Newcastle Tissue
- Human Tissues for Industry

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The Newcastle EPSRC/MRC Molecular Pathology Node
Medicines Discovery Catapult

Please could you indicate how much you agree/disagree with these statements about the NHS?

<table>
<thead>
<tr>
<th>Disagree</th>
<th>Agree</th>
</tr>
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<tbody>
<tr>
<td>The NHS is a unique and differentiating asset for the UK cluster</td>
<td>Neither agree nor disagree</td>
</tr>
<tr>
<td>The NHS is easy to navigate and work with for industry</td>
<td>Somewhat agree</td>
</tr>
<tr>
<td>Access to biosamples for commercial development is hugely important</td>
<td>Strongly agree</td>
</tr>
<tr>
<td>It is easy to access high quality NHS biosamples for commercial research</td>
<td>Strongly disagree</td>
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</tbody>
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Newcastle University

EPSRC Engineering and Physical Sciences Research Council

MRC Medical Research Council

The Newcastle upon Tyne Hospitals NHS Foundation Trust

newcastle
node
molecular pathology
Supplying human tissue to industry

- Patient consent
- Ethics approval
- Human Tissue Act and the HTA
- Funding – mechanisms for proper cost recovery
- Patient – nurse – laboratory – transfer
- Time frame for collection, sample quality
- Uncertainty – easier to say no! - education

Human Tissue Authority
The regulator for human tissue and organs

The Newcastle upon Tyne Hospitals
NHS Foundation Trust
Sale of bodies, body parts and tissue

Description

This policy describes the Human Tissue Authority’s (HTA’s) policy on the sale of human bodies, body parts and tissue.

Purpose

The purpose of this policy is to inform stakeholders of the HTA’s position on the sale of human bodies, body parts or tissue.
Under section 32 of the HT Act, it is an offence to engage in commercial dealings in 'controlled material'. Controlled material means material which consists of or includes human cells (excluding gametes and embryos), which is – or is intended to be – removed from a human body for the purpose of transplantation.’

‘A person guilty of an offence under section 32 is liable to imprisonment and/or a fine. The HT Act is, however, silent on the sale of bodies, body parts or tissue for other purposes and such sales are therefore outside the remit of the HTA.’
“Research tissue banks may charge for providing human tissue samples to researchers, including those working for private companies, so that their running costs are recovered and the viability of the bank is maintained. Where cost recovery, or any other charging mechanism, is in place it is important that research tissue banks are able to satisfy themselves that the information provided to potential donors is sufficient to ensure they understand that their tissue may be shared, subject to a fee being charged. The HTA also recommends that research tissue banks ensure transparency by providing easily accessible information about how and why they charge, and to whom they will supply tissue samples. This is important to ensure that the consent sought from donors to the research tissue bank is fully informed.”
Creation of the CEPA Biobank

• To fulfil requests for samples by commercial companies to the Trust
• To facilitate and encourage research
• To ensure that excellent governance arrangements are in place for human tissue
What the public told us

Adults

• This is definitely something the Trust should be doing
• Particularly keen to support local industry
• Tissues should be a gift, no personal remuneration
• The NHS should recover its full costs
• The Trust must vet the commercial concern – no brokers
• Tissues must be tracked and recoverable if needed
• Would like to know what the tissue were used for - company website
What the public told us

Young persons advisory group

• OK to supply industry, no problem with that!
• Felt consent for that could be given by a 13 year old
• Would like to know that the tissue was used for
• Asked if consent could really be fully informed
• Agreed tissue should be gifted and not sold
• Wanted information to be available on social media
• Several felt that supply to industry should be publicised in news media
What the public told us

Women’s Institute

• Endorsed most of the principles of the other groups
• Stressed the need for transparency
• Two way relationship
• Bring new developments to our patients
• Really interested to find out what hospital pathologists do
CEPA BIOBANK - Progress

- Ethics approval March 2017
- Research notification August 2017
- First samples November 2017
- Official launch 19th January 2018
- Three staff now appointed
CEPA BIOBANK – Current position

‘Collect to order, collect to protocol’

Working with several companies

• Assessment of companies
• Contract/CDA/MTA
• Confirming tissue requirement
• Costs

Working with clinical teams

• Assessment of capacity
• Costs
• Pathway
• Clinician engagement
Newcastle University Biobanks

- Newcastle Academic Health Partners Bioresource Research Tissue Biobank
- Newcastle Brain Tissue Resource
- Great North Biobank
- United Kingdom Primary Sjogren's Syndrome Registry
- Newcastle Biobank for Research of Neuromuscular Disorders
- Human Developmental Biology Resource (HDBR)
- Newcastle Institute of Transplantation Tissue Bank
- Children's Cancer and Leukaemia Group (CCLG)
- Newcastle Bone and Joint Biobank
- Newcastle Uteroplacental Tissue Bank
- Newcastle Dermatology Biobank
- Biobank for Patients with Retinal Degenerations and Dystrophies
- Great North Neonatal Biobank