

Human Tissue Act (HT Act)

Informed Consent

"The Human Tissue Act 2004 regulates the removal, storage and use of human tissue. This is defined as material that has come from a human body and consists of, or includes, human cells."

See <https://bit.ly/3OW02cg>

PromoCell complies with this fundamental principle of the HT Act. All PromoCell cells are isolated with an explicit informed consent of the donors and/or their next-of-kin.

Other guidelines that focus on the informed consent:

- The Convention of Human Rights and Biomedicine: <https://bit.ly/3WTq1TM>
- Declaration of Helsinki: <https://bit.ly/3J09LdY>

Relevant material

Specifically identified relevant material

This includes material like bodily organs and tissues, consisting largely or entirely of cells, and clearly identifiable and regarded as such. This category of relevant material includes human bodies, internal organs and tissues, skin and bone; and specifically the following:

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| <ul style="list-style-type: none">▪ Stem cells created inside the human body▪ Non blood derived stem cells▪ Umbilical cord blood stem cell▪ Bone marrow▪ Primary human cell cultures | But not : | <ul style="list-style-type: none">▪ Cultured cells which have divided outside the human body▪ Artificially created embryonic stem cells▪ Cell lines▪ Embryonic stem cells▪ DNA, RNA▪ Extracted material from cells e.g. nucleic acids... |
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See <https://bit.ly/3J0unmh>

Most human cells from PromoCell have been cultured outside the human body after isolation (at least one passage). Certain blood cells (CD34⁺ progenitor cells, mononuclear cells) provided by PromoCell have been frozen immediately after isolation and therefore have not undergone any expansion process outside the body yet.

Licensing at HT Authority

Every researcher has to ensure on her/his own whether a licensing at the HT authority is necessary or not since the licence is not only dependent on the material used but also on the research purpose as well as local ethics committee approval.

For further information :

<https://bit.ly/43plmdE>

As well as :

<https://bit.ly/43gzeYF>

Or contact HT authority to check whether licensing is necessary or not :

enquiries@hta.gov.uk

Please do not hesitate to contact our technical support team if you need any further assistance concerning specifications and isolation details of PromoCell cell types.

Heidelberg, April 27, 2023



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Intended for research use only. Not intended for direct administration to humans or animals.
