Human Tissue Act may have helped research, says study

September 1 2009

Fears that medical research using tissue such as blood or material from biopsies would be obstructed by the Human Tissue Act 2004 may have been unfounded, a new study from the University of Leicester reveals.

In fact, the research suggests that the Act may have helped medical research by giving Research Ethics Committees clarity when making decisions.

The Human Tissue Act 2004 came into force in September 2006. It regulates the storage, use and disposal of human tissue in England, Wales and Northern Ireland.

Many medical researchers in UK universities and research institutions had feared that the legislation would unduly restrict research based on tissue samples and that ethics committees might struggle to interpret the Act.

But the study by University of Leicester researchers Emma Angell and Mary Dixon-Woods suggests these fears may have been misplaced. Based on an analysis of letters written by ethics committees - 50 before and 50 after the Act was implemented in 2006 - they conclude that the Act did not seem to make ethics committees more cautious about approving research involving human tissue. In fact, ethics committees were overall less likely to raise concerns about consent after the Act was introduced.

Commenting on the study, published in the *Journal of Clinical Pathology*, author Emma Angell said that Research Ethics Committees seemed clearer about what would and wouldn't be allowed by law after the Act came into force. "We think this is because both researchers and committees now have authoritative guidance and training on what is acceptable," she said. Researchers are now better informed about what to do to obtain approval, and committees know what to look for in applications, she added.

One important feature of the Act was that it allowed recognised research ethics committees to approve some studies to use anonymised tissue samples without consent in certain circumstances.

"Researchers were worried that committees would be too cautious about this, but our analysis suggests that is not the case", said Professor Dixon-Woods. "Committees are looking out for the interests of patients, and it seems to us that having the legislation has made them more confident about making decisions about what form of consent to insist on. Committees will want to ensure that patients' consent will be obtained unless there are very good reasons not to. When researchers present those reasons, it seems committees are prepared to give them due consideration".

Source: University of Leicester (news : web)