PHILIPPINE HEALTH RESEARCH ETHICS BOARD
Philippine Council for Health Research and Development
Department of Science and Technology

GOOD RESEARCH PRACTICE TRAINING

Regional Health Research Development Consortium XI

Davao City

October 26-27, 2016

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 Research Ethics Committees (ERCs)

PROGRAM

DAY 1: BASIC PRINCIPLES		
08:00 AM	P: Opening Ceremonies and Welcome Remarks; Orientation, Program Critic, and Revisions; Pre-test	RHRDC Representative
08:15 AM	L1: Introduction to Ethics in Research	Dr. Ricardo Manalastas, Jr.
08:30 AM	L2: Scientific Soundness	
08:50 AM	L3: Principle of Non-Maleficence	Dr. Doris Benavides
09:10 AM	L4: Principle of Beneficence	
09:30 AM	**BREAK**	
10:00 AM	L5: Principle of Autonomy/ Informed Consent	Dr. Doris Benavides
10:30 AM	SGW: Review of ICF using Informed Consent Assessment Form	Facilitators: Dr. Manalastas and Dr. Benavides
11:00 AM	P: Report on Review of Informed Consent Form	
11:30 AM	**WORKING LUNCH**	
12:30 AM	RP: The Informed Consent Process	
01:00 PM	P: Review and Critique of Informed Consent Process	
01:30 PM	L6: Principle of Justice	Dr. Doris Benavides
02:00 PM	SGW: Review of Protocol using Study Protocol Assessment Form	Facilitators: Dr. Manalastas and Dr. Benavides
02:30 PM	P: Report on Review of Protocol	
03:00 PM	L7: Social and Behavioral Research	Dr. Ricardo Manalastas, Jr.
03:30 AM	**BREAK**	
03:45 PM	L8: Conflict of Interests	Dr. Ricardo Manalastas, Jr.
04:00 AM	P: Worksheet on Conflict of Interests	Facilitators: Dr. Manalastas and Dr. Benavides
04:00 PM	P: Summary, Assignments, Daily Evaluation: – Review of the National Ethical Guidelines – End of Day Evaluation	Training Participants

DAY 2: ENSURING ETHICAL SOUNDNESS		
08:00 AM	Insights	Training Participants
08:20 AM	L9: Research Ethics Controls	Dr. Ricardo Manalastas, Jr.
08:40 AM	L10: International Controls	
09:00 AM	L11: National Controls	
09:30 AM	L12: Institutional Controls: REC	Dr. Doris Benavides
10:00 AM	**BREAK**	
10:15 AM	RP2: An REC Meeting: Reviewing a Research Protocol	Facilitators: Dr. Manalastas and Dr. Benavides
11:00 AM	P11: Critique of REC Meeting	
11:30 AM	L13: Revisiting Review and After-Review Processes	Dr. Doris Benavides
12:00 PM	**LUNCH BREAK**	
01:00 PM	L14: GCP: Principles, Characteristics, Peculiarities	Dr. Ricardo Manalastas, Jr.
01:30 PM	L15: Protecting present and future users: – Pharmacovigilance – Recognizing and Reporting ADR	Dr. Doris Benavides
02:00 PM	L16: Additional GCP Guidelines: Data Handling, Trial Material Handling	Dr. Ricardo Manalastas, Jr.
02:20 PM	SGW9: Worksheet on Rights and Responsibilities of Stakeholders	Facilitators: Dr. Manalastas and Dr. Benavides
02:40 PM	P16: Report of Stakeholder's Rights and Responsibilities	
03:00 PM	**BREAK**	
03:15 PM	L17: The Ethical Researcher	Dr. Ricardo Manalastas, Jr.
03:40 PM	SGW10: Impediments to Ethical Research	Facilitators: Dr. Manalastas and Dr. Benavides
04:00 PM	P17: Report on Impediments to Ethical Research	
05:00 PM	P20: Wrap-up – Training Evaluation and Recommendations – Closing Ceremony and Photo Ops	