**Process for Registration, Technical and Ethical Review of Researches of UPCM Faculty and Students**

**Technical Review**

1. Prepare a printed copy of proposal.
2. Secure/download and fill out the Technical Review Form from www.cm.upm.edu.ph/p/rido.
3. Submit above documents to:
	1. **For Faculty**: Research Coordinator/Assistant Chair for Research of your affiliated department to assign two technical review board members to evaluate your proposal.
	2. **For Medical Students:** Your adviser to evaluate your proposal.
	3. **For Graduate/MD-PhD Students:** Your thesis panel with thesis proposal defense form (UPM-NGOHS Form #03-01).
4. If with revisions, secure/download and fill out Principal Investigator’s Response to Technical Review from www.cm.upm.edu.ph/p/rido.

**RGAO Registration**

1. Register research at [www.rgao.upm.ph/registration](http://www.rgao.upm.ph/registration).
2. Registration certificate will be sent via email in one working day.

**RIDO Registration**

1. Log onto [www.cm.up.edu.ph](http://www.cm.up.edu.ph) with your UP email and add your research on “My Research” Tab. Input required information and upload relevant documents.
	1. Secure/download and fill out the Research Registration Form from [www.cm.upm.edu.ph/p/rido](http://www.cm.upm.edu.ph/p/rido) and submit to the RIDO Office if portal is down for more than one week. Together with a copy of the proposal and the TRB form.

**Ethical Review**

1. Request for ADS account to log into [www.ireb.up.edu.ph](http://www.ireb.up.edu.ph)
2. Accomplish online forms (application information, endorsements, declaration of conflict of interest, protocol assessment, and informed consent assessment) at [www.ireb.up.edu.ph](http://www.ireb.up.edu.ph)
3. Upload PDF attachments
4. Submit to UPMREB Office on Monday or Wednesday with necessary signatures
5. Follow up on decision letter 14 days after hard copy submission for expedited review, or 7 days after panel meeting date for full board. If disapproved, revise according to comments and resubmit

**Post-Approval**

1. Submit Progress Report Form accessed at www.cm.upm.edu.ph/p/rido each year the study is ongoing.
2. Submit Final Report Form accessed at www.cm.upm.edu.ph/p/rido and [www.reb.upm.edu.ph/ sops-and-forms](http://www.reb.upm.edu.ph/%20sops-and-forms) when research is completed.

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| **TECHNICAL REVIEW FORM** |  |
| RIDO-FORM-01(5.3) |  |

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| --- |
| **PART I: RESEARCH PROTOCOL INFORMATION** |
| **RIDO Study Code** (to be filled out by RIDO) |  |
| **Study Title** |  |
| **Name of Principal Investigator** |  |
| **Date sent to TRB Reviewer:** |  |
| **PART II: TECHNICAL REVIEW CHECKLIST** |
| **Instruction to TRB Reviewer:**Technical review needs to be explicit and comprehensive. For each section of this checklist, the Reviewer should ask the question “Is it done it correctly?” Please indicate your evaluation response in the right hand column. Legend is as follows: **Y** (Yes) **N** (No) **?** (Not sure) **R** (For referral to expert) **N/A** (Not applicable)This checklist provides guidance for the evaluation areas we would like you to comment on. Depending on your area of expertise, it serves as a guide only and we do not expect you to comment on every evaluation area if the answer is Y (Yes). Please indicate, however, reason and/or recommendation if there is an area which requires clarification and/or modification. Finalize the technical review by checking your recommended action in Part VIII and by signing in the space provided for the TRB Reviewer. |
| **PART III: EVALUATION AREAS** |
| **III(A). Title**  |
| Is the title a good reflection of the study? |  |
| **Reviewer’s comment:** |
| **III(B). Background** |
| 1. Does the background support the need for the study by providing sufficient information about the underlying clinical problem?
 |  |
| 1. Are the uncertainties in the clinical problem?
 |  |
| 1. Does the background address issues that are particularly important for its target readers?
 |  |
| **Reviewer’s comment:** |

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| --- |
| **III(C). Objectives** |
| 1. Was the main objective of the study specified clearly?
 |  |
| 1. Does the study address an important scientific issue?
 |  |
| 1. Will these be meaningful to patients and healthcare providers?
 |  |
| **Reviewer’s comment:** |
| **III(D). Methodology** |
| ***Study Design (please see Appendix-Form 1)*** |  |
| a. Is the study design clearly stated? |  |
| b. Is the study design appropriate to the objective of the study? |  |
| **Reviewer’s comment:** |
| ***Sample Population***  |  |
| a. Is the selection of study sample clearly stated and appropriate? |  |
| b. Are the inclusion / exclusion criteria clearly stated and appropriate? |  |
| c. Is the subject recruitment process described and consistent with the study design? |  |
| d. Is the sample size clearly stated and justified? |  |
| **Reviewer’s comment:** |

|  |  |
| --- | --- |
| ***Study Procedures***  |  |
| a. Are the study interventions and comparators clearly described? |  |
| b. Is the choice of interventions and comparators appropriate? |  |
| **Reviewer’s comment:** |
| ***Outcomes*** |  |
| 1. Is one (or a small number of) primary outcome(s) identified?
 |  |
| b. Are all other important (beneficial and harmful) outcomes considered? |  |
| c. Is the assessment of the outcomes clearly described or defined? |  |
| **Reviewer’s comment:** |
| **III(E). Data Analysis** |  |
| a. Is the method of data recording, analysis and reporting clearly described? |  |
| b. Are the statistical techniques to be used appropriate? |  |
| **Reviewer’s comment:** |
| **PART IV: OVERALL ASSESSMENT** |  |
| a. Is the protocol acceptable in its present form? |  |
| b. Is the protocol acceptable with minor revisions? |  |
| c. Does the protocol require substantial revisions? |  |

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| **PART V: DISCLOSURE-REVIEWERS** |  |
| Do you have any financial interest (cash or kind), paid consultancy or shareholding (current or otherwise), in any of the stakeholders involved in this protocol? |  |
| **Reviewer’s comment:** |
| **PART VI: RECOMMENDED ACTION** |
| **( ) FOR MODIFICATION** *(Instruction to PI: Accomplish RIDO-FORM-02(5.3)-2021-02-24 and submit back to TRB Reviewer)* **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature over Printed Name of TRB Reviewer Date**( ) DISAPPROVED**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature over Printed Name of TRB Reviewer Date**( ) APPROVED**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature over Printed Name of TRB Reviewer Date**ENDORSED BY:** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature over Printed Name of Department Chair Signature over Printed Name of RIDO Chief Department of: Date: Date: RIDO Study Code: |

# [Appendix-Form 1]

# For REFERENCE: Guide questions for review of methods/study procedures

COMPARATIVE CLINICAL TRIALS

1. Are the intervention groups clearly described?
	1. Is the comparator/control group appropriate?
2. Is the procedure for evaluation and assessment of the groups clearly described and appropriate?
3. For randomized trials:
	1. Is the method of randomization adequate and clearly described?
	2. Is allocation concealment secure?
	3. Is there adequate and appropriate blinding?
		1. Of patients?
		2. Of care providers?
		3. Of outcomes assessors?
4. For cohort studies:
	1. Are the cohorts well defined?
	2. Is the follow up adequate?
5. For case-control studies:
	1. Is the identification of cases and controls appropriate and adequately described?
6. Are the statistical tests appropriate?

QUESTIONNAIRE SURVEYS

1. Are the questionnaires properly developed?
2. Are the questionnaires validated?
3. If question 1-2 are answered NO, is there a provision in the protocol that will allow for these (questionnaire development and validation of the questionnaire) to be done?
4. Was there pilot testing done?

DIAGNOSTIC STUDIES

1. Are the procedures /tests clearly described?
2. Is there a gold standard? Is it appropriate?
3. Are the results interpreted in a blinded fashion?
4. Are the statistical tests appropriate?

BIOEQUIVALENCE STUDIES

1. In cases of multiple dose study, was the rationale given satisfactory?
2. Are the inclusion /exclusion criteria clearly specified and appropriate?
3. Is the dose and route of administration of the drug clearly specified and described?
4. Is the procedure of drug administration clearly described (relation to meals, activity, etc.)?
5. Is the manner of determining drug levels clearly described and appropriate?
6. Is the washout period adequate (minimum of 3-4x t1/2 life)
7. Are the criteria used to assume regulatory bioequivalence clearly stated? Is a deviation from the US FDA or EMEA guidelines justified?