



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 15, 2016

DEPARTMENT PERSONNEL ORDER

No. 2016- 1396

SUBJECT: Creation of the Oversight Committee for Programmatic Management of Drug-Resistant Tuberculosis (PMDT) Researches Using Novel TB Drugs and Treatment Regimen.

I. Rationale

The first operational research for Multidrug-resistant Tuberculosis (MDR-TB) involving the use of anti-TB drugs started in 2015 with the 9-month treatment regimen entitled "*Feasibility, Effectiveness, and Safety of 9-Month Treatment Regimen for Multidrug-resistant Tuberculosis in the Philippines*". New anti-TB drugs, such as Bedaquiline, are expected to be introduced in the country. Bedaquiline has already been approved by the Philippine Food and Drug Administration (FDA) and will be implemented in PMDT under operational research condition. The protocol "*Assessment of the Programmatic Approach in the Introduction of Bedaquiline for Drug-resistant Tuberculosis Treatment in the Philippines: An Operational Study*" has already been approved by Lung Center of the Philippines (LCP) Technical Review Board and Ethics Review Committee. Currently, the World Health Organization (WHO) recommendation is to use short regimen and Bedaquiline in the context of country-specific operational research and should be under close monitoring of the response to treatment.

In order to facilitate the effective and efficient conduct of the 9-month treatment regimen and Bedaquiline operational researches and other future PMDT researches, it is necessary to organize an Oversight Committee (OC) that will take the overall responsibility of all PMDT researches. This multi-sectoral representation shall ensure the appropriate conduct of operations, as agreed upon from the protocol and/or national implementation plan, that are in accordance to international standards and cognizant with experts' opinion.

II. Objective

To ensure quality implementation of PMDT researches on the use of novel TB drugs and treatment regimen, an oversight committee shall be created.

III. Functions of the Oversight Committee

1. Serves as the oversight for the conduct of PMDT researches on novel TB drugs and treatment regimen
2. Approves the technical/progress reports submitted by the Lung Center of the Philippines-National Center for Pulmonary Research (LCP-NCPR)
3. Conducts joint-monitoring with PMDT sub-Technical Working Group and LCP-NCPR Research Team and provide recommendations based on evaluation by monitoring team and on-site findings
4. Recommends final technical report for approval by the Secretary of Health
5. Provides recommendations to the Secretary of Health based on the research findings

IV. Frequency of Meeting

The Oversight Committee shall meet at least twice a year or as deemed necessary by the body.

V. Composition of the Oversight Committee

This committee is composed of managers and technical experts from Department of Health (DOH), partners in the public and private sectors and international experts.

Chairperson: Undersecretary of Health for Office for Technical Services (OTS)

Co-chairperson: Director of Disease Prevention and Control Bureau (DPCB)

Members:

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| 1. Department of Health (DOH)
Infectious Disease Prevention
and Control Division (IDPCD) | Division Chief |
| 2. World Health Organization (WHO) | Western Pacific Region Office-
Representative |
| 3. Philippine Coalition Against TB (PhilCAT) | Chairman of the Board |
| 4. United States Agency for
International Development (USAID) | USAID Project Management
Specialist for Public Health-
Infectious Diseases |
| 5. Philippine Country Coordinating
Committee (PCCM) | Committee Member |

Technical Secretariat:


National TB Program Manager
PMDT Specialist, Global Fund, National TB Control Program-Management Office
Account Officer for PMDT, Global Fund, National TB Control Program-
Management Office
EB Surveillance Program Manager

VI. Operational Support

The cost incurred by the Oversight Committee to perform its functions shall be charged against the Global Fund-TB New Funding Model (GF-TB NFM) until said Project ends. Thereafter, support shall be borne by the Government of the Philippines-National TB Control Program (GOP-NTP) budget.

VII. Effectivity

The creation of the PMDT Research Oversight Committee shall take effect immediately.


JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health