INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY CONDUCTED BY THE U.S. FOOD AND DRUG ADMINISTRATION

Title: High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides

Principal Investigator: Dr. Brandon Gallas, FDA

You are being asked to participate in a research study as a pathologist performing assessments of archived tumor slides. The following information is being given to you to explain the study purpose, what you will be asked to do as a participant, and the potential risks and benefits. You are encouraged to ask questions before deciding to participate, or at any time during the course of the study.

Purpose of the Study

The proposed research will collect pathologist annotations that identify and quantitate tumor infiltrating lymphocytes (TILs) in hematoxylin and eosin (H&E) anonymized breast cancer sections (marks, segmentations, counts, and density estimates). These annotations will be the reference (truth) data for validating algorithms that similarly identify and quantitate TILs in breast cancer sections.

What is the expected duration of participation?

The training includes written materials to be read (can be done ahead of time) and data-collection sessions take approximately 30 minutes each. The study is designed such that optimal participation includes the training session and two data-collection sessions (microscope-mode and digital-mode) with a washout time in between the two data-collection sessions. However, a single data-collection may be acceptable as may multiple data-collection sessions without any washout.

Do I have to participate in this study?

No. Taking part in this study is voluntary. Even if you decide to participate, you can change your mind and leave the study at any time. If you choose to leave the study after you begin data collection, your data may be saved and used in analysis. You may also choose to completely withdraw from the study, in which case, you should notify the study coordinators and your data will be removed from analysis.

What will I have to do if I agree to participate in this study?

If you decide to participate in this study, you will be asked to review de-identified, archived tumor "glass" slides in microscope mode, digital mode, or both. Your assessment of these samples will be used to evaluate and improve diagnostic algorithms.

Are there benefits to me if I participate in this study?

The study does not involve any benefits beyond the advancement of science and public health.

Are there risks to me if I participate in this study?

The study does not involve any risks beyond normal working conditions.

My rights as a research participant

Participation in this study is voluntary. There is no compensation for your participation. You have the right to choose not to participate in this study. You may leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled.

Confidentiality

All personally identifying information will be kept confidential but may be inspected by a federal entity or federal regulators. Upon enrollment, you will be assigned a participant ID that will link to your real name by a look-up table. This look-up table will only be used by the PI for follow-up purposes, and will otherwise be kept confidential by the PI. Participant consent may be collected electronically or by hard copy. Hard documents will be stored in locked cabinets by the PI through the end of the study. Deidentified data will be shared publicly. Any publications presenting data and results will not be linked to your identity.

What if I have questions?

If you have any questions now or in the future about your rights as a subject or this research, you can contact the PI: Dr. Brandon Gallas

- Email: Brandon.gallas@fda.hhs.gov
- Phone: (301) 796-2531
- Mail: US Food and Drug Administration, 10903 New Hampshire Ave, Building 62, Office 4104, Silver Spring, MD 20993;