
Is consent required for research?

**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.

Is a licence required for storage for research?

**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).

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

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*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.*