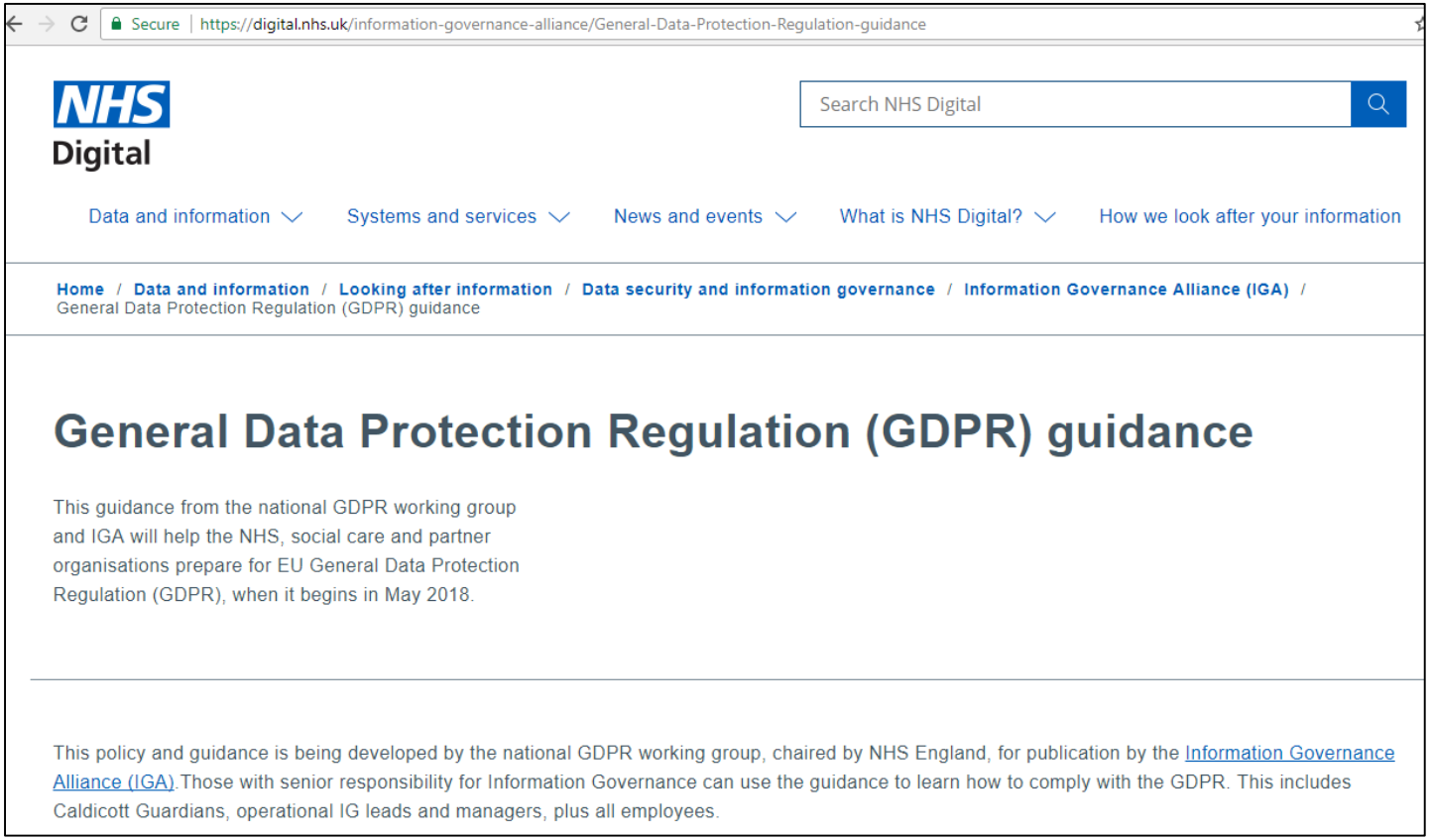
Cross-border biomedical research: What are the new challenges arising from the forthcoming data protection legislation?

NHS European Office

Healthcare providers perspective

NHS experience

National Working Group, chaired by NHS England preparing guidance which will go out across the NHS system



Health Research Authority chairs a sub-group on health and social care research

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/

General Data Protection Regulation (GDPR)

The new EU General Data Protection Regulation (GDPR) is expected to apply in the UK from 25 May 2018, when it will replace the Data Protection Act 1998.

For health and social care research, the new Regulation is not very different from the current Act and the Health Research Authority will not be adding to the existing effective safeguards. In particular, Research Ethics Committee (REC) approval and the legal gateway for processing confidential patient information on the advice of the Confidentiality Advisory Group (CAG) will continue, as will the other common law provisions. A summary of the key changes for all data processing (not just research) is available from the Information Governance Alliance.

The Information Commissioner's Office has published resources for GDPR preparation, but they are not specific to research. Preparation guidance for research managers is available from the Medical Research Council.

The HRA is working with partners to develop further research-specific guidance over the coming months. Topics we expect to cover include:

- legal basis – consent, legitimate interests, tasks carried out in the public interest;
- safeguards;
- transparency – privacy notices, fair processing, keeping records of data processing activities; and
- data subjects' rights.

As guidance becomes available, we will publicise it and link to it from this page.

For further enquiries, please e-mail hra.queries@nhs.net.

Legal basis

- Public interest
- Legitimate interest – private hospitals?
- Consent
- Need to account for this and publish it as part of transparency requirements
- Need to conform to other legal and ethical requirements, such as those associated with the common law duty of confidentiality.
- In such cases, research participants may be asked to consent should be informed of the specific legal basis used for processing under data protection law.

ico. Information Commissioner's Office blog

Home Contributors

← GDPR – sorting the fact from the fiction

GDPR is an evolution in data protection, not a burdensome revolution →

Consent is not the 'silver bullet' for GDPR compliance

Posted on August 16, 2017

By Elizabeth Denham, Information Commissioner.

Last week I launched a series of blogs to bust some of the myths that have developed around the General Data Protection Regulation (GDPR).

Before the new law comes into effect on 25 May 2018, I feel bound to sort the fact from the fiction.

Because there is a lot of misinformation out there and for many who are new to data protection and the GDPR it's creating uncertainty.

Search

Recent posts

- Pan fydd ymchwil farchnad wleidyddol yn croesi'r llinell October 24, 2017
- When political market research crosses the line October 23, 2017
- European guidance published – profiling and breach reporting October 19, 2017
- ICO fee and registration changes next year October 5, 2017

Links

- ICO website
- ICO international blog

Tweets by @ICOnews

Safeguards in UK's draft Data Protection Bill

- *Clause 18 Safeguards*

  Clause 18 of the Data Protection Bill makes clear that the requirement for appropriate safeguards for the rights and freedoms for the data subject established by GDPR *cannot* be satisfied if the processing is:

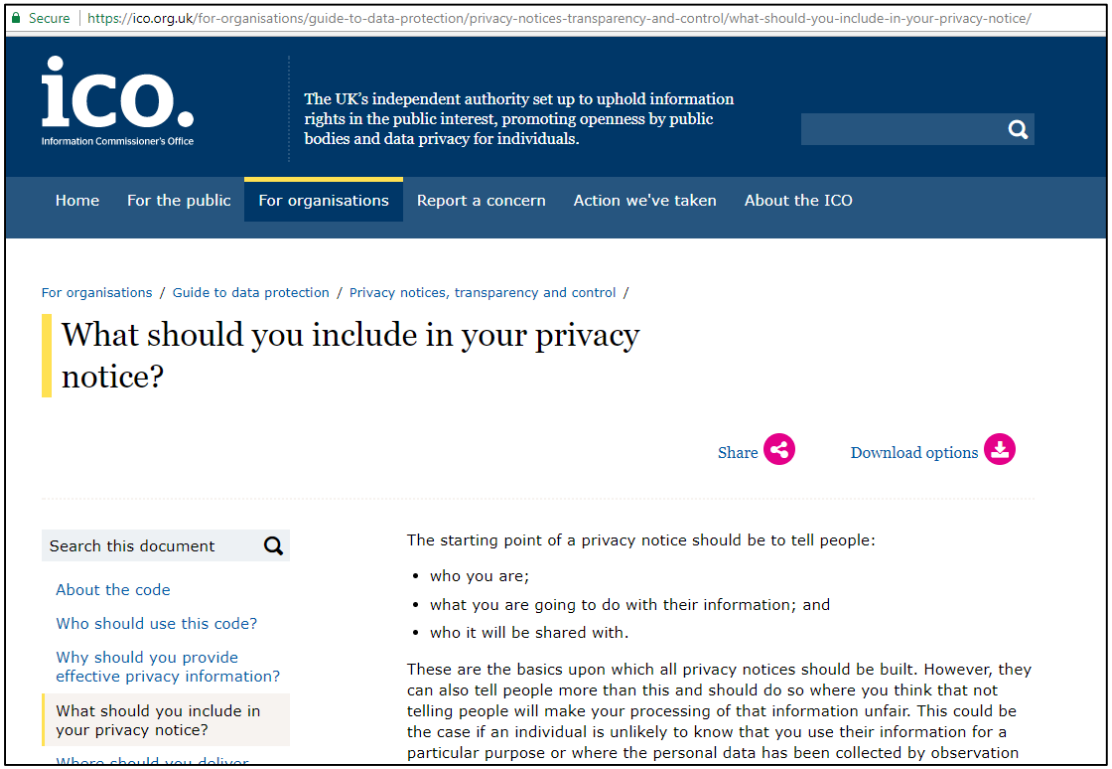
  carried out for the purpose of measures or decisions with respect to a particular data subject; or

  likely to cause substantial damage or substantial distress to an individual

- *Technical and Organisation Measures*

- *Conditions where a special category of data*

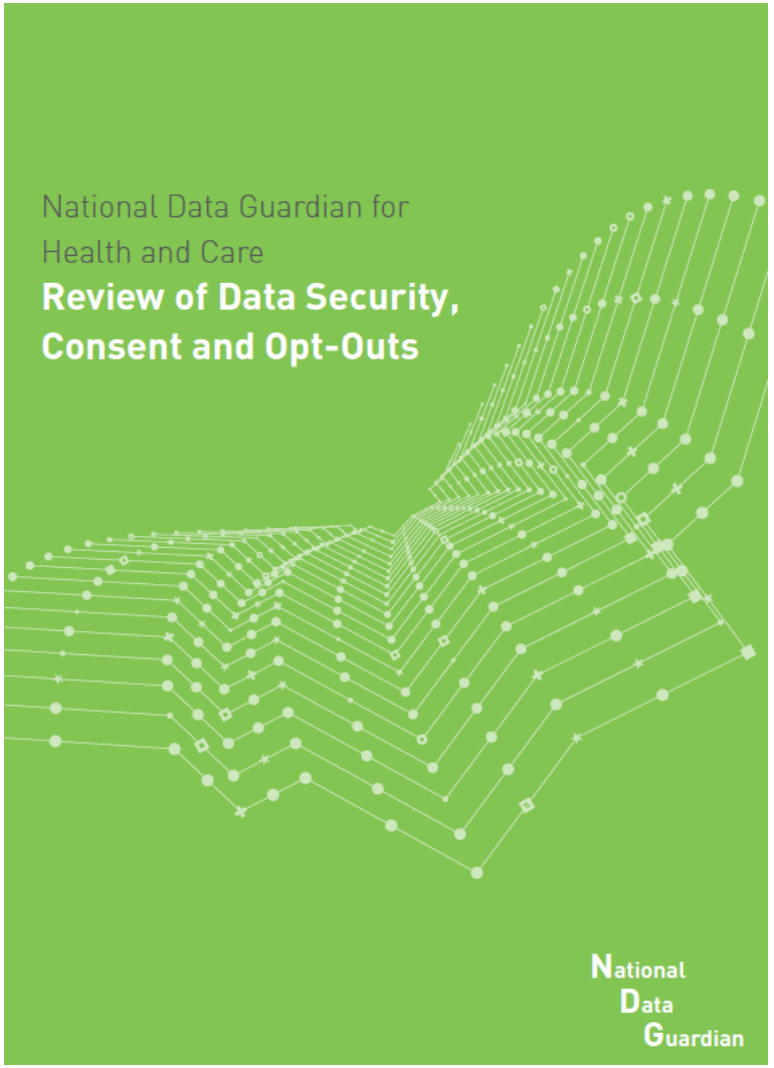
Transparency



National Survey of Health and Development

Data subject rights

- Access
- Rectification
- Erasure – health purposes exempt, but render impossible or seriously impair – removal of ‘disproportionate effort’.
- Data portability (MRI research ?)



Post Brexit agreement on sharing biomedical data?

UK is seeking adequacy or something equivalent to ensure data can continue to flow for vital medical research purposes.