Philippine Health Research Ethics Board: Registration and Accreditation Program

Dr. Cecilia V. Tomas

PHREB Sub Committee on Standards and Accreditation

A. PHREB Policies for Registration and Accreditation of RERCs

promote the establishment of standards that enable ethics committees to conduct quality scientific and ethical review of research protocols and thereby ensure the safety and protection of the rights and welfare of the human participants in research

B. Rationale

- **An effective human research protection system require oversight and proper recognition of research ethics review committees**

1. ERC REGISTRATION helps in monitoring performance and in the identification of ERCs that need assistance for quality review.

2. ACCREDITATION helps improve not only the substantive but also the procedural aspects of scientific and ethical review of research involving human participants.

A. REGISTRATION OF ERCS

- **DOST AO no. 001 series of 2008 – mandatory registration of ERCs doing review of research involving human participants.**
- **So far, only 103 ERCs have registered.**

A. PHREB ACCREDITATION

- **At the start , accreditation will be voluntary but later, mandatory.**
- **Only a duly-registered ERC may apply for accreditation.**

A. PHREB Criteria for Accreditation

1. Functionality of the structure & membership of the ERC
2. Adequacy of the Standard Operating Procedures and consistency in its implementation.
3. Adherence to international, national and institutional guidelines and policies.
4. Completeness of the review process
5. Adequacy of the after-review procedures

6. Adequacy of administrative support for ERC activities
7. Efficient and systematic recording and archiving

B. Accreditation Process

7077993. Application
2. Self-Assessment by ERC
3. Accreditation Team Assessment Visit
4. Issuance of Accreditation Certificate

A. PHREB Levels of Accreditation

Level	Features
Level 1 Qualifies an ERC to review researches involving human participants except clinical trials	• demonstrates sufficient competency and efficiency in ethical review • Adheres to a set of appropriate standard operating procedures • But no office and staff of its own
Level 2 Qualifies an ERC to review clinical trials not intended for registration of new drugs (e.g. non industry trial by Fellows/ consultants)	• Above features PLUS • Has adequate administrative support – office, standard equipment and administrative staff • BUT no database or adequate archiving system
Level 3 • **Gives ERC the privilege of** • **being part of the Ethics** • **Review Resource Committees** • **of the Philippine FDA** • **Allows the ERC to review** • **investigational new drugs** • **(IND) or device protocols** • **where results will be** • **submitted in support of** • **marketing authorization.** • **Complies with ICH GCP**	• • Demonstrate sufficient • competency and efficiency in • ethical review • Adheres to a set of • appropriate SOP • Has adequate administrative • support • Maintains an updated • database of reviewed • protocols and has established • an informative and very good • archival system •