



Of those subjects in answer B, did any discontinue for any other reason(s) or were any lost to follow-up?

No  Yes

If yes, you are **required** to identify the subject number and provide a description of the event for each:

**C. How many subjects at your site (to date) are in the screening stage?**

**Answer to C**

**D. How many total subjects at your site (to date) have signed an Informed Consent Form?**

**Answer to D**

Was informed consent obtained from all enrolled subjects prior to performing any study procedures?

No  Yes

If no, please explain:

*Note: No investigator may involve a subject without legally-effective informed consent of the subject or the subject's legally-authorized representative. If this has taken place, you will need to complete the ERC's Protocol Deviations / Violations Report Form.*

**THE FOLLOWING FORMULA MUST WORK-OUT OR YOUR REPORT WILL NOT BE ACCEPTED:**

$$\boxed{\text{Answer to A:}} + \boxed{\text{Answer to B:}} + \boxed{\text{Answer to C:}} = \boxed{\text{Answer to D:}}$$

**What date did the first subject sign their consent form?**

**What date did the last subject complete or discontinue from the study?**

By signing this form, I attest that this study was conducted as directed by the protocol and any variations from or violations to the protocol were reported in writing to the ERC.

**Principal Investigator Original Signature** \_\_\_\_\_ **Date** \_\_\_\_/\_\_\_\_/\_\_\_\_

Upon receipt, this information will be forwarded to the next regularly scheduled meeting of the Ethical Review Committee to be reviewed and recorded. An acknowledgment of receipt will be faxed to your site. File a copy of this completed form, and all documents you receive from the ERC, in your study file.