

NIGB Terms of Reference

 National Information Governance Board for Health and Social Care			
Title	NIGB Terms of Reference		
Document ID			
Director	Alan Doyle	Status	Approved
Owner	Alan Doyle	Version	1.0
Author	Karen Thomson	Version Date	22/09/2011

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Amendment History:

Version	Date	Amendment History
0/1	20/01/2011	Draft for comment
0/2	01/03/2011	Amended Draft
0/3	08/03/2011	Amended draft following comments from PW and GK
0/4	07/04/2011	Amended draft with further comments from KT
0/5	28/04/2011	Amended draft with new comments from KT
0/6	11/05/2011	Finalised draft following further comments from PW & GK
0/7	18/07/2011	Amended draft by ECC Chair for consideration by ECC
0/8	22/08/2011	Output from ECC Strategy day 22/08/11
0/9	22/09/2011	Considered by Board 22/09/11

Forecast Changes:

Anticipated Change	When

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NIGB		Board	22/09/11	1.0

Distribution: NIGB website.

Document Status: This is a controlled document.

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NIGB Terms of Reference

Related Documents:

These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
1		NHS Act 2006 s251	
2		Health and Social Care Act 2008 s157 and 158	
3		Human Fertilisation and Embryology Act 2008 s25	
4	SI 2008 No. 2558	National Information Governance Board for Health and Social Care Regulations 2008	
5	SI 2002 No. 1438	The Health Service (Control of patient information) regulations 2002	
6	SI 2010 No.995	The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010	

Glossary of Terms:

Term	Acronym	Definition
Ethics and Confidentiality Committee	ECC	The NIGB sub-committee responsible for the authorisation of patient identifiable data outside the care process.
Information		Information (however recorded) which relates to the physical or mental health or condition of an individual, to the diagnosis of their condition, care or treatment Information (however recorded) which is to any extent derived, directly or indirectly, from that information, whether or not the identity of the individual in question can be ascertained. Any other information generated delivering health and adult social care organisations.
Information Governance	IG	Information governance is the term used to describe the principles, processes, legal and ethical responsibilities for managing and handling information. It sets the requirements and standards that organisations need to achieve to ensure that information is handled legally, securely, efficiently and effectively.
National Information Governance Board	NIGB	Chair, 12 public members and representative members as agreed by the Secretary of State.
NIGB Office		The members of staff employed by the Department of Health Informatics Directorate that provide administrative support to the NIGB.
Secretary of State for Health	SS(H)	In legislation this can refer to the Secretary of State as an individual and any senior servant in the Department of Health
Sponsor		A designated person acting for and on behalf of the Secretary of State.

Contents

1	Background	5
2	Mandate	6
3	Scope of work of the NIGB	9
	3.1 Objectives	9
4	Ethics and Confidentiality Committee	11
	4.1 Scope	11
5	NIGB Office	13
6	Future of NIGB	14
7	NIGB Membership	15
	7.1 Members	15
	7.2 Chair	16
	7.3 Deputy Chair	16
	7.4 Observers	16
8	Proceedings	17
	8.1 Meetings	17
	8.2 Voting	17
	8.3 Ethics and Confidentiality Committee	17

1 Background

The NIGB was established as a statutory advisory committee to the Secretary of State for Health in November 2008.

The NIGB is an important part of the driver to deliver excellent standards in health and social care whilst maintaining the patient's right to privacy. This requires a careful balancing of public interests both to facilitate the effective use of patient and service user information to support and improve care and to protect public trust in the delivery of a confidential service. The NIGB must always take this in to account when considering its guidance. It must consider the law, policy, standards, patient's rights and the practical aspects of delivering health and social care.

The role of the NIGB is set out in legislation. Whilst the legislation sets out the scope of the NIGB it is not necessarily useful to use the legal definitions in day to day work. This document seeks to recast the legal framework in everyday language by providing Terms of Reference. In all cases the actions of the NIGB must be governed at all times by the mandate given in legislation.

The legislation refers to the Secretary of State throughout. In some cases this is enacted through the Departmental Sponsor on behalf of the Secretary of State.

2 Mandate



Overarching Objective:

The overall purpose of the NIGB is to improve information governance practice in health and social care in England.

Functions:

The functions of the Board are defined in the following legislation:

- Sections 250-252 of the NHS Act 2006 as amended by section 157 and section 158 of Health and Social Care Act 2008;
- National Information Governance Board for Health and Social Care Regulations 2008;
- The Health Service (Control of patient information) regulations 2002;
- Section 25 of the Human Fertilisation and Embryology Act 2008;
- The Human Fertilisation and Embryology (Disclosure for Research Purposes) regulations 2010.

The remit of the NIGB concerns the governance of information relating to the physical or mental health or condition of individuals. It includes information obtained or generated in the course of providing health services or exercising adult social service functions. We will do this through:

A) The general functions of the Board, which are to:

- Monitor the practice followed by those engaged in providing NHS and social care services in relation to the processing of this type of information;
- Keep the Secretary of State and such bodies as the Secretary of State may designate by direction, informed about the practice being followed by all NHS and Social Care providers in relation to the processing of this information;
- Publish guidance on the practice to be followed in relation to the processing of this information;
- Advise the Secretary of State on particular matters relating to the processing of this information by any organisation or person;
- Advise organisations or persons on matters relating to the processing of this information as the Secretary of State designates by direction.

These functions apply to NHS and Social Care organisations in England.

National Information Governance Board for Health and Social Care

B) Specific functions relating to Section 251 approvals:

The second set of functions relate to the advice provided to the Secretary of State regarding the Health Service (Control of patient information) regulations 2002. In particular, the NIGB provides advice in relation to Secretary of State approvals, under regulation 5 which enable the Secretary of State to set aside the common law duty of confidentiality, to enable the use of confidential patient information for medical purposes where anonymised information cannot be used and where consent is not practicable.

In relation to new regulations to be made under Section 251, the functions of the NIGB are to:

- Advise the Secretary of State by providing views on the proposed regulations¹;

In relation to the established regulations - Health Service (Control of patient information) regulations 2002, the NIGB does not have delegated authority from the Secretary of State. In practice, however, the NIGB, its Ethics and Confidentiality Committee (ECC) and the NIGB Office undertake the following functions in support of the Secretary of State:

- Maintain the register of activities approved by the Secretary of State (under regulation 6);
- Annually advise the Secretary of State whether, in NIGB's view, the regulations remain appropriate and necessary²;
- Advise the Secretary of State on whether the conditions of approval and restrictions and exemptions listed under regulation 7 are being complied with.

The ECC advises the Secretary of State through its recommendations both for approval and if the NIGB and ECC were of the view that there was a need to vary or revoke the regulations.

These functions apply to England and Wales.

¹ Section 252 of the NHS Act 2006 as amended by Section 158 of the Health and Social Care Act 2008

² Section 251(5) and paragraph 5 of regulations 2 and 3

C) Specific functions relation to Human Fertilisation and Embryology data

The third set of functions, relate to the arrangements for the regulation of human fertilisation and embryology related patient data for medical research in the UK. These functions derive from section 33D³ of the Human Fertilisation and Embryology Act 1990 (as amended by section 25 of the Human Fertilisation and Embryology Act 2008) and are set out in the Human Fertilisation and Embryology (Disclosure for Research Purposes) Regulations 2010.

Under regulation 5 of the above HFE regulations, the NIGB may provide advice and assistance to the HFEA in relation to the exercise of the HFEA's functions under the regulations or other matters relating to the processing of information under these regulations as requested by the HFEA. Regulation 6 permits the HFEA to authorise disclosure of HFE protected information for studies supported under the Health Service (Control of patient information) regulations. Thus enabling studies that require HFE protected information to be linked with other confidential patient information.

The legal authority under these provisions currently rests with the Human Fertilisation and Embryology Authority (HFEA). The regulations made provision for the HFEA to delegate the application process for use of these powers for medical research to the NIGB. The NIGB's role in relation to this work extends to Scotland and Northern Ireland as well as England and Wales and is undertaken on behalf of NIGB by the Ethics and Confidentiality Committee.

³ And section 45(1) to (3A) of the HFE Act 1990.

3 Scope of work of the NIGB

Whilst the mandate sets out the overall responsibilities for the NIGB, at an operational level the Board has delegated some its functions to its Ethics and Confidentiality Committee. This section therefore sets out functions that are the focus of the work of the Board itself and the next Chapter the functions which have been delegated to the Ethics and Confidentiality Committee. The NIGB oversees the work of the Committee and the Ethics and Confidentiality Committee is accountable to the Board.

The functions which are the particular focus of the work of the Board are the general functions, listed in the previous chapter namely to improve information governance practice in health and social care organisations in England by:

- Monitoring the practice followed by those engaged in providing NHS and social care services in relation to the processing of patient information (defined in legislation as information relating to the physical or mental health or condition of individuals, including information obtained or generated in the course of providing health services or exercising adult social service functions and hereafter referred to as patient and service user information);
- Keeping the Secretary of State and such bodies as the Secretary of State may designate by direction, informed about the practice being followed by all NHS and Social Care providers in relation to the processing of patient and service user information;
- Publishing guidance on the practice to be followed in relation to the processing of patient and service user information;
- Advising the Secretary of State on particular matters relating to the processing of patient and service user information by any organisation or person;
- Advising organisations or persons on matters relating to the processing of patient and service user information as the Secretary of State designates by direction.

3.1 Objectives

The key objectives which have been derived from these functions are to improve information governance practice within the NHS and adult social care. It will accomplish this by:

- Monitoring and reporting to the Department of Health on information governance practice followed by all bodies using or holding NHS or Social Care information
- Publishing guidance to promote higher standards of information governance across health and social care. This will ensure that ethical, legal and policy issues are considered appropriately. The Department of Health, health and social care organisations must follow where possible guidance issued by NIGB
- Providing advice to the Department of Health on information governance practice. This includes providing the views of the board on any proposed statutory instrument concerning the disclosure of patient identifiable data.
- Providing an annual report on its activities to the Secretary of State
- Publishing the NHS Care Record Guarantee for England and the Social Care Record Guarantee for England, including regular review and consultation
- Oversight of and advising on the confidentiality management and access control frameworks implemented through the NHS National Programme for IT as previously requested by the DH Director General for Informatics.

Information governance is defined by the Information Standards Board standard 1512 'Information Governance Framework' as 'the term used to describe the principles, processes, legal and ethical responsibilities for managing and handling information. It sets the requirements and standards that organisations need to achieve to ensure that information is handled legally, securely, efficiently and effectively'.

4 Ethics and Confidentiality Committee

4.1 Scope

The NIGB has established the Ethics and Confidentiality Committee (ECC) to:

- Advise the Secretary of State on whether to approve requests for the use of patient identifiable data for secondary purposes within England and Wales where criteria in the regulation are met (under regulation 5 of the Health Service Control of Patient Information regulations 2002).
- Review annually the regulations made under section 251, in light of the applications received and the information provided annually (under Regulation 2 (5) and 3 (5) of the Health Service Control of Patient Information regulations 2002). and to advise the NIGB about whether to make any recommendations to the Secretary of State about any need to vary or revoke the regulations
- Advise the HFEA on applications to use the powers set out in Human Fertilisation and Embryology (Disclosure for Research Purposes) Regulations 2010.
- Advise on ethical issues relating to the processing of health or social care information as referred to it by the NIGB

The NIGB retains accountability for the ECC. The NIGB shall approve an ECC terms of reference which follows the principles defined in this document. The ECC must act in all cases within its terms of reference and the boundaries set by law, Department of Health policy and NIGB guidance.

The NIGB Director shall be responsible for the operational running of the ECC. The Chair of the ECC shall be accountable to the NIGB for advice given by the Committee.

The ECC will make regular reports to the NIGB and contribute to the NIGB Annual Report to the Secretary of State.

4.2 Objectives

The key objectives are to:

- Advise the Secretary of State on whether to approve requests for support under regulation 5 of the Health Service (Control of patient information) regulations 2002
- Advise the Secretary of State in support of his Annual Review of the Regulations
- Consider issues relating to compliance with conditions of approval and the restrictions and exemptions under regulation 7 in order to advise the Secretary of State
- Ensure that the process by which the Secretary of State provides approvals is supported effectively;
- In consultation with members, review and amend the application process to streamline it;
- to implement a database which will provide a record of Committee opinion and advice to the Secretary of State and also function as the register of approvals;
- Continue to develop the relationship with the HFEA to ensure that the integrated approvals process works effectively;
- Work with the Department of Health in relation to the transfer of its advisory and administrative roles relating to approvals under regulation 5 relating to research to the new Research Regulator or other specified body⁴;
- Work with the Department of Health in relation to the transfer of its advisory and administrative roles relating to non-research activities needing support under section 251⁵;
- Reporting to the Board on key issues arising from the work of the Committee and contributing to the NIGB Annual Report.

⁴ Subject to Parliamentary approval of the Health and Social Care Bill

⁵ Subject to Parliamentary approval of the Health and Social Care Bill

5 NIGB Office



The NIGB shall be supported by a secretariat provided by the Department of Health Informatics Directorate (DHID). The NIGB Office will:

- Provide secretariat services to the board, committees and work groups;
- Promulgate NIGB approved guidance to the NHS and adult social care services;
- Follow a formal process of continuous service improvement to ensure value for money, efficiency and good customer service;
- Administer and advise users about the approvals under regulation 5 of the 2002 Regulations;
- To assemble information to support NIGB ECC advising the Secretary of State on whether the conditions of approval and restrictions and exemptions listed under regulation 7 are being complied with;
- Provide subject matter expertise in information governance within health and adult social care and develop web based resources to support this;
- Respond efficiently and effectively to information governance enquiries relating to the role of NIGB and its sub-groups, to guidance published by NIGB, and to matters which the Secretary of State has directed the NIGB should advise on;
- Liaise effectively with all Stakeholders to ensure that issues are raised with the Board in a timely manner and all guidance is produced in consultation with appropriate bodies.

The NIGB Office will be part of the DHID. Subject to resource constraints, it will have access to and draw upon DHID resources to accomplish the aims of the NIGB.

6 Future of NIGB

The Secretary of State has announced the abolition of the NIGB on 31 March 2013. The Health and Social Care Bill 2011 proposes that the Care Quality Commission (CQC) will retain responsibility for the following functions:

- Monitor the practice followed by those engaged in providing NHS and social care services in relation to the processing of information relating to the health of an individual and other information obtained or generated in the course of providing health services or exercising social service functions.
- Keep the NHS Commissioning Board and Monitor informed about the practice being followed by all NHS and social care providers in relation to the processing of this information.

In the Bill it is proposed that the CQC will be required to improve information governance practice in a similar way to the role currently fulfilled by NIGB. They will also be required to establish a National Information Governance Committee to advise on this until 31 March 2015.

The NIGB will plan for the transfer of its functions as documented, and as further clarification is provided by the Sponsor as the Bill progresses through Parliament. Once the Bill receives Royal Assent the NIGB and the NIGB Office will actively work to implement the proposals.

7 NIGB Membership

7.1 Members

- The NIGB shall consist between 15 and 34 members, each appointed by the Secretary of State. There will be 12 publically appointed members and a number of representative members at the discretion of the Secretary of State.
- Members may be disqualified from appointment to the NIGB if they have a criminal conviction within the last 5 years, bankruptcy restriction, has been dismissed⁶ from office or employment within the public sector or fails to attend meetings. If a member subsequently becomes disqualified they must notify the Sponsor in writing.
- Where the Sponsor⁷ refuses an application, no further application shall be made for 2 years from the original application date.
- The appointment to the NIGB shall specify the tenure. This shall not exceed 4 years. On expiry of the tenure the member will be eligible for reappointment however no member shall hold office for more than 6 years in total.
- Any member of the Board may submit their resignation from the Board by giving notice in writing to the Sponsor.
- Where the Sponsor is of the opinion that it is not in the interests of, or conducive to the good management of, the NIGB that the member should continue to hold office, the Sponsor may immediately remove the member from office by giving him notice in writing to that effect.
- If the member fails to attend three consecutive meetings of the Board, the Sponsor shall immediately remove the member from office unless satisfied that the absence was due to a reasonable cause and the member will be able to attend subsequent meetings.
- The Sponsor may suspend a member from office in certain cases defined in Law. They shall notify the member in writing. The period of suspension shall not exceed 6 months and can be reviewed.

⁶ Dismissal following disciplinary procedures. It would not include redundancy other than in the case of representative members whose role is ex-officio for their organisation.

⁷ A designated person acting for and on behalf of the Secretary of State.

7.2 Chair

The Secretary of State shall appoint the Chair who will also be a member. They are governed by the same constraints as defined in the member section above with the exception that the period as Chair will not exceed 4 years.

7.3 Deputy Chair

- The NIGB may by a majority vote of members elect a member to be the Deputy Chair.
- Where there is no member willing to act as Deputy Chair, the Sponsor may appoint a Deputy Chair who shall be a member of NIGB.
- The Deputy Chair shall perform the duties of the Chair for any period in which the Chair is unable to discharge their duties.
- They are governed by the same constraints as defined in the member section above with the exception that the period as Deputy Chair will not exceed 4 years.

7.4 Observers

The Board may invite a person to attend a meeting of the Board as an observer. An observer shall not have a right to vote at a meeting of the Board. Observers will include:

- Information Commissioner's Office;
- Information Standards Board for Health and Social Care;
- Department for Education;
- Representatives of devolved administrations.

8 Proceedings

8.1 Meetings

- The NIGB shall have at least four and no more than six formal meetings each year.
- NIGB can establish committees or work groups that contain nominees who are not members of the board. The NIGB can choose to delegate its functions to a committee, member or to staff.
- The proceedings of the formal meetings shall also be publicly available on the [NIGB website](#). Draft minutes shall be published within 3 weeks after the meeting.
- The NIGB shall follow the principles of openness and transparency in its proceedings. In general information will be proactively published on the [NIGB website](#).

8.2 Voting

- The quorum of the NIGB shall be at least half the membership of the Board.
- Members and observers shall declare any conflicts of interest when discussing an agenda item.
- Where members hold differing views on any matter which falls for decision, a majority vote shall be taken.
- Where there is no majority, the Chair shall have the casting vote.
- Where a vote is taken, the minutes of the meeting shall record the number of votes in favour and the numbers of votes against the decision.

8.3 Ethics and Confidentiality Committee

The ECC will follow the principles established for proceedings of the NIGB in all respects except for the following:

- The ECC will have 16 members.
- The ECC will be in 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 nominated and if necessary elected by the ECC.
- If the Chair is unavailable for a meeting then the Deputy Chair will act as Chair, or should both be absent, the Chair will ask one of the members to act

NIGB Terms of Reference

as Chair or, if necessary, the members present will agree on a member 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.