**Informed Consent Form for eeDAP Feature Study**

**[Name of Principle Investigator]:** Brandon D. Gallas

**[Name of Organization]:** Division of Imaging, Diagnostics, and Software Reliability

Office of Science and Engineering Laboratories

Center for Devices and Radiological Health

Food and Drug Administration (FDA)

**[Name of Sponsor]:** FDA

**[Name of Project and Version]:** *eeDAP Feature Study: Mitotic Counting 1*

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the study with you)**
* **Certificate of Consent (for signatures if you agree to participate)**

**You will be given a copy of the full Informed Consent Form**

**Part I: Information Sheet**

**Introduction**

One component of the evaluation of whole slide imaging (WSI) scanners is to compare pathologist performance and reproducibility using WSI to pathologist performance using the microscope. Instead of a clinical trial, feature studies provide an alternate means to make the comparison. Feature studies can be designed to stress imaging characteristics and have the potential to be less burdensome than clinical trials (faster and more precise comparisons). The Food and Drug Administration (FDA) in Silver Spring, MD and Memorial Sloan Kettering Cancer Center are collaborating on the design, execution, and analysis of feature studies with a hardware/software tool (eeDAP) that allows the same fields of view to be evaluated with WSI and on the microscope.

**Purpose**

The objectives of the project are to:

a) Quantify the within- and between-reader reproducibility of pathologists at the mitotic counting task using WSI and the microscope. The data will be collected using eeDAP which allows the same fields of view to be evaluated with WSI and the microscope.

b) Compare the reproducibility of the data collected using eeDAP to the reproducibility of the data using the standard clinical protocol (previous study) in which every pathologist selected his or her own fields of view for counting.

**Type of Research Intervention**

Your participation in this study involves the counting of mitotic figures in pre-selected fields of view on the microscope and using WSI.

**Selection of Participants**

Participation is open to all interested pathologists or others trained in the detection of mitotic figures.

**Voluntary Participation**

Participation is voluntary and can be terminated at any point of the study by the participant.

**Procedure**

The system will sequentially present the pre-specified fields of view on the microscope and using WSI. There will be fiducial marks defining the evaluation area for counting. In microscope mode, the fiducial marks are created by a reticle in the eyepiece. On the WSI, the fiducial marks are made on the image (an annotation square). We ask that you count the mitotic figures in each evaluation area and enter that count into the GUI interface.

**Duration**

There will be two sessions that need to be separated by two weeks. In each session you will evaluate half the data on the microscope (30-45 min, microRT mode) and half the data using the WSI (30-45 min, digital mode). A break, where you leave and come back another time/day, is possible between the two modes, but a break is not possible in the middle of a mode. However, it is possible to take a short pause within a mode for the bathroom, to stretch, and to refresh. We don’t want to lose your work, so please finish the modes that you start in one sitting.

**Risks and Discomforts**

No risks other than the minimal risks associated with typical review of pathology slides on a microscope or the review of digital images on a monitor.

**Benefits**

Your participation will improve the design, execution, and analysis of feature studies that can be used to evaluate WSI scanners and related technologies (image analysis programs). Your participation will also inform the community on the reproducibility of mitotic counting.

**Reimbursements**

There will be no monetary reimbursement for participation in the study.

**Confidentiality:**

The name of each participant will not be directly linked to reported results. Results per participant will be reported in an anonymized manner. The name of the participant will only be publicized if participant agrees. *All files containing the participants’ data will only be accessible to the PIs and will be stored in a manner to protect the identity of the participant.*

**Sharing of Research Findings**

At completion of the study, research findings will be published in peer-reviewed journals and will be presented in scientific conferences and other seminars. After publishing, the raw data will also be shared.

**Right to refuse or withdraw**

Participants can withdraw at any point from the study without any repercussions.

**Who to Contact**

For any questions contact Brandon D. Gallas, Ph.D:

*Brandon D. Gallas, Ph.D.*

*Division of Imaging, Diagnostics, and Software Reliability*

*Office of Science and Engineering Laboratories*

*Center for Devices and Radiological Health*

*Food and Drug Administration*

*Tel: (301) 796-2531 (office)*

*Email: Brandon.gallas@fda.hhs.gov*

**PART II: Certificate of Consent**

**Certificate of Consent**

I have been asked to give consent for my participation in this research study which will involve my review of pathology slides and answering related questions. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

**Print name of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**Statement by the researcher/person taking consent**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1. Participation in a study to compare counting mitotic figures on the microscope and using WSI.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

**Print Name of Researcher****/person taking the consent:**

**Signature of Researcher/person taking the consent:**