**Status Report/Continuation/Closure**

**Note: This form should be submitted to the IRB every two years for Exempt Studies, Yearly for Non-Exempt Studies or at the time a study is completed. Projects being reported as “closed” or projects approved prior to January 21, 2019 requesting continuation must also complete page 2 of this form.**

Project Title:

PI Name:

Protocol #:

Submission date of this report:

List all research personnel here:

**Status of Project**

|  |  |  |
| --- | --- | --- |
| [ ]  Ongoing | Enrollment is open |  |
| [ ]  Ongoing | Not enrolling new subjects |
| [ ]  Ongoing | Long term follow up of subjects only |
| [ ]  Ongoing  | All research related interventions are complete; research activities are limited to data analysis |
| [ ]  Completed | Date Project Completed:      If the study is being reported as closed, **please complete page 2 of this form.** |
| [ ]  Not Applicable | Research project cancelled / not started. There is no need to renew protocol. | [ ]  Please check here if project was contingent upon funding that was not received |
| [ ]  Incomplete | Please explain:       |
| [ ]  Pending | Research project not yet started.  | Anticipated start date:       |

**Have there been any Changes in the Protocol Since the last Status report?** (Check One)

|  |
| --- |
| [ ]  No |
| [ ]  Yes, (Includes change in project title or investigators)If yes, please provide a brief overview of the amendment/modifications made to the research since last year, including the date of approval by the IRB. If approval was not obtained by the IRB prior to the implementation of said changes, please provide justification. ***Note- it is not necessary to include the actual modification request form, only a brief overview in narrative form.***       |

**Adverse Events / Problems**

Have there been any adverse events or unanticipated problems involving risks to subjects or others since the last progress report?

[ ]  Yes [ ]  No

If yes, please explain below:

**Please Complete This Page to Report Project Closure**

**Or**

**To request continuing review of studies approved prior to January 21, 2019.**

**Level of Risk** (Check One)

|  |
| --- |
| [ ]  Minimal Risk |
| [ ]  More than minimal risk (and/or the project involves special populations) |

**Updated Information on Protocol**

**1. Describe the objectives of the study:**

**2. Provide the total number of participants enrolled and summarized demographics (e.g. age, gender, occupation, etc, as known) of subjects enrolled since the beginning of the project. If applicable, please include the enrollment date of the first subject:**

**3. How many participants have discontinued participation and why?**

**4. How many subjects have signed consent forms? Have the subjects had any difficulties or problems understanding the consent forms?**

**5. Briefly summarize the study progress, preliminary findings and any recent significant literature in the field relevant to research risks:**

**6. Explain the research plans for the upcoming year:**

**7. Do you plan to enroll additional subjects? If so, approximately how many? Have there been any difficulties in meeting the projected enrollment for this study? If so, why?**

**8. Have there been any complaints received about the research?**

[ ]  Yes [ ]  No

**If yes, please explain below, including how they were handled:**

**Privacy**

Have there been any breaches of privacy/confidentiality involving risks to subjects or others since the last review?

[ ]  Yes [ ]  No

If yes, please explain below: