

Samples and Data for Research: Template for Access Policy Development



NCRI

National
Cancer
Research
Institute



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NCIN 
national cancer
intelligence network
Using information to improve quality & choice


onCore^{UK}

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:

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NCRl Partners



Llywodraeth Cynulliad Cymru
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Foreword by Prof. Sir Kenneth Calman and Mr David Ardron

We are pleased to introduce this template for access policy development, which is the result of a joint initiative between the National Cancer Research Institute, the National Cancer Intelligence Network and onCore UK, and which has been informed by wide consultation amongst NCRI members and other interested parties. The creation of an access policy can be daunting; it is often easier to say no to sharing, and avoid the difficulty, than to venture to say yes. But there is a great deal to be gained if we can all say yes more often.

When we ask them, cancer patients are often surprised or even dismayed by how little use we make of their samples and information. Informed consent remains the gold standard and we must not assume that we know how individual patients would wish their samples and data to be used and shared. Where patients give consent, we have an ethical duty to generate the most knowledge possible from the data and samples they provide. The goal of this document is to enable the responsible sharing of data and samples for the benefit of all: patients, the public and researchers.

While the use of personal data and biosamples for research is subject to statutory regulation there is scope, within the regulatory framework, for individual institutions to work together and harmonise their individual policies and practice for the sharing of such resources. The opportunities for this were highlighted in a 2006 report¹ to two NCRI partners, the Medical Research Council and the Wellcome Trust, by Dr William Lowrance, who has also contributed to developing this template. Greater harmonisation will enable the linking of resources to open up new avenues of research, and to avoid unnecessary duplication. As a step in this direction, example terms, which may be adapted or adopted as appropriate, are provided throughout this document.

In producing this document, we have worked closely with the Information Commissioner's Office, the National Information Governance Board and the National Research Ethics Service. Circumstances of individual collections will vary, however, and if users of the template have queries about regulatory compliance they should seek advice from the relevant authority directly.

This template aims to provide a practical starting point for preparation of an access policy, rather than to add to the myriad guidelines that already exist, though these are valuable and many have been referenced. We aim to plot a course through the forest of regulation and guidance so that organisations can be confident that there is nothing major they have overlooked. We hope that the template will be used by those who need to develop a policy for access to their collections, by those who already have a policy and might find areas for improvement or clarification, by research funders, and by those involved with government policy and regulation. We hope too that it will be useful to those outside the cancer research community, as the principles involved are not specific to cancer. Finally, we want this resource to stimulate thought and debate. We have published it as an open draft; please let us know what you think and we will evolve it further in response to your experience and any regulatory changes.



Professor Sir Kenneth Calman
Chair, NCRI



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¹ Lowrance W.W., Access to Collections of Data and Materials for Health Research, 2006

Introduction

1. Background

- 1.1. There is growing awareness that without the sharing of data and samples, medical research will become increasingly wasteful of resources. Funds will be spent on unnecessary duplication of research or the collection of new data when existing data could serve the purpose just as well^{2,3}. The public expects that money collected through taxes or charitable giving will be used wisely^{4,5}, and this has created an imperative for more effective sharing of data and samples.
- 1.2. At the same time it is recognised that there must be safeguards around the movement of samples and data, to protect the interests of the individual donors or data subjects. These are provided by a regulatory and ethical framework which, among other things, sets the boundaries for access. Within these boundaries it is incumbent on institutions to minimise the barriers to research that has the greater public good as its ultimate aim.
- 1.3. In this context, the National Cancer Research Institute (NCRI), together with onCore UK and the National Cancer Intelligence Network (NCIN), ran a consultation on 'Access to Samples and Data for Cancer Research' from August to October 2008. The consultation received responses from research funders, regulatory bodies and biobanks, as well as individual researchers, healthcare professionals and patient representatives. These responses have been summarised in a document available from the NCRI⁶, and they have been used to inform the development of this template.

2. Aim

- 2.1. The aim of this document is to provide a template for access policy development that can be considered for adaptation to their purposes by a variety of individual funding and research organisations.
- 2.2. The exercise is not intended to impose policy and practice but rather to provide a practical instrument which (i) reflects established good practice principles, (ii) can be tailored to particular circumstances, and (iii) helps avoid unnecessary duplication of effort.
- 2.3. This version of the document is published as an open draft for consultation and will be updated based on comments received. If you have any suggestions or comments on the document please send them to access@ncri.org.uk or use the form available from the access pages of the NCRI website.

3. Scope and Applicability

- 3.1. The template concerns access to data and/or samples that have already been collected and are being held. Samples may include tumour tissue, healthy tissue, or body fluids; they may be from healthy people or from patients.

² OECD, Principles and Guidelines for Access to Research Data from Public Funding, 2007

³ National Institutes of Health, Final NIH Statement on Sharing Research Data, 2003

⁴ HM Treasury, *Managing Public Money*, 2008

⁵ The Charity Commission, Charities and Public Benefit. 2008

⁶ NCRI, Summary of responses to consultation on 'Access to Samples and Data for Cancer Research', 2009

- 3.2. 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.
- 3.3. Although the initial creation of a collection is not addressed, it should be emphasised that access considerations need addressing at the earliest possible stage. This will, for example, ensure that appropriate consent is gained to cover both the primary purpose of the collection and to allow sharing of samples and data. Much of what follows is dependent on the nature of consent originally obtained. Broader advice on the creation of a collection can be obtained from other sources such as the Medical Research Council's Data and Tissues Toolkit (see Appendix A for details of this and other useful resources).
- 3.4. This template document is mainly intended to apply to data or samples whose collection has been supported through public funding either by government bodies or charity. In granting access to such collections there is a special need to balance the public interest with the interests of the originator/funder and the patient. It is hoped that the issues rehearsed here will also be of value to other organisations, both commercial and not-for-profit.
- 3.5. The data or samples to be accessed may have been collected expressly for research as the primary purpose, or they may have been collected for another purpose, such as healthcare, whilst having the potential for secondary use in research. Although this template has been prepared primarily for cancer research, it should be equally applicable to other areas of research.

4. Structure and use of the template document

- 4.1. The main body of this document describes the principal topics that may be encountered in the development of an access policy and some of the considerations that may influence that policy. The second part of the document covers the development of the data access or and material transfer agreements (MTA) that would be based on the policy.
- 4.2. Each section includes example terms for inclusion in a policy or agreement, as shown here.

Example policy terms:

Example language for use in an access policy is included in each section, with variations suitable for collections of differing types or situations. Points where collection specific information should be inserted are indicated in square brackets: [Collection specific details].

The material in this document, including the example material transfer agreement, is for information only and is not intended to constitute a definitive or complete statement of the law on any subject, nor is it intended to constitute any form of legal advice.

You should not use or otherwise view the content of this document as a substitute for obtaining your own specific legal advice. If you wish to use the content of this document in any jurisdiction other than the UK, we would strongly suggest that that you obtain your own specific local legal advice before proceeding.

Although we try to ensure that the information in this document is accurate, we cannot be held responsible for any reliance that you place on it and we give you no warranty or assurance in that respect.

Part I. Template list of access policy terms

5. Terminology

- 5.1. The first part of this document defines a series of terms that will be used throughout. Not all of these will be required in any particular access policy but it may be helpful to include the most relevant. A glossary and list of abbreviations is provided in Appendix B.
- 5.2. In what follows, 'Collection' denotes any dataset, including summary datasets, or set of human samples with associated data, that may be offered for research to investigators ('Recipients') beyond the 'Originator' i.e. the person or leader of the team who collected the data and/or samples.
- 5.3. The originator may have compiled the collection:
 - i. For a specific, focused research project, or
 - ii. For use as a broad research resource by others, or
 - iii. For health service provision, planning or policy.
- 5.4. A further distinction can be made between collections that are easily replenished or inexhaustible and those that are rare and depletable.
- 5.5. The 'Custodian' is the person, organisation, body or committee, who has formal responsibility for the collection at the time a request for access is received. The custodian is accountable for maintaining the integrity and security of the collection and for providing access under whatever governance terms may be in place. The custodian may or may not be the same person as the originator.
- 5.6. The 'Requestor' is an individual or group seeking access to data and/or samples. Once access has been granted, a requestor becomes a 'Recipient'.
- 5.7. There is no consistent term in use for individuals who provide samples or to whom data may apply. 'Donor' is frequently used in respect of samples and 'Data subject' in respect of data. Since in the UK the regulations and principles governing data are different from those applying to tissue samples, both of these terms are used in this document.
- 5.8. When considering data protection issues, the term 'Transfer' generally refers to international transfers of personal data. Throughout this document, however, it is used in its most general sense to include all transfers of data between parties. Further guidance on transfers of personal data is available from the Information Commissioner's Office (ICO)⁷.
- 5.9. In some contexts it may be necessary to define 'Research'. For example, research requires ethics approval while audit and service evaluation do not. The National Research Ethics Service (NRES) has published outline guidance on the distinction between research, clinical audit and service evaluation⁸.

⁷ ICO, The eighth data protection principle and international data transfers, 2008

⁸ NRES, Defining research, 2008

- 5.10. 'Research Ethics Committees' (RECs) oversee clinical research in the four countries of the UK. REC approval is a legal requirement for research involving NHS patients, their identifiable data or their tissues (full details of the requirements are available from NRES).

6. Overview of the collection and the access process

- 6.1. An access policy usually begins by describing the nature of the collection and the purpose for which it was collected. The policy can then provide leads to further information (for example online catalogues and sample metadata, mechanisms for checking availability, and methodological and ethical documentation) and contact details for the custodian.

Example collection description:

The collection consists of [type of samples / data] collected from [details of donors / data subjects] for use in [details of original purpose]. A searchable online catalogue is available at [website address] and further information (including details of sample availability) can be obtained from [Custodian contact details].

- 6.2. The access policy can then describe the major steps in gaining access to the collection. The generic steps that will form part of any access process are set out in Figure 1. This document covers each of these stages in turn, describing the main issues that an access policy may wish to address and the considerations that may help decide the policy.

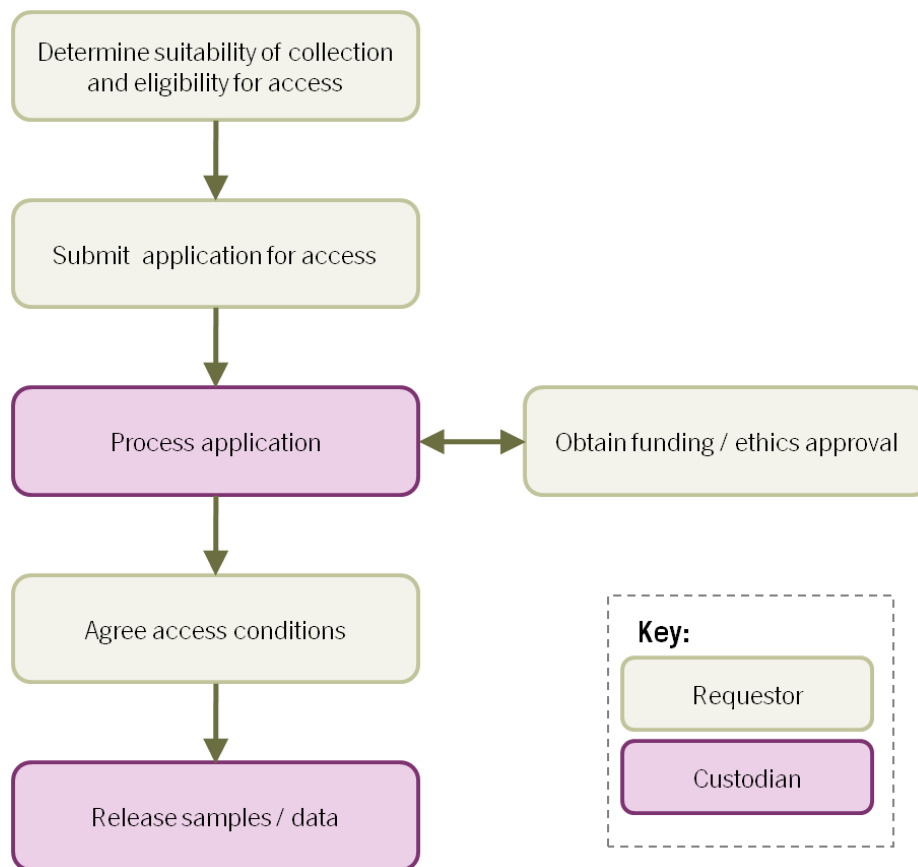


Figure 1. Major steps in an access process

Example of an outline access process:

Access to the collection consists of four stages, which must be completed before [samples or data] are provided:

1. Determining the suitability of the collection and the eligibility of the proposed study for access
2. Completing the application and providing any supporting information required
3. Consideration by the custodian of the application for approval
4. Agreeing to the conditions of access and/or signing the MTA

7. Eligibility for access

- 7.1. This part of an access policy can set out details of the types of studies and recipients that are eligible to apply for access.

Limitations on use of the collection

- 7.2. The uses to which the collection can be put will be limited by the consent obtained when the samples or data were originally collected. The nature of this consent may usefully be stated in the access policy to ensure that applications are consistent with it.
- 7.3. Even where broad consent has been obtained for the use of a collection, it may be appropriate to prioritise certain uses based on the original purpose of the collection (for example, collections created for cancer research or translational research may prioritise these uses). Any such prioritisation could usefully be explained in the policy.

Example description of consent:

The collection holds consent for use in [scope of consent].

Applications are welcome for studies in all areas but, where samples are limited, priority will be given to research directly related to [original purpose of collection].

- 7.4. Certain collections' consent may not cover secondary research or include research at all. In such cases it may be helpful to outline the conditions under which access to the collection may be granted. Anonymised samples or data may be made available for ethically approved research⁹ or it may be possible to approach donors / data subjects for further consent (this should be done via the custodian or team who originally collected the data or samples). Where neither of these is practical, application may be made to the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care (who consider the applications for the use of identifiable patient data without consent under Section 251 of the Health and Social Care Act 2008).

⁹ Human Tissue Authority (HTA), *Code of Practice – Consent*, 2006

Use of samples beyond original consent:

The [collection] was generated for [original purpose] and does not have consent for the use of identifiable samples in secondary research. Anonymised samples can be made available for research approved by an appropriate REC.

Use of data beyond original consent:

Requestors who wish to access identifiable information must supply evidence that either consent has been granted by all data subjects or that approval has been secured from the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care (who consider the use of identifiable data under Section 251 of the Health and Social Care Act 2008).

Limitations on the availability of the collection

- 7.5. Where collections are created for a specific purpose (for example, in a clinical trial), the requirements of this primary purpose may initially restrict secondary uses. This may require reserving either the entire collection or a percentage of it for a defined period of time. In some cases, for example where the sample forms part of a diagnostic archive, a portion of each sample may need to be reserved indefinitely.
- 7.6. Once the primary purpose of the collection has been achieved, the reserved portion may be released for secondary uses. Where possible, an estimated date by which the collection will be opened for secondary access should be given.

Collection with reserved portion:

The collection exists to support [primary purpose]. However, [agreed portion] of each sample is available for other research uses and any remaining material beyond this will be made available once [primary purpose] is completed (expected to be by [date]).

- 7.7. Access policies may also recognise the contribution of originators by asserting their rights to, for example, first publication from their research and by requiring recipients to appropriately acknowledge originators in publications¹⁰ (see also paragraph 10.19).

Collection made available pre-publication:

The collection is made available as a community resource and detailed information on this is provided in the project description (see [publication details]). Recipients are free to use material in their research but are asked to respect the originator's interest in conducting the studies included in the project description and to discuss any overlapping uses with the originator in advance.

Users of the collection are also requested to reference the project description on the website and acknowledge [originator group] in their work.

¹⁰ Wellcome Trust, Sharing Data from Large-scale Biological Research Projects, 2003

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 identifiable data or their tissues. Collections of samples (research tissue banks) are able to seek generic REC approval for research conducted on their collections¹¹ and a similar process is available for research databases¹².
- 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 ICO¹³.

¹¹ NRES, Standard Operating Procedures for Research Ethics Committees, 2008

¹² NRES, Guidance on research database applications, 2008

¹³ www.ico.gov.uk/

- 7.15. There are no restrictions on exporting human tissues from the UK¹⁴. However, the possibility of export should be made explicit in consent forms and accompanying information where this may occur. Consideration should also be given to whether any information that might accompany the sample would be covered by the Data Protection Act or the common law duty of confidentiality and custodians should ensure that they comply with the import requirements of the receiving country.
- 7.16. Access to publicly or charity funded resources by commercial organisations can be controversial but the public good that can arise from commercial research is widely recognised^{15,16}. Where commercial users may receive access, it is good practice for consent forms to explicitly state this and for the access policy to specify whether such users are eligible for access.
- 7.17. If access restrictions are proposed then it may be necessary to discuss them with funders who are likely to have their own policies and requirements in these areas.

Collection with access limitations based on institutional affiliation:

Requestors should be employees of a recognised academic institution or NHS organisation; or of a commercial research organisation with experience in [research area].

Collection with access limitations based on researcher track record:

Requestors should be able to demonstrate, through their peer reviewed publications in [research area], their ability to carry out the proposed study.

Prioritisation of access to the collection

- 7.18. Even where there are no absolute limitations on access by particular groups of researchers, resource limitations may require some prioritisation of access. If it is considered appropriate to give priority to certain groups (for example, researchers local to the collection or those supported by the bodies that fund the collection), it may be helpful to describe the criteria.

Collection with prioritisation for access:

Where demand for material exceeds its availability, access will be prioritised based on:

1. Scientific merit (as judged by [body conducting peer review])
2. Priority to researchers working in [priority institution or research area]
3. Priority to researchers funded by [funding body]

8. Application for access

- 8.1. Once applicants have determined that they are eligible for access, either through reference to the collection's policies or by an informal approach to the custodian, the next stage is to formally apply for access.

¹⁴ HTA, Code of Practice – Import and export of human bodies, body parts and tissue, 2007

¹⁵ Pharmaceutical Industry Competitiveness Task Force, *Value of the Pharmaceutical Industry to the UK Economy*, 2000

¹⁶ HM Treasury, Science and innovation investment framework 2004-2014: next steps, 2006

- 8.2. This section can describe the mechanisms for application; details of whether requests will be considered before or after funding and other approvals are obtained, and timing for the applications and decision process.

Information to be supplied by requestors

- 8.3. The policy may describe how applications should be submitted (i.e. whether this should be on paper or via a website) and whether particular application forms need to be completed.
- 8.4. It is probably not necessary for an access policy itself to describe the information required for an application as this can be left to a separate form. An example of the types of information it may be useful to collect is included in Box 1.
- 8.5. Information may be collected in a single form, or custodians may consider it more appropriate to request a shorter preliminary application to assess sample availability and the likelihood of a request being approved before inviting requestors to submit a full application.

Application submission – single stage:

Applications for access to the collection should be provided on the form available from the collection website and submitted to [contact details]. All of the details on the form should be completed as any missing information may delay the application.

Application submission – two stage:

Researchers who wish to access the collection should initially contact the custodian [provide contact details] giving a brief outline of the proposed study, the methodology to be followed and the number and type of samples required. The custodian will assess the suitability of the application and respond to the applicant.

Box 1. Example of information required

Details of the requestor:

Name, institution / organisation, contact details, research CV

Details of the study:

Study outline, proposed methodology, funding sources (and evidence of funding), evidence for ethical approvals, evidence of consent held, evidence of other approvals required (e.g. Section 251), details of collaborators, plans for publication of results, lay summary of the study.

Details of the material requested:

Description of the material requested, justification for the type and amount of material requested, reason for approaching this collection

Timing for requests for access

- 8.6. It may be helpful to describe the timing of when requests for access will be considered. This could be on an *ad hoc* basis or only at particular times.
- 8.7. Considering applications on an *ad hoc* basis is likely to provide faster access to data or samples but may be difficult to achieve if there is a requirement for a committee to consider an application (although it may be possible to do this via email / teleconferencing). This approach is also likely to prevent comparison of applications for prioritisation.
- 8.8. An *ad hoc* approach is likely to be appropriate for collections to which access will be granted on a first-come, first-served basis. It is also likely to be more suitable for collections that receive limited numbers of requests.

Collection with *ad hoc* consideration of requests for access:

Applications may be submitted at any time and will be considered in the order in which they are received.

- 8.9. Conversely, considering applications on a fixed cycle may be more appropriate if a committee meets to prioritise applications for a limited resource. However, this is likely to slow access and may not be appropriate if only a small number of applications are expected.

Collection with specific deadlines for access requests:

Applications for access to the collection are considered [insert figure] times per year. The deadlines for applications are: [deadline dates].

- 8.10. The same policy may not be appropriate throughout the lifetime of a collection. For example, a collection may take an *ad hoc* approach to requests for access while it is established, before switching to regular application cycles later. Alternatively, a hybrid approach may be taken in which, for example, an *ad hoc* approach is applied for most applications but with those where further peer review is deemed necessary (see paragraph 9.9 below) referred to a regular scientific review meeting.
- 8.11. To help requestors plan their application, the policy may also provide estimates of how long it will take for a decision to be reached once an application is submitted for consideration.

Target timeline for applications:

[Collection] aims to acknowledge all applications within [time for acknowledgement] of receipt and to provide a decision within [time for decision].

Consideration of requests before funding and ethics approvals are in place

- 8.12. An access policy may wish to be flexible about whether requests can be considered before funding or ethical approval is obtained. This can be helpful to applicants, who may need to demonstrate to funding bodies that they will be able to access the samples or data required for their proposal.

Collection where applications can be made before or after funding and ethical approval is secured:

Applications to the collection can be made before funding and ethical approvals are obtained. In these cases, a letter stating the intent to grant access subject to the appropriate conditions will be issued to the requestor.

- 8.13. If access in principle will be granted, the access policy should detail for how long such access will be valid and whether it will guarantee access to the resource (i.e. a part of the collection will be reserved for a period) or whether access will still be subject to availability.
- 8.14. If samples will not be reserved, it may be useful to state what will happen if the requested samples are no longer available once funding or approvals are secured. For example, collections may be able to suggest alternative samples that they or other collections hold.

Collection where a letter of intent reserves the samples:

Any 'letter of intent' will be valid for [a time period to be stipulated] from the date of issue and will reserve the requested samples. After this time the samples will be made available to other applicants and the requestor will be required to reapply for access.

Collection where a letter of intent does not reserve the samples

Any 'letter of intent' will be valid for [time period] from the date of issue but does not guarantee access to particular samples. If the requested samples are not available when funding and other approvals are secured, the custodian will attempt to provide similar samples although this will not always be possible and cannot be guaranteed.

9. Processing applications

- 9.1. This section can describe how applications will be considered once submitted and how a decision will be made on whether or not to grant access.
- 9.2. A generic process for the dealing with applications is shown in Figure 2. This section will cover each step in turn, although not all steps will be relevant to every collection.

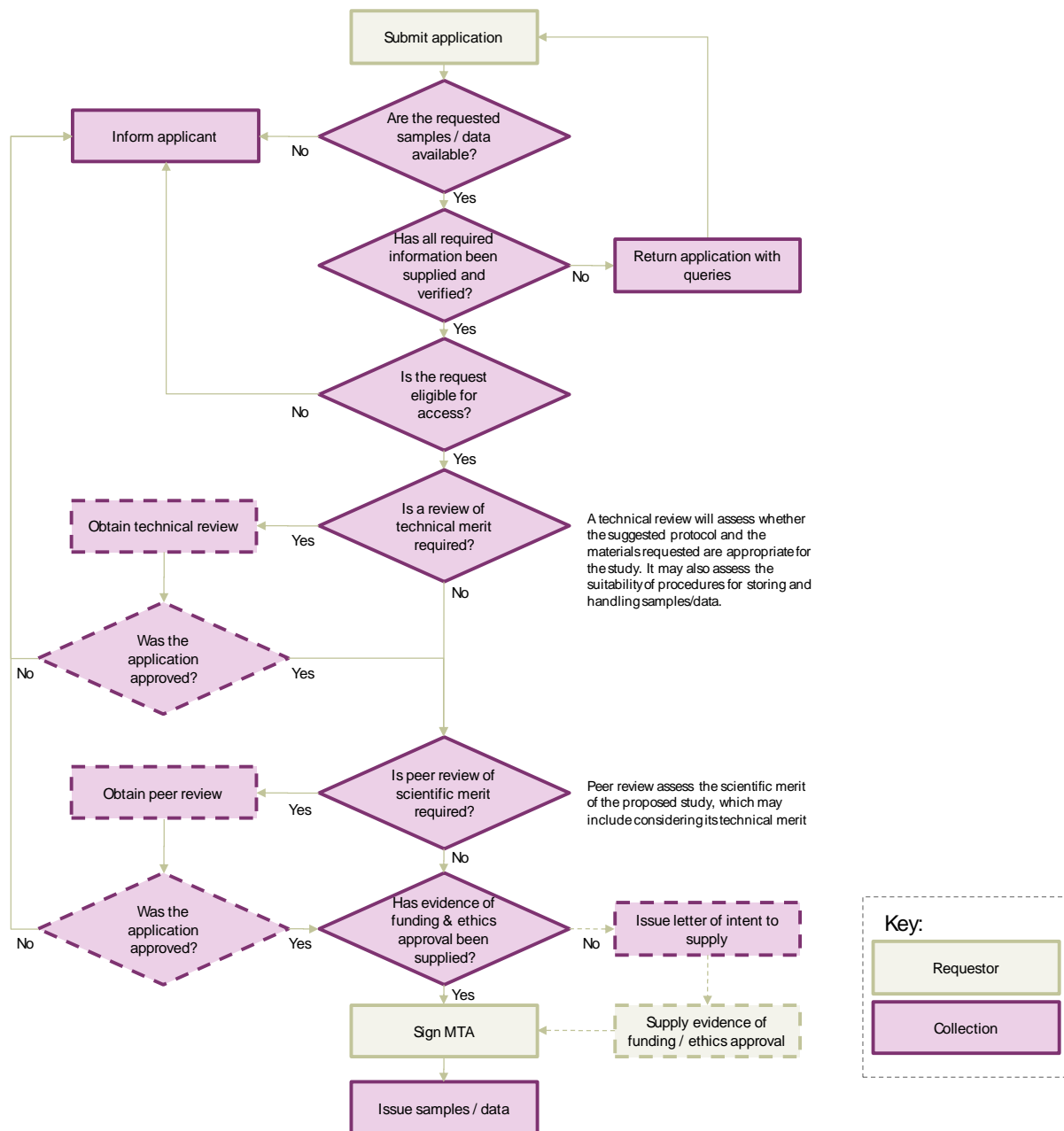


Figure 2. Generic depiction of application handling

Administrative checking

- 9.3. Any application will require some administrative checking to ensure that the correct information has been supplied, that the study and requestor are eligible for access and that the samples requested are available.
- 9.4. The access policy may wish to give details of these processes and what will happen if, for example, samples are not available or the information supplied cannot be verified.

Example description of administrative checking:

On receipt of the application, the custodian will check to ensure that the requested samples are available and that all required information has been supplied. If samples are not available the requestor will be notified with details of possible alternatives. If any information is missing from the application the requestor will be asked to supply this before the application is considered further.

Technical review

- 9.5. For some very limited or complex collections, it may be appropriate for custodians to arrange for the proposed study methodology to be reviewed to ensure best use of the collection. Recipients' standard operating procedures for handling and storing data or samples may also be included in such a review. As with any process that may limit access to a collection, the justification for a technical review should be stated and the process should be as transparent as possible.
- 9.6. Such a review may be conducted by the custodian (if they are sufficiently knowledgeable); by a technical review panel or by an independent expert.
- 9.7. However the review is arranged, if the original protocol is not considered appropriate but is of promising quality, ideally the reviewer will provide guidance to requestors that will allow them to submit an improved protocol¹⁷.

If technical review is required:

The proposed study protocol will be reviewed by [custodian or other panel / independent expert] for suitability. If the protocol is not considered appropriate the custodian will contact the requestor to explain why this is the case and may suggest improvements.

If a review of standard operating procedures is required:

The requestor will need to submit copies of standard operating procedures for storing and handling [tissues / data] and these will be reviewed by the custodian as part of the application.

Screening for scientific merit

- 9.8. Most collections will wish to screen applications for scientific merit, or see evidence of scientific merit, before granting access. For non-depletable collections, the peer review required to gain funding may be sufficient. However, depletable collections may require their own peer review to distinguish between applications which have all been funded.
- 9.9. There may be occasions when further peer review is required for access to non-depletable collections. For example, custodians may decide that applications may require further peer review if they are funded as part of a large programme grant or by funders that are not a UK research council, member of the Association of Medical Research Charities or non-UK equivalent. Alternatively, the resources needed to extract and process samples or data may limit the number of applications that can be fulfilled.

¹⁷ A template System Level Security Policy is available from the NIGB (<http://www.nigb.nhs.uk/ecc/applications-and-guidance>) which may be helpful for collections involving patient identifiable or other sensitive data.

- 9.10. Custodians should also consider whether they will require further peer review for applications from commercial organisations or whether they will accept a company's internal review processes as sufficient.
- 9.11. The access policy may wish to specify when further peer review will be sought and who will be involved in the process. If requestors will be allowed to ask that certain referees are excluded then this should be explained, together with who will make the final decision.

Peer review in all cases:

Due to the rare and depletable nature of the collection all applications for [data or samples] will be peer reviewed and prioritised on the basis of scientific and technical merit. The reviewers will be [details of reviewers]. If requestors would like to exclude particular individuals from acting as reviewers (for example, where a conflict of interest may exist) then they should inform the custodian with an appropriate justification. The final selection of reviewers, however, remains with [details of who will make the decision].

Collection reserves the right to peer review:

Some applications to the collection may be referred for peer review as part of the screening process. If this is the case, requestors will be informed and provided with details of the reviewers. Requestors may request that certain reviewers be excluded but the final decision will be made by [details of who will make the decision].

Handling of competing applications

- 9.12. The access policy may also include details of how competing applications will be handled. It may not be possible or appropriate to fulfil two very similar applications and the policy may explain what action the custodian will take to resolve this.
- 9.13. In some cases, the custodian may ask the two requestors whether they would like to be put in touch with one another and suggest that they collaborate. In other cases, or where collaboration is not possible, the custodian may rely on independent peer review to select between the applications or may prioritise them based on other criteria (see section 7 above).

Collection that will put competing applicants in touch:

As the amount of material available is limited, requestors who propose similar studies may be put in touch with a suggestion that they collaborate. If the requestors are not willing to collaborate then both applications will be considered as usual. However, it is very unlikely that access to the collection will be granted for two very similar studies.

Requests made without funding or ethics approvals in place

- 9.14. If access will be granted subject to funding and ethical or other approvals, the access policy can provide details of what evidence is required and how it should be submitted once obtained. It may also be useful to explain the procedure if obtaining funding or approvals will require significant changes to the proposed study.

Submission of approvals:

Once the conditions for access specified in any 'letter of intent' are met, evidence of this (for example letters from funding bodies or RECs) should be submitted to the custodian.

If gaining funding or the required approvals will require significant changes to the study, the custodian should be informed as soon as possible together with details of the changes. Depending on the nature of these changes, a new application may be required.

Appeals

- 9.15. The access policy may wish to describe any mechanism for resolving disputes or challenges to the application process. This could include an explanation of how the dispute will be resolved (for example, disputes may be decided by the ultimate governing body overseeing the collection) and of any processes around this (such as time limits for appeals against decisions).

Appeals:

If access to the collection is refused an appeal may be made to [details of governance body that will deal with disputes]. This should be made in writing within [time limit] and will be considered at the next meeting. The decision of [governance body] is final. [Governance body] will also deal with any other disputes that may arise from the functioning of the collection.

10. Conditions of access

- 10.1. Once access has been approved, the final step before releasing data or samples is likely to be agreement of the conditions of access by the recipient and their institution.
- 10.2. These conditions will be included in a transfer agreement to be signed by authorised signatories of the custodian and recipient institutions. The main elements may also be set out in the access policy so that requestors are aware of them at the time of application.
- 10.3. The following paragraphs discuss the major terms that may form part of the conditions of access.

Introduction to the conditions of access:

Before access to the collection is granted, requestors must agree to the conditions of access set out below and return a signed [data or materials] transfer agreement to the custodian.

Fees

- 10.4. Any fees charged for access should be clearly stated in the access policy or elsewhere. Even if detailed fees are not shown in the access policy, the conditions of access should state what costs the recipient will be required to pay.

- 10.5. Human tissue samples cannot be 'owned' and should not be assigned a value based on high demand or rarity¹⁸. However, the costs incurred in collecting, storing and supplying the samples may be recovered from recipients. Similarly OECD guidance¹⁹ is that data should be available at the lowest feasible cost.
- 10.6. Depending on the nature and funding of the collection and on the type of requestor, fees might be charged to cover only the costs of retrieving, processing and dispatching to the recipient, or fuller costs including some costs of collecting and maintaining samples or data in the first place or of facilitating consent for a particular study.
- 10.7. Custodians may choose a simple fixed rate fee. However any differences in the fees charged for different users should be clearly explained. Custodians should carefully consider the rationale for differential fees in terms of whether the costs to be incurred are different, whether extra value has been added before sharing the data or materials, or whether prospects of eventual profit justify higher charges than for other requestors.
- 10.8. In the case of requestors whose research will be funded by the same body that has funded the collection, that body may legitimately expect that any fee should only cover the costs of retrieval, processing and dispatch.

Fees:

The recipient will be required to cover the costs of retrieving, processing and dispatching [data or samples]. Details of these costs are available from the collection website.

Transparency

- 10.9. An access policy may state what information will be published to ensure visibility of the collection's research uses. Such information may include: study titles, brief research summaries (lay and technical), details of the researchers and institutions and the kind of data or types and numbers of samples supplied.
- 10.10. These details may be posted on the collection's website, published in annual reports or provided on request. The choice of what information to publish, and how openly, will depend on balancing openness with research confidentiality, researcher privacy / security issues and intellectual property sensitivities.

Transparency:

Study titles will be published on the collection website, together with lay summaries and the names of the institutions where the work is taking place. Contact details for the principal investigator of each study will be provided by the custodian upon request.

Requestors who do not wish details of their study to be openly available should state this in their application to the collection and give the reason.

¹⁸ CCB, CCB Guiding Principles, 2006

¹⁹ OECD, Principles and Guidelines for Access to Research Data from Public Funding, 2007

Usage Limitation

- 10.11. The access policy may contain a clause which limits use of the data or samples to that agreed with the custodian.

Usage Limitation:

[Data or samples] supplied from the collection must only be used for the purposes stipulated by the custodian and described in the [data or materials] transfer agreement.

Onward transfer

- 10.12. The conditions of access will almost certainly limit onward transfer of data or samples by the recipient. This may be restricted to collaborators of the recipient, named in the application and approved by the custodian, for instance. Or it may be prohibited unless, for example at a later time, the custodian approves. Discipline as regards onward transfer usually will be a responsibility of the recipient.

Onward transfer to collaborators:

[Data or samples] supplied from the collection may only be transferred to collaborators named at the time of the original application or in subsequent applications and specified in the [data or materials] transfer agreement or later amendments.

No onward transfer:

[Data or samples] from the collection may not be transferred to individuals outside the requestor's research group.

Data identifiability

- 10.13. Where anonymised or pseudonymised samples or data are supplied, the conditions of access should require that recipients do not attempt to identify any donors or data subjects (since even de-identified data may retain a degree of risk of identifiability). They will also generally be required not to link the data supplied with any other datasets unless this has been agreed.
- 10.14. A clause may forbid recipients from recording or disclosing the identity of any data subject or donor whom they may inadvertently identify. Another clause may provide that recipients must make no attempt to contact any such individual.

Protection of anonymity:

Recipients must agree not to link the anonymised [data or samples] provided with any other data set without the permission of the custodian.

Recipients must not attempt to identify any individual from the [data or samples] provided.

Should recipients believe that they have inadvertently identified any individual, they must not record this, share the identification with any other person or attempt to contact the individual.

- 10.15. Custodians may require recipients to notify them if they do inadvertently identify any individual in anonymised or pseudonymised data or samples. This would allow protocols to be improved to reduce the risk of further breaches of confidentiality.

Actions on inadvertent identification:

If recipients believe that they have inadvertently identified any individual from the [data or samples] provided they must inform the custodian and provide details of the circumstances under which this occurred.

- 10.16. If identifiable samples or data are provided then there should be no attempt to contact the donors or data subjects unless this is covered by consent and has been agreed as part of the study protocol. If subjects will be re-contacted then this should be done via the custodian or the team that created the collection.

Identifiable data:

No attempt to contact [donors or data subjects] should be made by the recipient. Any contact required as part of the study protocol must occur through the custodian.

Exploitation of Intellectual Property

- 10.17. Donors and data subjects will usually be required to waive their intellectual property (IP) rights at the time of a donation (the 'sample as a gift'). The Confederation of Cancer Biobanks (CCB) suggests that collections (in this case biobanks) also waive their IP rights²⁰.
- 10.18. However, it is important that any IP generated from the collection is adequately protected and recipients should agree to work with their funders and host institutions to achieve this.

Protection of Intellectual Property (IP):

Although the collection has waived its right to any IP arising from the [data or samples] provided, recipients must make every effort to protect this in line with the policies of their host institution and funders.

Publication

- 10.19. Custodians may wish to include a publication policy specifying that recipients should submit their results to a peer reviewed publication within a reasonable time following the completion of the study. The policy may wish to allow recipients to delay publication for a limited period to protect IP.
- 10.20. The policy may also specify whether publication should be in an open access journal and whether the manuscript should also be submitted to a database such as UK PubMed Central.

Publication policy:

Recipients are expected to submit their results to a peer reviewed publication within [time limit] of completing their study. If the researchers wish to have this period extended to protect IP, they should discuss this with the custodian.

Publications should also be deposited in the UK PubMed Central database within [time limit] of publication.

²⁰ CCB, CCB Guiding Principles, 2006

- 10.21. The conditions of access may require that recipients attempt to publish any negative results and, where this is not possible, submit them to the custodian to ensure that work is not unnecessarily repeated.

Negative results:

Recipients should aim to publish the results of all studies, including negative results. If it is not possible to publish negative findings, the manuscript should be submitted to the custodian for inclusion in the collection.

- 10.22. Generally, recipients who have satisfied the requirements for accessing a collection should be considered competent and free to publish their results without restriction, although they may benefit from discussing their results and interpretation with the custodian before publishing. Where there is a real risk of misinterpreting the results from especially complex collections this should usually be handled through collaboration with the custodian, rather than by restricting freedom to publish results. Circumstances in which it is appropriate for the custodian to require that manuscripts or other draft public presentations (including oral or poster presentations, or press releases) based on the collection be submitted in advance to the custodian for review are expected to occur only rarely.
- 10.23. To maintain a record of publications based on the collection, the custodian will frequently ask recipients to provide copies of papers upon publication.

Record of publications:

Recipients should provide a copy of any publications based on [data or samples] from the collection to the custodian.

- 10.24. Finally, a publication policy may wish to specify the form of acknowledgment.

Acknowledgement of the collection:

Any publication or presentation using [data or samples] from the collection should include an acknowledgement using the text below:

[Acknowledgement text]

Maintenance and enrichment of the collection

- 10.25. Custodians may require recipients to provide raw data and any derivative or composite materials generated during their studies, along with documentation, to the collection. The access policy may specify what data and materials are required and the mechanisms by which they should be submitted. This submission may need to be delayed to protect IP and custodians may wish to provide for this in the policy.

Enrichment of the collection:

On completion of their study, recipients should provide their [data or materials to be provided] to the custodian for possible inclusion in the collection. [Data or materials] should be provided within [time limit] unless a delay is required to protect IP.

Submission of results to the collection does not affect the requirement for recipients to maintain their own research records.

- 10.26. If derived data or materials are provided to the custodian, the terms under which they may be made available to others should be made clear. This will depend on the exact nature of the collection and possibly the consent held; examples of four approaches are provided below.

Derived data and materials made publicly available:

[Derived data or materials] submitted to the collection maybe made publicly available.

Derived data and materials made available to other users of the collection:

[Derived data or materials] submitted to the collection may be made available to other registered users of the collection.

Derived data and materials made available on request:

[Derived data or materials] submitted to the collection may be made available on request to the custodian via the collection's standard application process.

Derived data and materials available with permission of the originator:

[Derived data or materials] submitted to the collection may only be made available with the permission of the originator of the [data or materials].

- 10.27. While the details of running a collection are beyond the scope of this document, custodians should consider the resource requirements of receiving, managing and making available the data / materials derived by recipients. The period for which records or materials will be maintained should also be considered.

Withdrawal of consent

- 10.28. The process to be followed if consent is withdrawn should be made clear and must be in line with the promises made in the original consent. Where samples or data have been provided by the collection the policy should explain whether recipients will be required to destroy these themselves or return them to the custodian for destruction. It is generally recognised that once samples or data have been used for research this cannot be undone and that the information acquired can still be used²¹, although such data / tissue, where obtained in identifiable form, should be de-identified as soon as practicable.
- 10.29. If a fee has been charged to the recipient for the samples or data, and these then must be destroyed, the conditions of access should state whether some part of the fee will be refunded.

Withdrawal of consent – samples:

If consent is withdrawn for issued samples, recipients will be informed of the relevant sample numbers and asked to [destroy any unused samples and certify that they have done so, or return them to the custodian for destruction]. Results obtained from samples that have already been used for research need not be destroyed.

The sample fee is non-refundable if consent is withdrawn.

²¹ HTA, Code of Practice – Consent, 2006

- 10.30. For linked anonymised data, the Patient Information Advisory Group (now replaced by the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care) has decided that if consent is withdrawn shortly after data is provided, the recipients should be asked to destroy the relevant data. If consent is withdrawn after a longer delay, the links to the person's identifiers should be destroyed, rendering the data effectively anonymised. Cases should be considered individually to balance the impact on the research with the potential distress possibly caused to individuals.²²

Withdrawal of consent – linked anonymised data:

If data subjects withdraw their consent within [time period] of provision of the information, recipients of linked anonymised data will be informed of the relevant identifiers and must delete the corresponding data rows. Beyond this time, the linkage data held by the custodian will be destroyed and recipients may continue to use the anonymised data in their study.

The data handling fee is non-refundable if consent is withdrawn.

- 10.31. If identifiable data are provided, the access policy should require recipients to delete the records of any data subject who withdraws consent. If already incorporated into analysis, records should be de-identified. The custodian should maintain a record of such requests.

Withdrawal of consent – identifiable data:

Recipients of identifiable data will be informed if a data subject withdraws their consent and will be required to delete the appropriate data rows and inform the custodian in writing that this has been done.

The data handling fee is non-refundable if consent is withdrawn.

End of study

- 10.32. The access policy may wish to specify whether samples should be destroyed by the recipient at the end of the study or returned to the custodian or another party, such as a funder, for disposal or future use. For data, the policy may state that the recipient must delete the data files, or it may specify longer periods of data retention (such as the very long time that regulations require for clinical trial data).

Samples destroyed by recipient:

Once the study agreed with the custodian is complete, any remaining samples must be destroyed by the recipient. The recipient should notify the custodian in writing that all samples have been destroyed.

Samples returned to custodian:

Once the study agreed with the custodian is complete, any remaining samples must be returned to the custodian together with a statement that all samples have now been destroyed or returned.

²² Minutes of Patient Information Advisory Group meeting 9th September 2008

For data:

Once the study agreed with the custodian is complete, the recipient must ensure that any data files are deleted. The recipient should notify the custodian that the study is complete and that the data has been destroyed. Alternatively, other, longer periods of retention may be stipulated.

Monitoring of compliance

- 10.33. The conditions of access may set out any mechanisms for monitoring compliance with the policy and with the data or materials transfer agreement. This may take the form of an annual declaration (including, as appropriate, details of the number of samples used; the number of samples remaining and any publications based on the collection) or the custodian may wish to physically audit the recipient.
- 10.34. As always, any procedures put in place should be proportional to the scale of the collection, the nature of the studies based on it, and the effectiveness of the security and confidentiality measures used to safeguard the samples or data. When designing an access policy, the resources that can realistically be devoted to monitoring compliance should be considered. Although auditing recipients is likely to be the best way to monitor compliance, it may be more realistic to reserve the right to audit recipients as required rather than aim to use this as the main monitoring method.
- 10.35. The conditions of access may also include mention of sanctions that can be applied for non-compliance. The main sanction available to custodians will be denial of further access to the collection. But also they may decide to inform host institutions, funders and even regulatory authorities depending on the circumstances and these may apply their own sanctions (potentially including financial or other penalties).

Compliance policy:

Recipients must complete a declaration to the custodian using the form available from the collection website every [frequency] until all samples have been used or destroyed. This form includes a declaration that the recipient has complied with the terms of the [data or materials] transfer agreement.

The custodian also reserves the right to audit the recipient's use of samples if this is considered necessary.

Recipients found to be in breach of the [data or materials] transfer agreement will be denied future access to the collection and their institutions and funders informed.

11. Governance processes

- 11.1. Although governance arrangements are beyond the scope of this document, an access policy may outline the mandate and membership or general composition of the governance bodies and committees that are involved with the collection.
- 11.2. The following paragraphs give examples of the type of bodies that may play a role in a collection's access policy. However, not all of these bodies will be relevant to every collection and the scale of the governance arrangements should be proportionate to a collection's size and the sensitivity of the data or samples held.

- 11.3. Where several similar collections exist there may be benefits in combining their governance structures to reduce the number of committees and ensure consistent approaches.

Oversight Committee

- 11.4. This is the committee with overall responsibility for the collection. It is likely to include representation from the major stakeholders (for example: the originator, the custodian, the institution hosting the collection, funders, independent researchers and lay members). For smaller collections, this may be the only governance body.
- 11.5. An oversight committee's role with respect to access is likely to focus on the formulation of the policy and any subsequent modifications. The committee may also help prioritise access, and act as an appeals panel such as for when an unsuccessful applicant feels badly treated or custodian feels improper pressurising by some party.

Scientific Review Panel

- 11.6. A scientific review panel advises the custodian and other governance bodies on scientific matters. They may be involved in reviewing and prioritising applications on the basis of scientific merit or recommend reviewers.
- 11.7. The scientific review panel may be a subgroup of the oversight committee or a separate body. It may comprise experts in fields relevant to the particular collection or others with suitable experience to review applications and provide advice.

Technical Review Panel

- 11.8. A technical panel will provides advice on the suitability of proposed methodologies, such as regards sample handling or security of a data enclave. The panel may help review applications for their technical merit.
- 11.9. The technical review panel may be the same body as the scientific review panel, a subset of this or have a separate membership.

Ethics panel

- 11.10. The ethics panel advises the custodian and other governance bodies on ethics matters. It is likely to play a role in the development of an access policy, reviewing the ethical issues and ensuring consistency with the terms of the consent in the collection. The ethics panel may also play a role in implementing particular policies, especially where a collection holds generic REC approval and decisions must be made on whether this covers particular applications.
- 11.11. The ethics panel may be a subgroup of the oversight committee or a separate body. Its membership will depend on the individual collection but is likely to include ethicists, researchers and lay representatives.

Part II. Developing a data or materials transfer agreement

12. Introduction

- 12.1. A data or materials transfer agreement (“MTA”) is a legal agreement which sets out the conditions under which a recipient is granted access to data or samples (“Materials”).
- 12.2. Many of the items covered by the MTA will also be covered in the collection’s access policy or will relate to the terms of that policy. The MTA is likely to be a shorter document setting out only conditions especially pertinent to provision of data or samples.
- 12.3. This section does not repeat the earlier discussion of access terms but does refer to the appropriate paragraphs. As before, appropriate language to draft an MTA is provided and, where applicable, this corresponds to the example policy terms in the previous section. It is likely that not all clauses will be applicable to every collection and the appropriate subset should be selected.
- 12.4. The content of the MTA is for guidance/information only. The MTA is not intended to constitute a definitive or complete statement of the law on any subject, nor is it intended to constitute any form of legal advice. You should not use or otherwise view the content of the MTA as a substitute for obtaining your own specific legal advice. If you wish to use the MTA in any jurisdiction other than the UK, we would strongly suggest that you obtain your own specific legal advice before proceeding.

13. Terms of a data and material transfer agreement

Date and Parties

- 13.1. The MTA should begin by giving details of the date it is agreed and the parties to the agreement.

Date and Parties to the agreement:

This Agreement is entered into on the [Insert day] of [Insert Month and year]:

BETWEEN:

(1) [Insert name of Custodian] of [Insert address of Custodian] (‘the **Custodian**’),

And

(2) [Insert name of Recipient Institution] of [Insert address of Recipient Institution] (‘the **Recipient Institution**’)

Specification of Materials

- 13.2. The MTA should give details of the Materials that will be provided, either in the text of the agreement (if brief) or as an appendix.

1. Supply of Materials:

1.1 The Custodian agrees to supply the [data] [samples and data] described at Appendix 1 (“the **Materials**”) upon the terms and conditions of this Agreement (which shall include the Custodian’s data/sample access policy set out [at Appendix 3][on the Custodian’s website] (as may be reasonably amended by the Custodian from time to time)) (“the **Access Policy**”).

Or

1.1 The Custodian agrees to supply the following [data] [samples and data] (“the **Materials**”) upon the terms and conditions of this Agreement (which shall include the Custodian’s data/sample access policy set out [at Appendix 3][on the Custodian’s website] (as may be reasonably amended by the Custodian from time to time)) (“the **Access Policy**”):

[Insert details of Materials]

13.3. The details of the Materials to be transferred will vary, but examples of the information that may be included are shown in Box 2.

Conflict of terms

13.4. The MTA may deal with what happens in the event of any conflict between the terms of the MTA and the terms of the Custodian’s Access Policy.

1.2 In the event of any conflict between the terms of this Agreement and the terms of the Access Policy, the terms of this Agreement shall prevail.

Agreed usage

13.5. The MTA should contain details of the agreed use (for example a description of the Study) as an appendix to the MTA, and the persons who may access and use the Materials (including the Recipient ensuring that such persons are bound by and comply with the requirements of the agreement in relation to such use). The agreement might also make it clear that the permitted purposes for the use of the Materials may not be varied without the Custodian’s consent.

Box 2. Example details of material supplied

For samples:

Number of samples, tissue type, sample types (e.g. paraffin block, EDTA blood, etc.), sample identifiers, preservation and storage details.

For data:

Number of files, format of files, data fields, number of records, time period covered by data.

General:

Method of dispatch, fees.

- 1.3 The Recipient Institution agrees that the Materials may only be used:
- 1.3.1 for the permitted purpose(s) agreed with the Custodian (“the Study”), details of which are set out in Appendix 2 to this Agreement;
- 1.3.2 by the Recipient Institution’s staff, agents, subcontractors and other authorised users (“**Authorised Users**”) who have a need to access and use the Materials for the purposes of the Study.
- 1.4 The Recipient Institution shall procure that its Authorised Users are made aware of and will be bound by terms similar to those in this Agreement so that each of the Authorised Users comply with all relevant duties, obligations and restrictions imposed on the Recipient Institution by this Agreement. Any act or omission of any such Authorised User which, if it had been committed or omitted by the Recipient Institution would have been a breach of this Agreement, will be deemed to be a breach of this Agreement by the Recipient Institution.
- 1.5 The terms of the Study, including the permitted purpose(s) for which the Materials may be used by the Recipient Institution, must not be varied without the prior written consent of the Custodian.

Power to distribute

- 13.6. If the Custodian wishes to ensure that it can freely distribute data and samples to parties other than the Recipient, the MTA should make this clear for the avoidance of any doubt.

- 1.6 Nothing in this Agreement shall restrict or otherwise prevent the Custodian from distributing any data or samples to other third parties.

Quality assurance

- 13.7. The MTA may give details of how data or samples have been collected and stored or may simply state that this has been in line with the collection’s standard procedures (if these are publically available).

2. Quality assurance:

- 2.1 The Materials have been collected and stored in accordance with the following procedures:

[Insert details of how the Materials have been collected]

Or

- 2.1 The Materials have been collected and stored in accordance with the Custodian’s standard procedures for the collection and storage of such [data] [samples and data], details of which are set out on the Custodian’s website.

Consent and approvals

- 13.8. If appropriate, the MTA should state that the Custodian holds valid consent for the proposed use of the samples or data from all donors or data subjects. If the Custodian does not have consent for the agreed use, the Recipient should confirm that they either hold the necessary consent or that they have the necessary approvals to conduct their Study without consent (e.g. under section 251 of the Health and

Social Care Act 2008) for identifiable patient information or ethical approval from the appropriate Research Ethics Committee for anonymised materials.

Where the Custodian holds consent:

2.2 The Custodian confirms that valid consent from the applicable donor and/or Data Subject (as defined in the Data Protection Act 1998) is held for the Materials to be used for the permitted purpose(s) described at Appendix 2 of this Agreement.

Or

Where the Recipient holds consent:

2.2 The Recipient Institution confirms that valid consent from the applicable donor and/or Data Subject (as defined in the Data Protection Act 1998) is held for the Materials to be used for the permitted purpose(s) described in Appendix 2 to this Agreement.

Or

Where consent is not held (for data):

2.2 The Recipient Institution confirms that approval for the Study has been obtained from the Ethics and Confidentiality Committee of the National Information Governance Board.

Or

Where consent is not held (for anonymised tissue):

2.2 The Custodian confirms that use of the Materials for the purposes described in this Agreement falls within the Custodian's generic approval from [Insert REC details].

13.9. If the study is covered by a Custodian's generic REC approval (see paragraph 7.8), then this can be stated in the MTA. Otherwise, the Recipient should confirm that their study has ethical approval.

Study covered by generic REC approval:

2.3 The Custodian confirms that use of the Materials for the purpose(s) described in this Agreement falls within the Custodian's generic approval from [Insert REC details].

Or

Study with project specific REC approval:

2.3 The Recipient Institution confirms that ethics approval for the Study has been obtained from the appropriate Research Ethics Committee.

Warranties

13.10. Each party should provide certain warranties (legal promises) to the other e.g. that they are authorised to enter into this Agreement.

3. Recipient and Custodian Obligations

3.1 Each of the Recipient Institution and the Custodian hereby warrants to the other that:

- 3.1.1 it has full power and authority to enter into this Agreement and all governmental or official approvals and consents have been obtained and are in full force and effect;
- 3.1.2 all information supplied by it to the other leading to the execution of this Agreement is, to its reasonable knowledge and belief, true and accurate; and
- 3.1.3 to the best of its knowledge, nothing will have, or is likely to have, a material adverse effect on its ability to perform its obligations under this Agreement.

Warranties from the Recipient

13.11. The Recipient should be required to provide certain additional warranties in relation to its ability to use, and subsequent use of, the Materials.

- 3.2 The Recipient Institution hereby warrants to the Custodian that:
 - 3.2.1 all work in relation to the Materials will be carried out in compliance with all applicable laws, regulations, guidelines and approvals, including without limitation the Human Tissue Act 2004, the Data Protection Act 1998 and any approvals required from a Research Ethics Committee or the National Information Governance Board;
 - 3.2.2 the Recipient Institution, and (if applicable) all of its Authorised Users having access to the Materials, are properly registered with all applicable professional regulatory bodies; and
 - 3.2.3 the confirmations given at clause 2 above are true and accurate.

Co-operation and Information

13.12. The Custodian may need to obtain certain additional information from the Recipient during the term of the agreement.

- 3.3 The Recipient Institution shall co-operate with the Custodian and provide the Custodian with such information and assistance as the Custodian may reasonably require from time to time.

Onward transfer

13.13. Normally, the Access Policy will limit onwards transfer of data or samples by the Recipient (see paragraph 10.12) and the MTA should contain an appropriate clause. The MTA might also set out details of those third parties to whom the Materials may be transferred.

Onward transfer to collaborators:

- 3.4 The Recipient Institution will not assign, transfer, sell, lease or rent the Materials to any third party except with the prior written agreement of the Custodian. It will be a condition of any such consent if given that the third party recipient validly executes a copy of this Agreement and that such copy is provided to the Custodian.

Or

No onward transfer:

- 3.4 The Recipient will not assign, transfer, sell, lease or rent the Materials to any third party.

Transfer to certain agreed third parties:

3.5 The Recipient Institution may only transfer the Materials to the following parties, subject to those parties having validly executed a copy of this Agreement and that copy having been provided to the Custodian:

[Insert details of agreed transferees]

Monitoring of compliance

13.14. The MTA should include terms covering the monitoring of compliance based on the Custodian's Access Policy (see paragraph 10.33). The MTA should also make it clear that those sanctions (if any) referred to in the Custodian's Access Policy (see paragraph 10.34) will apply in the event that the Recipient breaches the terms of the MTA.

Compliance policy:

3.6 The Recipient Institution must complete and provide an annual declaration to the Custodian with details of the Materials currently held by them (or which are under their control) and a statement that all use in that respect has been in compliance with the terms of this Agreement.

3.7 The Recipient Institution must keep accurate records regarding its use of the Materials and, if required by the Custodian, the Recipient Institution will allow the Custodian to conduct (or to direct an appropriate third party to conduct on the Custodian's behalf) during normal business hours an audit of the Recipient Institution's use of the Materials and records arising from such use to verify their accuracy. The audit will be at the Custodian's expense unless the audit reveals that the Recipient Institution is using or has used the Materials in a manner or to an extent not authorised by this Agreement, in which case the Recipient Institution will pay all reasonable expenses associated with the audit.

3.8 In the event that the Recipient Institution (or, where applicable, any of its Authorised Users) are found to be in breach of this Agreement, the Custodian may immediately impose such sanctions as are set out in the Access Policy.

Withdrawal of consent

13.15. The process to be followed if consent is withdrawn should be defined in the Access Policy and agreed by the Recipients. The procedure may be outlined in full (see paragraph 10.28) or, for brevity, the MTA may simply require that Recipients comply with the Custodian's policy on consent provided separately.

4. Withdrawal of consent:

4.1 The Recipient Institution will comply with the Custodian's procedure for withdrawal of donor and/or Data Subject consent, details of which are included at Appendix 3.

Or

4.1 The Recipient Institution will comply with the Custodian's procedure for withdrawal of donor and/or Data Subject consent, details of which are set out on the Custodian's website.

- 13.16. If a fee has been charged for the data or samples, the MTA should state whether this will be refunded. For example:

4.2 Any fee or other charges paid in relation to the Materials is [non-refundable][refundable] if consent is withdrawn by a donor or Data Subject.

Data identifiability

- 13.17. Pursuant to paragraph 10.13, where anonymised or linked anonymised samples or data are supplied, the MTA should require that Recipients not attempt to identify any donors or data subjects. They will also generally be required not to link to other datasets unless the agreement specifically approves.

5. Protection of anonymity:

5.1 The Recipient Institution will not link the Materials with any other data set.

Or

5.1 The Recipient Institution will not link the Materials with any other data set except as agreed in writing with the Custodian for the purposes of the Study.

5.2 The Recipient Institution will not attempt to identify any individual from the Materials provided.

- 13.18. Where appropriate, non-disclosure clauses should be included in line with the provisions of the Custodian's Access Policy (see paragraph 10.14).

Non disclosure:

5.3 Should the Recipient Institution inadvertently identify any individual donor or Data Subject included in the Materials they will neither record this fact nor share the identification of that individual with any other person, and nor will they attempt to contact the individual themselves.

- 13.19. Also, depending on the details of the Access Policy (see paragraph 10.15), the MTA may require Recipients to notify the Custodian if they do inadvertently identify any individual.

Inadvertent identification of individuals:

5.4 If the Recipient Institution does inadvertently identify any individual, they will inform the Custodian as soon as reasonably practicable, giving reasonable detail of the circumstances under which this occurred.

- 13.20. If identifiable data is provided then the MTA should include a clause prohibiting any attempt to contact the donors or data subjects (unless this is covered by consent and has been agreed as part of the Study protocol).

Identifiable data:

5.5 The Recipient Institution will not attempt to contact any of the donors or Data Subjects included in the Materials supplied.

Publication and acknowledgement

- 13.21. If a publication policy is included in the Access Policy, the MTA may either reiterate this fully (see paragraph 10.19) or simply contain a clause requiring Recipients to comply with the Custodian's policy.

6. Publication:

6.1 The Recipient Institution will comply with the Custodian's policy for publications and presentations based (in whole or part) on the Materials supplied by the Custodian, details of which are included at Appendix 3.

Or

6.1 The Recipient Institution will comply with the Custodian's policy for publications and presentations based (in whole or part) on the Materials supplied by the Custodian, details of which are set out on the Custodian's website.

- 13.22. Even where the full publication policy is not included in the MTA, Custodians may wish to include a term reinforcing the requirement to acknowledge the Custodian's contribution to the Study in any publications or presentation.

Acknowledgement of the Custodian:

6.2 The Recipient Institution will ensure that any publication or presentation that is based (in whole or in part) on any Materials obtained from the Custodian will include the following acknowledgement:

"We gratefully acknowledge the contribution to this [study/publication/presentation] made by [Insert name of Custodian]"

Or

[Parties to insert form of acknowledgement required]

Transparency

- 13.23. If information about studies that are using data or samples from the Custodian will be made available (see paragraph 10.9), then Recipients should agree to this in the MTA.

Transparency:

6.3 The Recipient Institution agrees that the title of the Study may be published on the Custodian's website, together with a lay summary of the Recipient Institution's work and the names of the institutions where such work is taking place. The Recipient Institution also agrees that, at the Custodian's discretion and if requested, the name and contact details for the principal investigator in relation to the Study may also be provided.

Data sharing

- 13.24. If the Access Policy requires the Recipient to submit derived data or materials to the Custodian (see paragraph 10.25), then a clause covering this should be included in the MTA. The details of what data or materials should be submitted and the mechanisms for submission can be given in the main Access Policy.

Enrichment of the collection:

6.4 The Recipient Institution agrees to provide the Custodian with any data and/or information arising from the use of the Materials (“**Derived Information**”) in accordance with the Access Policy. All such data and/or information must be provided within [Insert time limit] of the Recipient Institution’s completion of the Study unless a delay is agreed with the Custodian to protect any applicable intellectual property rights.

13.25. The Recipient should also agree to the ways in which derived data or materials submitted to the Custodian will be used. This will depend on the exact nature of the data and/or information but examples of several possible approaches shown in paragraph 10.26 are provided below.

Derived Information and materials made publically available:

6.5 The Recipient Institution agrees that Derived Information submitted to the Custodian may be made publically available.

Or

Derived Information and materials made available to other users of the Collection:

6.5 The Recipient Institution agrees that Derived Information submitted to the Custodian may be made available to other registered users of the Custodian’s data and/or samples.

Or

Derived Information and materials made available on request:

6.5 The Recipient Institution agrees that Derived Information submitted to the Custodian may be made available on request to the Custodian via the Custodian’s standard application process, details of which are available from the Custodian’s website.

Or

Derived Information and materials made available with permission of the originator:

6.5 The Custodian agrees that any Derived Information submitted to it by the Recipient Institution may only be made available with the Recipient Institution’s prior written consent.

Protection of intellectual property

13.26. The MTA may contain a clause reflecting the Custodian’s policy on Intellectual Property. The example below matches that given in paragraph 10.18. If the parties wish to deal with intellectual property differently, they should seek their own specific legal advice in this respect.

7. Protection of intellectual property:

7.1 Any and all intellectual property rights in the Materials are the sole and exclusive property of the Custodian or its licensors.

7.2 Subject to the above, the Custodian waives all rights to any intellectual property developed by the Recipient Institution whilst using the Materials in accordance with this Agreement.

7.3 The Recipient Institution agrees that any intellectual property developed whilst using the Materials will be protected in line with the Recipient Institution's own internal practices and policies, or that of their funders, so as to ensure the adequate protection of such intellectual property.

Indemnity for intellectual property

13.27. The MTA may include a reasonable indemnity provision to protect the Recipient against any third party claims alleging breach of their intellectual property rights arising from the Recipient's use of the Materials in accordance with this Agreement. If this provision is included, it is important that the Custodian ensures they have the appropriate authority and the permissions to supply the Materials.

7.4 The Custodian will indemnify the Recipient Institution and hold the Recipient Institution harmless in respect of any claim brought against the Recipient Institution by a third party alleging the use of the Materials in accordance with this Agreement infringes that third party's intellectual property rights provided that:

7.4.1 the Custodian shall be notified promptly in writing by the Recipient Institution of any claim or impending claim of which it is aware;

7.4.2 the Custodian shall have sole control of the defence of any action or claim and all negotiations for settlement or compromise as long as such settlement shall not include a financial obligation on the Recipient Institution; and

7.4.3 the Recipient Institution will provide all reasonable assistance in defending any action or claim.

Charges

13.28. To the extent that any charges or fees are payable in relation to the retrieval, processing and dispatch of the data and/or samples, pursuant to paragraph 10.4 the MTA should include details of these charges and how they will be payable.

8. Charges:

8.1 The Recipient Institution shall pay the cost of retrieving, processing and dispatching the Materials in accordance with the invoicing procedure specified in Appendix 4.

8.2 Details of these costs (if any) are set out in Appendix 4.

Completion of work

13.29. If the Access Policy specifies how data or samples should be handled on completion of the Study, this should be reflected in the MTA. Clauses matching the options presented in paragraph 10.32 are given below.

9. Completion of Study

Materials destroyed or returned at Custodian's discretion:

9.1 Subject to clause 9.3, the Recipient Institution agrees that it will, on the instruction of the Custodian, either destroy or return to the Custodian any Materials remaining in its possession or under its control:

9.1.1 in the event that any applicable consent is withdrawn; and

9.1.2 once the Study is complete

And the Recipient Institution will, if applicable, notify the Custodian in writing of such destruction.

For data:

9.2 In the event that any applicable consent is withdrawn or should the Study be completed, the Recipient Institution will notify the Custodian forthwith and the Recipient Institution will delete all data files and securely destroy any removable media containing the data and they will then notify the Custodian that such data has been destroyed.

9.3 Nothing in this clause 9 shall require the Recipient Institution to return or destroy, or otherwise prevent the Recipient Institution from continuing to use, any information and/or data acquired by the Recipient Institution from their research using the Materials.

Indemnity

13.30. The MTA may include a reasonable indemnity provision to protect the Custodian against any claims arising from the Recipient's use of the Materials.

10. Indemnity:

10.1 The Recipient Institution will indemnify the Custodian and hold the Custodian harmless in respect of any loss, claims, damage or liability of whatsoever kind or nature, which may arise out of or in connection with the use, handling, storage or disposal of the Materials by the Recipient Institution.

Limitation of Liability

13.31. The MTA should include disclaimers about the quality of the data or samples and liability for the consequences of use. These terms aim to protect the Custodian from adverse consequences suffered by the Recipient or others as a result of the Recipient's use of the Materials. Since such disclaimers are open to challenge, Custodians should seek their own legal advice on the appropriate wording. An example of how such a provision might look is set out below.

11. Limitation of Liability:

11.1 The Materials are provided by the Custodian "as is" without any warranty of satisfactory quality or fitness for a particular purpose or use or any other warranty, express or implied.

11.2 In no event shall the Custodian be liable to the Recipient Institution or any third party for any special, incidental, consequential, exemplary, punitive or indirect damages including, without limitation, loss of goodwill, loss of profits or revenue, loss of savings, work stoppage or data loss arising out of or in any manner connected with this Agreement.

11.3 Nothing in this Agreement shall be deemed or construed so as to limit, restrict or exclude the liability of a party for death or personal injury caused by that party's negligence or for any loss, damage or other liability arising out of that party's fraudulent or criminal acts, statements or omissions.

Termination

- 13.32. The MTA should include details of how long the agreement will last and the circumstances in which either party may terminate the agreement, including what happens after such termination.

12. Term and Termination:

- 12.1 This Agreement shall commence on the date set out above and shall continue until terminated in accordance with its terms.
- 12.2 Either the Custodian or the Recipient Institution may terminate this Agreement, upon written notice to the other, if the other party materially breaches any term or provision of this Agreement and fails to cure that breach within [Insert time period] after receiving written notice thereof from the non-breaching party.
- 12.3 Within [Insert time period] after the termination of this Agreement, the Recipient Institution shall (at the Custodian's option) destroy or return to the Custodian any of the remaining Materials in its possession or under its control, and the Recipient Institution will certify to the Custodian that all of the Materials have been destroyed or returned as appropriate.
- 12.4 The terms of this Agreement that by their nature should survive the termination of this Agreement shall so survive, including without limitation provisions dealing with protection of intellectual property, charges, completion of the Study, indemnity, limitation of liability, term and termination, third party rights, and law and jurisdiction.

General Provisions

- 13.33. The MTA should include various general provisions (often referred to as boilerplate clauses) to deal with issues such as law and jurisdiction, the service of notices, variation of the Agreement, circumstances beyond the reasonable control of a party and the contractual rights of third parties.

13. General:

- 13.1 No term of this Agreement is intended to be enforceable by any person who is not a party to this Agreement.
- 13.2 All variations to the terms of this Agreement must be agreed, set out in writing and signed on behalf of the parties before they take effect.
- 13.3 This Agreement (and the Appendices) sets out all of the terms that have been agreed between the parties in relation to the subjects covered.
- 13.4 In this Agreement, references to any legislation shall be to that legislation as amended, extended or re-enacted from time to time.
- 13.5 Nothing in this Agreement shall create a partnership, joint venture or relationship of agency between the parties or give the rights of a partner to either party.

- 13.6 Neither party will be liable to the other for any failure or delay in performance under this Agreement due to circumstances beyond their reasonable control including, without limitation, Acts of God, labour disruption, war, terrorist threat or government action provided that if either party is unable to perform its obligations under this Agreement for one of these reasons it shall give prompt written notice thereof to the other party and the time for performance, if any, shall be deemed extended for a period equal to the duration of the conditions preventing performance.
- 13.7 This Agreement may be signed in two counterparts, each of which shall be deemed an original and which shall together constitute one agreement.
- 13.8 Neither party may assign any of its rights or obligations under this Agreement without the prior written consent of the other.
- 13.9 Any notices given under this Agreement shall be in writing and shall be served by hand, post or electronic mail by sending the same to the address for the relevant party. Notice by (i) post shall be effective upon the earlier of actual receipt, or 4 days after mailing; (ii) hand shall be effective upon delivery; and (iii) electronic mail shall be effective when sent in legible form, but only if, following transmission, the sender does not receive a non-delivery message.
- 13.10 This Agreement is governed by English law and the parties submit to the exclusive jurisdiction of the English courts in relation to any dispute concerning this Agreement.

Signatures

- 13.34. The MTA should be signed by the Custodian and by the authorised representative of the Recipient.

SIGNED by or on behalf of both parties on the date set out above

Signed by [Insert name of Custodian – where an individual]

Or

Signed by [Insert name of Custodian – where a corporate entity]

Acting by [Insert name of authorised representative]

Signed by [Insert name of Recipient Institution]

Acting by [Insert name of authorised representative]

Appendices to MTA

- 13.35. The MTA must include the applicable Appendices, completed with the relevant details.

Appendices:

Appendix 1 – Materials;

[Insert details of the Materials]

Appendix 2 – Permitted Purpose(s)

[Insert details of the purposes for which the Materials may be used/details of the Study]

[Appendix 3 – Access Policy]

[Unless it is decided to rely upon referring to the Access Policy on the Custodian's website, insert the Custodian's latest Access Policy (including details of any publication policies where applicable)]

Appendix 4 – Charges and Payment

[Insert details of any costs payable by the Recipient Institution for retrieving, processing and dispatching the Materials, and the payment terms in that respect]

Appendix A. Useful Resources

Human Tissue Authority

Provides information on licensing and other requirements for the use of human tissue under the Human Tissue Act 2004.

www.hta.gov.uk

Integrated Research Application System

Aims to provide a single application system for gaining permissions and approvals for health research in the UK. Includes applications to Research Ethics Committees, NHS R&D Offices and the NIGB.

www.myresearchproject.org.uk

Information Commissioner's Office

Provides information and guidance on the implementation of the Data Protection Act 1998.

www.ico.gov.uk

MRC Data and Tissues Toolkit

Legislative and good practice requirements relating to the use of personal information and human tissue samples in healthcare research in the UK. Focuses on the planning and approvals stage of setting up a research project.

www.dt-toolkit.ac.uk

National Research Ethics Service

Information on applying to recs for ethical review of research.

www.nres.nhs.uk

National Information Governance Board for Health and Social Care

Information on the NIGB and on the Ethics and Confidentiality Committee that reviews applications under Section 251 of the NHS Act 2006.

www.nigb.nhs.uk

Wellcome Trust

Information on the Wellcome Trust, including reports on biomedical ethics.

www.wellcome.ac.uk

Appendix B. Glossary and Abbreviations

AMRC	Association of Medical Research Charities
CCB	Confederation of Cancer Biobanks
Collection	Any dataset, including summary datasets, or set of human samples with associated data
Custodian	The person, organisation, body or committee with responsibility for a collection (this may or may not be the same person as the originator)
Data Subject	An individual who is the subject of personal data that forms part of a collection
Donor	An individual who provides samples that form part of a collection
GMC	General Medical Council
HTA	Human Tissue Authority
ICO	Information Commissioner's Office
IP	Intellectual Property
IRAS	Integrated Research Application System
MRC	Medical Research Council
MTA	Data and Material Transfer Agreement
NCIN	National Cancer Intelligence Network
NCRI	National Cancer Research Institute
NIGB	National Information Governance Board for Health and Social Care
NRES	National Research Ethics Service
Originator	Person or leader of the team who collected the data and/or samples comprising a collection
PIAG	Patient Information Advisory Group (now superseded by the Ethics and Confidentiality Committee of the NIGB)
REC	Research Ethics Committee (encompasses such committees operating in respect of clinical research conducted in the four countries of the UK)
Recipient	An individual in receipt of data and/or samples from a collection
Requestor	An individual seeking access to data and/or samples from a collection

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