|  |  |
| --- | --- |
| **PI NAME** |       |
| **STUDY TITLE** |       |

**\* If your research is regulated by the FDA, you cannot use this form.\***

|  |  |
| --- | --- |
| Is this research funded by a federal agency (e.g., NIH, NSF, DoD, etc.)**If yes,** identify the funding agency**:**  | [ ] Yes [ ] No |

**Status of Research (choose one)**

|  |  |  |
| --- | --- | --- |
| **1.** | **[ ]**  | I have not initiated the research and no one has been enrolled. Explain:       |
| **[ ]**  | I will continue to consent and enroll subjects |
| **[ ]**  | I will NOT continue to consent and enroll subjects; however, I am either:* continuing to do research-related interventions with subjects or continuing to obtain/gather data about subjects; **OR**
* accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care; **OR**
* performing data analysis (all subject information has been collected) **Note**: If all data have been permanently de-identified, you may be eligible to close the research but still continue analysis – please review F-12, Research Closure Form.
 |
| **[ ]**  | All research (including data analysis) is complete and the research should be closed. **STOP!** **DO NOT SUBMIT THIS FORM.** Please fill out and submit F-12 Research Closure Form. |
| 2. | Describe the study progress so far, including how many subjects have completed the research, any new information (published or unpublished) or interim findings, and plans for the next year:       |

**Reminders**

This is a reminder that any of the following **MUST** be submitted for review and/or reported to the IRB. If any of these occurred in this review period and have not been reported, please do so ASAP.

* Use F-14 Reportable Information Form to report unanticipated problems involving risk to subjects or others; adverse events; protocol deviations; subject complaints; or independent data and/or safety monitor (such as a DMC, DSMB, etc.)reports.
* Use F-11 Change to Research Protocol to submit for review any revisions to the approved protocol, consent form(s), recruitment materials, or other study documents. Changes must be approved PRIOR to implementation.
* Use F-17 Change to Research Personnel to submit any additions or deletions to research study personnel.

**Principal Investigator Attestation**

|  |
| --- |
| By submitting this form electronically through the IRBNet, you (the Principal Investigator or designee) are certifying the following:* The information contained in this report is true, complete, and accurate to the best of your knowledge;
* The research will be conducted in accordance with applicable laws, regulations, and Baylor University policies and procedures;
* You are aware, as the Principal Investigator, you are ultimately responsible for the conduct of this research and the individuals to whom you delegate research responsibilities.
 |