A template for the development of policies for access to data or biological samples for research

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Abstract

There is growing awareness that without the sharing of data and samples, medical research will become increasingly inefficient. At the same time, it is recognised that there must always be safeguards around the movement of samples and data to protect the interests of the donors or data subjects. Protection is provided by a regulatory and ethical framework which sets the boundaries for access. However, we believe that the lack of practical resources in this area is leading to duplication of effort as researchers and funders repeat the same background work each time a policy is needed for a new study or collection.

We present a template for access policy development that can be considered by a variety of funding and research organisations for adaptation to their purposes. This is not intended to impose policy and practice but rather to provide a practical instrument which (i) reflects established good practice, (ii) can be tailored to circumstances, and (iii) helps avoid unnecessary duplication of effort. It differs from existing guidelines which simply (though usefully) state principles by providing example text that can be used directly in a policy or MTA.

The template has been informed by a consultation, which received responses from research funders, regulatory bodies and biobanks, as well as individual researchers, healthcare professionals and patient representatives. The consultation responses strongly supported our aims and indicated a high degree of agreement on the general principles whilst also highlighting the need to allow flexibility and minimise bureaucracy

Introduction

The last ten years have seen significant changes in the environment for sharing data and samples (figure 1 shows some selected events). In general the result of these changes was an increase in the amount of legislative and regulatory complexity surrounding the sharing of data and samples for research.

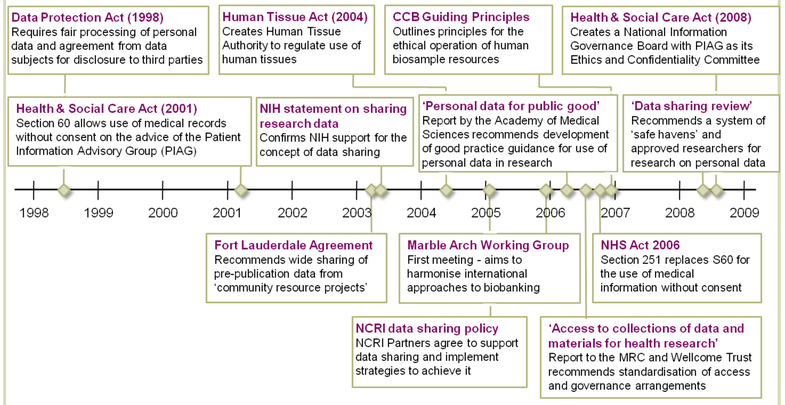
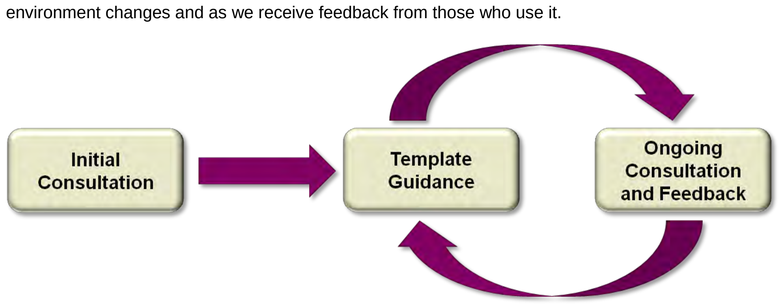


Figure 1. 'Access Timeline' 1998-2009 (selected events).

In response to this increased complexity many organisations have produced their own guidance. However, we believe that there is still confusion about the legal and regulatory requirements and that this unnecessarily reduces the amount of sharing. In turn, this leads to wasteful repetition in the collection of both data and samples. Similarly, where organisations do decide to share their collections, each must repeat the same background work. Such duplication of effort is not in the public interest. Finally, once access policies have been agreed, the variation in the resulting agreements make it difficult to combine resources from different collections.

Our work aims to reduce duplication of effort and increase sharing through the provision of a practical template for developing an access policy; we do not want to add further generic guidance or define policy. We know that there are differences of both interpretation and opinion in some areas and that each collection has its own needs based on individual circumstances. To ensure that we reflect where there is general consensus and conversely where there is greater sensitivity and perhaps more work to be done, the development of the template has been informed by wide consultation with interested parties. We expect the document to develop over time as the legislative and regulatory environment changes and as we receive feedback from those who use it.



Results of the Consultation

The original consultation document was distributed to over 130 interested parties and a total of 61 responses were received. The responses were split between organisations (44%) and individuals (56%), with the majority received from researchers and healthcare professionals and the institutions / organisations that represent them (figure 2 shows the breakdown of responses).

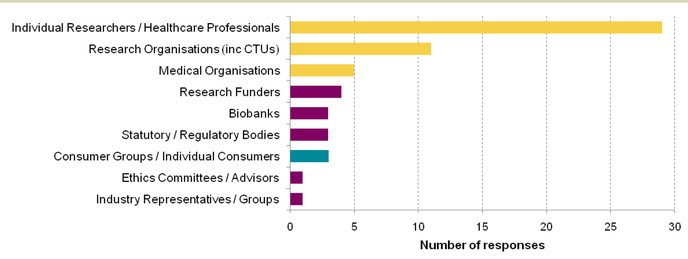


Figure 2. Responses to the NCRI consultation.

The responses were strongly supportive of the work and the need for any template to be flexible to meet the varying needs of different collections and to avoid unnecessary bureaucracy was highlighted. Several respondents also recognised that the issues addressed by this consultation apply beyond the cancer research community and wished to see a broad base of users addressed.

We have summarised the responses to the consultation in a document available from the NCRI website (www.ncri.org.uk)[14]. In this, we have tried to highlight where existing good practice guidelines exist or where regulators or similar bodies have expressed an opinion. Where there is no consensus or regulatory guidance, we have attempted to represent the range of opinions expressed; our approach to this is shown in figure 3. Although we considered working to facilitate an agreement on some issues, no clear need for this emerged.

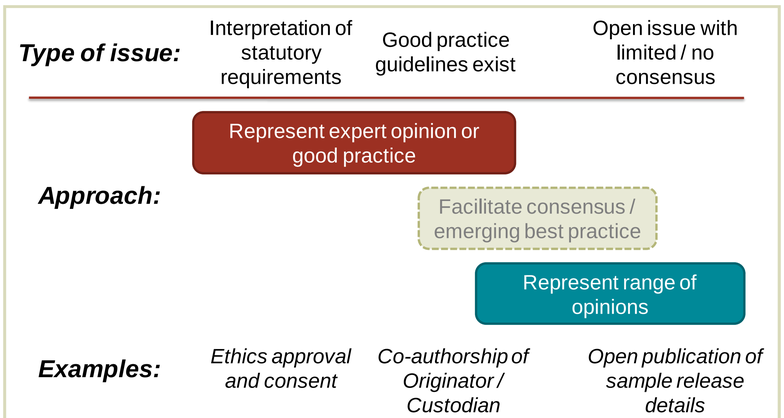


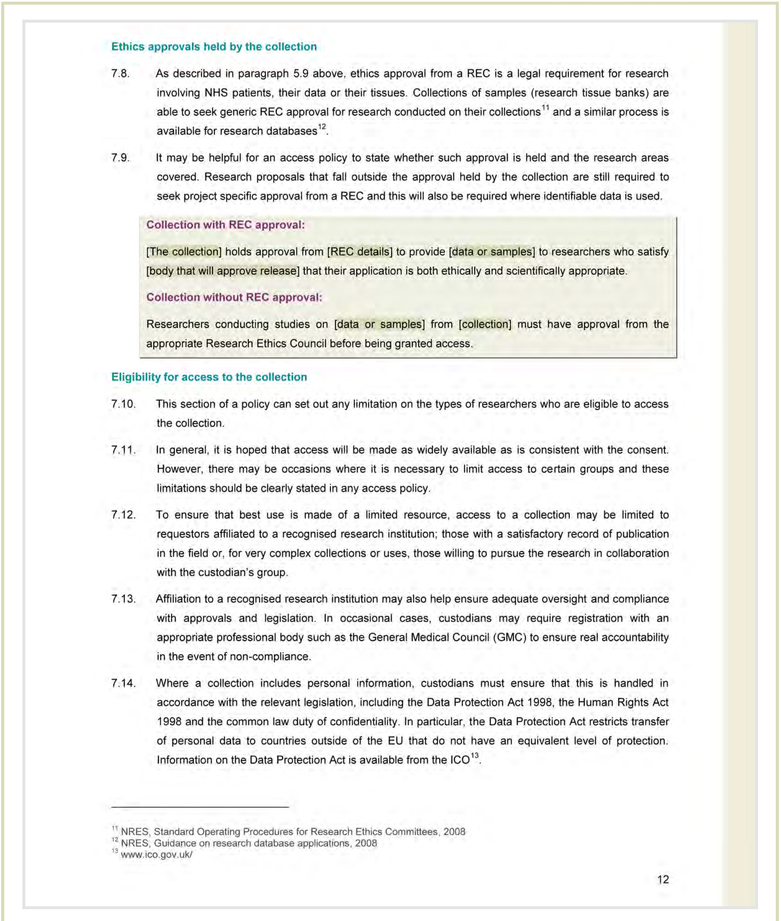
Figure 3. Approach to summarising responses to the consultation.

A Template for Access Policy Development

Based on the consultation responses, we have created the first version of a 'Template for Access Policy Development'. This does not attempt to define or impose policy and we expect it to evolve based on feedback from users and changes to the regulatory environment. The publication of the first iteration will, therefore, be the start of an ongoing process of updates.

The template concerns access to data and/or samples that have already been collected and are being held. It does not cover the initial collection and holding of samples or data per se. However, where appropriate, it does take account of the interests of organisations and individuals who contributed to the forming of the collection, as well as the interests of those whose samples or data are included, and the wider public.

The document covers the principal topics that may be encountered in the development of an access policy and some of the considerations that may influence that policy. Where appropriate, it provides references to detailed guidance from regulators and other bodies. For each area we have provided example text that may be used directly or adjusted to fit a specific collection and, where necessary, we include options for tailoring to the varying circumstances of different collections. An example page is shown in figure 4.



Ethics approvals held by the collection

7.8. As described in paragraph 5.9 above, ethics approval from a REC is a legal requirement for research involving NHS patients, their data or their tissues. Collections of samples (research tissue banks) are able to seek generic REC approval for research conducted on their collections[11] and a similar process is available for research databases[12].

7.9. It may be helpful for an access policy to state whether such approval is held and the research areas covered. Research proposals that fall outside the approval held by the collection are still required to seek project specific approval from a REC and this will also be required where identifiable data is used.

Collection with REC approval:

[The collection] holds approval from [REC details] to provide [data or samples] to researchers who satisfy [body that will approve release] that their application is both ethically and scientifically appropriate.

Collection without REC approval:

Researchers conducting studies on [data or samples] from [collection] must have approval from the appropriate Research Ethics Council before being granted access.

Eligibility for access to the collection

7.10. This section of a policy can set out any limitation on the types of researchers who are eligible to access the collection.

7.11. In general, it is hoped that access will be made as widely available as is consistent with the consent. However, there may be occasions where it is necessary to limit access to certain groups and these limitations should be clearly stated in any access policy.

7.12. To ensure that best use is made of a limited resource, access to a collection may be limited to requestors affiliated to a recognised research institution; those with a satisfactory record of publication in the field or, for very complex collections or uses, those willing to pursue the research in collaboration with the custodian's group.

7.13. Affiliation to a recognised research institution may also help ensure adequate oversight and compliance with approvals and legislation. In occasional cases, custodians may require registration with an appropriate professional body such as the General Medical Council (GMC) to ensure real accountability in the event of non-compliance.

7.14. Where a collection includes personal information, custodians must ensure that this is handled in accordance with the relevant legislation, including the Data Protection Act 1998, the Human Rights Act 1998 and the common law duty of confidentiality. In particular, the Data Protection Act restricts transfer of personal data to countries outside of the EU that do not have an equivalent level of protection. Information on the Data Protection Act is available from the ICO[13].

[11] NRES, Standard Operating Procedures for Research Ethics Committees, 2008
[12] NRES, Guidance on research database applications, 2008
[13] www.ico.gov.uk/

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Figure 4. Example page from the template.

As a key element in the development of an access policy, the second part of the template addresses the creation of a corresponding materials transfer agreement. To ensure that the wording of this (and the remainder of the document) is legally sound, we have had it reviewed by a firm of solicitors specialising in this area. In addition to this legal review, we have met with representatives of the main regulators and consumer representatives to discuss the draft document and ensure that they support this initiative.

The template was launched in June 2009 and is available from the NCRI website[15]. As described above, this document is expected to evolve; its launch, therefore, marks the beginning of a further round of consultation with interested parties and updates based on feedback from those using the template. We hope that awareness of the template will spread beyond the cancer research community - nothing in the document is specific to cancer.

Acknowledgements

This work has been informed by the views of all those who responded to the consultation on 'Access to Samples and Data for Cancer Research' during autumn 2008 and we are grateful for their input. However, we would particularly like to acknowledge the assistance of the following:

- Members of the NCRI Consumer Liaison Group who read and commented on the draft template
- The Information Commissioner's Office, National Information Governance Board and National Research Ethics Service for their review and helpful comments
- Morgan Cole Solicitors for assistance with the MTA section of the template

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