

	DOCUMENT TYPE: <input checked="" type="checkbox"/> Policy	ORIGIN DATE IN TITLE 21
CLIA Lab Director: Name and Credentials of CLIA Lab Director	LAB DEPARTMENT: Stem Cell Transplant and Cellular Therapy (SCTCT) Lab	CONTACT: SCTCT Lab Management

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 SCTCT 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 SCTCT lab staff, management and medical director.

DEFINITIONS

- A. 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.
- B. 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.
- C. CAPA: Corrective Action, Preventive Action

POLICY GUIDELINES

- A. Communication of potential issues in any step of the stem cell process.
1. There should be immediate communication any time that there is a potential problem/issue/error in the stem cell collection, testing or processing process.
 2. Any problem/issue/error that results in adverse patient reaction or affects the quality, identity, potency, or purity of the product should be reported.
 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 SCTCT lab at any step in the product testing/collection/processing/infusing should be included. Examples include but are not limited to:
 - a. Flow lab results
 - b. Pheresis issues
 - c. Labeling discrepancies
 - d.
 5. The following individuals should immediately be emailed:
Lab Medical Director
Program Medical Director
SCTCT Quality Program Manager
Apheresis Manager
SCTCT Lab Supervisor and Management
 6. 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.
 - a. State the facts that are known.
 - b. State any investigation that is in progress.
 7. Phone notification should occur immediately to the medical director(s).
 - a. Dr. Fadeyi or designee (Dr. Pomper/Dr. Maracaja)
 - b. Dr. Howard can be contacted at 859-608-5822.
 - c. Dr. Howard will notify Dr. Powell if necessary.
 - d. Notify the SCTCT Program Manager if Dr. Howard is not available.
 8. Medical Directors in consultation with Dr. Howard can make appropriate decisions while further investigation occurs.
 9. 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.