VIA CHRISTI HOSPITALS WICHITA, INC.
INSTITUTIONAL REVIEW BOARD

APPENDIX D – PAGE 1

4.21
08/2018

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, Eli Lilly, University of Alabama-Birmingham, Dupuytrens 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: 375
B. Number of Active Subjects: 529
C. Number of Subjects in Follow-up: 53,941
D. Number of Subjects Withdrawn from the Study: 20,510
E. Number of Consented Subjects who Failed Screening: 407
F. Number of Subjects Who Have Completed the Study: N/A

A + B + C + D + E + F = Total Number of Consented Subjects: 75,762

Total Number of Consented Subjects Reported on the Previous Continuing Review Report: 74,858

Number of Subjects Withdrawn from Study Since the Previous Continuing Review Report: 721

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.

_____ **Date** 7/26/2018

Investigator Signature

IRB REVIEWER RECOMENDATIONS

BENEFIT/RISK: [X] Less than Minimal Risk [ ] Minimal Risk [ ] More than Minimal Risk

[X] Approve to Continue [ ] Conditionally Approve to Continue [ ] Approve to Permanently Close

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

Comments, if any:_____

Reviewer: Judy Dusek Review Date 8/9/18

VCH-W IRB USE ONLY

- [X] **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, PharmD, 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, PharmD IRB Mtg. Date 8-10-2018