Principal Investigator: [redacted]

Title: Optical Biopsy Using Optical Coherence Tomography

1. Purpose of study: This is a research study to develop a new imaging method to identify and survey changes in the gut associated with inflammation, injury, abnormal cells, prior therapy, and possible progression of lesions to cancers with hopes of improving detection and treatment. The new technology is called optical coherence tomography (OCT). You are being asked to participate in this study because you will undergo endoscopy: sigmoidoscopy (___), colonoscopy (___) or upper endoscopy (___). (Please check appropriate procedure). This study will involve a total of 300 patients. This study is sponsored by the National Institutes of Health.

The technology used in this study was developed by the research group of James G. Fujimoto, Ph.D. at the Massachusetts Institute of Technology (MIT) working in collaboration with Lightlab Imaging. This study is being performed in collaboration with Dr. Fujimoto's research group at MIT and Dr. Fujimoto is a co-investigator. Dr. Fujimoto receives payment for intellectual property licensed by MIT to LightLab Imaging and Carl Zeiss under the MIT institutional royalty sharing plan. Promising results from this study may positively affect the commercial development of optical coherence tomography systems by LightLab Imaging.

2. Description of the study, procedures to be used, and how long it will last: We invite you to participate in this study. Your participation in this research is completely VOLUNTARY. You have been invited to volunteer for this study by Dr. Hiroshi Mashimo, M.D., Ph.D., or Dr. Ashish Sharma, M.D., at the VA Boston Healthcare System. If you agree to participate in this research study by signing this form, then high resolution pictures of your gut will be taken in addition to normal endoscopy. During the normal colonoscopy or endoscopic procedure, pictures (images) of your gut will be taken with light from a small imaging device that will be inserted into your gut through the working channel of an endoscope or through an external catheter adjacent to the endoscope. The pictures (images) will be taken and stored on videotape and computer.

This procedure will take a maximum of 5 to 10 minutes. After this imaging, you will continue with the normal endoscopy examination. The imaging should not affect the endoscopy procedure, restrict normal activities, or affect long-term follow-up. No additional biopsies will be taken as a result of the images. There will be no increased discomfort and this will not prolong your recovery time.

3. Reasonably foreseeable discomforts or inconveniences of the study: The typical length of normal colonoscopy usually takes about 30 – 45 minutes. The typical length of normal endoscopy usually takes about 20 – 30 minutes. The OCT imaging will last only 5 – 10 minutes, so the length of your procedure

will be increased by 5 – 10 minutes. There should be no increased discomfort compared to a normal endoscopy procedure.

4. Reasonably foreseeable risks of study: The risks of the imaging procedure are very low. There should be no increased discomfort compared to a normal endoscopic procedure. Since low amounts of light are used to take the pictures (images), there should be little to no risk from the imaging itself. The chance of infection by the imaging device will be low because it will not penetrate the surface of the gut and it will be disinfected prior to use. The imaging device is contained in a plastic casing, so there is little to no risk of breakage. There is very little risk of perforation since the imaging device is flexible and does not have sharp edges. The risk is greatly minimized by the rounded shape of the plastic catheter tip and the gentle movement of the imaging device. Since the probes will be properly insulated in compliance with the International Standard for medical electrical equipment (IEC60601-1), there is little to no risk of electrical shock. The imaging will last only 5 to 10 minutes, so the length of the endoscopy procedure will not be substantially longer. The imaging procedure does not result in increased risk beyond the normal risk associated with an endoscopic evaluation. However, the procedure may involve risks that are currently unforeseeable. Because this is a new device, we do not know all of its bad effects.

5. Expected benefits of study: There are no known direct benefits to you for being in this study.

6. Other treatment available:
This is not a treatment study and therefore, will not alter any treatment you are receiving at the VA.

7. Use of research results and Confidentiality: Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way. (a) The study investigators will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

(b) Your medical information and any data obtained from the study, including endoscopic video or imaging data, will be regarded as confidential and confidentiality will be maintained according to the VA Boston Healthcare System requirements. Your data will be analyzed by researchers at the VA

Principal Investigator: [redacted]

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Boston Healthcare System and the Massachusetts Institute of Technology (MIT), a collaborating institution in this study. Your medical records, including video data, will be maintained according to this medical center's requirements. This information will be assigned by de-identified codes respectively according to the Health Insurance Portability and Accountability Act (HIPPA) guideline and only accessed by the researchers. These files will be kept at both the VA and MIT in a locked cabinet and only the researchers have the keys. The identification codes will be destroyed in accordance with the VA Record Retention schedule (www1.va.gov/VHA Publication/RCS10/res10-1.pdf).

(c) If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, by video image, or by any other means without your specific consent.

Your records will be destroyed in accordance with the VA Record retention schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed in the following manner:

- *Paper records will be shredded*
- *Electronic records will be destroyed in a manner in which they cannot be retrieved*
- *Digital images (photographs, x-rays, scans, video/audio recordings, etc) will be destroyed in a manner in which they cannot be retrieved.*
- *Audio/visual recordings on tape and/or printed photographs will be shredded.*
- *Tissue samples will be discarded at the end of the stud with biological laboratory waste for pick-up and disposal by VABHS Environmental Management Service.*

Your research records and the information within them will not be used for any purpose other than that which is described in the study as approved by the IRB.

Your data may be entered into a database and used for future studies related to this study.

8. New Findings: You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained.)

VA FORM
JAN 1990 **10-1086**

_____
Subject's Initials

VA Boston IRB
Approved: [redacted]
Expires:

Form valid only if above completed

Principal Investigator [redacted]

Title: Optical Biopsy Using Optical Coherence Tomography

9. Special circumstances: You will not be paid for being in the study. A veteran subject will not be required to pay for medical care and services received as a subject in an approved VA research study. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

10. Rights of Recourse: In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

11. Study Monitoring: You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Human Studies Subcommittee of this hospital, the VA, the Massachusetts Institute of Technology (collaborating institution of this study), involved federal agencies, the Office for Human Research Protection (OHRP), the Government Accountability Office (GAO), and other national research oversight and accreditation organizations. You understand that because this research study involves things that are regulated by the FDA they may choose to access and inspect your records. You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff.

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above.
The study person named below has explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that if I have any medical questions about this research study, I can call **Dr. Hiroshi Mashimo, MD, PhD at** *(857) 364-4327*during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr.Hiroshi Mashimo, MD, PhD at** *(857) 364-4327* during normal working hours.

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

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I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Hiroshi Mashimo, MD, PhD at** *(857) 364-4327 or (857) 203-5640* and **after hours** I can *call the Medical Center operator at (617) 323-7700 and ask for the GI fellow on call.*

I understand that, if at any point during or after this study I have any questions about my rights as a research subject or I want to discuss problems, complaints, concerns, and questions about the research; obtain information; or offer input, I may contact the Research Compliance Officer (857) 364-4182.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Subject's Signature	**Month**	**Day**	**Year**	**Name (print)**
Signature of Person Obtaining Consent	**Month**	**Day**	**Year**	**Name (print)**
Signature of Witness	**Month**	**Day**	**Year**	**Name (print)**

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained.)

VA FORM
JAN 1990 **10-1086**

_____
Subject's Initials

VA Boston IRB # [redacted]
Approved: _____
Expires: