Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUL 1 1 2017

DEPARTMENT ORDER
NO. 2017-0265

SUBJECT: **Guidelines for the Streamlined Research Ethics Review Process in the Department of Health**

I. Background

Research must ensure that the rights of the participants are safeguarded and researchers are accountable to the public for ensuring these rights. Research ethics review is thus critical in the technical and ethical acceptability of research involving human participants. The rise in commissioned health policy and systems researches has surfaced some inefficiencies and variations in the administration of the ethics review process for researches in the country. Slow turnaround time of research ethics committee (REC) decisions and the spiraling cost of ethics review are some of the bottlenecks that were identified that delay the production of research evidence to inform policy and program development in the DOH. In view of DOH's commitment to uphold the ethical conduct of research, minimize unnecessary red tape, and given the DOH hospitals' ability to retain income per General Appropriations Act (GAA) 2017, this guideline is being issued to update current standard operating procedures of the DOH RECs and provide mechanisms for accountability.

II. Objectives

A. General Objective:

This Order shall standardize, streamline, and facilitate research ethics review process and other supporting activities in the Department of Health.

B. Specific Objectives:

1. To develop standards for ethics review process and other supporting activities
2. To institute monitoring mechanisms and accountability framework for ethics review process and other supporting activities

III. Scope and Coverage

This Order shall cover all DOH units including regional offices, hospitals, and attached agencies with research ethics committees.

IV. Definition of Terms

A. **Above Minimal Risk** - when the vulnerability and magnitude of possible harm implied by participation in the research is greater than those encountered by

participants in the aspects of their everyday life that relate to the research (*BC Ethics Harmonization Initiative, 2013*)

B. **Minimal risk** - when the vulnerability and magnitude of possible harm implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research (*BC Ethics Harmonization Initiative, 2013*)

C. **Principal Investigator-Initiated Research** - the principal investigator initiated a prospective study for funding

D. **Review Fee** - refers to the fees charged to the sponsor by the RECs for the ethics review of protocol submission

E. **Sponsor-initiated Protocols** - refers to protocols coming from the pharmaceutical industries in which the nature of the study deals with investigational new drugs (IND)

V. General Guidelines

A. **Accreditation.** All DOH units with RECs shall seek accreditation by the Philippine Health Research Ethics Board (PHREB), and as such, follow general guidelines set forth by the PHREB.

B. **Standard Operating Procedures.** All DOH unit-RECs shall publish revised Standard Operating Procedures (SOPs) reflecting the changes set forth by this Order by 4th Quarter of 2017. All DOH unit-RECs shall fully implement the revised SOPs by 2nd quarter of 2018.

C. **Management of Funds for RECs**. All DOH units shall create a subsidiary ledger for RECs to ensure sound financial management.

D. **Sources and Uses of Funds for RECs.** All DOH units shall:

a. Allocate the prescribed amount based on REC level to be sourced from their 2% MOOE for research, institutional and ethics review fees;

b. Adhere to guidelines set forth on charging of institutional and ethics review fees;

c. Adhere to guidelines set forth on honoraria of review committee members, and other appropriate activities; and

d. Utilize the hospital income for REC operations provided that 25% of the income shall be allotted for purchasing and upgrading of hospital equipment and the delivery of health services and 5% for preventive and promotive health services as per GAA FY 2017 Special Provision

E. **Monitoring & Accountability.** All DOH units shall be monitored for compliance to the prescribed standards.

VI. Specific Guidelines

A. **Standard Operating Procedures.** The revised standard operating procedures, available in https://goo.gl/309FJ2, incorporates the key provisions of the 2017 National Ethical Guidelines as well as the new standards for turnaround time.

1. **Classification of Review**. Level of risk shall be determined after a preliminary assessment of the vulnerability of participants and anticipated harm.
   a. **Full Board Review**. All REC members or at least two of the reviewers from the REC (a scientific and a non-scientific/non- medical member) shall review and critique the submitted proposal for discussion and final actions.
   b. **Expedited Review**. Research protocols that pose at least minimal risk may be subjected to an expedited review. The review shall be conducted by a minimum number of REC members. The following are the type of studies that may be classified under this:
      i. **Retrospective records or chart review**
      ii. **Survey on non-sensitive nature**. Questionnaire(s)/ FGD that do not involve the collection of highly personal, sensitive or incriminating information; vulnerable populations; and/or impose a substantial burden on participants
      iii. **Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data**
   c. **Exemptions from Review**. Research protocols that present no more than minimal risk or harm do not need to be subjected to either a full board or expedited type of review. Exempt protocols are studies that pose no more than minimal risk to study participants. Example of researches that may be exempted from review:
      i. Program evaluation of public programs
      ii. Quality control studies to evaluate organizational performance
      iii. Disease surveillance and public health researches/activities
      iv. Research involving existing database or large statistical data without identifiers

2. **Timelines.** DOH RECs shall comply with the recommended turnaround time for ethics review of 30-60 calendar days. Specific turnaround times are summarized in **Annex A.**

3. **Ethical and Technical Review of Protocols**. All externally funded research protocols shall not be subjected to technical review provided that they have secured technical review clearance from the funding institution. Institutional RECs may only require technical review for studies funded by the home institution. Ethical review shall apply both for internally and externally funded research studies.

E. Sources and Uses of Funds

1. The annual appropriation for an REC depends on its level of accreditation. Capacity requirements for each level are summarized in **Annex B.**
2. The appropriate amount of Ethics Review Fees shall correspond to the **type of protocol.** These allocated funds shall be utilized by the DOH RECs in

improving its capacity and the overall REC operations. Refer to **Annex C** for details.

3. All REC members shall be compensated based on their attendance to REC meetings. The allowable honorarium for members per meeting is Php 1,000 - Php 3,000, and Php 3,000 - 5,000 for the Chair. REC members who are staff of the institution may receive honorarium provided that the meetings are undertaken after office hours.
4. The pooled REC income from review fees may be used to augment other activities of the REC and its members and other related REC operation expenditures such as:
    a. Participation in ethics related trainings and seminars
    b. Attendance to ethics related local and international conferences
    c. Accreditation of RECs and membership to ethics related organizations
    d. Meals and snacks during ethics review meetings
    e. Office supplies and/or equipment used to maintain REC operations

. Key Performance Indicators and Targets

1. **DOH-Wide**
    a. **Level of accreditation of DOH RECs**. By 2020, all Level 3 DOH hospitals shall have level 3 PHREB accreditation and all DOH units including regional offices, hospitals, and attached agencies with RECs shall have at least Level 2 PHREB accreditation.
    b. **Per Cent (%) of DOH RECs with >80% of the protocols reviewed on time**. By 2020, 100% of DOH RECs shall have reviewed more than 80% of their protocols on time.
    c. **Per Cent (%) of DOH RECs compliant with standards for institutional and review fees.** By 2018, 100% of DOH RECs shall be fully-compliant.
2. **DOH-unit-REC Specific**
    a. By 2017, policy issued on updated SOPs
    b. By 2018, policy issued on standard fees
    c. By 2018, budget allocated for REC from 2% MOOE
    d. By 2018, % of protocols reviewed on time

. Reporting

1. All DOH RECs shall submit DOH REC Form 1 (See **Annex D**) every **2nd week of December** to the Health Research Division of the Health Policy Development and Planning Bureau. This report shall contain updates and progress for the following:
    a. Log of the Protocol Review Turnaround Time;
    b. Copy of Institutional Policy reflecting amendments proposed by this Order;
    c. Annual MOOE Allocation for DOH RECs
        i. Approved Work and Financial Plan (WFP) of the current year

ii. Proposed WFP of the succeeding year

2. All DOH RECs shall submit the accomplished DOH REC Form 1 to the Health Research Division of the Health Policy Development and Planning Bureau.

3. All DOH RECs shall submit a utilization report regarding the income generated by the institution's RECs to the DOH Financial Management Service and copy furnished the Health Facility Development Bureau.

VII. Roles and Responsibilities

A. Health Policy Development and Planning Bureau shall:

1. Provide oversight of the ethics review process in the DOH;
2. Monitor DOH RECs compliance with the DOH guidelines/SOPs for RECs;
3. Provide technical support on ethics-related activities of DOH unit;
4. Design and implement capacity building activities for all DOH RECs; and
5. Represent DOH REC issues to PHREB.

B. DOH units including regional offices, hospitals, and attached agencies with research ethics committees shall:

1. Develop/update hospital policies and provide technical and administrative support for research ethics related activities including REC operations;
2. Adopt the standard operating procedures (SOPs) developed by HPDPB; and
3. Comply with the PHREB guidelines.

VIII. Effectivity

This Order shall be effective immediately.

PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II
Secretary of Health

Annex A: Timelines for Ethics Review

Activity	Turnaround Time
Receipt of protocol submission from the sponsor or principal investigator (PI) to identification of primary reviewers	7 – 15 calendar days
From appointment of primary reviewers and review of the protocol	7 – 15 calendar days
Communicating decision of the REC (either approved, disapproved, or with minor/major revisions) to sponsor or PI	7 – 15 calendar days
Resubmission of the revised protocol from the sponsor or PI for REC's final decision	7 – 15 calendar days

Annex B. Minimum Requirements for REC Operations and Items for Appropriations

<table>
<tr><th>Level</th><th>Minimum Requirements for REC Operations</th><th>Items for Appropriation</th></tr>
<tr><td>Level 1</td><td>1. Shared office space
2. Dedicated staff secretary</td><td rowspan="3">A. Capital Expenditure (CAPEX)
1. Provision of office space and its maintenance for REC operations
2. Provision of basic office equipment and materials

B. Personnel Services (PS)
1. Appointed Secretary for REC
a. Minimum Salary Grade 10
b. Plantilla position, if available

C. Maintenance and Other Operating Expenses (MOOE)
1. Honoraria for REC Chair and affiliated, non-affiliated, and independent consultants. The REC shall have at least 9 members.
2. Monthly meeting expenses
3. REC quality improvement activities such as accreditation-related activities and trainings</td></tr>
<tr><td>Level 2</td><td>1. Dedicated office space with basic equipment
a. computer with internet connection and printer
b. Telephone
c. filing cabinets with locks
2. Dedicated staff secretary</td></tr>
<tr><td>Level 3</td><td>1. Dedicated office space with basic equipment
a. computer with internet connection and printer
b. Telephone
c. filing cabinets with locks
2. Full-time staff secretary</td></tr>
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Annex C. Ethics Review Fees

Type of Protocol	Review Fee (Initial, Renewal)
Sponsor initiated protocols	For Investigational New Drugs (IND): a. Full Board Review fee not exceeding Php 50,000 b. Expedited Review fee not exceeding Php 30,000
Principal investigator-initiated protocols	
Protocols from professional researchers (e.g., researchers from the academe, consultants affiliated to recognized local and international organizations, etc.)	a. Full Board Review not exceeding Php 10,000 b. Expedited Review not exceeding Php 5,000
Protocols from trainees such as: hospital fellows, residents, graduate and undergraduate students	For trainees *of the home institution*, no fees shall be charged For trainees *of other institutions*, the following fees shall apply: a. Undergraduate students - not to exceed Php 1,000 b. Fellows, Residents, and Graduate Students - not to exceed Php 5,000

ANNEX D. DOH REC Form 1. Annual Report on DOH Research Ethics Committee Operations

Name of REC: _____
Date Accomplished: _____

A. Log of the Protocol Review Turnaround Time

- Provide the necessary information on the table below

Study ID No.	**Study Title**	**Type of Study** (Sponsor initiated, PI Initiated)	**Risk Level** (No Risk, Minimal, Above Minimal)	**Date Received** (*mm/dd/yy*)	**Date Completed** (*mm/dd/yy*)	**Decision** (*Approved, Disapproved, with Major/Minor Revisions*)	**Remarks**
	1.						
	2.						
	3.						
	4.						
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	15.						

B. Institutional Policy for DOH REC operations

- Attach copy of the updated policies

C. Annual Maintenance and Other Operating Expenses (MOOE)

- Attach copy of the Work and Financial Plan (WFP) for the current year and the proposed WFP for the succeeding year