



Applic Number: _____ Applic Rec'd: _____

Sent to ATBMC: _____ Date approved: _____

Samples issued: _____

APPLICATION FOR ACCESS TO SAMPLES

- I. This application is intended for the use and processing of samples utilised by the laboratory and/or personnel that fall under the supervision of the Principal Investigator listed in the application. Any transfer of custodianship of samples or aliquots to personnel or laboratories that are not under the supervision of the indicated PI requires the following:

- An explanation of the need to transfer the materials and benefit to the investigator's research
- A copy of the enclosed Arden Tissue Bank agreement page signed by the collaborator

The ATB does not supply samples to banks solely for distribution to third party researchers; those researchers should be encouraged to apply to the ATB directly.

The information requested in these forms is necessary in order to correctly document your request for tissue and other services and to ensure that the ATB operates within the guidelines of the Human Tissue Authority. When submitting a written request for supply of material:

- A. Please print neatly or type.
- B. Ensure that the "Lay Summary" (page 4, section B) is written in plain English, without unexplained acronyms or medical terminology. Failure to provide a comprehensive and easy to understand lay summary will result in a request for a rewrite of the summary prior to its acceptance for consideration.
- C. Patient identity is confidential. Samples will be coded and supplied with a minimum data set. The cost recovery and/or processing fee per sample will vary according to the type of sample/data requested.
- D. The Arden Tissue Bank is authorized by the Wales 5 REC to release samples to researchers. Researchers receiving samples from ATB are NOT required to have approval from NRES for the use of these samples as samples will be provided anonymously with only the minimum data set. However, researchers must be able to satisfy the Management Committee and advisors of the ATB that the project they submit is both ethically and scientifically valid. If researchers are already in possession of NRES approval for their projects, a copy of the NRES letter should be supplied with the application. Researchers are advised that it is their responsibility to ensure that they comply with the Human Tissue Act or other appropriate laws that cover the use of human material in research. An HTA licence is NOT needed to store tissue sourced from ATB for an approved project that is subject to a signed Material Transfer Agreement.
- E. The transfer of custodianship of samples from ATB to researchers will be by Courier. Researchers are required to cover the cost of transport of their samples and supply appropriate customs declarations if appropriate.
- F. Please email the completed application form to ardentissuebank@uhcw.nhs.uk and send hard copy of the signed Material Transfer Agreement (final page) to:

Arden Tissue Bank
Pathology Department
University Hospitals Coventry & Warwickshire NHS Trust
Clifford Bridge Road
Coventry
CV2 2DX

- G. For additional information please contact the Arden Tissue Bank on +44 (0)2476 96 7033
- H. The ATBMC will review applications and aim to provide a decision within 1 calendar month from receipt of a valid submission, for applications that require further review/clarification we will aim to approve these within 8 weeks of initial receipt. (for further details please see 'Application Workflow
- Arden Tissue Bank Application for Biomaterials Version 5.5 02/05/2023 Page 1 of 8

II. INVESTIGATOR DATA

Principal
Investigator:

Last Name

First Name

*Middle
Initial*

Degree

Investigator's
Title:

Address:

Address

City

Country

Post Code

Phone / Fax:

Email:

Contact Person (if different from above)

Name:

Contact Number:

Email:

B. Shipping Address (*if different from above*):

Address:

Address

City

Country

Post Code

C. Invoice information. Is a purchase order required for shipment of specimens to your institution?

Yes ☐ No ☐ If yes, please supply purchase order when project has been approved.

Invoices will be sent to the shipping address listed in section B. If you would like the original invoice to be provided by post to another location (eg. your finance department), please enter that address below. A shipping list will be included with the samples, please complete and fax back to ATB to acknowledge receipt.

Person to whom invoice should be addressed (if different from above):

Name: _____

Invoice Address (if different from above):

Address: _____
Address

City	Country	Post Code
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Courier services are provided by either DHL (Europe and Japan) or Federal Express (USA). Please state if you require another Courier and provide the appropriate customer number below.

Preferred Courier: _____ Customer Number: _____

D.

How did you discover or become aware of Arden Tissue Bank? E.g. web search, UKCRC Tissue Directory, Recommendation.

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III. RESEARCH INFORMATION

Title:

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Specimens will be provided to all investigators, based either in Academia or Industry

- A. Please indicate the source of funds for your proposed project. If this is Institutional Funding, please enclose a letter from your Head of Department indicating that funds and premises are available to complete your project.

Funding Source

Period of Support

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- B. Please provide a short lay summary (max 200 words) of the intended research. Please note, this information will be used on the Arden Tissue Bank website, in ATB reports to funders & NRES, therefore only include information that is not commercially sensitive.

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IF YOUR PROJECT HAS ALREADY BEEN REVIEWED AS PART OF A GRANT APPLICATION, YOU MAY OMIT THIS SECTION AND SUPPLY A COPY OF THE SCIENTIFIC PART OF THAT GRANT APPLICATION AND FUNDING APPROVAL.

- C. Please provide the **title** and a short research summary (2-4 pages of A4) of the proposed research on the samples you are requesting from the ATB (*use additional pages where necessary*). Sufficient information should be provided to enable the External Review Panel to determine the scientific validity of your study. Please fully justify the number and type of samples requested and address ALL the headings below.

- i. Introduction (including an overview of the state of the art in your proposed project area):

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- ii. Hypothesis & Aim(s) (please clearly state the aims(s) of your project):

- iii. Experience of group and/or company carrying out analysis (please provide information to indicate that your research group has experience in the techniques you intend to use, either by use of preliminary data from other work carried out in your group or by providing references to publications from your group/company that are relevant to this application):

- iv. Methods (please detail the methods you intend to use, indicating controls and the experimental design you will use where relevant include statistical information):

- v. Please could you provide evidence of any quality management system(s) you will be using (e.g. standard operating procedures):

- vi. Are assays used in the analysis if research samples validated? If assays are not validated, are external quality processes used to validate results? (E.g. commercial standards or external quality assessments)

IV. SPECIMENS REQUESTED *(The ATB will undertake bespoke collection of material if required. If you require a bespoke collection, please supply details of your request on a separate sheet.)*

Please specify **exactly** what you require e.g. 20 unstained sections per case from 20 ER positive invasive ductal carcinoma of the breast.

Material required:	Number of cases required
Fresh Frozen Tissues (state max ischemic time)	
PPFE blocks (state no of blocks/case and any other requirements)	
Tissue Microarrays (state no. of cases, cores/case, core diameter)	
Unstained sections	
Scrolls (state required thickness)	
<i>Continued over</i>	

Whole Blood	
Serum	
Plasma	
Buffy Coat	
Others	

Please list sample requirements and format (tissue microarray, serum, sections, frozen tissue etc). Ensure any age, pathological sub-types are clearly indicated

A. Sample Information Required: (*Anatomic site of tissue, pathological diagnosis, patient age, sex will be provided for all samples.*) Additional patient information may be available, but you must request it in this application and justify its necessity for your research. It may be possible to provide some samples with details of treatment and outcome – although this may not be possible for all samples.

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B. Sample Storage: Please indicate which of the below options is correct for your proposed study;

- Samples supplied by Arden Tissue Bank will be destroyed during the course of the intended analysis.
Yes No
- Samples surplus to the proposed study analysis will be transferred to a HTA licensed establishment at the end of the study.
Yes No
- Other- please detail _____

N.B

Transfer of sample associated data internationally may require the completion of an International data transfer agreement to comply with Article 46 of the UK GDPR.

Further details can be found: <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/international-data-transfer-agreement-and-guidance/>

AGREEMENT FOR USE OF TISSUE

The recipient/investigator agrees that the tissues provided by the Arden Tissue Bank (ATB) will be used only for the purposes specified in this application.

The recipient agrees not to attempt to obtain information identifying the individuals providing tissues to the ATB. The recipient agrees that it shall not sell any portion of the tissues provided by the ATB, or products directly extracted from these tissues (e.g. construct TMA's for commercial benefit, protein, mRNA or DNA).

The recipient also agrees that they shall not transfer tissue (or any portion thereof) supplied by the ATB to third parties without the prior written permission of the ATB. Any subsequent transfer that may be made to other parties, with prior agreement from ATB, will require signature of this agreement between the final recipients of the material and the ATB.

The recipient understands that while the ATB attempts to avoid providing tissues that are contaminated with highly infectious agents such as hepatitis and HIV, all tissues should be handled as if potentially infectious. The individuals who have supplied tissue to the ATB have not agreed to have clinical tests performed on this tissue (e.g. for the presence of infective agents such as hepatitis), therefore, the recipient agrees not to perform such tests on the tissues supplied by the ATB. The recipient acknowledges that the institution where the tissue will be used follows Human Tissue Authority or appropriate local regulations if outside England, Wales and Northern Ireland, for handling human specimens and will instruct their staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

Tissues are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. The ATB accepts no responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use.

The recipient agrees to acknowledge the contributions of the Arden Tissue Bank in all publications resulting from the use of these tissues.

The institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of tissues from the Arden Tissue Bank. It further agrees to indemnify and hold harmless the Arden Tissue Bank and the University Hospitals Coventry & Warwickshire NHS Trust from any claims costs, damages or expenses resulting from the use of the tissues provided by the ATB. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT

Typed Name of Principal Investigator	Institution	Division or Department

Signature of Principal Investigator	Date	Institutional signatory (if applicable)

UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTED ABOVE,
THE ARDEN TISSUE BANK WILL CONSIDER THIS REQUEST.

Specific questions about your application should be directed to:

Email: ardentissuebank@uhcw.nhs.uk

Arden Tissue Bank, Pathology Department, University Hospitals Coventry & Warwickshire NHS Trust, Clifford Bridge Road, Coventry, CV2 2DX.
Tel +44 (0)2476 967033,