



This statement was issued by the Association of Medical Research Charities of which “Heart Research UK” is a member Charity

## **AMRC Statement on the Use of Human Tissue**

### What is Human Tissue?

The term ‘human tissue’ includes a range of different types of material from whole organs and large pieces of tissue removed at post mortem, to surgically removed tissue such as tumours and small samples of body fluids such as blood or urine taken from living patients as part of medical treatment. The importance individuals attach to each of these types of tissue differs widely. Human tissue for research comes from healthy people, patients and from those who have died and research on all of them is important for increasing our understanding of human disease and in advancing treatments and cures.

Human organs, tissues and cells are used in many different ways for medical research and teaching and today, much modern biological and medical research depends on the use of tissue samples. This is because one of the best ways of developing an understanding of how the human body works, and how it is affected by disease, is to study the tissues themselves. Research involving human tissue samples is therefore an essential part of medical research. It may also help to reduce the use of animals.

Most people are familiar with giving tissue samples for use in the diagnosis and the treatment of their own illness, for example blood or urine for diagnostic tests. Some therapies also involve the use of donated tissue, such as blood transfusions, bone marrow or organ transplants. Other human tissue is obtained during post mortem which aims to establish the cause of death. Some tissue is discarded but others are then retained and managed in archives which provide a valuable resource for medical and biological research. Where there has been a continuing and growing need for research in a particular field – for example, the brain – tissue banks have been established specifically to enable more research.

### Research involving human tissue

Tissue specimens taken during diagnosis, treatment and autopsy are stored in archives or tissue banks and provide a resource for research. Such research is currently governed by a range of regulations and legislation and includes a requirement for approval from an ethics committee. Research undertaken on this type of stored tissue has played a role in almost all areas of human health:

- The link between asbestos and lung disease
- The discovery of the BRCA2 gene (a mutation of the gene that increases the risk of developing breast cancer) was enabled through the use of retained tissue in medical research. The tissue samples used to assist in the identification of the mutation of the BRCA2 gene were originally collected for diagnostic and prognostic purposes many without a specific recorded consent. The knowledge gained strengthened not only diagnostics, but also the development of preventative measures and the use of such tissue for medical research greatly empowered the research.
- For very rare cancers it can take many years to build up an *histopathology* archive (to enable the study of microscopic changes in diseased tissues) with sufficient samples to be useful for research.
- The understanding of the type of defect in muscular dystrophy cases can have a significant impact on the quality and length of life diagnoses. However, there are many people in the UK that do not yet have a confirmed diagnosis. Muscle samples

of these rarer cases are used to try and locate the defect and thus provide a diagnosis. Once a "new" defect is found, stored muscle samples of the patients with similar symptoms are evaluated to see if they have a similar defect. The storage of muscle samples means that repeat muscle biopsies are not required and that a speedier trawl can be done.

- HIV/AIDS in haemophiliacs. The experimental confirmation of HIV/AIDS in haemophiliacs who had received blood transfusions was critically dependent on the ability to refer back to previous samples, obtained when the patients were pre-symptomatic for AIDS. Often this had to be done without consent (because the patient was unable to be contacted, or had since died). This work also helped to establish that HIV was the cause of AIDS.
- Some conditions can only be confirmed after post mortem pathological examination of tissue. An example is Progressive Supranuclear Palsy or PSP, a neurodegenerative disease of the brain. Without this confirmation, trials on living patients are hard to validate because it is uncertain whether the individual had the disease. More importantly, these brain tissue collections enable further research which can reveal important clues about the causes of PSP.
- Biopsy material has been used for work on insulin signalling and insulin resistance in Type 2 diabetes. This focuses on skeletal muscle but also includes work on fat deposits and liver, which are the three main insulin-responsive tissues. To maintain research progress, a reliable supply of tissues from healthy and diabetic subjects is essential.
- Blood samples are taken for many diagnostic tests, and small amounts of serum can easily be stored providing a potentially invaluable (and easily anonymised) source for further investigation. For instance, sera sent for routine screening for possible immune-mediated neurological disorders, have been stored and re-tested as further insights into these, often very disabling diseases, have occurred. This has led to the definition of new antibody-mediated neurological diseases that can be successfully treated by immunotherapies, with immediate patient benefit.

AMRC considers that:

- human tissue (including organs) should not be retained post mortem without authority or consent
- the importance that individuals attach to different types of human tissue differs and this should be recognised in regulation
- the principle of consent should underpin the retention and use of human tissue for research wherever practicable;
- the requirement for consent should take account of the balance between the interests of the individual and of society as a whole
- where consent or authority is deemed necessary the processes for giving and acquiring it should be appropriate and practicable
- it is essential that the importance of human tissue based research across all areas of medical and biological research is better understood
- the regulation of the retention and use of human tissue in the UK and Europe should enable research for public and patient benefit

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