Wake Forest Baptist Medical Center	**Limb Perfusion Study** **BB.SP.1054**	**Dept:**	**324311**
		Dept Name	**Blood Bank**
		Effective Date:	
		Revised Date:	
Name & Title: CLIA Laboratory Medical Director		**Contact:**	**MR Jones/JH Simmons**
Signature: Gregory Pomper		**Date:**	**3/20/19**

1. General Procedure Statement:

A. Purpose: The goal of the study is to extend graft preservation times over 24 hours and improve donor pool/access across geographic spans and to ensure graft quality and establish tissue viability and perfusion parameters prior to limb transplantation. The current goal is to study ex vivo upper extremity preservation without transplantation using typed and matched blood for reperfusion injury assessment in the preserved limbs.

B. Responsible Department/Scope:

i Procedure owner/Implementer: Mary Rose Jones/Julie H. Simmons
ii. Procedure prepared by: Julie H Simmons
iii. Who performs procedure: Department staff/management

C. Definitions:
Principal Investigators: Vijay Gorantla, MD and Fatih Zor

D. Sections:
I. Issue of Packed red cells and Plasma
II. Charging for Packed red cells and plasma

E. Protocol:

1.0 One set of products (One Group O packed cell and one thawed A or AB plasma) will be transferred to Research Limb Study (rlimb) in SCC and two copies of the transfer paperwork will be printed from SCC.

2.0 The researchers will bring a cooler.

3.0 If more than one (1) packed cell and (1) plasma is requested, then pack up in a small blood supplier box and use a bag of ice appropriate for the larger box.

4.0 Blood Bank will put the packed cell(s) and plasma(s) into the cooler with sufficient wet ice to transport back to WFIRM with one copy of the transfer paperwork.

5.0 The original copy of the transfer paperwork will be given to management for billing reconciliation.

2. Procedure: I. Issue of Packed red cells and Plasma

Chemical Risk Assessment: low
Biological Risk Assessment: low
Protective Equipment: Lab coat, gloves
Reagents: NA
Supplies:
Equipment: NA
Specimen Requirements: NA

STEPS	INSTRUCTIONS	CHANGE / APPROVAL
1.0	**Receive notification of need for packed cells and plasma.**	
2.0	**Thaw the number of Group AB plasma needed.** 2.1 If Group AB thawed plasma or liquid plasma is available and short dated, then it may be used.	
3.0	**Go to SCC>Inventory>In/Out>Transfer** 3.1 Select Research study (rlimb) from drop down box by Destination.	
4.0	**Scan each product unit number and product type that is being transferred to the study.** 4.1 F12 when complete to Accept unit list.	
5.0	**Print 2 copies of the transfer paperwork.** *Refer to Attachment 1: Example of Transfer Paperwork from SCC*	
6.0	**Place transfer paperwork and units to be transferred on the 'XM in progress' shelf until researcher comes to pick up.**	
7.0	**Obtain cooler from researcher or small supplier blood box.** 7.1 Fill a zip lock bag from drawer at Front Desk with ice but leave enough room to close the bag for cooler. 7.2 Alternately, obtain a bag of ice appropriate for the supplier blood box.	
8.0	**Retrieve units and paperwork.** 8.1 Place units in cooler/box with appropriate bag containing ice on top.	
9.0	**Have researcher sign one copy of transfer paperwork.** 9.1 Sign the other transfer paperwork and return to researcher to travel with units. 9.2 Take the transfer paperwork signed by researcher and give to management for Billing reconciliation.	

2. Procedure: II. Charging for Packed Red cells and Plasma

Chemical Risk Assessment: low
Biological Risk Assessment: low
Protective Equipment: Lab cost, gloves
Reagents: NA
Supplies: NA
Equipment: NA
Specimen Requirements: NA

<table>
<tr><th>STEPS</th><th>INSTRUCTIONS</th><th>CHANGE / APPROVAL</th></tr>
<tr><td>1.0</td><td>Obtain the transfer paperwork with the unit numbers.

1.1 Keep in a folder titled ‘Limb’ study located in closet outside management office.</td><td></td></tr>
<tr><td>2.0</td><td>Reconcile the number of sets paid for with the number of sets actually used.

2.1 WFIRM paid in advance for 24 sets ($250) of the below for a total payment of $6000.

a. $183 per red cell
b. $28 per plasma
c. $35 handling fee</td><td></td></tr>
<tr><td>3.0</td><td>Determine the total number of sets used when notified that the study has ended and request refund if study did not use 24 sets.

3.1 Print a list of products transferred to RLIMB and compare to transfer documents.
3.2 Add the number of sets.
<table>
<tr><th>If number of sets:</th><th>Then:</th><th>Additional steps:</th></tr>
<tr><td>< 24</td><td>Submit a request for payment.</td><td>Obtain information from Ernie Lookabill on routing.</td></tr>
<tr><td>>24</td><td>Contact Ernie Lookabill</td><td>Request payment</td></tr>
<tr><td>= 24</td><td>No action needed</td><td></td></tr>
</table></td><td></td></tr>
</table>

3. Review/Revised/implemented:

All protocols must be reviewed according to Document Control Protocol.
All new protocols that have major revisions must be signed by the CLIA Director.
All reviewed protocols with minor revisions can be signed by the designated section medical Director or designee.

4. Related Policies/Procedures:

5. References: NA

6. Attachments:

Attachment 1: Example of Transfer Paperwork from SCC

7. Revised/Reviewed Dates and Signatures:

See Document Change Control

Document Change Control			
Title: Limb Perfusion Study			
Previous title:			
Written date	2/11/19	Written by:	Julie H Simmons
Validation date	3/15/19	Validation by	Julie Jackson
Reviewed date	3/18/19	Reviewed by	Julie H Simmons
Approved date	3/22/19	Approved by	Mary Rose Jones
Approved date	3/19/19	Approved by	E Fadeyi
Effective date in use	3/22/19	In use by	Julie H Simmons

Revisions

Revised Date	By	MD Date	By	MD Date	By	Review Date	By	Effective Date	By
Validate Date	By	Revisions:							
Revised Date	By	MD Date	By	MD Date	By	Review Date	By	Effective Date	By
Validate Date	By	Revisions:							
Revised Date	By	MD Date	By	MD Date	By	Review Date	By	Effective Date	By
Validate Date	By	Revisions:							
Revised Date	By	MD Date	By	MD Date	By	Review Date	By	Effective Date	By
Validate Date	By	Revisions:							

Locations		Out of Use: Date:		By	
		Reason			

Reviews: Record date/initials

Date	Initials	Date	Initials	Date	Initials	Date	Initials