

NCBI Eligibility & Qualifications

Disparities between banks with a BLA
and those continuing to bank under IND

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The Problem

- After finalization of the guidance for BLA for public cord blood banks, HRSA modified the contracts of banks receiving their BLAs to limit accrual to licensed units
- Thus, eligibility for the NCBI differs for CBUs banked in licensed or unlicensed banks.
- Banks with a BLA (n=6), can only accrue licensed units to the NCBI
- Banks without a BLA (n=11) can accrue IND units to the NCBI

Another Challenge for Banks with a BLA

- This unintended consequence of licensure creates additional hardship for the licensed banks
- Units that would qualify for distribution under the NMDP IND are not reimbursed by HRSA if banked by a licensed bank but reimbursed if banked by an unlicensed bank
- Licensed banks may forgo banking valuable units
- FDA has no timeline for requiring licensure

- Licensed banks have had otherwise IND qualified units removed from funding and have been required by HRSA to replace those units
- These units would be acceptable to HRSA if they were listed by a bank without a license
- This disparity makes no sense
- Licensed banks are disadvantaged once again

Examples

- Units banked on day of BLA approval
- Units banked with late PM on a piece of equipment
- Units banked subjected to later reagent or supply recalls that could not be predicted by the bank and didn't affect the SQIPP of the CBU
- Units released to TC prior to clearance of FDA review of a minor change in the package insert even though the change did not apply to that bank
- Units released to TC under urgent medical need:, e.g. before CT is resulted. N.B. CT results were confirmed before transplantation

Other Considerations

- Other than the BLA change, NCBI eligibility requirements have not been updated for 10 years
- They should be reviewed and updated
- All accrual to the NCBI should be based on these requirements, rather than on the licensure status of the bank or cord blood unit

Recommendations

- Accrual to the NCBI should be based on NCBI requirements that apply to all banks
- The licensure status of the bank should not be included in NCBI eligibility
- HRSA requests for replacement of IND units meeting NCBI eligibility, banked by licensed banks should be cancelled
- The NCBI eligibility requirements should be reviewed and updated by members of the CBAG and CBCC

THANKS