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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 | **INFORMED****CONSENT** **TEMPLATE** |
| **I INSTITUTIONAL REVIEW BOARD****79 F. RAMOS ST., CEBU CITY****Tel. 253-7413 Fax. (63-32) 253-9127** |  | **FORM 2.6** |

**[Title of Study]**

**Introduction**

You are invited to participate in a research study conducted by [PI name or names], a [title] in [the Department Name] at Cebu Institute of Medicine OR Cebu Velez General Hospital. The purpose of this research is to [describe the purpose of the study in lay terms]. Your participation is entirely voluntary.

This form includes detailed information on the research to help you decide whether to participate. Please read it carefully and ask any questions you have before you agree to participate.

**Procedures**

Your participation will involve [please give a detailed description of what participants will be asked to do, taking care to use easily understandable terms. Ensure that you include a task-by-task and total time estimate (e.g. “you will participate in three separate surveys which should each take 15 minutes. Your total participation in this project is expected to be 45 minutes”)]. If you agree to participate, the researchers will also collect [discuss any data about the participant that you will gather that you are not receiving directly from them, as well as the source (e.g. “collect information about your ACT scores, high school GPA, college major, and completed courses from the Registrar’s Office at your institution”)]. We anticipate that [#] people will participate in this research study [at this site, and that a total of # people will participate among all # sites]. *Bracketed information in that last sentence is only required if this is a multi-site study.*

*If your procedures are experimental or making use of waitlists, you must identify exactly which procedures are experimental and/or the probability of being placed in a control/waitlist group. If you do not want to reveal all of those details to your participants, please be sure that you apply for an alteration of the requirements for informed consent, which allows you to reveal those details later if all of the appropriate criteria are met.*

*If you collected screening information prior to obtaining informed consent, please include this paragraph, indicating what you will do with that data, e.g.* Before you read this form, [you responded to some questions regarding *eligibility description* OR we collected information from *third party/system* regarding your eligibility for this study, including *list information you collected here*. Researchers will [maintain/destroy] that data once you agree to enter the full study.

*If your study deals with biospecimens, you must include the following information; you may delete this paragraph otherwise.* The study team [will/will not] return clinically relevant information to you. *If you will return clinically relevant research results, you must describe the circumstances under which you will do so (e.g. participants scoring less than X will discuss their results with the research team and be encouraged to seek additional medical care).* This research [will/will not] include whole genome sequencing.

*If your procedures are experimental or require you to interface with participants and non-participants in the same setting, please include this header. If not, you may delete the entire Alternative Procedures subsection.* **Alternative Procedures**

Rather than participate in this research, you might prefer alternatives such as [list any appropriate alternatives here].

**Risks**

This is a minimal risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities. **OR** This study is greater than minimal risk, meaning that the risks are [slightly/significantly] higher than those you encounter in everyday activities. The foreseeable risks or discomforts include [list all foreseeable risks here, and ensure it is consistent with the prompt in your protocol, recalling that loss of confidentiality is nearly always a risk in research studies]. In order to minimize those risks and discomforts, the researchers will [list what the research team is doing to minimize those risks, and ensure it is consistent with the prompt in your protocol]. [*If the nature of the research is experimental and you believe it carries unforeseeable risks, please add this phrase:* This research may involve risks that are not yet known.] If you have a bad research-related experience, please [contact PERSON]. *If your protocol is greater than minimal risk, you must explicitly state whether compensation and/or medical treatment is available if there is an injury and where to go or who to contact for compensation/treatment. For greater than minimal risk protocols or if you feel it is applicable*: If you are injured in any way, [compensation/medical treatment] [is/is not] available. Please [contact PERSON/go to RESOURCE] immediately if you are injured so that further information can be provided.

*If physical injury or mental health risks are present, please add a sentence stating whether and the extent to which the research-related injuries will receive treatment from the research team or from the research team’s resources.*

**Benefits**

Although you will not directly benefit from this study, it has been designed to learn more about [insert purpose or topic]. **OR** Participation in this study may directly benefit you by [list benefits, e.g. “exposing you to a math intervention that has helped others”]. We cannot guarantee that you will directly benefit from this study [but it has been designed to learn more about *insert purpose or topic]*. *Please note that it is incredibly common not to have direct benefits to participants, so please do not go out of your way to overstate direct benefits.*

**Confidentiality**

The researchers will make every effort to ensure that the information you provide as part of this study remains confidential. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. [However, it may be possible for someone to recognize your particular story/situation/response (particularly applicable in focus group/ethnographic/oral history research projects).] *If you are doing research in a group setting, please add a statement that:* While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.

We will collect your information through [video recordings, audio recordings, interviews, email… whatever mechanism(s) you are using to collect it, including indirect ones like seeking the information from a third party]. *If you will collect or store data online,* Online activities always carry a risk of a data breach, but we will use systems and processes that minimize breach opportunities. [This information or Data] will be securely stored [in a restricted-access folder, an encrypted, cloud-based storage system [and/or] in a locked drawer in a restricted-access office. *If you have data where identifiers can be separated and destroyed, please state the timeframe for doing so. If your data is necessarily identifying (e.g. videos, extensive demographic data, etc.) please state the timeframe for destruction of that data and what, if anything, will be kept.* This form will be kept for three years *three is the minimum* after the study is complete, and then it will be destroyed.

It is unlikely, but possible, that others (Cebu Institute of Medicine, [funding sponsor,] or government officials) may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

**Voluntary Participation & Withdrawal**

Your participation in this research is completely voluntary. If you agree to participate now and change your mind later, you may withdraw at any time by [please provide instructions on how a participant should withdraw once they have initiated research participation]. If you choose to withdraw after we have already collected information about you, [state what you will do with that information, or the extent to which withdrawal is possible (e.g. completely anonymous participation cannot be withdrawn, as you will be unable to determine whose data is whose)]. *If participant is already or may in the future receive services from your clinic/department/unit*, If you decide not to participate, the services you receive from [researcher clinic/department/unit] will not be affected in any way. The researchers may choose to terminate your participation in this research study if [state any circumstances that would lead to termination of a participant’s continued participation. Also state whether and how they will be notified if this happens].

**Payment** or **Compensation [& Costs]**

For your participation in this research study, you will receive [amount and type of payment. This must be concrete before your submission]. *State whether compensation will occur if participation is incomplete, either due to their withdrawal or your termination of their participation, including whether compensation can occur in increments. If the compensation is in the form of extra credit, you must ensure that there is an alternative, non-research related extra credit opportunity available, and you must state what that alternative is here. If you are giving SONA credits for participation, you must state how many credits participants are eligible to receive – note that in-person lab components are often able to award more credit than online procedures.*

*If biospecimens are collected as a part of this research project will be used for the research team or institution’s commercial profit, you must disclose:* Your biospecimens, even once de-identified, may be used for the [research team’s, sponsor’s, institution’s, etc.] commercial profit. You [will/will not] share in that commercial profit.

Your participation may require that you incur additional costs, including [include any additional costs here, such as parking fees to come to campus, any procedures that may not be covered by health insurance, etc. If none, delete this whole sentence].

**Findings [& Future Participation]**

*If your procedures are experimental, please include this paragraph:* If the researchers learn anything new during the course of this research study that might affect your willingness to continue participation, you will be contacted about those findings. This might include changes in procedures, changes in the risks or benefits of participation, or any new alternatives to participation that the researchers learn about. *You may delete this paragraph if your procedures are not experimental and only the next two are relevant. Please note that if you learn about something study-related that results in increased risks to participants, you must notify them, whether you include this section or not.*

*You must include one of these statements if you collect identifying information/biospecimens:* Identifiers may be removed from your [information/biospecimens]. These de-identified [data/biospecimens] may be used or distributed for future research without additional consent from you. If you do not wish for us to use your [information/biospecimens] in this way, please state so below. **OR** Your [information/biospecimens], identified or de-identified, will not be used or distributed for future research studies, even if all of the identifying information has been removed.

*If you plan to share your findings with the participants once the study has concluded* once the research study is complete, the researchers will [email you, mail you, call you with, etc.] the findings of the study, including [aggregate, individual, etc.] results relating to your participation. *If you do this, please ensure you are capturing adequate contact information at the end of this document to follow up on this commitment.*

*If you would like to be able to contact this participant about future studies of yours, t*he researchers would like to keep your contact information in order to invite you to participate in future research studies. If you would like them to keep your contact information, please initial here: \_\_\_\_\_\_. This information will be entered into [please detail how the information will be maintained] that is completely separated from anything to do with this research study and maintained for [time period you plan to keep this information]. You can contact the Principal Investigator at any time to be removed from this list.

**IRB Review**

The Institutional Review Board (IRB) for the protection of human research participants at Cebu Institute of Medicine has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at [phone number] or [email address]. If you have questions about your rights or would simply like to speak with someone *other* than the research team about questions or concerns, please contact the IRB Chair at (+63) 917-3204149 or cimcvghirb@gmail.com. *The signature blocks below look funny now but will sort themselves out once information is filled in and deleted.*

*Please replace this line with an electronic signature, if you would like.*

[Principal Investigator Name]

Principal Investigator

((XXX) XXX-XXXX email@usu.edu

[Co-Investigator or Student Researcher Name]

Co-Investigator OR Student Investigator

(XXX) XXX-XXXX; email address

**Informed Consent**

By signing below, you agree to participate in this study. You indicate that you understand the risks and benefits of participation, and that you know what you will be asked to do. You also agree that you have asked any questions you might have, and are clear on how to stop your participation in the study if you choose to do so. Please be sure to retain a copy of this form for your records.

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Participant’s Signature Participant’s Name, Printed Date

[ ]  I do **not** agree to allow my de-identified information/biospecimens to be used or shared for future research. *You may delete this if, above, you decided that you would not de-identify and store data for potential future research use.*

*Please be sure that if you need to collect additional information in order to recontact with new findings, study results, or future research purposes, you do so here. If you are using any kind of differential consent procedures (e.g. allowing participants to consent or not consent to video recordings while still participating in the study) please add those initial or check boxes in this area of the consent form as well.*

You can ask any questions you have, now or later. Your parents know about this research study, and they have said you can participate, if you want.

If you would like to be in this study, please sign your name and write the date.

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Name                                                           Date

*You should also feel free to develop a separate assent document using this template – it does not need to be appended to the informed consent document. In all cases working with minors, please do be sure that the consent form is written to the parents/guardians, and not the child themselves – only the assent should be addressed directly to the children.*

*The IRB strongly recommends the development of separate consent forms where you have both minors and adults as direct participants.*