IRB Continuing Review Form

Principal Investigator:_____

Study Title: _____

_____

Study 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 pt. is followed off- protocol. Explain below.
_____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).

Number of enrollees in *past year* at Institution name: Female____ Male____ Total____

Total number of participants since starting study:

Institution name Female_____ Male_____ Total_____

All sites (if multi-center) Female_____ Male_____ Total_____

Respond to following questions in detail sufficient for appropriate review (use additional pages as needed). If study is being terminated provide a final summary:

1. Summarize revisions previously reviewed and approved by IRB:

2. Summarize revisions not yet reviewed by IRB:

3. Synopsis of activities to date (include the progress of the study as compared to the hypothesis):

4. Have unexpected events, toxicities, or complications occurred that may indicate a need for a change in the protocol or consent? Yes_____ or No_____ If yes, please explain:

5. Has information (publications, presentations, etc.) become available since starting this study that indicate a need to modify this study? Yes_____ or No_____ If yes, please explain:

6. Were any grievances or complaints received about this study?
   Yes_____ or No_____ If yes, please explain:

Signature of PI: _____ Date:_____