



HBM \_\_\_\_\_

## HUMAN VERTEBRAL BODY MARROW PROCESSING FORM

### I. Summary Sheet: Donor & Recipient

Processing Date/Time: \_\_\_\_\_ Processing Team: \_\_\_\_\_

<input type="checkbox"/> Donor Information (from donor chart)		Initials
Donor Name:	Donor # (JMH, UNOS, other):	
<input type="checkbox"/> Important Information		
Patient / Recipient ID:		
Patient study # (if applicable):		
Protocol Name:		
IND #:		
Other:		
Other Organs Transplanted:	<input type="checkbox"/> Islet Cells <input type="checkbox"/> Other (specify):	

### II. Media and reagents, supplies and equipment

MEDIA & REAGENTS				
Name	Manufacturer	Lot #	Expiration Date	Initials
Betadine				
DNase	Roche			
Trypan Blue				

AUTOCLAVABLES				
Name	Chemical Control	Load Number	Load Date	Sterilization Date within 6 months
Nalgene	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Translucent PP Jar	<input type="checkbox"/> Y			<input type="checkbox"/> Y
BM Machine Pack	<input type="checkbox"/> Y			<input type="checkbox"/> Y
BM Isolation	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Steel Glove	<input type="checkbox"/> Y <input type="checkbox"/> Y			<input type="checkbox"/> Y <input type="checkbox"/> Y
Flask	<input type="checkbox"/> Y			<input type="checkbox"/> Y



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Tray	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Bowl	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Curtain	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Metal Paddle	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Beaker : ____ ml	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Scoop	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Round Pan	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Sieve(80 micron)	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Sieve (40 micron)	<input type="checkbox"/> Y			<input type="checkbox"/> Y
Gauze	<input type="checkbox"/> Y			<input type="checkbox"/> Y

**DISPOSABLES**

Name	Manufacturer	Lot #	Expiration
Aspirating pipette	Falcon		
Pipette, 1 ml	Co-Star		
Pipette, 10 ml	Co-Star		
Pipette, 25 ml	Co-Star		
Transfer Pipettes, 3ml	VWR		
Syringe, 1 ml	B-D		
Syringe, 3 ml	B-D		
Syringe, 10 ml	B-D		
Syringe, 20 ml	B-D		
Syringe, 60 ml	B-D		
Graduated Cylinder	Corning		
Conical Tubes, 250 ml	Corning		
Needles	B-D		
Scalpels	B-D		
Transfer Bags: ____ml	Baxter		
Cryocyte Freezing Bags	Baxter		
Y Type blood set	B. Braun Medical, Inc		
Coupler	Cobe		
Sampling Site Coupler	Cobe		



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EQUIPMENT			
Name	Serial # / DRI #	QC Performed	Initials
Centrifuge		<input type="checkbox"/> Yes	
Balance		<input type="checkbox"/> Yes	
Microscope		<input type="checkbox"/> Yes	
Pipette Aid		<input type="checkbox"/> N/A	
Pipette Aid		<input type="checkbox"/> N/A	
Pipette Aid		<input type="checkbox"/> N/A	
Heat Sealer		<input type="checkbox"/> Yes	
BSC		<input type="checkbox"/> Yes	
BM Machine		<input type="checkbox"/> N/A	
BM Shaker		<input type="checkbox"/> N/A	
Ac T Diff Hematology Analyzer		<input type="checkbox"/> Yes	
		<input type="checkbox"/>	

**IV. Processing**

Lab Set-up	Performed (√) or info	Initials
Verify Sanitization Occurred within the last 10 days:	<input type="checkbox"/> Date: _____	
<input type="checkbox"/> Bring in HBM number		
<input type="checkbox"/> Set up Centrifuges		
<input type="checkbox"/> Set up Curtain		
<input type="checkbox"/> Calibrate Heat Sealer		
<input type="checkbox"/> Blowers are operating in BCS(s)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Set up Table		
<input type="checkbox"/> Set-up BSC #1 (Assemble BM machine)		
<input type="checkbox"/> Set-up BSC #2 (Sieves & Collection)		
<input type="checkbox"/> Set-up BSC #3 (Media Preparation & Freezing)		
<input type="checkbox"/> Place necessary Garbage Bags, Sharps, & Waste Collection pans		
<input type="checkbox"/> Assemble Vacuum System		
<input type="checkbox"/> Assemble Sterility Sample Paperwork		



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(follow SOP HCPF-005 for details):		
<input type="checkbox"/> Assemble Necessary Forms	<input type="checkbox"/> HCPF-004, Att I <input type="checkbox"/> HCPF-001, Att II	
<b>Media and Reagent Preparation</b>		
<input type="checkbox"/> Processing & Resuspension (P&R) Media		
<input type="checkbox"/> Add DNase to P&R Media	<input type="checkbox"/> _____ mg _____ ml <input type="checkbox"/> _____ mg _____ ml <input type="checkbox"/> _____ mg _____ ml	
<input type="checkbox"/> Fill Bowl and Jar with Processing Resuspension Media with 1 vial of DNase		
<input type="checkbox"/> Fill jar with Betadine		
Comments:		
<b>VB Cleaning</b>	<b>Performed (√) or info</b>	<b>Initials</b>
<input type="checkbox"/> Weight of Nalgene jar for VB (tare balance)	<input type="checkbox"/> _____ g	
<input type="checkbox"/> Take sterility sample(s) #1	Aerobic    Anaerobic    Fungal _____ _____	
<input type="checkbox"/> Rinse VB in Betadine	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Rinse VB in RPMI	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Number of VB	# _____	
<input type="checkbox"/> Weight of Chopped VB	_____ g	
<b>Filter and Wash</b>		
<input type="checkbox"/> First Wash (30 minutes):	<input type="checkbox"/> start: _____ <input type="checkbox"/> stop: _____	
<input type="checkbox"/> Centrifuge @ 280 x g, for 10 minutes, at room temperature		
<input type="checkbox"/>		
<input type="checkbox"/> Second Wash (30 minutes):	<input type="checkbox"/> start: _____ <input type="checkbox"/> stop: _____	
<input type="checkbox"/> Centrifuge @ 280 x g, for 10 minutes, at room temperature		
<input type="checkbox"/>		
<input type="checkbox"/> Quick Spin to Remove Bone Fragments <i>When centrifuge reaches 275xg, at room temperature, turn it off.</i>		
<input type="checkbox"/> Transfer to a 2L transfer bag		



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<input type="checkbox"/> Filter cells using Y-Type blood filter (170µm)			
<input type="checkbox"/> Product Final Volume:	_____ ml		
<input type="checkbox"/> Take sterility Sample(s) #2:	Aerobic	Anaerobic	Fungal
<input type="checkbox"/> Take sample for viability, cell count, flow (check if performed)			
<input type="checkbox"/> Product viability (refer to SOP HCPF-004, Att I):	_____ %		
<input type="checkbox"/> Product cell count: WBC from Coulter counter print-out	_____		
<input type="checkbox"/> Final Cell Count (WBC from printout x 10 <sup>3</sup> x volume = total nucleated count, TNC)	_____		
<input type="checkbox"/> Flow result (record):	_____ _____ _____		

**Final Product Disposition** (check all that apply):

- CD34+ Selection
- Transplant immediately following processing
- Transplant Date: \_\_\_\_\_
- Cryopreserved (indicate location) \_\_\_\_\_
- Transplanted at University of Miami
- Transplanted at Alternate Site (indicate location): \_\_\_\_\_

<input type="checkbox"/> Processing completed (Date/Time):		
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Comments:

**REVIEWED BY:** \_\_\_\_\_ **DATE:** \_\_\_\_\_  
 cGMP Facility Operations Director or designee