Telecon, January 5, 2012 - HPC Cord Blood

Telcon date: 1/5/12

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FDA Participants: Safa Karandish, Ramani Sista

The following issues were discussed with the sponsor:

1. Does the bank store and release units from ineligible donors? Contradictory information is noted in the following SOPs and report:

- SOP C1.200.5
- SOP C1.110.5
- SOP E5.100.11
- Ineligible status is on the Unit Release Report

Sponsor explained that after the BLA approval, they will no longer bank any units from ineligible donors. However, they will be releasing units from ineligible donors that were collected after May 25, 2005 but before licensure, under the IND. SOPs C1.200.5 and C1.110.5 will be revised and submitted.

2. Are HIV (b)(4) and --(b)(4)-- assay currently performed on all units? Both tests are listed in SOP C1.110.5.

   Sponsor explained that the above tests are only performed on older units and such units will be released under IND. SOP C110.5 will be revised and submitted.
3. Are confirmatory CMV (b)(4), Hepatitis C virus (b)(4), and HIV-1 and HIV-2 (b)(4) testing currently performed (SOP C1.200.5)?.

   Sponsor explained that the (b)(4) assays may be performed for units collected prior to May 25th, 2005. CMV (b)(4) was being performed on units until Oct 2011. SOP C1.200.5 will be revised and submitted.
4. Sponsor will make the following revisions to the Unit Release Report (E5.103.12):

- -(b)(4)- will be replaced with Syphilis
- (b)(4) will be spelled out
- Table header will be changed to “Maternal Infectious Disease and RBC antibody results.

5. Sponsor will provide SOPs that describe how the reason(s) for donor ineligibility or incomplete DE are documented on the Unit Release Report and the Medical Director Review report (D3.101.6).
6. In SOPs, sponsor specifies that syphilis testing is performed in triplicates. This is in accordance with the manufacturer’s instructions. However, the sponsor doesn’t specify other tests that may be performed in duplicates or triplicates in accordance

to the manufacturer's instructions. It was recommended that the description regarding the syphilis test result interpretation in the SOPs to be revised.

7. Discussed the options for assessing the birth mothers for possibility of plasma dilution. Sponsor was informed that the information provided in SOP C3.110.6 was not adequate. SOP(s) should define the information that is obtained regarding blood transfusion or infusion of colloid, the documentation of any transfusion or infusion including volumes, the responsible person for making the determination regarding the acceptance of the infectious disease specimen and the acceptance criteria. The procedures should apply to both the collections at fixed sites and state-wide program. Sponsor will reconsider their overall process and submit the applicable SOP(s).
8. Sponsor will ensure that the acceptable time frame for administering the donor history questionnaire is consistent in all applicable SOPs (B6.200.2, B4.610.1). Revised SOPs will be submitted:

The following requests (FDA letter Oct 28, 2011) were addressed:

- Item #10: SOP B6.200.2 emailed on 1/5/12
- Item #11: Updated Form C2.103.5 emailed on 1/5/12
- Item #12: Sponsor explained that per SOP, for units collected at non-fixed sites, if the maternal medical records are not provided with the unit, cord bank obtains the medical records from the hospital directly. This is acceptable approach.