



Department
of Health

Consultation on the roles and functions of the National Data Guardian for Health and Care

Prepared by the Department of Health

September 2015

Foreword



Since my appointment as Secretary of State for Health, it has become increasingly apparent that data and information are at the heart of achieving the Government's ambitions for the health and social care system.

New technology and innovative approaches to the delivery of health and care have driven rapid progress, resulting in more people surviving the devastating effects of life-threatening and debilitating illnesses. This technological revolution has benefited individuals, their families, friends and the country at large. But it would not have happened without a step change in the quantity and quality of health and care data and information usage. Our ambition for health and care – to deliver ever more effective and efficient services and to support the most powerful patients in the world – requires that we move even faster on the delivery of digital solutions and the use of data to improve lives. This carries with it the same challenges to health and care data as we see in every aspect of our digital lives: to ensure that the public trusts those organisations that hold their personal confidential data.

Equally, the public must be confident that there is an authoritative independent voice to fearlessly represent their interests and to speak out where improvement is needed. That is why, last year, I asked Dame Fiona Caldicott to become the first ever National Data Guardian for Health and Care, tasked with acting as the public's champion: scrutinising and challenging those that hold our data, to ensure that they protect it and use it appropriately and safely. Because of her established expertise and credibility, Dame Fiona has already begun to make a positive impact across the health and care system.

My pledge to place this role on a statutory footing at the earliest opportunity confirms the Government's commitment to the long term future of the National Data Guardian.

Everyone – whether professionals, managers, politicians, voluntary organisations – has a part to play in ensuring that the unique and valuable information that the health and care system holds in trust, is used to improve services and benefit the whole country. But they must also demonstrate to the people who trust them with their personal data that they can protect and care for it. The National Data Guardian will be vital in holding us all to account.

Jeremy Hunt

Secretary of State for Health, September 2015

Introduction

1. This consultation seeks views on the roles and functions of the statutory National Data Guardian for Health and Care (the National Data Guardian), and is the starting point for identifying the key principles that should define the role. Our analysis of the responses will form part of the basis for developing the more detailed proposals for establishing the National Data Guardian role on a statutory footing. The Government will consult further on the detail of any legislation and, at that stage, will include a full Impact Assessment.

2. Data and information have driven many of the advances in health and care over the past few decades. Medical research relies on people's health data to develop new medicines and treatments to transform and save people's lives. Therefore, the Government is committed to do all it can to encourage people to allow their data and information to be used to help realise the opportunities for further progress. There is a need to continue to build on the public's confidence in how data about individuals is used and safeguarded.

3. The role was established in November 2014 to act as the independent patient and service user voice on how data from the health and care sectors are used. The National Data Guardian will help to ensure that personal confidential data is held and used to support better outcomes from health and care services, at the same time providing confidence that there are robust safeguards in place to protect people's information. This public consultation was a commitment of the previous Government, and has been reaffirmed by the new Government. The consultation is divided into a number of distinct sections to facilitate participation and engagement.

- **Section 1** provides the rationale for establishing the National Data Guardian.
- **Section 2** sets out the Government's proposals for the statutory powers of the National Data Guardian.
- **Section 3** explains the distinct role and functions of the National Data Guardian and their relationship to those of existing organisations with responsibilities for data and information.
- **Section 4** includes proposals as to how the National Data Guardian might relate to organisations which are not formally part of the health and care system but might wish to use personal confidential data for health and care purposes.
- **Section 5** considers the impact of the proposals on equality and the burden of regulation.

Three Annexes contain summary and background information:

Annex A: Summary of consultation proposals.

Annex B: Guidance on how to make any comments on the consultation process.

Annex C: Details of how to respond and by when.

Section 1: The purpose of the National Data Guardian for Health and Care role

The need for a National Data Guardian for Health and Care

1.1 Health and care data and information are increasingly central to the health and care system. Safe, effective and efficient services that are integrated around the needs of individuals and communities and which meet the expectations of a digitally literate society will depend on information – including personal and confidential information – to understand the needs of individuals, target packages of care on the most needy, understand the cost and impact of services and monitor the health of communities. It will only be possible to provide these services if the right information is available; and people will only allow their information to be used if they trust those who hold and use it to do so safely and with their interests at heart. This means that those who have a responsibility for providing and commissioning care will need to have in place strong and robust systems for capturing, holding and managing information.

1.2 Central to achieving that trust will be the existence of a strong and independent voice to speak up for those whose data is needed and to challenge those who need to use it. The Government intends that the National Data Guardian will provide that strong and independent voice: established in law and able to speak up and challenge openly.

1.3 The establishment of the National Data Guardian is a central element in a wider programme of work aimed at maintaining public trust. This is being taken forward under National Information Board Workstream 4, established following the publication in November 2014 of the National Information Board Framework, *'Personalised Health and Care 2020'*. The establishment of the National Data Guardian, with other activity under the oversight of this Workstream, including the development and implementation of a preference model and enhancements to cyber and information security, provides a coherent framework for the way that individuals' information will be looked after in the future.

The current role of the National Data Guardian for Health and Care

1.4 Dame Fiona Caldicott was appointed as the first National Data Guardian in November 2014. Dame Fiona is widely acknowledged as a leading figure in the use and protection of health and care data. In 2012, following a commission from the Secretary of State, she undertook a review of Information Governance in the health and care system. Her report, *'Information: to Share or not to Share? The Information Governance Review'* was published in April 2013 and, in October 2013, the Government accepted the findings of the review. Dame

Fiona has, since October 2013, been supported by the Independent Information Governance Oversight Panel, which will be superseded by a group supporting her enhanced role.

1.5 In establishing the National Data Guardian, the Government built on the existing functions of Dame Fiona and her Independent Panel (including providing advice and challenge to the health and care system on information governance issues and providing updates and reports to the Secretary of State) and gave her new functions:

- The power to refer an issue that warrants formal investigation to bodies with responsibility for ensuring that health and care organisations are operating effective data sharing procedures. These include the Information Commissioner's Office, the Care Quality Commission, the NHS Trust Development Authority and Monitor;
- The ability to scrutinise and challenge the Department of Health and its arm's length bodies on information governance issues;
- At the request of the Secretary of State, to work with health and care organisations on particularly complex or novel Information Governance issues, including advising on whether the approaches they adopt on these matters, adequately protect and safeguard people's health and care data, wherever it is held.

1.6 One impact of this enhanced role is the decision by the Secretary of State that data will not be extracted as part of the care.data programme until the National Data Guardian has advised him that she is satisfied with the programme's proposals and safeguards.

Why is placing the National Data Guardian for Health and Care on a statutory footing necessary?

1.7 Despite the current lack of a legislative foundation, the National Data Guardian and the Independent Information Governance Oversight Panel are already making progress towards being seen as an effective and authoritative voice in the field of information governance. They have helped to ensure that data and information is increasingly shared in a way that allows the health and care system to have access to the information it requires to improve outcomes for people, while protecting against its inappropriate use.

1.8 However, it is important that the Government secures and enhances the impact of the role as a powerful and independent voice on the long-term use of health and care data.

1.9 By establishing the National Data Guardian in law, the Government will send a clear message that the concerns and views of the public will be heard and reflected back to health and care organisations. It also provides a means by which the National Data Guardian function will be embedded into the work of the health and care system and sustained in future years. Whilst the National Data Guardian will seek to influence and encourage positive change, it is important to put beyond doubt that the role will not simply be to lobby for change but to hold individuals and organisations to account for how they use and share people's data.

1.10 The legislation will also provide an opportunity to require those holding and using health and care data to act upon the views and advice of the National Data Guardian. This is an

important balancing provision which will ensure not only that the National Data Guardian will be able to challenge, but that those who are being challenged must respond and take action.

1.11 The Government will place the National Data Guardian role on a statutory footing at the earliest opportunity and will provide an update on progress as part of its response to this consultation, early in 2016.

Section 2: Proposed roles and functions of the National Data Guardian for Health and Care

The remit of the National Data Guardian for Health and Care

2.1 The remit of the National Data Guardian concerns health and care data generated within the health and care system in England. In preparing this consultation the Government has considered how to define the organisations that will fall within the National Data Guardian's overview, which it can comment on, provide advice to and challenge about its use of health and care data. The Government's view is that the remit for the National Data Guardian should follow the health and care data generated within the health and care system, recognising that there are organisations outside of the health and care sector that need to use health and care data collected within the health and care system, for example academic institutions carrying out research.

(1) The Government proposes that: the remit of the National Data Guardian role should follow the health and care data.

2.2 Children's social care is governed by a different legislative framework from adult social care and has not traditionally been in scope of the arrangements made for health and care services for adults; for example, there are separate arrangements for inspecting and regulating children's social care services; and the interests of children and young people are overseen and protected by the Children's Commissioner for England.

Therefore, before concluding what the National Data Guardian role might be in relation to children's social care, officials will work to understand better the risks and benefits of extending the National Data Guardian remit to children's social care. This will include consideration of whether it would be appropriate for the National Data Guardian to have any role in relation to individual child care cases and the National Data Guardian's role at the interface between children's services and health services.

(2) The Government is seeking your views on:

What are the key factors and issues that need to be considered when determining whether children's social care should be part of the National Data Guardian remit and where the National Data Guardian could make a positive contribution to care services for children and young people?

The remit of the National Data Guardian includes the ability to comment and challenge where the protection of people's data is compromised as a result of failure to adequately comply with required standards of information and cyber security. This would extend to any powers that are agreed in respect of making a referral to a regulator or to applying sanctions.

Formal advice giving powers for the National Data Guardian for Health and Care

2.3 The National Data Guardian's role will apply to England only. In cases where health and care data is sent to an organisation outside England (including outside the UK) the National Data Guardian's role would be to make certain that the sending organisation in England has taken all necessary steps to ensure that the receiving organisation has robust arrangements in place. Where the National Data Guardian believes they did not do this, depending on the nature of the breach and where the data is sent to, the National Data Guardian will consider what referral options might be available to hold the sending organisation to account and to protect the data which was sent. Where health and care data is sent to England from elsewhere, then the National Data Guardian remit will naturally extend to its handling and use in England.

2.4 At the time the National Data Guardian was established, it was agreed that the role – once on a statutory footing – should have formal advice-giving powers. The National Data Guardian already has these powers informally. Formalising them through legislation will define precisely to which organisations and individuals the National Data Guardian's advice should apply.

2.5 The National Data Guardian's informal advisory powers have been applied to Government and national health and care organisations. These powers will be formalised so that the National Data Guardian will continue to provide advice to national bodies.

2.6 It is important that there is coherence between the National Data Guardian's role and functions and those of other regulators in the health and care system. For example, the National Data Guardian might formally advise the Care Quality Commission on the way that it assesses the quality of an organisation's compliance with good information governance practices. This consultation therefore seeks views on the following proposals and comments on how the proposals might be implemented.

The Government proposes that:

- (3) The National Data Guardian should be able to provide advice to all organisations that hold health and care data which could be used to identify individuals.**
- (4) Any regulators with a responsibility for overseeing organisations which routinely hold, use and share health and care data, should consult the National Data Guardian on the criteria they use to assess an organisation's use of data.**

Duties on recipients to act on formal advice from the National Data Guardian for Health and Care

2.7 Clearly, where the National Data Guardian is being provided with formal advice giving powers, it is important that those organisations to which that advice is addressed are required to act upon it. Therefore, the legislation that establishes the National Data Guardian will include a requirement for organisations to consider and act upon that advice.

2.8 The public needs to be confident that an organisation that has been advised by the National Data Guardian takes action to address the advice. Transparency – of the advice given and the response made – will be key to this. To achieve this, organisations which hold and use or share personal confidential data who have been given advice from the National Data Guardian will be required to publish details of how they have responded to advice from the National Data Guardian annually. This can either be as part of a wider publication such as an Annual Report or as a stand-alone document. Where possible these reporting requirements will be integrated into existing reporting processes to minimise any additional bureaucratic burden on organisations.

2.9 In addition, there should be a parallel responsibility on the National Data Guardian to publish an Annual Report, which will both consolidate the formal advice that the National Data Guardian has provided in that year and provide an overview of responses.

The Government proposes that:

- (5) Organisations holding health and care data which could be used to identify individuals should be required to publish all materials demonstrating how they have responded to advice from the National Data Guardian.**
- (6) The National Data Guardian should be required to publish an annual report which should include a report of all the advice provided in the relevant year and an overview of how the relevant organisations responded to it.**

2.10 When Dame Fiona Caldicott was appointed as the first National Data Guardian, a commitment was made that she would be able to speak out in an independent and unfettered manner. To enable that commitment to be upheld, the National Data Guardian will be free to publish any advice given at the time that advice is made, and to require recipients of that advice to publish a report of how they have responded, at a time that will be determined by the National Data Guardian. The requirement to publish an annual report should not in any way be taken as fettering the ability of the National Data Guardian to immediately make advice public.

Reference mechanisms to the CQC and the Information Commissioner's Office

2.11 From the time of establishing the role, the National Data Guardian has needed to work closely with a range of individuals and organisations. The relationship with the Care Quality

Commission (CQC) and with the Information Commissioner's Office (ICO) are especially important.

2.12 The ICO has a statutory responsibility to seek compliance with the provisions of the Data Protection Act and to take action as needed where breaches are identified.

2.13 The CQC is the regulator of the quality of care across health and care. All providers of health and care services (except those providing solely children's social care) are required to register with the CQC and are thereafter obliged to adhere to the standards it sets. Information Governance is one of the key lines of enquiry it uses to review organisations.

2.14 The CQC and ICO have agreed that they will take referrals from the National Data Guardian (including in the period before the function is placed on a statutory footing) in relation to data and information issues and consider whether they should take action under their powers. In the future, such a referral could also arise where the National Data Guardian is concerned that an organisation has failed to comply with relevant information or cyber security principles or requirements.

2.15 The approach described here ensures that where the organisation involved is registered with the CQC, or the breach identified is within the remit of the ICO, the National Data Guardian is able to rely on their powers and sanctions in bringing the organisation back into compliance, including the application of sanctions where deemed appropriate. These existing sanctions and powers include the ability to withhold or place conditions on an organisation's registration and also the levying of fines.

2.16 The CQC acts on a wide range of information, including referrals from the Parliamentary and Health Services Ombudsman, Monitor, the NHS Trust Development Authority, NHS England, the General Medical Council, the Nursing and Midwifery Council and the Allied Health Professions Council. The CQC agrees with those organisations how it will take account of the information it receives from them, through Memoranda of Understanding (which also addresses the reciprocal sharing of data). The relationship between the CQC and the ICO (and, as necessary, other organisations) and the National Data Guardian should be governed by a similar Memorandum of Understanding.

The Government proposes that:

- (7) The referral role of the National Data Guardian with the CQC and ICO should be set out in a Memorandum of Understanding.**

Formal reference mechanisms to regulators of professionals working with health and care data

2.17 The National Data Guardian will inevitably focus largely on how health and care organisations use and share data. However, individuals working in the health and care system will need support and guidance on how to use and share data effectively and safely. The National Data Guardian will therefore on occasion need to advise individual professionals on breaches of data and information legislation and on established professional practice. It is

important therefore that there is a relationship between the National Data Guardian and those organisations responsible for registering and regulating health and care professionals.

2.18 To reflect this, the National Data Guardian should have a power to refer actions by an individual professional to the appropriate regulator or the employing organisation.

2.19 This arrangement will also provide a mechanism by which the National Data Guardian will be able to provide to the professional regulators more generic and formal advice on information issues. For example, where the National Data Guardian has concerns about the practices of a group of professionals, or of all the professionals working in a single organisation or a specific setting, it will be possible to work with the relevant professional regulator to address the issues.

The Government proposes that:

(8) The National Data Guardian should have power to refer actions by an individual to the appropriate regulator for the profession concerned.

(9) Please also provide any other comments on how the National Data Guardian might advise and challenge professionals working outside the regulated professions or organisations.

National Data Guardian for Health and Care powers to apply sanctions

2.20 Where concerns in relation to data use and security are identified by the National Data Guardian, enforcement action to address these issues, or to impose additional sanctions such as the levying of fines or the application of conditions associated with the organisation or individual's registration will be through existing regulatory mechanisms.

2.21 The existing regulators have powers to sanction organisations. The Government considers that, rather than setting up additional or potentially parallel or conflicting processes which would require new legislation, the National Data Guardian should be able to rely on existing regulators' powers to apply sanctions and fines, in particular the Care Quality Commission (CQC) and Information Commissioner's Office (ICO), as outlined elsewhere in this document.

Therefore, the Government is seeking views on:

(10) How the National Data Guardian and regulators can maximise the appropriate use of existing sanctions and fines.

Location of the National Data Guardian for Health and Care

2.22 The National Data Guardian is currently hosted by the HSCIC but a longer term solution to the location of the National Data Guardian will be needed as part of placing the role on a statutory footing. Possible options might include establishing the role as an Advisory Non-Departmental Public Body, creating a new Arms Length Body or embedding the function within an existing ALB.

The Government is therefore:

- (11) Seeking views on the most suitable long-term location for the National Data Guardian.**

Engagement with the Public

2.23 A key element of the National Data Guardian's role will be to seek, understand and represent the views of patients, service users and the public so that their concerns are reflected to those holding and using personal confidential data. The National Data Guardian and the structures put in place to support the role will wish to develop an operating model and process for ensuring that it can represent this wide range of voices and views most effectively. This will include developing relationships with patient representative organisations in the voluntary sector, with local Healthwatch and Healthwatch England. One way of demonstrating this engagement is for the National Data Guardian to reflect in the Annual Report how the patient, service user and public voice have been understood and how it has impacted upon and influenced the work of the National Data Guardian.

The Government proposes that:

- (12) The National Data Guardian's annual report should include a section demonstrating how the National Data Guardian has sought and gathered the views of the public and how those views will inform work in the future.**

Section 3. The National Data Guardian for Health and Care and the Information Commissioner's Office (ICO)

3.1 As indicated already in this consultation document, the National Data Guardian will need to maintain and build a set of relationships with a broad range of organisations in order to fulfil its role. However, prominent among these is how the National Data Guardian will complement the ICO existing statutory responsibilities on data and information, and be able to work effectively with that organisation and articulate their distinct but complementary functions.

3.2 The ICO is responsible for ensuring that organisations and individuals comply with legislation in relation to access, use and sharing of data. This section explores the relationship that the National Data Guardian will have with the ICO. The ICO ensures compliance with the provisions of the Data Protection Act and has powers to sanction those organisations and individuals who are in breach of the Act.

3.3 The National Data Guardian will need to have a strong relationship with the ICO that reflects their similar focus on data issues, yet recognises their distinct roles.

3.4 The ICO has a statutory remit in respect of compliance with the Data Protection Act in relation to **all** data, including health and care data. The National Data Guardian's role is solely focused on health and care data and, whilst compliance with legislation will be considered, the remit differs from that of the ICO in a number of ways:

- The National Data Guardian will take an overview of the complete legislative framework in relation to information use and sharing (for example, the provisions of the 2012 Health and Social Care Act and the 2006 NHS Act), not just the Data Protection Act;
- As well as reflecting on compliance issues, the National Data Guardian will be able to address issues of practice, governance, leadership and culture;
- Following this consultation, the National Data Guardian may have limited powers to apply sanctions directly, but will otherwise work closely with the regulatory organisations that can already do so. A substantial element of the role of the National Data Guardian will be to improve practice and help develop the right culture of security and trust.

3.5 The National Data Guardian will refer to the ICO any potential breaches or a need for clarification of the Data Protection Act under the proposed memorandum of understanding.

3.6 The National Data Guardian and the ICO will work closely to ensure that together they promote the need for appropriate use of data by health and care organisations.

Section 4. Organisations outside the health and care sector

4.1 The establishment of the National Data Guardian for Health and Care provides a real opportunity to help increase public confidence in how their health and care data are being accessed, used, and shared, wherever they are used. In addition to this, other new safeguards for the use of health and care data have been put in place. These include:

- Provisions in the 2014 Care Act which require that personal confidential data collected within the health and care sectors by the Health and Social Care Information Centre (HSCIC) must only be used for health and care purposes and for health promotion;
- In the same Act, a requirement that, in releasing data to external organisations, the Health and Social Care Information Centre (HSCIC) must seek the advice of the independent Confidentiality Advisory Group (CAG) and have regard to that advice. The 2014 Act also provides a power for the Secretary of State to set out what issues the CAG must consider in providing their advice;
- The HSCIC has established new arrangements to provide it with advice on releases of data to external organisations. The HSCIC has also established a principle of transparency, so that it reports publicly on every release of data it makes.

4.2 The relationship of the National Data Guardian to those new arrangements will be clarified as the legislation and structures are implemented. However there will need to be clear and transparent processes for the referral of issues to, and the sharing of information with, CAG and the HSCIC's independent advisory committee, in line with those put in place for relations with the ICO and other organisations.

The Government proposes that:

- (13) The National Data Guardian, CAG and the HSCIC should agree and publish a Memorandum of Understanding that sets out the National Data Guardian remit in relation to the additional safeguards that are being put in place as described at para 4.2.**

4.3 The National Data Guardian will also need to develop an approach to working with the regulators of organisations that are outside of the health and care sector, which are not regulated by the Health Research Authority (which the CAG advises in relation to consent for research) and which have access to personal confidential data. Because of the new safeguards put in place by the 2014 Care Act, these organisations can only have data to improve health and care (i.e. not solely for commercial purposes) but may nonetheless be commercial companies. It is important that the National Data Guardian is able to engage with regulators and governance mechanisms outside the health and care sector and agree a way of working together.

The Government proposes that:

(14) The National Data Guardian should engage with the relevant regulators of organisations outside the health and care system to ensure that they understand their obligations and responsibilities in relation to the health and care data to which they have access.

Section 5. Equality and regulatory impact

Equality Issues

5.1 The Government believes that the overall impact of the proposals in this consultation will either be neutral or positive in relation to the provisions of the 2010 Equality Act.

5.2 With improved practice in data use that will result from the activities of the National Data Guardian for Health and Care, there will be more opportunities to use data and information to improve services for everyone. The resultant improvement in integration of services and the ability to target services at the most needy will help to improve outcomes for those with the highest level of health need and thereby help to reduce health inequalities. The impact on other protected characteristics will be either positive or neutral.

5.3 The Government, when analysing responses to the consultation, will consider how its final proposals address and promote the importance of its Equality duty and commitment to reducing health inequalities.

(15) Do you have any comments or views on the potential impact that these proposals have on equality between different groups and health inequalities?

Administrative and financial burdens

5.4 The government recognises that these proposals will potentially add a small additional burden to those organisations that are formally required to respond to advice given by the National Data Guardian. However, this will be largely limited to organisations that are adopting practices which are not consistent with their duties. Therefore, bringing their practice back into compliance is not something that should be regarded as having placed an additional burden on them.

5.5 In addition, the improvements to services – for example in targeting services and better integration – that will result from the advice and challenge by the National Data Guardian will improve the efficiency and productivity of health and care services.

(16) Do you have any comments or views on the potential impact that these proposals have on the potential for additional administrative and financial burdens?

Annex A. Summary of consultation proposals and questions

- 1) The Government proposes that: the remit of the National Data Guardian for Health and Social Care role should follow the health and care data.
- 2) The Government is seeking your views on: what are the key factors and issues that need to be considered when determining whether children's social care should be part of the National Data Guardian remit and where the National Data Guardian could make a positive contribution to care services for children and young people?
- 3) The Government proposes that: the National Data Guardian should be able to provide advice to all organisations that hold health and care data which could be used to identify individuals.
- 4) The Government proposes that: any regulators with a responsibility for overseeing organisations which routinely hold, use and share health and care data, should consult the National Data Guardian on the criteria they use to assess an organisation's use of data.
- 5) The Government proposes that: organisations holding health and care data which could be used to identify individuals should be required to publish all materials demonstrating how they have responded to advice from the National Data Guardian.
- 6) The Government proposes that: the National Data Guardian should be required to publish an annual report which should include a report of all the advice provided in the relevant year and an overview of how the relevant organisations responded to it.
- 7) The Government proposes that: the referral role of the National Data Guardian with the CQC and ICO should be set out in a Memorandum of Understanding.
- 8) The Government proposes that: the National Data Guardian should have power to refer actions by an individual to the appropriate regulator for the profession concerned.
- 9) Please also provide any other comments on how the National Data Guardian might advise and challenge professionals working outside the regulated professions or organisations.
- 10) Please also provide any other comments on how the National Data Guardian and regulators can maximise the appropriate use of existing sanctions and fines.
- 11) The Government is seeking views on the most suitable long-term location for the National Data Guardian.

- 12) The Government proposes that: the National Data Guardian's annual report should include a section demonstrating how the National Data Guardian has sought and gathered the views of the public and how those views will inform work in the future.
- 13) The Government proposes that: The National Data Guardian, CAG and the HSCIC should agree and publish a Memorandum of Understanding that sets out the National Data Guardian remit in relation to the additional safeguards that are being put in place as described at paragraph 4.2.
- 14) The Government proposes that: The National Data Guardian should engage with the relevant regulators of organisations outside the health and care system to ensure that they understand their obligations and responsibilities in relation to the health and care data to which they have access.
- 15) Do you have any comments or views on the potential impact that these proposals have on equality between different groups and health inequalities?
- 16) Do you have any comments or views on the potential impact that these proposals have on the potential for additional administrative and financial burdens?

Annex B. Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

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Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Annex C. How to respond

This document sets out the Government's proposals and also seeks views on how the National Data Guardian can best contribute to enhancing public trust in how their health and care data is used, shared and secured. The consultation proposals and questions are set out in Sections 2 to 5 above and Annex A.

The consultation will be undertaken over a 3 month period and will close on 17 December 2015.

In response to this consultation, you can:

- Answer the questions online at: <https://consultations.dh.gov.uk/ndgp/national-data-guardian-for-health-and-social-care>
- Email your responses to: tommy.denning@dh.gsi.gov.uk
- Post your responses to:

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