EndoVigilant
with AI

Permission to Take Part in a Human Research Study & HIPAA Authorization for Release of Health Information for Research Purposes

A General information about this form

You may be eligible to take part in a research study. This form will give you important information about why this study is being done, what will happen during the study, the risks and possible benefits. Please read it carefully. After you finish, talk with your physician and ask questions. If you decide that you would like to take part in this study, you will be asked to sign this form and you will be given a copy of the signed form to keep.

B General information about the study and the researchers

B.1 Study title

Impact of use of EndoVigilant Computer Aided Detection (CAD) Software in detection of Adenomatous Polyps during Colonoscopy Procedures

B.2 Company sponsoring this study

EndoVigilant, Inc.

B.3 Name of researchers conducting this study

1. David Siegel, M.D., acting as Principal Investigator for Greenbelt Endoscopy Center
2. Raja M. Din, M.D.
3. Ritu M. Sachdev, M.D.
4. Radman Mostaghim, M.D.

C Purpose of this study

C.1 Why is this study being done?

This study is being done to study the use of EndoVigilant ColonCAD software by gastroenterologists during colonoscopy procedures to determine if it improves detection of adenomatous polyps.

D Information about study participants

D.1 Why am I being asked to take part in study?

You are being asked to take part in this study because you meet the inclusion criteria for this study – patient aged between 22-85 years undergoing routine colonoscopy for screening and/or surveillance purposes.

D.2 How many subjects are expected to enroll in this study?

Up to 200 participants undergoing colonoscopy procedures from one of the aforementioned gastroenterologists are expected to be enrolled from this study.

D.3 If I decide not to join this study, what other options do I have?

Participation in this study is voluntary. You always have the option to not be in this study. You will undergo normal colonoscopy by your gastroenterologist without the involvement and use of EndoVigilant ColonCAD software. Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled.

E Information about study procedures

E.1 What exactly will be done during this study?

1. Colonoscopy will be performed in the standard manner. The video signal from the colonoscope will be fed into a computer running the EndoVigilant software in addition to the standard video output to the procedure monitor.

2. The EndoVigilant software will display an annotated video on an additional monitor that includes both the colonoscopy picture and annotation by the software indicating the location of any polyps on the screen. The EndoVigilant software will not perform a recording of the procedure.
3. The gastroenterologist performing the procedure will therefore be able to observe a standard colonoscopy video on the primary monitor and the annotated video on the second monitor. See picture below.
4. The endoscopist will primarily rely on the second monitor (augmented with annotation from EndoVigilant ColonCAD software) but the standard procedure monitor will be always operational and available for maneuvers such as fast insertion, polypectomy etc.

F Information about risks and benefits

F.1 What risks will I face in this study?

You will not face any additional risks over and beyond what is encountered during a routine colonoscopy procedure that have been already previously discussed with you by your gastroenterologist.

F.2 How can I benefit it I take part in this study? How could others benefit?

The presence and use of EndoVigilant ColonCAD software during the colonoscopy procedure may identify additional adenomatous polyps which the gastroenterologist would have otherwise missed. The gastroenterologist may decide to biopsy and/or remove them based on further analysis.

G Information about the costs

G.1 If I join this study, will it cost me anything?

You do not have to pay anything to be in this study. However, if taking part in this study leads to detection of adenomatous polyps, which may have otherwise been missed, it may lead to added costs for you or your insurance company.

G.2 Will my insurance company or will I be billed for any costs?

You or your insurance company, will be charged for any care that is considered standard of care. You will be responsible for any co-payments and deductibles that are standard for your insurance coverage.

G.3 Will I be paid or reimbursed for anything for taking part in this study?

You will not be paid or provided any other form of compensation at this time or in the future for participating in this study.

G.4 Who could profit or benefit from the study results?

Following gastroenterologists have financial interest in this study. An IRB approved Conflict of Interest Management Plan is put in place to manage any conflict of interests that might arise.

Dr. Ritu M. Sachdev owns stock in the company, is an unpaid advisor to the company sponsoring this study and an immediate family member has significant financial interest in the company sponsoring this study.

Dr. Radman Mostaghim owns stock in the company and is an unpaid advisor to the company sponsoring this study.

H Information about confidentiality

H.1 How will my privacy be protected?

All personally identifiable information about you will be anonymized prior to use in clinical study being performed and any subsequent any publishing or presentation of results which may result after the completion of the study. In order to understand the impact of certain patient specific variables on the results of the study, following personal information may be collected from the electronica medical records maintained at the Greenbelt Endoscopy Center

- Demographic information

- Prior history of polyps including prior colonoscopy procedures

Organizations that may inspect and copy your information for quality assurance and data analysis include:

- Food and Drug Administration (FDA)
- PRIME Review Board (IRB)
- The Sponsor of the research **EndoVIgiliant Inc.** or its agents (monitors, auditors)

I Contact information

I.1 Who can I contact about further information about this study?

If you have general questions,

Contact the following primary investigator or co-investigators members of the research team by contacting Greenbelt Endoscopy Center at (301) 552-1801.

1. David Siegel, M.D., acting as Principal Investigator for Greenbelt Endoscopy Center
2. Raja M. Din, M.D.
3. Ritu M. Sachdev, M.D.
4. Radman Mostaghim, M.D.

I.2 Who can I contact in the event of injury?

The device used for this research is being integrated with existing endoscopy systems in a manner that should not increase risk for injury. Further Information about how risks and complications arising from Colonoscopy procedures are captured in the General Informed Consent provided to you by Greenbelt Endoscopy Center.

I.3 Who can I contact about research subject rights?This research has been reviewed and approved by the PRIME Review Board. You may talk to them at info@primereviewboard.com for any of the following:

- Your questions, concerns, or complaints are not being answered by the investigator or research team.
- You cannot reach the investigator or research team.
- You want to talk to someone besides the investigator or research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

J. General

J.1 What else do I need to know?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

By signing this consent form, you will not be waiving any of your legal rights which you otherwise would have if you were not participating in a research study.

K. HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

This section describes the way that Greenbelt Endoscopy can share your information with the researchers, research team, sponsor, and people with oversight responsibility for this study. The information we are asking to collect, use and share is called Protected Health Information (PHI). PHI is protected by a federal law called the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

The people who see your health information for this research study might not be required to follow HIPAA. It is also possible that anyone who receives your health information may re-release it. Because some of these individuals who receive your health information for this study may not be required by law to keep your information confidential, we cannot guarantee that your

information will not be released or made available to another party once it leaves Greenbelt. Therefore, we will share your information only if necessary for the study and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

K.1 Why am I being asked to sign this form?

You have been asked to participate in this research study. If you sign this Authorization Form, you agree to the use and disclosure of your health information for the research study, as described in this Authorization Form.

K.2 How long will my PHI be used?

This authorization will remain valid with no expiration date unless and until you decide to revoke (take back) this authorization.

K.3 Can I stop my Protected Health Information from being collected and disclosed?

Yes, you may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization *the* investigator and sponsor of the study may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the research study.

To revoke this authorization, you must write or email

Jennifer Sin

Greenbelt Endoscopy Center

9821 Greenbelt Rd #103, Lanham, MD 20706

Jennifer.Sin@greenbelt@endoscopy.com

L. Certificate of consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to discuss the information presented with my physician and have my questions answered to my satisfaction. I consent voluntarily to be a participant in this study.

Printed Name of the Participant _____

Signature of the Participant_____

Printed Name of the Witness_____

Signature of the Witness_____

Printed Name of the Physician Obtaining Consent_____

Signature of the Physician Obtaining Consent_____

Date_____

Subject ID -