ESTABLISHING A RESEARCH ETHICS COMMITTEE: A CONSOLIDATED NARRATIVE

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NARRATIVE OUTLINE

1. Inspiration & Instigation

2. Support from Administration

3. Operational Planning

4. Consultation, Confirmation, Cooperation

5. Preparations for Accreditation

6. Application for Level 1 Accreditation

7. OPERATIONS

1. INSPIRATION/INSTIGATION: LIGHT IS LIT!

- A faculty member whose article was refused publication because of lack of ethical clearance.

- A medical consultant who missed being principal investigator because her Medical Centre had no REC.

- A colleague who thinks that a family member who participated in a clinical trial was not treated fairly.

- A stressed research director who was informed by the funding agency a project cannot be supported without ethical clearance.

- A university president who has read the CHED Memo regarding ethical review of research involving human participants.

- A returning faculty fellow whose research proposal underwent ethical review in the foreign university, and hence, appreciated the process.

- A head of an institution who is supportive of scholarship among his/her constituents and wants to practice quality assurance .

- Constituents who want to do the right thing.

2. SUPPORT FROM ADMINISTRATION: KEEPING THE LIGHT LIT.

* Recognition that doing research is an institutional mandate that must be done right if it must contribute to knowledge.

* Identification of a point person / 3-5 key   people to prepare an initial concept paper and prepare for operational plaaningt:

  * Rationale for the establishment of the REC

  * Description of roles and functions an composition of REC.

  * Location of the REC in the organisational structure of the institution.

  * Assignment of a physical location of the office.

3. OPERATIONAL PLANNING

Needed Information

A. Average Annual Volume of research in the institution: Students?, Faculty?, Staff?

B. Types of research conducted/ need to be conducted in the institution

C. Existing Quality Assurance System: Technical Review Panel? IACUC (Institutional Animal Care and Use Committee)? Biosafety Committee?

D. Financial and physical resources

E. Adoption of an appropriate ethics review system

1. Centralized System: Single REC

2. Panel Review System :

  * **Coordinating Office**

  * **Several Review panels, same accreditation level,**

3. Multi-level System: (Levels 1,2, and 3)

  * **Coordinating Office**

  * **Several review panels, different accreditation levels**

THE OPERATIONAL PLAN

* Rationale for Ethics Review: emphasize the importance of scholarship, quality research and respect for rights of research participants;

* Define mandate, functions and responsibilities of the REC;

* Policies /guidelines- what, who will be involved in ethics review; and how

* Selection of potential members (multidiscipline, multisector, gender and age representation, scientists and non-scientist/s, non-affiliated) of the REC

  * Expertise must reflect the type of research expected .

  * Basic research ethics training. Description of the Review system

* Timetable for implementation.

* Budget source

4. CONSULTATION, CONFIRMATION, COOPERATION:

* Consult and involve other stakeholders in refining the concept paper and operational plan - and widen acceptance.

* Obtain support of constituents and formal approval from the institution's policy makers.

Process

A. Dissemination of Concept paper and Operational Plan

B. Consultation with stakeholders: faculty, students, staff

C. Consolidation of opinions and recommendations: (review system, academic calendar, fees)

D. Revision of policies and plan appropriately

E. Finalization of plan and approval by authorities

5. PREPARATION FOR ACCREDITATION

1. Refer to PHREB Policies and Requirements (2017 Sept 07)

2. Choose officers (chair, vice chair, secretary). Specify tasks and responsibilities.

3. Plan activities, identify milestones, time lines

4. Prepare standard operating procedures and forms (Use PHREB SOP Workbook): review application, protocol coding, protocol files, meetings, minutes, forms. Prepare logbook for incoming and outgoing documents. Design a protocol database for tracking status of protocols received for review.

5. Schedule regular meetings and agenda that require attention.

6. REC APPLICATION FOR ACCREDITATION (LEVEL 1)

Required Documents:

- Letter signifying intent

- REC Mandate: constitution and responsibilities of the REC.

- Institutional certificate of support for the REC

- PHREB Form 1.1. Application for Accreditation

- PHREB Form 1.3. Summary of Protocols in the past year (if available)

- PHREB Form 1.4. Self Assessment (Level 1)

7. OPERATIONS

Indicators of readiness

* **Office organised**

  * **Physical set-up and staff work**

* **Review Process Flowchart established**

  * **Review Fees rationalised**

* **Coordination with program directors and other review committees in place.**

* **Go signal from PHREB**

START accepting applications for review

Have a good committee!!