Western Institutional Review Board®
3535 7th Avenue SW | Olympia, WA 98502-5010
PO Box 12029 | Olympia, WA 98508-2029
Office: (360) 252-2500 | Toll Free: (800) 562-4789
www.wirb.com

Certificate of Approval

THE FOLLOWING WERE APPROVED

INVESTIGATOR: Wayne Drevets M.D.
6655 South Yale Avenue
Tulsa, Oklahoma 74136

BOARD ACTION DATE: 08/22/2011
PANEL: 6
STUDY APPROVAL EXPIRES: 08/05/2012
STUDY NUM: 1126576
WIRB PRO NUM: 20111159
INVEST NUM: 160921
WO NUM: 1-683377-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Semi-Annual

SPONSOR: Laureate Institute for Brain Research (LIBR)
PROTOCOL NUM: 2011-002-00
AMD. PRO. NUM:
TITLE:
MINOCYCLINE AND ASPIRIN IN THE TREATMENT OF BIPOLAR DEPRESSION

APPROVAL INCLUDES:
Subject Information Sheet - Visit Five #9212383.0 - As Submitted
Subject Information Sheet - Visit Four #9212382.0 - As Submitted
Subject Information Sheet - Visit One #9212379.0 - As Submitted
Subject Information Sheet - Visit Six #9212384.0 - As Submitted
Subject Information Sheet - Visit Three #9212381.0 - As Submitted
Subject Information Sheet - Visit Two #9212380.0 - As Submitted
Consent Form [IN1]

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:
Laureate Institute for Brain Research, 6655 South Yale Avenue, Tulsa, Oklahoma 74136
University of Kansas Medical Center Research Institute, 8911 East Orme, Wichita, Kansas 67207

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.

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.

Robert A Taylor RD for

Theodore D. Schultz, J.D., Chairman

8/23/2011
(Date)

This document electronically reviewed and approved by Taylor, Robert on 8/23/2011 1:46:33 PM PST. For more information call Client Services at 1-360-252-2500.

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 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.
    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 this research is federally funded or conducted under an FWA, obtain pre-approval from WIRB 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 WIRB 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 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

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Rebecca Fears, Laureate Institute for Brain Research
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