DEPARTMENT OF PATHOLOGY & LABORATORY MEDICINE

CRITERIA FOR PATHOLOGY CLINICAL RESEARCH OVERSIGHT COMMITTEE (CROC) REVIEW

ESTIMATED TURNAROUND TIME

Expedited Review: 1-week for review

Full Review: 2-weeks for review

Special Review: Determined on a case-by-case basis

EXPEDITED REVIEW

• Laboratory results are not used for patient care.

- Minimal laboratory resources are needed. Minimal being defined as little to no CLS time (1% time or less), limited storage of specimens as determined by the Lab Section, and no laboratory equipment use by undesignated personnel.
- Approved quality improvement project that does not impact routine patient testing.
- Specimens requiring testing using automated platforms, not restricted by Pathology (e.g., all manual and Specialty Testing Center tests), and not requiring manual manipulation of the specimen prior to testing.
- Less than 100 specimens per year.

FULL REVIEW

- Results are used for patient care and the test is being applied beyond its intended use (e.g., laboratory developed test) and/or with workflow that is outside the routine laboratory process.
- Studies requiring CLS time (1% time) with or without funding reimbursement.
- Studies requiring esoteric testing, testing with substantial manual steps, or a restricted Pathology test.
- Use of a new test not currently built or offered through the clinical laboratory.
- 100 or more specimens per year.
- Requiring informatics that is currently not offered by the clinical laboratory.

SPECIAL REVIEW

- Study does not meet above criteria.
- Non-human or non-biological samples.

Version 1.1