

Cord Blood Transplantation Scenarios as of October 20, 2011

Guide to which IND and Protocol-Specific Consent(s) needed

Depending on investigational drugs used in addition to cord blood investigational drug

CBU Status	IF: Additional Drug (Not Cord Blood)	THEN: IND and Protocol-Specific Consent(s) Needed
Unlicensed	None	NMDP 10-CBA/Other Sponsor CBU IND
	Unlicensed new drug (e.g. chemotherapy agent, GVHD prophylaxis)	NMDP 10-CBA/Other Sponsor CBU IND and Drug Manufacturer/Other Sponsor IND for new unlicensed drug
	Off-label use of licensed drug (new regimen); no new drug indication (i.e. not under IND)	NMDP 10-CBA/Other Sponsor CBU IND and TC clinical research protocols, as required by the TC
	Licensed drug where new indication is being sought	NMDP 10-CBA/Other Sponsor CBU IND and Drug Manufacturer/Other Sponsor IND for new indication
Licensed	None	None
	Unlicensed new drug (e.g. chemotherapy agent, GVHD prophylaxis)	Drug Manufacturer/Other Sponsor IND for new unlicensed drug
	Off-label use of licensed drug (new regimen); no new drug indication (i.e. not under IND)	TC clinical research protocols, as required by the TC
	Licensed drug where new indication is being sought	Drug Manufacturer/Other Sponsor IND for new indication

Depending on manipulation of cord blood

CBU Status	IF: Manipulation of the Cord Blood	THEN: IND and Protocol-Specific Consent(s) Needed
Unlicensed	Minimal manipulation	NMDP 10-CBA/Other Sponsor CBU IND
	More than minimal manipulation (e.g. ex vivo expansion) of the unlicensed cord blood unit	TC/Commercial IND for cord blood manipulation NOTE: patient not enrolled on NMDP 10-CBA/Other Sponsor CBU IND
Licensed	Minimal manipulation	None
	More than minimal manipulation (e.g. ex vivo expansion) of the licensed cord blood unit	TC/Commercial IND for cord blood manipulation

The presented information reflects current understandings of regulatory requirements and anticipated guidance, based on communications with FDA. It is subject to change, for informational purposes only, and is not intended to provide legal or technical advice, medical advice, or prescribed treatments. The NMDP makes no representations or express or implied warranties regarding any information presented here; expressly disclaims all legal liability and responsibility for the accuracy, completeness, currency, suitability, validity, or usefulness of such information; and is not and will not be liable for any statements, errors, or omissions in posted information, or for any losses, injuries, or damages that arise or are alleged to arise from such information.