

II. TECHNICAL REVIEW OF RESEARCH PROTOCOLS

1. OBJECTIVES

This chapter of the manual aims to determine the procedures to be observed by the Technical Review Board member upon submission of the initial research protocol and/or protocol modification for recommended action. This aims to guide Principal Investigators also of the process for the technical review of their research protocols prior proceeding to ethics review requirements.

2. SCOPE

The TRB of RIDO conducts the technical review of all research proposals of UPCM constituents prior submission to Ethics Review Board. TRB members can conduct technical review of non-UPCM and/or non-UPM Principal Investigators also.

This chapter likewise intends to provide guidelines for TRB members, Department Chair (including administrative support staff) and RIDO Chief for processing research protocols submitted to them for technical review, and for the RIDO staff for maintaining the research database.

3. RESPONSIBILITIES

It is the responsibility of the Principal Investigator (PI) to submit the research protocol to be reviewed to the concerned Department, including the **Technical Review Form** to be filled out by the TRB Reviewer. In case of research protocol evaluated as for modification, the PI is to accomplish the **Principal Investigator's Response to Technical Review Form** and submit to the Department for TRB Reviewer's re-evaluation.

It is the responsibility of the UPCM Department Chair (or its authorized Department member) to assign its roster of TRB Reviewers, to keep the list updated whenever changes have effected, to assign a particular TRB Reviewer to a research protocol, and to endorse same after approval.

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It is the responsibility of the assigned TRB Reviewer to evaluate the relevance and scientific merit of the research protocol by accomplishing the prescribed Technical Review Form. TRB Reviewer is responsible also to specify his/her comment(s) when he/she deems that the research protocol needs to be modified, and to indicate recommended action (approval or disapproval) thereafter.

It is the responsibility of the RIDO staff to process endorsement of the approved Technical Review Form to the RIDO Chief, to register the research protocol onto the database by generating a unique RIDO study code, and to inform the PI that the signed Technical Review Form can be secured from RIDO for its next step processing (RGAO, UPMREB, etc.)

4. PROCESS FLOW OF TECHNICAL REVIEW FOR RESEARCH PROTOCOLS BY UPCM FACULTY/NON-UPM PIS

Activity		Responsible Person
Submits the protocol package and Technical Review Form to the concerned Department		PI
Checks completeness of documents		Department Staff
Evaluates research protocol and accomplish the Technical Review Form		TRB Reviewer
If approved, sends research protocol documents to Department Chair	If for revision, notifies PI	Department Staff
	Re-evaluates protocol and indicates final decision	TRB Reviewer
	If revisions are approved, sends research protocol documents to Department Chair. If disapproved, notifies PI	Department Staff



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WORK INSTRUCTIONS

4.1. Preparation of documents to be submitted for Technical Review

- 4.1.1. The PI must submit the following documents to the concerned Department:
 - Printed copy of the research protocol
 - Technical Review Form
- 4.1.2. The PI must fill out only the Name of PI and the Study Title sections of the Technical Review Form.
- 4.1.3. The Department Staff checks if the required documents are complete prior handling over to the assigned TRB Reviewer.

4.2. Technical review of the research protocol

- 4.2.1. The Department Staff checks the Department decking to identify the TRB Reviewer who will conduct the review of a research protocol.
- 4.2.2. The TRB Reviewer evaluates the research protocol in accordance with the specified areas in the Technical Review Form.
- 4.2.3. The TRB Reviewer must state recommendations and/or clarifications in the Reviewer's comment sections of the Technical Review Form if modification of the research protocol is assessed to be appropriate.
- 4.2.4. Recommended actions indicated in the form are **For Modification**, **Disapproved**, **Approved**.

4.3. Amendment/revision of the research protocol

- 4.3.1. A research protocol which is recommended for modification is to be notified to the PI by the Department staff.
- 4.3.2. The PI accomplishes the Principal Investigator's Response to Technical Review to reflect revisions and submits to the Technical Reviewer for re-evaluation.



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4.3.3. When the TRB Reviewer finds the response(s) to be satisfactory, he/she approves the protocol by signing in the appropriate space provided in the same Technical Review Form.

5. PROCESS FLOW OF ENDORSEMENT OF APPROVED RESEARCH PROTOCOLS BY UPCM FACULTY/NON-UPM PIs

Activity	Responsible Person
Endorses the approved research protocol	Department Chair
Submits to RIDO for endorsement and registration	PI
Signs the Technical Review Form	RIDO Chief
Registers to research database	RIDO Staff

WORK INSTRUCTIONS

5.1. Endorsement of the research protocol

- 5.1.1. The Department Staff requests Department Chair to endorse the approved Technical Review Form by signing in the space provided in the form.
- 5.1.2. The PI submits the duly signed Technical Review Form to RIDO for endorsement and registration along with the following:
 - Duly accomplished Request for Registration of Research Form
 - One printed copy of the research protocol
 - Electronic copy of the research protocol (sent to RIDO's email, rido.upcm@gmail.com)
 - Principal Investigator's Response to Technical Review (if applicable)
- 5.1.3. The RIDO Chief endorses the research protocol by signing in the Technical Review Form.

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5.1.4. Only those research protocols with complete requirements will proceed to endorsement and registration to RIDO.

6. PROCESS FLOW OF ENDORSEMENT OF RESEARCH PROTOCOLS OF GRADUATE STUDENTS AND LU3 STUDENTS

Activity	Responsible Person
Submits requirements to the concerned Department	PI
Checks completeness of documents	Department Staff
Endorses the research protocol	Department Chair
Submits to RIDO for endorsement and registration	PI
Signs the Technical Review Form	RIDO Chief
Registers to research database	RIDO Chief

WORK INSTRUCTIONS

6.1. Technical review and endorsement of research protocols by Graduate students

- 6.1.1. In case of a graduate student, the review of his/her research protocol done by the postgraduate review panel of the respective department shall suffice for the required technical review.
- 6.1.2. The Department Chair endorses the research protocol by signing in the space provided in the Technical Review Form.
- 6.1.3. A copy of the panel review sheet is to be attached to the signed Technical Review Form with the Name of the PI and the Study Title written in the form, to include the following to be submitted to RIDO:
 - Duly accomplished Request for Registration of Research Form
 - One printed copy of the research protocol
 - Electronic copy of the research protocol (sent to RIDO's email, rido.upcm@gmail.com)



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6.2. Technical review and endorsement of research protocols by LU3 students

- 6.2.1. In case of an LU3 student, the Certification of Approval from IDC 211 Course Coordinator (certifying that such research paper has undergone review and approval by the LU3 Defense Panel) shall suffice for the required technical review.
- 6.2.2. The Department Chair endorses the research protocol by signing in the space provided in the Technical Review Form.
- 6.2.3. A copy of the Certification of Approval from IDC 211 Course Coordinator is to be attached to the signed Technical Review Form with the Name of the PI and the Study Title written in the form, to include the following to be submitted to RIDO:
 - Duly accomplished Request for Registration of Research Form
 - One printed copy of the research protocol
 - Electronic copy of the research protocol (sent to RIDO's email, rido.upcm@gmail.com)

7. PROCESS FLOW OF HANDLING RECORDS (REVIEWED RESEARCH PROTOCOL RECORDS)

Activity	Responsible Person
Record details of reviewed research protocols	RIDO Staff
Confirms receipt of signed/endorsed Technical Review Form	PI
Files copy of research protocol records to the TRB folders	RIDO Staff

WORK INSTRUCTIONS

7.1. Registration and management of reviewed research protocols

7.1.1. The RIDO Staff generates a unique Study Code for research protocols endorsed to RIDO.



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- 7.1.2. All research protocols submitted and endorsed to RIDO must be registered to its research database.
- 7.1.3. The RIDO staff collates the research protocol records submitted by the PI and store a copy of the files for future reference.
- 7.1.4. All hard copies of research protocols submitted to RIDO must be returned to the PI. Any unclaimed research protocols a year after its registration to RIDO must be properly disposed.