VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Visualization of the papilla through use of the NuView device in patients with FAP
Version Date:	07/21/2022
PI:	Dr. Keith L. Obstein

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to take part in this research study because you are undergoing screening related to Familial Adenomatous Polyposis (FAP) and your medical team has recommended you as an excellent candidate for endoscopic visualization of the papilla (the location where your bile duct enters into your small intestine that is susceptible to polyps and cancer). The purpose of this study is for us to evaluate a new device that attaches to the endoscope to allow your physician to visualize your papilla using a single forward facing gastroscope instead of having to use two different endoscopes. This research has the potential to reduce procedure time for future patients, reduce the chance of infection, and to offer a lower cost option for FAP screening.
This study is a low-risk study that involves all of the usually performed steps in the standard of care for patients undergoing a routine gastroscopic examination of the mucosal lining for FAP. The study includes a single investigational step in which the physician will attempt to visualize your papilla by using the investigational NuView end cap. This step will include attaching the NuView to the endoscope and then inserting the endoscope in the standard clinical method to confirm visualization of your papilla. Following this step, the investigational device will be removed from the gastroscope and remainder of your endoscopy will be performed as usual per the standard of care. The exposure to anesthesia will be within the standard of care duration (time period) of an upper endoscopy for screening in patients with FAP.

There will be no additional visits beyond the usual standard of care required for this research and the overall amount of time required for the investigational step is negligible in the course of treatment. Similarly, no additional restrictions or limitations on daily activities due to the investigational step are expected.

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You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Side effects and risks that you can expect if you take part in this study:
There are risks associated with any endoscopic procedure and with Anesthesia (Monitored Anesthesia Care: MAC). These risks are rare (less than 1%) and include but are not limited to bleeding, infection, tissue trauma, stroke, and/or the need for additional surgery. These surgical risks associated with endoscopy and anesthesia are rare and no greater for patients receiving the investigational procedure than for the standard of care procedures.

Additional risks associated with this study are as follows:
Detachments events: *as with any distal endoscope attachment, the device may become detached from the endoscope. This event is expected to be rare (less than 1%) and the only harm expected is a slight delay (45-120 seconds) to in the procedure time as the device is retrieved.*

Sterility: as with any endoscopic procedure, sterility is an important consideration in order to prevent infection. The investigational device has been sterilized prior to use.

Biocompatibility: as with any medical device biocompatibility is important to prevent allergic reactions. The investigational device is made from 100% biocompatible materials that have been tested to ISO 10993-1 standards.

Tissue trauma and device breakages/failures: as with any endoscopic medical device, tissue trauma is a potential safety consideration. The investigational device has been designed to be atraumatic and has undergone verification testing to verify its safety.
Device failures and breakages: as with any medical device there is a potential for device breakages and failures during the procedure. With regard to the investigational device, even if the device does break or fails, the only expected harm would be a slight increase *(45-120 seconds) in procedure time as the device is retrieved and discarded.*

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Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Other Risks:
N/A

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:
Subsequent physicians may benefit from the proposed research by having access in the future to the best potential patient care options, reducing infections, and by having a more cost-effective treatment option available.

Subsequent patients may benefit from the proposed research by having a decreased overall procedure time during FAP examination and by a reduction of potential for tissue damage by decreasing the number of endoscope insertions during the procedure (the investigational device has the potential to eliminate one of the two endoscopes from being used in the standard of care for patients with FAP). Further, wide scale adoption of the investigational device has the potential to reduce costs associated with the procedure.

Procedures to be followed:
The below table outlines the planned study procedures. The procedure will include 1) Informed consent, 2) review of the inclusion/exclusion criteria, 3) review of medical history, 4) a routine pregnancy test for women of childbearing age, 5) gastroscope assessment of tissue, 6) endoscopic validation of the target with the investigational device, 7) endoscopic confirmation of the target using a standard duodenoscope, 8) review of adverse events, and 9) endoscopic post-op NASA/questionnaire completed by the physician.

	Screening	Endoscopic Examination	Follow up
Obtain Informed Consent	X		
Review Inclusion/ Exclusion Criteria	X		
Review Medical History	X		

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Routine Pregnancy Testing (urine or blood)		X[a]	
Gastroscope assessment of tissue		X	
Endoscopic confirmation of target using a standard Duodenoscope		X[b]	
Review Adverse Events		X	X
Endoscopic Post-Op NASA/Questionnaire			X[b]

(a) Performed pre-operatively for women of childbearing potential
(b) The Investigational Step in this study procedure. All other steps within the protocol will be performed per the standard of care

Payments for your time spent taking part in this study or expenses:
You will not be compensated for taking part of this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

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Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator (with input from EndoTheia, Inc.) that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or EndoTheia, Inc. to pay for the costs of any additional care. There are no plans for Vanderbilt or EndoTheia, inc. to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Casey Koza, RN at (615) 875-6642 or Dr. Keith Obstein at (615) 875-5856. If you cannot reach the research staff, please page the study doctor at 615-831-6292.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Participants will be removed from this study if they ask to be removed. Subjects may decline participation at any time by informing Keith Obstein (615-875-5856).

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Confidentiality:
Participants will receive a 3-digit identification number from 001-003 in the order of their enrollment. Patient identification numbers will be linked to their name on a password secured Vanderbilt University Computer only accessible by approved research study staff. The field notes and interview notes taken by any observers will not contain any identifiable information. Any endoscopic video/audio recording will not contain any identifiable information. At the conclusion of the research study, the PI will maintain all the information on a secure, encrypted, Vanderbilt University computer.
Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Obstein (the PI), and his staff will comply with any and

all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:
Information the procedure may be made available to others to use for research. To protect your privacy, we will not release your name.

Study Results:
Results will be shared (upon request) with participants for their respective procedure.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

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How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Time: _____