

December 16, 2009

Hi Rick,

The Board approved this study conditionally at the meeting yesterday based on the following conditions:

1. Changes to consent form. I have attached this form with the Board's changes tracked for your review. Please let us know if the changes are accepted.
2. The Board has requested written justification to explain why post-treatment EKGs and labs are not being performed.

If you have any questions regarding the conditions, please feel free to contact me.

Thank you!

[The IRB]