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BIORESOURCE PAPER

Ethical Tissue: A Bioresource Specialising in Broad Prospective Supply of Tissue from a Wide Range of Participants

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Ethical Tissue (ET) is a Research Tissue Bank specialising in researcher led prospective collection of tissues. ET does not focus on specific conditions nor is it restricted in who it can supply. We consider requests for any type of tissue, including biofluids such as blood, serum, plasma and urine, from researchers in academia or industry from any part of the world. Tissues and biofluids are collected under generic and lasting consent, maximising reuse/sharing potential. ET also provides tissue processing services including tissue micro-arrays from both fresh frozen tissues and FFPE blocks, primary cell cultures, subcellular fractions and DNA/RNA preparations. A list of banked tissues, including biofluids, cell lines and processed samples is available on the ET website.

Keywords: Researcher led; prospective; difficult-to-source; generic and lasting consent

Funding statement: The major source of income for Ethical Tissue is through cost recovery. In addition the authors would like to acknowledge the ongoing support of the University of Bradford.

(1) Bioresource Overview

Project description

When Ethical Tissue was founded in 2007 the aims were a) to provide a researcher led tissue supply service across most diseases and conditions, b) to make it as simple as possible for researchers to access tissues, c) to maximise tissue supply and minimise tissue banking, "supply not store" and d) to be self-sustaining through a cost recovery model [1] Sustainability and sound business planning has become increasingly important due to constrained budgets in higher education institutes and elsewhere [2, 3]. Currently ET recovers over 80% of its costs through service charges to researchers.

Over time an appreciation of the importance to participants of the donation process have also developed leading to a new aim, e) to meet the expectations and fulfil the wishes of participants. To this end we have developed feedback systems to better understand the participant motivation and satisfaction.

Ethical Tissue now collects tissues on behalf of researchers throughout the world in both academic and commercial organisations. Tissue collected are Healthy Volunteer (HV – including blood, urine, saliva, tears, nipple aspirate fluid, teeth, hair and skin), Surplus Tissue (ST – often with matched normal tissues and including paediatric participants), Additional Tissue (AT – mainly body fluids, e.g. blood, urine, sputum, from patient cohorts), Tissue Donation After Death (TDAD). This latter service has been developed due to the demand for difficult to source tissues that cannot easily be obtained by other routes.

Tissues are collected and supplied to researchers around the world, to academic groups as well as commercial organisations. This is made clear to participants during the consenting process, as is the cost-recovery process and the purpose of generic and lasting consent. Additional services include processing to provide tissue sections and microarrays (FFPE and fresh frozen), cellular fractions and DNA/RNA.

As a research tissue bank ET has supported nearly 100 different projects since inception and receives a steady supply of new project enquiries. Operating under our broad ethics approval, researchers can get rapid access to existing collections or bespoke collection services. Our review panel will normally provide an opinion on suitability of any proposed project within 2–3 weeks. This review covers the type of tissue requested, number of tissues/donors required and the aims of the project and that funding for the project is in place. The latter is to ensure cost recovery but also that resources are available to ensure that the project will proceed. Once approved a Material Transfer Agreement is all that is required to enable tissue supply.

This bioresource operates under licence from the UK government's regulatory agency, the Human Tissue Authority – HTA (Licence number12191). At present all EU regulations have also been adopted by the UK and are enforced as part of the HTA remit.

Classification (1)
Human

Species
Homo sapiens

Classification (2)
Biological samples and associated data.

Context
Spatial coverage
The majority of tissues collected by ET are from sources in the English region of West Yorkshire. Other UK collection sites are in Cambridgeshire and Suffolk. For specific collaborative projects we have also received samples from other countries including Montreal, Canada (45.504785, –73.577151), Nicosia, Cyprus (35.168239, 33.314415) and Lahore, Pakistan (31.448676, 74.271876).

Temporal coverage
Ethical Tissue formally commenced operations from 2007 when it received a Favourable Opinion from the Leeds Research Ethics Committee to become a Research Tissue Bank. At this point Ethical Tissue took over responsibility for the tumour bank previously established by the University of Bradford. Specific projects run by Ethical Tissue may have defined timelines but the bioresource itself will continue indefinitely under its current sustainability plan.

Temporal coverage for accessibility
Currently tissues are stored for a maximum of 10 years at which point they may be destroyed. We are currently developing quality assurance procedures to support, destroy or retain decisions. As collection is mostly prospective and ongoing, accessibility will be maintained indefinitely.

(2) Methods

Steps
Approval of researcher request by independent advisors; participants are identified by a variety of means including:

1. Call for volunteers e.g. through website (HV),
2. Identification of potential donors through pre-assessment clinics (ST),
3. TDAD requests to gift tissue via web site, hospices or clinician.

All participants are consented, with specific forms used for each type of donation (e.g. HV, ST, TDAD). Whilst specific projects are not discussed all donors receive information about the type of research for which their gift has been requested. Participants can restrict usage, e.g. not for export, and may withdraw their consent at any time. If consent is withdrawn, any tissues retained from the donation will be destroyed.

Following collection, which may be local, post-operatively at hospitals or via post mortem procedures at local mortuary, all samples are transported to the ET facility, anonymised and processed as appropriate for supply to researchers. Where possible, some tissue may be retained for wider sharing.

Standard Operating Procedures (SOPs) have been developed covering all aspects of collection, storage and supply. In addition SOPs covering infrastructure, laboratory methods and equipment are in use. Additional policy documents covering management and governance process are in place.

Stabilisation/preservation
Samples are processed according to researcher requests.

Type of long-term preservation
The majority of stored tissues are fresh-frozen. Freezers have alarms and automated messaging to alert staff to any issues. Liquid nitrogen containers, whilst not alarmed, are inspected and topped up on a regular basis.

Storage temperature
Storage at –196°C, –80°C or –20°C depending on tissue type and future use.

Shipping temperature from patient/source to preservation or research use
Generally shipping from source to ET facility will be at 0–4°C (on ice) or room temperature (18–25°C). Some may be flash frozen in liquid nitrogen (–196°C). The method used will depend on tissue type and researcher requirements.

Shipping temperature from storage to research use
Onward shipping to researchers can be at –80°C, 0–4°C (on ice) or ambient temperature depending on researcher requirements and location.

Quality assurance measures
HV samples are collected in accordance with relevant SOP; ST collection normally involves pathologist or consulting clinician confirmation of tissue type, e.g. tumour or normal, along with collection in accordance with SOP. TDAD samples are retrieved by an experienced pathologist following a specific SOP.

Internal audits of the operations are carried out by the University of Bradford's Designated Individual under the licence granted by the Human Tissue Authority. The authority also carries out audits of the bioresource on a regular basis with the most recent inspection being in March 2020.

Source of associated data
Data is derived from direct contact, questioning, interviewing, and questionnaires where appropriate to the consenting situation. Some information is obtained from health records. All data is anonymised prior to being released with the samples. The type of data will include donor age, gender, ethnicity, medical history, medication, height and weight. Other information which may be sought would include lifestyle questions such as smoking and alcohol details. All data is entered onto the database, however personal identifiers are not.

Relevant linked anonymised information in the form of a non-identifiable data set is released to researchers in conjunction with the biological sample.

Generally all donor specific information is collected by tissue bank personnel who are GCP trained and have appropriate NHS Trust authorisation to access clinical records following donor consent. Other information may be supplied directly by other Health Professionals, for example, copies of relevant histopathology reports may be requested when appropriate consent has been obtained.

NHS records, questionnaires and information supplied on consent forms, e.g. medication use, smoking/alcohol consumption, are used to collect data as appropriate.

Ethics Statement

Ethical approval has been granted by the Yorkshire & The Humber – Leeds East Research Ethics Committee. The original Favourable Opinion was dated 14th August 2007. Review in 2012 and most recently on the 5th May 2017 have maintained the favourable opinion. The 2017 REC reference is 17/YH/0086.

All our consent forms ask for permission to send tissue samples to properly approved research programmes both in the UK and abroad. In addition researchers are also required to sign an MTA which states that the recipient agrees that the Material and Data provided by Ethical Tissue: Will not be used in any activity that contravenes the Human Tissue Act 2004 or other legislative body if outside the UK; will not be used for human application such as transplant use; will not be used in research that falls under the Human Fertilisation and Embryo Authority (HFEA) or other foreign national equivalent bodies and involve activities such as reproductive cloning and cell nuclear replacement as described by HFEA; will not be tested for known inherited diseases; will only be used for biomedical research and not for the testing of cosmetics.

Any unused samples may be destroyed after a period of 10 years.

Constraints

Currently we collect from a range of sources in the West Yorkshire region.

(3) Bioresource description

Object name

Human tissue, cell lines and derived subcellular fractions.

Bioresource name

Ethical Tissue (ET)

Bioresource location

Ethical Tissue, Institute of Cancer Therapeutics, University of Bradford, Bradford BD7 1DP, UK

Bioresource contact

Contact details are available at https://www.bradford.ac.uk/business/ethical-tissue/contact-us/
Tel: +44 (0)1274 235897
Email: enquiries@ethicaltissue.org

Bioresource URL

https://www.bradford.ac.uk/business/ethical-tissue/

Identifier used

Bioresource type

Prospective collection for most conditions, difficult to source tissues, healthy volunteer samples, RNA, DNA, cellular fractions, primary cells, tissue microarrays arrays. Where possible a portion of donated samples are retained for wider sharing.

Type of sampling

Researcher led and defined.

Anatomical site

Any

Disease status of patients/source

Any with the explicit exception of HIV, Hepatitis B/C. Other conditions will be considered on a case by case basis.

Clinical characteristics of patients/source

Inclusion criteria are defined for each project on a case-by-case basis. Participants to date cover both males and females, paediatric and adult with no upper age limit.

Size of the bioresource

The vast majority of tissues collected are transferred directly to researchers. However, we have approximately 10,000 tissue samples stored and available.

Vital state of patients/source

Fit and well, pre- and post-operative and postmortem.

Clinical diagnosis of patients/source

Where appropriate, clinical diagnosis is obtained before sampling, and tissue sample status is confirmed by pathologist.

Pathology diagnosis

Where appropriate, tissue sample status is confirmed by pathologist at the time of collection.

Control samples

Healthy volunteer (fit and well) samples or matched normal tissues as specified by the pathologist at post-operative collection.

Biospecimen type

Various tissues, snap frozen – 7019; whole blood – 149; plasma – 1663; serum – 127; urine – 998, PBMCs – 351, hepatocytes – 78, other primary cells – 451.

Release date

No embargo exists.

Access criteria

Access to banked samples, listed on ET website, is via a request form. Researchers are requested to give a brief description of the tissue(s) required, the purpose of the research and the availability of funding to complete the research.

For prospective collection researchers are requested to contact ET to discuss feasibility of tissue collection in the first instance. Subsequently the same procedure outlined above is followed.

Requests for tissue are reviewed by an independent scientific advisory group. All members of this group are researchers and/or healthcare professionals with experience of running research projects involving human tissues. Membership of the group is by invitation, often on the recommendation of existing or former members of the scientific advisory group. If approved, researchers must complete a Material Transfer Agreement before any tissues can be supplied.

ET operates on a cost recovery basis and as such does not have set costs for prospective collection, which can vary from project to project. Costs are discussed with researchers at the earliest opportunity and calculated using the University of Bradford's full economic costing model. The majority of costs for any project are generally staff time. Consideration is given to the identification of clinicians to work with, identification of donors and consenting, tissue collection and processing, database maintenance and transportation charges.

ET does not place any geographical restrictions on access and will supply tissues to both academic and commercial organisations.

(4) Reuse potential

All tissues collected are under a generic consent allowing use outside the specific project that drove the collection. In addition lasting consent is requested so that residual tissues do not have to be destroyed at the end of a particular project. The majority of tissues collected by ET are immediately transferred to the appropriate researchers with no retained sample for verification purposes. All samples despatched are logged against specific projects to maintain traceability of usage. Where ET retains a portion of any donation, the availability of these samples is added to the collection database to maximise sharing/reuse on additional projects.

Acknowledgements

Mrs Sandie Martin, former Head of Ethical Tissue, now retired; Dr Samantha Patterson, former Business Development Manager at the University of Bradford; Professor Laurence Patterson, whilst Director of the Institute of Cancer, were key players in the establishment of Ethical Tissue. Dr Susan Boyce, former Head of Ethical Tissue, was a key initiator of growth plans and the TDAD service.

Competing Interests

The authors have no competing interests to declare.

Author Roles

K Adams – Founding member of management board; W Burrill – Bioresource Manager; J Mullarkey – Research Nurse.

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