

## Research and Development Department Using Human Tissue in Research- Guidance for researchers

The Human Tissue Authority regulates the use and storage of human tissue for the purpose of research. This summary guidance outlines the governance requirements for the use of human tissue (cellular human biological material) in research projects. If you are wishing to use human tissue in research it is recommended that you contact the Research Office for support.

You will require some form of approval if you wish to use human tissue in a research project.

The USE of human tissue in research and the STORAGE of tissue for future research will need to be made clear in applications for approval. You will need informed consent from the patient for BOTH.

### What approvals are required to obtain and transfer a sample for research?

<b>Relevant material</b> (material, other than gametes, which consists of or includes human cells but does not include embryos outside the human body, or hair and nail from the body of a living person)		
<b>Prospectively gather</b> cellular human biological material for a new research		REC and R&D approval
<b>Use of stored samples</b>	With consent for research and anonymous	R&D approval
	With consent for research and identifiable	REC and R&D approval
	Where the sample predates 1 <sup>st</sup> September 2006 – no consent and anonymous	R&D approval
	Where the sample predates 1 <sup>st</sup> September 2006 – no consent and identifiable	REC and R&D approval
	From a REC approved Biobank	Biobank approval and R&D registration
<b>Residual/surplus samples (diagnostic archive)</b>	With consent for research and anonymous	R&D approval
	No consent and anonymous	REC and R&D approval
<b>Non-relevant material</b> (material which does not consist of or include human cells, ie, acellular)		
	With consent for research and anonymous	R&D approval
	With consent for research and identifiable	REC and R&D approval

If you initiate a study and your protocol specifies that the samples obtained will be consented for future research, the samples, if relevant material, **MUST** be stored in a Human Tissue Authority-licensed

research tissue bank, unless you intend to obtain ethical approval for the future research **before** the end of the current study.

Other approvals may be required if you are using:

Cell lines, embryonic stem cells, embryonic stem cell lines, embryos outside of the body, gametes or sperm, please contact the Research Office for advice.

## **What approval is required to transfer samples?**

The Human Tissue Act states that if you wish to transfer samples it is good practice that an Material Transfer Agreement (MTA) is in place. An MTA is required for all samples leaving and entering the Trust, including samples transferred to KCL. This is to provide organisational assurance that material is used in line with patient consent, traceability of the samples and the details of the approvals issued for the research project.

If your protocol, and study documentation, is explicit as to how tissue will be handled throughout the duration of your project an MTA may not be necessary if a site agreement is used.

Exporting samples outside of the UK will require an MTA. The samples must be used in line with the consent given.

Importing samples from outside of the UK will require an MTA. There is no requirement for REC approval to use imported tissue in research as long as it is stored in line with Trust policy.

## **More Detailed guidance is available from the Research Office**

If you would like advice or assistance on HTA and your project, please contact the Research Office:

[Kch-tr.research@nhs.net](mailto:Kch-tr.research@nhs.net)

02032991980