Quorum REVIEW IRB

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Site Status Report Checklist
Materials to be Provided by an Investigator for Periodic Site Review

You must return your completed Site Status Report by the date specified on page 1 of the report to allow sufficient time to schedule it for review. **If a Report is not received by the due date, Board approval may expire. A Board finding of continuing noncompliance must be reported to the study Sponsor and FDA.**

❑ Site Status Report

- **You must indicate that you wish to submit for periodic site review and indicate the current study status of your site. If you are submitting for periodic site review the "Site Closure" question on Page 1 should remain unanswered.**
- **Enrollment Section.** All questions in this section must be completed.
- **Yes/No Questions.** All yes/no questions must be completed (except those that are follow-up questions to the previous question and are not applicable to your site) and required supporting documentation is attached.
- **Information and Consent Form(s) Section.** All parts of this section must be completed.
- **Signature and Date.** The Site Status Report does not require a signature if you submit the Report through the OnQ™ Portal and the PI (or designee) printed name and/or title (for designee) are complete. The Site Status Report must be signed and dated by the Principal Investigator (PI) or PI's designee, if the Site Status Report is not submitted by you through the OnQ™ Portal.

❑ Supporting Documentation

- **Letters of Explanation** must be submitted for any questions marked "yes" in the Risk and Benefit, Community and Site Information, Human Research Participant Protection Training, and/or Auditing and Licensing sections.
- **Regulatory agency Audit Documentation** (including all FDA and other regulatory agency audit correspondence and/or 483s issued not yet submitted to Quorum Review) must be submitted for inspections of the Principal Investigator that have occurred during the current approval period.
- **Unreported Serious Adverse Event (SAE), Major Protocol Deviation/Violations (PD), and/or Unanticipated Problems (UP)** involving risk to participants or others not yet submitted to Quorum Review must be submitted. (For definitions and examples of each category please see the "Safety Information and Unanticipated Problems Reporting Guidelines" document on our website.)
- **Updated Curriculum Vitae (CV)** Please submit an updated CV if any information in it relating to clinical research or this study has changed significantly

Please call us at (206) 448-4082 or 1-877-472-9883 if you have any questions. Incomplete or missing documents **will** cause a delay in review of your submission.

Submission Options:

- **Electronically** via Quorum's OnQ™ Portal at www.QuorumReview.com
- **Mail:**

  Quorum Review, Inc.
  1501 Fourth Ave., Ste. 800
  Seattle, WA 98101
- **Fax:** (206) 448-4193

The materials in this packet can be found at http://www.quorumreview.com