



NHS European Office



## Information Commissioner's Office Consultation: GDPR Consent Guidance

---

### Response by health and research organisations

31 March 2017

#### KEY MESSAGES

- Overall the guidance is clear. However, there are specific points that need to be amended or clarified, including whether universities are considered public authorities and the identity of third parties.
- We welcome the inclusion of the section on scientific research. However, further clarification is needed. It would also be helpful to have better signposting to this section, given the contrast on specificity of consent for other purposes.
- Further sector specific guidance will be needed for scientific research, including options for legal bases, further processing and safeguards. We suggest the Health Research Authority and the Devolved Administrations prepare guidance with input from the ICO.
- The example on implied consent in the health service is confusing and unhelpful, and should be removed or amended.

#### GENERAL POINTS

1. Overall the guidance on consent is easy to understand and provides a clear understanding of the requirements for consent as a legal basis for processing under the GDPR.
2. Describing the different legal bases for processing early on in the guidance would help data controllers better understand if consent is the appropriate mechanism for their processing, and that other options are available if not.
3. The guidance does not define "public authority", and suggests public authorities should not use consent as a legal basis for processing. The guidance must clarify whether universities are considered to be public authorities, and whether consent can be an appropriate legal basis for universities and other research organisations, for example for scientific research. This clarification is also important to understand whether universities can rely on legitimate interests as an alternative legal basis.

## SCIENTIFIC RESEARCH

### **Comments on page 27**

4. We warmly welcome the specific section on rules for scientific research (Page 27). It is very helpful to have clarification that consent does not need to be as specific in scientific research as it is in other sectors.
5. The guidance requires that research participants should be told “general areas of research”. However, it is not clear what this means for studies that operate using broad consent, using terms such as “health related research” or “scientific research”. This creates uncertainty as to whether these studies can rely on consent as a legal basis. We suggest that the guidance is amended to indicate that consents of this type would be sufficient to meet this criterion when approved by a relevant ethics committee. At minimum, clarity is needed on the status of these consents.
6. The guidance also notes that research participants should be given the option to consent for part of a research project “where possible”. This caveat is important and must be maintained, as in some cases it may be impracticable or undermine the science for participants to sign up to some elements of a project not others.
7. Recital 33 refers to the need for the approach to consent to be “in keeping with recognised ethical standards”. We therefore recommend adding the following sentence to the guidance:

*Your approach to consent should be in keeping with recognised ethical practice, for example seeking relevant ethics committee approval and establishing appropriate governance arrangements.*

This is important to ensure consent under the GDPR is consistent with current good practice in research (see box 1; page 4).

### **Further guidance and signposting**

8. Page 27 is the first point where important details about consent for scientific research are discussed. However, earlier the guidance notes that consent must be specific. We suggest briefly highlighting the different position for research clearly, as early as possible in the guidance, to avoid confusion. For example, this significant difference could be highlighted where the provisions for consent for scientific research purposes are first mentioned on Page 7 and /or under “at a glance” (Page 3).
9. More detailed guidance on the GDPR will be needed for health research, including guidance on the most appropriate legal basis for different types of organisation, safeguards and further processing for scientific and research purposes (Article 5(1)(b)). We recommend that the Health Research Authority prepares guidance on these issues, in conjunction with the Devolved Administrations, with input from ICO. It would be useful for this consent guidance to be amended in the future to include a reference to any sector specific guidance on consent.

## ***Specific issues for research***

### *Identity of third parties*

10. The guidance notes that in order for consent to meet the requirements for processing, data subjects must be told the identity of the data controller and any third parties who will also be relying on consent for processing (Page 7 and 21). We recommend that this requirement is amended, to be consistent with Article 13 of the GDPR, which requires only that data subjects are given categories of third parties. The current interpretation of the requirement for third party identities would undermine the option of using broader forms of consent in scientific research, since the identity of third parties will not be known at the time of consent.

### *Withdrawal of consent*

11. Withdrawal of consent is an important principle in scientific research. However, there may be practical difficulties in contacting all third parties that data has been shared with. The guidance does not consider the situation where there may be limitations on the ability to stop processing, particularly by third parties data has been shared with, when a data subject withdraws their consent. It is not clear how this limitation on withdrawal affects the legitimacy of consent, and researchers will need further guidance on this issue. We suggest that the Health Research Authority prepares guidance on this issue, with input from ICO.

## **HEALTH DATA AND IMPLIED CONSENT**

12. The example provided on page 15 regarding implied consent in the healthcare setting is confusing. Currently, implied consent is not a lawful basis for processing under the Data Protection Act and healthcare providers are using an alternative legal basis, such as public interest. The example, although correct, could be read as suggesting that healthcare providers are currently doing something that will become unlawful under the new GDPR, which is not the case. It is important that this example is removed or amended.
13. There is significant risk aversion about health data sharing, and it is important that the guidance does not discourage data controllers from sharing data for legitimate and ethical purposes, including research. Given the specific challenges in this sector, it would be valuable for the discussion of inappropriate use of consent (Page 15) to refer to relevant professional guidance (such as the GMC Confidentiality Guidance) and/or the National Data Guardian.

**Box 1: Ethical standards and governance for broad consent in scientific research**

- Scientific research, particularly health research, is a highly regulated sector.
- Good governance is essential to underpin broad consent, particularly to control whom personal data can be shared with, and what it can be used for.
- It is common practice for research projects to limit who can access data (e.g. only *bona fide* researchers) or the context of the research (e.g. health related research, or for non-commercial purposes only).
- Research studies must also be approved by a relevant research ethics committee, for example an NHS research ethics committee for studies involving NHS data. The research ethics committee will consider the consent and governance arrangements for the study.
- Governance arrangements may include how participants will be made aware of future uses of their data and data access committees that review and approve data release.
- The guidance could include an example of broad consent which has been approved in keeping with recognised ethical standards, or link to subject specific guidance on this.