



STEM CELL LABORATORY (STCL)



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DOCUMENT TITLE:

CBU Cryopreservation FRM1

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Control Information

Author: WATE02

Owner: WATE02

Previous Number: EMMES 6D.100 v 10

Change Number: STCL-CCR-090



BAR CODE LABEL

CBU Cryopreservation

1. Labels placed on: Cryobag ☐ Yes Cryovials ☐ Yes Study ID
 2. DMSO/Dextran kit manufacturer: _____ Lot #
 - Expiration Date: / / Study ID

mm
dd
yyyy
 3. Date and starting time for DMSO addition: / / :

mm
dd
yyyy
hrs
mins (24 hr clock)
 4. Syringe Pump: ☐ Medfusion/Protégé SN
 5. ☐ Coolmix ☐ Rocker/ice packs SN: Study ID
 6. Date and time of start of freezing / / :

mm
dd
yyyy
hrs
mins (24 hr clock)
- Time from addition of DMSO to start of freezing
- Time from collection to start of freeze
7. Date and end time of freezing / / :

mm
dd
yyyy
hrs
mins (24 hr clock)
 8. Control rate freezer trace ok: ☐ Yes ☐ No Study ID
 9. Freezer Locations:

Cord blood unit:

Sample cryovials:

Comments: _____

Signature of Final Reviewer

Date

Study ID

STCL-PROC-045 FRM1 CBU Cryopreservation
Stem Cell Laboratory, DUMC
Durham, NC

Field	Requirements
1. Labels placed on Cryobag and Cryovials, Study ID	Confirm that unique barcodes are on bag and vials. Record Study ID
2. DMSO/Dextran manufacture, lot number and expiration date	Enter manufacturer, lot number, and expiration date of DMSO/Dextran.
3. Date and starting time of DMSO addition	Enter date and time of start of syringe pump for DMSO/Dextran infusion.
4. Syringe Pump	Enter serial number for the syringe pump.
5. Coolmix, Rocker/ice pack, serial number	Mark which mixing/cooling device is used and serial number
6. Date and time of start of freeze	Enter date and time control rate freezer is inserted in thermo freezer.
7. Date and end time of freezing	Enter date and time of storage as recorded on freeze graph report.
8. Control rate freezer trace ok. Trace ID#	Check yes if freeze graph was acceptable. Acceptable values: Freezing rate between -20 to -40 degrees within 7-12 minutes. Final temp on graph reached -50°C.
9. Freezer Locations for cord blood unit and cryovials	Enter freezer location for cord blood unit as recorded on freeze graph (rack, ring, slot and thermo). Enter freezer location for Cryovials.
Signature of Final Reviewer, Date and Study ID	Record Signature and Study ID of individual who reviews freeze graph and enters storage location of unit.

Signature Manifest**Document Number:** STCL-PROC-045 FRM1**Revision:** 11**Title:** CBU Cryopreservation FRM1**STCL-PROC-045 FRM1 CBU Cryopreservation****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		11 Jan 2013, 04:28:01 PM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		11 Jan 2013, 04:28:33 PM	Approved

Medical Director Approval

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QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		13 Jan 2013, 08:14:34 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		14 Jan 2013, 02:58:07 AM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		14 Jan 2013, 02:58:08 AM	Email Sent
Sharon Hartis (SH259)		14 Jan 2013, 02:58:08 AM	Email Sent
Linda Sledge (SLEDG006)		14 Jan 2013, 02:58:08 AM	Email Sent
System Administrator (SYSADMIN)		14 Jan 2013, 02:58:08 AM	Email Sent