

# Enabling responsible sharing: NCRI Tissue & Data Access Template

Dr Brian J Clark  
onCore UK



Sharing Human Tissue:  
New opportunities, new horizons  
Birmingham, September 2010

# Outline:

- Background
- The need for a template
- Approach to project
  - Initial consultation
  - Template development
- Key content of the template
- Online directories of biosample collections

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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**



<http://www.ncri.org.uk/ccb>

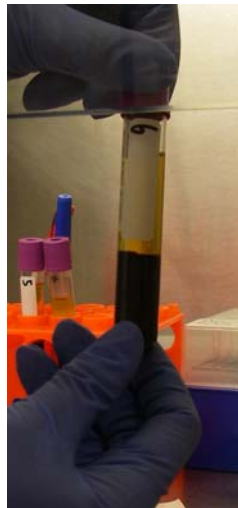
# What do biobanks provide access to?

## Samples

### Annotating personal / clinical information



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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?**



# Our work aimed 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

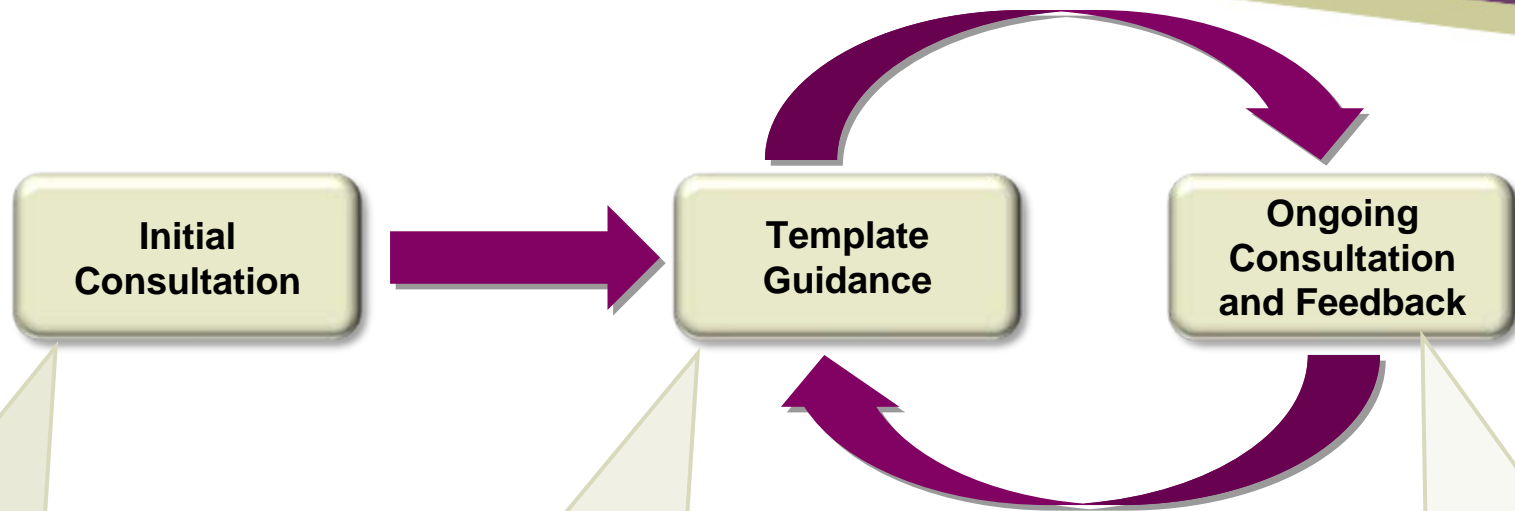
## *Our aims:*

- 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 have created a 'Template for Access Policy Development' informed by wide consultation with interested parties



## Initial Consultation:

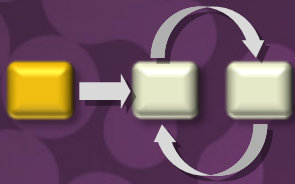
- Ran from **Aug to Oct 08**
- High response from **users of data and samples**
- Fewer responses from **consumers and those who collect data / samples**

## Template Guidance:

- Does **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

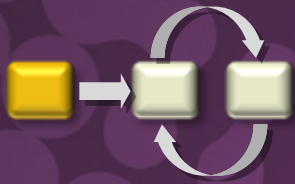


Responses to our initial consultation have been published - <http://www.ncri.org.uk>

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**.
- **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 it was seen as **reasonable to accept peer review carried out by funding bodies**.



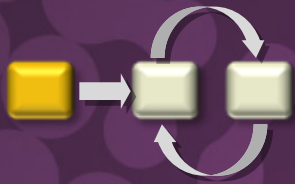


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- Where collections are created for a particular purpose, **this primary purpose** must have priority over any **secondary access**.
- However, beyond this the **collection should be made as widely available** as possible and that the **original consent should cover other research uses**.

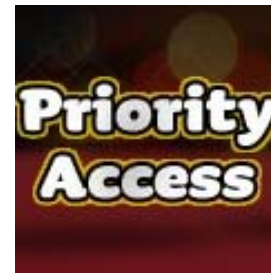




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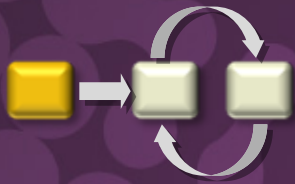
Summary of responses to consultation on  
'Access to Samples and Data for Cancer Research'

- Respondents recognised that it might be necessary to **give originators priority access** to their collections.



- Many respondents felt that **samples should not be stored 'in case' a new application emerges while blocking potentially valuable work now.**

**ACCESS  
REQUIRED**



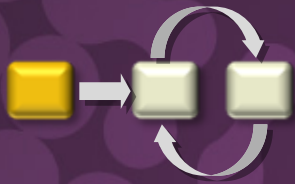
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- The importance of **protecting donor and data subject confidentiality** was universally recognised.

**CONFIDENTIAL**

- Where **consent is withdrawn**, regulators' responses to the consultation provided clear guidelines for the approach.

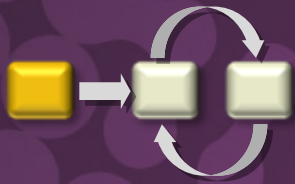


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- **Communication of research outcomes to both donors / data subjects and the general public was seen as important, although communicating individualised results was not considered appropriate,**
- Most respondents believed that it is **appropriate to recoup any costs** incurred in supplying a recipient with data or samples.

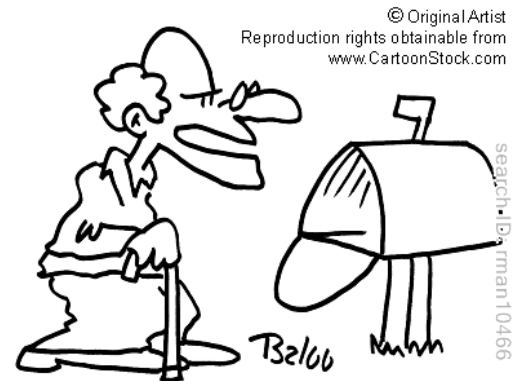
**COST  
RECOVERY**



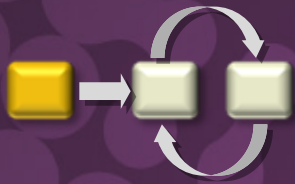
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Summary of responses to consultation on  
'Access to Samples and Data for Cancer Research'

- 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.**



"Dang! — Still no lifetime achievement award!"

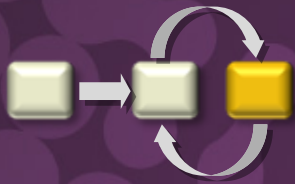


Responses to our initial consultation have been published - <http://www.ncri.org.uk>

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

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





## 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

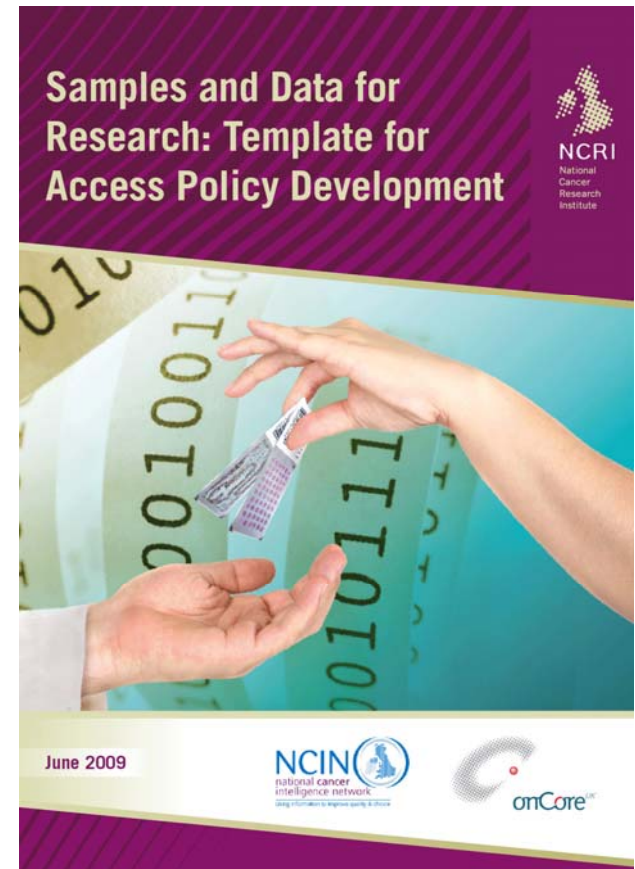
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- **Key content of the template**
- Online directories of biosample collections

# 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)



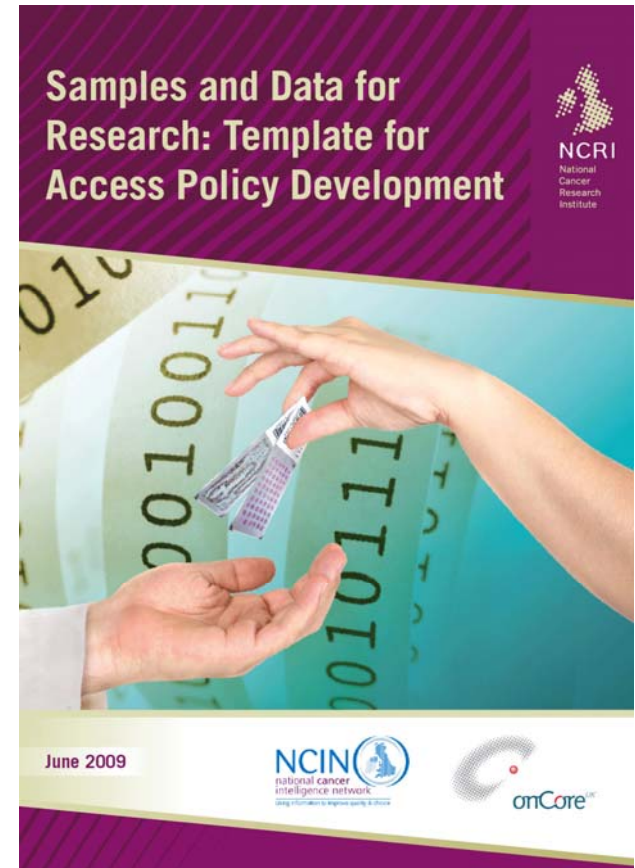
# Key Content of the Template

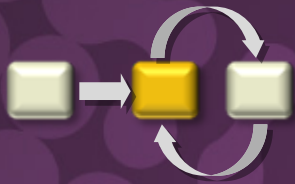
- Part II. Developing a data or materials transfer agreement
  - Introduction
  - Terms of a data and material transfer agreement

Morgan Cole 

- 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:
  - i. Reflects good practice and consensus
  - ii. Can be tailored to circumstances
  - iii. Avoids duplication of effort

## – 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.
- 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.

- 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

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- **Online directories of biosample collections**

# Online directories of available sample resources

- Need for both a “yellow pages” for researchers and a “shop window” for sample collections.



- Need to be
  - Simple to contribute information.
  - Simple to update and maintain.
  - Simple to search and use.
- Based in the NCRI Informatics Initiative’s ONIX portal
  - <http://www.ncri-onix.org.uk/portal/>

NCRI Oncology Information Exchange - Windows Internet Explorer

http://www.ncri-onix.org.uk/portal/#S1

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Welcome to the NCRI Oncology Information Exchange [Text-only version](#)

The NCRI ONcology Information eXchange (ONIX) is a **free-to-use portal** that connects many of the main public sources of cancer research data. ONIX allows users to run **searches simultaneously against multiple, selected resources**. ONIX also holds a **searchable catalogue of cancer-relevant resources** which allows users to find new information and collaborative opportunities.

Sequence

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Metabolomics

Proteomics

Structure

Epidemiology & Top Studies

Tissue Bank

Quick Search searches simultaneously across a range of biomedical databases

1 2 3

**Need More Information About Data Standards?**

Then view the [Cancer InfoMatrix](#) where you can discover what standards exist or are in development in your area of interest.

**Did you know that..**

The Resource Catalogue now functions as a 'catalogue of catalogues'. Visit the [Resource Catalogue](#) today to explore its new design.

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### Resource Catalogue The Resource Catalogue brings together and describes a diversity of biomedical resources which include databases, analytical tools, projects, initiatives and research technologies. This information has either been entered directly to ONX forming the ONIX Resource Catalogue or imported from similar catalogues. These catalogues are listed below and you can select which you want to search across. Look for Search in BioCatalogue The BioCatalogue is a curated registry of biological Web Services. The BioCatalogue website is freely accessible to the world as it is searchable and indexable to search engines. It provides an open platform for biological Web Services registration, annotation and monitoring. NCRI Cancer Biosample Directory This is a directory of biosamples (tissue, blood and other biological samples, including extracted derivatives) held in the UK in cancer biobank collections. It can be searched by a variety of parameters, including specific tumour and biosample type. The directory provides information about how to contact custodians and how access may be possible. NCRI Cancer Clinical Trials Biosample Directory A directory of biosamples (tissue, blood and other biological samples, including extracted derivatives) held in the UK from cancer clinical trial collections. Searchable by a variety of parameters, the directory provides information about how to contact custodians and how access may be possible. Help me choose which catalogues to search across... by domain type resource type I am looking for: - Nanotechnologies - RNA - DNA - Genomics - Proteomics - Metabolomics - Pathways & Interactions - Biomodelling - Pathology & Tissue Bank - Imaging - Model Organisms - Clinical Research - Epidemiology

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## Resource Catalogue

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Resource Catalogue

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### Search results display options:

Filter by catalogue:  NCRI Cancer Biosample Directory (11)  NCRI Cancer Clinical Trials Biosample Directory (1)

Sort by:

First    Prev    page 1 of 2    [showing results 1 to 10 of 12]    Next    Last

### Exeter Operative Tissue Bank

ONIX Interoperability: Catalogue: **BIOSAMPLE DIRECTORY**

*last updated: Apr 12, 2010*  
*url: <http://www.peninsulaicrf.org>*

This collection includes samples from patients with cancer affecting the following body sites: Breast, Digestive/Gastrointestinal, Genitourinary

[Show additional info](#)

### HYMN-T

ONIX Interoperability: Catalogue: **BIOSAMPLE DIRECTORY**

*last updated: Jul 07, 2010*  
*url: <http://www.uclh.nhs.uk>*

This collection includes samples from patients with cancer affecting the following body sites: bladder cancer

[Show additional info](#)

### Liverpool Tissue Bank

ONIX Interoperability: Catalogue: **BIOSAMPLE DIRECTORY**

*last updated: Apr 30, 2010*  
*url: <http://www.liv.ac.uk/ltb>*

This collection includes samples from patients with cancer affecting the following body sites: Breast, Digestive/Gastrointestinal, Eye, Genitourinary, Gynaecologic, Head & Neck, Lung/Respiratory/Thoracic, Musculoskeletal

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**NHS**  
National Institute for  
Health Research



## Exeter Operative Tissue Bank

ONIX Interoperability: 

Catalogues



last updated: Apr 12, 2010

url: <http://www.peninsulecrf.org>

This collection includes samples from patients with cancer affecting the following body sites: Breast, Digestive/Gastrointestinal, Genitourinary

[Hide additional info](#)

### Information submitted by:

[gillian.baker@pms.ac.uk](mailto:gillian.baker@pms.ac.uk)

### Contact Information (Postal address, work phone, email and the collection keeper):

Gillian Baker, Peninsula NIHR Clinical Research Facility, Peninsula Medical School, Barrack Road, Exeter, EX1 2SR, 01392 406791, [Gillian.Baker@rdefh.nhs.uk](mailto:Gillian.Baker@rdefh.nhs.uk), Peninsula NIHR Clinical Research Facility, Royal Devon & Exeter NHS Foundation Trust

### Status:

Completed

### Specific Subtypes of Cancer/Diseases in this collection:

Breast Cancer, not otherwise specified, Colon Cancer, Bladder Cancer, Kidney (Renal Cell) Cancer, Prostate Cancer

### Collection Status:

Accrual in Progress

### Access arrangements:

Contact: [crf@pms.ac.uk](mailto:crf@pms.ac.uk)

### Accessibility:

Open to Applicants, Open in Response to Specific Calls, Open Only Through Collaboration with Controlling Group, Variable dependent on tissue type

### Sample types:

Frozen Disease-Affected Tissue, Frozen Unaffected Tissue, Paraffin Embedded Disease-Affected Tissue

### Sample derivatives:

DNA, RNA

### Biomarkers already measured in these samples:

### Annotating information available:

Pathology Report, Summary of Health Record/Medical Information, Variable dependent on tissue type.

### Publications arising from the use of this collection:

Two publications in prep.

### Funders of this collection:

National Institute for Health Research

### Location where this collection is stored:

Exeter, East Devon, UK

### Additional Information:

last updated: Jul 07, 2010

url: <http://www.uclh.nhs.uk>

This collection includes samples from patients with cancer affecting the following body sites: bladder cancer

[Hide additional info](#)

**Status:**

Completed

**Name of Body/Organisation/Individual who controls the collection:**

UCLH (under the care of Prof John Kelly)

**Contact information below:**

Kathryn Matthews, 0121 414 9524, [k.r.matthews@bham.ac.uk](mailto:k.r.matthews@bham.ac.uk), CRCTU, School of Cancer Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT

**Full Trial Name:**

A randomised controlled phase III trial comparing

**Trial Acronym:**

HYMN

**Brief Trial Summary:**

A randomised controlled, phase III trial comparing hyperthermia plus mitomycin to a second course of bacillus Calmette-Guérin or standard therapy in patients with recurrence of non-muscle invasive bladder cancer following induction or maintenance bacillus Calmette-Guérin therapy. The trial aims to recruit at least 242 patients over a 36 month accrual period. Hyperthermia and mitomycin treatments or control (BCG) will be given over a 2 year period. Primary outcome measures: (1) Disease-free survival time (2) Complete response rate at 3 months, in the subgroup of trial patients with CIS. Secondary outcome measures: (1) Recurrence-free survival time (2) Progression-free survival time (3) Overall survival time (4) Disease-specific survival time (5) Safety and tolerability of HM (6) Quality of life (7) Cost effectiveness. Translational outcome measures: HYMN will incorporate translational components: blood, urine and tissue will be collected for future studies.

**The current status of the collection:**

Accrual in Progress

**Location of the access policy and material transfer terms and conditions:**

As this is a trial collection it will be under the control of the trial management group. Any interested parties should contact the Chief Investigator of the trial (Prof John Kelly) or Trial coordinator (Kathryn Matthews tel: 0121 414 9524) for further details.

**The current accessibility for the collection:**

Access Restricted at Present

**Primary sample types and the number of donors:**

Paraffin Embedded Disease-Affected Tissue, Blood, Urine, Frozen tissue and unaffected tissue may also be collected if available.

**Sample derivatives and the number of donors:**

DNA, RNA, Tissue Microarrays, No derivatives as of yet. Sample collection and processing ongoing.

**Annotating information:**

Treatment, Follow-up/Outcome, Cancer Registry Record, All information will be fully anonymised and cancer registry information will not be sent once the patient has completed the clinical trial

**Biomarkers (e.g. name of Biomarker, measurement method, etc):**

# 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>
Louise Jones	<i>Cancer Research UK</i>
Bill Lowrance	<i>Independent Consultant</i>

## ***Biosample Directories:***

Brian Clark	<i>onCore UK</i>
Louise Jones	<i>Cancer Research UK</i>
Mitch Dowsett	<i>NCRI Biomarkers &amp; Imaging CSG</i>
The team at the	<i>NCRI Informatics Initiative</i>
The team at	<i>onCore UK</i>



## Contact me via



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- 0208 731 4591



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