

# 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.

| <b>Material</b>   | <b>‘Relevant material’ for the purposes of the Human Tissue Act 2004?</b> |
|---|---|
| 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<br>(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).