



a. Have you made modifications to the protocol which affect subject treatment?

Yes

No

If yes, have the changes been approved by the IRB?      Yes              No

b. State any changes to the protocol you wish to request at this time:

7. What preliminary findings or evaluations of the study have you received? State both the positive and negative results received at this time.

Attach to this Progress Report a copy of your current consent form and a copy of a memo from your Project Review Panel addressing the following questions:

1. Has the Panel's assessment of the risk-benefit ratio of this project changed? If yes, please explain.
2. Does the Panel have any recommendations regarding the protocol or the consent form?