

ACCESS TO SAMPLES AND DATA FOR CANCER RESEARCH

Response by the Wellcome Trust

September 2008

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. As a member of the National Cancer Research Institute, the Wellcome Trust is pleased to respond to the NCRI's consultation on the development of templates for [access to samples and data for cancer research](#).

General comments

3. The Wellcome Trust believes strongly that data and sample collections should be shared as widely as feasible in order to maximise the public benefit that can be gained from these resources. Such sharing should be undertaken in a timely and responsible manner, ensuring that it provides adequate safeguards for research participants and is fully consistent with the purposes for which consent was obtained.
4. The proposed template could have significant value for those who hold cancer collections that could be shared for added benefit. It will encourage researchers to think through access and governance arrangements in a structured manner, and promote wider discussion of these issues and development of best practice in the cancer research community. We therefore strongly support the NCRI and its partners in taking forward this initiative.
5. It is important to recognise that a large amount of work has already been undertaken to develop best practice principles in relation to the governance and access issues associated with biological resources, most of which is applicable to cancer collections. The proposed template should build upon this work, and might usefully include a list of existing resources and guidelines of this type.
6. In particular, we would highlight several ongoing activities in this area:
 - the OECD consulted earlier this year on draft guidelines for human biobanks and genetic research databases, which include a series of principles and best practices for access;
 - the Council for International Organisations of Medical Sciences (CIOMS), in partnership with WHO, has developed International Ethical Guidelines for Epidemiological Studies;
 - the Public Population Programme on Genomics (P3G) is undertaking work to identify common standards for governance across major biobank resources – including ongoing work to develop template material transfer agreements;
 - the MRC, the ESRC and Wellcome Trust are currently finalising a joint framework document on governance arrangements for longitudinal cohort studies that sets out principles and procedures for stewardship and management of access;
 - The Wellcome Trust, together with the Health Metrics Network, is hosting a workshop to develop a draft Code of Conduct for the Collection, Analysis and Sharing of Health Related Research Data in Developing Countries.

7. In addition, several of the major resource initiatives supported by the Wellcome Trust have considered access issues and developed associated materials – which might form useful templates for other studies. Key examples include the International Cancer Genome Consortium, the UK Biobank Ethics and Governance Framework and the Avon Longitudinal Study of Parents and Children (ALSPAC). The Trust is happy to share our experience in this area with the NCRI, and with the cancer research community more broadly, and provide any additional information that would be helpful.
8. The consultation document sets out a range of detailed questions on specific operational aspects of access policies, most of which would need to be considered on a case-by-case basis depending on the nature of the collection in question. In particular, access considerations will necessarily depend upon the size of the collection, the type of material or data in question (including, for samples, whether it is a limited resource), the level of sensitivity, and the likely level of value for secondary research use. In addition, it might be appropriate for a single collection to establish a range of different access conditions. For example, it is likely in many cases that the process for accessing samples might be different to that for the data derived from them, and that access provisions might vary for different data types.
9. We would suggest that the guidelines should have a clear up-front statement on the need to ensure that access procedures are established in a manner proportionate to the nature of the resource and associated level of risk. The imposition of unnecessary or over-burdensome access procedures would be counter-productive, and could be particularly detrimental to smaller specialist collections.
10. In considering the role of funders, it is important to note that many existing collections will have been developed through a range funding sources and therefore it can be problematic for any one funder to dictate the specific operation of a resource.
11. Because a large number of the questions raised in the document would need to be addressed on a case-by-case basis, we have restricted our comments to a few key issues – focusing in particular on questions highlighted for research funders.

Specific comments in relation to the consultation questions

12. We would query the description of scope of the document (section 1.2) in stating that it considers “matters relating to data and/or samples that have already been collected and held”. The clear implication is that the guidelines are not of relevance to those establishing new collections, which we do not believe should be the intention. Indeed, this section could usefully clarify that, where a new collection is to be established that could have value for secondary research use, issues of access should be considered from the earliest possible stage. This would include ensuring that the consent gained enables the samples and data to be shared in a way that maximises the resulting public benefit, whilst providing appropriate safeguards for participants.
13. In relation to the issues raised in section 2.1.1, we would not support the imposition of blanket restrictions on access for particular types of research users. Where a managed access process is required for UK-based collections, this should ensure that the requestor has relevant ethical and methodological approvals from the relevant UK oversight bodies (even if the requestors are not UK-based). It should also ensure that the proposed use is consistent with the consent under which the materials were provided. Where it is necessary to prioritise access requests, this should consider the relative scientific merit of the proposed use, and not exclude or prioritise requests based simply on, for example, the sector or geographical location of the user.

14. The issue of commercial use is raised in several places throughout the document and we do not see a situation where this should form the sole basis for a restriction on access. It may, however, be justifiable to charge commercial users higher fees for access in some cases.
15. In relation to the questions in section 2.1.3 on the timing of access approval, the Wellcome Trust will, where access to a particular resource is essential to a research proposal, make our funding conditional on the researcher attaining the necessary approvals to use the resource. We believe that it is important to maintain a degree of flexibility and allow for the fact that it is not always appropriate for access to be considered before funding has been obtained. It is clearly sensible for requestors to at least establish the feasibility with the custodian of accessing a particular resource which is integral to a research proposal before applying for funding. However, we would have reservations about the imposition of a 'letter of intent' system – there is a question once again of proportionality here, and a danger this could create an unnecessary bureaucracy and burden on smaller-scale collections.
16. In relation to the issues highlighted in Section 2.1.4, we would agree that it will often be beneficial to retain a small portion of each sample in perpetuity. We recognise, however, that this raises questions of long-term sustainability.
17. With regard to the issues raised in section 2.1.5 – where the Wellcome Trust is providing funding specifically for the establishment of a research resource, we ask applicants to detail their proposed governance and access arrangements and assess these as an integral part of the funding decision. Similarly, in considering funding renewals for resources, we will review their access arrangements as a key part of this decision. Where we feel access provisions are not sufficient, we will ask applicants to revise these before a funding decision is made.
18. In addition, our data management and sharing policy requires that all proposals involving the establishment of a data resource, or which will generate large volumes of data that could be shared for added benefit, provide a data sharing plan as part of their application – which is once again assessed as an integral part of the funding decision. As set out in this policy, we believe it is good practice for researchers to consider at the proposal stage how they will manage and share the data they produce. Likewise, we agree it is good practice for funders to encourage researchers to consider how they can maximise the value of data and samples in this way.
19. We do not believe that it is acceptable to block requests for access solely on the basis that they might be competitive to the originator's own research. Where the Wellcome Trust is funding a project as a research resource, we take quite a firm stance that decisions on access requests should be made independently of the principal investigator (although the group making this decision may often draw upon their expertise and advice). For limited sample collections, however, we recognise that there might be some situations where proposals for access that would essentially duplicate research being undertaken by the originator could reasonably be denied. Such decisions must be based on a sound scientific judgement aimed at maximising the lifespan (and hence the long-term value) of the resource.
20. With regard to identifiability (Section 2.1.6), we agree with the principles outlined in the italicised text. It is important for collections to keep safeguards under review in light of technological developments that might increase the potential to identify individuals and to consider what steps they would take should a participant be identified. Where these risks exist, it is important that they are explained to participants when seeking their consent. It might also be appropriate to note the standards being developed for safe havens for electronic patient records as part of the Research Capability Programme of Connecting for Health.
21. With respect to recontacting research participants (Section 2.2.2), the extent to which this is appropriate will depend upon the terms of the original consent. We would agree that it is good practice to make lay summaries of research outcomes available, but wouldn't suggest this was

an absolute requirement. Again potential participants should ideally be informed as to the availability of research outcomes as part of the consent process.

22. We agree that it is essential that access procedures for collections are stated clearly and are transparent (Section 2.2.6), and that the custodian should maintain a clear audit trail, no matter what the size of the collection is (Section 2.2.7).
23. With regard to the issues raised in Section 2.3, the Wellcome Trust takes a formal role in the governance of several of the major resources we support on the basis of our level of investment and strategic importance. Whilst we ask for and assess information on access and data sharing arrangements as part of our funding decisions, it would not be feasible in practice for us to formally monitor and audit data and materials sharing practices for collections across all of the many grants we support (as suggested in Section 2.3.3). We do agree though that funders should have appropriate sanctions in place which they can use in cases where resource providers or users are failing to comply with agreed best practice principles.