Dear Dr. Fischbach:

On May 19, 2015, the renewal for the above-mentioned study was reviewed and approved by expedited review, category #8a, by the Chair of the Columbia University Medical Center Institutional Review Board #2. It is noted that study enrollment is permanently closed, subjects have completed all research related procedures, and the research remains active only for long-term follow-up of subjects.

Important Reminders:
1) It is noted that the Boston Children's Hospital IRB approval expired 1/28/2015. Please provide the most recent IRB approval letter for Boston Children's Hospital to Deirdre Lombardi at dl2971@cumc.columbia.edu.
2) The Data Security section confirms that PHI/PII will be collected and stored on encrypted, password protected endpoint devices. In your next submission, please revise the Confidentiality of Study Data section of the Study Description to state data will be stored on encrypted, password protected endpoint devices.
3) Per the 10/03/2011 renewal, 266 subjects were accrued and completed the study. Please be reminded to update the Subjects section pertaining to enrollment in its entirety in your next submission.
4) As previously noted, the Oversight Monitoring section is incomplete. Though some of the sections may not apply to the study, all fields should be completed at the time of renewal.
5) In your next submission to the IRB, please remove or archive all documents that are inactive, no longer in use or that have been superseded by modifications. Previous versions of these documents will remain in RASCAL with the submission under which they were approved.

Any proposed changes in the protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants. Additionally, any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the CUMC Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy. All submissions for modifications and unanticipated problems must be submitted through RASCAL.

Renewal applications should be submitted 60 days before the expiration date of this study through RASCAL. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including data analysis. You must inform the IRB when your study has been completed via a Closure report in Rascal.

To reduce returns to researchers and IRB review time, the Rascal IRB module has undergone extensive revision. The enhanced module (IRB 2.0) went live on May 31, 2015. At the time of the first submission after the release date (May 31, 2015), all new fields must be completed. As of June 1, 2015, the system will require a substantial number of new fields for the next renewal or modification associated with this protocol. Please direct questions about the new system, or requests for departmental training, to the Human Research Protection Office via email at irboffice@columbia.edu. Details can be found on the IRB website: http://www.cumc.columbia.edu/dept/irb/.

If you have any questions regarding this approval, please call Deirdre Lombardi (212) 305-6485.

Columbia University appreciates your commitment towards the ethical conduct of human research.

Thank you,
Prena Etchen, CIP
Assistant Manager, IRBs 1 & 2