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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** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |