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

Michael Chapman1, Chris Carrigan2, Brian Clark3, Jane Cope3, Karen Groot4, William Lowrance4
1National Cancer Intelligence Network, London, UK; 2onCore UK; 3National Cancer Research Institute; 4Independent Consultant

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.

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).

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.ncrini.org.uk). 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.

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 turning 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.