

THE FOLLOWING WERE APPROVED

INVESTIGATOR: Stephen L. Barrett D.P.M.
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5620 W. Thunderbird
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BOARD ACTION DATE: 01/16/2013
PANEL: 1
STUDY APPROVAL EXPIRES: 12/27/2013
STUDY NUM: 1136491
WIRB PRO NUM: 20122035
INVEST NUM: 179488
WO NUM: 1-759329-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Semi-Annual

SPONSOR: Stephen Barrett, DPM

PROTOCOL NUM: None

AMD. PRO. NUM:

TITLE:

A Prospective Study of Recurrence Risk in Diabetic Foot Ulceration after Nerve Decompression

APPROVAL INCLUDES:

Research Subject Screening Document #10501551.1 - As Submitted
Consent Form [IS0]

WIRB APPROVAL IS GRANTED SUBJECT TO:

RE-CONSENTING INSTRUCTIONS: Subjects currently enrolled are not required to sign the enclosed version(s) of the consent form(s). All subjects who will be enrolled in the future for this study must sign the most current WIRB-approved consent form(s).

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

Thunderbird Internal Medicine, Suite G-2, 5620 W. Thunderbird, Glendale, Arizona 85306
Maria M. Buitrago, D.P.M., M.S., Barrett Foot & Ankle Center, Suite D, 4120 Directors Row, Houston, Texas 77092
Damien Dauphinee, DPM, Complete Foot and Ankle Care of North Texas, PA, Suite 111, 3319 Unicorn Lake Blvd, Denton, Texas 76210
Richard P. Jacoby D.P.M., #202, 7301 E 2nd St., Scottsdale, Arizona 85251
Indiana Foot & Ankle, 645 W, 5th Street, Jasper, Indiana 47546
Southern Arizona Limb Salvage Alliance, Arizona Health Science Center, 1501 N. Campbell Ave., Tucson, Arizona 85724

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. Obtain pre-approval from WIRB for changes in research.
 5. 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.

6. Promptly report to WIRB 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.

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

7. Provide reports to WIRB 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 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:

Contact, Company

HSPP Office Human Subjects Protection Program, The University of Arizona
D. Scott Nickerson, Association's Extremity Nerve Research Foundation
Stephen L Barrett D.P.M., Stephen Barrett, DPM