

To: HTA licensed establishments

Human Tissue Authority

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15–17 Furnival Street
London EC4A 1AB

Tel 020 7211 3400

Email enquiries@hta.gov.uk

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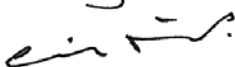
Date November 2010

Dear Colleague

Regulation of cord blood collection (procurement) by the Human Tissue Authority

We are writing further to our letter dated 9 March 2010 which set out the circumstances in which cord blood collection is unlawful. The additional letter gives further clarification about the circumstances in which cord blood collection is lawful under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. It has been sent to NHS Trusts and private hospitals that carry out cord blood activities on behalf of HTA-licensed establishments. This has been sent to you for information.

If you have any queries please contact the HTA on 020 7211 3400 or email enquiries@hta.gov.uk

Yours sincerely


Craig Muir
Chief Executive

To: Organisations that carry out cord blood activities on behalf of an HTA-licensed establishment

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Date November 2010

Dear Colleague

Regulation of cord blood collection (procurement) by the Human Tissue Authority

We are writing further to our letter dated 9 March 2010. This new communication is prompted by feedback from stakeholders. We have become aware that some NHS Trusts and private hospitals have changed their policies and no longer allow cord blood collection, stating that it is unlawful. This letter is to provide clarification about the circumstances in which cord blood collection is lawful under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

A key principle underpinning the regulatory requirements for any donation of tissues and cells is that the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood donation the health and care of both the mother and baby must not be compromised.

When is cord blood collection (procurement) lawful?

Cord blood can be collected on premises which are licensed by the HTA for cord blood procurement. It is also lawful for cord blood to be collected, on premises that are not licensed by the HTA, if the person collecting the cord blood (the procurer) is acting under the authority of a Third Party Agreement (TPA) with a HTA-licensed establishment

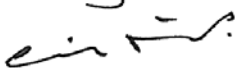
An NHS Trust is entitled to develop its own policies on cord blood collection. However, if a TPA is in place, it is entirely lawful for an appropriately trained person (such as a phlebotomist), to collect cord blood on unlicensed premises. The person collecting the cord blood should have undergone training that has been approved by the Designated Individual named on a cord blood establishment's licence.

We recommend that hospitals have systems to confirm that TPAs are in place between cord blood banks and procurers before allowing cord blood to be collected. This might be achieved by updating

local policies to request cord blood banks to provide written notification of the third party and confirm that a TPA is in place before they enter the premises. These measures help ensure the quality and safety of the cord blood sample that is collected which is of benefit to parents and recipients of the cord blood.

The aim of this letter and our previous communication is to ensure you have sufficient information to understand the regulatory and legal requirements so that cord blood procurement only occurs lawfully.

If you need any more information please refer to the HTA website www.hta.gov.uk and <http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/stemcellsandcordblood.cfm> Alternatively please contact the HTA on 020 7211 3400 or email enquiries@hta.gov.uk and address your enquiry to a Regulation Manager.

Yours sincerely


Craig Muir
Chief Executive