|  |  |
| --- | --- |
| **Date** |  |
| **IRB Application #** |  |
| **IRB Title** |  |
| **IRB approval Expiration date** |  |
| **PI Name** |  |
| **E-mail** |  |
| **School / Dept** |  |
| **Faculty Sponsor Name** |  |
| **Faculty Sponsor Signature** |  |
| Research Coordinator:  | Date Received:  |
|  | Date approved:  |

1. **Research Activity Status**
2. RENEW IRB application because:

[ ] New subject enrollment still in progress

[ ] Enrollment closed but subjects are still providing data

[ ] Enrollment not yet begun

[ ] Funding has changed

[ ] Other, explain:

1. **Subject Numbers**

|  |  |
| --- | --- |
| 1. No. of subjects approved to complete the research |  |
| 2. No. of subjects enrolled since initial IRB approval |  |
| 3. No. of subjects enrolled since last IRB approval |  |
| 4. No. of subjects actively involved in research projects |  |
| 5. No. of additional subjects needed to complete research |  |

* *NOTE: Attach a note if the above table does not cover how you would like*

*to report the number of subjects in your study.*

1. **Summaries**
2. **Provide a brief summary of the project. Provide the following:**
* **A summary of the purpose of this research activity.**
* **A summary of the procedures.**
* **A description of the subject population(s).**
* **A description of any funding changes as related to this research.**
1. **Provide a summary of the research progress to date.**
* **If you have not yet enrolled subjects, please explain why.**
1. **Adverse Events and Other Problems:**
* *Provide this information about adverse events and/or other issues surrounding non-compliance for the approval period since your last status report by answering the questions below.*
* *If there were no adverse events or other problems, write* ***“None.”***
1. **List the adverse events that were related, non-serious, but unexpected in the table below:**

|  |  |  |
| --- | --- | --- |
| **Event type/description** | **Number of events** | **Number of subjects affected** |
| *EXAMPLE: Nausea* | 3 | 2 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Does the occurrence of any of the adverse events listed above suggest that the risk(s) to subjects are greater than described in your initial IRB application?** [ ] Yes [ ] No [ ] Not applicable
* If yes, provide an explanation:
1. **Other problems (unanticipated problems, protocol violations, protocol deviations)**
2. **Number of complaints:**

**Describe each complaint, and explain how you handled each one.**

1. **Number of subject withdrawals**:

**For each withdrawal, explain:**

* **why the subject chose to withdraw, or**
* **why you withdrew the subject from the research, and/or**
* **how the withdrawal affects your subject enrollment numbers for the past year as well as your overall enrollment totals.**