Wake Forest Baptist Medical Center	Document Management Policy	Dept:	Pathology
		Effective Date:	June 2004
		Revised Date:	Jan 8, 2019
		Contact:	Lab Compliance, QA and Safety
Name & Title: CLIA Laboratory Director		Date:	2/1/19
Signature:			

1) General Procedure Statement:

Scope: Defines the manner in which documents are controlled within each laboratory section. The document management system applies to all procedures within each laboratory section of the Department of Pathology.

Note: Our current management process is a manual system.

Note: Due to the complex nature of procedures and numerous forms utilized in the Blood Bank/Transfusion Medicine section, their document management system may differ slightly from other laboratories.

Responsible Department/Party/Parties:

i. Procedure owner: Department of Pathology
ii. Procedure: Department of Pathology
iii. Supervision: Department of Pathology Section Medical Directors, Section Managers and CLIA Laboratory Director
iv. Implementation: Department of Pathology Medical Directors and Department of Pathology Section Managers, Laboratory Compliance and Quality and the CLIA Laboratory Director.

2) **Definitions:** None

3) **Procedure:**

a. Procedure Writing

- All laboratory procedures should be written in compliance with NCCLS GP2-A3.
- All procedures and policy should adhere to template and document formatting as stated in the Medical Center Policy on Creating and Amending Policy.
- All procedures should be kept up to date and reviewed in accordance with CAP and CLIA requirements.
- Only persons holding a CLIA role of Technical Supervisor/Consultant or Cytology General Supervisor or higher may make revisions of any kind (major or minor) to a procedure. (Typically this task falls to a Section Manager or Assistant Manager)
- Technical Staff are not allowed to hand write changes or add modifications of any kind to a procedure or policy. This includes working documents, forms, logs, attachments or any other documents associated to a procedure or policy.

b. Revising Protocols and Procedures

Major Revisions

- Major changes include any change or series of instructions which affect the clinical/technical outcome of the patient, test result or product; changes in Standards; change that would alter test result interpretation, and/or changes in Good Laboratory Practices (GLP).

    - Major changes require both the CLIA Laboratory Director and the Section Medical Director signatures for approval once revisions have been made.
    - Major revisions may only be made to the document by persons with a CLIA delegation of Technical Supervisor/Consultant or Cytology General Supervisor or higher. (Typically the Section Manager or Assistant Manager)
    - To ensure change audit history is traceable, revisions must be recorded in a manner that allow for a sequential timeline showing
        1. Change(s) made
        2. Date and identity of person making the change
        3. Signature approval of the CLIA Lab Director
        4. (Section Medical Director and/or Technical Supervisor/Consultant.)

    *Document Change Control Logs and Forms that are separate from individual policies and procedure may be used but are not required in all sections.

Minor Revisions

- Minor revisions include but are not limited to:
    - Typing corrections
    - Changes to routing and/or storing documents
    - Updating references
    - Minor instructions that will not affect the clinical outcome of the patient, test result or product.
    - Computer keystroke instructions that do not affect the clinical outcome of the patient, test result or product.
    - Moving instruction from one section to another section
    - Including and/or updating Beaker/CoPath/WakeOne/SCC codes
    - Clarifying an instruction with the same outcome

    - Minor revisions require only the signature approval of the Section Medical Director, if available.
    - Minor revisions may be implemented by persons with a CLIA delegation of Technical Supervisor/Consultant or Cytology General Supervisor or higher. (Typically the Section Manager or Assistant Manager).Section Medical Director should be informed of revision as soon as possible, we available for signature.

- Testing Personnel may not make minor changes or revisions to any policy/procedure or documents associated with them.
- Minor revisions can be made by authorized individuals by adjusting information within the body of a procedure by using hand written methods.
- As long as the minor revision can be made using a single horizontal line to strike through the old information and new information can be clearly written in next to the erred out information and the procedure does not need to be re-typed at this time. The authorized individual making the change should date and initial beside of the change being made.
- The Section Medical Director can acknowledge and sign for approval of the change using the revision chart at the bottom of the procedure. (In sections where Document Change Control Logs and Forms are used, these minor changes would be documented using this process.)

c. Changes to Documents

- Date of changes and identity of the authorized individual who changed the record shall be documented in accordance with the section defined instruction, using either the Revision History Review charts at the end of procedures or Document Change Control Logs/Forms.
- Change information will be retained for the retention period of the policy/procedure record.
- Record changes will not obscure the previously recorded information.
- Any handwritten changes should not be excessive to the point that the procedure becomes difficult to read/follow or becomes generally unprofessional in presentation.

d. Attachments

- Any log sheets or forms used in conjunction with a procedure should contain some form of reference to the parent procedure such as the name of the parent procedure or the corresponding number of the parent procedure if a numbering system is used.

  This also includes any "tip sheets", flow charts, manufacturer's inserts or bench documents that may be used by staff as quick reference in place of the entire written procedure.

- Any of these associated attachments, forms, logs, charts, insets etc. should be included within the written procedure. They may be included within the body of the procedure if appropriate (i.e. charts or tables) or may be included as attachments or an appendix.

  *If manufacturer's inserts are referenced and used as supporting documentation as part of the procedure, the CLIA Lab Director and/or the Section Medical Director are also required to periodically review, approve and sign this document when the procedure is reviewed or revised.

d. Authorization of New Policy or Procedure

- All new policy/procedures must be authorized, signed and dated prior to implementation by both the Section Medical Director and the CLIA Lab Director. The CLIA Lab Director may not delegate this responsibility.

e. Procedure Distribution
   - For new or revised procedures that will require staff review prior to implementation the following process should be followed:
     - The Section Manager will upload a copy of the new procedure signed by the Section Medical Director (if applicable) and CLIA Lab Director under Manage Content from the MTS (University of Washington) main menu. From there, click the NC Baptist Hospital Content Tab, then choose either your Section Folder or Existing Content Folder depending on where the new procedure will be uploaded.
       - If a procedure is specific to the Section only then place the new procedure in the Section specific folder. If the procedure is a department level procedure that is appropriate for all sections across Pathology, use the Existing Content Folder.
       - Department of Pathology Compliance Level Procedures may be found under the Laboratory Compliance Procedures Folder.
     - The Manager will then assign the task of procedure review to the appropriate employees within the MTS system. The managers will have the option of assigning a, read receipt, "test" or quiz to go along with the required reading and a deadline for completion (no longer than 2 weeks).
     - The employees will be notified by email of their assigned task and the deadline for completion.
     - The employee will log in to the MTS application and complete the assigned task.
     - The Manager will be able to monitor and verify completion and compliance of staff participation via MTS generated reports.
     - Once section has reached a target of 90% compliance with staff participation, the new procedure can be implemented and patient testing can begin. Procedures should not be implemented until the 90% goal has been reached unless approval is received from the CLIA Lab Director. If emergency situations arise where procedures need to be expedited, only the CLIA Lab Director may give direction to proceed without the 90% participation requirement.
     - Each section will be responsible for the distribution of procedures and/or procedure manuals that are specific to their areas.

f. Procedure Review
   - Procedures are reviewed, signed and dated at least biennially by the Section Medical Director or Technical Supervisor/Consultant or Cytology General Supervisor.
   - Documented employee review of new or revised procedures must occur prior to implementation of the procedure. (90% of employees within a section must have reviewed the new or revised procedure in order to proceed with the initial implementation. Only the CLIA Lab Director may over rule this requirement) Staff who are on medical or long term leave and not able to review new or

revised procedures in a timely manner need to be indicated as such on the review roster. These individuals will have 3 weeks upon their return to work to review missed procedure updates.

- Employees are required to review all procedure manuals at a minimum of once annually unless there are revisions to individual procedures or new procedures added.

g. Discontinued Documents
   - The discontinued date should be recorded on the document.
   - Discontinued documents are kept in a separate location.
   - These documents are retained for 2 years (Blood Bank 5 years) after the date of discontinuation or cessation of laboratory operation.

c) Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Pathology

d) Related Policies:

e) References, National Professional Organizations, etc.:
NCCLS GP2-A3

Medical Center Policy – *Policy and Creating and Amending Policy*

f) Attachments:

g) Revision History Dates: 1/2017, 1/2019

Review Date	Revision Date	Signature
	1/8/2019 MH Removed the numbering from the title column, further clarified the Procedure Review section to clarify when Section Director's sign vs. Lab Director. Added reference to Medical Center Policy on Creating Policy, added the 90% goal of expected review by staff prior to implementation of new procedure.	