# Applicable Laboratory(s)):

North Carolina Baptist Hospital (NCBH)

Lexington Medical Center (LMC)

Davie Medical Center (DMC)

Wilkes Medical Center (WMC)

High Point Medical Center (HPMC)

Westchester

Clemmons

# Procedure Statement

The purpose of this policy is to outline the communication chain that BMT lab staff should initiate when any potential problem is identified. Communication is critical to the safety of the patient and notification should occur promptly while investigation is occurring.

# Scope

This policy applies to BMT lab staff, management and medical director.

# Definitions

1. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH.  A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
2. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
3. CAPA: Corrective Action, Preventive Action

# Policy Guidelines

1. Communication of potential issues in any step of the stem cell process.
2. There should be immediate communication anytime that there is a potential problem/issue/error in the stem cell collection, testing or processing process.
3. This communication should occur quickly and prior to investigative steps to determine if there is an issue and/or the exact nature of the issue.
4. Any problem/issue/error that is identified by BMT lab at any step in the product testing/collection/processing/infusing should be included.
   1. Flow lab results
   2. Pheresis issues
   3. Information obtained
5. The following individuals should immediately be emailed:

Emmanuel Fadeyi, MD

Dianna Howard, MD

Rebecca Damron

BMT Program Manager (To be determined)

Julie H Simmons

Christina S Warren

Emily Wilson

1. The email should state that there is a potential problem/issue/error and state what is currently known. Indicate that an investigation is in progress and additional information will be provided. Include most knowledgeable person to be contacted in regards to the issue.
   1. State the facts that are known.
   2. State any investigation that is in progress.
2. Phone notification should occur immediately to the medical director(s).
   1. Dr. Fadeyi or designee (Dr. Pomper/Dr. Maracaja)
   2. Dr. Howard can be contacted at 859-608-5822.
   3. Dr. Howard will notify Dr. Powell if necessary.
   4. Notify the BMT Program Manager if Dr. Howard is not available.
3. Medical Directors in consultation with Dr. Howard can make appropriate decisions while further investigation occurs.
4. Root cause analysis and/or CAPAs may be initiated to document any identified issues to improve the safety of the entire process.

# References

# Related policies/procedures (navex)

# Attachments/Linked documents (title 21)

# Revision Dates: Review Change Summary as represented in Title 21.