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| --- |
| 1. **General Information**
 |
| **IRB Log No.** |       |
| **Study Title:** |       |
| **Protocol Number:** |       |
| **Sponsor:** |       |
| **Principal Investigator:** |       |
| **Email:** |       | **Telephone:** |       |
|  |
| 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’s Signature** | **Date** | **Stamp** |
|  |
| 1. **Type of Report**
 |
| [ ]  Interim | [ ]  6-Monthly Progress Report |
| [ ]  Continuing Review | [ ]  Annual Progress Report |
| [ ]  Final |  |
| * Date of final contact with last study subject:
 |       |
| * Are any subjects still participating in the study, including follow-up or subjects being followed until death for survival analysis?
 | [ ]  Yes [ ]  NoIf YES, this cannot be a final report! |
|  |  |  |
| 1. **Provide a brief summary of the progress of the study.**
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|  |
|       |
|  |  |  |
| 1. **Review Category**
 |
| This project qualifies for: | [ ]  **Expedited** Review (**please select from list**) [ ]  **Full** Review |
| **Research was originally reviewed and approved under expedited review:** | [ ]  Yes | [ ]  No |
| **Expedited Category 8:** |  |
| **Expedited Category 8A:** The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; **and,** the research remains active only for long-term follow-up of subjects. | [ ]  Yes | [ ]  No |
| **Expedited Category 8B:** No subjects have been enrolled and no additional risks have been identified. | [ ]  Yes | [ ]  No |
| **Expedited Category 8C:** The remaining research activities are limited to data analysis only. | [ ]  Yes | [ ]  No |
|  |
| 1. **Initial IRB approval on:**
 |       |
| 1. **Date first subject was consented:**
 |       |
| 1. **Planned enrollment of last subject by:**
 |       |
| 1. **Submit copy of current consent document (approved on**       )
 |
| 1. **Have there been any complaints about the research? \***

**\*** If **YES**, please explain. | [ ]  Yes | [ ]  No |
|       |
|  |
| 1. **Cumulative number of subjects**
 |
| **Study Stage \*** | **Protocol** | **Extension** |
| **Previous Report** | **Current** | **Previous Report** | **Current** |
| 1. Specified by protocol/contract
 |       |       |       |       |
| 1. Consented
 |       |       |       |       |
| 1. Screen failures
 |       |       |       |       |
| 1. Allocated to study treatment
 |       |       |       |       |
| 1. Dropped/Withdrawn **\***
 |       |       |       |       |
| 1. Completed
 |       |       |       |       |
| Continuing (7=4-5-6) |       |       |       |       |
| **\*** 1. Explain any changes in number specified by protocol/contract.2. List reason(s) for dropped/withdrawn subjects during this report interval. |
| **Comments:** |
|       |
|  |
| 1. **Demographics of consented subjects**
 |
|  |
| Gender |       | Male |       | Female |
| Origin \* |       | Saudi Arabia |       | Middle East |
| Not Applicable | [ ]  | Africa |       | Central Asia |
| Data Not Available | [ ]  | Philippines |       | Other |
|  |
| 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
 | [ ]  YesNumber:       | [ ]  No |
| 1. Unexpected adverse events at your site
 | [ ]  YesNumber:       | [ ]  No |
| 1. Serious/unexpected adverse events reported by sponsor [ ]  N/A
 | [ ]  YesNumber:       | [ ]  No |
| **NOTE:** Any **YES** answers should have been reflected by an appropriate submission to the IRB at the time of their occurrence. Please assure all required information has been provided to the IRB. |
| 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). (Please summarize if **YES**.)
 | [ ]  Yes | [ ]  No |
| **Comments:**       |

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| 1. **Specific risk considerations. Questions relate to events since previous report, if applicable. \***
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|  |
| 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 |
| 1. Has any information been provided to subjects that might affect their willingness to stay in the study?
 | [ ]  Yes | [ ]  No |
| 1. Have any subjects sought compensation for research-related injury or made complaints regarding the conduct of the study?
 | [ ]  Yes | [ ]  No |
| 1. Has anything occurred in the study that you believe might alter the study’s original risk/benefit status?
 | [ ]  Yes | [ ]  No |
| **\* Explain any “YES” answers.** |
| **Comments:** |
|       |
|  |
| 1. **Have any subjects been recruited from vulnerable groups since the last report?**
 | [ ]  Yes | [ ]  No |
|  |
| **If YES, check all that apply.** |
| [ ]  abortuses | [ ]  KFMC employees or students |
| [ ]  AIDS/HIV patients | [ ]  minorities |
| [ ]  children | [ ]  elderly |
| [ ]  cognitively impaired | [ ]  physically disabled |
| [ ]  institutionalized (not prisoners) | [ ]  pregnant women |
| [ ]  fetuses | [ ]  prisoners |
| [ ]  in-vitro fertilization | [ ]  other (please specify):       |
|  |
| 1. **For IRB Action**
 |
|  |
| **Section** | **Comment** |
|       |       |
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