

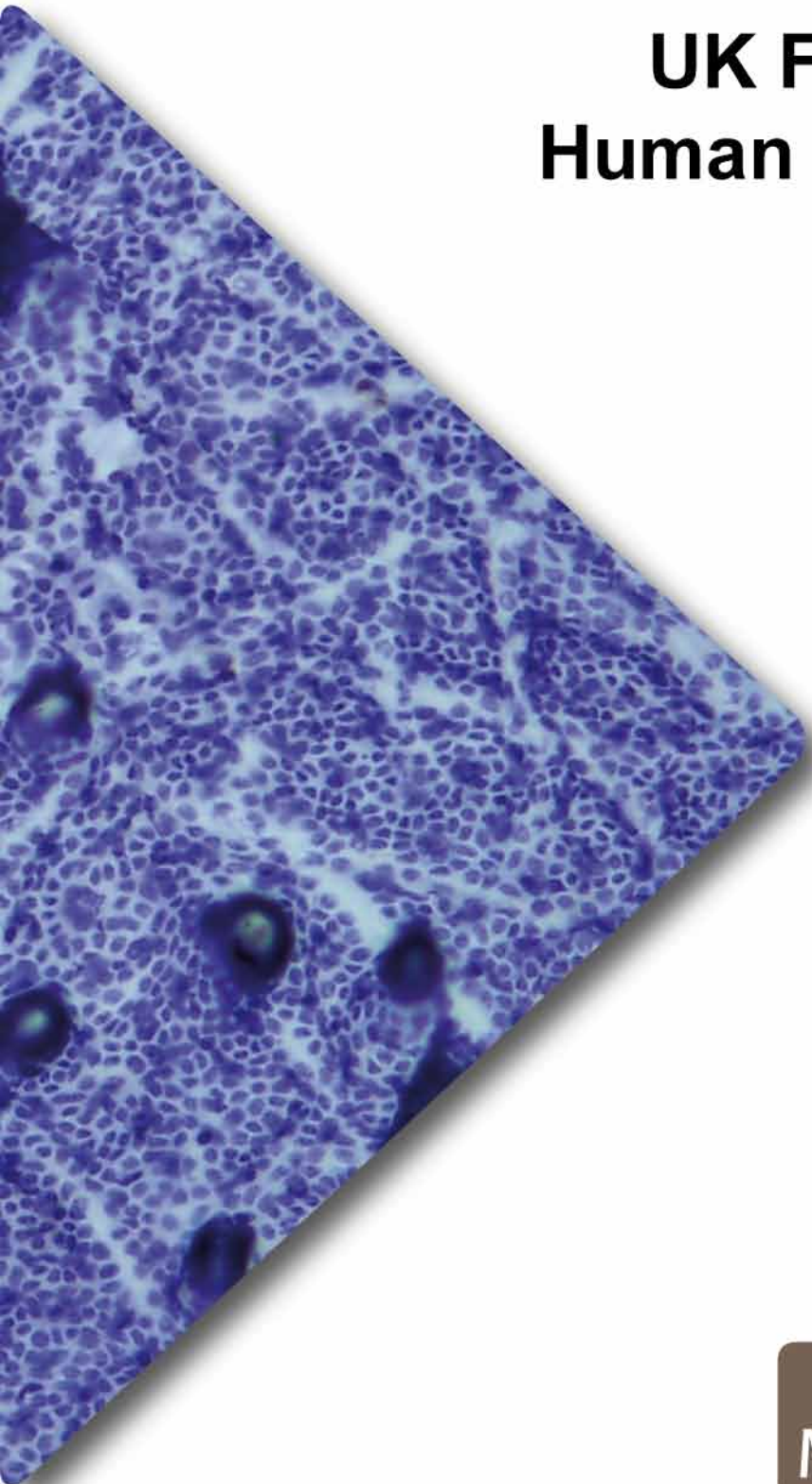


igniting our potential

UK Funders' Vision for Human Tissue Resources

September 2011

Lay Summary



Background and summary of proposals

This document accompanies a report by the Medical Research Council (MRC) and National Cancer Research Institute (NCRI), prepared in consultation with the major funders of research on human tissues. The report proposes a common vision for research using human tissue to the organisations which fund this work. It aims to promote a more joined up approach to the collection and use of human tissue in research. If successful, this will allow samples to be used more effectively and efficiently for everyone's benefit.

The report contains full details of the vision and the associated recommendations; a brief overview of the background to this work and a summary of the key recommendations are given below.

Why are human tissues important for research?

A wide range of human tissues is used in medical research. These samples provide an important bridge between laboratory based research and trials in actual patients. They do this by enabling researchers to study the characteristics of tissue in the laboratory and to link these with what is known about the behaviour of the disease. Specifically, human tissue samples can be used to:

- Identify and test new drugs;
- Identify how diseases develop;
- Identify and test new ways to screen for or diagnose disease;
- Identify groups of patients likely to respond to new drugs or experience side-effects from drugs.

Such samples are becoming increasingly important as scientists are now turning to the study of diseases at the most detailed levels, by identifying genes and their function, and understanding the role that specific molecules play in the origin and progression of disease. These fields of study are expected to discover new means of preventing, diagnosing or treating a range of diseases.

Why is a common vision required?

The organisation that fund research in this area (including the Government, charities and the private sector) believe that it is important that the samples which are donated for use in research are used to the best effect, and are confident that the donors of samples share this view.

A range of organisations have led various initiatives to improve the UK's effectiveness in collecting and using tissue. These initiatives communicate with each other but are not very closely coordinated and there are risks of duplicating of effort and of separately inventing solutions that do not join up.

To address this risk, the major funders have agreed to work together to define a common 'vision' for human tissue resources in research and to understand where they can better harmonise and co-ordinate their work. While differences of policy and approach will remain, a shared vision will help funders to direct their efforts in a more co-ordinated fashion.

What are we recommending?

The funders have agreed the following shared vision:

“Funders aim to maximise the value of human tissue samples and resources while minimising duplication of effort. This requires better characterisation of tissue samples, asking for generic consent, and increased linkage to accurate clinical data. Sample collections must then be made more easily discoverable and accessible for use in high quality, ethical research.”

To help achieve this we are asking funders to work towards a set of common principles, which will be included in their terms and conditions of funding, and to support a range of other actions to help achieve the vision.

Funders who have signed up to the vision have agreed, among other principles, that they will now require applicants to:

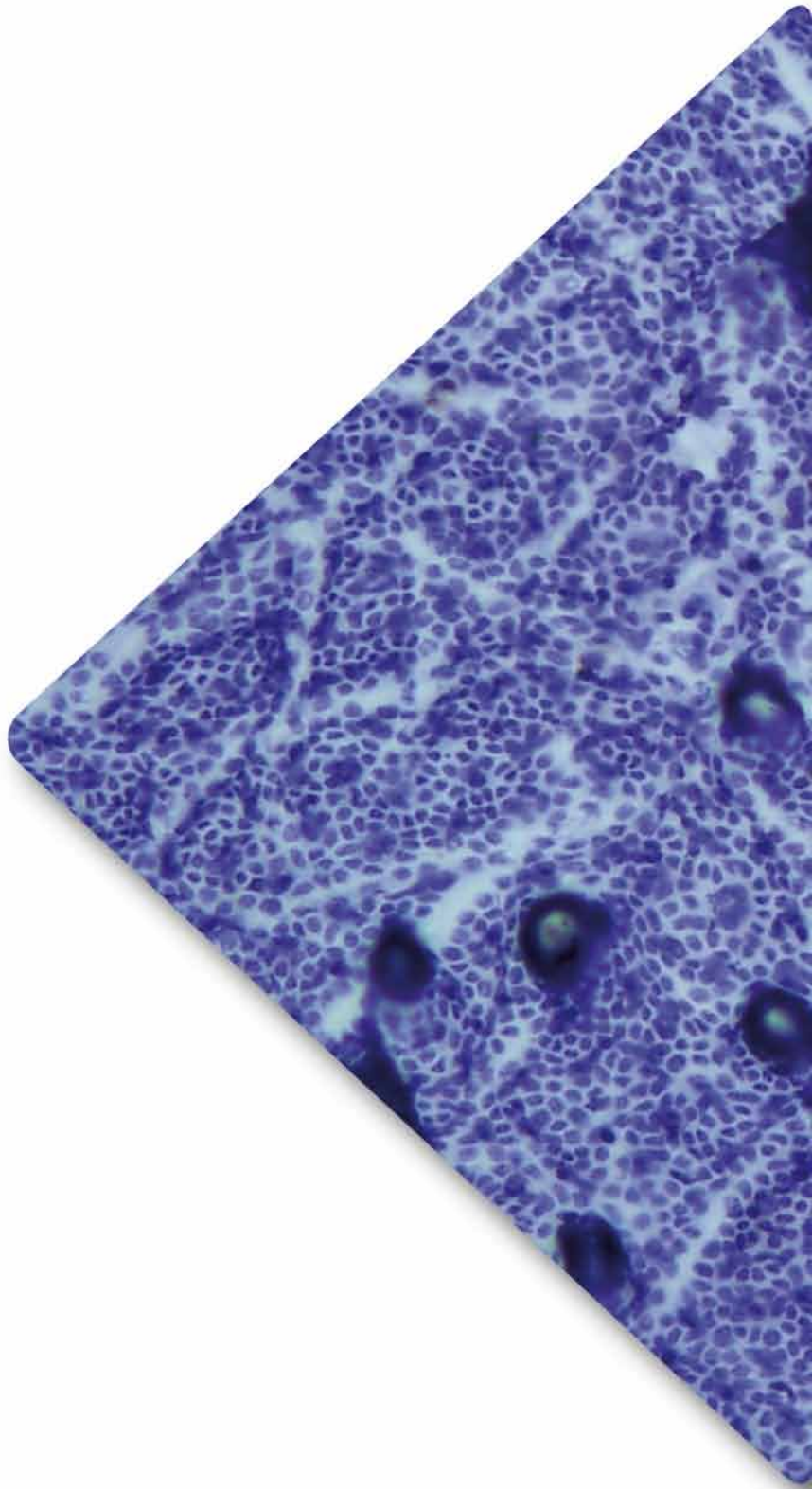
1. Justify the need for new collections and consider opportunities to link the collection of samples to existing studies or trials collecting high quality clinical data.

This aims to reduce duplication of effort by ensuring that existing tissue samples are used in preference to collecting new ones and that sample collection is linked where possible to other studies.

2. Seek generic consent from the donors of samples or justify why this would not be appropriate.
Generic consent means that consent is given for the storage and future use of the tissue in a broad range of ethically approved research, rather than for a single, specific study. Such consent must still be accompanied by an explanation of the ways in which the tissues might be expected to be used, the circumstances under which they will be destroyed and any other relevant circumstances.
While generic consent will not be appropriate in every circumstance we would like to make this the standard where possible (this is in line with advice from the National Research Ethics Service and the Human Tissue Authority, which regulates work in this area). Making generic consent the standard aims to ensure that collections are available for use beyond the study for which they are collected. Donors will need to be given sufficient information about the ways in which their samples may be used; funders will consult with patients and the public to understand their views and then prepare guidance to support researchers in doing this (see below).
3. Describe how their collection and storage of samples complies with existing good practice.
This aims to help funders ensure that tissue being collected is suitable for both any immediately intended study and for possible future uses.
4. Make appropriate arrangements for access to collections and register them in a publicly accessible directory.
This aims to support the use of existing collections of tissue by ensuring that potential users know that they exist (for example through inclusion in a web-based catalogue of sample resources) and that appropriate mechanisms are in place for access to the samples.

To assist with the implementation of these principles we are asking funders to support a range of other actions. The main actions are:

- Understanding the views of patients and the public about the use of tissues in research to inform other actions.
Research on human tissue relies on the agreement of patients and the public to donate their tissue and so policy must reflect their views. A variety of work has already been carried out on the views of patients and public on using human tissues in research. We are asking funders to support a literature review to assess what is already known followed by more targeted work to fill in some of the gaps and broader public engagement to support the other proposed actions.
- Actively developing and promoting detailed guidance on seeking generic consent, incorporating the views of patient and public groups.
Asking donors to give generic consent for the use of their samples requires building a relationship of trust and carefully explaining the controls and limitations on the use of tissue in research. Such guidance will help support researchers in providing the right information to donors. (This aims to support (2) above).
- Working towards a common set of good practice requirements for tissue collection and storage and associated mechanisms for assessing compliance.
Funders cannot say which method of sample collection is the 'best' for any given circumstance but can put in place methods of assessing how well a proposed collection will comply with existing good practice. Where possible, funders will share approaches and work towards a common set of requirements for this. (This aims to support (3) above).
- Providing practical mechanisms for potential users to discover the existence of human tissue collections and basic details about them.
This will involve supporting the creation of a cross disease directory of tissue resources to support potential users in discovering suitable collections and to help the creators of collections advertise their existence. (This aims to support (1) and (4) above).
- Developing practical guidance on access to collections, consolidating that which already exists, and addressing practical issues of acknowledging the contribution of investigators who generate collections.
Maximising the value of collections means ensuring that samples are available for a range of uses. Seeking generic consent enables this but appropriate mechanisms for potential users to access the samples must also be in place. A range of guidance on access to resources already exists – funders will aim to consolidate what already exists and add new guidance if this is needed. (This aims to support (4) above).



UK Clinical Research Collaboration

C/O Medical Research Council
14th Floor
1 Kemble Street
London WC2B 4AN

Medical Research Council

14th Floor
1 Kemble Street
London WC2B 4AN

National Cancer Research Institute

Angel Building
407 St John Street
London EC1V 4AD