|  |  |  |  |
| --- | --- | --- | --- |
| C:\Users\Admin\Desktop\LOGO SEAL.png | C:\Users\Admin\Desktop\CIM CVGH.png | C:\Users\Admin\Desktop\cebu velez 07222011_20110721214530_10.JPG | **PROGRESS REPORT**  **FORM** |
| **I INSTITUTIONAL REVIEW BOARD**  **79 F. RAMOS ST., CEBU CITY**  **Tel. 253-7413 Fax. (63-32) 253-9127** | |  | **FORM 4.2** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IRB REFERENCE NO.** | | |  |  |  |  | **-** |  |  | **-** |  |  |
| **PRINCIPAL INVESTIGATOR (P.I.)** | **SPONSOR** | | | | | **DATE SUBMITTED** | | | | | | |
|  |  | | | | |  | | | | | | |
| **INSTITUTION:** | **P.I. CONTACT NO.** | | | | | **P.I. EMAILL ADDRESS** | | | | | | |
|  |  | | | | |  | | | | | | |
| **TITLE** | | | | | | | | | | | | |
| 1. ACTION REQUESTED:    * Renew - New participant accrual to continue    * Renew - Enrolled participant follow up only    * Terminate - Protocol discontinued 2. AMENDMENTS SINCE THE LAST REVIEW?    * NO    * YES (Describe briefly in attached narrative) 3. PROTOCOL PARTICIPANTS SUMMARY:   Accrual ceiling set by IRB  New participants accrued since last review  Total participants accrued since protocol began  Number of participants who are lost to follow up  Number of participants who experienced SAEs/SUSARs   1. ACCRUAL EXCLUSIONS    * NONE    * MALE    * FEMALE    * OTHER (specify):\_ 2. IMPAIRED PARTICIPANTS    * None    * Physically    * Cognitively    * Both 3. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?    * NO    * YES (Explain changes in attached narrative) 4. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?    * NO    * YES (Explain changes in attached narrative) 5. CHANGE IN PRINCIPAL INVESTIGATOR?    * NONE    * DELETE:   ADD: | | 1. IS THERE NEW INFORMATION FROM SIMILAR RESEARCH THAT MIGHT AFFECT THE RISK/BENEFIT RATIO OF THE HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?    * NO    * YES (Discuss in the attached narrative)   10. HAVE ANY UNEXPECTED COMPLICATIONS OR ADVERSE EVENTS BEEN NOTED SINCE LAST REVIEW?   * + NO   + YES (Discuss in the attached narrative)  1. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?    * NO    * YES (Discuss in the attached narrative) 2. HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?    * NO    * YES (Identify all changes in the attached narrative) 3. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?    * NO    * YES (Identify all changes and provide an explanation of changes in the attached narrative) 4. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?    * NO    * YES (Append a statement of disclosure) 5. WERE THERE PROTOCOL DEVIATION/ VIOLATION REPORTS?    * NO   YES (Summarize and what corrective actions were taken) | | | | | | | | | | |