

The Human Tissue Act 2004 – Summary of Consent and Licensing Provisions for Research.

Is consent required for research?

Is a licence required for storage for research?

Note: where consent is not legally required under the HT Act, it is still considered good practice to obtain it wherever practicable.

YES – consent is required if tissue is from a living person AND samples are identifiable AND samples were obtained after 1 Sept 2006.

YES – consent is required if tissue is from a deceased person collected post mortem (both identifiable and anonymised* samples) AND tissue is not imported AND not existing holdings (i.e. obtained after 1 Sept 2006).

YES – qualifying consent is required if DNA analysis is intended AND samples are identifiable AND were obtained after 1 Sept 2006 (this is also a legal requirement in Scotland). Where possible it is good practice to obtain consent for anonymised* samples.

NO - consent not required if tissue is an existing holding (from living or deceased persons), i.e. samples obtained before 1 Sept 2006.

NO – consent is not required if tissue was obtained from a living person after 1 September 2006 AND samples are anonymised* AND project is NHS REC approved.

NO - consent is not required for imported tissue (from living or deceased persons). It is good practice to ensure that where possible consent is obtained when using imported samples for research.

NO – in cases where tissue is from an adult who lacks capacity to consent, consent is not required in certain circumstances e.g. for the purposes of a clinical trial under UK Clinical Trial Regulations, or where consistent with Mental Capacity Act 2005.

YES – a licence is required if storing tissue for distribution to other researchers i.e. acting as tissue bank. This includes samples that were collected before 1 Sept 2006 and imported material.

YES – a licence is required if storing tissue for use in research projects that have not been submitted for NHS REC approval. This includes samples that were collected before 1 Sept 2006 and imported material.

NO – a licence is not required if storing tissue solely for use in a specific NHS REC-approved project.

NO – a licence is not required to store extracted DNA for use in research i.e. where no whole cells remain.

NO – a licence is not required if storing tissue for purpose of research from person who died at least 100 years before 1 Sept 2006.

NO – a licence is not required if storing tissue in establishments in Scotland. (It is good practice to meet equivalent storage standards).

*Anonymised means that all necessary steps have been taken to prevent identifying the person from whose body the material has come, links to identifiers do not need to be broken.