*Tuguegarao, Cagayan; 27-28 February 2012*

# K. ACCREDITATION OF ETHICS REVIEW COMMITTEES

## Philippine Health Research Ethics Board

# *Rationale for Accreditation*

1. Responds to the need for oversight and proper recognition of ethics review committees.

2. Sets standards for quality ethics review thereby ensuring national, regional and institutional consistency in ethics review.

3. Stimulates and accelerates growth and development of ERCs desiring to achieve excellence and effectiveness

# *Criteria for Accreditation*

1. Functionality of Structure and Membership
2. Adequacy of SOPs and 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
7. Efficient and systematic recording and archiving

# *Process of Accreditation*

1. Application
2. Self-assessment
3. Assessment Visit
4. Issuance of Accreditation Certificate

# *(1) Application*

Documents for submission:

1. Composition of the ERC and record of training of members
2. Documents pertaining to creation of ERC
3. Information regarding Office & Secretariat
4. Type and number of research protocols/year.
5. Information on review fees
6. Copy of Registration Certificate

# *(2) Self-Assessment*

Indicative of the degree to which the ERC has complied with requirements:

A. Structure and composition of the ERC
B. Staff support and facilities
C. Adherence to international, national, institutional guidelines and policies
D. Adequacy of Standard Operating Procedures and consistency of implementation and compliance
E. Completeness of the Review Process
F. Adequacy of After-Review procedures
G. Efficiency of the recording and Archiving system.

# *3. Assessment Visit*

Visit scheduled in coordination with applicant ERC

Purpose: To ascertain degree of compliance with accreditation criteria through the conduct of various activities, i.e.,

1. Opening Meeting
2. Orientation on the ERC history, structure and functions.
3. Tour of ERC facilities including archives.
4. Review of documents: membership files, meeting minutes, communications, protocols
5. Interviews staff and selected members
6. Observation of a regular ERC meeting
7. Closing Meeting

# 4. Issuance of Accreditation Certificate

Level 1 – Sufficient competency and efficiency in ethical review and adheres to a set of appropriate SOPs but has no office/staff of it own.

Level 2 – Sufficient competency and efficiency in ethical review and adheres to a set of appropriate SOPs and has adequate administrative support.

Level 3 -Sufficient competency and efficiency in ethical review and adheres to a set of appropriate SOPs and has adequate administrative support, maintains an updated database and informative archival system.

# *Accreditation Levels*

Level 1 – ERC can review researches involving human participants except clinical trials.

Level 2 – ERC can review clinical trial protocols not intended for drug registration.

Level 3 – ERC can review drug/ device trial protocols for registration purposes or marketing authorization and is a member of the Ethics Review Resource Committees of the FDA.

# *Assessment Team*

1. Trained
2. Committed
3. No conflict of interest
4. Independent of the applicant ERC/ Institution
5. Bound to keep confidentiality

# *Assessment Team Members*

Are expected to-

1. Be aware of the schedule of activities and to come on time for these.
2. Be familiar with the ERC Self-assessment.
3. Conduct the accreditation process according to the SOPs.
4. Document findings and observations.
5. Conduct themselves with sobriety and dignity.
6. Refrain from behavior that can undermine the integrity of the accreditation process.

# *Funding*

Joint Funding from PCHRD and Applicant Institution

1. Transportation (air/ land) to and from site
2. Accomodations for 2 nights/3 days for team of 3 members.
3. Meals and snacks for 5-7 trainees
4. per diem allowance for team of 3 members