WIRB®

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Western Institutional Review Board®

Western International Review Board®

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Certificate of Approval

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Harshadkumar Sanghvi
1615 Thames Street, Suite 100
Baltimore, Maryland 21231-3492

BOARD ACTION DATED: 06/06/2003
PANEL: 6
STUDY APPROVAL EXPIRES: 06/13/2004
STUDY NUM: 1039559
WIRB PRO NUM: 20020842
INVEST NUM: 68829
WO NUM: 1-220892-1

SPONSOR: JHPIEGO Corporation
PROTOCOL NUM: 2007 WIRB
AMD. PRO. NUM:
TITLE:
A Safety, Acceptability, Feasibility and Program Effectiveness Study of Community-based Distribution of Misoprostol for Prevention of Postpartum Hemorrhage in Rural Indonesia

APPROVAL INCLUDES:

Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

WIRB APPROVAL IS GRANTED SUBJECT TO:

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). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

William C. Jacobs, Chairman

6/16/2003
(Date)

This document electronically reviewed and approved by Gadde, Ron on 6/16/2003 12:33:54PM 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 as required by the Protocol.

2. Conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

    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 of recruitment materials from WIRB before use.

3. Obtain pre-approval from WIRB of any changes in the research activity (except when necessary to protect human subjects); immediately report to WIRB any such emergency changes for the protection of human subjects.

4. Promptly report to WIRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.

    a. Report to WIRB all adverse events that are serious, unexpected and related, within 10 days of the investigator becoming aware of them. Other unexpected adverse events that involve risks to study subjects or others are to be submitted with continuing review reports.

    b. Provide reports to WIRB concerning the progress of the research, when requested.

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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