**HUMAN TISSUE ACT 2004**

In relation to England and Wales, (and corresponding orders in Northern Ireland), the Human Tissue (HT) Act 2004 became enforceable on 1st September 2006.

If you are conducting research work on biological samples collected from humans, the HT Act serves to regulate the removal, storage and further utilisation of such human-derived specimens (tissue biopsies and biofluids). It is unlawful to perform these licensable activities without holding a license, and here the HT Act definition of human-derived tissue specimens includes biofluids such as saliva, urine and breast milk since they may contain human cells.

The HT Act has created a new offence of DNA ‘theft’ since the possession of such human-derived tissue coupled with the intention of analysing this biomolecule without the consent of the specimen donor is unlawful.

This Act defines human-derived tissue as material collected from a human body which consist of, or may include, human cells (such samples/specimens include blood, blood plasma, sputum, mucus, saliva, urine, hair, nail, faeces, lavage fluid, gametes and primary cell lines).

With regard to the collection of biofluids and, where required, tissue biopsies from research investigation participants, there are several exemptions to the HT Act. These are:

**(1) Research approved by an NHS Research Ethics Committee (NRES); indeed, in such investigations, it is assumed that the research work conducted/to be conducted is already in compliance and will be subjected to an audit performed by a further, appropriate NHS body.**

**(2) Samples collected and stored for educational and training purposes; however, such activities will still be subjected to ethical approval and good laboratory practice (GLP) procedures, but since this is not considered a research activity, it should be noted that datasets acquired therefrom must not be included in research documents, manuscripts and publications arising therefrom.**

**(3) Research programmes in which human-derived specimens are correctly disposed of within 48 hours are also exempt, although it is essential that such investigations remain subject to the usual Faculty ethical approval processes, and must also comply with GLP procedures.**

Materials collectable from humans and included in the HTA’s list as ‘relevant’ ones are classified as cellular-containing specimens (as outlined above), although please note that they may be rendered exempt (acellular) according to the general guidelines:

* **They have been divided or created outside the human body**
* **If such specimens have been processed, treated or lysed via a procedure which is intended to render them acellular, including freeze/thaw cycles performed on cells, and only when that particular process is conducted in order to render them acellular**
* **Biofluids collected from humans may be rendered acellular through the application of selected processes, particularly an adequate level of centrifugation and/or the above freeze-thaw cycles; these biofluids include unclotted (‘whole’) blood, knee-joint synovial fluid, saliva/sputum/phlegm, cerebrospinal fluid, cystic and pleural fluids, mucus, nasal and bronchial lavage, stomach contents, bile, breast milk, and urine (exhaled breath condensate and exhaled airways gases are excluded and therefore exempt).**

**Table: Relevant Tissue Biopsy/Biofluid Materials for Purposes of the Human Tissue Act 2004 (adapted from Human Tissue Authority Supplementary List of Materials Document)**

|  |  |
| --- | --- |
| Antibodies | No |
| Artificially-created cells | No |
| **Bile** | **Yes** |
| **Blood (whole)** | **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 |
| **Cerebrospinal fluid (CSF)** | **Yes** |
| **Cystic fluid** | **Yes** |
| DNA | No |
| Eggs\* | No |
| Embryos (outside the body)\* | No |
| Extracted materials from cells (e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, biomolecules such as proteins, carbohydrates, lipids, etc.) | No |
| **Faeces** | **Yes** |
| **Foetal tissue** | **Yes** |
| **Fluid from cystic lesions** | **Yes** |
| Gametes\* | No |
| **Hair (from deceased person)** | **Yes** |
| Hair (from living person) | No |
| **Joint aspirates (e.g. knee-joint synovial fluid)** | **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-feotal products of conception ( specifically, the amniotic fluid, umbilical cord, placenta and membranes)** | **Yes** |
| **Organs** | **Yes** |
| **Pericardial fluid** | **Yes** |
| Blood Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and further blood cells. If any of these cells are present then the plasma must be viewed as a 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\* | No |
| **Sputm (or phlegm)** | **Yes** |
| **Stomach contents** | **Yes** |
| **Teeth** | **Yes** |
| **Tumour tissue samples** | **Yes** |
| **Umbilical cord blood stem cells** | **Yes** |
| **Urine** | **Yes** |

\*Whilst outside the definition of relevant material for the purposes of the HT Act, these materials fall under the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the

**Human Fertilisation and Embryology Authority (HFEA)**.

\*\* Cell lines and embryonic stem cell lines fall within the regulatory remit of the HTA by virtue of the

Human Tissue (Quality and Safety for Human Application) Regulations 2007, which regulates the

processing, storage and distribution of stem cell lines for human application. Both the HFEA and the

Medicines and Healthcare products Regulatory Agency (MHRA) also have a regulatory remit with regard to cell lines and embryonic stem cell lines. A joint position statement issued by the HTA,

HFEA and MHRA provides guidance on the relevant regulatory remits.

\*\*\* Breast milk does not constitute tissue or cells for human application under the (Quality and

Safety for Human Application) Regulations 2007, but is classified as a relevant material for the

purposes of the Human Tissue Act 2004 where it is stored or employed for scheduled or selected purposes.