

# Email - Information Request, May 31, 2011 - HPC Cord Blood

From: Sista, Ramani V  
Sent: Tuesday, May 31, 2011 12:42 PM  
To: 'Miller, Sharon'  
Subject: BLA 125391 - Information Request-1  
Importance: High

Hi Sharon,

We look forward to speaking with you later today. Please see below for information requested by the Clinical reviewer:

1. Please provide the following information or identify where the following information located in the submission:
  - a. This product may be subject to the Pediatric Research Equity Act and if the data to support intended indications do not cover all pediatric age groups (including neonates), you need to include in your submission a request for a waiver or deferral of the pediatric assessment.
  - b. Copy of data set used for your safety outcome analysis. The data set must be submitted as a SAS transport file.
  - c. SOP for elicitation and handling of post donation information
  - d. SOP for elicitation and handling of recipient adverse events
  - e. SOP for notification of mothers or their responsible physicians of positive or indeterminate test results according to local or national regulations
  - f. Validation of physician training materials
  - g. Please clarify if B5.100.4 is your plan for assessment of clinical outcome data in the post marketing period

Thanks,

Ramani

Ramani Sista, PhD, RAC  
Regulatory Project Manager  
Office of Cellular Tissue & Gene Therapies  
CBER, FDA  
Phone: 301-827-5152  
Fax: 301-827-9796  
Ramani.Sista@fda.hhs.gov

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