

Daisy Tumour Bank: Access Policy

1. Overview of the DTB collection

- 1.1. The Daisy Tumour Bank (DTB) collection consists of cancer tissue and blood products collected from cancer patients for use in cancer research. A catalogue of current holdings is available via e-mail from DTB@hyms.ac.uk.
- 1.2. Researchers are encouraged to send an informal enquiry, detailing the nature of their access request, via e-mail in the first instance. The DTB team will then advise whether a formal Access request should be submitted.
- 1.3. The University of Hull has provided funding for the setup of the DTB to Hull York Medical School (HYMS).

2. Access Process (see Access Policy Appendix A)

- 2.1. Access to the DTB collection is open to researchers within the UK and European Economic Area, providing research does not conflict with current or proposed research at the University of Hull. The Access Policy has been created using the National Cancer Research Institute template in accordance with their guidelines.
- 2.2. Access to the DTB collection consists of four stages which must be completed before samples are provided:
 1. Determination of the suitability of the DTB collection and the eligibility of the proposed study – via initial e-mail enquiry.
 2. Completion and submission of DTB application form ‘Application for Access to Materials’ and provision of any supporting information required.
 3. Consideration of the application by the DTB Access Committee. Access may be conditional based upon the successful outcome of any required Research Ethics Committee (REC) approvals or grant funding applications which are outstanding.
 4. Agreement to access conditions and signing of the DTB Materials Transfer Agreement.

3. Eligibility for Access

Limitations on use of the DTB collection:

- 3.1. The DTB collection holds consent for use in cancer research, to allow investigation into the causes and development of cancer, to assess new treatment options and to identify the genetic basis of cancer.
- 3.2. The DTB collection was generated for cancer research and does not have consent for the use of identifiable samples in secondary research. Samples are not available for purposes other than cancer research.
- 3.3. Identifiable information is not available to researchers.

Limitations on the availability of the DTB collection:

- 3.4. The DTB Access Committee aims to make samples readily available, however in exceptional circumstances, access to rare samples may be restricted to prevent their depletion.

- 3.5. The DTB collection is made available as a research community resource in line with the UK Research Clinical Research Collaboration 'UK Funders' Vision for Human Tissue Resources'. However, priority for access may be given to local researchers who have contributed to the acquisition and maintenance of the DTB collection.

Ethics approvals held by the DTB collection:

- 3.6. The DTB is covered by research ethics approval from [REC details] for the provision of data and/or samples to internal researchers at the University of Hull who satisfy the DTB Access Committee that their application is both ethically and scientifically appropriate.
- 3.7. External researchers wishing to conduct research using data and/or samples from the DTB collection must provide evidence of approval from an appropriate Research Ethics Committee before being granted access.

Eligibility for access to the DTB collection:

- 3.8. Applicants should be employees of a recognised academic institution or NHS organisation; or of a commercial research organisation, with experience in cancer research.
- 3.9. Applicants should be able to demonstrate, through their peer reviewed publications in cancer research, their ability to carry out the proposed study.

Prioritisation of access to the DTB collection:

- 3.10. Where demand for material exceeds its availability, access will be prioritised based on:
 1. Priority to research groups within the University of Hull or working in collaboration with the University of Hull.
 2. Priority to research groups within Hull and East Yorkshire NHS Trust.
 3. Priority to researchers in Hull York Medical School or working in collaboration with Hull York Medical School.
 4. Scientific merit (as judged by the DTB Access Committee).

4. Application for Access

- 4.1. Stage I: Researchers who wish to access the DTB collection should initially contact the DTB via e-mail (DTB@hyms.ac.uk) giving a brief outline of the proposed study, the methodology to be followed and the number and type of samples required. The DTB will assess the suitability of the application and respond to the applicant with confirmation on whether they can proceed to stage II.
- 4.2. Stage II: Should the proposed study be assessed as suitable, applications for access to the DTB collection should be detailed on the application form 'Application for Access to Materials', which is available via the DTB website (www.hyms.ac.uk/dtb). The form should be submitted via e-mail to (DTB@hyms.ac.uk). All of the details on the form should be completed as any missing information may delay the application.
- 4.3. Applications may be submitted at any time and will be considered in the order in which they are received.
- 4.4. The DTB team aims, but cannot guarantee, to acknowledge all applications within 1 week of receipt and to provide a decision within 4 weeks of receiving a full application.
- 4.5. All applications will be treated in a confidential manner by the DTB team and the DTB Access Committee.

5. Processing Applications (See Access Policy Appendix B)

- 5.1. On receipt of the application, the DTB will check to ensure that the requested samples, surplus to those samples committed for local research are available and that all required information has been supplied. If samples are not available the applicant will be notified with details of possible alternatives. If any information is missing from the application the applicant will be asked to supply this before the application is considered further.
- 5.2. The proposed research study will be peer reviewed and prioritised on the basis of scientific and technical merit by members of the DTB Access Committee (members are listed on the DTB website www.hyms.ac.uk/dtb). If the protocol is not considered appropriate the DTB Access Committee will contact the applicant to explain why this is the case and may suggest improvements.
- 5.3. Applications to the DTB collection can be made before any required funding or Research Ethics approvals are obtained. If the DTB Access Committee decides to support the request then a letter stating the intent to grant access to the required samples, subject to appropriate conditions, will be issued to the applicant by the DTB Access Committee. Any such 'letter of intent' will be valid for 4 months from the date of issue and will reserve the requested samples. After this time the samples may be made available to other applicants and the applicant will be required to reapply for access.
- 5.4. The DTB Access Committee reserves the right, in exceptional cases, to seek further external advice or external peer review before reaching a decision. The applicant will be notified before any project details are shared, in confidence, with external reviewers.
- 5.5. As the amount of material available is limited, applicants who propose similar studies may be put in touch with each other, with the suggestion that they collaborate. If the applicants are not willing to collaborate then both applications will be considered however, it is very unlikely that access to the collection will be granted for two very similar studies.
- 5.6. Once the conditions for access specified in any "letter of intent" are met, evidence of this (for example letters from funding bodies or research ethics committees) should be submitted to the DTB team. If the process of gaining funding or research ethics approvals has resulted in significant changes to the study, the DTB Access Committee should be informed as soon as possible, outlining the details of the changes. Depending on the nature of these changes, a new application may be required.
- 5.7. There is no right of appeal if access to the collection is refused; the decision of the Access Committee is final.

6. Conditions of Access and Compliance by the Recipient Institution

- 6.1. Before access to materials from the DTB collection is granted, applicants must agree to the conditions of access and compliance set out in the Material Transfer Agreement/ Material Transfer Statement in the agreed form and return a signed copy to the DTB team.
- 6.2. The applicant will be required to cover the costs of collecting, maintaining, retrieving, processing and dispatching samples and data, as applicable and this is set out in the Material Transfer Agreement/Statement.
- 6.3. A tiered discount structure will apply as relevant (see Access Policy Appendix C). Details of current costs are available via e-mail from DTB@hyms.ac.uk.

- 6.4. If the Access Committee has reason to believe that the Applicant will not comply with any of the following it may reject the application:
- 6.4.1. Data or samples supplied by the DTB collection must only be used for the purposes described herein and in the Materials Transfer Agreement.
 - 6.4.2. Data or samples supplied by the DTB collection must be used only by the applicant(s) named in the original application. Data or samples supplied by the DTB collection may not be transferred to individuals outside the applicant(s) research group.
 - 6.4.3. Recipients of DTB samples must not attempt to identify any individual from the data or samples provided. Should such 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. If recipients believe that they have inadvertently identified any individual from the data or samples provided they must inform the DTB team immediately, providing details of the circumstances under which this occurred.
 - 6.4.4. The DTB collection has waived its right to any Intellectual Property arising from the samples or data provided and recipients must make every effort to protect this in line with the policies of their host institution and funders.
 - 6.4.5. Recipients are expected to submit their results to a peer reviewed publication as soon as possible after completion of their study.
 - 6.4.6. Any publication or presentation using data or samples provided by the DTB collection should include an acknowledgement using the text below:
“We gratefully acknowledge the Daisy Tumour Bank (University of Hull, United Kingdom) for supplying the samples and/or data used in this research”.
 - 6.4.7. A copy of each publication arising from the samples or data provided by the DTB collection should be forwarded to the DTB team as soon as it becomes available.
 - 6.4.8. All publications and new data arising from the samples or data provided by the DTB collection should be made openly available to the cancer research community as soon as possible.
 - 6.4.9. If patient consent is withdrawn for issued samples, recipients will be informed of the relevant sample numbers. Recipients will be required to destroy any unused samples control by incineration, as separate clinical waste and certify that they have done so to the DTB team, or return the Materials to the DTB for destruction. Results obtained from samples that have already been used for research need not be destroyed. The sample fee is non-refundable if patient consent is withdrawn.
 - 6.4.10. Once the study is complete, any remaining samples must be destroyed by the recipient control by incineration, as separate clinical waste and certify that they have done so to the DTB team, or return the Materials to the DTB for destruction

7. Compliance policy

- 7.1. Recipients must complete an annual declaration to the DTB team using the ‘Annual Report’ form available from the DTB collection website, until all samples have been processed or destroyed. This form includes a declaration that the recipient has complied with the terms of the Materials Transfer Agreement.
- 7.2. Recipients must complete an ‘End of Study Report’ to be submitted to the DTB team using the form available from the DTB collection website, confirming all samples have been processed or destroyed. This form includes a declaration that the recipient has complied with the terms of the Materials Transfer Agreement.
- 7.3. Recipients found to be in breach of the Materials Transfer Agreement will be denied future access to the DTB collection and their institutions and funders informed.