

Please complete all of the following boxes with respect to any activity that has occurred since IEC/IRB approval of this project. The responses submitted to the requested information and compliance monitoring review of documents or site visit from IRB representative will provide basis for continued approval of your project.

Please note that Incomplete or Inaccurate reports may delay continuing approval.

IRB Approval Expiry Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If exceeded the duration of the study, this project cannot continue and all work on the project must be withheld temporarily. A letter requesting extension must be sent to the IRB for renewal, with justification for approval. Work may resume after receiving approval letter.

Is this protocol still an active study? YES NO

|  |  |
| --- | --- |
| **General Information** | |
| Study Title: |  |
| Principal Investigator: |  |
| IRB Project No: |  |
| Name of Sponsor or Funding agent: |  |
| Department/College: |  |
| Work address: |  |
| Phone: |  |
| Email: |  |

1. **Type of report:**

☐ 6 months

☐ 12 Months

☐ Final Report

☐ Early Termination

Will you be submitting also for a Renewal Application? YES  NO 

|  |  |  |
| --- | --- | --- |
| **STATUS OF THE PROJECT (**Tick, appropriate Box**)**  Enrolment has not begun | |  |
| Actively enrolling subjects  If you have enrolled subjects using a written consent form since the last approval, submit a copy of a signed and dated consent form (pls. redact the name) so we may verify that you are using the correct document version. | |  |
| Enrolment closed on\_\_\_\_\_\_\_\_\_ (insert date)  Subjects are receiving treatment / intervention. | |  |
| Enrolment closed on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(insert date)  The research is permanently closed for enrollment of new subjects.  All subjects have completed all research-related interventions.  The research remains active only for subjects with long-term follow-up. | |  |
| Project NOT YET STARTED (List reasons and date expected to begin). | |  |
| Project ON HOLD (List reasons and date expected to resume). | |  |
| Project TERMINATED before completion (list date and reason project was terminated). | |  |
| Project has not been and will not be conducted (list reason why project not pursued).  Project has been COMPLETED. Date of Completion: | |  |
| Project has been COMPLETED and the remaining research activities are limited to data analysis only. | |  |
| 1. **Initial IRB approval date:** |  | |
| 1. **Date first subject was consented:** |  | |
| 1. **Planned enrollment of last subject by:** |  | |

1. **Submit copy of current consent document (approved on** *\_\_\_\_\_\_\_\_\_. Please also submit the last amended consent form, if applicable*
2. **Have there been any complaints about the research?**

|  |  |
| --- | --- |
| ☐ Yes | ☐ No |

**If yes**, please provide:

|  |
| --- |
|  |

1. **Cumulative number of subjects:**

|  |  |  |
| --- | --- | --- |
| **Study Status** | **Total No.** | **Current** |
| 1. Sample size as approved by IRB |  |  |
| 1. Consented |  |  |
| 1. Screen failures |  |  |
| 1. Allocated to study treatment |  |  |
| 1. Dropped / Withdrawn |  |  |
| 1. Completed |  |  |
| 7. Continuing |  |  |

Use comments section to:

1) Explain any changes in number specified by protocol/contract.

2) List reason(s) for dropped/withdrawn subjects during this report interval.

1. **Activities since last report**

|  |  |  |
| --- | --- | --- |
| * 1. New advertisements / recruiting materials | ☐ Yes | ☐ No |
| * 1. Major protocol deviations | ☐ Yes | ☐ No |
| * 1. Protocol amendments | ☐ Yes | ☐ No |
| * 1. Change of principal investigator | ☐ Yes | ☐ No |
| * 1. Change in other study staff | ☐ Yes | ☐ No |
| * 1. Serious adverse events at your site | ☐ Yes | ☐ No |
| * 1. Unexpected adverse events at your site | ☐ Yes | ☐ No |

**NOTE:** ***Any yes answers should have been reflected by an appropriate submission to the KSU-REC at the time of their occurrence. Please assure all required information has been provided to the KSU- REC.***

|  |  |  |
| --- | --- | --- |
| * 1. Minor protocol deviations:   A minor deviation is one that does not impact subject safety, compromise the integrity of the study data, or affect subjects' willingness to participate in the study) | ☐ Yes | ☐ No |
| ***If yes please summarize*** |  | |

1. **Specific risk considerations. Questions relate to events since previous report, if applicable.\***

|  |  |  |
| --- | --- | --- |
| 1. Were there any unanticipated problems involving risk to subjects or others (e.g., greater AE/SAE incidence that expected, breach of confidentiality, or cost to subject)? | ☐ Yes | ☐ No |
| ***If yes please Explain.*** |  | |
| 1. Has any information been provided to subjects that might affect their willingness to stay in the study? | ☐ Yes | ☐ No |
| ***If yes please Explain.*** |  | |
| 1. Have any subjects sought compensation for research-related injury or made complaints regarding the conduct of the study? | ☐ Yes | ☐ No |
| ***If yes please Explain.*** |  | |
| 1. Has anything occurred in the study that you believe might alter the study’s original risk/benefit status? | ☐ Yes | ☐ No |
| ***If yes please Explain.*** |  | |

|  |  |  |
| --- | --- | --- |
| 1. **Have any subjects been recruited from vulnerable groups since the last report?** | ☐ Yes | ☐ No |

If **yes**, check all that apply:

|  |  |
| --- | --- |
| ☐ abortuses  ☐ AIDS/HIV patients  ☐ children  ☐ cognitively impaired  ☐ elderly  ☐ institutionalized (not prisoners)  ☐ fetuses  ☐ in-vitro fertilization | ☐ KSU employees or students  ☐ minorities  ☐ physically disabled  ☐ pregnant women  ☐ prisoners  ☐ other: |

|  |  |  |
| --- | --- | --- |
| 1. **If study was terminated, specify reason.** | ☐ Yes | ☐ No |

1. **PROGRESS REPORT SUMMARY** - Describe the progress of the study over the past approval and its current status and address the following:

• Progress towards achieving research objectives.

• Barriers to meeting research objectives and strategies applied to overcome barriers.

• Likelihood of meeting original timelines.

• If this is a Final Report, attach a copy of the abstract.

|  |
| --- |
| **Principal Investigator Certification.**  As a condition of continuing approval, I certify that the above research project and protocol has been and will be conducted in full compliance with all Federal Regulations and KSU-IRB policies governing human subject research.  I assert that, the information in this report is accurate. Any changes in the research activity, research proposal and consent forms must be approved by the IRB prior to implementation, and that all serious adverse events must be reported to the IRB.  I certify that I have thoroughly reviewed the information provided on this report form. I also certify that the information provided is true and accurate.  Principal Investigator Name & Signature Date |

*For more information, please visit the website of the Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm\_Policies*)*