Medical Council - Jane O'Brien**

Jane joined the GMC in 1990, becoming head of the Standards & Ethics team in 1995, and Assistant Director in the Standards & Fitness to Practise Directorate in 2006. Jane is responsible for the development of GMC policy and guidance on standards of professional conduct and medical ethics and she has worked on a number of publications for the GMC. Other key areas of focus include professional standards on consent, confidentiality and withholding and withdrawing life prolonging treatment.



### **Medical Protection Society - Nick Clements**

Dr Nick Clements has worked in the NHS for 10 years, first as a GP and then as a full time medical adviser to the Benefits Agency. Nick joined the Medical Protection Society as a Medicolegal Adviser in 1996, providing medicolegal advice and representation to the doctors from the Leeds office of MPS. He completed an LLB in 1998 and was granted Fellowship of the Faculty of Forensic and Legal Medicine of the Royal College of Physicians in 2008. Nick currently works as the Head of Medical Services (Leeds).



### **Strategic Health Authority Chief Information Officers Council - Graham Folmer**

Graham started his career in IM&T at the Queen's Medical Centre in Nottingham working for Trent RHA. He has a degree in Computer Studies and an MBA from Warwick University. He worked in the private sector for eight years before returning to the NHS. He was Director of Information and Performance Management at Addenbrookes Hospital, then Director of Programme and Service Delivery at the NHS Information Authority. Graham is now Chief Information Officer at East of England Strategic Health Authority (SHA), previously having this role for Norfolk, Suffolk and Cambridgeshire SHA.

\*The Strategic Health Authority CIO Council representative member since October 2010 is Tad Matus.



### **Ministry of Defence - Surgeon Rear Admiral Lionel Jarvis QHS**

Surgeon Rear Admiral Lionel Jarvis QHS is Assistant Chief of the Defence Staff (Health). He qualified in Medicine in 1977, thereafter joining the Royal Navy. He trained as a Radiologist, was accredited Consultant in 1990, appointed to RNH Haslar and promoted to Surgeon Commander. He was appointed Defence Consultant Adviser in Radiology 1995–2002 and was promoted to Surgeon Captain in 1999. He also served as an Executive Director of Portsmouth Hospitals NHS Trust. He was promoted to Surgeon Commodore in 2005, and was Director of Medical Policy in the Defence Medical Service Department in MOD. He was appointed Honorary Surgeon to Her Majesty the Queen in 2006.



### **Royal College of Midwives - Jeanne Tarrant**

Jeanne qualified as a nurse in 1990 and as a midwife in 1993. Jeanne worked at University College London Hospitals where she was talent spotted by the Royal College of Midwives. She was seconded to the RCM in 2001 as a part time trade union officer/professional advisor while still working at UCLH. In early 2008, Jeanne joined the RCM full time as a team manager for the North of England.

## Annexe 4 - ECC and DMsG Members

### Members of the Ethics and Confidentiality Committee

**Dr Andrew Harris**, ECC Chair, **Dr Tony Calland** and **Professor Carol Dezateux** are members of both the NIGB and the ECC and their biographies can be found in the previous section. The other members of the ECC are:



**Pauline Brown**

Pauline Brown is a senior member of Ashton, Leigh and Wigan PCT's Information Governance team. She is an advocate for the rights of individuals particularly to ensure the fair and lawful use of information. She has a longstanding interest in information law and human rights and is an active member of a number of local Information Governance and Freedom of Information Networks.



**Michael Catchpole**

Professor Michael Catchpole is a Consultant in Public Health Medicine and Deputy Director of the Centre for Infections of the Health Protection Agency. He is a member of the Advisory Forum of the European Centre for Disease Prevention and Control and chairs the Faculty of Public Health's Information and Intelligence Committee. He has an extensive record of managing national surveillance systems for infectious disease and of research in the areas of sexually transmitted infections, HIV and emerging response.



**Patrick Coyle**

Dr Patrick Coyle is a member of the Clinical Governance Support and Development Unit of the Welsh Assembly Government and was formerly Medical Director of the Glan-y-Mor NHS Trust and Bro Morgannwg NHS Trust and Consultant Surgeon at Neath General Hospital. Patrick was Chair of the Security and Confidentiality Advisory Group before it became the DMsG in April 08.



**Tricia Cresswell**

Dr Tricia Cresswell is a Consultant in Public Health Medicine, currently working for the Health Protection Agency and as Deputy Medical Director for the North East Strategic Health Authority. Previously she was Director of Public Health for County Durham PCT and Darlington PCT, and prior to that Associate Director of the North East Public Health Observatory, Director of Public Health in Newcastle and North Tyneside and a General Practitioner. She has managed and developed regional databases in relation to maternal and infant health.



**Fiona Douglas**

Dr Fiona Douglas is a Consultant in Clinical Genetics at the Institute of Human Genetics in Newcastle. She is co-author of the guidance document for the Joint Committee on Genetics about consent and confidentiality in clinical genetics. She is a member of the Northern and Yorkshire Research Ethics Committee.



**Stephanie Ellis**

Stephanie Ellis is currently Chair of Camden and Islington Community NHS Local Research Ethics Committee and a Special Adviser to Patient Concern ( a network of health campaigners) working in the areas of patient representation, ethics of consent and information provision.



### **Denis Pereira Gray**

Professor Sir Denis Pereira Gray worked for 38 years in NHS general practice. He was Director of the Postgraduate Medical School of the University of Exeter for 10 years and is a former Chairman of the Academy of Medical Royal Colleges. He has also chaired the Nuffield Trust and is currently President of the charity What About the Children?



### **Michael Hake**

Michael Hake is Director of Counterpoint Consulting Ltd. Until March 2005 he was a Director of Social Services, a role held for 14 years. He also had the corporate lead on information governance within his Council and was involved in extensive partnership working with the NHS. He is a Lay Member of the Information Tribunal and is an Independent Chair of a Safeguarding Adults Partnership Board in London. He served on the Healthcare Commission between 2003 and 2009 and the National Care Standards Commission between 2001 and 2004.



### **Ros Levenson**

Ros Levenson is an independent researcher in health and social care and has published widely on a range of health-related topics. She was formerly Director of the Greater London Association of Community Health Councils and has many years experience of working for the involvement of users and carers in the health service. From 1997-2007 she was a Non-executive Director of a NHS Trust and from 2004-2006 she was a member of the Health Professions Council. She currently serves as a member of the General Medical Council and is also a lay member of the National Commissioning Group.



### **Roy McClelland**

Professor Roy McClelland is Emeritus Professor of Mental Health, Queen's University and a consultant psychiatrist at Belfast City Hospital. He is Chairman of the Privacy Advisory Committee for Northern Ireland and former Chairman of the Royal College of Psychiatrist's Confidentiality Committee.



### **Susan Parroy**

Susan Parroy is a state registered physiotherapist and has worked as an independent project manager and researcher for 20 years. Sue has recently been working on self referral for patients and she was part of the team behind the DH self referral pilots of physiotherapy. Sue has been a local governor of a NHS trust, a member of a Medical Research Ethics Committee and is currently working on projects in the South West and Scotland.



### **Mark Taylor**

Dr Mark Taylor is a Lecturer in the School of Law and Assistant Director of Learning and Teaching for the Faculty of Social Sciences, at the University of Sheffield. He gained his PhD in 2004 for research into the legal and ethical issues raised by the acquisition and use of genetic information within the contractual context. A Fellow of the Salzburg Seminar (session 392) on 'Biotechnology: Ethical, Legal and Social Issues' he is joint Principal Investigator on an EU FP6 funded project considering privacy and research using genetic data.



### **Terence Wiseman**

Terence Wiseman is a retired accountant and company director. He is currently a member of Trent NHS Research Ethics Committee, an Ethicist member of the CJD Incidents Panel and sits on a number of local committees for NHS Lincolnshire and United Lincolnshire Hospitals Trust as a patient representative or lay member. He has been Chairman of Lincolnshire Research Ethics Committee, Vice-Chairman of Lincolnshire Community Health Council and a member of a number of national, regional and local committees.

## **Members of the Database Monitoring Subgroup (DMsG)**

**Dr Patrick Coyle**, DMsG Chair, **Terence Wiseman** and **Ros Levenson** are members of both the ECC and the DMsG and their biographies can be found in the section above. The other members of the DMsG are:



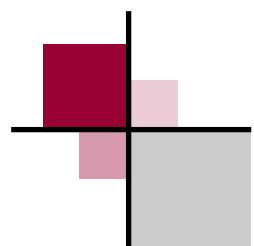
### **Manny Devaux**

Manny Devaux was formerly an Assistant Director of Social Services, a London Magistrate and member of South London Health Authority. In 1996 he was appointed by the Privy Council as a member of the General Medical Council and in 2002 became an Associate of the Council and has since chaired Fitness to Practice Panels. He has also served as an Adjudicator for the Criminal Injuries Compensation Appeals Panel. He is also a Hospital Manager for Cygnet Health Care Ltd and in the past has served as a trustee in three separate voluntary organisations in London and in Kent.



### **Ian Goodman**

Dr Ian Goodman qualified from Cambridge University 1982 and is senior partner in the Mountwood Surgery Practice, Northwood, Middlesex. He is Caldicott Guardian for Hillingdon PCT, GP IT advisor to Hillingdon PCT and has been involved with NHS IT projects since mid 1990s including for example, GP member of the RFA 99 project; GP representative on NHS Clearnet initiation project.



## ***Annexe 5: Summary of Applications considered by the Ethics and Confidentiality Committee October 2009 - October 2010***

Reference	Title	Applicant	Outcome	Comments
<b>PIAG 2-05 (b)/2007</b>	Secondary Uses Service	Department of Health	Partially approved	All activities within the SUS application, excluding commissioning Genito-Urinary Medicine (GUM) services
<b>ECC 6-06(a)/2009</b>	Evaluation of preterm images (ePrime).	Imperial College London	Approved with conditions	
<b>ECC 6-06(b)/2009</b>	Validation of risk assessments for patients from MSS (VoRAMSS)	University of Manchester	Approved with conditions	
<b>ECC 6-06(c)/2009</b>	Followup of First Episode Psychosis	East London NHS Foundation Trust	Approved with conditions	
<b>ECC 6-06(d)/2009</b>	Seascale Birth and Schools Cohorts	University of Southampton	Approved with conditions	
<b>ECC 6-06(e)/2009</b>	Population based study of cytogenetic & clinical factors in leukaemia	University of Newcastle	Approved	
<b>ECC 6-06(f)/2009</b>	Evaluation of the linked antenatal and newborn NHS Sickle Cell and Thalassaemia Screening Programme: outcomes of newborn screening	Kings College London	Approved after resubmission	
<b>ECC 6-06(g)/2009</b>	C difficile Life Table Study (CDLTS)	Health Protection Agency	Approved	Activity fell under the Health Service (Control of Patient Information) Regulations 2002
<b>ECC 6-06(h)/2009</b>	Epidemiology and long term outcome of Pulmonary Arterial Hypertension in the UK and Ireland 2000-2009	Scottish Pulmonary Vascular Unit	Declined	
<b>ECC 6-06(i)/2009</b>	The British Intestinal Failure Survey (BIFS)	Leeds Teaching Hospital NHS Trust	Declined	
<b>ECC 6-06(j)/2009</b>	Audit of the efficacy of screening colonoscopy in patients with a family history of Colorectal Cancer	Heatherwood and Wexham Park Hospitals NHS Trust	Approved with conditions	
<b>ECC 6-06(k)/2009</b>	Integrated self-care in family practices / Looking after Ourselves	Institute of Health Services Research	Declined	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 6-06(l)/2009</b>	An Evaluation of the Effectiveness of Different Treatment Pathways and Service Provisions for Adolescents with Eating Disorders	South London & Maudsley NHS Trust	Approved after resubmission	
<b>ECC 6-06(m)/2009</b>	MoD Access To PDS via Demographic Batch Service (DBS)	Ministry of Defence	Section 251 not required	Records required for a primary care purpose
<b>ECC 6-06(n)/2009</b>	Access to NN4B data for validation of birth details	West Midlands Perinatal Institute	Declined	
<b>ECC 6-06(o)/2009</b>	Cambridge Acute Stroke database	Cambridge University Hospitals NHS foundation Trust	Section 251 not required	Applicants directly employed in the relevant team on honorary clinical contracts
<b>ECC 6-06(q)/2009</b>	Comparison of culture tools with holistic evaluation of an organisation's culture	City University London	Declined	
<b>ECC 6-07 (FT1)/2009</b>	Evaluation of antenatal syphilis screening	University College London	Approved by fast track process	
<b>MR 1175</b>	Prospective study of Outcomes in sporadic versus Hereditary breast cancer (POSH)	Southampton University Hospital Trust	Approved	
<b>ECC 1-04 (a)/2010</b>	High dependency, high containment, difficult to manage psychiatric inpatients: finding solutions (HICON study)	City University	Approved with conditions	
<b>ECC 1-04(b)/2010</b>	Evaluating the age extension of the NHS Breast Screening Programme	University of Oxford	Approved	
<b>ECC 1-04(c)/2010</b>	The Epidemiology of Cycle Related Injuries	University of Leicester	Declined	
<b>ECC1-04(d)/2010</b>	Evaluation of functional capacity testing in cardiovascular patients	University of Essex	Approved after resubmission	
<b>ECC 1-05(a)/2010</b>	International Cancer Benchmarking Project	Department of Health	Approved	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 4-05(k)/2007</b>	Iron Deficiency Anemia	University of Birmingham	Declined after resubmission	
<b>ECC/BPSU 1-03 (FT1)/2010</b>	Surveillance of Gonorrhoea, Syphilis, Chlamydia, and Trichomonas infections in children aged under thirteen years presenting to secondary care	Norfolk and Norwich University Hospital	Approved by fast track process	
<b>ECC/BPSU 1-03 (FT2)/2010</b>	British Paediatric Surveillance Unit Study of Infants and Children who Develop a Chylothorax	University Hospitals Bristol NHS Foundation Trust	Approved by fast track process	
<b>ECC 2-03(b)/2010</b>	Honest Broker Pilot - Oesophago-Gastric Cancer Audit	The Information Centre for Health and Social Care (The NHS	Declined	
<b>ECC 2-03(c)/2010</b>	Honest Broker Pilot - Oral contraception	The Information Centre for Health and Social Care (The NHS	Declined	
<b>ECC 2-04(b)/2010</b>	Project Sutton	The Information Centre for Health and Social Care (The NHS IC)	Approved with conditions	
<b>ECC 2-04(c)/2010</b>	Central Register	The Information Centre for Health and Social Care (The NHS IC)	Approved with conditions	
<b>ECC 2-05(a)/2010</b>	Hospital Episode Statistics	The Information Centre for Health and Social Care (The NHS IC)	Approved with conditions	
<b>ECC 2-05(b)/2010</b>	Renal Dataset	The Information Centre for Health and Social Care (The NHS IC)	Declined	
<b>ECC 2-05(c)/2010</b>	Hip Fracture	The Information Centre for Health and Social Care (The NHS IC)	Approved	
<b>ECC 3-03(a)/2010</b>	Count Me In	Care Quality Commission	Approved after resubmission	
<b>ECC 3-04(a)/2010</b>	Childrens' Health and Well-being Data Linkage Project	Liverpool John Moores University	Approved after resubmission	
<b>ECC 3-04(c)/2010</b>	Teenage and Young Adult Cancer Survivor Study (TYACSS)	University of Birmingham	Approved with conditions	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 2-06(e)/2009</b>	Prospective analysis of bruising in children with and without inherited bleeding disorders.	Cardiff & Vale NHS Trust	Approved	
<b>ECC 1-06(c)/2009</b>	NCASP - 8 Month review	The Information Centre for Health and Social Care (The NHS IC)	Approved with conditions	
<b>ECC/BPSU 3-01 (FT1)/2010</b>	Glutaric Aciduria 1 Paediatric Surveillance Study	Great Ormond Street Hospital NHS Trust	Approved with conditions	
<b>ECC 3-02/2010 (FT2)</b>	Clinical Decision Making at the end of life qualitative study	University of York	Approved	
<b>ECC/HFEA 5-04 (a) /2010</b>	Childhood cancer after assisted reproduction	University College London	Approved with conditions	
<b>ECC/HFEA 5-04 (b) /2010</b>	Do hormonal treatments for assisted reproduction increase risks of cancer or mortality in women? A national cohort study	University College London	Approved with conditions	
<b>ECC 5-04 (c) /2010</b>	History of presentation of cervical cancer in young women in England	Kings College London	Declined	
<b>ECC 5-04 (d) /2010</b>	Retrospective Analysis of Acute Kidney Injury (AKI) at Nottingham University Hospitals	Nottingham University Hospitals NHS Trust	Approved with conditions	
<b>ECC 5-04 (e) /2010</b>	An investigation of genetic factors involved in predisposition to and pathogenesis of serrated polyps and cancers of the large bowel: The Predisposition to Serrated Neoplasia and Tumours (PRESENT) study	The Wellcome Trust Centre for Human Genetics	Approved with conditions	
<b>ECC 5-04 (f) /2010</b>	ProActive: Followup Study	University of Cambridge	Approved with conditions	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 5-04 (g) /2010</b>	Stroke Improvement National Audit Programme (SINAP)	The Information Centre for Health and Social Care (The NHS IC)	Approved with conditions	
<b>ECC 5-04 (h) /2010</b>	Aging with Down Syndrome and Intellectual Disability (ADSID) Research Database	University College London	Approved with conditions	
<b>ECC 5-04 (i) /2010</b>	Mortality and SUDEP rate in epilepsy patients undergoing VNS	King's College Hospital	Approved after resubmission	
<b>ECC 5-04 (j) /2010</b>	British Paediatric Neurosurgery Group (BPNG) Audit/HES analysis	National Cancer Services Analysis Team (NATCANSAT)	Declined	
<b>ECC 5-04 (k) /2010</b>	Child and Adolescent Psychiatric Surveillance System survey of Childhood-Onset Non-affective Psychosis in the United Kingdom and Republic of Ireland	University of Durham	Approved after resubmission	
<b>ECC 5-03 (a) /2010</b>	Advancing Quality - Calculation of Standardised Mortality Rates for Coronary Artery Bypass Graft patients	NHS Northwest	Approved after resubmission	
<b>5-03 (b) /2010</b>	Advancing Quality - Monitoring adherence to clinical process standards for AMI Patients	NHS Northwest	Approved after resubmission	
<b>ECC 5-03 (c) /2010</b>	Advancing Quality - Using Patient Reported Outcome Measures in the identification of trends and characteristics of quality health services	NHS Northwest	Approved after resubmission	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 4-01/2010 (FT1)</b>	Psychological impact and cost effectiveness of Chronic Granulomatous Disease	Newcastle University	Approved with conditions by fast track process	
<b>ECC 4-02/2010 (FT2)</b>	Defining dialysis withdrawal: a retrospective cohort study	King's College London	Approved by fast track process	
<b>ECC 6-02 (FT1)/2010</b>	Sepsis - Pathophysiological & Organisational Timing: SPOT(Light)	London School of Hygiene and Tropical Medicine	Approved with conditions by fast track process	
<b>ECC 6-02 (FT2)/2010</b>	Confidential Inquiry into premature deaths with people with learning disabilities	University of Bristol	Approved with conditions by fast track process	
<b>ECC 6-05(a)/2010</b>	Greater Manchester Drug related Deaths Early Warning Surveillance System	Greater Manchester Public Health Practice Unit	Declined	
<b>ECC 6-05 (b)/2010</b>	Abdominal Aortic Aneurysm Quality Improvement Programme	University of Bristol	Approved with conditions	
<b>ECC 6-05 (c)/2010</b>	International Study of Incident Cancer (ISICA) Breast Cancer & Diabetes	LASER Europe Ltd	Declined	
<b>ECC 6-05 (d)/2010</b>	East Midlands Patient Experience Survey (EMPES)	Nottinghamshire PCT	Approved	
<b>ECC 6-05 (e)/2010</b>	Cambridge Centre for Ageing and Neuroscience (Cam-CAN) study	University of Cambridge	Approved	
<b>ECC 6-05 (f)/2010</b>	A clinical, economic and operational evaluation of the pilot Women's Enhanced Medium Secure Services (WEMSS)	University of Manchester and Manchester Mental Health and Social Care Trust	Approved with conditions	
<b>ECC 6-05 (g)/2010</b>	Health Care Needs Assessment: Vulnerable Groups with Long Term Conditions	NHS Tower Hamlets	Declined	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 6-05 (h)/2010</b>	Improving the effectiveness of multidisciplinary team meetings (MDM's) for patients with chronic disease	University College London	Approved with conditions	
<b>ECC 6-05 (i)/2010</b>	A randomised stepped wedge trial comparing the effects of an integrated electronic "Track and Trigger" system and a paper-based "track and trigger" system	Oxford Radcliffe Hospitals Trust	Approved with conditions	
<b>ECC/BPSU 3-02 (FT1)</b>	British Paediatric Surveillance Unit Study of Infants and Children who Develop a Chylothorax	University Hospitals Bristol NHS Foundation Trust	Approved with conditions	
<b>ECC 7-02 (FT1)/2010</b>	Language used to convey doubt and certainty in radiology projects	University of Cumbria	Approved by fast track procedure	
<b>ECC 7-02 (FT2)/2010</b>	European Urban Health Indicators System Part Two (EUROURHIS 2): Urban Health Monitoring and Analysis to Inform Policy	University of Manchester	Approved with conditions by fast track procedure	
<b>ECC 7-02 (FT3)/2010</b>	Care in the last days of life: aspects of decision making	University of Nottingham	Approved via fast track procedure	
<b>ECC 7-02 (FT4)/2010</b>	Evaluating the needs of patients living with chronic cancer: interviews and survey development	University of Leeds	Approved with conditions by fast track procedure	
<b>MR1121</b>	UK Childhood Cancer Study	University of York	Approved	
<b>ECC 1-06(c)/2009</b>	NCASP 4 month review	The Information Centre for Health and Social Care (The NHS IC)	Approved with conditions	
<b>ECC 7-04(a)/2010</b>	Pilot HRSS (RCP) Overarching Application	Research Capability Programme	Approved with conditions	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 7-04(b)/2010</b>	Association of Public Health Observatories	Public Health Observatories	Declined , advised to submit under class support	Application for specific support
<b>ECC 7-04(c)/2010</b>	Commissioning Support for London	Camden PCT	Declined	
<b>ECC 7-04(d)/2010</b>	Stratify	NHS Redbridge	Declined	
<b>ECC 7-04(e)/2010</b>	Children's National Services Framework (NSF) Data Sets	Department of Health	Declined	
<b>ECC 7-04(f)/2010</b>	Improving Access to Psychological Therapies (IAPT) data set	Department of Health	Declined	
<b>ECC 7-04(g)/2010</b>	Tower Hamlets Bespoke Social Marketing Population Segmentation	Experian Public Sector	Declined	
<b>ECC 7-04(h)/2010</b>	Small Area Health Statistics Unit – Updated datasets/permission request	Imperial College	Pending	Waiting for clarification
<b>ECC 7-04(i)/2010</b>	Blood Stream Infections: Focus on Outcomes	North Bristol NHS Trust	Approved with conditions	
<b>ECC 7-04(j)/2010</b>	Long-term risks of paediatric fluoroscopic cardiology	Newcastle University	Pending	Waiting for clarification
<b>ECC 7-04 (k)/2010]</b>	Fenland Study - study of interaction between genetic and lifestyle factors in determining obesity and related metabolic disorders.	Medical Research Council	Approved with conditions	
<b>ECC 7-04 (l)/2010</b>	Factors associated with recurrence and length of survival following relapse in patients with neuroblastoma	Newcastle University	Declined	
<b>ECC 8-08 (FT1)/2010</b>	Emergency Stroke Calls: Obtaining Rapid Telephone Triage Phase 4A	University of Central Lancashire	Approved with conditions by fast track procedure	

Reference	Title	Applicant	Outcome	Comments
<b>ECC 8-02 (FT2)/2010</b>	Predicting Response to Chemotherapy in Malignant Melanoma: The role of DNA repair genes.	University of Leeds	Approved by fast track procedure	
<b>ECC 8-02 (FT3)/2010</b>	Census of care in hospitals	University of Sheffield	Approved with conditions by fast track procedure	
<b>ECC 8-02 (FT4) 2010</b>	Does adding a facilitated behaviour change intervention improve outcomes among people with recently diagnosed type 2 diabetes receiving intensive treatment in General Practice? The ADDITION Plus 5year follow-up study	Addenbrooke's Hospital	Declined	
<b>ECC 8-02 (FT5)/2010</b>	Southall And Brent REvisited. Ethnic differences in risks and outcomes of the cardiometabolic syndrome (SABRE STUDY)	Imperial College London	Declined	
<b>ECC 8-02 (FT6) /2010</b>	Caring for seriously ill older people on acute hospital wards	University of Nottingham	Declined	



## *Annexe 6: Summary of Applications considered by DMsG October 2009 - September 2010*

### **HES Applications**

Reference	Title	Applicant	Outcome	Comments
041109-6-a	HES extract to continue developing the methodology and test the efficiency of person record linkage of hospital episodes (HES extract data) and death registrations (ONS death extracts)	University of Oxford	Approved	
041109-6-b	Million Women Study	Cancer Research UK	Approved	
041109-6-c	Health Survey for England	National Centre for Social Research	Approved with conditions	
230210-5-a	Application for HES extract from Medtronic Vascular:	Medtronic Vascular, California	Declined	
230210-5-b	Investigate the impact of cancer waiting times on individual and long term outcomes	University of Leeds	Approved	
230210-5-c	Examination of the effect of data quality on conclusions regarding differences in death rates between trusts	St Georges University	Declined	
230210-5-d	Access to HES for the support of CQC functions.	Care Quality Commission	Approved	CQC have own statutory powers to receive information.
230210-5-e	Application for HES extract from the Cooperation and Competitions Panel	Cooperation and Competition Panel	Approved	
230210-5-f	Million Women Study	Oxford University	Approved	
070510-5-a	Application for HES extract from CMPO / Imperial College	Centre for Market and Public Organisation (CMPO)	Approved	
070510_5_b	HES extract for Kings Fund studies	Kings Fund	Approved	
070510-5-c	Exploring and explaining variation in activity rates of hospital consultants: generating and testing hypotheses about the determinants of consultant productivity in the English NHS	University of York	Approved	

Reference	Title	Applicant	Outcome	Comments
<b>070510-5-d</b>	1.Patient Times Analysis Application 2: Analysis of variations in Coronary Heart Disease (CHD) provision Application 3: Collection of data for use in the development of Cancer Service Guidance	Clatterbridge Centre for Oncology	Approved	Covered under existing s251 approval
<b>070510-5-e</b>	Access to HES for the support of CQC functions.	Care Quality Commission	Approved	CQC have own statutory powers to receive information.
<b>070510-5-f</b>	National Confidential Inquiry into Suicide and Homicide (NCISH)	Centre for Suicide Prevention	Approved	Covered by existing section 251 approval - PIAG 4-08(d)/2003
<b>070510-5-g</b>	Public Health Observatories Mental Health Minimum Dataset Extract request	North East Public Health Observatory	Approved	
<b>070510-5-h</b>	Public Health Observatories national HES extract	Public Health Observatories	Referred to ECC	Requesting identifiable data
<b>200710-5-a</b>	Application for Mental Health Minimum Dataset ("MHMDS") Extended Scope Use	Dr Foster Intelligence	Approved	
<b>200710-5-b</b>	Sudden unexplained death study	Centre for suicide prevention	Approved	Covered by existing s251 approval
	Collection of HES data for the BINOCAR register	National Perinatal Epidemiology Unit	Approved outside Committee	Covered under existing 251 approval
	Healthcare acquired infections	Health Protection Agency	Approved outside Committee	Covered under existing 251 approval
	Healthcare associated infections within Imperial college	Dr Foster	Approved outside Committee	
	SCOOP	University of East Anglia	Approved outside Committee	

## Annexe 6 continued...

### Central Register Applications

Reference	Title	Applicant	Outcome	Comments
MR1159	Ethnic differences in mortality from prostate cancer among Asian, White and African Caribbean people in East London area	St Bartholomew's Hospital	Approved	
MR1164	The Asymptomatic Carotid Surgery Trial (ACST-2)	St George's University	Approved	
MR1174	Adjuvant Urokinase in the treatment of Malignant Pleural Effusion.	Oxford Centre for Respiratory Medicine	Approved	
MR1176	Defining the risk of kidney function decline and cardiovascular disease among patients with chronic kidney disease stage 3.	Derby Hospitals NHS Foundation Trust	Approved	
MR1178	The Molecular Epidemiology of Lymphomas: The Epidemiology and Genetics Unit's Lymphoma Case-Control Study (ELCCS).	Epidemiology and Genetics Unit, University of York	Approved	
MR1179	INFANT study: A multicentre randomised controlled trial of an intelligent system to support decision making in the management of labour using the cardiotocogram.	University of Oxford	Approved	
MR1187	Post-Authorization Safety Study (PASS) of GlaxoSmithKline Biologicals. Pandemic influenza Vaccine (GSK2340272A) in the United Kingdom.	Medical Research Council	Approved	
MR1171	Getting out of the House study	University of Nottingham	Approved	
MR1168	IMPROVE aneurysm trial	Imperial College London	Approved	
MR1181	Phenotypic and genotypic characterisation of a COPD longitudinal cohort	Churchill Hospital	Approved	
MR1188	Optimisation of the Management of Stroke and TIA	University of Birmingham	Approved	
MR1189	Vertebral artery Ischaemia Stenting Trial (VIST)	St Georges University	Approved	
MR1201	Frequency of follow-up for patients with intermediate grade colorectal adenomas	Imperial College	Approved	Covered by existing section 251 application PIAG 1-05(e)/2006)

Reference	Title	Applicant	Outcome	Comments
MR1180	A comparative study of early and later onset Parkinson's disease	University Hospital Wales	Approved	
MR1182	Healthy Ageing in Twins Study (HATS)	St Thomas' Hospital	Approved	
MR1185	Does the presence of thrombophilia increase the risk of developing idiopathic pulmonary fibrosis?	Nottingham City Hospital	Approved	
MR1184	Screening for diabetes and intermediate hyperglycaemia in primary care (NewHype)	Newcastle University	Approved	
MR1193	Investigation of the effects of Interleukin 1-receptor antagonist (IL-1ra) on markers of inflammation in non-ST evaluation acute coronary syndromes. The MRC-ILA-Heart Study	Royal Brompton Hospital	Approved	
MR1196	The CHiP Trial	London School of Hygiene and Tropical Medicine	Approved with conditions	
MR1148	Markers of risk and myocardial injury in patients undergoing coronary angioplasty The OPERA study	British Heart Foundation Heart Research Centre	Approved with conditions	
MR1192	A randomised controlled trial of iodine supplementation in preterm infants (I2S2)	University of Oxford	Approved with conditions	
MR1202	BALTI-2: Beta Agonist Lung injury Trial 2		Approved	

