

	<b>Retrospective Review of BDY Cases</b>	<b>Dept:</b>	<b>Pathology</b>
		<b>Effective Date:</b>	<b>3/26/18</b>
		<b>Revised Date:</b>	
		<b>Contact:</b>	
<b>Name &amp; Title:</b> <i>Amber CLIA Lab Director</i>		<b>Date:</b>	<i>4/16/18</i>
<b>Signature:</b> <i>[Signature]</i>			

1) **General Procedure Statement:** WFBMC, the Department of Pathology, and the NCBH laboratory will facilitate a 100% retrospective review of the BDY cases, including external review for discrepancy, secondary review of discrepant cases, focused tumor board, and patient and physician notification processes until case closure.

- a. **Scope:** All accession numbers (cases) originally signed out by BDY at WFBMC requiring microscopic examination and/or diagnostic interpretation.

List of specimens excluded from review:

1. Gross only specimens: Specimens for which no microscopic examination is ordered to be performed (e.g., surgical hardware, pacemaker).
2. Incidental specimens: Specimens submitted to pathology for documentation purposes and primarily limited to microscopic identification of tissues (see Attachment 1: Table of Incidental Specimens)

b. **Responsible Department/Party/Parties:**

- i. Procedure owner: WFBMC Medical Review Committee (MRC), as authorized by the Medical Executive Committee (MEC)
- ii. Procedure: Department of Pathology
- iii. Supervision: WFBMC MRC and MEC
- iv. Implementation: WFBMC MRC and Department of Pathology

2) **Definitions:**

- Accession number: A unique alpha-numeric identifier assigned to all specimens obtained during a single procedure. May include more than one specimen (e.g., breast biopsy plus lymph nodes).

Case: All specimens associated with an accession number. Note: a single patient can be associated with multiple cases, so the number of patients is less than number of cases.

Specimen: A sample of tissue taken for diagnostic examination or evaluation. For example, "colon biopsy", "lung lobectomy".

### 3) Procedure:

The MEC charged the MRC to oversee this procedure until completion of the case review.

The MRC oversees this procedure until completion, and:

- Maintains a list of all cases open and closed.
- Convenes every 2 weeks;
- Documents meetings with detailed meeting minutes;
- Documents the summative opinions of the internal pathologists from the prior two weeks;
- Documents which tumor boards or patient centered groups need to convene;
- Ensures the process is being followed as defined;
- Provides resources as needed;
- Keeps the MEC and the Board of Directors informed via executive summary documents;
- Documents monthly updates to the quality committee, a subcommittee of the Board;
- Documents ongoing escalation if needed to the MEC and the quality committee of the Board of Directors;
- Membership includes the CLIA Laboratory Director.

The Review Process:

- External pathologists will review cases. External pathologists will be vetted for license, diploma and board certification.
- These external reviews will be conducted in reverse chronologic order by accession number.
- If the review agrees with Dr. DeYoung's interpretation: review complete; case closed.
- If the review disagrees with Dr. DeYoung's interpretation in any respect: cases are categorized as major or minor. Both major and minor pathologic disagreements will be brought to the internal pathologists who will provide a consensus pathologic interpretation.
  - o If internal pathology review agrees with the original BDY diagnosis, then review is complete and the case closed.
  - o If internal pathology review disagrees with the original BDY diagnosis, then these cases are referred to the MRC for review by a focused tumor board or similar disease-specific multispecialty provider group.

- Focused tumor boards or other similar disease-specific multispecialty provider groups, will be convened to determine patient harm based on medical judgment, which will answer two questions:
  1. Would WFBMC do something different now regarding patient care = attempt immediate notification by all available means (within 2 business days).
  2. Would WFBMC have done something different at the time regarding patient care = attempted notification will occur by all available means (within 7 business days).
- The focused tumor board or other similar disease-specific multispecialty provider group will document answers to the two questions for each case reviewed.

**The Notification Process:**

- In all cases where the diagnosis changed, treating physicians and patients will be notified.
- At the direction of the MRC the treating physician will be notified first.
- Subsequent to that notification, the CMO office along with a representative from Patient Experience will coordinate patient contact, and will document the notification in the patient's medical record.
- After the initial patient contact, the treating physician will explain further to the patient, and document the disclosure in the medical record
- After the treating physician notifies the patient the pathology report will be amended by a pathologist and reflected in the medical record.

**4) Review/Revision/Implementation:**

- a. Review Cycle: This procedure will be reviewed when changes may be required or authorized by the MEC, MRC, or Department of Pathology.
- b. Office of Record: Department of Pathology

**5) Related Policies:**

**6) References, National Professional Organizations, etc.:**

**7) Attachments:**

Attachment 1: Table of Incidental Specimens

**8) Revision Dates:**

**ATTACHMENT 1**

Table of Incidental Specimens:

Abortion Adhesions, pelvic Aneurysm Anus, hemorrhoids Anus, skin tag Artery, Biopsy/segment Artery, Plague Artery, Temporal Blood Clot Bone Exostosis Bone, Fragments Branchial Cleft, Cyst Cholesteatoma Cornea Debridement, other than skin Debridement, other than skin w/Blocks Dupuytren's Contracture Fatty Tissue Fibroadipose Tissue Foreign body Foreign Material Foreskin Ganglion Hardware, Surgical Heart Valve Heart Biopsy Hemangioma, skin Hematoma Hydrocele Intervertebral Disc IUD	Joint, Cartilage, Shaving  Meniscus Misc Gross Muscle Biopsy (SP use only)Nail (finger or toe) Nasal Septal contents Nasal Septum Nasal, Inflammatory polyp Nerve Neuroma-SP Pannus Papilloma Pilonidal Cyst Rib-Gross only Sinus Contents sinus, Inflammatory Polyp Skin, debridement Skin, plastic repair Skin, skin tag Teeth Tendon Testicular, appendage Testis, fertility Testis, castration Thyroglossal Duct, Cyst Tonsils adenoids umbilical cord Vagus Nerve Vas Deferens Sterilization Vein segment Biopsy Vein, Varicosity
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