

TRAINING AND GOVERNANCE

All University staff and students who work with human tissue must be familiar with the [Human Tissue Act 2004](#), and have undertaken the University of Liverpool [human material training](#) and the [UK Research and Innovation training on working with human material](#).

Human material governance arrangements apply to **any work** with human material. A first step for anyone working with human material should be to contact the [Human Material Governance Team](#) to discuss their responsibilities, which may include University [Sponsorship](#), [HRA approval](#), and other health governance related approvals.

Researchers should be aware of, and keep up to date with, all ethical, legislative, regulatory and governance requirements relating to their area of research, including the [University's Policy on human material research](#).



Human Material and Ethics

Key Considerations



Research Ethics and Integrity Team

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ETHICAL APPROVAL

All use of human material must be covered by ethical approval.

Regarding the collection of new material, University of Liverpool staff and students should ensure that research ethics approval is sought from either the [University of Liverpool](#) (in the case of material from healthy volunteers), or from the [National Health Service Research Ethics Service](#) (in the case of material sourced from NHS patients).

Regarding the use of an existing collection of human material, it is fundamental to ensure that there is consent and ethical approval in place which covers the proposed new use of the material.

The Research Ethics team have developed a [decision tool](#) to help researchers decide if their human material studies require University of Liverpool research ethics approval.⁸

INFORMED CONSENT

It is fundamental to ensure that informed consent is in place for any project involving human material – and this extends to studies involving previously collected material and commercially purchased material.

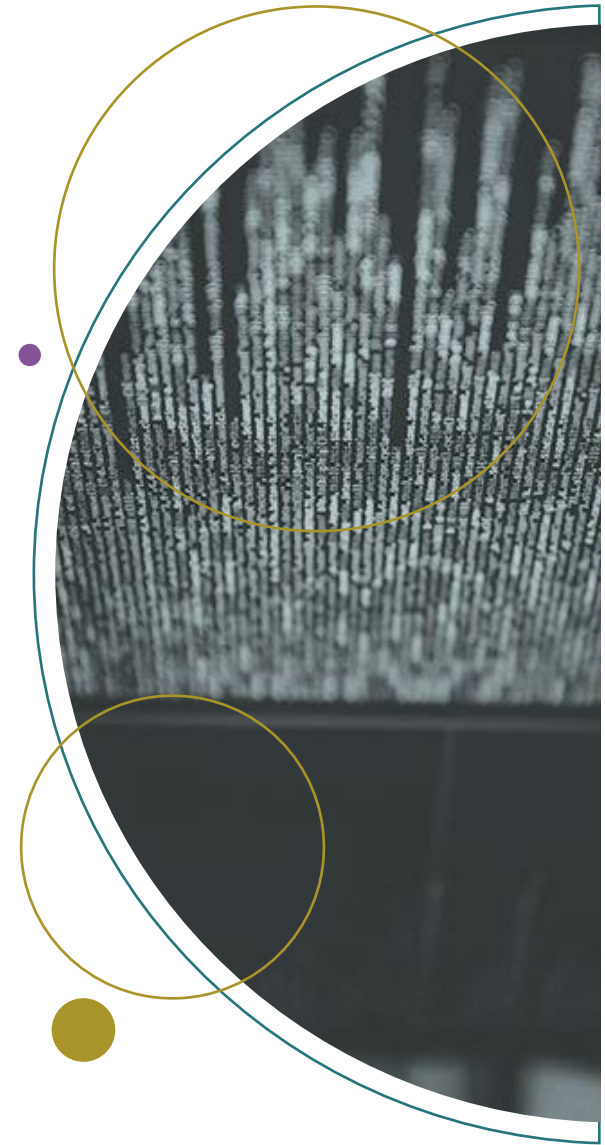
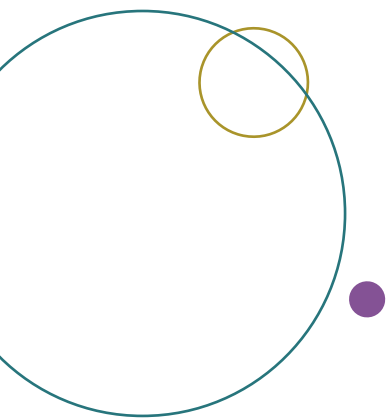


When obtaining consent for the collection of new material, participant information sheets and participant consent forms should seek 'broad' consent for the use of the human material in future research. This approach considers the value of using the material in future research projects, and avoids the need to go back to participants to obtain further consent following the initial collection of the material. However, the consent sought should provide some specificity to guide the participants on how their material is likely to be used, for which type of research projects, and who is likely to use the material.

STORAGE AND TRACEABILITY

Samples of human material should be treated as donations, and research involving these samples should be conducted with respect and transparency. This includes appropriate storage that maintains integrity of sample; adequate labelling and tracking of samples to ensure traceability; provisions for the transfer of samples, such as a Materials Transfer Agreement (for external transfer) or a sample transfer Standard Operating Procedure and signed transfer log (for internal transfer); and sensitive disposal of samples.

Researchers should treat all personal and medical information relating to research participants as confidential. A clear and sensitive disposal plan should be in place, and (where applicable) should reflect consent given and any specified wishes. Any Human Material held at the University should be registered in the [annual human material return](#).



LEGAL VS ETHICAL CONSIDERATIONS

Researchers working with human material should be mindful that the ethical threshold for acceptable use of the material may be higher than the legal threshold. For example: a commercial supplier may outline possible legal uses for a tissue sample; however, the proposed use of the material may not be ethically permissible. Another example is that the Human Tissue Act does not apply to material collected before the Act's introduction in 2006 – but this does not mean that there are no restrictions on the use of material collected before this date.

