Joel H. Saltz, MD, PhD
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October 17, 2018

Brandon D. Gallas, PhD
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Division of Imaging, Diagnostics and Software Reliability

Dear Dr. Gallas:

On behalf of the Department of Biomedical Informatics at Stony Brook University it is my pleasure to give support to your proposal entitled, "High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides: data (images + annotations) as an MDDT."

As a leader in research in Pathology Informatics, over the past twenty years, I have led the development of several highly impactful, innovative systems to support the analysis, visualization, and management of whole slide imaging data. My published whole slide virtual microscope system with concepts was ultimately adopted by many commercial vendors and embodied in the NCI supported caMicroscope system. I have also led a variety of multi-disciplinary efforts for creating cutting-edge machine learning algorithms for analysis of whole slide tissue imaging data and extraction and classification of imaging features. These algorithms include methods for classifying whole slide images and image regions, segmenting microanatomic structures and for carrying out analysis of IHC stained tissue. My overall research program focuses on the development of principles, techniques and tools that can be used in cancer research studies to assemble a coherent biomedical picture by integrating information from multiple complementary pathology, clinical, radiology and molecular data sources.

Much of this research has been in collaboration with Dr. Sharma's group at Emory University; one key Emory collaboration has been the development of high resolution segmentation of TILs in multiple tumor types, and high resolution classification of tumors in breast cancer with ongoing efforts to generalize to additional tumor types. Our current efforts in this area are supported by the National Cancer Institute Information Technology for Research (ITCR) program, CBIIT and SEER programs. I am PI of NCI ITCR U24 CA180924 and NCI SEER UG3 CA225021 both with focus on digital Pathology visualization, algorithms, data management and applications and MPI of ITCR U24 CA215109 (with Drs. Fred Prior PI and Ashish Sharma MPI) with work that includes integrating digital Pathology capabilities into TCIA. Finally I lead the Stony Brook subcontract for Dr. Sharma's CBITT funded digital pathology informatics project.

The Stony Brook Department of Biomedical Informatics looks forward to collaborating with the FDA in the management of whole slide imaging data including images and derived metadata as well as in the development and evaluation of pathology related deep learning algorithms. We are delighted to make available software and systems for management of annotation/markup data from pathologists and from algorithms. We will work with your team to support the data collection activity and will host images, annotations and derived metadata in TCIA. In collaboration with Emory, we will run our algorithms on WSIs submitted to the FDA and will also make the code available to the FDA. We are also delighted to offer help in the ground truth generation process; the Chair of the Department of Pathology at Stony Brook, Dr. Kenneth Shroyer, has offered the services of his pathologists to help support the crucial truthing effort.

Sincerely,

Joel H. Saltz