January 8, 2008

Melissa Martinek, DO
PhD Candidate


Dear Dr. Martinek:

The proposed research is eligible for expedited review according to the specifications authorized by 45CFR 46.110 and 21 CFR 56.110. Your revised protocol has been reviewed via expedited procedure by two members of the VCOM IRB. Reviewers had requested clarification regarding the date of implementation of your research. Your email response has satisfactorily clarified that concern and your project has been approved.

Federal guidelines dictate that IRB-approved research must be reviewed no less than once a year. Note that your continuation review will be January 8, 2009. Approximately 30 days before this date, you will receive a Progress Report Form from the IRB Coordinator. Please fill out this report and submit it to the IRB Coordinator at least two weeks prior to your review date.

Please remember that as the PI, you are responsible for promptly reporting to the IRB any proposed changes in the research activity prior to being implemented. You are also responsible for promptly reporting any injuries or adverse events or unanticipated risks to subjects.

Please be advised that the VCOM IRB will be conducting routine audits as a means of ensuring compliance with VCOM and federal policies in an effort to assure the protection of human subjects. Your project may, at any time throughout the approval period, be subject to this type of monitoring.

Thank you for your cooperation. If you have any questions or concerns, please do not hesitate to contact the IRB Coordinator, Sharon Kauffman at skauffman@vcom.vt.edu or 231-4512.

Sincerely,

Hara P. Misra, DVM, PhD
Chairman, VCOM Institutional Review Board