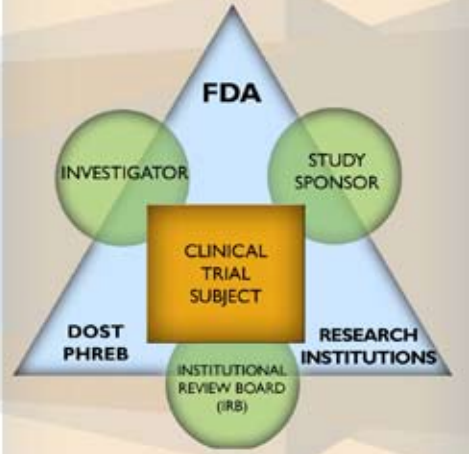
FDA
Food and Drug Administration
PHILIPPINES

GUIDELINES

Regulation of Clinical Trials in the Philippines

CLINICAL TRIAL UNIT
POLICY PLANNING AND ADVOCACY DIVISION
FOOD AND DRUG ADMINISTRATION



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FDA CIRCULAR 2012-007

June 7, 2012

FDA Circular
No. 2012-007

SUBJECT: Recognition of Ethical Review Board/Committee (ERB/ERC) For Purposes of the Conduct of Clinical Trials on Investigational Medicinal Products in the Philippines and for Other Purposes

I. RATIONALE AND BACKGROUND

The Philippines: An Emerging Destination for Global Clinical Trials

In recent years there has been an increase in the number of clinical trials in the Philippines. Of the 10 countries in Southeast Asia, the Philippines ranks third in terms of the number of clinical trials (US NIH, http://clinicaltrials.gov/ct2/search/browse?brwse=locn_cat_SE, Accessed on May 19, 2012).Based on the 2009 report by the European Medicines Agency, the Philippines is ranked as number 8 among the top 10 countries worldwide with a high annual growth rate of 30.9 % in clinical trials. Clinical trials emanating from the European Union increased from 2 in 2005 to 25 in 2008 with a corresponding increase in the number of trial participants from 67 to 3,042 respectively. Likewise, trials emanating from the US increased from 3 in 2000 to 363 in 2009. The Philippines currently ranks third in Southeast Asia with 528 ongoing global trials, after Thailand with 1094, and Singapore with 958 (www.clinicaltrials.gov, accessed on June 5, 2012). FDA received 396 clinical trial applications in 2009; 339 in 2010, and 335 in 2011.

As recruitment for volunteers become more intense with the anticipated increase in clinical studies and given the vulnerabilities of the majority of our people because of poor health, economic status, abuse or poor orientation and lack of awareness of their rights, there is an urgent need to improve regulatory function and promote cooperation between DOH-FDA and other quasi-regulatory agencies suchas the Philippine Health Research Ethics Board (PHREB) of the Philippines National Research Health System (PNHRS) to better ensure that every Filipino patient who volunteers to participate in clinical research studies is accorded due protection as embodied in the Philippine Constitution.

As part of the quest to attain a higher level of competitiveness for the country, there is a need to find a more efficient system that should be benchmarked with global models.

II. OBJECTIVES

In addition to the objectives laid down in the Rules and Regulations implementing Republic Act No. 9711, this Order is hereby formulated to:

To accord due protection to human subjects of clinical trials and ensure the generation of research findings of strong scientific merit, FDA grants recognition and empowersselected institution-based

Ethical Review Board/Committees (ERB/ERCs)undertaketheethical and technical evaluation of clinical trials for the purpose of recommending, to the FDA, the approval of such studies for conduct in the Philippines.

To require mandatory ethical and technical reviews by accredited independent review committees of experts in accordance with existing national regulations (PNHRS Ethics Guidelines) as well as Good Clinical Practice (GCP ICH-E6 1996) guidelines and any supplements and amendments thereof, which are hereby adopted.

To require mandatory inclusion for all clinical trials (Phases I, II, III and IV) in the Philippine Clinical Trials Registry (http://registry.healthresearch.ph).

III. COVERAGE AND SCOPE

This Circular covers the recognition of ERB/ERCs to serve as ethical and technical reviewers for clinical trial applications and is for the compliance is for the compliance of the sponsor companies, Clinical Research Organizations (CROs), and Ethical Review Board/Committees (ERB/ERCs).

This regulation covers Phase I, II, III and IV clinical trials of investigational medicinal products defined as any substance or combinationof substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Investigational medicinal products cover new chemical entities under the investigational phase of drug development as well as existing drug preparations already in the market seeking approval for new or additional indications.

IV. DECLARATION OF POLICIES

Pursuant to the mandates provided under the 1987 Constitution to protect and promote the right to health of the people, Republic Act 3720, as amended by Executive Order 175, otherwise known as the "Food, Drugs and Devices, and Cosmetics Act", to adopt measures that ensure the purity and safety of foods and cosmetics, and, in addition to purity and safety, the efficacy and quality of drugs and devices in the country and as reiterated by Republic Act No. 9711 or the "The Food and Drug Administration (FDA) Act of 2009," the adoption of the International Conference on Harmonization Guideline for Good Clinical Practice or ICH GCP (E6) in the review, approval and regulation of clinical trials not only for vaccines but for all pharmaceutical products as may be applicable or supported by local guidelines as expressed under Administrative Order 47-a, series of 2001 entitled Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials and Lot or Batch Release Certification of Vaccines and Biologic Products is hereby reiterated.

This circular strengthens the technical and ethical review through the use of independent ethical and technical panels that have been audited and accredited by Philippine Health Research Ethics Board (PHREB), the national body constituted under the Philippine National Health Research System (PNHRS)under the Department of Science and Technology (DOST) to ensure that ERB/ERCs comply with international and national standards in the performance of their function. In keeping with international standards to safeguard the quality of research and protect the public from the negative effects of biased reporting and publication, clinical trials are hereby mandatorily required to be posted on the clinical trials registry established under the mandate of PNHRS.

A. FDA Recognition of PHREB-Accredited IRBs to Serve as Ethical and Technical Reviewers for Clinical Trial Applications

The FDA recognizes the following IRBs/ERCs of institutions based on the recommendation of the PHREB:

1. University of the Philippines Manila –National Institutes of Health (UPM-NIH)
2. De La Salle University Health Sciences Institute
3. St. Luke's Medical Center for Clinical Trials

The list will be subject to updating based on PHREB's continuing accreditation of institutions and compliance with other requirements of FDA.

As shown in Figure 1, the ERB/ERCs will submit recommendations to the FDAfor the approval or denial of clinical trial protocols subjected to review. FDA, after due deliberation will renderthe decision for approval or denial.

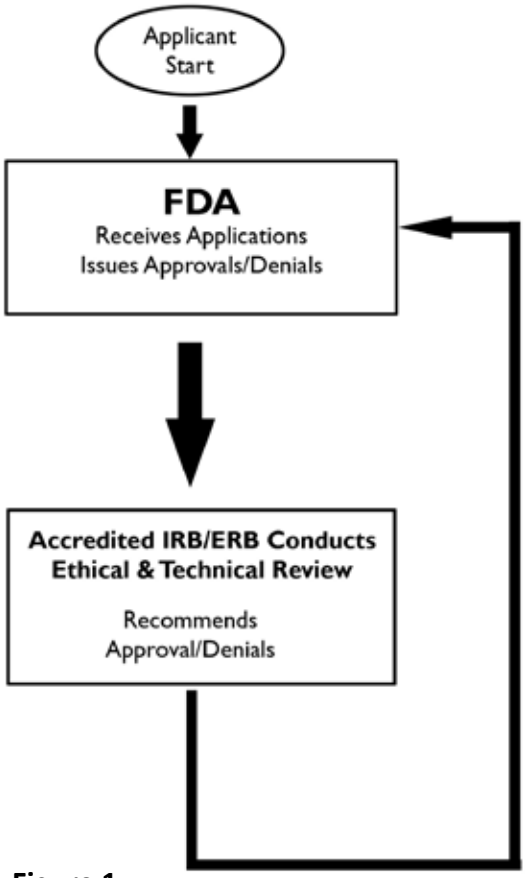


Figure 1
Approval Process for Clinical Trial Applications

The FDA will also coordinate with the ERB/ERCs as well as the PHREB on all matters related to the applications under review to resolve whatever issues will arise.

B. Mandatory FDA Approval for All Phase I to IV Clinical Trials

All clinical studies, from Phase I to IV, including amendment(s) thereto, require mandatory approval from the FDA to ensure that clinical trials intended to be conducted in the country that involve the recruitment of Filipinos as volunteer subjects conform to the highest ethical and technical standards of clinical research. Approval will be based on results of the evaluation that will be carried out by accredited ERB/ERBs.

V. IMPLEMENTATION GUIDELINES

A. In line with the recognition of accredited ERB/ERCs, the Policy Planning and Advocacy Division (PPAD) of the FDA is mainly responsible for providing supervision and oversight (VI. Supervision and Oversight) in the regulation of clinical trials. The Clinical Trial Management Unit under PPAD will be:

1. Responsible for handling the filing of the application, issuance of the ***Clinical Trial Reference No***. and ***"Permit for ERB/ERC Review"*** and approval to conduct clinical trials. PPAD is also responsible for handling amendments to the clinical trial protocols that must be approved by the FDA Director.
2. Responsible for coordinating with the ERB/ERCs on matters relevant to the conduct of the ethical and technical review of clinical trial protocols.
3. Coordinating with PSD who will conduct the review of Part B- Pharmaceutical Data and the issuance of the ***Import Permit***.In addition, PPAD must ascertain that the Regulation Division I beproperly informed of ***Import Permit*** issuances to facilitate processing with the Bureau of Customs.
4. Receiving and acting on amendments and other changes to the clinical trial protocol and coordinating closely with ERB/ERCs
5. Monitoring compliance to mandatory requirement for participation in the Philippines Clinical Trial Registry
6. PPAD will be responsible for conducting on-site inspections of clinical trials; it is imperative that capacity for this be developed as soon as possible.
7. Coordinating with the FDA ADR Unit which is mainly responsible for receiving, analyzing and reporting on Safety Reporting
8. Responsible for maintaining data on statistics and formulating reports for submission regularly to the FDA Director.

B. The Product Services Division is responsible for evaluating the pharmaceutical data of new pharmaceutical products to ascertain that Chemistry, Manufacturing and Controls (CMC) and Good Manufacturing Practice (GMP) standards are met to ascertain the safety of the product for use by clinical trial subjects. Furthermore, PSD is also responsible for issuing the ***Import Permit***. The review of pharmaceutical data must be accomplished within a reasonably efficient timeframe not to exceed thirty (30) calendar days from receipt thereof from PPAD, and issuance of the ***Import Permit*** not to exceed seven (7) working days from receipt of application.

C. The ADR Unit will be the unit responsible for receiving and analyzing reports on Adverse Events.

D. FDA reserves the right to terminate any clinical trial found to be violative of existing regulations or deviates from the approved protocol and monitoring plan.

E. Submission of Application to the FDA

1. Applicant company files applications to the FDA which will set one day of the week, schedule subject to announcement, for receiving applications from eight (8) in the morning to three (3) in the afternoon.

2. Steps in the filing:
   a. File application to PPAD-PAICS for assessment
   b. Go to Accounting Section for validation of Order of Payment
   c. Go to Cashier Section to pay the fee and secure an Official Receipt (OR)
   d. Return to PPAD-PAICS, present OR and secure Clinical Trial Reference Number. Submit documents and receive "Permit for ERB/ERC Review" which will signal the accredited ERB/ERCs to conduct the ethical and technical review.

3. Documents to be submitted will include those in Parts A, B and C and such other documents or data as hereinafter be required by FDA to ascertain safety, efficacy and quality of the products

that will be subject to clinical study.

a. PART A: Clinical Trial Protocol and other Pertinent Documents
   - Name and dosage form of product
   - Title and aim of the trial
   - Description of the trial design
   - Description of the subjects
   - Treatment profile
   - Operational aspects
   - Adverse events
   - Evaluation of results
   - Informed consent form, Case Report Form and Patient Information Sheet
   - Resumes of Principal and other Investigators
   - For multi-center studies, a list of Principal Investigators (and CVs) including trial sites

b. PART B: Pharmaceutical Data

   To ascertain the quality and safety of the IPand to protect clinical trial subjects, FDA needs to ensure that the IP's CMC and manufacturing process is in compliance with acceptable standards (GMP).
   - GMP statement from manufacturing/Certificate from Regulatory Body
   - Certificate of Analysis
   - Stability Data (storage conditions)
   - Manufacturing Data & Formulation
   - Product labeling (coded & labeled: blinding)

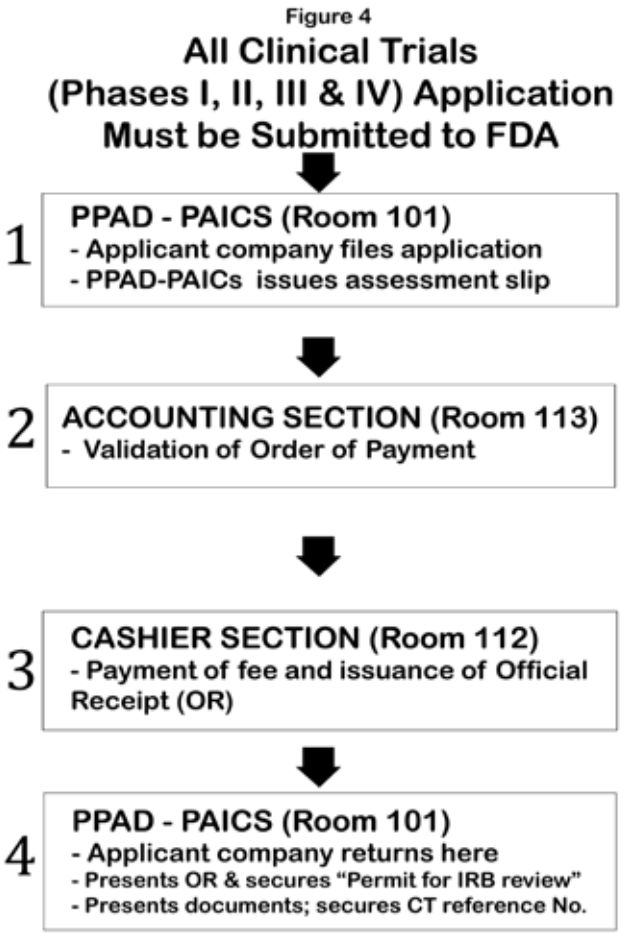
c. PART C: Investigator's Brochure (Efficacy and Safety Data)

   Safety Data:
   - Non-Clinical Studies
   - Pharmacology; PK/PD studies
   - Toxicology Studies
   - Marketing Experience, Periodic Safety Update Reports (PSUR), product status if marketed abroad
   - Risks and ADR anticipated

   Efficacy Data
   - PK/PD Data in human subjects
   - In-house preliminary data
   - Summaries of clinical trial studies conducted (Phase I, II, III)
   - Published clinical data

4. Submission of documents:
   Documents may be submitted as hardcopy or electronic file based on preference of FDA and ERB/ERC.
   Figure 2 below shows algorithm of submission of application to the FDA.

Figure2



5. Amendments, notifications and other reports to be submitted to the FDA will be coursed through the same process (Figure 4). Any amendment to the protocol and accompanying documents will have to be approved by the FDA in close coordination with the ERB/ERCs.

B. Ethical/Technical Review of Applications for Clinical Trials by ERB/ERC

The FDA will accredit the ERB/ERCs of institutions based on the recommendation of the PHREB and the list will be subject to updating based on PHREB's continuing accreditation of institutions. Guidance on the filing, review and approval process must be guided by the following:

1. Approvals of study proposals will be guided by the highest ethical and technical standards.
2. As shown in Figure 3, the initial step entails the submission of an application to the FDA which will issue the Permit for the ethical and technical review of the clinical trial protocol to be done by an accredited ERB/ERC.Accreditation is based on the recommendation of PHREB which conducts audits to assess the capability of ERB/ERCs all over the Philippines.
3. The accredited ERB/ERCs should be guided by the following conditions:
   a. Fees to be charged per project as fee for technical and ethical review by the ERB/ERC will be standardized at THIRTY THOUSAND PESOS. This amount will be subject to regular review every two years.

b. The timeline for the review from acceptance to completion should not exceed 60 days.

c. The institutions will ensure that the individuals who will conduct the review process must have established competence in their areas of specializations and properly disclose conflicts of interest. Participation in the review process, by its nature, grants access to privileged information and thus, is subject to exercising confidentiality on the details of the documents submitted for review by the study sponsor. Reviewers and the study sponsor must adhere to a strict code of ethical conduct that ensures independence of reviewers and objectivity as basis for decisions.

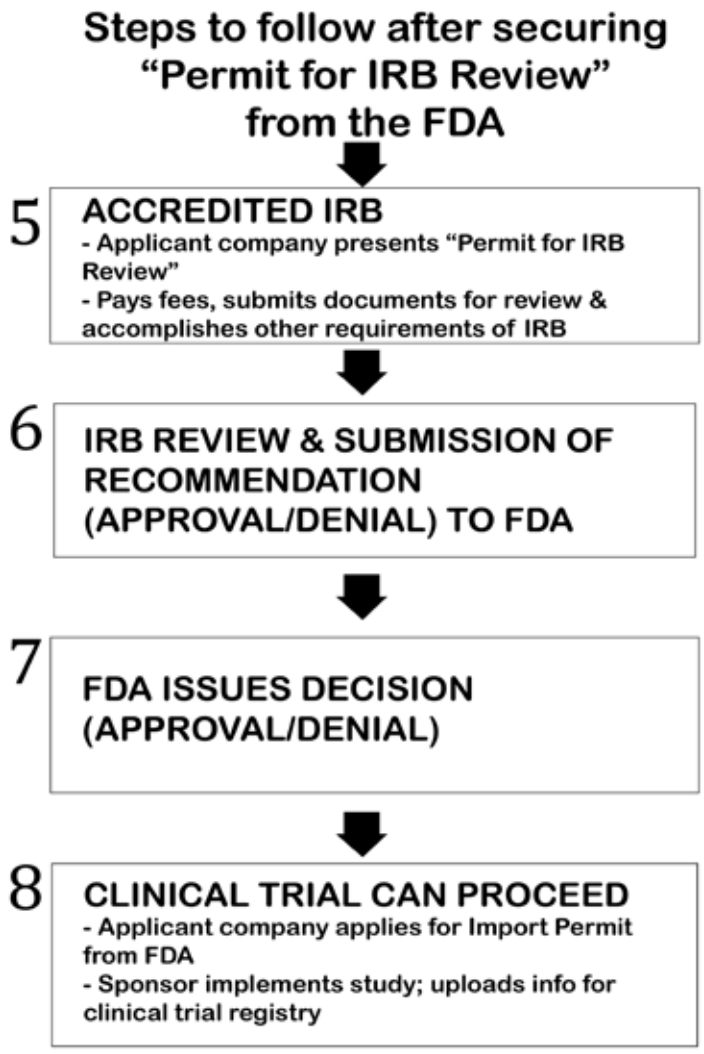
4. FDA will be in close coordination with the ERB/ERCs during the process and will be provided information on the progress of the review and all pertinent matters of the review.

5. The FDA will give the final decision to approve or deny an application based on the recommendation, submitted in written format, emanating from the ERB/ERC review. A document granting approval for the conduct of a clinical trial based on the completed technical and ethical review by the ERB/ERC will be issued by the FDA to the study sponsor.

C. Mandatory inclusion of clinical trials in the Philippine Clinical Trial Registry

All clinical trials are required to be uploaded in the Philippine Clinical Trial Registry. It is the responsibility of the study sponsor to upload information related to the clinical trial it is conducting to the Registry (http://registry.healthresearch.ph) 30 days after the application to conduct the clinical trial has been granted.

Figure 3



D. Access to medicines for use in clinical trials using the Import Permit

The FDA, as mandated by law, grants approval to all locally manufactured and imported drug products seeking entry into the Philippine market by the issuance of a Certificate of Product Registration (CPR). Only such drug products with CPRs are allowed to be imported and sold in the country. For purposes of clinical trials use, medicines not registered by the FDA can be accessed by an Import Permit. In addition to drug products, the Import Permit allows the inclusion of ancillary supplies such as laboratory kits, reagents, and other materials to be used for the clinical trial concerned to be imported.

The procedure to secure an Import Permit will be defined by FDA based on what capacity is available at its disposal. Specifically, it is currently done under the existing practice of securing permits using a manual system but may, in the futureand pending ongoing feasibility studies, utilize a computerized online system such as the National Single Window (NSW).

1. The Import Permit authorizes the importation ofdrug products and materials for purposes of clinical trials provided that the clinical trials protocol has been reviewed and ascertained to comply with acceptable ethical and technical standards by a duly-accredited Institutional Review Board and granted the approval to proceed by the FDA.
2. The following can apply for the Import Permit:
    a. Principal investigator
    b. Authorized representative of the Study sponsor (registered pharmaceutical company with permanent address in the Philippines
    c. CRO, with permanent Philippine address, representing the sponsor through a letter of authorization
3. To secure an Import Permit, the application must be supported by the FDA document attesting to the approval of the clinical trials to proceed based on compliance to ethical and technical requirements as ascertained by the ERB/ERC.
4. Under the existing FDA system, the Import Permit will be issued by PSD with the cooperation of the Regulation Division I which has linkage with the Bureau of Customs in this regard.

E. Inspections of clinical trials:

FDA shall conduct random inspections on the clinical trial sites to monitor complianceto the approved study protocol and monitoring plan of the sponsor. It shall specifically look into adherence to the GCP:

F. Safety Reporting

Reporting must be consistent with ICH Topic E2A- Clinical Data Management: Definitions and Standards for Safety Reporting.

1. Suspected Unexpected Serious Adverse Drugs Reactions (SUSARs)
    a. Fatal or Life-Threatening Unexpected ADRs

    All adverse drug reactions (ADRs) that are both serious and unexpected are subject to expedited reporting. Fatal (deaths) or life-threatening, serious unexpected ADRs occurring in clinical trials, onsite or offsite (for multi-site studies) should be reported. The FDA should be notified (landline/mobile phone, facsimile transmission, email or written letter) as soon as possible **but no later than 7 calendar days** after first knowledge by the sponsor that a case qualifies, followed by a complete report as soon as possible **within 8 additional calendar days**. The CIOMS-I form has been a widely accepted standard for expedited adverse event reporting

b. All Other Unexpected Serious ADRs

Serious, unexpected reactions (ADRs) that are not fatal or life-threatening, whether onsite or offsite, must be filed as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

2. ExpectedAdverse Drug Reactions

a. Serious adverse drug reactions which are expected based on information from Investigator's Brochure will be reported in the regular progress report and final report.

b. Adverse drug reactions which are not serious will also be reported in the regular progress report and final report.

G. Termination of Clinical Trial and Sanctions

For the effective implementation of this Circular, this Office shall order the termination of an on-going clinical trial without need of a hearing should the result of random trial sites inspections reveal any major violation(s), notifying only the concerned establishment of such termination. Other sanction(s) to concerned entities shall be imposed respectively under the following instances of violations and the table below:

1. The result of the random clinical trial sites inspections shall have the following categories:
   a. No violation - No objectionable conditions or practices were found during the inspection, or the significance of the documented objectionable conditions found does not justify further FDA action (from USFDA). Compliant to GCP rules and approved protocol
   b. Minor violations - Regulatory violations uncovered during the inspection are few and do not seriously impact subject safety or data integrity.
   c. Major violations-The regulatory violation(s) uncovered is/are significant/serious and/or numerous, and the scope, severity, or pattern of violation(s) support a finding that:
      1) Subjects under the care of the investigator would be or have been exposed to an unreasonable and significant risk of illness or injury.
      2) Subjects' rights would be or have been seriously compromised. OR
      3) Data integrity or reliability is or has been compromised.
      4) Non disclosure of conflict of interest by the investigator and other members of the trial team
      5) Failure to get an informed consent is a major violation

Any pharmaceutical product the clinical trial of which has been ordered terminated by FDA shall be a ground for the invalidation of data for drug registration purposes and accordingly disapproval of subsequent application for product registration pursuant to Paragraphs (1) or (6), Item B, Section 4, Article I, Book II of the Implementing Rules and Regulations of Republic Act No. 9711 on ground that application requirements does not meet the required technical requirements or appropriate standards, or such other analogous grounds or causes as determined by the FDA.

2. Disciplinary actions shall be imposed on the following after finalizing the Inspection Report by the Legal Division of the FDA.

Entity/Individual	Minor Violation(s)	Major Violation(s)
Researcher	Warning, re-inspection	Suspension from conduct of researches from (range in months or years) depending on the type and degree of violation
Sponsor	Warning, re-inspection	Termination of trial, invalidation of data for drug registration purposes
Ethics Review Committee The FDA shall recommend appropriate action to the PHREB based on inspection findings.	Warning, re-inspection	Suspension from the conduct of reviews for (range in months/ years) depending on the type and degree of violation

H. Archiving and Database Management

All original and latest approved versions of CT protocols, IB, Informed Consent, ERC proof of approval, summary of amendments, and final CT report including summary of safety reports shall be recorded, filed and archived by the clinical unit of the FDA.

Stored files shall be accessed only by duly authorized personsand shall be stored and disposed thereafter in a manner as may be provided by existing laws, rules and regulations. Disposal of files shall be in coordination with the Records Section of the Administrative Division which shall seek approval from the National Archives of the Philippines.

VI. SUPERVISION AND OVERSIGHT

The Policy Planning and Advocacy Division (PPAD) shall supervise and provide technical guidance in the implementation of this Circular. The Clinical Trial Management staff shall prepare and submit quarterly reports to the Chief of the PPAD on the status of implementation, issues and problems and proposed solutions.

Likewise, the PPAD shall provide the FDA MANCOM an annual report on the implementation of this Circular.

In pursuit of good governance and transparency the PPAD shall organize and convene regular meetings with concerned partners and networks to provide updates and reports on the implementation or any matter concerning this Circular.

VII. SEPARABILITY AND REPEALING CLAUSE

In the event that a rule, section, paragraph, sentence, clause or words of this Circular is declared invalid for any reason, the other provisionsnot affected/ or without material significance shall remain in force and effect.

All provisions of previous issuances and other related issuances inconsistent or contrary with the provisions of this Circular are hereby revised, modified, repealed or rescinded accordingly. All other relevant provisions of existing issuances supporting this Circular shall remain valid and in effect.

VIII. EFFECTIVITY

This Circular shall take effect immediately. A Task Force to facilitate the transition has been set up under the supervision of PHREB to coordinate the smooth transitioning into the new system that will involve the technical and ethical evaluation to be carried out by the institutional ERB/ERCs.

(Signed)
SUZETTE H. LAZO, MD
Acting Director IV, FDA

CLINICAL TRIAL APPLICATION FORM

DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

CLINICAL TRIAL REGISTRATION & APPLICATION FORM

APPLICATION NO.:_____

1. STUDY SPONSOR:					
2. ADDRESS:					
3. STUDY TITLE:					
4. DATE OF SUBMISSION		TELEPHONE:		FAX:	
5. THIS SUBMISSION CONTAINS THE FOLLOWING *(Check all that apply)*	☐ INITIAL APPLICATION	PROTOCOL AMENDMENT ☐ CHANGE IN PROTOCOL ☐ ADDITIONAL INVESTIGATOR ☐ ADDITIONAL STUDY SITE(S) ☐ RESPONSE TO REQUEST FOR INFORMATION ☐ INFORMATION AMENDMENTS		OTHERS:	
6. PHASE(S) OF CLINICAL TRIAL TO BE CONDUCTED:	☐ PHASE I	☐ PHASE II	☐ PHASE III	☐ PHASE IV (POST MARKETING SURVEILLANCE)	
7. NAME OF DRUG:	*(Include Proprietary, Generic, Code):*				
10. STUDY DURATION:					
11. STUDY SITE(s):					
12. PRINCIPAL INVESTIGATOR:	NAME:				
	TELEPHONE/MOBILE:	EMAIL ADDRESS:			
	(other) IRB Approval Details				
8. IS ANY PART OF THE CLINICAL TRIAL TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION (CRO):	☐ YES ☐NO If YES, state the name of the CRO:_____ *Attach a statement containing the name and address of CRO and the summary of responsibility*				
9 . NAME AND CONTACT DETAILS OF PERSON RESPONSIBLE FOR MONITORING CONDUCT AND PROGRESS OF THE CLINICAL TRIAL:	NAME:				
	TELEPHONE/ MOBILE:	EMAIL ADDRESS:			

13. Documents Submitted	PART A: Clinical Trial Protocol and other Pertinent Documents ☐ Name and dosage form of product ☐ Title and aim of the trial ☐ Description of the trial design ☐ Description of the subjects ☐ Treatment profile ☐ Operational aspects ☐ Adverse events ☐ Evaluation of results ☐ Informed consent form, Case Report Form and Patient Information Sheet ☐ Resumes of Principal and other Investigators ☐ For multi-center studies, a list of Principal Investigators (and CVs) including trial sites
	PART B: Pharmaceutical Data ☐ GMP statement from manufacturing/Certificate from Regulatory Body ☐ Certificate of Analysis ☐ Stability Data (storage conditions) ☐ Manufacturing Data & Formulation ☐ Product labeling (coded & labeled: blinding)
	PART C: Investigator's Brochure (Efficacy and Safety Data) <u>Safety Data</u>: ☐ Non-Clinical Studies ☐ Pharmacology; PK/PD studies ☐ Toxicology Studies ☐ Marketing Experience, Periodic Safety Update Reports (PSUR), product status if marketed abroad ☐ Risks and ADR anticipated <u>Efficacy Data:</u> ☐ PK/PD Data in human subjects ☐ In-house preliminary data ☐ Summaries of clinical trial studies conducted (Phase I, II, III) ☐ Published clinical data
14. Submitted by:	
CLINICAL TRIAL REFERENCE (CTR) NUMBER:	
DATE OF ISSUE:	
RECEIVED BY:	

PERMIT FOR REVIEW

DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

PERMIT FOR ERB/ERC REVIEW

PERMIT NO._____

STUDY SPONSOR		
ADDRESS:		
CRO (REPRESENTING SPONSOR)		
ADDRESS		
CONTACT INFO:	TELEPHONE/FAX:_____ MOBILE:_____ EMAIL ADDRESS:_____	
3. NAME OF DRUG	*(Include Proprietary, Generic, Code):*	
4. STUDY TITLE		
5. STUDY SITE(s)	1. 2. 3.	
6. PRINCIPAL INVESTIGATOR:	NAME:	
	TELEPHONE/MOBILE:	EMAIL ADDRESS:
7. ERB/ERC REVIEW TO BE CONDUCTED AT:	☐ UP NIH ☐ De La Salle University ☐ St. Luke's Medical Center	☐ _____ ☐ _____ ☐ _____
CLINICAL TRIAL REFERENCE (CTR) NUMBER:		

_____

THERESE IRYNNE GONZALEZ
Chief of PPAD

DATE:_____

FDA ASSESSMENT FORM

FDA Form No _____

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

I. ADMINISTRATIVE INFORMATION		
1. Clinical trial number		<FDA-issued unique code>
2. Clinical trial protocol title		<Full protocol title>
3. Clinical trial version number		<As indicated in the protocol>
4. Clinical trial version date		< As indicated in the protocol> <dd/mm/yyyy>
5. Clinical trial phase (*Note: Review by FDA-recognized institutions is limited to phases indicated in this form*)		___ Phase 1 ___ Phase 2 ___ Phase 3 ___ Phase 4 *Type*: _____
6. Sponsor-applicant:		<Name of sponsor>
7. CRO-applicant:		<Name of CRO>
8. Date received by institution:		<dd/mm/yyyy>
9. Reviewing institution:		<Name of reviewing institution>
	9.1. Address	
	9.2. Signatory official:	<Title, Name, Surname>
	9.3. Position & Designation:	<Institutional position & review designation>
	9.4. Signature:	
	9.5. Review date:	<dd/mm/yyyy>
	9.6. Telephone:	
	9.7. Fax:	
	9.8. Email:	

10. Declaration of conflict of interest (COI)

The <NAME OF INSTITUTION> declares that the institution and the experts involved in this review have no COI in any form related to the abovementioned clinical trial/that the <institution/experts involved in this review/both> have <financial, proprietary, professional> conflict of interest related to the abovementioned clinical trial due to <describe COI> and managed such COI by <describe COI management>.

11. Confidentiality Agreement

The <NAME OF INSTITUTION> as well as the experts involved in this review agreed to take reasonable measures to protect the confidential information pertinent to this review, subject to applicable legislation, not to disclose confidential information to any person; not to use confidential information for any purpose outside this review, and in a manner which would result in a benefit to itself or any third party; and to return all confidential information and documents (including any minutes or notes) upon demand of the FDA.

12. Recommendations to the FDA:

☐ **Approval**

☐ **Deferment of action** pending resolution of conditions detailed under **Section 8** (see assessment information)

☐ **Disapproval** of the conduct of clinical trial in the Philippines due to:

- Objections as indicated in: <indicate relevant sections>
- Deficiencies as indicated in: <indicate relevant sections>

FDA CLINICAL TRIAL ASSESSMENT FORM

Version 1.2/16 July 2012

II. ASSESSMENT INFORMATION

Information under this section should be compiled through full board deliberation of the documents submitted to the relevant committee in the institution that performed this review. Recommendations issued through this review are based on the assessment of components outlined in this section. This template is accomplished electronically, but must be printed, then verified and signed by the designated institutional signatory official. A fully accomplished form should be signed and submitted to the FDA within 30 days of receipt of protocol package.

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
1. SCIENTIFIC AND SOCIAL VALUE	**Yes**	**No**		
1.1. Philippine community health priority addressed				
1.2. Disease priority addressed				
1.3. Potential Impact on deeply-held values of the Filipino				
1.4. Conclusions on the potential **SCIENTIFIC AND SOCIAL VALUE** of this clinical trial:				

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
2. PRE-CLINICAL DATA	**Yes**	**No**		
2.1. Toxicology				
2.2. Environmental risk				
2.3. Conclusions on the **PRE-CLINICAL DATA** supporting this clinical trial application:				

COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT** *(Dose-response studies, clinical studies in special populations such as pediatric populations, pooled and meta-analysis, and other supporting studies)*
3. PRIOR CLINICAL DATA	**Yes**	**No**		
3.1. Pharmacodynamics and pharmacokinetics				
3.2. Phase 1 (completed)				Years conducted
				Sites

FDA CLINICAL TRIAL ASSESSMENT FORM

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				Enrolment: <number of patients>
				Findings
3.3. Phase 2 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.4. Phase 3 (completed)				Years conducted
				Sites
				Enrolment: <number of patients>
				Findings
3.5. Conclusions on the **PRIOR CLINICAL DATA** supporting this clinical trial application:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
4. STUDY DESIGN	**Yes**	**No**		
4.1. Duration				
4.1.1. Main phase				<time><N/A>
4.1.2. Run-in phase				<time><N/A>
4.1.3. Extension phase				<time><N/A>
4.2. Hypothesis				<Superiority> < Equivalence> <Non-inferiority> <Exploratory: specify> <Others: specify>
4.3. Treatment groups				
4.3.1. Group 1				<treatment>,<duration>, <number randomized>
4.3.2. Group 2				<treatment>,<duration>, <number randomized>
4.3.3. Group 3				<treatment>,<duration>, <number randomized>
4.3.4. <if placebo group included>				<scientific and methodological justification for the use of placebo>
4.4. Endpoints and definitions				
4.4.1. Primary				<appropriateness of endpoint and method of measurement>
4.4.2. Secondary/Other (specify)				<appropriateness of endpoint and method of measurement>
4.4.3. Secondary/Other (specify)				<appropriateness of endpoint and method of measurement>
4.4.4. <add rows as needed>				<appropriateness of endpoint and method of measurement>
4.5. Statistical analysis for primary endpoint				<Intent to treat> <Per protocol> <other: specify><time point>
4.6. Statistical analysis for				<Intent to treat> <Per protocol>

FDA CLINICAL TRIAL ASSESSMENT FORM

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secondary endpoint				<other: specify><time point>
4.7. Conclusions on the **STUDY DESIGN** proposed for this clinical trial:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
5. CLINICAL SAFETY	**Yes**	**No**		
5.1. Expected adverse events				
5.2. Expected serious adverse events and deaths				
5.3. Expected adverse laboratory events				
5.4. Safety in special populations				<adequate identification of populations wherein precaution/ safety measures/exclusion is exercised>
5.5. Adverse immunological events (if applicable)				
5.6. Drug-drug interactions and other interactions				
5.7. Pharmacovigilance system and plan				<adequacy of compliance with regulatory reporting systems for AEs>
5.8. Risk management system and plan				<appropriateness of risk management method *vis à vis* expected risks>
5.9. Conclusions on the **CLINICAL SAFETY** plan proposed for this clinical trial:				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	**ASSESSMENT**
6. BENEFIT-RISK ASSESSMENT	**Yes**	**No**		
6.1. Beneficial effects of the intervention to the target population				<Uncertainty/certainty in the knowledge about the beneficial effects>
6.2. Unfavorable effects of the intervention to				<Uncertainty/certainty in the knowledge about the unfavorable

FDA Form No _____

FDA CLINICAL TRIAL ASSESSMENT FORM

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the target population				effects>
6.3. Vulnerable populations involved				<Justification of risks to vulnerable populations>
6.4. Use of placebo				<Compliance with international and national ethical guidelines in the use of placebo>
6.5. Benefit-risk balance				<Significance of favorable and unfavorable effects as detailed above>
6.6. Conclusions on the **BENEFIT-RISK** ratio of this clinical trial: <favorable or unfavorable>				
COMPONENT ASSESSED	*Do the documents submitted have adequate information for assessment?*		*Documents assessed & relevant sections*	
7. STUDY SITES	**Yes**	**No**		
7.1. List of sites				

STUDY SITES	TYPE	PROFILE	ERC	If none
7.1.1.<Name of site>	<tertiary/ secondary> <teaching hospital> <others: specify>	Facilities, accreditation, government classification, etc	<PHREB registration number>	<justification if no institutional or local ERC>
7.1.2.<add rows as needed>				

7.2. Conclusions on the appropriateness of the proposed **STUDY SITES** for this clinical trial:

8. SUMMARY OF RECOMMENDED CONDITIONS FOR APPROVAL OF IMPLEMENTATION OF CLINICAL TRIAL IN THE PHILIPPINES (with reference to the above discussions)

8.1. Social and Scientific Value

8.2. Assessment of Pre-Clinical Data

8.3. Assessment of Prior Clinical Data

8.4. Study design assessment

8.5. Safety assessment

8.6. Benefits and risks assessment

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8.7. Study Sites Assessment
9. SUMMARY OF REGULATIONA APPLICABLE TO THIS CLINICAL TRIAL APPLICATION (and used in this assessment)
9.1. Regulation 1
9.2. Regulation 2
9.3. Regulation 3
9.4. Regulation 4
10. SUMMARY OF INTERNATIONAL AND NATIONAL GUIDELINES APPLICA TO THIS CLINICAL TRIAL APPLICATION (and used in this assessment)
10.1. Guideline 1
10.2. Guideline 2
10.3. Guideline 3
10.4. Guideline 4
11. SUMMARY OF OTHER REFERENCES USED IN THIS ASSESSMENT
11.1. Reference 1
11.2. Reference 2
11.3. Reference 3
11.4. Reference 4

DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

APPROVAL TO CONDUCT CLINICAL TRIAL

APPROVAL NO:_____

1. STUDY SPONSOR		
CRO (If represented)		
2. ADDRESS		
3. NAME OF DRUG	*(Include Proprietary, Generic, Code):*	
4. STUDY TITLE		
5. STUDY SITE(s)		
6. PRINCIPAL INVESTIGATOR:	NAME:	
	TELEPHONE/MOBILE:	EMAIL ADDRESS:
7. ERB/ERC REVIEW CONDUCTED AT:	(Please attach recommendation)	
8. DATE COMPLETED		
CLINICAL TRIAL REFERENCE (CTR) NUMBER:		

Approval is hereby granted to conduct the clinical trial.

APPROVED:

_____

ASEC NICHOLAS LUTERO III, Esq., CESO III

OFFICER-IN-CHARGE, FDA

DATE OF APPROVAL:_____

LIST OF ACCREDITED INSTITUTIONS AS OF JULY 2012
AND THEIR
STANDARD OPERATING PROCEDURES OF ACCREDITED INSTITUTIONS

ACCREDITED INSTITUTIONS

1. De La Salle Health Sciences Institute
2. Research Institute for Tropical Medicine
3. Philippine Heart Center
4. St. Luke's Medical Center
5. University of Santo Tomas
6. University of the Philippines

De La Salle Health Sciences Institute

Dasmarinas City, Cavite, 4114 Philippines

Guidelines for Regulatory Review of Clinical Trials

1. The company or study sponsor must first file an application for assessment at the Food and Drugs Administration (FDA). The applicant company shall likewise obtain necessary papers for the conduct of an ethical and technical review and submit to the FDA the required documents to ascertain safety, efficacy and quality of the products that will be subject to clinical study.

2. The FDA shall inform the applicant company to which Institutional Review Board/Ethics Review Board (IRB/ERB) they shall be assigned to. Study sponsors assigned to the De La Salle Health Sciences Institute (DLSHSI) IRB/ERB shall submit the protocols and other requirements to Mr. Andrew Casipi, the Project Coordinator for Clinical Trials, at the following address:

   Office of the Vice Chancellor for Research
   3/F Room 6301, Angelo King Medical Research Center,
   De La Salle Health Sciences Institute,
   Gov. D. Mangubat Ave., Burol Main,
   Dasmariñas City, Cavite 4114

3. Documents to be submitted will include those in Parts A, B and C and such other documents or data as required by FDA to ascertain safety, efficacy and quality of the products that will be subject to clinical study.

   3.1 PART A: Clinical Trial Protocol and other Pertinent Documents

   3.1.1 Name and dosage form of product
   3.1.2 Title and aim of the trial
   3.1.3 Description of the trial design
   3.1.4 Description of the subjects
   3.1.5 Treatment profile
   3.1.6 Operational aspects
   3.1.7 Adverse events
   3.1.8 Evaluation of results
   3.1.9 Informed Consent Form, Case Report Form and Patient Information Sheet
   3.1.10 Resumes of Principal and other Investigators
   3.1.11 For multi-center studies, a list of Principal Investigators (and CVs) including Trial Sites

3.2 PART B: Pharmaceutical Data to ascertain the quality and safety of the Investigational Product and to protect clinical trial subjects, FDA needs to ensure that the IP's CMC and manufacturing process is in compliance with acceptable standards (GMP).

3.2.1 GMP statement from manufacturing/Certificate from Regulatory Body
3.2.2 Certificate of Analysis
3.2.3 Stability Data (storage conditions)
3.2.4 Manufacturing Data & Formulation
3.2.5 Product labeling (coded & labeled: blinding)

1.3 PART C: Investigator's Brochure (Efficacy and Safety Data)

1.3.1 Safety Data
3.3.1a Non-Clinical Studies
3.3.1b Pharmacology; PK/PD studies
3.3.1c Toxicology Studies
3.3.1d Marketing Experience, Periodic Safety Update Reports (PSUR), product status if marketed abroad
3.3.1e Risks and ADR anticipated

1.3.2 Efficacy Data
3.3.2a PK/PD Data in human subjects
3.3.2b In-house preliminary data
3.3.2c Summaries of clinical trial studies conducted (Phase I, II, III)
3.3.2d Published clinical data

3 The following are required to be submitted for the regulatory review at DLSHSI:
3.3 One (1) electronic copy (compact disc) of Parts A and C.
3.4 Four (4) hard copies of Parts A and C
3.5 One (1) hard copy of Part B
3.6 Clinical Trial Reference Number from FDA
3.7 Permit for Regulatory Review from FDA
3.8 Check payment for Regulatory Review

4 The check payment must be payable to <u>De La Salle Health Sciences Institute</u> in the amount of Thirty Thousand Pesos (PhP 30,000.00 – not subject to tax). The review process will commence only upon receipt of the full payment for regulatory review. You will be provided with an Official Receipt and a Regulatory Review Receipt Form by the Project Coordinator.

5 A tracking system that is secure yet accessible to FDA and the study sponsor will be used to monitor the status of the screening process. To have access to this tracking system, the sponsor should provide the project coordinator with an e-mail address of their designated contact person. We will also inform you through text, email, or telephone call.

5.1 If applicable or necessary, an Interim Recommendation from DLSHSI IRB/ERB will be communicated to the FDA and the Study Sponsor within thirty (30) days from the start of the review process. The study sponsor should respond to DLSHSI IRB/ERB within two (2) weeks upon receipt of the Interim Recommendation.

5.2 A final recommendation from the DLSHSI IRB/ERB will be communicated to the FDA within sixty (60) days from the start of the review process.

For further inquiries, please contact:

Mr. Andrew C. Casipi
Project Coordinator for Clinical Trials
Mobile No: 09207316391 or 09166194617
Telefax: (046) 481-8000 local 4000
e-mail: casipi_andrew@yahoo.com

RITM-FDA-ERB SUBMISSION SOP

(TIMELINES EXPRESSED HERE ARE IN WORKING DAYS, EXCLUDES WEEKENDS AND HOLIDAYS)

	Steps	Timeline
1	FDA sends review packet to RITM-FDA-ERB Subcommittee	Day 0
2	RITM-FDA-ERB gives a statement to pay the review fee	Day 0
3	Sponsor pay **PhP 30,000 (net of tax)** to the **Research Institute for Tropical Medicine, Dept of Health. Proceed to the cashier's counter of the RITM and an government receipt will be issued upon payment.**	Day 0
4	RITM-FD-ERB Subcommittee Secretariat checks completeness of packet The sponsor must provide a checklist of all documents submitted in duplicate copies, one is retained by sponsor as acknowledgment copy and the other to be retained by RITM-FD-ERB. Five (5) copies of all documents (5 sets of documents) must be submitted to the Chair through the Secretariat of RITM-ERB.	Day 0
5	RITM-FD-ERB Subcommittee Chair assigns review panel and sends out review packet to reviewers together with the declaration of the conflict of interest and assessment form. Any member who withdraws due to COI will be replaced from the pool of RITM-ERB members	Day 2
6	Reviewers perform the review the protocol and other materials within twelve working days using the assessment form.	Day 4– 17
7	All reviewers send their assessment forms to the RITM-FD-ERB.	Day 18
8	Chair of the RITM-FD-ERB Subcommittee collates the assessment forms	Day 19
9	Chair of the RITM-FD-ERB Subcommittee schedules the committee meeting	Day 21
10	RITM-FD-ERB Subcommittee Chair convenes the board to discuss the RITM-FDA-ERB Sub Committee recommendations.	Day 25
11	RITM-FDA-ERB Subcommittee finalizes its recommendation.	Day 25
11a	If final recommendation go to item 18	Day 25
11b	If recommendation is to obtain additional documentation, Secretariat communicates request to sponsor. Sponsor will be given 5 days to submit additional requirements.	Day 26
12	Additional document requirements expected to be received by RITM-FDA-ERB	Day 31
13	Additional document requirements sent out to reviewers.	Day 32
14	Reviewers review additional document requirements for three days.	Day 33 - 35
15	All reviewers send their assessment forms to the RITM-FDA-ERB.	Day 36
16	Chair of the RITM-FDA-ERB Subcommittee collates the assessment forms	Day 37
17	RITM-FDA-ERB Subcommittee finalizes its recommendation.	Day 38
18	RITM-FD-ERB Subcommittee prepares communication of its decision to the FDA.	Day 25/40
19	RITM-FD-ERB Subcommittee Secretariat submits final recommendation to the FDA.	Day 26/41
20	RITM-FD-ERB Subcommittee returns all documents used for the review to the sponsor.	Day 27/42

by: Gemiliano D. Aligui, MD, MPH,PhD
Co-chair, RITM IRB

15 August 2012

PHILIPPINE HEART CENTER QUALITY MANUAL	Department / Division INSTITUTIONAL ETHICS REVIEW BOARD	Page Number	Page 1 of 8
		P/P Number	PHC-IERB-01-31-00
	Title	Date Reviewed	
	3.6 MANAGEMENT OF PROTOCOL SUBMITTED BY FDA-PPAD	Registration Date	9 July 2012
		Effective Date	16 July 2012

1. Purpose

To describe how the Institutional Ethics Review Board (IERB) manages protocol submitted by sponsor/s for regulatory review by FDA-PPAD.

2. Scope

It covers the actions done from the time of submission of documents for IERB review by the sponsor to the IERB Secretariat to the return of same regulatory review documents to the FDA-PPAD.

3. Responsibility

Secretariat – receives the initial protocol package and payment for the protocol review
PPAD – sends the notification letter to the PHC IERB
Sponsor – submits protocol package and payment for protocol review to PHC IERB
IERB – evaluates the protocol and sends report and recommendations to FDA-PPAD

4. Policy

4.1 The PHC IERB shall receive permit letter regarding a protocol for regulatory review from FDA-PPAD.

4.2 The sponsor shall submit a protocol package to the PHC IERB.

4.3 Requirements for protocol submission can be accessed from the IERB Secretariat or through email (irbphc@gmail.com). The protocol package will be send by FDA to IERB.

4.4 The sponsor shall pay PHC-IERB an amount of P30,000.00 for every protocol review.

- 4.4.1 The sponsor shall give payment to PHC cashier for PHC IERB protocol review.
- 4.4.2 A copy of official receipt shall be forwarded to the IERB secretariat.

4.5 The Chairman shall invite an independent consultant for non-cardiology and non-pulmonary protocol.

4.6 The Board Secretary shall document all meetings regarding review of all protocols including decisions and recommendations to the FDA-PPAD.

4.7 The Chairman shall designate the secretariat to be the liaison officer to the Task Force and FDA-PPAD.

5 Procedure

5.1 Receipt of the protocol package

The Secretariat:

5.1.1 receives the notification from FDA-PPAD

5.1.2 receives ten (10) copies of the initial protocol package with Initial IERB Application Form - PHC-IERB-03-21-01

5.1.3 stamps "RECEIVED" on the protocol package and signs the document receipt form

5.1.4 encodes the accession number of the protocol package to the assigned FDA-PPAD database.

5.2 Management of the protocol package

The Secretariat:

5.2.1 Prepares copies of the protocol package for distribution to the reviewers.

5.3 Conduct of Full Board Review

5.3.1 The IERB Chairman schedules the protocol review

5.3.2 The IERB evaluates the protocol as a full board review in an en banc meeting.

5.3.3 The IERB makes a decision and gives recommendations to the FDA-PPAD.

5.3.4 The IERB members sign the IERB's decision form.

5.4 Communication of recommendation to FDA -PPAD

5.4.1 The recommendations to FDA-PPAD are categorized into:

5.4.1.1 Approval

5.4.1.2 Deferment of action pending recommendation of condition under section 8

5.4.1.3 Disapproval

5.4.2 The IERB copy furnishes the FDA-PPAD of all communications with the sponsor.

5.4.3 The IERB gives final recommendation/s to the FDA-PPAD within 60 days.

5.4.4 The Secretariat returns all regulatory review documents to FDA-PPAD for archiving.

7 Annex

Annex 1 - Document Receipt Form - PHC-IERB-03-14-01
Annex 2 - Initial IERB Application Form - PHC-IERB-03-21-01

8 References

8.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
8.2 FERCAP SOP 2006
8.3 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

Annex 1

PHILIPPINE HEART CENTER
Institutional Ethics Review Board
8/F Medical Arts Building
East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

PHC-IERB-03-14-01

Document Receipt Form

1. Accession Number:		Submitted date:	
2. Source of Fund:	☐ PHC Funded	☐ Non-PHC Funded	
3. Protocol Number:		Sponsor Number	
4. Sponsor	PHC		
5. Principal Investigator:			
6. Protocol Title:			
7. Type of Submission:	___Initial Review ___Resubmission for a re-review ___Protocol Amendments	___Continuing Review ___Approved Protocols ___Protocol Termination	
8. Delivery Route:	☐ Post	☐ In Person	
9. Documents Submitted	☐ Full Protocol ☐ Declaration of No Conflict of Interest ☐ Data Collection Form(s) ☐ Informed Consent Form (English & Local Dialect) ☐ Assent Form (English & Local Dialect) ☐ Subject Worksheets/ Patient Diary /Alert Cards (English and Tagalog Versions) ☐ Pharmacokinetics ICF (English and Tagalog Versions) ☐ Questionnaire (English and Tagalog Versions) ☐ Philippine Food and Drug Administration (PFDA) Approval	☐ GANTT Chart ☐ Ads for Advertisement, if applicable ☐ Information for subjects ☐ Case Report Forms (CRF) ☐ Investigator's Brochure ☐ Certificate of Insurance ☐ (if applicable) ☐ CV of Proponent; GCP Certification ☐ Others	
10. Remarks	☐ Complete	☐ Incomplete, will submit on_____	
11. Documents to be submitted later	___Information for subjects ___Informed consent/assent form ___Others.....	___Study budget ___Investigator's brochure ___Case report forms (CRF)	
12. Submitted by:		13. Signature:	14. Date submitted:
15. Received by:		16. Signature:	17. Date received:

NOTE TO APPLICANTS: Please make sure that you have a copy of this form duly signed by the person who received the application

Annex 2

PHC-IERB-03-21-01

PHILIPPINE HEART CENTER
Institutional Ethics Review Board
8/F Medical Arts Building
East Avenue, Quezon City, 1100 Philippines
Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

Initial IERB Application Form

For Initial IERB Review Only

Accession No.	
Protocol No.	

Administrative Information

Sponsor No.		**Date of this Request**	
Study Title			
Department		**Division**	

Role	Name	Email	Mobile/Phone /Fax	License #
Principal Investigator				
Contact Person				
Co-Investigator				
All personnel listed above have completed GCP training *Please attach current certificate*			☐ Yes	☐ No

Category Review

Select the category of review you believe your study falls under	☐ Full Board Review ☐ Expedited Review Expedited Review Category ☐ The research presents no more than the minimal risk of harm to subjects; explain:

Study Summary

Summarize your study. The summary should be written in language intelligible to a moderately educated, non-scientific layperson. It should contain a clear statement of the rationale and hypothesis of your study, a concise description

Summary	
Proposed length (time period) of the study *State number of years, months, or weeks*	
Purpose of the Study	
Research Procedures *Describe the source of the data and the data collection procedures*	
Risks	☐ Minimal; justify why this category is appropriate ☐ Greater than minimal What precautions have been taken to minimize these risks and what is their likely effectiveness? Describe other alternative and accepted procedures, if any, that were considered and why they will not be used: ☐ Unknown, describe
Vulnerable subjects *If this study involves vulnerable subjects describe additional safeguards included in the protocol to protect the rights and welfare of these subjects*	☐ No ☐ Yes, describe:
More than Minimal Risk of Harm *If the research involves more than minimal risk of harm to subjects, describe the provisions for monitoring the data to ensure the safety of subjects*	☐ No ☐ Yes, describe:
Benefits *Assess the potential benefits to science and/or society which may occur as a result of this research. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits*	

General Study Information

Participants Recruitment Numbers	Participant Ages (Please check)
_____Females _____Males **Estimated Project Duration** Start Date: _____ End Date:_____	☐ 0-7 (parental permission and child assent) ☐ 7-11(parental permission and Child assent) ☐ 12-17 (parental permission and Child assent) ☐ 18-65 ☐ 65+
Will this Study Involve Long-Term Follow-Up with participants: ☐ Yes ☐ No.	

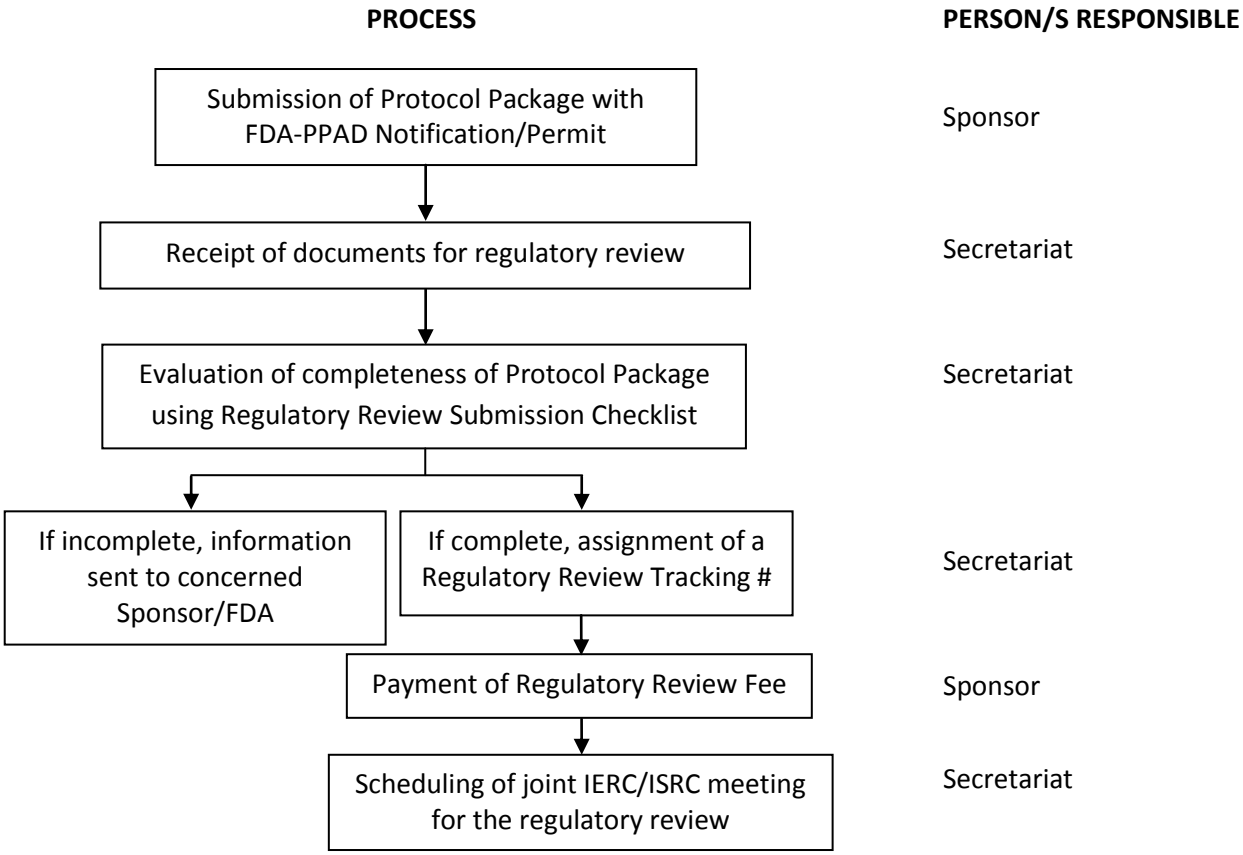
1. PURPOSE

To ensure a standard process of submission of protocols for regulatory review.

2. SCOPE

From the submission of protocol package, payment of regulatory review fee, conduct of review and forwarding of final recommendation to FDA

3. FLOWCHART



4. PROCEDURE

4.1. Submission of Protocol: The sponsor shall submit the complete protocol package to:

St. Luke's-Institutional Ethics Review Committee
Research and Biotechnology Division, Center for Clinical Trials
Annex III, 5th Floor
St. Luke's Medical Center-Quezon City
279 E. Rodriguez Sr., Blvd, Quezon City
Philippines 1102
Contact Person: **Anita B. Ahorro**
Clinical Trials Administrator
Tel. No.: (632) 727-5562/7230101 local 7391

4.2. Receipt of documents for regulatory review.

4.2.1. The Secretariat shall receive the complete protocol package with the following:

- FDA Clinical Trial Reference No.
- Permit to Review from FDA

4.2.2. The Secretariat shall log receipt of the protocol package using the Regulatory Review Tracking Form and a designated logbook. ***(Refer to SL-IERC Form #20A)***

4.3. Evaluation of completeness of the protocol package based on the Regulatory Review **Submission Checklist**. ***(Refer to SL-IERC Form#20B)***

- If the protocol package is incomplete, Secretariat informs the concerned sponsor/FDA. This is logged in the appropriate Tracking Form.
- If the protocol package is complete, the Secretariat assigns a Regulatory Review Tracking # (RRT#) to the protocol.

4.4. Payment of Regulatory Review Fee

4.4.1. Regulatory Review Fee shall be paid in cash or cheque upon confirmation of completeness of protocol package submitted.

4.4.2. All cheque payments shall be made payable to St. Luke's Medical Center.

4.5. Schedule for review: Secretariat shall

- schedule the meeting for the regulatory review after payment of the regulatory review fee.
- inform the sponsor of the schedule of the meeting
- notify the concerned sponsor that a representative shall be present in case the committee en banc raises issues or questions.

---Nothing Follows---

UNIVERSITY OF SANTO TOMAS

UNIVERSITY OF SANTO TOMAS
FACULTY OF MEDICINE AND SURGERY

UST FACULTY OF MEDICINE & SURGERY – INSTITUTIONAL REVIEW BOARD (USTFMS – IRB)

LIST OF REQUIREMENTS FOR RESEARCH PROTOCOL REVIEW AND APPROVAL

Protocol for the study should include the following:

I. Research Protocol
- 1.1 Title – with protocol number, protocol/version dates
- 1.2 Objectives of the study
- 1.3 Methodology
- 1.4 Subject selection
- 1.5 Contemplated sample size
- 1.6 Control of bias e.g. randomization of samples, blinding, techniques,
- 1.7 Dose, route, duration of administration and clinical laboratory examinations
- 1.8 Statistical design (suggest prior consultation with a biostatistician regarding data collection, data handling and statistical analysis to form statistically valid conclusions)

II. Endorsement letter by the Chairman of the Division
III. Cover letter addressed to the Chairman of IRB signed by the Investigator
IV. Written Informed Consent Form (in English and Tagalog)
V. Case Report Form (CRF)
VI. Budget for the study (including honorarium to the investigator)
VII. BFAD product registration for marketed study drug or BFAD import permit if study drug is not yet BFAD registered. (for drug trials)
VIII. List of local and international names of investigators in other institutions or countries if study is multinational or multicenter with contact numbers and address
IX. Investigator's Brochure
X. Curriculum Vitae of Investigator
XI. Good Clinical Practice (GCP) Certificate of Attendance of Investigator
XII. IRB Review Fee P 30,000. Check payable to **UST Faculty of Medicine & Surgery** and must be given before the initial review of research protocol.

** Please provide 5 sets of the above requirements with a blank page for the comments and recommendations.*

BERNARDO M. CUEVAS, JR. MD
Chair, USTFMS - IRB
Office of the Dean, Faculty of Medicine & Surgery
2nd Floor St. Martin de Porres Building
University of Santo Tomas
España, Manila
740-9707 / 741-5314

UST 400 UNENDING GRACE

FACULTY OF MEDICINE AND SURGERY, 2nd Floor St. Martin De Porres Building, UST España Boulevard, Sampaloc, Manila, Philippines 1015
Tel. Nos.: (63-2) 741-5314 / (63-2) 406-1611 loc. 8239 Telefax: (63-2) 731-3126 • Website: www.ust.edu.ph

UNIVERSITY OF SANTO TOMAS
FACULTY OF MEDICINE AND SURGERY

UST FACULTY OF MEDICINE & SURGERY – INSTITUTIONAL REVIEW BOARD

USTFMS-IRB COMMITTEE COMPOSITION

for the period of August 2012 to _____

Name of Members	Title and Occupation
Bernardo M. Cuevas Jr. MD	*Chair, USTFMS-IRB* Department of Surgery & Clinical Epidemiology Finished ICH Good Clinical Practice Course Master of Science in Clinical Epidemiology
Ma. Graciela M. Garayblas-Gonzaga, MD	*Member, USTFMS-IRB* Department of Medicine & Pharmacology Finished ICH Good Clinical Practice Course Masters of Science in Health Development & Management & Clinical Epidemiology
Victoria Edna G. Monzon, MD	*Member / Bioethicist, USTFMS-IRB* Department of Medicine & Bioethics Finished ICH Good Clinical Practice Course Units in Masters in Public Administration
Nilo C. Delos Santos, MD	*Member / Biostatistician, USTFMS-IRB* Department of Surgery & Clinical Epidemiology Finished ICH Good Clinical Practice Course Master of Science in Epidemiology
Mary Agnes S. Regal, MD	*Member, USTFMS-IRB* Department of Pediatrics & Clinical Epidemiology Finished ICH Good Clinical Practice Course Masters of Science in Clinical Epidemiology

UST 400 UNENDING GRACE

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University of the Philippines Manila
NATIONAL INSTITUTES OF HEALTH

UPM-NIH FDA REVIEW

SPONSOR SUBMISSION PROCESS

Step 1 : Sponsor submits review package to UPM-NIH FDA Review Panel Secretariat.

DR. VICENTE Y. BELIZARIO, JR
Executive Director
National Institutes of Health
University of the Philippines Manila

Delivery Address :
c/o Office of the Deputy Executive Director
(Attn: FDA Review Panel Secretariat)
G/F National Institutes of Health Building
623 Pedro Gil St., Ermita, Manila
Tel No : (02) 528-4041, 526-4349
Fax No : (02) 525-0395
Email : nih-ded@post.upm.edu.ph

Step 2 : Secretariat assesses completeness of review package based on the document checklist. This should include the permit to review issued by the FDA.

Step 3 : Secretariat issues billing statement with instructions to Sponsor.

Step 4 : Sponsor pays review service fee to UPMDFI, Inc and submits proof of payment to Secretariat.

Once Steps 1-4 is completed, FDA review timeline starts at UPM-NIH.

OVERVIEW OF THE REVIEW PROCESS

Step 1 : FDA Review Panel Chair assigns a lead and a secondary reviewer for each protocol.

Step 2 : Secretariat provides a copy of the protocol and the FDA Review Assessment Form to each reviewer.

Step 3 : Reviewers submit their review to the FDA Review Panel Secretariat who disseminates copies of the completed assessment forms to all panel members.

Step 4 : FDA Review Panel meets en banc and discusses the protocol, finalizes the assessment and makes its recommendation.

Step 5 : Secretariat completes all documentation and completes the FDA review recommendation package.

Step 6 : Secretariat informs FDA that the package is ready for pickup.

GENERAL TIMELINE

If the review will not require a clarification from the Sponsor, UPM-NIH expects to complete the FDA assessment form and submit its recommendation within 45 days.

If the review will require a clarification from the Sponsor, UPM-NIH will complete the FDA assessment form and submit its recommendation after 60 days, excluding the time spent for the Sponsor to respond to UPM-NIH's request for additional documents or attendance to a clarificatory interview/discussion with the Review Panel.

PROCESS OF SUBMISSION OF RECOMMENDATION TO FDA

Once the Review Panel has completed the Assessment Form and has prepared its recommendation to the FDA, the Secretariat will compile the following to be submitted back to the FDA:

1. All documents submitted by the Sponsor, including additional documents, as applicable
2. Completed FDA Assessment Form, signed off by the NIH Executive Director

The following documents will be retained and filed by UPM-NIH:

1. Permit to review issued by the FDA
2. Copy of the completed FDA Assessment Form
3. Minutes of the meeting of the Review Panel