

Informed Consent

“The HT Act makes consent the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display.”

see: www.hta.gov.uk/about_hta/human_tissue_act.cfm

PromoCell complies with this fundamental principle of the HT Act. All PromoCell cells are all isolated with the explicit informed consent of the patients or their relatives.

Other guidelines that focus on the informed consent:

- The Convention of Human Rights and Biomedicine:
www.conventions.coe.int/treaty/en/Reports/Html/164.htm
- Declaration of Helsinki:
www.wma.net/e/policy/b3.htm

Relevant material

"1. 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:

- stem cells created inside the human body
 - embryonic stem cells
 - non blood derived stem cells
 - umbilical cord blood stem cell
 - bone marrow
 - primary human cell cultures
- but not:
- cultured cells which have divided outside the human body
 - artificially created embryonic stem cells
 - cell lines
 - extracted DNA..."
 - plasma extracted DNA..."

see: www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm

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) and hepatocytes 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 on local ethics committee approval.

For further information :

www.hta.gov.uk/_db/_documents/2006-06-28_Designed_Research_Compliance_Report_on_the_website_amended.pdf

as well as

www.hta.gov.uk/_db/_documents/2006-08-23_Application_guidance_research_v1_200612140314.pdf

or contact HT authority: enquiries@hta.gov.uk to check whether licensing is necessary or not.

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.

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