

Ethical Review Committee, Inc.

14400 E. 42nd St., Suite 240

Independence, MO 64055

Phone: 816.421.0008 ♦ Fax: 816.356.2227

Sponsor Continuing Review Report

Date:

RE:

Sponsor:

Dear:

The above referenced clinical trial is due for re-approval in ENTER DATE. The Committee is requesting specific information regarding the ongoing study before they can review the trial for continuation. Please return by ENTER DATE

Please answer the questions below and return this form to our office by the above date so we may prepare for Committee review. (If you are not seeking re-approval, please request and complete the Final Report Form.)

PLEASE ATTACH ADDITIONAL DOCUMENTATION, IF REQUIRED.

1 Enrollment status of the study: [] Opened [] Closed Projected Date of Closure:

Table with 5 columns: SITES, 2, A, B, C, D, 2A+, 2B+, 2C+, 2D+, and a blank column for answers.

Table with 6 columns: SUBJECTS, 3, A, B, C, D, E, F, 3A+, 3B+, 3C+, 3D+, 3E+, 3F+, and a blank column for answers.

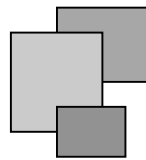
4 Total number of serious adverse events: Please provide a listing of event(s) descriptions.
5 Have there been any protocol revisions or amendments since last review? [] No [] Yes
If yes, list amendments or revisions:
Does the ICF contain all previously approved revisions? If No, please provide explanation. [] No [] Yes
6 Have there been any Safety Reports since the last review? If Yes, please ensure documentation was provided. [] No [] Yes
7 Is there any new information available since the last review? If Yes, please provide documentation. [] No [] Yes
8 Is the study progressing as planned? If No, please provide explanation. [] No [] Yes

Authorized Signature _____ Date ____/____/____

Thank you for providing this information so we may process your request for continuation of this study.

ERC Use Only
[] Expedited [] Full Committee
Complaints Received? [] No [] Yes
ICF Changes Needed? [] No [] Yes

Ethical Review Committee, Inc.
CR Sponsor Report
Version 12/3/08



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SAMPLE CONTINUING REVIEW

Corresponding Answers: 2A = 100 sites 3A = 10 subjects 3D = 10 subjects
 2B = 50 sites 3B = 5 subjects 3E = 20 subjects
 2C = 20 sites 3C = 5 subjects 3F = 50 subjects
 2D = 170 sites

| | Answer | Question # | Question Reads: |
|-------|--------------|-------------|--|
| SITES | 100 | 2A | Number of sites still active <i>(Sites that have subjects on study drug, in follow-up, in recruitment, or pending closure.)</i> |
| | + 50 | + 2B | Number of sites closed |
| | + 20 | + 2C | Number of sites that have IRB approval, but not initiated by Sponsor |
| | = 170 | = 2D | Total number of IRB approved* sites (A+B+C=D) |

| | | | |
|----------|-------------|-------------|--|
| SUBJECTS | 10 | 3A | Total number of subjects active at this time <i>(Subjects on study drug/ completed study drug and in follow-up)</i> |
| | + 5 | + 3B | Total number subjects consented but never started on treatment and/or drug |
| | + 5 | + 3C | Total number of subjects discontinued after treatment began |
| | + 10 | + 3D | Total number of subjects lost to follow-up |
| | + 20 | + 3E | Total number of subjects who have completed the study, <i>including follow-up</i> |
| | = 50 | = 3F | Total number of subjects consented across all sites (A+B+C+D+E=F) |

*Approved sites are those that have received an institutional review board or ethics review committee approval. These terms may be used differently outside the United States. Please use appropriate interpretations.