

**WIRB**<sup>®</sup>

(360) 252-2500  
FAX: (360) 252-2498  
1-800-562-4789

**Western Institutional Review Board**<sup>®</sup>

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3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010  
P.O. BOX 12029, OLYMPIA, WA 98508-2029

*Certificate  
of  
Approval*

**THE FOLLOWING WERE APPROVED:**

**INVESTIGATOR:** Sherry L. Aliotta BSN, R.N.  
Susan A. Rogers BSN  
19912 Rothert Lane  
Huntington Beach, California 92646

**BOARD ACTION DATED:** 10/04/2005

**PANEL:** 2

**STUDY APPROVAL EXPIRES:** 10/26/2006

**STUDY NUM:** 1061571

**WIRB PRO NUM:** 20041454

**INVEST NUM:** 109270

**WO NUM:** 1-335130-1

**SPONSOR:** Case Management Society of America and Pfizer, Inc.

**PROTOCOL NUM:** CMAG-1

**AMD. PRO. NUM:**

**TITLE:**

CMAG-1 Validation Protocol

**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.**



Theodore D. Schultz, J.D., Chairman

10/11/2005

(Date)

This document electronically reviewed and approved by Reese, Owen on 10/11/2005 4:09:30PM 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. 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.
  - 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.
3. Obtain pre-approval from WIRB for any planned deviations and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Immediately report to WIRB any such emergency changes implemented.
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. Promptly report to WIRB other unanticipated problems involving risks to human subjects or others. These events do not readily fit the formal definition of Adverse Event, but could impact human subject safety and/or rights. Examples include theft of a computer containing private identifiable subject information, or study staff getting ill from inhaling a study agent.
  - c. Provide reports to WIRB concerning the progress of the research, when requested.
5. Report to WIRB any unplanned protocol variance that could adversely affect the safety or welfare of subjects, or the integrity of the research data, within 10 days of becoming aware of the variance. Other unplanned variances may be recorded on a log and submitted with continuing review reports.

**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**

Sherry L. Aliotta BSN, R.N.  
Susan A. Rogers BSN  
Jeanne Boling  
David Day  
Liza Greenberg

**Company Name**

Case Management Society of America (CMSA)  
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Case Management Society of America and Pfizer, Inc.  
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Case Management Society of America (CMSA)

**SITES: If the PI has an obligation to use another IRB for any site listed below 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.**

**Address**

Suite 230, 8201 Cantrell Road, Little Rock, Arkansas 72227