*Write on department letterhead*

[Insert date letter is written.]

Office of Sponsored Projects

Yale University

25 Science Park-150 Munson Street

P.O. Box 208327

New Haven, CT 06520-8327

**RE: [Insert title of the clinical trial]**

**IRES#: [Insert IRES number here]**

This letter is to certify that the work to be done on the above referenced project, described below, will not involve human subjects until after execution of the clinical trial agreement and IRB approval of the human subject protocol.

The work to be performed prior to execution of the clinical trial agreement and IRB approval will be regulatory document preparation and submission, negotiation of contract and budget, clinical trial management system initiation and management and other general clinical trial activation activities.

We anticipate execution of the clinical trial agreement will occur within ninety days and are planning on submitting/have submitted the IRB protocol (IRB number) on [insert date] and it should be approved by [insert date]

Sincerely,

[Insert PI signature]

[Insert typed name of PI]