|  |  |  |  |
| --- | --- | --- | --- |
| C:\Users\Admin\Desktop\LOGO SEAL.png | C:\Users\Admin\Desktop\CIM CVGH.png | C:\Users\Admin\Desktop\cebu velez 07222011_20110721214530_10.JPG | **WAIVER OF INFORMED CONSENT** |
| **I INSTITUTIONAL REVIEW BOARD****79 F. RAMOS ST., CEBU CITY****Tel. 253-7413 Fax. (63-32) 253-9127** |  | **FORM 2.1A** |

**Waiver of Informed Consent Form**

 **Requested for the following Protocol:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IRB ref No.** |  |  |  |  | **-** |  |  | **-** |  |  |  |  |  |
|  |  |  |  |  |
| **Protocol Title:** |  |
| **Principal Investigator:** |  |

**To be filled up by CIMCVGH IRB lay representative/non medical members**

**Please tick as appropriate:**

* The research presents no more than minimal risk; including archival research involving publicly available documents that it is impractical to get an informed consent
* The waiver or amendment will not adversely affect the rights and welfare of the participants.
* The research cannot be practicably carried out without the waiver.
* The participants will be provided with additional pertinent information after their participation (debriefing whenever appropriate).
* Research that uses the method of naturalistic observation (often described as “covert” method) in data collection if all the following requirements are complied with:
	+ - Thorough justification for the use of naturalistic observation;
		- There is a plan for how the data collected will be used;
		- There is an assurance that risks to participants are unlikely;
		- There is an existing mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).

Recommended IRB Decisions:

* Approved
* Disapproved

Chair IRB: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Application for waiving an informed consent**:

A waiver of Informed consent should be applied for in writing by the Investigator addressed to the IRB. Informed consents may be waived only with the CIMCVGH IRB’S written consent.

**The informed consent process may be waived in specific research contexts, such as:**

* Archival research involving publicly available documents that it is impractical to get an informed consent
* Research that uses the method of naturalistic observation (often described as “covert” method) in data collection if all the following requirements are complied with:
	1. Thorough justification for the use of naturalistic observation;
	2. Plan for how the data collected will be used;
	3. Assurance that risks to participants are unlikely;
	4. There is an existing mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).

Some or all the elements in the informed consent may be waived or amended (with prior approval of the REC) if all the following conditions are met:

1. The research presents no more than minimal risk.
2. The waiver or amendment will not adversely affect the rights and welfare of the participants.
3. The research cannot be practicably carried out without the waiver or alteration.
4. The participants will be provided with additional pertinent information after their participation (debriefing whenever appropriate).