


NMDP Protocol 10-CBA: A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) in pediatric and adult patients with hematologic malignancies and other indications

Institution Name:

Site #:

DELEGATION OF AUTHORITY LOG

The following is a complete list of all persons authorized to be part of the institution's study staff. This document is a required essential document that must be maintained throughout the life of the study and be kept current and legible. Inform your RCI BMT Study Team with any updates to the log for staff changes.

**Principal Investigator Initial/Date is the acknowledgement of personnel's delegations and study start date*

PLEASE PRINT LEGIBLY IN ALL COLUMNS EXCEPT FOR SIGNATURE AND INITIAL COLUMNS

Name and Credentials <small>First name, last name, and credentials (i.e. MD, RN)</small>	Role on Study <small>(i.e. Coordinator, PI, Sub-I, Data Manager) Ensure PI and Primary Coordinator are identified</small>	Study Responsibilities <small>(Refer to key below)</small>	Signature	Initials	Start Date for Study <small>(dd-mmm-yyyy)</small>	Principal Investigator Initial/Date* <small>(dd-mmm-yyyy)</small>	End Date for Study <small>(dd-mmm-yyyy)</small>

Responsibilities:

1. Obtain Informed Consent	6. Perform Study Procedures	10. Investigator Study File Administration	14. Sample Collection/Processing/Shipment
2. Determine Subject Eligibility	7. Data Collection	11. Prepare/Submit Regulatory Documents	15. Other: _____
3. Adverse Event Reporting	8. CRF Completion	12. Investigational Product dispensing/administration	16. Other: _____
4. Adverse Event Assessment (AE/SAE)	9. CRF Review/Sign Off	13. Investigational Product Accountability	17. Other: _____
5. Perform Subject Assessments			

**Principal Investigator's Signature
(To be signed ONLY at log Close Out):**

Date:



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Responsibilities:

18. Obtain Informed Consent	23. Perform Study Procedures	27. Investigator Study File Administration	31. Sample Collection/Processing/Shipment
19. Determine Subject Eligibility	24. Data Collection	28. Prepare/Submit Regulatory Documents	32. Other: _____
20. Adverse Event Reporting	25. CRF Completion	29. Investigational Product dispensing/administration	33. Other: _____
21. Adverse Event Assessment (AE/SAE)	26. CRF Review/Sign Off	30. Investigational Product Accountability	34. Other: _____
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