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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 | **PROTOCOL EVALUATION**  **FORM** |
| **I INSTITUTIONAL REVIEW BOARD**  **79 F. RAMOS ST., CEBU CITY**  **Tel. 253-7413 Fax. (63-32) 253-9127** | |  | **FORM 2.3** |

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| **IRB REFERENCE NO.** | | |  |  |  |  | | **-** |  |  | **-** |  |  |
| **PRINCIPAL INVESTIGATOR (P.I.)** | | **SPONSOR** | | | | | **DATE OF REVIEW** | | | | | | |
|  | |  | | | | |  | | | | | | |
| **CATEGORY OF THE INVESTIGATOR:** | | | | | | | | | | | | | |
| * CIM Faculty * CIM students Year Level \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Residents-in-Training \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | * Fellows -in-training \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | |
| **P.I. CONTACT NO.** |  | **EMAIL-ADDRESS** |  | | | | | | | | | | |
| **PROTOCOL NO. & TITLE** | | | | | | | | | | | | | |
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| **QUESTIONS** |  |  |  | **Recommendations** |
| 1. Are the objectives clear? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is there a need for human participants?  * Are the subjects vulnerable? (if yes- for full Board review) | Y🗖 | N🗖 | N.A.🗖 |  |
| Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is there an informed consent? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the background information sufficient? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the study design appropriate for the objectives? | Y🗖 | N 🗖 | N.A.🗖 |  |
| * Are the control arms appropriate? (for clinical trials) | Y🗖 | N 🗖 | N.A.🗖 |  |
| 1. Is the approximate number of subjects involved in the trial specified? | Y🗖 | N🗖 | N.A.🗖 |  |
| * Are the inclusion criteria appropriate? | Y🗖 | N 🗖 | N.A.🗖 |  |
| * Is the proposed subject population appropriate for the nature of the research? | Y🗖 | N 🗖 | N.A.🗖 |  |
| * Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation? | Y🗖 | N🗖 | N.A.🗖 |  |
| * Are the exclusion criteria appropriate? | Y🗖 | N 🗖 | N.A.🗖 |  |
| * Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the setting of the study clearly identified? | Y🗖 | N🗖 | N.A.🗖 |  |
| * Are the facilities and infrastructure of the participating sites adequate | Y🗖 | N🗖 | N.A.🗖 |  |
| * Is the duration of the study specified? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Are the procedures to be done in the study clearly described and understandable? | Y🗖 | N🗖 | N.A.🗖 |  |
| * Are blood/tissue samples sent abroad? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Are research data recorded and maintained with strict confidentiality? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the principal investigator competent to do the study? (by training, expertise or subspecialization) | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the principal investigator assessed for any Conflict of Interest for this study? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the mechanism for providing information to the IRB if unexpected results are discovered appropriate? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Has due care been used to minimize risks and maximize the likelihood of benefits? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Are the subjects given incentives or compensation for study-related expenses? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Are there adequate provisions for a continuing reassessment of the balance between risks and benefits? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Is the research expected to have an impact on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study? | Y🗖 | N🗖 | N.A.🗖 |  |
| 1. Does the institution have a data and safety monitoring board? | Y🗖 | N🗖 | N.A.🗖 |  |
| If so, should it be asked to monitor the project under review? | Y🗖 | N🗖 | N.A.🗖 |  |
| If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project? | Y🗖 | N🗖 | N.A.🗖 |  |
| Recommendations:     Approve   Minor Modifications   Major Modifications   Disapprove   Others  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Primary Reviewer    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name & Signature / Date | | | | |