



**GOOD RESEARCH PRACTICE TRAINING**  
PHILIPPINE NURSES ASSOCIATION  
Malate, Manila  
May 2 - 3, 2019

**OBJECTIVES**

- Promote dialogue and provide guidance regarding ethical dimensions of research
- Sensitize to the basic principles
- Clarify the rights and obligations of stakeholders
- Value controls
- Avoid, recognize, and correct common issues
- Motivate participants towards doing, approving, and advocating quality ethical research
- Achieve PHREB/Food and Drug Administration (FDA) accreditation of clinical investigators and Ethics Review Committees (ERCs)

**PROGRAM**

<b>DAY 1 (May 2, 2019): BASIC PRINCIPLES</b>		
08:00 AM	P1: Opening Ceremonies and Welcome Remarks;	PNA Representative
08:10 AM	Orientation, Program Critic, and Revisions; Pre-test	Dr. Rosario Angeles Alora /PNA Representative
08:15 AM	L1: Introduction to Ethics in Research	Dr. Rosario Angeles Alora
08:30 AM	L2: Scientific Soundness	
08:50 AM	SGW1: Protocol Review: Scientific Soundness	Facilitators: Dr. Alora & Dr. Manalastas
09:10 AM	P2: Report on Scientific Soundness	
09:30 AM	<b>BREAK</b>	
09:50 AM	L3: Principle of Non-Maleficence & Beneficence	Dr. Ricardo Manalastas, Jr
10:10 AM	SGW2: Protocol Review: Harms, Risk, and Benefits	Facilitators: Dr. Alora & Dr. Manalastas
10:30 AM	P3: Report of Harms and Benefits	
11:15 AM	L4: Principle of Respect for Person/ Informed Consent	Dr. Ricardo Manalastas, Jr.
11:30 AM	<b>LUNCH BREAK</b>	
12:30 PM	RP1: The Informed Consent Process	Facilitators: Dr. Alora & Dr. Manalastas
01:00 PM	P4: Review and Critique of Informed Consent Process	
01:30 PM	L5: Principle of Justice	Dr. Rosario Angeles Alora
02:00 PM	SGW3: Review of Protocol –Was Justice Served?	Facilitators: Dr. Alora & Dr. Manalastas
02:20 PM	P5: Report on Justice	
02:40 PM	L6: Conflict of Interests	Dr. Rosario Angeles Alora
03:00 PM	<b>BREAK</b>	
03:20 PM	L7: Social and Behavioral Research	Dr. Ricardo Manalastas, Jr.
03:40 PM	SGW4: Identifying Social Issues in the Research Proposal	Facilitators: Dr. Alora & Dr. Manalastas
04:00 PM	P6: Presentation of Social Issues	
04:15 PM	P7: Summary, Assignments, Day Evaluation Take Home Assignments: > Review Research Protocol > Review the Guidelines > End of Day Evaluation	
04:30 PM	L8: The Ethical Researcher	Dr. Ricardo Manalastas, Jr.
<b>END OF DAY 1</b>		

**DAY 2 (May 3, 2019): ENSURING ETHICAL SOUNDNESS**

08:00 AM	P8: Review by Participant; Preview; Report of Assignment	Facilitators: Dr. Alora & Dr. Manalastas
08:30 AM	L9: Research Ethics Controls, International and National Controls	Dr. Rosario Angeles Alora
08:50 AM	SGW 5: Discussion of International Control	Dr. Alora & Dr. Manalastas
09:10 AM	P7: Report on International Control	
10:00 AM	<b>BREAK</b>	
10:20 AM	L11: Institutional Controls: Institutional Ethics Review Committee	Dr. Ricardo Manalastas, Jr.
10:40 AM	RP2: An IERC Meeting: Reviewing a Research Protocol	Facilitators: Dr. Alora & Dr. Manalastas
11:10 AM	P9: Critique of IERC Meeting / Assessing Research Protocol Using the Protocol Checklist	
11:30 AM	L12: Review and After-Review Processes	Dr. Ricardo Manalastas, Jr.
12:00 PM	<b>LUNCH BREAK</b>	
01:00 PM	L13: Introduction to Standard Operating Procedures (SOPs)	Dr. Rosario Angeles Alora
01:30 PM	SGW5: Preparing SOPs	Facilitators: Dr. Alora & Dr. Manalastas
01:50 PM	P10: Report on SOPs	
02:10 PM	L14: GCP: Principles, Characteristics, Peculiarities	Dr. Ricardo Manalastas, Jr.
02:30 PM	L15: Protecting present and future users: - Pharmacovigilance - Recognizing and Reporting ADR	Dr. Rosario Angeles Alora
03:00 PM	SGW6: Recognize ADR and Fill the ADR report	Facilitators: Dr. Alora & Dr. Manalastas
03:20 PM	<b>BREAK</b>	
03:40 PM	P11: Report on ADR	Facilitators: Dr. Alora & Dr. Manalastas
04:00 PM	L16: Additional GCP Guidelines: Data Handling, Trial Material Handling Rights and Responsibilities of Stakeholders	Dr. Rosario Angeles Alora
04:20 PM	SGW7: Impediments to Ethical Research/Promoting	Dr. Alora & Dr. Manalastas
04:40 PM	P12: Report on Promoting Ethical Research	
05:10 PM	P13: Wrap-up - Post Test - Post Seminar Evaluation and Recommendations - Closing Ceremony and Photos	Dr. Alora & Dr. Manalastas/ PNA Representative
<b>END OF THE TRAINING</b>		