November 15, 2017

MEMORANDUM
via E-mail

TO: Investigators and Clinical Research Staff at Active Sites on the NHLBI-MDS Study

FROM: ECOG-ACRIN Operations

SUBJECT: NHLBI-MDS – GlobalTrace Procedure Updates

This memo provides updates regarding the procedures for entering Bone Marrow Kits into GlobalTrace and new instructions for handling expired specimen collection kits.

Bone Marrow Kit Entry into GlobalTrace

When bone marrow aspirate is not collected at baseline due to dry tap or other issues, the Central Laboratory/Biorepository (CL/B) now requires **return of the empty Bone Marrow Kit and entry of the kit into GlobalTrace**.

- GlobalTrace now allows entry of an empty Bone Marrow Kit. Enter both tubes as not used.
- A new question regarding dry tap is available for entry when both bone marrow tubes are reported as not used.

As a reminder, if an individual tube/specimen from a kit is missed, return the tube with the kit and enter the tube/specimen as not used in GlobalTrace.

If other kits (Peripheral Blood, Buccal Swab, or Eyebrow Follicle) are not collected, no action in GlobalTrace is required, and the kit should remain in your inventory for future use.

Expired Specimen Collection Kits

Sites are no longer required to return expired specimen collection kits to the CL/B. Expired kits must be discarded at your site. There is no documentation requirement in GlobalTrace when disposing of expired kits.

Your site will have the following types of kits available for this study: 1) Peripheral Blood Kit, 2) Bone Marrow Kit, 3) Buccal Swab Kit, 4) Eyebrow Follicle Kit, 5) Histopathology Kit, 6) Core Biopsy Kit. Peripheral Blood, Bone Marrow, and Buccal Swab Kits have expiration dates. Please do not dispose of Eyebrow Follicle, Histopathology, and Core Biopsy Kits as these kits do not expire.
Please note:

- The CL/B will distribute replacement kits before expiration of kits in your site’s inventory. If you do not receive replacement kits, please contact the lab staff at MDS_CLB@m2gen.com.
- Site staff with GlobalTrace access will receive an email reminder regarding disposal of expired kits before the kit expiration date.
- Carefully check the expiration date on the label of each kit before use or disposal.

For questions, please contact Brianna Johnson (bjohnson@emmes.com) and Mary Ellen Walker (Mary.Walker@m2gen.com).

cc: NHLBI: N. DiFronzo, M. Klauzinska, J. Thomas