NHS
Research and Development Forum

To:

http://www.rdforum.nhs.uk
Email: info@rdforum.nhs.uk

NDGReviewConsultation@dh.gsi.gov.uk

7th September 2016

To whom it may concern.

- Thank you for providing an opportunity for comment on the National Data Guardian for Health & Care's Review of Data Security, Consent and Opt-Outs. Consultation 7th September 2016.

- We submit these comments on behalf of the NHS R&D Forum, which is a professional network and community of practice representing the health and care research management, support and leadership workforce. We are a non-profit organisation.

- Please be aware that this response has been drafted by a very small number of working group members and as such has not been through a wider review from the Forum membership.

- We welcome the emphasis placed on research in the report and the positive statements made in relation to the benefits that can be driven through good research using high quality data.

- We also welcome an opt-out models to provide greater access to research opportunities for patients as a pragmatic solution **but clear messages and communication are critical for any scheme to succeed**. We believe the opt-out statements for research as written are confusing and may risk a lack of trust, which the research community have worked hard to improve. As the intention of the scheme is to build trust we believe further work should be undertaken to ensure there is complete clarity and understanding before taking the scheme forward.

- Our members have a clear interest in this area and its potential for impact on research in the NHS, health and care. We would therefore welcome further opportunity to consult and to help shape this work. For further comment please contact kate.greenwood@rdforum.org.uk or info@rdforum.org.uk

(1) Summary comments about the standards

- The standards seem reasonable for NHS providers but others (including GP practices, research Sponsors and smaller research organisations processing identifiable health & care personal data) may struggle. We therefore advise close working with the NHS Information Governance community and anticipate that they will provide the detail around any support that may be required. We have therefore not included this in our review or response, however we do consider that standards should be achievable across all organisations.

- The emphasis on personal accountability is good and we welcome this. However we withhold judgment on the suggestion of criminal sanctions at this time.

- We have specific comments to make with regard to Standard 10:

  "Suppliers are to held accountable via contracts for protecting the personal confidential data they process and meeting the National Data Guardian's Data Security Standard"

- We recommend further clarity on whether research organisations in receipt of identifiable information from a health and care organisation but *not as a supplier,* would be within scope of the standards. For example we are not clear whether a University, commercial or non-profit Sponsor conducting a study 'in or with the NHS' would be required to meet these same standards.

- We recommend further clarity around the definition of a supplier to be really clearly differentiated from *'contracting research Sponsors and organisations'*. These are organisations that might contract with an NHS organisation as a site to undertake their research, requiring information from that site to be sent to other organisations (a central laboratory or clinical trials unit for example).

- We recommend further clarity around whether *'holding suppliers accountable via contract'* means checking that clauses are present in that contract, or whether it means having evidence and oversight via audit for example, which might be much more onerous and difficult to implement.

- We anticipate some practical complexities in enabling a health care system-wide opt-out scheme for research as patients may be offered research in any number of health and care organisations and this information would need to be clearly accessible across systems, which are not currently aligned.

(2) Comments about the consent/opt out model

This opt-out covers: (*p12 of the review*)

Personal confidential information being used to support research and improve treatment and care, for example:

- *A university researching the effectiveness of the NHS Bowel Cancer Screening Programme*
- *A researcher writing to an individual to invite them to participate in a specific approved research project This choice could be presented as two separate opt-outs. Or there could be a single opt-out covering personal confidential information being used both in running the health and social care system and to support research and improve treatment and care.*

- It is not clear from the wording above what change is being brought by the new opt-out system. The NDG review itself provides much greater detail but it is still difficult to understand what is intended that is different to the current system.

- We believe the wording above is confusing at present and does not make clear that opting out does *not* confer consent to access beyond what is currently legally possible, as stated in **3.2.23** of the actual review (see below).

  "3.2.23 The Review recommends that the new model should apply to uses of personal confidential data that are specifically authorised under law, *e.g. in accordance with Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002. Where a patient does not opt out this does not mean that they have consented for their information to be used for purposes beyond direct care. In the absence of consent, there will always need to be a specific legal authority for sharing (e.g. in accordance with regulations under section 251 of the NHS Act 2006)*

3.2.24. *This is consistent with the stance taken by the Confidentiality Advisory Group (CAG). CAG provides independent expert advice on whether applications to access patient confidential data without explicit consent should be supported under Regulations 2 and 5 of the Health Service (Control of Patient Information) regulations. It has taken a position that it will advise that it is not in the public interest to override an opt-out in anything other than the most exceptional circumstances, e.g. serious public safety concerns."*

- We believe the current opt-out wording (in the text box above) ***may currently imply*** that:

a) Opting out of research also excludes 'researchers' who are a part the patient care team and who may be offering a research opportunity to their patient.

b) By *not* opting out you effectively opt-in, conferring access to all researchers of any type of organisation. (For example, as it is written it is not clear if you would be opting out of giving access to University researchers who are only evaluating national screening programmes, or all sorts of researchers who are evaluating national screening programmes, or all national screening programmes but not university researchers doing other sorts of research)

- **We do not think that either (a) or (b) are intended by the review** and we would not want to prevent any health care professional being able to provide information about properly conducted and approved research to their patients. There are a myriad of research scenarios that this all-inclusive statement does not cover and if patients are unclear whether 'not opting out' confers access to all research organisations then they *may* chose a default 'no' position. We therefore call for a revision of this statement and further clarity on scope and intention of the scheme.

- We would like to note that there are research staff within a health care setting (including those who are not necessarily always considered to be 'researchers' in the traditional sense), who are part of the research endeavour and part of the 'NHS family' but who may not be part of the immediate care team, and with whom sharing access to personal information would enable them to support that organisation's ability to offer further opportunities for research. They may be research office staff for example. It would therefore be useful to know how 'approach to participate' in research by those outside of the care team but within

the 'NHS family', is viewed in the proposed scheme.

- The scenarios when defined should be split out as it is suggested, to allow opt-out for one but not the other. There is currently no clear mention of the use of data for evaluation or audit in the document although this may be implied.

- During implementation it might be better to explain the current legal situation and then what new things are added or changed for the benefit of research.

- On reading section 3.2.23 the review recommended that the new model should apply to uses of confidential data that are specifically authorised under law. It is not clear whether the model under consultation also intends this.

- We request further clarity on whether 3.2.24 replaces CAG approval (as long as patients haven't opted out) or whether CAG approval would still be required despite this (the current position). In addition if CAG also cannot override a patient opt-out under s251 (except in exceptional circumstances, which does not include research into rare diseases) there is some concern that the opt-out may risk a negative impact on research into rare disease (if one patient should opt-out of a research project that might otherwise have been approved by CAG in the current system, they may prevent a valuable study occurring however we are not clear how many studies CAG currently approve in rare disease and accept patients may likely be directly approached to explicitly consent to these studies.)

- In principle we would like to encourage greater support, interest and participation in research and therefore clarity around access to patient information for research would be welcome for all. There is a robust UK-wide research review system in place to ensure research is conducted to high quality standards and this could be emphasized further to help patients understand how their information can contribute. We do however not want to risk any additional confusion that may result in patients adopting a default opt-out position due to a lack of confidence in what participation means. There are a number of Trusts who have implemented both opt-out and opt-in schemes for finding out about research that could share lessons learned with the review and we should welcome the opportunity to support further work.