Methodist Health Services Corporation & UnityPoint Health Methodist	Page # 1 of 4	Section: UPM CP	Policy #: CP:001.010
Laboratory CELL PROCESSING	Approved by: see signature block at end of policy		Created Date:12/6/1999
	Date Revised: 01/21/2004, 04/20/04, 9/27/04, 1/31/08, 1/20/09, 5/09,9/09, 4/10, 6/12, 3/14, 4/19/17		
	Policy/Revision Submitted by: Debra Rinne, CLS		
	JCAHO Standard: NA		
POLICY GUIDELINE ON: Standard Operating Procedure Requirements			

I. POLICY:
All Methodist Health Service Corporation policies and procedures will be organized and written in the approved format and approved by the appropriate administrator. Any deviation from Standard Operating Procedure will be documented when appropriate.

II. PURPOSE:
To ensure a uniform format for writing policies and procedures.

III. GENERAL INFORMATION:
- A. The policies and procedures specific to the Cell Processing Laboratory will be in the Cell Processing Manual.
  1. Policies and procedures will be approved by the Laboratory Director / Laboratory Quality Management designee.
  2. All cell processing personnel shall follow the Standard Operating Procedures.

- B. Definition of Terms
  1. Policy
     a. A plan of action designed to influence and determine decisions, actions, and other matters (rules).
     b. A course of action or guiding principle considered to be expedient, prudent, or advantageous.

  2. Procedure
     a. A manner of proceeding; a way of performing or affecting something.
     b. An act composed of steps; course of action.

IV. PROCEDURE:
- A. Policy format
  1. Heading section, including:
     a. Institution name and logo
     b. Submitting individual
     c. Subject of the policy
     d. Page number
     e. Policy number
     f. Revision dates
     g. Issue date of the new policy or revision date of existing policy
     h. Approving director's signature.

  2. Policy
  3. Purpose – consists of concise information answering the questions: "Why does this policy exist?" and "What is it intended to achieve?"
  4. General Information – all pertinent information
  5. Procedure
  6. References

- B. Procedure
  1. Heading
     a. Institution name
     b. Effective date
     c. Page number

d. Procedure number
e. Title

2. Purpose or Clinical Significance
3. Principle – a Brief description of the principle of the procedure
4. Specimen Requirements
5. Reagents
6. Equipment/Supplies
7. Calibration
8. Quality Control
9. Stepwise Procedure
10. Calculations
11. Objectives and acceptable endpoints and range of expected results, where applicable
12. Reporting and interpreting results
13. Procedural Notes/Problem Solving Tips
14. References/Author
15. Schedule for Review/Signature of Reviewer
16. Examples of correctly completed orders, worksheets, reports, labels and forms, where applicable. There are standardized formats for all forms, including the cell processing report (worksheet), deviation log, equipment out of control log, event report form, adverse occurrence form, engraftment data form, reagent / supply problem log, audit report form, and discrepant results log, Each policy or procedure states which form is to be used, if applies. The form is to be used as stated, and follows each policy or procedure in the Standard Operating Procedure manual as appropriate. UnityPoint Health- Methodist Cell Processing Laboratory and title of form should be present. Font size may be 10 or 12, as appropriate and style "Universal" or "Times New Roman", if possible. "Put into use" and "Removed from use" dates should be present, as applicable.

C. Not every policy or procedure will contain all of the elements listed in A and B above, thus, variations in format may occur. A policy or procedure may reference another policy, procedure, or form required for its completion.

D. 1. Creation of policies, procedures, forms, and labels occurs as need arises by a designated cell processing person.
2. Approval by the cell processing lab director is required
3. Implementation occurs after any required training and / or review is completed by cell processing personnel. Documentation of review and training will be available in file labeled "New/Revised Policy/Procedure Documentation. All personnel will be trained and deemed competent by the Cell Processing designee before performing any procedures alone.
4. Revision occurs as a need arises.
5. Review is accomplished every two years for policies and procedures, and for forms, anytime a revision occurs.
6. Archival occurs when a policy, procedure, form, or label is no longer in use. Policies/procedures/ forms / labels no longer in use shall be maintained in historical sequence in the Cell Processing Laboratory files ten years stating the inclusive dates of use.

E. 1. Documents (includes policies, procedures, forms, worksheets, checklists) will be numbered as follows:

CP: 001.01

a. CP designates the document is in the Cell Processing Laboratory manual. The Quality Management Policy is included in the Cell Processing manual, so is also designated as CP.
b. The 3 digit number following the colon (CP:001.01) is the specific document number. These numbers are assigned sequentially starting with 001.
c. The 3 digit number following the period (CP:001.01) is the current version number of the document. All subsequent versions shall be numbered sequentially.
For example: CP: 011.02 designates the second version of the document 011 in the Cell Processing Manual.

2. Labels

HPC product tie tags are numbered by the Methodist Print Shop as 7000-11023 and the date printed. The date change indicates a revised version. The 7000 designation is the Laboratory department number.

F. The SOP will be kept in the Cell Processing Laboratory during all procedures so as to be available to staff at all times.

V. REFERENCES:

FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration, Fourth Edition, October 2008

VI. Distribution

A hard copy of this procedure is located in the Cell Processing manual at the Cell Processing bench

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
March 4, 2017	Elizabeth A. Bauer-Marsh, M.D.	Elizabeth A. Bauer-Marsh MD
SECTION MEDICAL DIRECTOR		
May 13, 2016	Julia Adams, M.D.	Julia Adams, M.D.

REVISION HISTORY (began tracking 2011)			
Rev	**Description of Change**	**Author**	**Effective Date**
1	Updated system name, removed following SOP of ACTS	D. Rinne	3/19/14
2	Form review change	Deb Rinne	01/31/17

Lead	Date	Coordinator/Manager	Date	Medical Director	Date
				DMcBrady MD	6/2012
		Kathy L. Turpin	3/19/14	DMcBrady MD	3/20/14
D. Rinne	2/23/16	Kathy L. Turpin	7/11/16	James Adams, M.D.	7/11/16
D. Rinne	1/22/17	June Bombenek	2/3/17	James Adams, M.D.	4/19/17