

List of materials considered to be ‘relevant material’ under the Human Tissue Act 2004

This list is intended to supplement the HTA’s guidance on ‘relevant material’.

The list is not intended as exhaustive or exclusive, but is intended to provide guidance to stakeholders in respect of a number of materials that might be considered relevant material. The HTA will review the list periodically and update it as required.

Where a material is not included within the following list, stakeholders should use the information on our website to make their own assessment about whether it is relevant material, seeking advice from us where necessary.

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:

- They have divided or been created outside the human body
- They have been treated, processed or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

Although cell damage can be minimised by controlling the rate of temperature change and/or by adding one or more ‘cryoprotective’ agents, freezing/thawing can cause cell damage such that no whole cells remain. Centrifugation can be used to remove residual platelets from plasma, rendering it acellular, but the effectiveness is dependent on the protocol used. In either case, sufficient validation data (either in-house or published research) should be provided if the techniques are to be relied on to render samples acellular.

Material	‘Relevant material’ for the purposes of the Human Tissue Act 2004?
Antibodies	No
Bile	Yes
Blood	Yes
Bone marrow	Yes
Bones/skeletons	Yes
Brain	Yes
Breast milk	Yes
Breath condensates and exhaled gases	No
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines	No
Cells that have divided in culture	No
CSF (cerebrospinal fluid)	Yes

Cystic fluid	Yes
DNA	No
Eggs (ova)*	No
Embryonic stem cells (cells derived from an embryo)	No
Embryos (outside the body)*	No
Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint aspirates	Yes
Lysed cells	No
Mucus	Yes
Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and bronchial lavage	Yes
Non-blood, derived stem cells (i.e. derived from the body.)	Yes
Non-fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material).	No
Platelets	Yes
Pleural fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Serum	No
Skin	Yes
Sperm cells (spermatozoa)*	No
Sputum (or phlegm)	Yes
Stomach contents	Yes
Sweat	No

Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

Notes

* While outside the definition of relevant material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).