

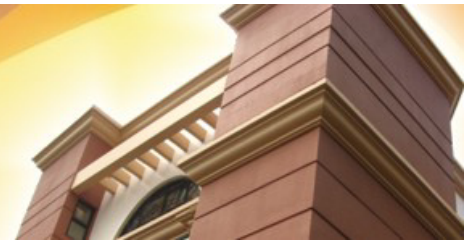


UNIVERSITY OF SANTO TOMAS
THE GRADUATE SCHOOL

THOMAS AQUINAS RESEARCH COMPLEX
ESPAÑA MANILA, PHILIPPINES

Ethics Review Committee

(Adapted with Permission from the UP-NIH Ethics Review Board)



PARTICIPANTS INFORMATION AND INFORMED CONSENT FORM TEMPLATE

FORM 34

* ALL CAPS preferred for this field

* PROJECT TITLE/RESEARCH STUDY

[Blank line for project title]

* PROPONENT (SURNAME)

(FIRSTNAME)

(MIDDLENAME)

[Blank line for proponent names]

* CONTACT NUMBER OF PRIMARY INVESTIGATOR

* ADVISER

* INSTITUTION/AFFILIATION:

[Blank line for contact and affiliation]

Dear Participant/s:

Greetings!

I am a graduate student of the UST Graduate School currently undertaking a research-study on

[Blank line for research topic]

(state title).

(Please state the following:)

*Purpose and conduct of study: Why is the study being done?

- What has been done previously?
• How will the present study be conducted?
• What is the nature and extent of involvement of research participants?

*Risks and inconveniences

- Will there be discomforts? Are these described clearly?
• Will there be risks? Are these explained fully?
• Are there other effects the participants need to know in order to make a decision?

*Possible benefits for the participants

- What benefits can the participants expect?

*Compensation

- Will there be reimbursement of travel expenses? Compensation for loss of income? Meal expenses?
• Are there other financial considerations?

*Provision for injury or related illness

- How will potential injury/ies of participant/s be managed?
• Will the participant/s be given free treatment in case of injury or illness incurred as a result of participating in the study?

*Contact person

- Who is the person knowledgeable about the research and rights of the participant? How can he/she be contacted?

*Voluntariness of participation

- Is/are the participant/s free of any coercion in participating?
• Is there assurance that the participant/s can withdraw anytime without affecting treatment/care due him/her?
• Is there provision for obtaining the informed consent from the legal representative in case of minors, the mentally handicapped or the incapacitated?

*Confidentiality

- Is there a statement that describes the measures that will be taken to keep and ensure the confidentiality of the participant's records?
• Is/are participant/s informed of the results of the research study?

Thank you very much.

Sincerely yours,

[Blank line for signature]

Printed name of investigator and signature (include contact numbers)

Noted by:

Adviser/s

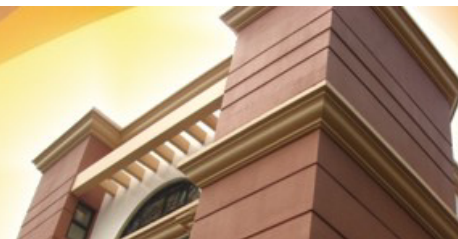


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CONSENT FORM

FORM 34

I have read and understood the above information and have been given the opportunity to consider and ask questions on the information regarding the involvement in this study. I have spoken directly to the investigator/s of this study who has/have answered to my satisfaction all my questions. I have received a copy of this Participant's Information and Informed Consent Form. I hereby voluntarily agree to participate.

Participants Signature

Printed Name of Participant

Signature of Participant

Date

Printed Name of Legal Guardian

Signature of Legal Guardian

Date

(Only when participant cannot read or sign this Informed Consent)

Witness Signature

Printed Name of Participant

Signature of Participant

Date

Medical Clearance *(if needed)*

I, the undersigned, certify that to the best of my knowledge, the participant signing this consent form has read the above information sheet fully, that this has been carefully explained to him/her, and that he/she clearly understands the nature, risks, and benefits of his/her participation in this study.

Physician's Signature:

Printed Name of Physician

Signature of Physician

Date

(N.B. The participant's information sheet (*pormularyo ng impormasyon*) and the consent form (*pormularyo ng pahintulot*) must be written/explained in Filipino or in any language understood by him/her, when needed.)

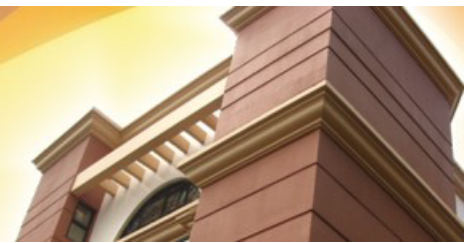


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CONSENT FORM FOR MINORS

FORM 34

I have read and understood, with the assistance of my legal guardian, the above information and have been given the opportunity to consider and ask questions on the information regarding the involvement in this study. I have spoken directly to the investigator/s of this study who has/have answered to my satisfaction all my questions. I have received a copy of this Participant's Information and Informed Consent Form. I hereby voluntarily agree to participate.

Minor-Participant's Assent: *(applicable only if participant is a minor, below 18 yrs. of age)*

Printed Name of Minor

Signature of Minor

Date

Printed Name of Legal Guardian

Signature of Legal Guardian

Date

Witness Signature

Printed Name of Witness

Signature of Witness

Date

Medical Clearance *(if needed)*

I, the undersigned, certify that to the best of my knowledge, the participant signing this consent form has read the above information sheet fully, that this has been carefully explained to him/her, and that he/she clearly understands the nature, risks, and benefits of his/her participation in this study.

Physician's Signature:

Printed Name of Physician

Signature of Physician

Date