



**REQUEST FOR REVISION/AMENDMENT**

I. Title of Protocol: National Databank for Rheumatic Diseases

II. Principal Investigator: Frederick Wolfe, MD

Phone : 316-263-2125

III. Office Research Coordinator  
or contact person (for IRB): Rebecca Schumacher

Phone : 316-263-2125

Address: 1035 N. Emporia, Suite 230, Wichita, KS 67214

IV. Revision Description:

- Revision to currently approved protocol
- Revision to currently approved consent form
- Other (such as advertisements)

V. Check one:

- This revision *does not* increase risks to participants enrolled in the study.
- This revision *does* increase risks to participants enrolled in the study. (Include explanation in revision description.)

VI. Describe revision request: Addition of Amendment 13 to the NDB protocol with a revised consent form and SLE form for Amendment 13. ARION/NDB/Report methods will be applied to the additional set of patients in Amendment 13.

VII. Attach revised documents (**HIGHLIGHT ALL REVISIONS**)

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

Date 11/9/2005

Principal Investigator Signature

**IRB REVIEWER RECOMENDATIONS**

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

Approved

NOTE TO REVIEWER: PLEASE CONTACT THE IRB STAFF WITH COMMENTS FOR FOLLOW-UP ON OTHER OPTIONS

Conditionally Approve     Disapprove     Defer

Reviewer: \_\_\_\_\_

Review Date 11/18/05

**VCRMC IRB USE ONLY**

- Approved by Expedited Review
- Approved by Full Board Review

**THIS SIGNIFIES NOTIFICATION OF IRB APPROVAL OF THE REVISION DESCRIBED ABOVE.**

- Conditionally Approved**  
Letter attached describing requirements for approval.
- Disapprove**
- Deferred**

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;

N/A

The Board requests to be notified within five working days of any unexpected adverse reaction as a result of the use of this protocol.

IRB Chair:



IRB Mtg. Date

11/15/09