Wake Forest Baptist Medical Center	Compliance with CAP Accreditation	Dept:	Pathology
		Effective Date:	Jan 2007
		Revised Date:	April 10, 2019
		Contact:	Laboratory Compliance, QA, Safety
Name & Title: CLIA Laboratory Director		Date:	4/10/19
Signature:			

1) **General Procedure Statement:**

   a. **Scope:** Defines compliance with CAP terms of accreditation which apply to all Department of Laboratory Pathology sections.

   b. **Responsible Department/Party/Parties:**
      i. Procedure owner: Department of Pathology
      ii. Procedure: Department of Pathology
      iii. Supervision: Department of Pathology
      iv. Implementation: Department of Pathology

While personnel should report concerns to laboratory management, the laboratory must ensure that all personnel know that they may communicate with the CAP directly if they have a concern not addressed by laboratory management, and that the CAP holds such communications in strict confidence. This laboratory prohibits harassment or punitive action against any employee in response to a complaint or concern made to the CAP or other regulatory organization regarding laboratory quality or safety.

2) **Definitions:** None

3) **Procedure:**
   a. Accreditation by the College of American Pathologists' (CAP) Accreditation Programs is contingent on compliance with the terms and obligations listed below.

- A laboratory that is accredited by CAP or that has applied for accreditation must:
- Cooperate in any CAP investigation or inspection and promptly notify the CAP if the laboratory becomes:
    1. The subject of an investigation by a government entity (including federal, state, local, or foreign), or other oversight agency, or adverse media attention related to laboratory performance; notification must occur no later than two working days after the laboratory learns of an investigation, this notification must include any complaint investigations conducted or warning letters issued by any oversight agency (eg Centers for Medicare and Medicaid Services (CMS), State Department of Health, The Joint Commission, FDA, OSHA).
    2. The subject of a validation inspection, or

3. The subject of adverse media attention.

- To report any of the items related to a, b, or c send an e-mail to accred@cap.org.

- Promptly notify the CAP if the laboratory discovers actions by laboratory personnel that appear to violate federal, state (provincial), or local laws that regulate laboratories.

- Have a written procedure for employees to communicate concerns about quality and safety to management and for management to investigate employee complaints. Incorporate corrective or preventive actions into the laboratory Quality Management Plan.

- Provide a trained inspection team comparable in size and scope to that required for its own inspection if requested by the regional and/or state commissioner at least once during the two-year accreditation period.

- Participate annually in a CAP accepted proficiency testing program, if applicable and, if subject to US CLIA regulations, meet the proficiency testing requirements in subpart H of the US CLIA regulations.

- Promptly notify the CAP and, if subject to US CLIA regulations, the US Department of Health and Human Services (CMS/CLIA), in writing 30 days prior to any changes in the following: directorship, location, ownership, name, insolvency or bankruptcy. Notification must occur within 30 days prior to the changes or in the case of unexpected changes, no later than two working days afterward. Laboratories subject to US regulations must also notify CMS.

- Promptly notify the CAP when there is a change in the laboratory's test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.

- Authorize the CAP to release its inspection and proficiency testing data and other information required by law to the appropriate regulatory or oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, Joint Commission, HFAP(AOA), UNOS, or state/provincial agencies.

- If the laboratory is subject to US CLIA regulations:

  o Make available on a reasonable basis the laboratory's annual PT results upon request of any person;

  i. Allow HHS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operation and permit HHS to monitor the correction of any deficiencies found through such an inspection;

ii. Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.

- Submit a completed Self-Inspection Verification Form in the interim year.

- Accept and adhere to the Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design, if the laboratory is/or will use the CAP Certification Mark of accreditation. The Agreement may be downloaded and printed from the CAP web site.

- Submit only documentation and other materials to CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations unless the laboratory must submit PHI to CAP in order to respond to a deficiency or patient complaint.
- Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory preparing for such an inspection.

4) **Review/Revision/Implementation:**
   a. Review Cycle: 2 years
   b. Office of Record: Department of Laboratory Medicine and Pathology

5) **Related Policies:** N/A

6) **References, National Professional Organizations, etc.:**
CAP Standard GEN.26791

7) **Attachments:** N/A

8) **Revision Dates:** **July 2014** - lab director change

July 2015- section ownership and updated terms

August 2016 – update to include current CAP verbiage for compliance agreement.

Review Date	Revision Date	Signature
	January 2019 – updated to include harassment or punative action prohibition.	
	April 10, 2019 – updated to reflect additional wording as stated in CAP checklist standard GEN.26791	MH

	revised 8/21/2018	