Wake Forest Baptist Medical Center	**Laboratory Record Retention Policy**	**Type:**	**Tier * 3**
		Original Effective Date:	**June 1, 2016**
		Current (Revised) Date:	**April 10, 2019**
		Contact:	**Laboratory Compliance and QA Manager**
Approval Signature:		**Date of Signature:**	4/10/19
Name and Title: Gregory Pomper, MD			

1) **General Policy Statement:**
It is the policy of the Department of Laboratory Medicine of Wake Forest Baptist Medical Center to maintain laboratory records such as: patient data, test requisitions and authorizations, records and other materials in accordance with CAP and CLIA retention guidelines.

a) Scope: All WFBMC Department of Laboratory Medicine and Pathology employees, Faculty and staff are responsible for complying with this policy.

b) Responsible Department/Party/Parties:
   i. Policy Owner: Department of Laboratory Medicine and Pathology
   ii. Procedure:: Department of Laboratory Medicine and Pathology
   iii. Supervision: Department of Laboratory Medicine and Pathology
   iv. Implementation: Department of Laboratory Medicine and Pathology

2) **Definitions:** For purposes of this Policy, the following terms and definitions apply:

a) **WFBMC**: Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.
b) **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 WFBMC. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
c) **CLIA:** Clinical Laboratory Improvement Amendments
d) **CAP:** College of American Pathology

3) **Policy Guidelines:**
a) **General Requirements** : Each clinical section within the laboratory must have clearly defined and documented policies to ensure that retention of all records related to patient data, test order/authorization and other general records and materials are maintained within the guidance issue by both CLIA and CAP. The minimum retention requirements are listed here:

1. **Test requisition and authorizations**: at least 2 years
2. **Accession Logs**: 2 years; (Autopsy Logs, indefinitely)
3. **Test procedures**: at least 2 years after a procedure is discontinued.
4. **Quality control records**, including instrument printouts: at least 2 years.
5. **Records of test system performance specifications** that the lab used to establish or verify performance specifications: for the period of time the lab uses the test system but no less than 2

years.

6. **Proficiency test records** (including records of test handling, processing, examination, results reporting, and signed attestation statements): no less than 2 years.
7. **Laboratory quality systems assessment** records: retain for 2 years.
8. **Test reports:** Retain or be able to retrieve a copy or scanned image of the original report (including final, preliminary, supplemental, or corrected reports) after the date of reporting as follows:

    - **Surgical Pathology Reports**: minimum 10 years;
    - **Cytology Reports**: minimum 10 years;
    - **Non-Forensic Autopsy Reports**: minimum 10 years;
    - **Forensic Autopsy Reports**: Indefinitely;
    - **Cytogenetics Reports or diagnostic images (digitized prints or negatives):** 20 years.

9. **Slides and Specimen and Blocks:**

    - **Cytology slides**:
        - All Pap slides: 5 years
        - Non-gynecological slides: Keep 1994 to present
        - Fine needle aspiration slides: Keep 1994 to present

    - **Histopathology slides**: 10 years from the exam date.

    - **Cytogenetics slides**:
        - permanently stained slides, 3 years;
        - Fluorochrome stained slides, 5 years.

    - **Surgical Pathology/Histopathology specimens**:
        - Wet tissue, 2 weeks after final report
        - Paraffin blocks, keep 1998 to present

    - **Non-Forensic Autopsy specimens**:
        - Wet tissue, 1 year; or as dictated by availability of storage space.
        - Paraffin blocks, held 20 years.
        - All recorded consents are kept from 2013 to present to encompass a minimum of 10 years.
        - Autopsy written consent forms are made part of the permanent case file, thus held indefinitely.

    - **Forensic Autopsy specimens**
        - Wet stock tissue, 1 year; or as dictated by availability of storage space.
        - Case files are held indefinitely.
        - Paraffin blocks and dried blood stain or frozen tissues for DNA Analysis, are kept indefinitely.
        - Glass slides are retained for 50 Years.
        - Body fluids and tissues for toxicology, 2 years or as directed by the NC Office of the Chief Medical Examiner State Toxicology Laboratory Policy
        - All DNA (bloodspot) samples are retained indefinitely.

- **Clinical Pathology Specimens**
  - Serum/heparinized or EDTA plasma/CSF/Body fluids (except urine) 48 hours Urine 24 hours* *Exceptions may be made at the discretion of the laboratory director
  - Peripheral blood smears/body fluid smears 7 days
  - Permanently stained slides – microbiology (gram, trichrome, etc) 7 days
- **Cytogenetics specimens:**
  - Fixed cell pellet, 2 weeks after final report
  - Wet specimen / tissue, until adequate metaphase cells are obtained.

- **Flow Cytometry dot plots and histograms**: 10 years.

- **Bone Marrows**
  - Slides 10 years
  - Paraffin blocks 10 years

- **Laboratory Computer Services**
  - Computer system validation records - 2 years beyond the life of the system
  - Records of changes to software, the test library, and major functions of laboratory information systems – 2 years
  - Ongoing computer system checks (eg, calculation verification) – 2 years

** For data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., so long as the computer retains the data for at least two years. Manual computer entry of patient result data from worksheets, print-outs, etc. requires retention of all worksheets, printouts, etc. for at least two years (digitized or photographic images are acceptable). For results that are manually entered into the computer from 1) observation of an electronic display, with no paper print-out available, or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer.

10. If the laboratory ceases operation, the lab must make provisions to ensure that all records and, as applicable, slides, blocks, and tissues are maintained and available for the minimum time frames specified in this section.

4) Review/Revision/Implementation)

a) **Review Cycle**: This policy shall be reviewed by Department of Laboratory Medicine and Pathology at least every 2 years from the effective date.

b) **Office of Record**: After authorization, the Legal Department shall house this policy in a policy database and shall be the office of record for this policy.

5) Related Policies

None

6) Governing Law or Regulations

CLIA Regulation Sec. 493.1105 Standard: Retention Records
CAP Standard Retention of Laboratory Records and Materials.

7) Attachments

None

8) Review/Revision/Implementation: June 1, 2016

Revised 2/1/2018 – Increased the retention requirements to reflect archival necessity of teaching medical center. Times were increased to extend beyond 10 year recommendations of CAP and CLIA.

Revised 4/10/2019 – Included specimen retention requirements for Clinical Pathology specimens and LIS services. MH