

# Department of Veterans Affairs

## Memorandum

Date: March 23, 2009

From: First Alternate Chair, IRB

Subj: Revisions to Proposal, #09-010, Exacerbating Factors in Inflammatory Bowel Disease

To: Linda Feagins, M.D.

The IRB has received the changes to your proposal and consent form for the study referenced above, as required by the IRB.

2. The changes made to the proposal satisfy the concerns of the IRB, and your study has now been **Approved** for 12 months. The study will be subject to Continuing Review on or before March 1, 2010.
3. The study will now be forwarded to the Research & Development Committee for their consideration. Patients may not be enrolled, and the study is not to be considered fully approved, until the R&D committee has met and granted their approval of the study.
4. When you are ready to begin, a stamped copy of an approved consent form must be used for any new patients enrolled into this study. If you have submitted an electronic copy of the consent form, a stamped version has been sent to you via Email. If paper copies were submitted, please forward to the IRB Administrator an electronic copy of the approved consent form for this study so that the IRB approval stamp may be affixed. All signed Consent Forms for any new patients enrolled into this study must have a current stamp.
5. During the approval period, you should inform the IRB of any adverse events associated with this study, deviations from the approved protocol, requested changes to the consent form, or any other events that might affect the patient's perception of the risks and benefits associated with the study.
6. You will be notified via Email by the IRB Administrator when this approval of the study is nearing expiration.
7. Thank you for your submission.



Jonathan Dowell, M.D.  
First Alternate Chair, IRB