



# ST. PAUL'S HOSPITAL OF ILOILO, INC.

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## PROTOCOL AMENDMENT FORM (FORM 4.1)

IRB Protocol No.

Date Received (D/M/Y):

Protocol Title:

Sponsor:

Principal & Sub  
Investigators:

Primary  
Reviewer's:

### SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

Please check (✓) each of the boxes that pertains to your amendment request.

#### 1. PROTOCOL AMENDMENT

Major

Minor

#### 2. METHODS OR PROCEDURES.

I am requesting changes to the research methodology previously approved by the IRB.

#### 3. RISKS

The changes that I am requesting may result in increased risks to some or all of my research subjects.

#### 4. HUMAN SUBJECTS/SPECIMENS

I am requesting changes to the number of human subjects/specimens that I am authorized to use in my research.

#### 5. RECRUITMENT PROCEDURES

I am requesting changes to the recruitment procedures that I am using.

#### 6. CHANGES IN THE INFORMED CONSENT FORM/ASSENT PROCEDURES OR FORM

I am requesting changes to the informed consent form /assent procedures or form that have been approved for my research.

**7. CONFIDENTIALITY**

I am requesting changes to the confidentiality of participation previously approved by the IRB.

**8. CONFLICT OF INTEREST**

Events that have occurred which have changed the conflict of interest on the study personnel previously approved in the protocol.

**9. STUDY PERSONNEL**

I am requesting the following personnel changes to my protocol.

Add	Delete	Name	Position
<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>		

**10. OTHER CHANGES**

I am requesting changes to my research protocol that are not addressed above.

DETAILED DESCRIPTION OF THE AMENDMENT	REVIEWER'S COMMENT

**INVESTIGATOR'S ATTESTATION**

I certify that the information provided in this application is complete, accurate and necessary. The changes will not be implemented until IRB approval has been obtained.

\_\_\_\_\_  
Signature Over Printed Name of Principal Investigator

\_\_\_\_\_  
Date

*(IRB Use only)* Received by:

\_\_\_\_\_  
Signature Over Printed Name

\_\_\_\_\_  
Date

**SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER**

Type of Review

Expedited

Full Board

Reviewer's  
Comments:

Final Action:

- ( ) Approved
- ( ) Major Revision
- ( ) Minor Revision
- ( ) Disapproved
- ( ) Others: \_\_\_\_\_

Acknowledged by:

\_\_\_\_\_  
Name of Reviewer  
IRB Member

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date