

Summary of responses to consultation on 'Access to Samples and Data for Cancer Research'



Executive Summary

This document summarises the range of responses received to the consultation on 'Access to Samples and Data for Cancer Research' run by the National Cancer Research Institute, onCore UK and the National Cancer Intelligence Network between August and October 2008.

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 (27 responses) and individuals (34 responses), with the majority received from researchers and healthcare professionals and the institutions / organisations that represent them. Only a small number of responses were received from providers of data (e.g. cancer registries) and consumer groups. These stakeholders will be particularly targeted in any follow up work.

The responses were strongly supportive of the stated aim: *'to prepare a template policy for wide consideration and use by individual funding and research organisations'*. The need for any template to be flexible to meet the varying needs of different collections and not to add unnecessary bureaucracy was also highlighted. Several respondents also recognised that the issues addressed by this consultation apply beyond the cancer research community and wished to see a broader base of users addressed. A number of respondents suggested improvements to the terminology used, generally making this more granular to recognise the wide variation in possible collection types.

Respondents were largely in favour of the widest access consistent with a collection's consent and with ensuring the ability of recipients to complete the proposed study. Access by commercial organisations was more controversial but the majority of respondents were in favour. The importance of peer review to ensure scientific merit was widely recognised and, in general, it was seen as reasonable to accept peer review carried out by funding bodies. However, respondents also considered it important to allow custodians to implement their own peer review where that already conducted is not considered sufficient (e.g. for studies funded as part of large programme grants or for very rare collections where a greater quality threshold may be required).

A flexible system that allows requests for access to be made before or after funding is secured received wide support. However, there was less agreement on the practicalities of such a system (i.e. does granting access subject to funding reserve a portion of the collection or should this still be subject to availability). Processing applications on an *ad hoc* basis or only at certain times were both considered valid options, with the choice likely to depend on the nature of each collection.

Where collections are created for a particular purpose, respondents agreed that any secondary access must not interfere with this primary purpose. However, it was expected that beyond this the collection should be made as widely available as possible and that the original consent should cover other research uses. Respondents generally believed that while the custodian must be

involved in deciding when the collection is opened for secondary access, there should be some independent input into the decision.

Respondents recognised that it might be necessary to give originators priority access to their collections and also that there are justifications for not completely depleting collections (e.g. to maintain diagnostic archives). Beyond this however, many respondents felt that samples should not be stored 'in case' a new application emerges while blocking potentially valuable work now. The idea of reserving proportions of the collection for different purposes received mixed views – some felt it to be a useful mechanism and others overly prescriptive.

The importance of protecting donor and data subject confidentiality was universally recognised. It was expected that recipients would agree not to attempt to identify individuals; not to link the data received with any other data sets without approval and not to disclose the identity of, or attempt to contact any individuals who might be inadvertently identified. Where consent is withdrawn, regulators' responses to the consultation provided clear guidelines for the approach. However, respondents had mixed views on whether unused samples should be destroyed by the recipient or returned to custodians to maintain an audit trail.

Most respondents believed that recipients should only be able to transfer materials to collaborators named at the time of the original request and that records of such transfers should be held by the custodian. However, a few went further, stating that there should be no onwards transfers and that all material should be received directly from the custodian.

Recontacting donors or data subjects to obtain further consent was generally not considered appropriate, with respondents preferring a broad consent to cover secondary research being obtained initially. In addition, most respondents considered it inappropriate to recontact donors or data subjects with individualised results from a study. Where the results of a study could impact a donor or data subject's care, the consensus was that this should be considered by a research ethics committee, ideally when the study is originally designed. Where contact is necessary, respondents felt it should be arranged through the team that took the original consent.

Although communicating individualised results was not considered appropriate, communication of research outcomes to both donors / data subjects and the general public was seen as important. Respondents recognised that the appropriate mechanism for this will vary depending on the study but the internet was widely seen as an effective method of achieving wide dissemination.

Most respondents believed that it is appropriate to recoup any costs incurred in supplying a recipient with data or samples and perhaps also a proportion of the cost of collection (if this was not covered by other funding). The idea of charging differential fees to recipients was more controversial and some respondents felt that

it would be hard to justify if fees were designed to recover costs. Despite this, higher fees for commercial organisations and lower fees for collaborative access in line with the primary purpose both received wide support.

Co-authorship for custodians was not considered a reasonable condition of access unless the custodian has made a significant contribution to the work. However, appropriate acknowledgement of originators and custodians was recognised as important. Submission of papers to peer reviewed journals was seen as a key element of an access policy, as was publication in open access journals where possible, although some respondents suggested a need to balance this with publication in the highest impact journals available. Publication of negative results was recognised as difficult to achieve but important in principle.

Protecting intellectual property generated from the collection was seen as important by respondents. However, the issue of whether collections themselves generate any intellectual property was also raised. An arrangement in which recipients agree to protect any intellectual property that arises but without detailed arrangements in advance was held up as a pragmatic way to avoid spending time discussing these issues for studies that are unlikely to generate any commercialisable results.

Respondents thought that a policy of openness around the uses of collections is important to maintain public trust and involvement. However, what details should be published and in what format was more controversial. Generally, there is a need to balance openness with researcher confidentiality and, potentially, with protecting commercially sensitive information.

It was widely agreed that custodians should maintain a record of all releases from the collection and of publications arising from it. Raw data (depending on the nature of the collection) could also be submitted for inclusion in the collection and made available to other users. Once again, there was less agreement on the practical details of whether such data should be publically available or restricted to a more limited group (e.g. users of the collection) and on for how long records should be maintained.

Clear governance processes were considered important for determining policies and dealing with unforeseen circumstances.

The consensus of respondents was that the body making these decisions should have representatives from all stakeholders (custodian, originator, funders, independent experts, patients and the public). However, respondents emphasised that governance arrangements should also be proportionate to the size of the collection.

Some respondents saw value in encouraging competing recipients to collaborate, especially where material is limited. However, others felt strongly that the custodian should not play a role in arranging collaborations and that individual researchers are in a better position to select their collaborators.

Ensuring compliance with the terms of an access policy was recognised as a difficult area, with auditing of recipients seen as useful in theory but difficult to achieve in practice. Respondents believed that it may have to be left to institutions to ensure compliance with regulations and to annual reporting by recipients to custodians to ensure compliance with the access policy and materials transfer agreement. Although there was a wide desire for suitable sanctions to punish non-compliance it was generally recognised that this will largely be down to funders and institutions to enforce as the only real sanction available to custodians is to deny future access.

The responses outlined in this document will be used to inform the two-part resource promised in the original consultation:

- (i) A template list of terms for an access policy for a specific collection of data or samples, with options for tailoring to circumstance: this will be a practical instrument for writing new access policies, and;
- (ii) A template Data and Material Transfer Agreement (MTA), which can again be used by anyone as a starting point.

The intention of these resources is to provide a starting point for organisations and individuals needing to develop a policy, and a base for developing best practice, without wishing to dictate terms.