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| C:\Users\Admin\Desktop\LOGO SEAL.png | C:\Users\Admin\Desktop\CIM CVGH.png | C:\Users\Admin\Desktop\cebu velez 07222011_20110721214530_10.JPG | **ICF EVALUATION FORM** |
| **I INSTITUTIONAL REVIEW BOARD****79 F. RAMOS ST., CEBU CITY****Tel. 253-7413 Fax. (63-32) 253-9127** |  | **FORM 2.4** |

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| **IRB REFERENCE NO.** |  |  |  |  | **-** |  |  | **-** |  |  |
| **PRINCIPAL INVESTIGATOR (P.I.)** | **SPONSOR** | **DATE OF REVIEW** |
|  |  |  |
| **PROTOCOL NO. & TITLE** |
|  |
| **PRIMARY REVIEWER** |
|  |
| **QUESTIONS** |  |  | **Comments** | **Recommendations** |
| 1. Is there a statement saying the study involves research?
 | Y🗖 | N🗖 |  |  |
| 1. Is the purpose of the trial clearly stated?
 | Y🗖 | N🗖 |  |  |
| 1. Is there an explanation to the subjects why they were included in the study?
 | Y🗖 | N🗖 |  |  |
| 1. Are there provisions ensuring that the subject’s participation in the trial is voluntary?
 | Y🗖 | N🗖 |  |  |
| 1. Is the subject well-informed of his/her responsibilities?

(*This includes providing health information including symptoms or any changes made in her regimen.)* | Y🗖 | N🗖 |  |  |
| 1. Is the language and presentation of the information to be conveyed appropriate to the subject population? *(Consider the level of complexity and the need for translation into a language other than English.)*
 | Y🗖 | N🗖 |  |  |
| 1. For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained?
 | Y🗖 | N🗖 |  |  |
| 1. Is the expected duration of the subject’s participation in the trial specified?
 | Y🗖 | N🗖 |  |  |
| 1. Is the approximate number of study subject stated?
 | Y🗖 | N🗖 |  |  |
| 1. For experimental studies is the nature of the experiment explained well?
 | Y🗖 | N🗖 |  |  |
| 1. For studies using placebo is the use of placebo ethically applicable?
 | Y🗖 | N🗖 |  |  |
| 1. Is detailed explanation of the procedures or tests that are new or not widely used or combinations/doses of drugs never tested before provided to the subject?
 | Y🗖 | N🗖 |  |  |
| 1. Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits?
 | Y🗖 | N🗖 |  |  |
| 1. Are the risks to the study participants disclosed?
 | Y🗖 | N🗖 |  |  |
| 1. Are the potential adverse events disclosed?
 | Y🗖 | N🗖 |  |  |
| 1. Are the possible benefits to the participants discussed?
 | Y🗖 | N🗖 |  |  |
| 1. Are the potential benefit to the Community discussed?
2. Are there lists of alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks?
 | Y🗖 | N🗖 |  |  |
| 1. Are these any anticipated expenses to the subject in the course of the study?
 | Y🗖 | N🗖 |  |  |
| 1. Is there a compensation and/or treatment available to the subject in the event of trial-related injury?

Is there a person to contact in the event of trial-related injury? | Y🗖Y🗖 | N🗖N🗖 |  |  |
| 1. Is there a person to contact for further information regarding the trial and the rights of the trial subjects?
 | Y🗖 | N🗖 |  |  |
| 1. Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?
 | Y🗖 | N🗖 |  |  |
| 1. Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?
 | Y🗖 | N🗖 |  |  |
| 1. Will the subject or the subject’s legally acceptable representative (LAR) be informed, in a timely manner, of any new available information which may be relevant to the subject’s willingness to continue his/her participation?
 | Y🗖 | N🗖 |  |  |
| 1. Is the subject informed of his right to refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled?
 | Y🗖 | N🗖 |  |  |
| 1. Is the subject informed of any foreseeable events and or reasons which may cause his/her participation in the trial to be terminated?
 | Y🗖 | N🗖 |  |  |
| 1. In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?
 | Y🗖 | N🗖 |  |  |
| 1. Are the withdrawal criteria made known to the subject?
 | Y🗖 | N🗖 |  |  |
| 1. If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?
 | Y🗖 | N🗖 |  |  |
| 1. Are there provisions for medical / psychosocial support if applicable?
 | Y🗖 | N🗖 |  |  |
| 1. Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy?
* Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion?
* If privacy is to be invaded, does the importance of the research objective justify the intrusion?
* What if anything, will the subject be told later?
 | Y🗖 | N🗖 |  |  |
| 1. Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? (Unexpected results may raise the possibility of unanticipated risks to subjects)
 | Y🗖 | N🗖 |  |  |
| 1. Is there a provision allowing consent from the subject for other monitors/ auditors/ IRB/IEC access to the subject’s original medical record for verification purposes?
 | Y🗖 | N🗖 |  |  |
| 1. Are the records identifying the subject kept confidential and to the extent permitted by the applicable laws and/or regulations, not made available in public?
* Should the trial be published, will the subject’s identity remain confidential?
 | Y🗖Y🗖 | N🗖N🗖 |  |  |
| 1. For genetic studies is there a discussion on the precautions in place to prevent disclosure of results without the subject’s permission
 | Y🗖 | N🗖 |  |  |
| 1. Is the subject informed of the possible direct or secondary use of subject’s medical records & biological specimen in the course of clinical care
 | Y🗖 | N🗖 |  |  |
| 1. Are plans in place to destroy collected biological specimen at the end of the study or details of storage and possible future discussed with the patient?
 | Y🗖 | N🗖 |  |  |
| Recommendations: 🗖 Approve 🗖 Minor Modifications 🗖 Major Modifications 🗖 Disapprove |
| Primary Reviewer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name & Signature / Date |