



CONTINUING REVIEW APPLICATION

4/10
12/10

- I. Title of protocol: The National Databank for Rheumatic Disease
- II. Principal Investigator: Frederick Wolfe, MD Phone: 316-263-2125
- III. Associate Investigator(s): N/A Phone: N/A
- IV. Office Research Coordinator or contact person (for IRB) Rebecca Schumacher Phone: 316-263-2125
Address: 1035 N. Emporia, Suite 288, Wichita, KS 67214
- V. Sponsor (if any) or Potential Funding Source: Pfizer, Bristol Myers Squibb, UCB Inc.

- VI. Status:
- Active
- Enrollment closed. Participants are receiving study treatment.
- Enrollment closed. Participants are **not** receiving study treatment. Follow-up involves procedures that would not be done if the patient is followed off-protocol. Explain. _____
- Enrollment closed. Participants are **not** receiving study treatment. Follow-up procedures are the same for patients managed on or off protocol. Study will be terminated.
- Other. Explain. _____

- VII. Number of participants enrolled or records reviewed:
Since the last review: 5,262
Total participants reviewed or records reviewed: 47,798

- VIII. Number of participants dropped from the study since last review: 1,859

- IX. Number of Non-Serious Adverse Events which have occurred since last review: N/A

Respond to following questions in sufficient detail for appropriate review. Upon completion of study or if study is being terminated PROVIDE A FINAL SUMMARY. (Use additional pages if necessary.)

- X. Summarize revisions previously reviewed and approved by IRB.
1. Added Amendment 17 to the NDB protocol with a revised consent form for Amendment 17.

- XI. List revisions not yet reviewed by IRB.

- XII. Synopsis of activities to date (include the progress of the study as compared to the hypothesis). We continue to actively recruit new patients per revisions to Amendment 1, Amendment 8, Amendment 9, Amendment 10, Amendment 11, Amendment 12, Amendment 13, Amendment 14, Amendment 15, Amendment 16 and Amendment 17. Data collection activities continue on a 6-month basis as before. Data analysis is ongoing.

XIII. Summarize adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review: Have unexpected events, toxicities or complications occurred that may indicate a need for change in the protocol or the consent? If yes, explain.
 yes no

XIV. Has information (publications, presentations, etc.) become available since starting the study that indicates a need to revise the study or consent form? If yes, explain.
 yes no

XV. Please submit a copy of the current informed consent document along with any newly proposed document.

I ATTEST THAT THE INFORMATION PROVIDED ABOVE IS TRUE AND ACCURATE.

[Handwritten Signature]

Date 11/22/10

Principal Investigator Signature

IRB REVIEWER RECOMENDATIONS

BENEFIT/RISK: Minimal Risk Less than Minimal Risk More than Minimal Risk
 Approved Conditionally Approved

Reviewer: *J. Kahler ARNP-CNS* Review Date *12/9/10*

VCRMC IRB USE ONLY

Project/Study Approval Continued (Term of Approval: *1 YEAR*)
 Conditionally Approved
Letter attached describing requirements for approval.
 Not Approved
 Deferred
 Project/Study Closed

This is to confirm that the following member(s) of the Institutional Review Board abstained from voting on any submissions for the above mentioned study; _____
Taylor Gill, Pharm.D., Acting Chair, recused herself from the vote.

THIS SIGNIFIES NOTIFICATION OF IRB APPROVAL TO CONTINUE OR CLOSE THE STUDY AS INDICATED ABOVE. If project or study is continued, a renewal notice will be sent to you one month prior to the expiration of the term.

ACTING IRB Chair: *Taylor Gill, Pharm.D.* IRB Mtg. Date *12-10-10*

Consent form version (*4-7-03*)
has been verified as the most
current version on file.
GENERAL CONSENT
S. Scheller 12-1-10