MSK650T

PUBLIC HEALTH SERVICE
MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"), collectively referred to herein as the United States Public Health Service ("PHS") within the Department of Health and Human Services ("HHS"), in all transfers of research material ("Research Material") whether PHS is identified below as its Provider or Recipient.

Provider: FDA, Center for Devices and Radiological Health ("CDRH"), Office of Science and Engineering Laboratories ("OSEL"), Division of Imaging, Diagnostics, and Software Reliability ("DIDSR")

Recipient: Memorial Sloan Kettering Cancer Center ("MSKCC")

1. Provider agrees to transfer to Recipient's Investigator named below the following Research Material:

Olympus BX43 microscope, Prior H101 A/B stage and slide holder, Prior ProScan III (H31XYZE-US/A) controller and joystick, Point Grey Grasshopper 3 color camera (GS3-U3-50S5C-C), 3 Klarmann Rulings reticles (Concentric squares KR-871, multi-cross-hairs KR-32536, and ruler KR-207), DELL Latitude E6540 with eeDAP software (https://github.com/DIDSR/eeDAP), NEC PA301W Monitor

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for research purposes by Recipient's investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This Research Material will not be used by for-profit recipients for screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

   (a). Were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

   ____ Yes (Please provide Assurance Number:_____)
   ____ No
   X__ Not Applicable (Materials not collected from humans)

3. This Research Material will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

FDA/CDRH/OSEL has engineered a hardware+software system (eeDAP) to collect pathologists' evaluations of glass slides on a microscope and from corresponding scans of the glass slides. OSEL have been demonstrating this technology to the community in different settings. MSKCC

would like to try the system, but does not have all the equipment. To facilitate this, OSEL will share the equipment to give them that opportunity. eeDAP is expected to encourage the collection of higher quality data, something the Center is interested in encouraging the community to do. Engaging with individual investigators and groups to get them started on this, especially high-profile opinion leaders like MSKCC, will further promote the use of eeDAP, and the collection of high quality data.

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL", except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains. Recipient will share the results of the Research Project at the written request of the Provider. Neither party shall publish results without the written consent of the other party.

5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient's investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, or six months after the date of this agreement's execution, whichever occurs first, the Research Material will be returned to the Provider, as directed by the Provider.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

7. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Unless prohibited by law from doing so, Recipient agrees to hold the Government harmless for Recipient's use for any purpose of the Research Material.

8. Either party shall have the right to terminate this MTA upon thirty (30) days prior written notice. Upon termination of this MTA, Recipient shall, at Provider's option, either return or destroy any Research Material in Recipient's possession.

9. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

SIGNATURES BEGIN ON THE FOLLOWING PATE

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MSK6501

SIGNATURES

PROVIDER: FDA/CDRH/OSEL

Authorized Signatory
Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health

9/15/2017
Date

Brandon Gallas
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MSK6501

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Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).