

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

The screenshot shows a web browser window with the URL <https://digital.nhs.uk/information-governance-alliance/General-Data-Protection-Regulation-guidance>. The page features the NHS Digital logo and a search bar. A navigation menu includes links for Data and information, Systems and services, News and events, What is NHS Digital?, and How we look after your information. The breadcrumb trail reads: Home / Data and information / Looking after information / Data security and information governance / Information Governance Alliance (IGA) / General Data Protection Regulation (GDPR) guidance. The main heading is "General Data Protection Regulation (GDPR) guidance". The text states: "This guidance from the national GDPR working group and IGA will help the NHS, social care and partner organisations prepare for EU General Data Protection Regulation (GDPR), when it begins in May 2018." A footer note mentions: "This policy and guidance is being developed by the national GDPR working group, chaired by NHS England, for publication by the Information Governance Alliance (IGA). Those with senior responsibility for Information Governance can use the guidance to learn how to comply with the GDPR. This includes Caldicott Guardians, operational IG leads and managers, plus all employees."

← → ↻ Secure | <https://digital.nhs.uk/information-governance-alliance/General-Data-Protection-Regulation-guidance>

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General Data Protection Regulation (GDPR) guidance

This guidance from the national GDPR working group and IGA will help the NHS, social care and partner organisations prepare for EU General Data Protection Regulation (GDPR), when it begins in May 2018.

This policy and guidance is being developed by the national GDPR working group, chaired by NHS England, for publication by the [Information Governance Alliance \(IGA\)](#). Those with senior responsibility for Information Governance can use the guidance to learn how to comply with the GDPR. This includes Caldicott Guardians, operational IG leads and managers, plus all employees.

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.

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← 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.

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

Secure | <https://ico.org.uk/for-organisations/guide-to-data-protection/privacy-notices-transparency-and-control/what-should-you-include-in-your-privacy-notice/>

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Information Commissioner's Office

The UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

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What should you include in your privacy notice?

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About the code

Who should use this code?

Why should you provide effective privacy information?

What should you include in your privacy notice?

Where should you deliver

The starting point of a privacy notice should be to tell people:

- who you are;
- what you are going to do with their information; and
- who it will be shared with.

These are the basics upon which all privacy notices should be built. However, they can also tell people more than this and should do so where you think that not telling people will make your processing of that information unfair. This could be the case if an individual is unlikely to know that you use their information for a particular purpose or where the personal data has been collected by observation

www.nshd.mrc.ac.uk/study-members/birthday-card-gallery/

UCL MRC Unit for Lifelong Health and Ageing at UCL : LHA & MRC National Survey of Health and Development : NSHD

MRC Medical Research Council

National Survey of Health and Development

MRC LHA & NSHD > Study members > Birthday Card Gallery

Birthday Card Gallery

Birthday cards have been sent to study members since their 16th birthday in 1962. As part of the 65th celebrations we assembled the birthday cards we hold in our archive below and hope you enjoy a trip down memory lane. Several study members kindly sent us cards that were missing from our collection. We are now only missing a birthday card from 1973.

Study Members

- The Douglas Children
- Current research
- Data collection
- Future plans
- Impact of NSHD
- Taking Part
- Birthday Card Gallery**
- Newsletters
- Keeping in Touch
- 70th Birthday

SEE MORE SHARE



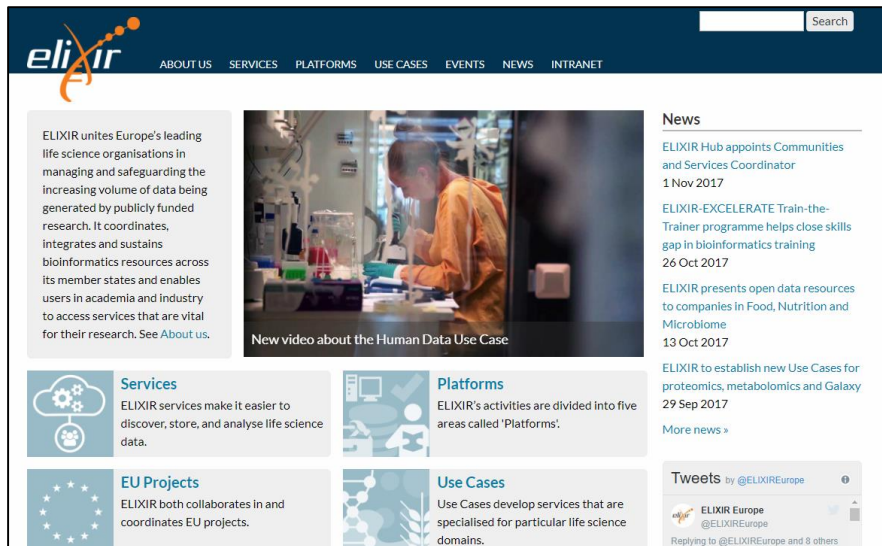
Data subject rights

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

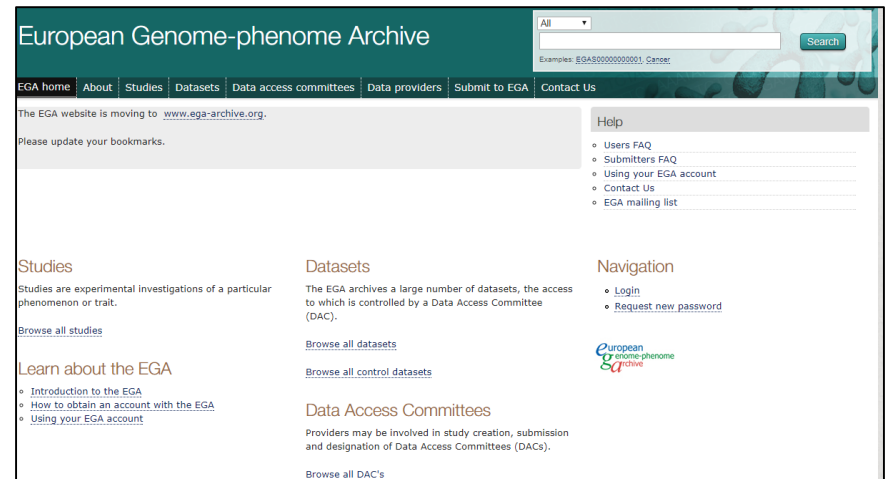


Post Brexit agreement on sharing biomedical data?

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



The screenshot shows the ELIXIR website homepage. The header includes the ELIXIR logo and navigation links: ABOUT US, SERVICES, PLATFORMS, USE CASES, EVENTS, NEWS, INTRANET. A search bar is located in the top right. The main content area features a large video player with the title 'New video about the Human Data Use Case' and a description of ELIXIR's role in unifying European life science organizations. Below the video are four service tiles: 'Services' (ELIXIR services make it easier to discover, store, and analyse life science data), 'Platforms' (ELIXIR's activities are divided into five areas called 'Platforms'), 'EU Projects' (ELIXIR both collaborates in and coordinates EU projects), and 'Use Cases' (Use Cases develop services that are specialised for particular life science domains). A 'News' section on the right lists recent updates, including the appointment of a new Communities and Services Coordinator and the launch of the ELIXIR-EXCELERATE training programme. A 'Tweets' section at the bottom shows a tweet from @ELIXIREurope.



The screenshot shows the European Genome-phenome Archive (EGA) website. The header includes the EGA logo and navigation links: EGA home, About, Studies, Datasets, Data access committees, Data providers, Submit to EGA, Contact Us. A search bar is located in the top right. The main content area features a large banner with the text 'The EGA website is moving to www.ega-archive.org.' and a 'Please update your bookmarks.' message. Below the banner are three main sections: 'Studies' (describing experimental investigations), 'Datasets' (describing the archive of datasets), and 'Data Access Committees' (describing the process of study creation, submission, and designation). A 'Navigation' section on the right includes links to 'Login' and 'Request new password'. A 'Help' section on the right includes links to 'Users FAQ', 'Submitters FAQ', 'Using your EGA account', 'Contact us', and 'EGA mailing list'.