Clinical Guideline for The Management of Commercial Umbilical Cord Blood Collection Following Birth

Document Control:

For Use In:	Norfolk and Norwich University Hospital Foundation Trust.		
	Maternity Services.		
Search Keywords	Cord, Blood, Commercial, Collection, Umbilical.		
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Document Owner:	Women and Childrens Division.		
Approved By:	Maternity Guidelines Committee.		
Ratified By:	Clinical Safety and Effectiveness Sub-Board.		
Approval Date:	03/09/2023	**Date to be reviewed by:** This document remains current after this date but will be under review	03/09/2026
Implementation Date:	N/A		
Reference Number:	837		

Version History:

Version	Date	Author	Reason/Change
V7.0	30/07/2023	Consultant Obstetrician, Matron for Intrapartum Care	Appendix 2. Letter to parents added. Guideline transferred to new template. Placental collection and third-party agreement added.
V5.0	25/10/2018	Unknown	superseded
V4.0	25/10/2018	Unknown	superseded
V3.0	29/10/2015	Unknown	superseded
V2.0	02/11/2012	Unknown	Aw. Approval
V1.0	06/12/2011	Unknown	Superseded.

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
None	Not applicable

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

- Legal Services department
- Consultant Obstetrician, Chief of Obstetrics

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g., changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to Norfolk and Norwich University Hospital Foundation Trust (NNUHFT); please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

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Contents Page

1.Introduction 6

1.1.Rationale 6

1.2.Objective 7

1.3.Scope 7

1.4.Placental Collection 7

1.5.Glossary 8

2.Responsibilities 8

3.Processes 8

3.1.Umbilical Cord Blood collection. Guidance for staff. 8

3.2.Compliance of guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) 9

3.3.Why doesn't the Trust apply for a licence from the HTA? 9

4.Training & Competencies 9

5.Related Documents 10

6.References 10

7.Audit of the Process 11

8.Appendices 12

8.1.Appendix 1 – Third Party Agreement for Placenta Collection 12

8.2.Appendix 2 – Stem Cell Collection 13

9.Equality Impact Assessment (EIA) 14

Quick reference

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1. Introduction

Several commercial organisations offer parents the opportunity to store haemopoietic stem cells (HSC) from their baby's umbilical cord blood. The purpose of this storage is that the stem cells might be available for use if the child or their. siblings ever develop a metabolic, immunological, or haematological disease that might be treated by autologous or related cord blood stem cell transplantation. The therapeutic use of stem cells of this kind is still speculative and directed stem cell storage is not recommended by professional guidance. Even so, some parents may wish to avail themselves of the commercial services that are now widely advertised.

Under the Human Tissue Act 2004, directions have been issued known as the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These regulations require that the procurement of cells and tissues for human treatment (including umbilical cord blood stem cells), must take place only on premises licensed by the HTA or under what is known as a Third-Party Agreement (TPA) with a licence-holder.

This Trust does not hold a HTA license for the collection of cord blood and there is no plan to apply for one. Furthermore, the Trust (following professional guidance) does not intend to contract under a TPA for its staff to take cord blood for commercial storage.

Collection of cord blood for commercial storage can therefore only take place in the Trust if the procedures set out at Section 3 are followed. Commercial umbilical cord blood collection outside these procedures must not be carried out by Trust staff. In the past some staff have obtained cord blood for parents who have requested this. **This is unlawful and a disciplinary offence and may lead to enforcement action by the Human Tissue Authority. This does extend to patients and relatives.**

1.1. Rationale

This document outlines guidance concerning requests from prospective parents for the collection of umbilical cord blood for commercial storage to enable possible future stem cell retrieval.

The rationale behind the Trust's decision not to apply for a licence for cord blood procurement includes:

- Commercial collection is not supported by professional guidance as evidence-based practice.
- The collection is made at a point when both mother and the new-born baby require close attention. Attempting collection could distract the attention of staff from their primary purpose of providing appropriate care for mother and baby.
- There is financial and bureaucratic cost associated with the licence that cannot be justified by the scientific evidence base or professional guidance.

1.2. Objective

The aim of the clinical guideline is to enable midwives and medical staff to provide appropriate information in response to requests for their baby's cord blood be collected at the time of delivery and stored commercially for later stem cell retrieval The objective of the clinical guideline is:

- To explain to parents why (in line with national guidance) the Trust does not support commercial stem cell retrieval.
- To inform parents that without a licence from the HTA the Trust is prohibited from performing this procedure.
- To advise that the Trust will not hinder parents who make their own private arrangements with an appropriate third-party collection agency, so long as those arrangements comply with the requirements of the HTA and professional guidance (as per section 4 below).

1.3. Scope

These clinical guidelines are intended for use by midwives and medical staff providing intrapartum care within the Norfolk and Norwich University Hospital Foundation Trust. This document does **not** apply to:

- The collection of cord blood for immediate therapeutic activity e.g., blood gas checks during or immediately following delivery; or
- The non-directed or altruistic cord blood banking service undertaken within the National Blood Service; or
- The collection of cord blood where procurement has been requested for medical purposes by a tertiary hospital/unit. In such a circumstance collection may be permitted under that unit's Human Tissue Authority (HTA) licence but these cases are rare, and advice should be sought from the Trust's Legal Services Department.

1.4. Placental Collection

There may be times when the Trust is unable to support commercial companies visiting the Trust to undertake collection of cord blood for stem cell. This would be at times of restricted visits such as the Covid -19 pandemic when NHSBT and Anthony Nolan Trust stopped visiting units. In situations such as these the commercial companies can extract the stem cells from the placenta. However, this must be undertaken outside of the hospital. The parents are responsible for transporting the placenta off site to the company, the midwifery staff can assist with placing the placenta into a sealed bag (see Quick reference). In this instance it is necessary to have an appropriate TPA (third party agreement) with the Trust. For example, see Appendix 1.

1.5. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
NNUHFT	Norfolk and Norwich University Hospital Foundation Trust
HSC	Haemopoietic stem cells
HTA	Human Tissue Authority
TPA	Third party agreement
NHSBT	National Health Service Blood Transfusion
O&G	Obstetrics and Gynaecology
RCOG	Royal College of Obstetrics and Gynaecology
RCM	Royal College of Midwives
NHSR	NHS Resolution

2. Responsibilities

Role	Responsibility
Matron for Intrapartum Care/ Deputy Matron for Intrapartum Care.	On becoming aware of the intention to arrange for a commercial company to take cord blood for stem cell retrieval, record the letter within the electronic record and send a letter to the parents advising of the Trust position (appendix 2)
All maternity Staff	To follow this guidance

3. Processes

Women who want to plan for the collection of cord blood may only do this on the Trust's premises if they comply with the necessary regulatory obligations.

3.1. Umbilical Cord Blood collection. Guidance for staff.

The woman must:

- Provide the Trust with written confirmation in advance, to the Matron for Intrapartum Care. The commercial company with whom they have made a private arrangement must hold a valid HTA licence. The Matron or their deputy will record this within the electronic record and send a letter to the parent's advising them of the Trust position (see appendix 2).
- Confirm they have planned for a phlebotomist or trained technician from the commercial company to obtain the sample or confirm that the person who will take the blood has a TPA with the commercial company. The application to the Matron for Intrapartum Care and subsequent correspondence should be copied to the Trust's Legal Services Department, where a record is kept.
- Women should be advised of the position on stem cell retrieval, **if the issue is raised with Trust staff. Staff may print and give one of the web links** at the end of this guideline.

3.2. Compliance of guidance from the Royal College of Obstetricians and Gynaecologists (RCOG)

In compliance with guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) and to maximise safety for mother, baby, and staff:

- Intended collection of cord blood should not proceed where the attending clinician believes it to be contraindicated, such as nuchal cord or maternal haemorrhage.
- Usual clinical practice should take precedence over elective cord blood collection e.g., there should be no pressure on clinical staff to avoid cutting the cord to allow delivery (e.g., where the cord is around the neck), additionally taking of umbilical blood samples for blood gas status should not be delayed.
- Collection of cord blood should be made from the ex-utero separated placenta i.e., blood must not be taken while staff are attempting to deliver the placenta.
- There should be no alteration or delay in the 'usual management' of the third stage e.g., controlled cord traction should not be withheld in the presence of post-partum haemorrhage to maximise the volume collected with the placenta still in utero.
- The person intending to take the blood must agree to abide by the Trust's health and safety policies and to take responsibility for the safe disposal of any needles/sharps.

An example of good practice quoted by the RCOG, used by the NHS Cord Blood Bank, where cord blood is collected aseptically after delivery of the placenta by trained NBS staff within the delivery unit but outside the delivery room. This ensures privacy for the mother and removes any conflict between collection of cord blood and care of the mother and baby.

3.3. Why doesn't the Trust apply for a licence from the HTA?

The Trust's position in relation to this procedure as set out in this Guidance is based on recommendations of the Royal College of Midwives (RCM), RCOG, and the NHS Resolution (NHSR). Guidance from the RCOG, RCM, and NHSR does not support commercial collection of umbilical cord blood for the purpose of retrieving and storing stem cells when there is insufficient scientific evidence to support this practice.

4. Training & Competencies

There is no training for this procedure as it is not undertaken by Trust staff.

5. Related Documents

Cord Blood Procurement FAQ's	Human Tissue Authority
Position Statement on Cord Blood Collection	Human Tissue Authority
Cord Blood Collection – FAQs for Parents	Human Tissue Authority
RCOG Opinion Paper 2: Umbilical Cord Blood Banking	The Royal College of Obstetricians and Gynaecologists Scientific Advisory Committee.
The Royal College of Midwives Position Statement No 1 2002	Royal College of Midwives
The Royal College of Midwives Guidance Paper 1a Commercial Umbilical Cord Collection 2002	Royal College of Midwives

Links for related documents can be found within section 6.

6. References

Cells4life https://cells4life.com/?gclid=EAIaIQobChMIoojqit2k6wIVBrDtCh3pewhVEAAYASAAE.g.Kc6_D_BwE

Human Tissue Authority - Cord blood procurement FAQ's:
Cord blood procurement FAQs | Human Tissue Authority (hta.gov.uk)

Human Tissue Authority – Position Statement on Cord Blood Collection (March 2010);
Position statement on cord blood collection | Human Tissue Authority (hta.gov.uk)

Human Tissue Authority – Cord Blood Collection – FAQs for parents:
Umbilical cord blood banking FAQs | Human Tissue Authority (hta.gov.uk)

RCOG (2006) *The Royal College of Obstetricians and Gynaecologists Scientific Advisory Committee*, Opinion paper 2: Umbilical Cord Blood Banking June 2006
Umbilical Cord Blood Banking (Scientific Impact Paper No. 2) | RCOG

RCM (2002) The Royal College of Midwives Guidance paper 1a Commercial Umbilical Cord Collection 2002
https://www.rcm.org.uk/media/2309/rcog-rcm-statement-on-umbilical-cord-blood-collection-and-banking.pdf

7. Audit of the Process

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Non NNUH staff to have taken umbilical cord blood sample	Review of maternal records	Intrapartum Matron/ Deputy	Obstetric Clinical Governance	Case by Case due to rare frequency

As this is a rare clinical event, monitoring of compliance will happen on a case by case basis by the Intrapartum Matron. Any highlighted issues with compliance will be discussed at the Maternity Governance Meeting whereby the cases are reviewed and **recommendations for further action are made.**

8. Appendices

8.1. Appendix 1 – Third Party Agreement for Placenta Collection

8.2. Appendix 2 – Stem Cell Collection

Ref:

{Name & Address}

Maternity Department
West Block, Level 3
Norfolk and Norwich University Hospital NHS Foundation Trust
Colney Lane
Norwich
NR4 7UY

direct dial: 01603 287

{Date}

Dear {Title & Surname}

Stem Cell Collection

Thank you for notifying us (via **NAME OF COMPANY**) of your wishes to have cord blood taken (for storage) at the time of your forthcoming birth.

I am sure that you are aware that, following guidance from the Human Tissue Authority (HTA), all Maternity Units wishing to undertake stem cell collection from umbilical cord blood for future use must have a licence from the HTA. The Norfolk & Norwich University Hospitals NHS Foundation Trust does not have such a licence.

I can confirm we are in receipt of a copy of the HTA Licence from **NAME OF COMPANY** Ltd: Licensing Number …….

As you are aware, the professional indemnity insurance held by Midwifery and Medical staff does not cover them to undertake this procedure and you have confirmed that you have enlisted the services of a fully training and certified Phlebotomist from **Phlebotomy UK or alternative.** In the absence of your phlebotomist attending, please do not ask our staff for assistance with blood collection as they are obliged to kindly decline.

I must reiterate that at the time of delivery, our priority is the health and well-being of you and your baby. Therefore, if another person in the room such as the phlebotomist compromises your safety and/or the care of your baby, they will be asked to leave. The collection of the sample by the phlebotomist must be taken from an ex-utero placenta and must not be taken while staff are attempting to deliver the placenta.

I wish you all the very best during the remainder of your pregnancy; if you have any further questions please do not hesitate to contact me.

Yours sincerely

{Name of Signatory}
{Job Title}

Encs
Copy to Company
Copy to Legal Services

9. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Women and Childrens	Department	Maternity
Name of person completing form	Nikki Hill	Date	26/07/2023

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	No	No	No	N/A
Pregnancy & Maternity	No	No	No	N/a
Disability	No	No	No	N/A
Religion and beliefs	No	No	No	N/A
Sex	No	No	No	N/A
Gender reassignment	No	No	No	N/A
Sexual Orientation	No	No	No	N/A
Age	No	No	No	N/A
Marriage & Civil Partnership	No	No	No	N/A
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?				

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.