Introduction:

1. The Health Research Authority (HRA) was established to promote and protect the interests of patients in health and social care research and to streamline the regulation of such research. We aim, with partners, to make the UK a great place to do health and social care research, to build confidence and participation in health and social care research, and so improve the nation’s health. Our responsibilities include the appointment and operation of statutory research ethics committees and the Confidentiality Advisory Group (CAG).

2. We would like to take this opportunity to set out our formal response to the National Data Guardian’s ‘Recommendation 17’ that "The Health Research Authority should provide the public with an easily digestible explanation of the projects that use personal confidential data and have been approved following advice from the Confidentiality Advisory Group".

2.1. The review recognises that the HRA does already publish a list of applications which are approved under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002. However, it suggests that this information can be hard to find and may not be easily understood by a non-specialist audience. We are already laying the foundations to be able to address this by developing the technology to support it. Our register of CAG reviews is available from the HRA web site at www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions, along with minutes of CAG meetings. This is currently downloadable as an Excel spreadsheet containing the list of projects and a link to more detail for each project, including an application summary. Work is underway to upload this information directly from our application management system, HARP, to the HRA web site in a format that will make it easier for people to read and navigate.

2.2. We also publish information about projects approved by Research Ethics Committees, available at www.hra.nhs.uk/news/research-summaries. This gives a
broader picture of research involving data beyond just those projects that are reviewed by the CAG; the CAG only reviews projects involving processing of confidential patient information where it is impossible or impracticable to obtain consent, whereas RECs review all research projects involving patients’ identifiable data, including those where participants give their consent.

2.3. We acknowledge the recommendation of the National Data Guardian and are considering further steps.

Our Comments:

Question 4: The Review proposes ten data security standards relating to Leadership, People, Processes and Technology. Please provide your views about these standards.

3. Standard 3: “All staff complete appropriate annual data security training and pass a mandatory test, provided through the revised Information Governance Toolkit.”

3.1. We have some concerns regarding the use of the Information Governance toolkit as a training vehicle as well as an Information Security Management System (ISMS) standard. These would seem to be quite distinct purposes; an ISMS standard is not a training programme. Specific training courses could be mandatory to fulfil the training criteria for the IG Toolkit standard. However, the ‘standard’ should be separate from the training programme. It is worth noting that the training for academics handling data (research datasets) and for clinicians handling data (patient notes/records) each have a very different focus. Any mandatory training would need to take this into account. Local organisations (e.g. universities, Trusts or CCGs) may be better placed to offer training focused at specific needs or the new mandatory training programme should offer training tailored to these different users. If various institutions want different training programmes would they be expected to switch and accept the new toolkit programme?

3.2. We note that the NDG ‘Review of Data Security, Consent and Opt-Outs’ recognises ISO/IEC 27001 and the ISF’s Standards of Good Practice (SoGP) as “undoubtedly the most comprehensive and detailed available commercially” but as “such standards were likely to prove to be overwhelming for those organisations lacking maturity in their cyber security capabilities” favours the IG Toolkit instead which can accommodate those without the capacity to reach the ISO standard and be externally audited on it. However, this means that organisations meeting the higher ISO standard who wish to handle NHS data will have to additionally complete the lower IG Toolkit standard rather than the ISO standard recognised in lieu of the Toolkit.

3.3. Standard 1: says “Personal confidential data is only shared for lawful and appropriate purposes”. Are “appropriate” purposes defined and, if so, where and by whom and how where these definitions arrived at? If not, who will be responsible and accountable for deeming whether a purpose is “appropriate” (as opposed to simply being a “lawful” purpose as set out in the Data protection Act) and how will they make that decision?

Question 6: By reference to each of the proposed standards, please can you identify any specific or general barriers to implementation of the proposed standards?

4. Standard 4: “Personal confidential data is only accessible to staff who need it for their current role and access is removed as soon as it is no longer required. All access to personal confidential data on IT systems can be attributed to individuals.” Whilst this is a statement we support there will be practical difficulties hindering compliance. For example, staff working on a busy ward may share a computer screen with someone else
who might also have access to the data under their name. Indeed, a healthcare professional may legitimately show a colleague data on a screen because they need to know it to undertake care for the individual patient, but in doing so their colleague will be accessing data in a non-attributable fashion. As data are passed (legitimately) to others who may use different non NHS systems it may be difficult or impossible to track. If personal data are legitimately passed onto a researcher then will that researcher need to have a system that provides a means to attribute subsequent access.

**Question 9:** What support from the Department of Health, the Health & Social Care Information Centre, or NHS England would you find helpful in implementing the ten standards?

5. It would support standards 1, 2 and 4 in particular if NHS Digital produced an agreed, documented procedure for seeking advice from the HRA’s Confidentiality Advisory Group, as provided for by the Care Act 2014.

**Question 11:** Do you have any comments or points of clarification about any of the eight elements of the model described above?

6. The eight statements regarding the recommendations for the new consent/opt-out model are not particularly easy to read and, if aimed at the general public, would benefit from rewriting in line with good practice guidance on plain English.

6.1. “4. You have the right to opt-out”: It is helpful that the report frames ‘opt-out’ in terms of uses of data rather than data flows as this approach emphasises better the valuable uses of health data to support clinical services and improve health. Of the two options currently presented the HRA prefers the ‘two separate opt-outs’ option over the ‘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.

6.2. However, the two opt-out models posed do not fully address the complexity of people’s preferences. For example, recent work undertaken by the Wellcome Trust suggests that many people care not only about the possibility of opting-out but also (if they agree in principle that information which identifies them can be used outside the care team) about the way their personal confidential information will be used, who will use the data, and whether the data will be used for public benefit or private profit. The focus groups found that very few people understood how their data were used at the moment so had little or no basis for making decisions about the risk of new uses. We suggest that more ‘engagement’ work which makes the NDG proposals and the role of NHS Digital clear is needed before a final consultation/decision taken on the opt-out question.

6.3. The suggestion that there could be an opt-out in relation to ‘personal confidential information being used to support research and improve treatment and care’ is not really dealt with in the main narrative of the review and only emerges in the eight point model. Consequently many people reading the review will not understand the issues involved. The example given in paragraph 4(e) of the eight point model simply refers to “a researcher writing to an individual...”; it does not specify whether this researcher is a member of the clinical care team or not which is not helpful. Many people answering this question will envisage the ‘researcher’ to be their doctor, when in fact this screening role is likely to be delegated to a research nurse.

---

1 Summary Report of Qualitative Research into Public Attitudes to Personal Data and Linking Personal Data (July 2013) and The One-Way Mirror: Public attitudes to commercial access to health data. Report prepared for the Wellcome Trust (March 2016)
This issue is not clearly spelt out in the consultation nor in the wording used for the proposed opt-out.

6.4. The HRA strongly supports the right to opt-out of personal confidential information being used to support research and improve treatment and care; in particular, the example of a researcher writing to an individual to invite them to participate in a specific approved research project. The HRA has concerns over the use of NHS staff such as research nurses (where they are not members of the care team or their supporting staff) screening patient notes in order to identify patients who might be eligible to take part in a research study. The HRA acknowledges that that a small proportion of research nurses may be part of the clinical care team, for example in cancer care research nurses form an integral part of the multidisciplinary team making decisions about future treatment including clinical trials.

6.5. The HRA has undertaken public engagement activities on this topic and has found that the general public do not expect research nurses, whom they have never met, to be screening their identifiable notes. The public confirmed that they would like to be offered the opportunity to opt-out of being contacted in this way. The suggested wording in both opt-out scenarios talks about how researchers can improve how diseases are treated and prevented but does not raise the expectation that individuals may be approached in writing with an invitation to take to take part in research, this could be made more explicit.

6.6. It is not clear how opt-out consent would work where a Research Ethics Committee (REC) approves a study taking place in an emergency context without the need for consent (in line with SI 2008 941 and SI 2006 2984)? How would researchers know that they had recruited someone to the study who had previously documented a decision to opt-out of all research?

6.7. The exceptional circumstances for overriding opt-out using ‘section 251 support’ could potentially be too narrowly specified in the report - i.e. serious public safety concern, natural disasters, and epidemics - this would appear to exclude s251 support allowing an override of opt-out for studies of rare disease which are neither a public safety concern or epidemic. The risk is that if those who opt out are a specific group (e.g. more severe disease, a single ethnic group, a particular UK region), then it would bias the incidence/surveillance studies undertaken through surveillance units such as the British Paediatric Surveillance Unit (a cornerstone of the epidemiological approach to rare disease in the UK Strategy on Rare Disease, and the only method for monitoring congenital rubella and the effectiveness of vaccination), British Ophthalmological Surveillance Unit, Child and Adolescent Psychiatry Surveillance System etc.

6.8. In light of public suspicion about the range of exceptions to the eight elements stated on pages 12 to 13 of the consultation document, it may have been helpful to document the HRA’s functions under Section 110 (1) (d) of the Care Act 2014 relating to approvals for processing confidential patient information through the Confidentiality Advisory Group (CAG).

**Question 12:** Do you support the recommendation that the Government should introduce stronger sanctions, including criminal penalties in the case of deliberate re-identification, to protect an individual’s anonymised data?

7. The risk of re-identification is a genuine one and there is real mistrust amongst the public that their anonymised data may be used in this way. The HRA supports stronger sanctions to protect anonymised data including introducing criminal penalties for the
deliberate or negligent re-identification of individuals and believes this is necessary to inspire the confidence of the general public.

**Question 13:** *If you are working within health or social care, what support might your organisation require to implement this model, if applicable?*

8. People and organisations will require support and guidance to help them share data legitimately. Whilst the standards are all sensible there is the possibility that their implementation will result in people and institutions taking the path of least resistance i.e. implementing IT systems that do not ‘talk’ to each other making it less likely that data will be shared (to the detriment of patients and the public).

**Question 15:** *What are your views about what needs to be done to move from the current opt-out system to a new consent/opt-out model?*

9. There is a need for very clear guidance explaining the use of the opt-out consent model with specific examples and perhaps a dedicated email/telephone query line for people to be able to speak to ‘experts’ to assist with decision making. There needs to be a clear mechanism for communicating with patients/public (possibly through primary care institutions if feasible) which ensures they know what questions they are being asked.

For further information, please contact Clive Collett, HRA Ethics Guidance & Strategy Manager, Health Research Authority (clive.collett@nhs.net).

[www.hra.nhs.uk](http://www.hra.nhs.uk)