

## SUMMARY PAGE

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**TITLE OF RCA: “High-Throughput Truthing of Microscope Slides to Validate Artificial Intelligence Algorithms Analyzing Digital Scans of Same Slides”**

**FDA Component:** Center for Devices and Radiological Health (“CDRH”)

**FDA Principal Investigator:** Brandon Gallas, Ph.D.

**Collaborator:** Stony Brook University

**Collaborator Principal Investigator:** Joel H. Saltz, M.D., Ph.D.

**TERM OF RCA:** Three (3) year from the Effective Date

### ABSTRACT OF THE RESEARCH PLAN:

Medical device companies are exploring new, digital mechanisms of tissue imaging to advance the current practice that relies on the light microscope. Additionally, pathology laboratories and care centers are expressing interest in algorithm development to quantify tissue staining and morphology and to assist the pathologist in tissue diagnoses. Accordingly, the U.S. Food and Drug Administration and the Collaborator are collaborating to collect pathologist annotations to validate artificial intelligence (AI) algorithms that quantitate specified cancer tissue sections and to develop associated statistical analyses. The proposed research will collect pathologist annotations that identify and quantitate specified cancer tissue sections (e.g., marks, segmentations, counts, and density estimates). These annotations will be the reference (truth) data for developing and evaluating the performance of algorithms which similarly identify and quantitate specified tissue sections. Research findings will be made publicly available through peer-reviewed publications and/or presentations.