Information Commissioner's Office: Draft Anonymisation Code of Practice

Response by the Wellcome Trust, the Academy of Medical Sciences and the British Heart Foundation

August 2012

KEY POINTS

- A lack of clarity around how the data protection framework relates to research has been a considerable concern for the research community. We warmly welcome the draft Anonymisation Code of Practice, which helps to clarify a number of issues in this area.
- The clarification that pseudonymised data can be considered anonymous is particularly helpful and the draft Code strikes a good balance between facilitating research while ensuring that safeguards are in place to protect individuals.
- The section of the draft Code on the research exemption of the Data Protection Act would benefit from strengthening and clarification.

INTRODUCTION

1. The Wellcome Trust, the Academy of Medical Sciences and the British Heart Foundation warmly welcome this draft Code of Practice and we are pleased to have the opportunity to respond to this consultation. As organisations with an interest in the safe and secure use of health information in research, our response focuses on the draft Code as it relates to health research.

2. Information from patient records provides the foundation for much health research, and offers significant potential to answer questions about the factors that influence health and disease. Information from patient records can be used for epidemiological research; to understand more about the causes of disease; to detect outbreaks of infectious diseases; to monitor the safety and efficacy of drugs and medical devices; and to study the effectiveness of treatments and interventions. Researchers generally seek to use anonymised information where this is possible and pseudonymisation is a commonly used technique to preserve confidentiality. The current legal framework for the use of information from patient records in research is complex, confusing and in urgent need of clarification to ensure that important research is not hindered.

RESPONSE TO CONSULTATION QUESTIONS

Q1. Do we adequately explain how the Data Protection Act relates to the issue of anonymisation?

3. We consider that the clear and pragmatic approach adopted by the draft Code will facilitate research by creating greater certainty within the current legal framework. There is a lack of clarity about how the Data Protection Act (DPA) applies to research, particularly relating to the status of pseudonymised or key-coded data and the section 33 research exemption. This lack of clarity contributes to those overseeing the use of patient information in research – including Research Ethics Committees and data controllers, such as GPs – taking a risk averse approach to data sharing. This draft, which seeks to clarify key issues that affect research, is therefore welcomed.

4. Clarification that pseudonymised data can be considered anonymous – where identification does not take place, or where identification does take place and the data protection principles are not breached – and therefore falls outside the scope of the Data Protection Act is particularly helpful. We are pleased that the draft Code recognises pseudonymisation as a vital tool for protecting information used in research and takes a proportionate approach to regulating this.

5. We welcome the explanation that "it is generally acceptable to anonymise personal data and to disclose it without the data subject's consent" provided that a number of conditions can be fulfilled. This addresses a lack clarity in the legislation and provides a helpful basis for the operation of safe havens for research, such as the new Clinical Practice Research Datalink.

Q2. Does the code explain adequately what anonymisation is, its technical aspects and how it's used in practice?

6. The code clearly explains these issues. The inclusion of case studies and explanations that relate specifically to research are very helpful and should make the Code accessible to the sector to ensure the greatest benefit.

Q4. Does the code strike the right balance between the protection of individuals' privacy and the benefits of making information publicly available?

7. We consider that the draft Code has reached an appropriate balance between protecting individuals and sharing information for societal benefit. Information from patient records has played a key role in advances that have benefited the health of many, for example demonstrating a link between smoking and lung cancer. It is vital that the data protection framework facilitates research to ensure that other benefits can be secured for future generations. We are pleased that this is recognised by the draft Code.

8. We have some concerns that the pragmatic approach taken by this draft Code is not shared by the draft Data Protection Regulation, currently being considered by the European Parliament and Council of Ministers. In the draft Regulation, pseudonymised data appears to be treated as personal data and subject to the full requirements of the Regulation. We consider this approach disproportionate and we hope that the Ministry of Justice and the Information Commissioner's Office (ICO) can use the Code to support the argument that pseudonymised data should be considered outside the scope of the Regulation in certain cases.

Q7. Does the code adequately explain the difference between publication and limited forms of disclosure?

9. We support the strong argument put forward in the draft Code that both safety and the utility of information must be taken into account in deciding in what form and through which mechanisms data should be made available. It is helpful that the draft Code recognises that researchers commonly rely on access control models to ensure the safety and security of anonymised data that are particularly sensitive or vulnerable to reidentification. We welcome the recognition that sometimes researchers will need access to information that can identify specific individuals and the inclusion of safeguards to protect these data.

Q8. Is the section 33 research exemption clearly explained?

10. It very helpful that the draft Code seeks to address the research exemption since a lack of clarity around this has been an issue for the community. However, we consider this section to be the least clear of the document. In places the draft Code reads as though there is significant remaining uncertainty on the interpretation of the law in this area since the wording is more ambiguous than that used through the rest of the document. The constructive tone taken throughout the document does not come across as strongly in this section. It would be helpful if this discrepancy could be addressed by bringing the research section more closely in line with the others.

11. We recommend that the language in this section is strengthened as far as possible to avoid propagating, or failing to eliminate, the current lack of clarity. For example,

    - "…other forms of research, for example social research, could benefit from the exemption" (paragraph one). This could be strengthened by amending to "the Information Commissioner considers that other forms of research, for example social science, could benefit from the exemption".

12. We consider that the drafting of this section could be tightened to improve its clarity and impact. For example:

    - Paragraphs five and seven both consider how the publication of research outputs relates to section 33. Paragraph five states that it "is certainly good practice to avoid the publication of research data in a form that identifies individuals where there are alternatives to this". However, in contrast, paragraph seven reads "it is bad practice –

and arguably a breach of the DPA – to publish or disclose for research purposes in a form which identifies individuals where there is an alternative to this". This creates a confusing conflict as bad practice and potential breach of the DPA is likely to be far more severe than failing to reach standards held as good practice. These paragraphs should be combined and redrafted to reduce the duplication and resolve the internal conflict in the way that this issue is presented.

- Paragraphs four and six both address the anonymisation of data for use in research. We agree that it is good practice to "anonymise data as early in the research process as possible". Grouping these paragraphs together would make the flow of this section more logical and coherent.

13. At present this section does not refer explicitly to health research, which may involve sensitive personal data. This may be because the ICO considers that health research will generally be undertaken on the grounds of "medical purposes" under schedule 3, section 8 of the DPA, rather than the section 33 exemption. It is not always possible to seek consent for the use of sensitive personal data in research and this is recognised by statutory provision for an exemption from the common law of confidentiality. We consider it essential that this section explicitly clarifies the ICO's position on health research with respect to the DPA, particularly in situations where it is not possible to seek consent, for example with reference to schedule 3, section 8.

Q9. Is the flow diagram useful?

14. The diagram provides a helpful summary in a simple format. The diagram would be even more useful if the boxes included page references to the relevant sections of the Code, so that it is easy to access more information when needed.

Q11. Is the code easy to understand?

15. The majority of the draft Code is clear and easy to understand. However, we consider that section 9 on the Data Protection Act research exemption could benefit from clarification (see paragraphs 10-13).