ALBANY MEDICAL CENTER
COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS
INSTITUTIONAL REVIEW BOARD (IRB)
47 New Scotland Avenue, MC-1, R102 / Albany, NY 12208
Office: (518) 262-5182 or 5181
irboard@mail.amc.edu

Certificate of Approval

IRB Meeting Date: 16-Jan-2018 **Date:** 08-Jan-2018

Submission Type: Initial Application

Review Type: Expedited

Review Decision: Exempt

Date of Approval: 08-Jan-2018

Principal Investigator/Co-Investigators: Sven Hida, MD
Juan Tejada Almonte MD
Nour Parsa MD
Eric Yoon MD
Muhammad Sohail Mansoor MBBS

Title of Research Protocol: Off-label use of lumen opposing metal stent for GI stricture (Exemption 4, collection of de-identified retrospective medical record data, single patient case study) (5043)

Approval Includes:
Case Report

AMC IRB has approved these additional study team members:

AMC IRB has approved the following locations to be used in the research:
Albany Medical College 47 New Scotland Ave, Albany NY 12208 (Main Campus)

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 AMC's IRB review of this research, please contact AMC's Office of Research Affairs.

Sincerely yours,

COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS

Marilyn Fisher, MD, IRB Chair

ALL AMC IRB 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. *If you have any questions regarding applicable laws or principles, hold enrollment and contact the Office of Research Affairs.*
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 participants 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 research conducted at international sites outside the United States and Canada where AMC IRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the AMC IRB approval stamp and regarding certification of translations are not applicable.)
    a. Use only the most current consent form bearing the AMC IRB "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 AMC IRB.
    c. Obtain pre-approval from AMC IRB for use of recruitment materials and other materials provided to subjects.
4. Obtain pre-approval from AMC IRB for changes in research.
5. Obtain pre-approval from AMC IRB for planned deviations and changes in research activity as follows:

    If this research is federally funded or conducted under an FWA, obtain pre-approval from AMC IRB for all planned deviations and changes in research activity, except where necessary to eliminate apparent immediate hazards to the human subjects. OHRP considers all planned protocol deviations to be changes in research that need prior IRB review and approval.

    If this research is **not** federally funded and **not** conducted under an FWA, obtain pre-approval from AMC IRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity, except where necessary to eliminate apparent immediate hazards to the human subjects. FDA has not adopted the policy that all planned protocol deviations are changes in research that need prior IRB review and approval.

    Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.
6. Promptly report to AMC IRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:
    a. Unexpected (in terms of nature, severity or frequency);
    b. Related or possibly related to participation in the research; and
    c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.
7. Provide reports to AMC IRB concerning the progress of the research, when requested.
8. 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 AMC IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from the Office of Research Affairs. These reports must be returned even though your study may not have started.