



## Department of Health

### National Data Guardian for Health and Care's Review of Data Security, Consent and Opt-Outs

#### Response Form

**Question 1: Please tell us which group you belong to? (Required)**

CLOSER (Cohort & Longitudinal Studies Enhancement Resources), based at the UCL Institute of Education.

Longitudinal studies follow individuals through time, collecting data at different points. The CLOSER partnership brings together some of the world's largest and longest running longitudinal studies (recognised as one of the most crucial sources of evidence for policy development in health, economics and society in the UK), the British Library and the UK Data Service. CLOSER's mission is to maximise the use, value and impact of the UK's longitudinal studies.

There are currently eight studies in the CLOSER network, with participants born as early as the 1930s to the present day:

- Hertfordshire Cohort Study
- 1946 MRC National Survey of Health and Development
- 1958 National Child Development Study
- 1970 British Cohort Study
- Avon Longitudinal Study of Parents and Children (Children of the 90s)
- Southampton Women's Survey
- Millennium Cohort Study (Child of the New Century)
- Understanding Society: The UK Household Longitudinal Study

Website: [www.closer.ac.uk](http://www.closer.ac.uk)

Twitter: @CLOSER\_UK

CLOSER is funded by the Economic and Social Research Council (ESRC) and the Medical Research Council (MRC).

**Question 2: If you are a member of an organisation or profession, please tell us if you are responding in a personal or private capacity**

N/A

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**Question 3: If the Department of Health or other organisations were to create further opportunities to engage on data security and the consent/opt-out model, would you be interested in attending? If so where would you find it helpful an event to be held?**

**Yes**  ~~No~~

Event location

London  
Bristol  
Essex

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

Which standard do you wish to comment on?

1  2  3  4  5  6  7  8  9  10

Comments

We welcome the proposed data security standards. Our views on these relate specifically to the research community and the need to support researchers (that is, those accessing and using health data in a research setting) and our concerns about the need to maintain two certifications:

In reference to **'People'** our view is that clearer guidance should be given as to who in a research setting should take the role of Caldicott Guardian and that appropriate support is provided to these persons in order to fulfil this role.

On **'Processes'**, we agree that ISO/IEC27001 series information security certification is the current gold standard, yet it remains out of reach for all but the largest/best resourced research studies. However we feel that for larger studies, such as cohorts who choose to adopt 27001, having to maintain two certifications is a disincentive. We therefore recommend that research organisations with ISO/IEC 27000 certification should automatically be considered as meeting the required standard.

With regard specifically to standard number 8, we would argue that it could be improved by providing greater clarity on the definition of the term "unsupported" and the intended scope of applicability to the "IT estate". This is especially important for Universities and other research organisations who may, for example, use imaging data analysis systems that may be using novel software.

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**Question 5: If applicable, how far does your organisation already meet the requirements of the ten standards?**

Where 0 = Not at all and 10 = Fully compliant

0  1  2  3  4  5  6  7  8  9  10

Please provide examples which might be shared as best practice

Many of the CLOSER studies have the NHS IG Toolkit standards in place and some studies (e.g. Avon Longitudinal Study of Parents and Children) are certified to ISO/IEC27000.

CLOSER studies typically outsource some elements of data custodianship to national infrastructure providers, for example the UK Data Archive and MRC Farr Institute, which are ISO/IEC27001 certified.

CLOSER studies, through a variety of mechanisms, operate 'Data Safe Havens'. These are technical/procedural level solutions to all aspects of the data pipeline (that is, the processes from data collection to analysis). These technical/procedures are embedded within wider governance frameworks (e.g. data access committees, participant involvement forums) which align to concepts such as MRC Bona Fide research or ESRC Safe Research - both frameworks to define appropriate research and institution attributes.

**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?**

Which standard do you wish to comment on?

1  2  3  4  5  6  7  8  9  10

Current implementation of NHS IG Toolkit (e.g. training modules) are not well suited to the research environment. A toolkit module aligned with the research environment would be beneficial.

**Question 7: Please describe any particular challenges that organisations which provide social care or other services might face in implementing the ten standards.**

Not applicable to CLOSER.

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**Question 8: Is there an appropriate focus on data security, including at senior levels, within your organisation?**

Yes  No

Please provide comments to support your answer and/or suggest areas for improvement

The CLOSER partnership is committed to preserving the confidentiality, integrity and availability of all the longitudinal studies' physical and electronic information assets.

There are robust procedures for accessing the data from longitudinal research. The Economic and Social Research Council (ESRC) funded studies are licensed through the UK Data Service (UKDS) to bona fide researchers for not-for-profit use. Anonymised data are deposited for use by the research community at the UK Data Archive, based at the University of Essex, and available via the UK Data Service. For more potentially sensitive or disclosive, but still anonymous, information the UKDS operates an application-based secure lab facility for accredited UK Higher Education Researchers only.

All studies funded by the Medical Research Council (MRC) must comply with the "MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies" (see <http://www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/>). This sets out the MRC's requirements and expectations for studies on matters including data standards, data sharing, the governance of data access, facilitation, and data-sharing agreements.

**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?**

New data security standards and assessment mechanisms should have components specifically tailored to the research community in addition to those for the applied health care community. The IG Toolkit is an appropriate mechanism to develop these new standards, but a refreshed version would need research tailored options and training courses. We would value support in this area and are happy to discuss this and specific research community requirements with the NDG Review Team.

**Question 10: Do you agree with the approaches to objective assurance that we have outlined in paragraphs 2.8 and 2.9 of this document?**

Yes  No

Please comment on your answer

New standards and assessment mechanisms should have components tailored to the research community in addition to those for the applied health care community.

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

Which standard do you wish to comment on?

1  2  3  4  5  6  7  8

Please provide details

We have provided comments on element 4 ('You have the right to opt out') as part of our response to question 15.

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**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?**

Yes. This will help to increase confidence and provide assurance to the public.

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

Not applicable to CLOSER.

**Question 14: If you are a patient or service user, where would you look for advice before making a choice?**

Not applicable to CLOSER.

**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?**

Yes  No

Please comment on your answer

It is essential that people are able to make informed choices about how their personal confidential data is used. We understand that many of these issues will be considered by a new independent patient data taskforce, hosted by Wellcome with support from the Medical Research Council, the Economic and Social Research Council and UK Clinical Research Collaboration partners. We support the ambitions of this taskforce, including the development of a framework for clear and transparent discussions with the public, patients and healthcare professionals about how data can be used to improve health.

The consultation document discusses different options for the proposed opt-out model (Section 4.4). It is vital that the final question(s) asked make clear what will and will not be done with patient data, and by whom. We note that neither of the two examples cited (“a university researching the effectiveness of the NHS Bowel Cancer Screening Programme” and “a researcher writing to an individual to invite them to participate in a specific approved research project”) address the issue of commercial access to patient data. However, we know from research funded by Wellcome (Ipsos Mori, 2015, see: <https://wellcome.ac.uk/news/how-do-people-feel-about-companies-accessing-health-data>) that public attitudes in this area are complex, and that there are a number of ‘red lines’ regarding who should and should not have access to confidential data. We are concerned that failing to recognise this distinction may result in anxiety about commercial access tarnishing **any** access for research purposes, in so doing having a negative impact on vital medical and social research of considerable public benefit.

This public anxiety and uncertainty points towards the need for further open conversation with the public to ensure that people understand how their medical records can be used, and what safeguards are in place. We also recommend that the consent/opt-out options recognise the fact that the public may take different views about the use of their data depending on whether or not it is being carried out for commercial gain. One option would be to make this distinction in the question wording, along the following lines:

1. Providing local services and running the NHS and social care system.
2. Supporting research and improvement of treatment and care **where there is no commercial gain.**
3. Supporting research and improvement of treatment and care **where commercial gain is allowed.**

In terms of implementation, we would also recommend that the three options are not ‘nested’ – that is, each option should be asked of all patients rather than those who gave specific responses to the previous option.

**Question 16: Do you think any of the proposals set out in this consultation document could have equality impacts for affected persons who share a protected characteristic, as described above?**

No comments.

**Question 17: Do you have any views on the proposals in relation to the Secretary of State for Health's duty in relation to reducing health inequalities? If so, please tell us about them.**

Linking survey data to patient data provides important information about those people who access services as well as those who are missed by the system. Potentially linked survey and administrative data could provide better information about vulnerable people and identify new ways of preventing or tackling health inequalities.

**Send your responses to:**

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