Wake Forest Baptist Medical Center	**Data Summary Process for Second Read Malignancies for the Department of Pathology**	**Dept:**	**Lab Compliance and QA**
		Effective Date:	**4/3/2018**
		Revised Date:	
		Contact:	**Lab Compliance**
Name & Title: Gregory Pomper, MD		**Date:**	4/10/18
Signature:			

1) General Procedure Statement:

a. **Purpose:** To explain the process of gathering data and preparing the summary of that data for required second read malignancies for the Department of Pathology. The process is also commonly referred to as the "Pink Sheet" Audit.

"Pink Sheets" and/or other forms of required second read documentation will be collected daily, by Compliance, from the designated Compliance drop box located in Pathology Administration.

Data, in the form of query based reports will be run using CoPath on Monday morning of each week of the month.

Data will be summarized by a monthly adherence report. Satisfactory performance will be achieved when 90% or better adherence to policy is obtained.

Anatomic sites used for data collection will vary month to month, with the exception of breast. Breast will always be the first anatomic site to be pulled with the remainder of sites chosen randomly until a total sample sample size of all combined anatomic sites for the month's reports has reached as sufficient sample size, 100-200 per month.

b. **Responsible Department/Scope:**
   i. Procedure owner/Implementer: WFBH Lab Compliance, Quality Assurance, POCT and Safety
   ii. Procedure prepared by: WFBH Lab Compliance, Quality Assurance, POCT and Safety
   iii. Who performs procedure: Laboratory Compliance Specialists

2) Procedure:

1. The Compliance Specialist responsible for performing the audit will first determine the selected anatomic sites to be used for the month. The first week of the month will always begin with Breast.
2. During the report review process to determine new malignancies, any cases identified as being those amended by the Department Chair as a result of the current Slide Case Review Process will be excluded from the second audit process. These reports will be kept in a separate section in the monthly binder with the rest of the audit information for that month.
3. As each pathology report is manually reviewed, a color coding system is used to identify which reports are "flagged" as requiring a second pathologist read:
    a. Green Highlights only = NO Malignancy
    b. Orange and Green Highlights together = Malignancy identified but it is not a new malignancy
    c. Orange and Pink Highlights together = New Malignancy identified – Pink sheet is required and documentation of second read in CoPath should be highlighted within the body of the report as well.
    d. Pink sticker/tab on top of page = New Malignancy identified – Pink sheet is required but documentation in CoPath is missing.
4. The audit form is completed using the surgical case numbers identified as having New Malignancies from the review process described in Steps 1-3, indicating the precense/absence of the Pink sheet and/or CoPath documentation.
5. Data is summarized and taken to the Director of Surgical Pathology for review.
6. The Director of Surgical Pathology will review the results and will follow up and document any pathologist who failed to follow proper procedure and require them the make the necessary corrective actions to meet 100% adherence. Failure to adhere to and follow proper procedure for second read requirements will be included as a bi-annual metric used for OPPE assessments.
7. Once the monthly data has reached 100% adherence, the Director of Surgical will share the results with the CLIA Lab Director for final approval.
8. The final approved documents and audit summaries will be maintained in the Laboratory Compliance and QA department and reported as required through QA/QI minutes and as part of individual pathologist review summaries for biannual OPPE reviews.

3) Review/Revision/Implementation:

All procedures must be reviewed at least every 2 years.

- All new procedures and procedures that have major revisions must be signed by the CLIA Laboratory Director.

- All reviewed procedures and procedures with minor revisions can be signed by either the designated section medical director or the CLIA Lab Director.

4) **Related Procedures:**
Anatomic Pathology Data Procurement Procedure
Breast Cancer Case Reviews Prior to Initiating Therapy

5) **References:**

6) **Attachments:**

7) **Revised/Reviewed Dates and Signatures:**