

PHILIPPINE HEALTH RESEARCH ETHICS BOARD Philippine National Health Research System c/o Philippine Council for Health Research and Development Department of Science and Technology

MEMORANDUM No. 2017- <u>002</u>

For	: All Research Ethics Committees (RECs), Researchers					
From	:	LEONARDO D. DE CASTRO, PhD Chair				
Date	:	07 June 2017				
Subject	:	Compliance of Research Ethics Committees and Researchers on the Free and Prior Informed Consent (FPIC) process of the National Commission on Indigenous Peoples and Quality Ethics Review in accordance with the Philippine Health Research Ethics Board Criteria and Guidelines				

The Philippine Health Research Ethics Board (PHREB) and the National Commission for Indigenous Peoples (NCIP) agreed in a Memorandum of Understanding signed on 13 May 2016 to collaborate and coordinate relative to all health research studies involving Indigenous Cultural Communities (ICCs) and Indigenous Peoples (IPs).

All PHREB accredited RECs are hereby directed to require researchers to abide with the FPIC process as part of the criteria in the recruitment, selection and promotion of ICCs/IPs as research participants, prior to issuance of ethical clearance. This is in compliance with NCIP Resolution No. 07-08.2016 and the Memorandum of Understanding between PHREB and NCIP signed in 2016 in support to the Philippine National Health Research System (PNHRS) Act of 2013 and the Indigenous Peoples Rights Act of 1997, protecting the dignity, rights, and welfare of human participants involved in research.

To ensure effective and efficient implementation of the above issuances, PHREB and NCIP shall monitor compliance to the said policies. Thus, all RECs are required to submit the list of all research projects involving ICCs/IPs to PHREB and NCIP Regional Office every end of June and December of each year using the prescribed template for tracking and records purposes.

Compliance with this Memorandum will form part of the evaluation of the accredited REC.

For strict compliance.



#### PHREB ACCREDITATION FORMS

# SUMMARY OF PROTOCOLS INVOLVING INDIGENOUS CULTURAL COMMUNITIES / INDIGENOUS PEOPLES (ICCs/IPs)

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#### A. RESEARCH ETHICS COMMITTEE (REC) INFORMATION

Name of Ethics Review Committee:	Click here to enter text.		
Name of Institution:	Click here to enter text.		
Address: (No., Street, Town/City, Province, Region)	Click here to enter text.		
Report prepared by:	Click here to enter text.		
Name of Contact Person:	Click here to enter text.	Position:	Click here to enter text.
Telephone:	Click here to enter text.	Mobile:	Click here to enter text.
Fax:	Click here to enter text.	<b>REC Email Address:</b>	Click here to enter text.

## B. PROTOCOL SUMMARY for the Period of 20\_\_\_\_ () January to June; () July to December

REC Protocol Code	Protocol Title	Names of Researcher(s)/ Investigator(s)	Name of ICC/IP group	Funding a	Researc h Type <sup>b</sup>	Date Received	Review Type <sup>c</sup>	Date of Meeting where Protocol is First Discussed (if full review)	Decision <sup>d</sup>	Date of First Decision Letter to the Pl / Researcher	FPIC (Y/N)	Status
XXXXX	Protocol Title	Researcher		R	FR	<mm-dd-yy></mm-dd-yy>	FR	<mm-dd-yy></mm-dd-yy>	А	<mm-dd-yy></mm-dd-yy>		R
XXXXX	Protocol Title	Researcher		R	FR	<mm-dd-yy></mm-dd-yy>	FR	<mm-dd-yy></mm-dd-yy>	Α	<mm-dd-yy></mm-dd-yy>		R
XXXXX	Protocol Title	Researcher		R	FR	<mm-dd-yy></mm-dd-yy>	FR	<mm-dd-yy></mm-dd-yy>	Α	<mm-dd-yy></mm-dd-yy>		R
XXXXX	Protocol Title	Researcher		R	FR	<mm-dd-yy></mm-dd-yy>	FR	<mm-dd-yy></mm-dd-yy>	A	<mm-dd-yy></mm-dd-yy>		R
XXXXX	Protocol Title	Researcher		R	FR	<mm-dd-yy></mm-dd-yy>	FR	<mm-dd-yy></mm-dd-yy>	A	<mm-dd-yy></mm-dd-yy>		R

How many of the above protocols came from researchers belonging to other institutions?

#### Legend:

<sup>a</sup> FUNDING	<sup>a</sup> Research Type	<sup>c</sup> REVIEW TYPE		<u>STATUS</u>
<ul> <li>R - Researcher-funded</li> <li>I - Institution-funded</li> <li>A - Agency other than institution</li> <li>D - Pharmaceutical companies</li> <li>O - Others</li> </ul>	Biomedical studies Health Operations Research Social Research Public Health Research Clinical Trials	FR – Full Review ER – Expedited Review EX – Exempt from Review	<ul> <li>A – Approved</li> <li>MN – Minor modification</li> <li>MJ – Major modification</li> <li>D – Disapproved</li> </ul>	OR – On-going review A – Approved and on-going C- Completed T – Terminated W – Withdrawn

# Flow chart for review of protocols involving Indigenous People (IP)

Researcher submit to REC the protocol involving IPs

REC review protocol involving IPs



Researcher applies for NCIP approval (FPIC process) with the endorsement letter from the REC attached. If review is ok, REC endorsement to NCIP. Endorsement letter is given to Researcher.



FPIC process - if there are changes in the protocol and ICF that will be recommended by the NCIP or IP community - the researcher should comply.

NCIP issues FPIC approval. Researcher attaches NCIP approval to protocol and resubmits to REC.

## **REC** issues ethical clearance.

The REC should take note of the changes in the protocol based on the NCIP review. If these are not acceptable - REC should initiate dialogue with the NCIP. The NCIP has the final say with regard to socio-cultural and traditional aspects of the study.