

THE FOLLOWING WERE APPROVED

INVESTIGATOR: David M. Kastenber MD
132 South 10th Street
Philadelphia, Pennsylvania 19107

BOARD ACTION DATE: 06/05/2015
PANEL: 3
STUDY APPROVAL EXPIRES: 03/18/2016
STUDY NUM: 1154701
WIRB PRO NUM: 20150338
ONLINE TRACKING:
INVEST NUM: 199849
WO NUM: 1-882806-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually
INST. NUM: 15C.273

SPONSOR: GI Solutions, Covidien

PROTOCOL NUM: MA-205 / COVGIC20482

AMD. PRO. NUM:

TITLE:

A Multicenter, Consecutive, Randomized Study to Optimize the Bowel Preparation Regimen for the PillCam COLON 2 Capsule Endoscopy Procedure

APPROVAL INCLUDES:

Investigator

Instructions for Subject in Clinical Study- PillCam Colon 2- Procedure – Prep A - Control #12857510.0 - As Submitted

Instructions for Subject in Clinical Study-PillCam Colon-2 Procedure Prep B - Test #12844729.0 - As Submitted

Protocol (02-02-2015)

Consent Form [IN0]

WIRB APPROVAL IS GRANTED SUBJECT TO:

The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

The Board determined that the device as used in this research study is a non-significant risk device.

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

Thomas Jefferson University, 132 South 10th Street, Philadelphia, Pennsylvania 19107

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.
2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.
3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)

- a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
 - b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB unless other arrangements have been made and approved by WIRB.
 - c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.
4. Enrollment of limited readers and non-readers: unless consent has been waived or the protocol excludes enrollment of limited readers or non-readers, involve an impartial witness in the consent process when enrolling limited or non-readers and document the participation of the impartial witness using the designated signature lines on the WIRB-approved consent form. In the absence of designated signature lines, download the WIRB standard impartial witness form from www.wirb.com.
 5. Obtain pre-approval from WIRB for changes in research.
 6. Obtain pre-approval from WIRB for planned deviations and changes in research activity as follows:
 - If the research is federally funded, conducted under an FWA, or is a clinical investigation of a drug or biologic, then all planned protocol deviations must be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].
 - However, if the research is a clinical investigation of a device and the research is not federally funded and not conducted under an FWA, then only planned protocol deviations that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].

The reason for these different requirements regarding planned protocol deviations is that the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) drug and biologic divisions have adopted the regulatory interpretation that every planned protocol deviation is a change in research that needs prior IRB review and approval before implementation; however, the FDA device division operates under a distinct regulation (See 21 CFR 812.150(a)(4).

Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

7. Report the following information items to the IRB within 5 days:
 - a. New or increased risk
 - b. Protocol deviation that harmed a subject or placed subject at risk of harm
 - c. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
 - d. Audit, inspection, or inquiry by a federal agency
 - e. Written reports of federal agencies (e.g., FDA Form 483)
 - f. Allegation of Noncompliance or Finding of Noncompliance
 - g. Breach of confidentiality
 - h. Unresolved subject complaint
 - i. Suspension or premature termination by the sponsor, investigator, or institution
 - j. Incarceration of a subject in a research study not approved to involve prisoners
 - k. Adverse events or IND safety reports that require a change to the protocol or consent
 - l. State medical board actions
 - m. Unanticipated adverse device effect
 - n. Information where the sponsor requires prompt reporting to the IRB

Information not listed above does not require prompt reporting to WIRB.

Please go to www.wirb.com for complete definitions and forms for reporting.

8. Provide reports to WIRB concerning the progress of the research, when requested.
9. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

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