

4.11
09/2017

CONTINUING REVIEW APPLICATION

- I. Protocol Number and Title: The National Databank for Rheumatic Disease, Improving Long Term Outcomes in Arthritis
- II. Principal Investigator: Frederick Wolfe, MD Phone: 316-263-2125
- III. Associate Investigator(s): Kaleb Michaud, PhD Phone: 316-263-2125
- 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: Bristol Myers Squibb, UCB Inc., Pfizer, University of Alabama-Birmingham, Dupuytren's Foundation

VI. Status:

1. Are you requesting permanent closure of this study at this time? Yes _____ No X
2. Study activities, including data review, are complete at this site? Yes _____ No X
3. Is this study still actively recruiting/accruing subjects at this site? Yes X No _____ N/A _____
If No, date recruiting/accruing permanently ceased: _____
OR
Date recruiting/accruing was temporarily suspended _____
4. Is this study still actively collecting data? Yes X No _____
If No, date recruiting/accruing or data collection permanently ceased: _____
OR
Date recruiting/accrual was temporarily suspended _____

COMPLETE SECTION VII or VIII BELOW:

VII. Studies/Projects Involving Interaction with Human Subjects: N/A

- A. Number of Subjects currently being screened but not yet Active: 417
- B. Number of Active Subjects: 1,338
- C. Number of Subjects in Follow-up: 52,908
- D. Number of Subjects Withdrawn from the Study: 19,789
- E. Number of Consented Subjects who Failed Screening: 406
- F. Number of Subjects Who Have Completed the Study: N/A
- A + B + C + D + E + F = Total Number of Consented Subjects: 74,858
- Total Number of Consented Subjects Reported on the Previous Continuing Review Report: 73,103
- Number of Subjects Withdrawn from Study Since the Previous Continuing Review Report: 1,916
- Reason for Withdrawal: Not Interested in Participating, Other Responsibilities, Unable to Participate Due to Health
- Detail Any Subject Complaints: _____

VIII. Retrospective or Prospective Data Collection Studies Involving No Interaction With Human Subjects: N/A

Total Number of Records Reviewed/Accessed to Screen for Inclusion: _____

Total Number of Records Included in Project: _____

IX. List Amendments/Revisions previously submitted, but not yet reviewed by IRB.

X. Provide a brief 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, Amendment 17, Amendment 20, and Amendment 21. Data collection activities continue on a 6-month basis as before. Data analysis is ongoing.

XI. Have unexpected adverse events or unanticipated problems occurred that have indicated a need to change the protocol or consent form? Yes _____ No X

If Yes, explain: _____

XII. Has information (publications, presentations, etc.) become available since starting the study that indicates a need to revise the study or consent form? Yes _____ No X

If Yes, explain: _____

XIV. If the study is open to accrual/actively recruiting or new data is being collected, submit a copy of the current informed consent document. If the study does not have a consent form, check here:

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

Frank W. [Signature]

Date 8/25/2017

Investigator Signature

IRB REVIEWER RECOMENDATIONS

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

Approve to Continue Conditionally Approve to Continue Approve to Permanently Close

If Not a Closure, Term of Approval: One Year Six Months Other: _____

Comments, if any: _____

Reviewer: *Julie Dusek* Review Date 9/6/17

VCH-W IRB USE ONLY

- Project/Study Approval Continued (Term of Approval: One Year)
- Conditionally Approved - See Attached Letter or Note Below.
- 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 PhamD, 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. If project or study is closed, IRB documents for this project will be slated for destruction no less than 3 years from date of last action.

IRB Chair: *Taylor Gill Pham* IRB Mtg. Date 9-8-2017