

# Statement of the Royal Society's position on the use of human biological material in research

The Royal Society believes that the use of human biological material in scientific and medical research has been, and will continue to be, essential for medical and scientific understanding and for the benefit of public health. Public support for research is key to ensuring future scientific endeavour and ongoing medical and scientific advances. Such support will only be given if the public is confident that the scientific work will be carried out responsibly, and that all donated material is treated with sensitivity and respect.

Human biological material is used in a wide variety of research areas including genetics, neuroscience, pathology and anthropology. Research can range from studies aimed at advancing fundamental scientific biological understanding, enhancing disease diagnosis or developing future therapies. The type of material used varies with the study area and includes DNA samples, tissue blocks and whole organs, or may involve the use of human subjects. Material may be obtained from routine biopsies taken as part of a surgical or diagnostic procedure, or post-mortem or donated after death. Different types of human biological material are recognised by law and subject to distinct consent and research approval processes. Researchers must ensure that they adhere to any relevant legislation based on this distinction when conducting their work.

This statement is intended to guide researchers from a wide range of scientific fields who work with the various types of human biological material. A wide variety of research areas involve consideration of the issues raised overleaf, and we encourage all researchers who use human subjects in some way to ensure that they address the issues raised in this statement. Clinical research or epidemiological studies have additional considerations to those of other research uses of human biological material, and researchers who are engaged in such work need to be conscious of both the issues detailed overleaf and the additional regulatory considerations that are applicable to these areas of research. The statement is also aimed at the relevant regulatory bodies that have a responsibility to ensure that research using human biological material is carried out appropriately and with the co-operation of the public. The Society believes that the legislative framework surrounding the use of human material in research should protect both the research subjects and the work of the research community.

The Royal Society supports the fundamental principles of existing UK legislation regarding the ethical approval of research involving human material, which aims to ensure public confidence in the regulation surrounding its storage and use. It is the responsibility of the relevant research ethics committees that scrutinise research proposals to ensure that human biological material is used sensitively and appropriately. The Royal Society is committed to actively monitoring and advising on legislation that governs the work of scientific researchers, to ensure that it is robust but not overly bureaucratic or restrictive.

Detailed overleaf are a number of key aspects, complementary to this legislation, which the Royal Society believes should be given careful consideration by all researchers who use human biological material.

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at [www.royalsoc.ac.uk](http://www.royalsoc.ac.uk)

### 1) Participation

Researchers should ensure that the benefit to any individual participating in research outweighs any potential risk, and endeavour to ensure that this risk is as minimal as possible. This assessment of benefit should also include consideration of the potential benefit to other individuals and subsequent generations. Researchers should satisfy themselves that participants have an adequate understanding of what the research will involve, using lay language where appropriate, and that appropriate weighting is placed on both potential benefits and risks during discussions about the research with potential participants.

Researchers should take measures to safeguard the confidentiality of personal medical information from research subjects. This may be through the appropriate anonymisation of material (where material has any identifying information removed, so neither the individuals that donated the material nor their relatives can be identified). However, this may make certain types of research impossible, for example in genetic analysis of families, so linkage to some aspect of personal information may be necessary. An individual's wishes should be respected at all times, and due care taken to ensure confidentiality.

### 2) Consent

A robust consent process for the use of human biological material for research is key to ensuring continuing public confidence and participation, and researchers must ensure that they comply with the legal consent requirements, as appropriate to their area of research.

However, it is important that the regulatory bodies determining the consent process should not impose unnecessarily restrictive conditions that would inhibit researchers from obtaining material that might be of great value to scientific and medical research. Procedural guidelines must be flexible so that researchers can make progress in their research without being limited by demands for high levels of specificity in the consent process. This includes both the burden that a requirement for retrospective consent would place on researchers, which is time-consuming and in some cases impossible to obtain, and the difficulty of predicting future research applications when obtaining consent for future research from an individual.

Where the research entails only minimal risk and burden for the participant, those granting regulatory approval may deem separate consent for research uses unnecessary. For example, tissue from biopsies or taken during surgical procedures for diagnosis may be covered by the individual's consent to undergo those procedures, which may include the removal of tissue for future use. The Royal Society believes that it is important that this procedural freedom is maintained, under the existing robust guidelines for such practices, to prevent research suffering from unnecessary bureaucracy.

### 3) Distinction of material type

Within the regulation concerning consent, differences in the type of material and the reasons for it being retained need to be taken into account. For example, whole organs removed during post-mortem examinations may have significant personal value to family members. By contrast, tissue samples obtained during routine surgery and used for disease diagnosis may not be associated with the same levels of attachment. The consent

procedure should be modified accordingly, reflecting the different values attached to these material types.

The Royal Society believes that researchers should be sensitive to this distinction and ensure that they adhere to the appropriate consent requirement and respect the rights of the individual/next of kin. If consent is refused, then material should be disposed of appropriately and sensitively.

### 4) Intellectual property

Researchers should discuss with individuals what access they will have to information generated from the research. The possible future uses of this information or of the biological material itself, such as by commercial organisations, should be explained, as individuals may not wish for their material to be used in these ways. Additionally, issues relating to the ownership of any intellectual property arising from research should be discussed with the individual.

### 5) Historical collections

It is important that researchers are able to maintain access to existing collections of human biological material, such as tissue collections. These collections provide invaluable historical insight into disease prevalence over time and can be of very great importance to public health. Given the value of these collections, and their irreplaceable nature, the Royal Society recommends relevant authorities grant them protected status, to prevent any possible threat to their future use that may arise when the consent status of such collections are unknown or consent cannot be obtained. When using such collections, researchers should consider the origin of the samples and only use those that were ethically obtained. In those cases where the origin is unclear, anonymising the samples, which would prevent any possible harm to the individual involved, could alleviate any concerns about their consent status.

## Other Royal Society work in this area

- Comment on the Human Tissue Bill, April 2004
- Royal Society response to the Retained Organs Commission Consultation on Tissue Blocks & Slides, January 2003
- Response to the Retained Organs Commission consultation on unclaimed and unidentifiable organs and tissues, June 2002

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## Other documents of relevance

- *Personal information in medical research* (Medical Research Council, 2003)
- *Code of conduct, ethical principles and guidelines* (British Psychological Society, 2002)
- *Human tissue and biological samples for use in research: operational and ethical guidelines* (Medical Research Council, 2001)
- *Consensus statement of recommended policies for uses of human tissue in research education and quality control* (The Royal College of Pathologists, 1999)
- *Human tissue: ethical and legal issues* (Nuffield Council on Bioethics, 1995)