

SECTION B: DRS REQUISITION - CORD BLOOD PRODUCTS

Cord Blood products may be requested from the San Diego Blood Bank for reasons other than clinical transfusion. Cord blood products provided under this agreement must NOT be transfused to a human subject unless treatment is FDA-approved, or under an investigational New Drug Application (IND).

DATE OF REQUEST: _____

1. Is the project and material to be used for human subject research? (Check one)

Yes* No

* If yes, IRB approved protocol, informed consent, waiver and/or related documents must be included with application to be considered.

2. Is the project related to a clinical investigation covered under FDA regulations? (Check one)

Yes** No

** If yes, IRB approved protocol, informed consent, waiver and/or related documents must be included with application to be considered.

3. Is the project and material use solely limited to quality assessments or quality improvements: (For example: an activity conducted to assess, analyze, critique and/or improve current procedures).

Yes*** No

***If Yes, is the usage for the FDA approval of a device that will be used in human subject research and testing or human product manufacturing under CLIA and/or FDA GMP guidelines? If applicable, IRB approved protocol, informed consent, waiver and/or related documents must be included with application to be considered.

Contact Information		
Primary Investigator / Title		
Requesting organization		
Business Address		
City:	State:	Zip:
Telephone:	Fax:	Email:
Contact Person Name		
IRB or IND Number		
Telephone:	Fax:	Email:

Billing Information			
Billing Contact Name			
Company Name			
Billing Address			
City:	State:	Zip:	
Telephone:	Fax:	Email:	
PRODUCT REQUESTED	# REQUESTED	FREQUENCY	
<input type="checkbox"/> CBU, Fresh			
<input type="checkbox"/> CBU, Frozen			
<input type="checkbox"/> Other _____			

CBU = Cord Blood Unit

Briefly explain product use or attach protocol and/or summary with request:

Approval Signatures:

Signature of Authorized Requestor

Printed Name

Date

Below this line, SDBB use only:

Approved

Not Approved

SDBB Chief Medical Officer or Designee

Printed Name

Date

Please return the completed request form, copy of protocol or summary, primary investigator C.V. and documentation of IRB approval or waiver to Cell Therapy:

Email: celltherapy@sandiegobloodbank.org Telephone: (619)-400-8320 Fax: (619)-296-5271