



**NATIONAL CENTER FOR MENTAL HEALTH
RESEARCH ETHICS COMMITTEE**

**FORM 3.1
PROTOCOL AMENDMENT APPLICATION
FORM**

Version no. 7

June 19, 2023

Page 1 of 2

Date of submission	REC Protocol Number	Sponsor Protocol Number
<input type="text"/>	<input type="text"/>	<input type="text"/>
Principal Investigator	Email / Mobile Number	Sponsor
<input type="text"/>	<input type="text"/>	<input type="text"/>

Title of Study	<input type="text"/>
----------------	----------------------

Study Site	<input type="text"/>	Date of Initial Approval	<input type="text"/>
------------	----------------------	--------------------------	----------------------

<u>Items to be Amended</u>	<u>List of Amendments*</u>	<u>Reasons</u>	<u>Reviewer's Comments</u> (REC use only)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

***Indicate pages in the document where the amendment is found. Underline or highlight the amendments done in the documents**

Name & Signature of Principal Investigator	<input type="text"/>	Date:	<input type="text"/>
--	----------------------	-------	----------------------

Received by:

REC Staff	<input type="text"/>	Signature	<input type="text"/>	Date	<input type="text"/>
-----------	----------------------	-----------	----------------------	------	----------------------



**NATIONAL CENTER FOR MENTAL HEALTH
RESEARCH ETHICS COMMITTEE**

Version no. 7

June 19, 2023

Page 2 of 2

**FORM 3.1
PROTOCOL AMENDMENT APPLICATION
FORM**

Type of review:

- Expedited review
- Full board review

FOR NCMH-REC USE

Assessment by Primary Reviewers	Type of amendments: Minor <input type="checkbox"/> Major <input type="checkbox"/>	<u>Comments</u>	<u>Recommendation</u>
	Does the amendment increase the risks to participants? Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Does the amendment increase the benefits to participants? Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Is there favourable benefit/ risk ratio? Yes <input type="checkbox"/> No <input type="checkbox"/>		

Primary reviewer:

Name of Reviewer:		Signature		Date	
-------------------	--	-----------	--	------	--

REC Final Decision	<input type="checkbox"/> Approve <input type="checkbox"/> Request further information / modification <input type="checkbox"/> Others: _____
---------------------------	---

Maurice L. Sañosa, MD, FPCGM		
NCMH-REC Chairperson	Signature:	Date