



NCRI  
National  
Cancer  
Research  
Institute

# A Template for Development of a Policy for Access to Data and/or Biological Samples

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World Biobanking Summit

Edinburgh

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The logo graphic for onCore UK, featuring a stylized 'C' shape composed of a grid of dots in shades of grey and red.

onCore<sup>UK</sup>

The logo graphic for the National Cancer Intelligence Network (NCIN), featuring a blue circle containing a white map of the United Kingdom.

NCIN  
national cancer  
intelligence network

# Outline: A Template for Development of a Policy for Access to Data and/or Biological Samples

- Background
- The need for a template
- Approach to project
  - Initial consultation
  - Template development
- Key content of the template
  - Review and further consultation

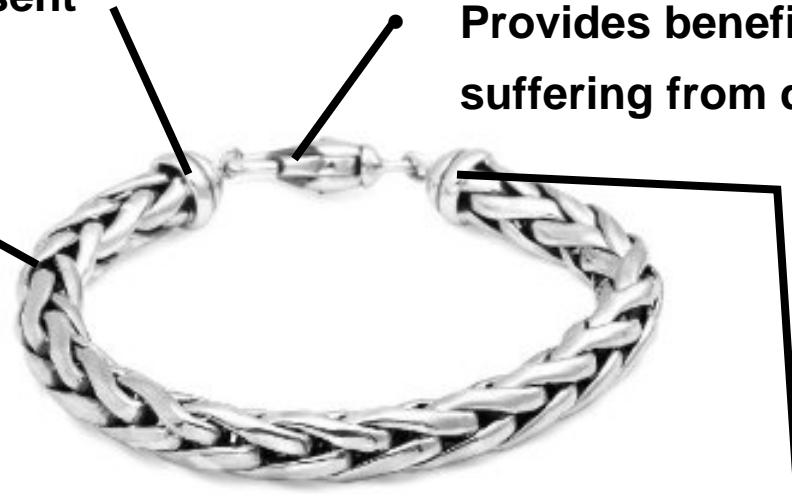
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- As more biobanks are launched, the key challenge for biobanking governance and effectiveness is to provide fair access.
- Donors consent to give samples with the expectation that they will be used, make a positive contribution to research and a real difference to future healthcare.
- Access is the key step to fulfil the agreement with donors and preserve the intertwined chains of
  - **Supply**
  - **Trust**
  - **Custody**
  - **Benefit**

- **Starts with donor consent**
- **Intertwined chains:**
  - Supply
  - Trust
  - Custody
  - Benefit
- **Provides benefit to others suffering from disease.**
- **Ends in advances against disease:**
  - fulfil the intentions of the donors.
  - provides benefit to others suffering from disease.



## **Access – the key to completing the “*chain of benefit*”.**

- **Any researchers who are capable of conducting studies to derive public benefit are valid end users of samples. This includes researchers in public and charitable sectors or commercial organisations.**
- **Access to samples should be provided on the basis of the likelihood of the samples being put to a good and beneficial use in as scientifically feasible a time as possible after donation.**
- **End-users of samples should only request access to samples from a bank when they are actually required for a funded and approved project.**



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**So what is the problem with access?**



**Funders, patients, researchers, employers and regulators *seem* to have different views on the best policies and practices for granting access to precious human biosample resources.**

**So how can biobanks set policy?**

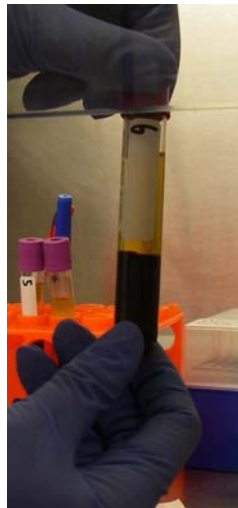
# What do biobanks provide access to?

## Samples

### Annotating personal / clinical information



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# Our work aims to reduce duplication of effort and increase sharing through the provision of a practical instrument

## *Current situation:*

- Variety of regulation and guidance
- Confusion
- Duplication of effort and variation in policies
- Difficult to combine resources from different sources
- More confusion
- More duplication of effort

## *Our aims:*

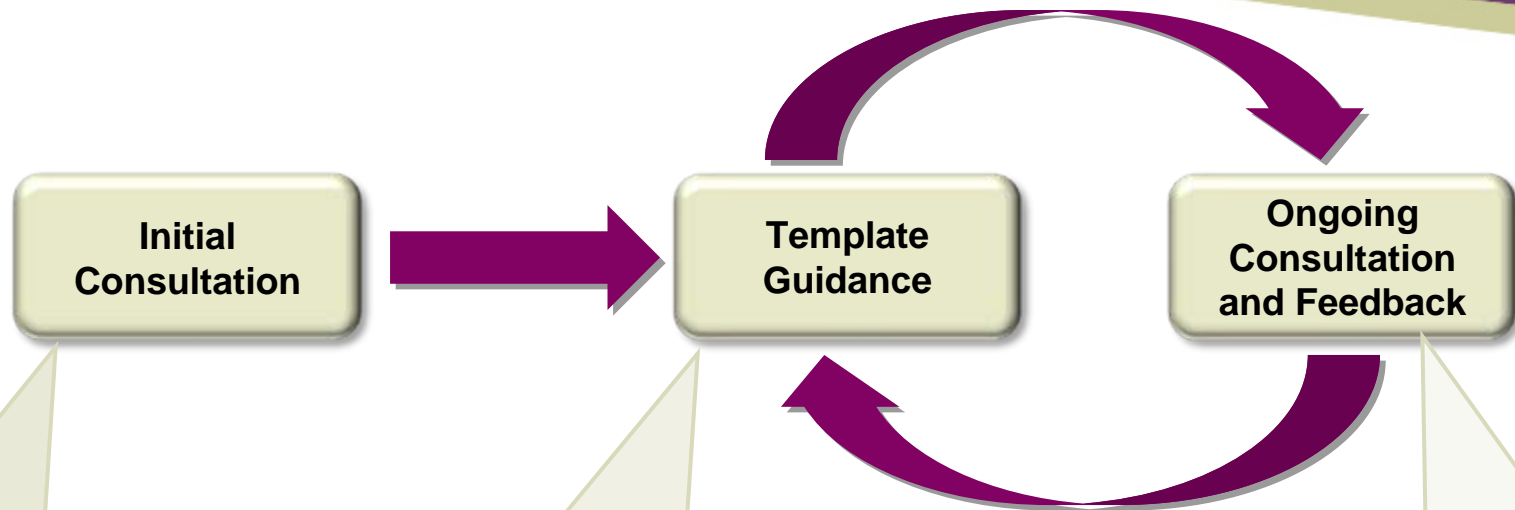
- A ***practical instrument*** for developing an access policy, including example language and options for tailoring, in 2 parts:
  1. A template list of terms
  2. A template data and materials transfer agreement
- Greater consistency
- More effective sharing/pooling of resources

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# We will create a 'Template for Access Policy Development' informed by wide consultation with interested parties



## Initial Consultation:

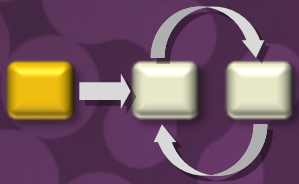
- Ran from **Aug to Oct 08**
- High response from **users of data and samples**
- Fewer responses from **consumers and those who collect data / samples**

## Template Guidance:

- Will **not define or impose policy**
- A **practical instrument**
- Start of an **ongoing process of updating**

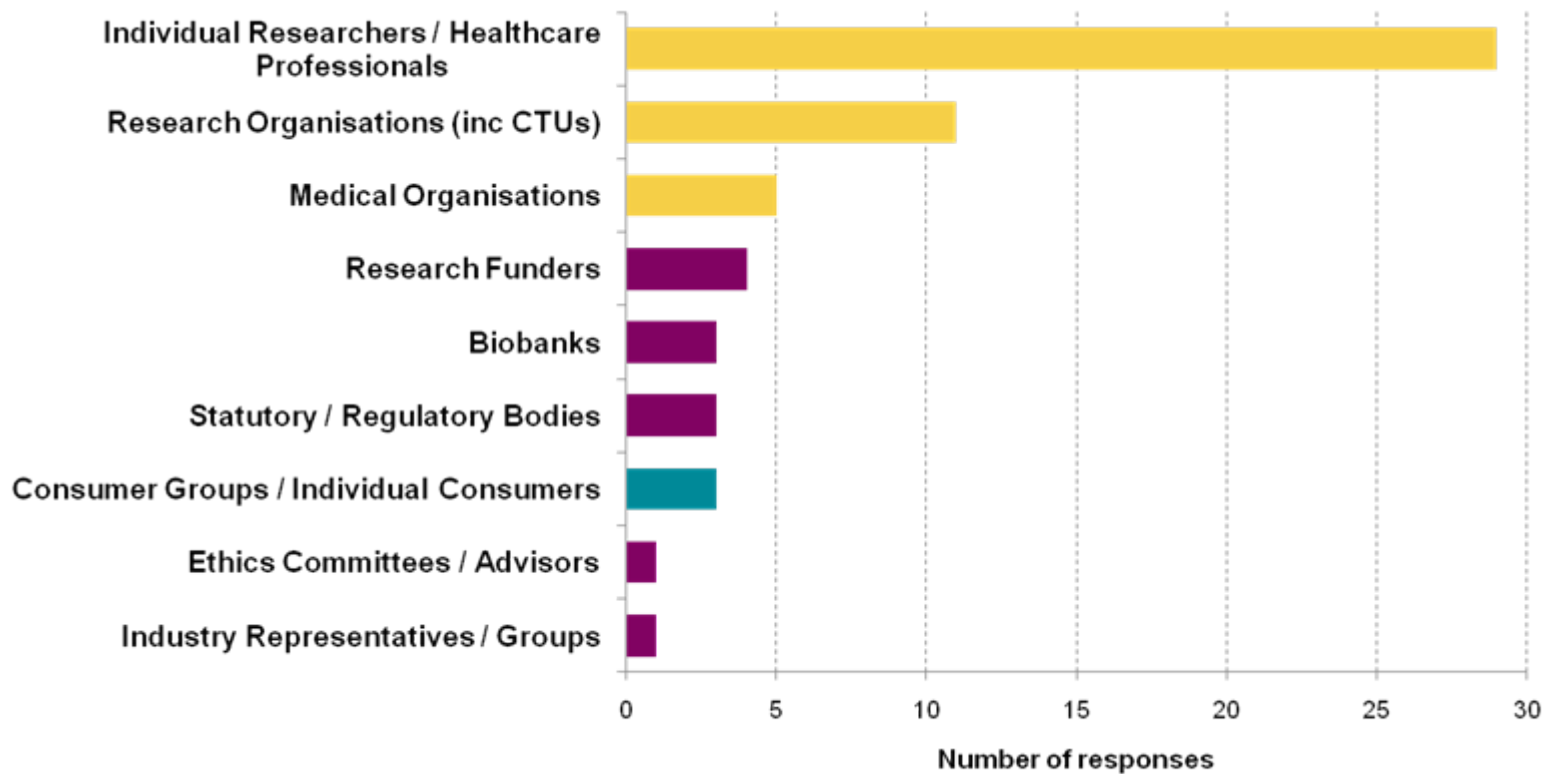
## Ongoing consultation:

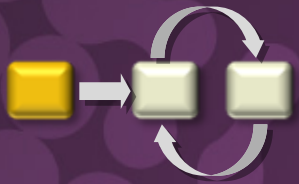
- With **regulators** – HTA, ICO, NIGB and NRES
- With **groups with low responses** in the original consultation



# Our initial consultation received a positive response but missed some important groups

– Consultation responses by source –

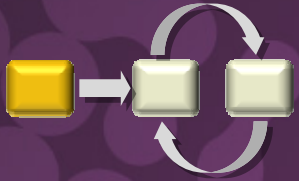




## Responses to our initial consultation have been published

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

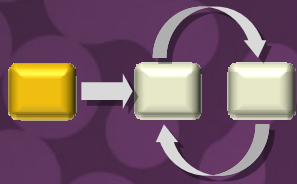
- Support for the **widest access consistent with a collection's consent**, ensuring the ability of recipients to complete the proposed study.
- **Access by commercial organisations** was more controversial, but the majority of respondents were in favour.
- The importance of **peer review to ensure scientific merit** was widely recognised and, in general, it was seen as reasonable to accept peer review carried out by funding bodies.



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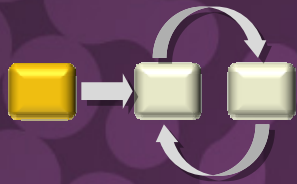
- Processing **applications on an *ad hoc* basis or only at certain times** were both considered valid options.
- Where collections are created for a particular purpose, any **secondary access must not interfere with this primary purpose.**
  - However, it was expected that beyond this the collection should be made as widely available as possible and that the original consent should cover other research uses.



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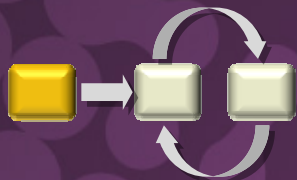
- Respondents recognised that it might be necessary to give **originators priority access** to their collections.
- There can be justifications for not completely depleting collections (e.g. to maintain diagnostic archives). Beyond this, however, many respondents felt that **samples should not be stored 'in case' a new application emerges while blocking potentially valuable work now.**



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- The importance of **protecting donor and data subject confidentially** was universally recognised.
- It was expected that recipients would agree not to attempt to identify individuals; not to link the data received with any other data sets without approval and not to disclose the identity of, or attempt to contact any individuals who might be inadvertently identified.
- Where **consent is withdrawn**, regulators' responses to the consultation provided clear guidelines for the approach.



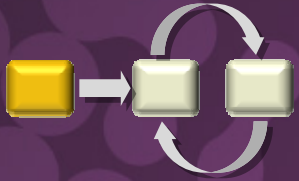
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- **Recontacting donors or data subjects to obtain further consent was generally not considered appropriate**, with respondents preferring a **broad consent to cover secondary research being obtained initially**.

- In addition, most respondents considered it **inappropriate to recontact donors or data subjects with individualised results** from a study.

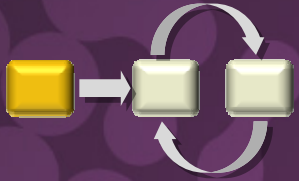
- Where the results of a study could impact a donor or data subject's care, the consensus was that this should be considered by a research ethics committee, ideally when the study is originally designed.



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

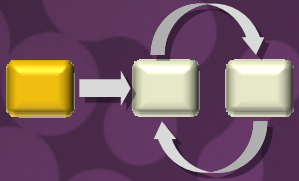
- Although communicating individualised results was not considered appropriate, **communication of research outcomes to both donors / data subjects and the general public was seen as important.**
- Respondents recognised that the appropriate mechanism for this will vary depending on the study but **the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



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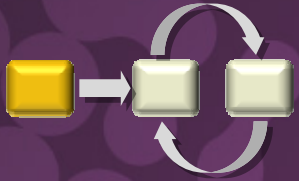
- Most respondents believed that it is **appropriate to recoup any costs** incurred in supplying a recipient with data or samples and perhaps also a proportion of the cost of collection (if this was not covered by other funding).
- The idea of **charging differential fees to recipients** was more controversial and some respondents felt that it would be **hard to justify if fees were designed to recover costs**.
  - Despite this, higher fees for commercial organisations and lower fees for collaborative access in line with the primary purpose both received wide support.



## Responses to our initial consultation have been published

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

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

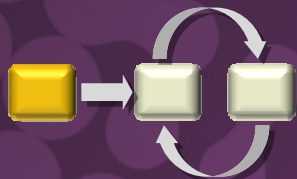


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- **Protecting intellectual property generated from the collection was seen as important by respondents.** However, the issue of whether collections themselves generate any intellectual property was raised.

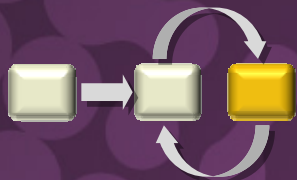
- An arrangement in which ***recipients agree to protect any intellectual property*** that arises but without detailed arrangements in advance was held up as a pragmatic way to avoid spending time discussing these issues for studies that are unlikely to generate any commercialisable results.



## Responses to our initial consultation have been published

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- The consensus of respondents was that the **body making governance decisions should have representatives from all stakeholders** (custodian, originator, funders, independent experts, patients and the public).
- However, respondents emphasised that **governance arrangements should also be proportionate to the size of the collection.**
- **Ensuring compliance with the terms of an access policy** was recognised as difficult.
- **Sanctions for breaching access conditions** - this will largely be down to funders and institutions to enforce as the only real sanction available to custodians is to deny future access.



## We have reviewed our template with some key groups before releasing it for wider feedback

### Legal review

- To ensure that language is legally sound

### Consultation with regulators

- Information Commissioner's Office
- National Information Governance Board
- National Research Ethics Service

### Consumer input

- Views on the terms included
- Clarity of language and presentation

### Released as an 'open draft'

- Usable document
- Further consultation and feedback

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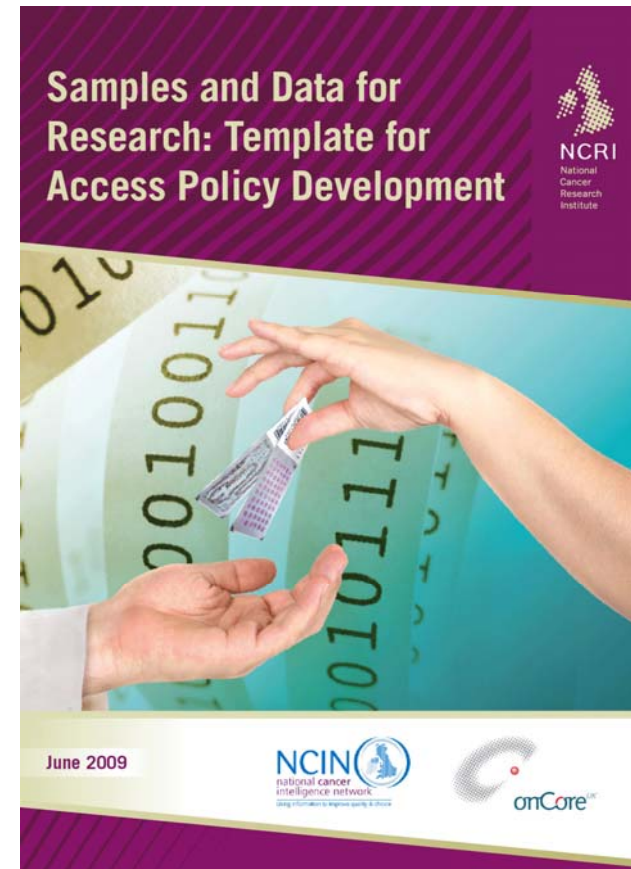


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# Key Content of the Template

- Part I. Template list of access policy terms
  - Terminology
  - Overview of the collection and the access process
  - Eligibility for access
  - Application for access
  - Processing applications
  - Conditions of access
  - Governance processes

[www.ncri.org.uk](http://www.ncri.org.uk)



# Key Content of the Template



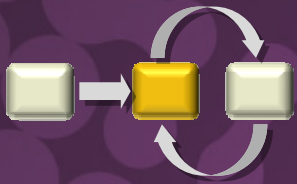
- Part II. Developing a data or materials transfer agreement
  - Introduction
  - Terms of a data and material transfer agreement



- Alison Patten-Hall
- Darren Curtis

[www.ncri.org.uk](http://www.ncri.org.uk)





# The 'Template for Access Policy Development' is a practical and flexible resource

- For use by a variety of funding and research organisations
- Intended as a practical instrument that:
  - Reflects good practice and consensus
  - Can be tailored to circumstances
  - Avoids duplication of effort

- 1 Covers the principal topics and considerations  
References detailed guidance
- 2 Example text may be used directly or adjusted to fit
- 3 Options for tailoring to circumstance

## – Template for Access Policy Development –

**Collection requesting advance notice of publication:**

Recipients must provide the custodian with manuscripts of any proposed publication or presentation of results based on material from the collection. Comments, if any, will be provided within [time limit].

**Submission of published papers:**

Copies of any publications or presentations using material from the collection should be provided to the custodian.

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

**Acknowledgement of the collection:**

Any publication or presentation using material from the collection should include an acknowledgement using the text below:

[Acknowledgement text]

**1 Maintenance and enrichment of the collection**

10.24. 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.

**2 Enrichment of the collection:**

On completion of their study, recipients should provide their [data / materials to be provided] to the custodian for possible inclusion in the collection. [Data and/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.

10.25. 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, examples of four approaches are provided below.

**3 Derived data and materials made publically available:**

[Derived data and/or materials] submitted to the collection maybe made publically available.

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

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

# There is more work to be done on access issues once the template document is published

- Published as a ***web based template*** - [www.ncri.org.uk](http://www.ncri.org.uk)
- ***Ongoing revision*** based on feedback from users of the template and changes to the legal and regulatory environment
- Address ***issues not covered in the initial release***
- ***What else should we be thinking about?***
  - ***International dimension?***

# Acknowledgements



## ***Access Working Group:***

Chris Carrigan	<i>NCIN</i>
Michael Chapman	<i>NCIN/onCore UK/NCRI</i>
Brian Clark	<i>onCore UK</i>
Jane Cope	<i>NCRI</i>
Karen Groot	<i>NCRI</i>
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