

UNIVERSITY OF THE PHILIPPINES MANILA
COLLEGE OF ARTS AND SCIENCES
DEPARTMENT OF PHYSICAL SCIENCES AND MATHEMATICS

**NIH-TRB Research Monitoring and
Tracking Information System (ReMTIS 2.0)**

A special problem in partial fulfillment
of the requirements for the degree of
Bachelor of Science in Computer Science

Submitted by:

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ACCEPTANCE SHEET

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ABSTRACT

The creation of the National Institutes of Health (NIH) under the UP Manila System was a boost to the University's existing research infrastructure. Research Monitoring and Tracking Information System (ReMTIS 2.0) enables research facilitators of NIH to manage health research records and ensure secured, convenient and systematic flow of information with emphasis on the Technical Review Board of NIH. Protocol information is stored in a single database. This reduces the problems of redundancy and inconsistencies using a paper-based system and OpenOffice applications. It also allows users to view protocol information depending on their role. This allows not only sharing but also distinction and confidentiality among the records. It also serves as an electronic tracking system of research projects with the use of a notification system and a calendar system that help prevent time management issues. The system also allows administrative report generation.

Keywords: Research Management, Technical Review Board

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I. Introduction

A. Background of the Study

Health researches among various institutions in the country have contributed to the improvement of the quality of health care of Filipinos. These researches have been crucial in the improvement of clinical care, formulation of health policies, and promotion of health programs through collaboration with appropriate agencies for proper utilization.

The University of the Philippines Manila is recognized as the country's leading institution in health research and development. The creation of the National Institutes of Health (NIH) in January 1996 under the UP Manila System was a boost to the existing research infrastructure [1]. The unit promotes science and technology research development in health, and development of study groups and research programs. It also establishes mechanisms for dissemination and utilization of research outputs [2]. The unit also collaborates with the Department of Health and Philippine Council for Health Research and Development (PCHRD) of the Department of Science and Technology [3].

NIH has various research institutes and active study groups that continue to develop and to produce outputs that serve as vital guideposts in shaping national programs and policies. It also has active committees that complement activities of the research institutes and study groups. These committees provide specialized assistance and offer recommendations to the NIH Executive Director on areas such as institutional animal care and use, institutional promotion, research capacity building/strengthening, management of facilities and staff development [4].

One of the UPM Research Committees is the Technical Review Board. The Board is tasked to evaluate all research proposals and technical reports submitted to the Office of the Vice Chancellor for

Research. It recommends awarding of research grants worthy proposals, then handles the monitoring and evaluation of these approved researches. Aside from these, the TRB facilitates institutional endorsement of research proposals and reports to other institutions. It also coordinates with existing college technical review committees in facilitating the conduct of research within UP Manila. Lastly, the Board provides technical advice to the Vice Chancellor for Research and the Executive Director of NIH on research directions and special initiative of UP Manila [5].

Research proposals which seek financial support from the University go through technical review. Proposals are reviewed by the committee in the unit of the proponent for their technical merit. The recommendation of the head of the unit is necessary before the proposal is submitted to the NIH, through the Office of the Vice Chancellor for Research/National Institutes of Health (OVCR/NIH). The technical review thus starts from the departmental or study group level, college or institutes level after which the NIH/UPM Technical Review Board acts on it [6].

For college funded researches, the Research Committee of the unit are responsible for the technical reviews. On the other hand, research projects that have external funding need not be reviewed by the NIH/UPM TRB, but may need to be referred to the NIH/UPM Ethics Review Board, Biosafety and Bioprospecting Committees for clearance as deemed necessary by the OVCR Executive Director [7].

B. Statement of the Problem

NIH currently uses Research Monitoring and Tracking Information System (ReMTIS) that enable research facilitators to manage health research records and ensure secured, convenient and systematic flow of information. Protocol submissions are stored in a single database that are viewed and accessed by the different users of the system. It also serves as an electronic tracking system for monitoring the

progress of research projects. It also generates administrative reports by extracting information stored in the database [8].

ReMTIS has a module for Technical Review but functions are only limited to monitoring and tracking of the progress of the reviews. Some limited functions include uploading/editing technical reviews, viewing the list of protocols pending for technical review and assigning reviewers. While these processes are necessary, these features lack the correct flow of data.

The processes before the submission of full protocols are also not included in the current version of ReMTIS. These processes include the submission of capsule proposals to which RMD members give score for merit and relevance. The capsule proposals are evaluated first by the RMD during the annual meeting for shortlisting. The decision during the meeting decides which capsule proposals are qualified for technical review and eventually for funding.

Currently, only the Research Management (RM) Secretariat and the Administrative Officer use the said system.

The Technical Review Board (TRB) Secretariat is responsible for managing protocols for technical review from the initial submission to the submission of the final report. Currently, the TRB Secretariat uses OpenOffice applications to store important information about the protocols. The details of the protocols being reviewed are recorded into a spreadsheet. Communication among people involved in the review of study protocols are done through snail mail or email. Delays occur all the time when notifications are not received immediately thus causing proponents to miss deadlines for submissions and tasks.

Using the said application as a database imposes limited capabilities for storage and retrieval of data because the application is not relational. Large amount of data can be difficult to handle if certain data are linked to other records. It could be a problem to the secretariat in retrieving data for report generation. Updating records could also be tedious since it requires searching through numerous records to find the correct cell to edit. Aside from speed, inconsistency is likely to occur if many people access and update the same data. Storage of paper-based protocols is also a problem for it takes up huge space in the office to store them.

C. Objectives

The system is a web-based system that aims to implement an electronic system that facilitates tracking and monitoring of study protocols undergoing technical review conducted by the National Institutes of Health. It allows principal investigators to upload necessary submission packages and forms to be reviewed by the NIH-Technical Review Board. It is incorporated to the current version of ReMTIS.

The system allows the following functionalities:

A. Research Management (RM) Secretariat

1. Log-in to RM web server
2. View list of study submission packages pending for registration or newly submitted by principal investigators
3. Create summary for each submitted proposal
4. Create summary table of proposals to send to RM Subcommittee Chair
5. Register study protocols
6. View/update/delete list of registered protocols
7. Upload meeting agenda for the annual meeting for proposal shortlisting

8. Forward submitted full protocols to Technical Review Board
9. Generate and send reports/acknowledgement or recommendation letters
10. Forward research mentoring invitation package to appropriate NIH Research Faculty
11. Set deadlines for tasks
12. View list of notifications regarding necessary requirements to be processed
13. View alerts of tasks needing immediate attention
14. Update progress of study protocols by displaying their status and accomplished actions
15. Generate administrative reports

B. RM Subcommittee Chair

1. Log-in to RM web server
2. Review and finalize proposal summary table
3. Forward capsule proposals to RM Subcommittee Members
4. Rank each proposal based on the collated scores
5. Assign research mentor to approved PEER Health grantee study protocols
6. View list of notifications regarding necessary requirements to be processed
7. View deadlines of tasks

C. RM Subcommittee Member

1. Log-in to RM web server
2. View capsule proposals
3. Give score for each capsule proposal
4. Forward scores to RM Subcommittee Chair
5. View list of notifications regarding necessary requirements to be processed
6. View deadline of tasks

D. Technical Review Board (TRB) Secretariat

1. Log-in to RM web server
2. View list of registered protocols forwarded by RM Secretariat
3. Assign technical reviewers
4. Generate and send invitation or recommendation letters
5. Forward invitation letter and protocol package to technical reviewers
6. Upload meeting agenda for the monthly en banc meeting
7. Forward revisions from PI to technical reviewers
8. Forward registered protocols and list of assigned technical reviewers to TRB Chair
9. Forward submitted final report package and list of assigned technical reviewers to TRB Chair
10. Set deadlines for tasks
11. Notify TRB members of important tasks
12. View list of notifications regarding necessary requirements to be processed
13. View alerts of tasks needing immediate attention
14. View progress of study protocols by displaying their status and accomplished actions

E. Technical Review Board (TRB) Chair

1. Log-in to RM web server
2. View list of registered protocols forwarded by TRB Secretariat
3. Approve the list of technical reviewers assigned by TRB Secretariat
4. View list of notifications regarding necessary requirements to be processed
5. View deadline of tasks

F. Principal Investigator

1. Log-in to RM web server
2. View submissions regarding study protocol

3. Manage submissions
4. Receive recommendation/acknowledgement letters from RM/TRB Secretariat
5. Respond to comments from the recommendation/acknowledgement letters
6. View list of notifications regarding necessary requirements to be processed
7. View deadline of tasks
8. View progress of study protocols by displaying their status and accomplished actions

G. Reviewer

1. Log-in to RM web server
2. View list of registered protocols to be reviewed
3. Receive and respond to invitation letter and protocol package for technical review
4. View list of notifications regarding necessary requirements to be processed
5. View deadlines of tasks

H. NIH Research Faculty

1. Log-in to RM web server
2. Receive and respond to invitation package to be a research mentor
3. View list of notifications regarding necessary requirements to be processed
4. View deadline of tasks

I. System Administrator

1. Log-in to RM web server
2. Manage user accounts

J. Guest

1. Request user account

D. Significance of the Study

The system is a web-based system that manages study protocols overseen by the National Institutes of Health, and stores them in a single database. It also provides a monitoring system for the TRB Secretariat and RM Secretariat regarding the status of the study protocols. It also provides a notification system for the users of the system regarding deadlines for submissions and tasks. The notification and alert system addresses the problems of delays RM is currently experiencing using snail mail. Study protocols and forms sent to the Technical Review Board are also archived online for easier storage and retrieval.

The system seeks to address the challenge of limited capabilities for storage and retrieval of data due to the current database being used that is not relational. With the use of a relational database, management of the protocols is made easier for both the RM Secretariat and TRB Secretariat. Any updates in a record are immediately reflected on other records linked to that updated record. The task of the TRB Secretariat and the RM Secretariat to manually encode data from protocol packages and forms to the database would be significantly reduced as submissions of these forms can now be done online. Generation of reports is also be automated with the use of the system.

With the many people involved in the technical review of protocols, it is important that they are well-coordinated. Online collaborations using the system allows information/data exchange among individuals involved to be done easier.

E. Scope and Limitations

1. Each user accesses the different data stored in the database depending on the roles and tasks given to them by the RM Secretariat or TRB Secretariat.
2. Processes such as the submission of the proposal summary table to the Executive Director and NIH Deputy Director, and the submission of study protocols to Research Grants Administration Office (RGAO) for registration are not included in the system.
3. Notifications and alerts are based on time computed from the computer server's time.
4. Alerts are sent to the email address registered by the user in the system. It is the user's responsibility to enter his correct contact details.
5. Only .doc, .docx, and .pdf file formats are supported as input files. For the e-signature, only .jpg and .png file formats are allowed.

F. Assumptions

1. Registered investigators seek financial support and/or technical review from NIH in conducting their studies.
2. Submitted proposals are consistent with the UP Manila research priorities, which is based on the National Unified Health Research Agenda (NUHRA) 2012-2016.
3. Submitted proposals have been reviewed by the committee in the unit of the investigator for their technical merit.

II. Review of Related Literature

The use of Information Systems (IS) in healthcare has become one of the solutions to problems of redundancy and inaccuracy brought about by paper-based systems. Because of the lack of reliable data, there is difficulty in making informed decisions about health.

In 2011, Uganda transitioned from a paper filing system to an electronic human resources information system (HRIS) to track and monitor the health workforce at the Uganda Nurses and Midwives Council (UNMC). The system provided information about country-specific health workforce questions. The HRIS data can then be used to address workforce planning questions [9].

Several researchers from Cedars-Sinai Medical Center, Los Angeles developed an integrated proactive surveillance system for prostate cancer (PASS-PC). It is a multi-institutional web-based system aimed at collecting a variety of data on prostate cancer patients in standardized and efficient way. The main goal of the system is facilitating the efficient and uniform collection of critical demographic, lifestyle, nutritional, dietary and clinical information to be used in developing new strategies in diagnosis, preventing and treating prostate cancer [10].

Cloud computing platforms provide big potential for increasing efficiency through web-based data collection interface. In medicine, many clinical trials that previously use paper case report forms as primary data collection tool are already migrating to the cloud. Clinical and biological data are no longer stored in one centralized database system. Haibin Wang of the Samuel Oschin Comprehensive Cancer Institute, Los Angeles developed C-PASS-PC which is a cloud-drive prototype of multi-center proactive surveillance system for prostate cancer. This is an upgrade of the PASS-PC previously mentioned [11].

A real-time web-based data monitoring and manipulation system such as the RTWebDMM was developed to improve the quality of translational research data. It was used as an auditor, monitor, and explorer for improving the way in which investigators access and interact with data sets in real-time using a web browser. The performance of the proposed approach was evaluated with different data sets from various studies. It is demonstrated that the approach yields very promising results for data quality improvement while leveraging on a web-enabled environment [12].

Having a web-based system also calls for standardization in data collection and reporting. The Breast Cancer Collaborative Registry (BCCR) is a multicenter web-based system that efficiently collects and manages a variety of data on breast cancer patients and survivors. The BCCR is aimed at facilitating rapid and uniform collection of critical information and biological samples to be used in developing diagnostic, prevention, treatment, and survivorship strategies against breast cancer [13].

Internet portal technologies that provide access to portions of electronic health records have the potential to revolutionize patients' involvement in their care. A study that shows the effects of portal technology on quality outcomes was conducted in 2010. This study examined data from patients who attended one of seven Duke Medicine clinics and who were offered the option of enrolling in and using the Duke Medicine HealthView portal (HVP). The HVP allows patients to manage details of their appointment scheduling and provides automated email appointment reminders in addition to the telephone and mail reminders that all patients receive. It tested whether email reminder functionality is significantly related to decrease in rates of appointment "no-shows," which are known to impair clinical operational efficiency. At the end of the study, no-show rates across all seven Duke Medicine clinics were significantly reduced among patients who registered for portal use, suggesting that in combination with an email reminder feature, this technology may have an important and beneficial effect on clinic operations [14].

An automated logging system also improves resident documentation compliance. A study was conducted to determine the effects of an automated procedure logging (APL) system in the number of procedure logged by emergency medicine (EM) residents. It also assessed the APL's effect on completeness and accuracy of procedure logging and to measure resident compliance with the system. After the study, there was a significant increase in the daily mean number of procedures logged after the implementation of APL. Recorded data were more complete and more accurate during this time frame. This innovative system improved resident logging of required procedures and helped in the assessment of Accreditation Council for Graduate Medical Education (ACGME) Patient Care and Practice-Based Learning Competencies for individual residents [15].

Traditional methodologies for healthcare-associated infection (HCAI) surveillance can be resource intensive and time consuming. Various electronic databases exist within the healthcare setting and may be utilized to perform HCAU surveillance. The study aimed to assess the utility of electronic surveillance systems for monitoring and detecting HCAI. After a systematic review of published literature on surveillance of HCAI, it was concluded that the implementation of electronic surveillance was found to be feasible in many settings, with several systems fully integrated into hospital information systems and routine surveillance practices [16].

Effectiveness of Chlamydia screening programs is determined by an adequate level of participation and the capturing of high-risk groups. A study aimed to evaluate the contribution of automated reminders by letter, email and short message service (SMS) on package request and sample return in an Internet-based Chlamydia screening among people aged 16 to 29 years in the Netherlands. Response and participation rates increased significantly after the reminders. The reminder letters also seemed to result in reaching more people at risk. Incorporation of automated reminders in Internet-based (Chlamydia) screening programs is strongly recommended [17].

Another study that shows the effectiveness of a notification system is shown in a study by Sharon Saw. The researchers report the use of text messages to notify critical laboratory results in a large teaching hospital to manage the documentation and audit requirements of critical result reporting by regulatory agencies. The text messaging system (critical reportable result health care messaging system [CRR-HMS]) allows a receiver to acknowledge or reject a critical result by short message service reply. The CRR-HMS is a clinically useful tool to rapidly communicate critical results to targeted physicians to facilitate rapid and timely intervention [18].

Though many organizations have developed their own approaches in ensuring reliable decision making processes, not many have used technology to ensure effective participatory based decision making. Another study presents a model that incorporates reliable participatory based decision making practices and quality management indicators through strategic use of technology. The model, called QuESt (Quality E-management System), integrates web-based technologies into an interconnected system to enable decision making by all stakeholders at multi levels of responsibility. The paper concludes with an assessment of the potentialities of the system in taking an organization's internal and external processes to the next level, using technology to ensure evidence based decision making, to interconnect staff roles and responsibilities and to use feedback to take appropriate action [19].

III. Theoretical Framework

A. Management and Monitoring of Research Grants

1. Processing of submitted proposals

NIH releases call for research proposals by the second week of January every year. Application ends every 30th of April. The Research Management and Development Committee (RMD) is expected to meet within 4 weeks of the deadline for submission, or on the 4th week of May of the same year the call of proposals was issued. The main agenda for the said meeting shall be the shortlisting of promising proposals. Shortlisted proposals shall be decided upon based on their research topics and technical merit of the capsule proposal.

Topics to be prioritized shall be based on the specified research interest of an external source of funding, if a particular research topic is specified by the external source, or on the National Unified Health Research Agenda (NUHRA) 2012-2016 if the source of funding originated from the National Institutes of Health or UP Manila.

Each RM member shall give a score for all capsule proposals, one for technical merit and another for relevance. The lowest possible score is zero with five being the highest. Technical merit and relevance pertains to the following contents:

- Merit – Objectives and methods are sound and feasible.
 - Plan for data analysis is appropriate for the design.
 - Proposal is feasible.
- Relevance – Potential impact to policy and practice
 - Benefits to target population
 - Significance of proposal, in reference to NUHRA 2012-2016

RM sends out letters to shortlisted grant applicants to submit 4 copies of the full protocol using the prescribed research proposal format (Form 3.1 A). In cases where the proposed budget of a project exceeds the maximum amount of a specific research grant, the principal investigator shall be informed, through the same letter, in which case he or she must secure additional funding from another institution.

RM checks for completeness of the full proposals, including budgetary requirements. Complete proposals applying for funding shall be endorsed by RM to the Technical Review Board (TRB) for review. After assigning scores for scientific and technical merit, each full proposal shall be endorsed by TRB to RM.

RM sends out letters to all successful applicants for funding. Chosen proposals shall be based on the score endorsed by the TRB. The number of grants provided each year shall depend on the ranking based on merit and the budget allocated by UP Manila for research.

2. Management of research grants for approved proposals

Once the PI has been informed of their successful application for research funding, the RM coordinates submission of the protocol to the Research Grants Administration Office (RGAO). At this point, RM also assigns a research mentor to the successful grantee.

Principal investigators are expected to submit final reports to RM, using the prescribed format. The final reports are endorsed to the TRB. The TRB in turn evaluates if the final report has addressed the objectives of the original protocol. The TRB endorses their recommendations on the final report to RM.

B. Information System (IS)

Information system is a combination of hardware, software, infrastructure and trained personnel organized to facilitate planning, control, coordination and decision making in an organization. It is used to collect, create and distribute useful data [20].

C. Monitoring System

A monitoring system can be defined as an observation system for the project managers to verify whether the project activities are happening according to planning and whether means are used in a correct and efficient manner. The system must supply the project management with a continuous flow of information throughout the course of the project to make it possible to take the right decisions. Monitoring is limited to the relation between the implementation of the activities and the results, in which the results are directly and only determined by the project activities [21].

D. Database Management System (DBMS)

A database management system (DBMS) is the software that allows a computer to perform database functions of storing, retrieving, adding, deleting and modifying data. Relational database management systems (RDBMS) implement the relational model of tables and relationships [22].

IV. Design and Implementation

A. Context Diagram

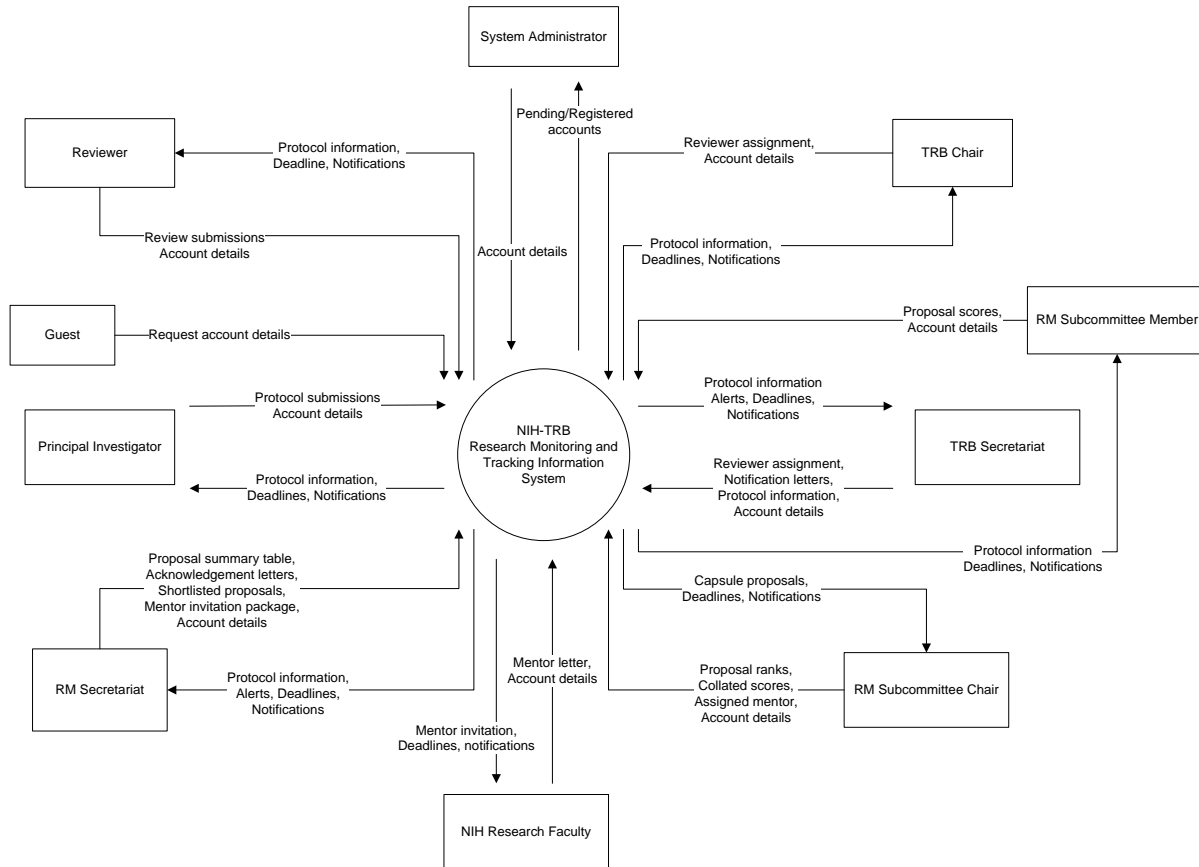


Figure 1: Context Diagram, NIH-TRB Research Monitoring and Tracking Information System (ReMTIS

2.0)

B. Data Flow Diagram

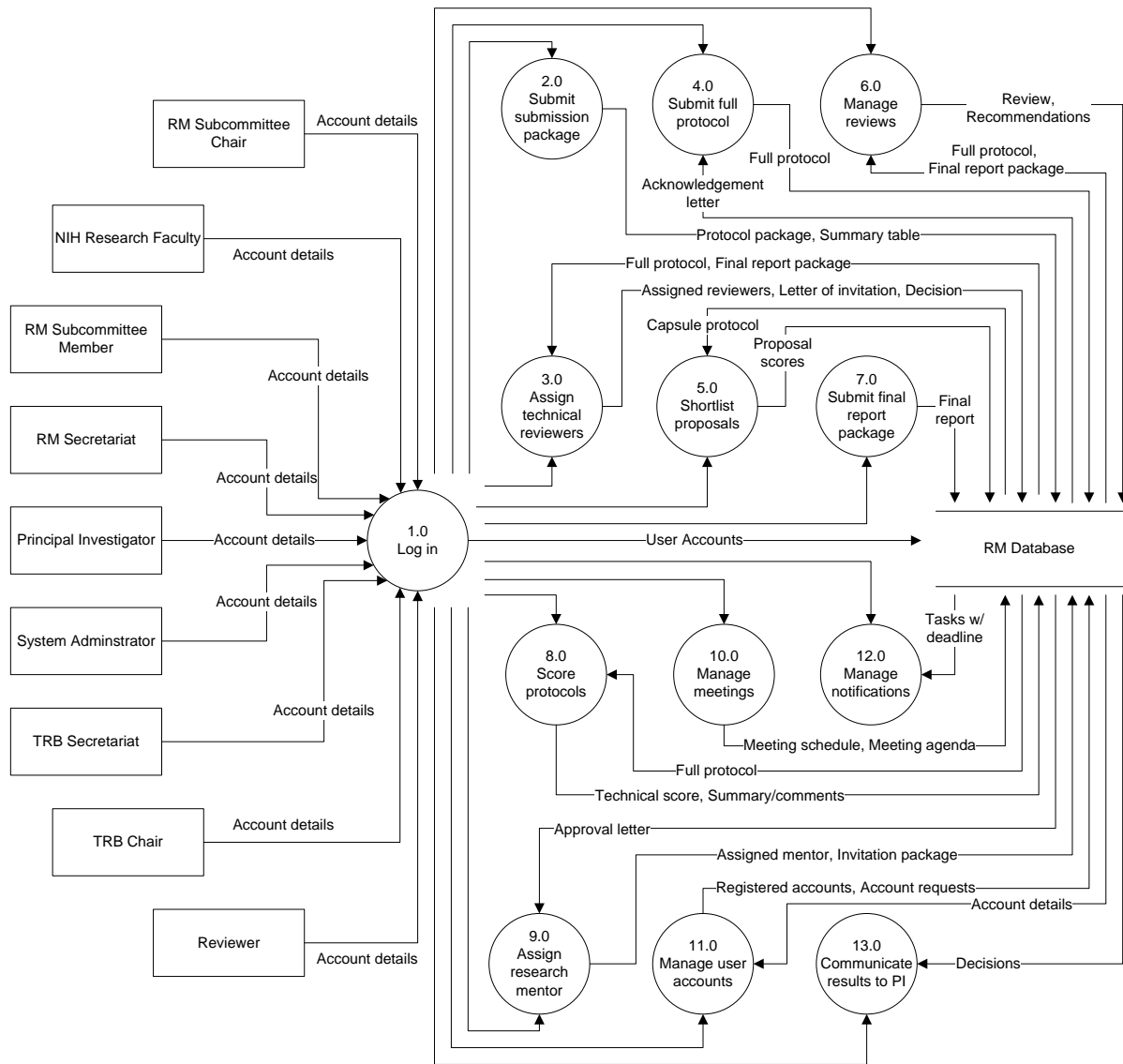


Figure 2: Data Flow Diagram, NIH-TRB Research Monitoring and Tracking Information System

(ReMTIS 2.0)

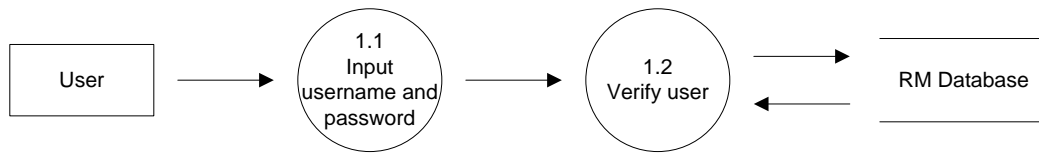


Figure 3: Sub-explosion of Process 1.0 Login

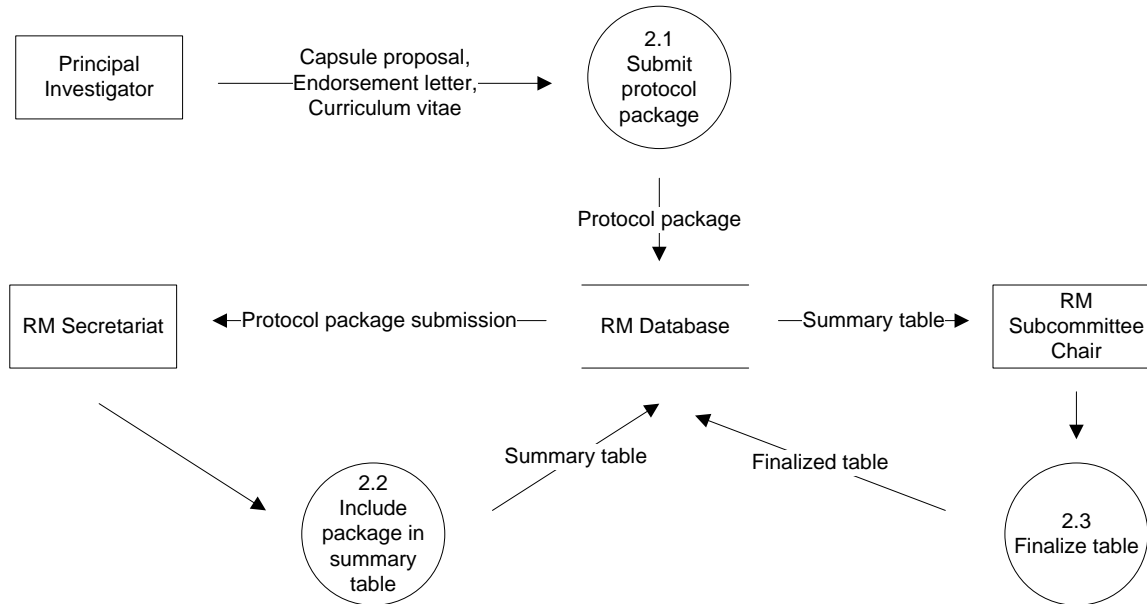


Figure 4: Sub-explosion of Process 2.0 Submit submission package

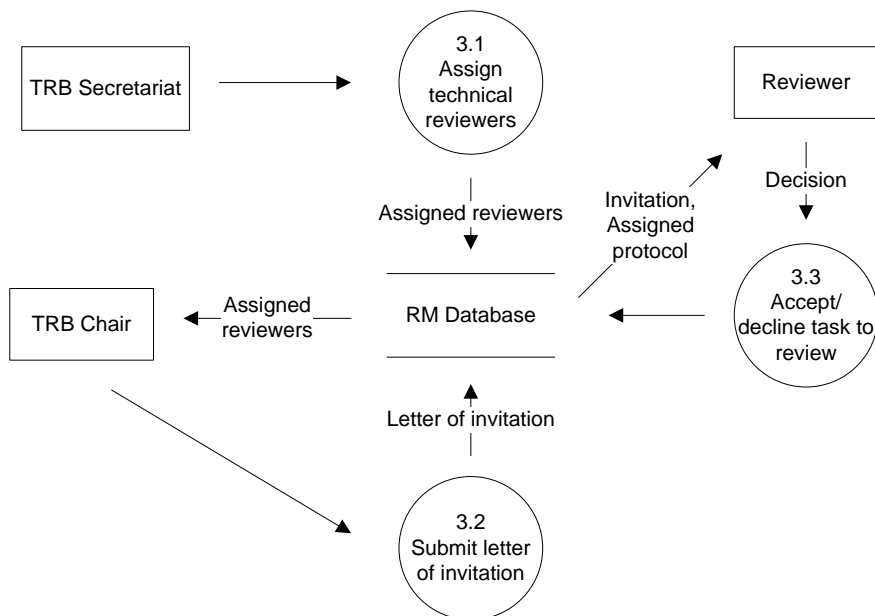


Figure 5: Sub-explosion of Process 3.0 Assign technical reviewers



Figure 6: Sub-explosion of Process 4.0 Submit full protocol

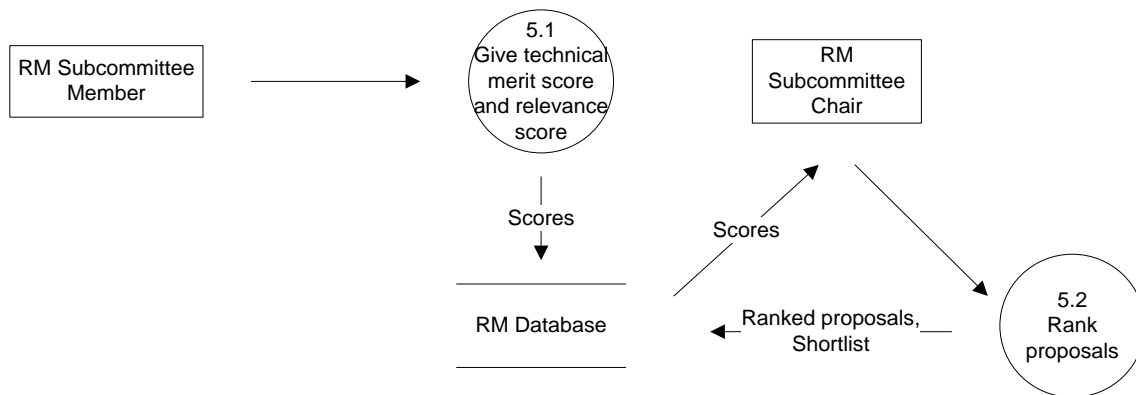


Figure 7: Sub-explosion of Process 5.0 Shortlist proposals

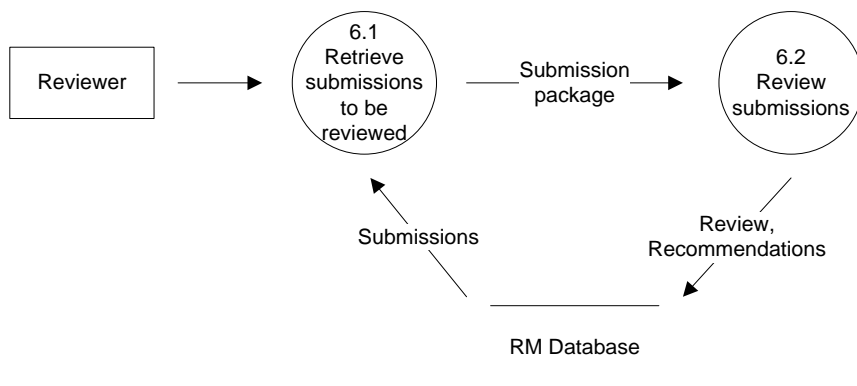


Figure 8: Sub-explosion of Process 6.0 Manage reviews

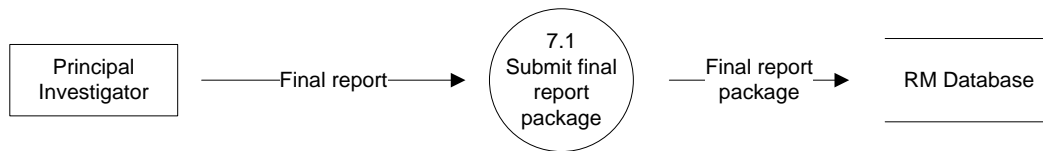


Figure 9: Sub-explosion of Process 7.0 Submit final report package

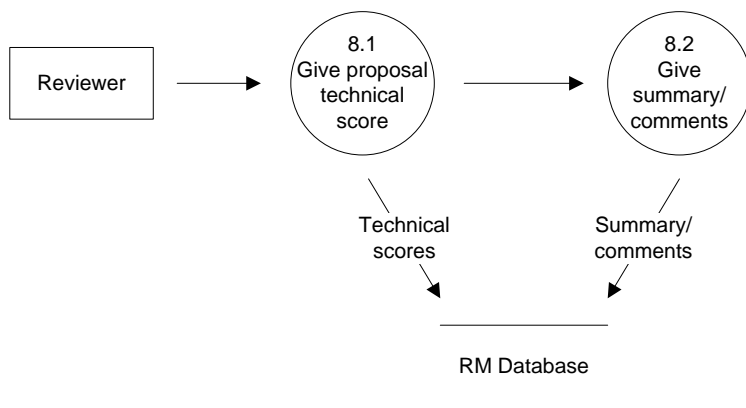


Figure 10: Sub-explosion of Process 8.0 Score protocols

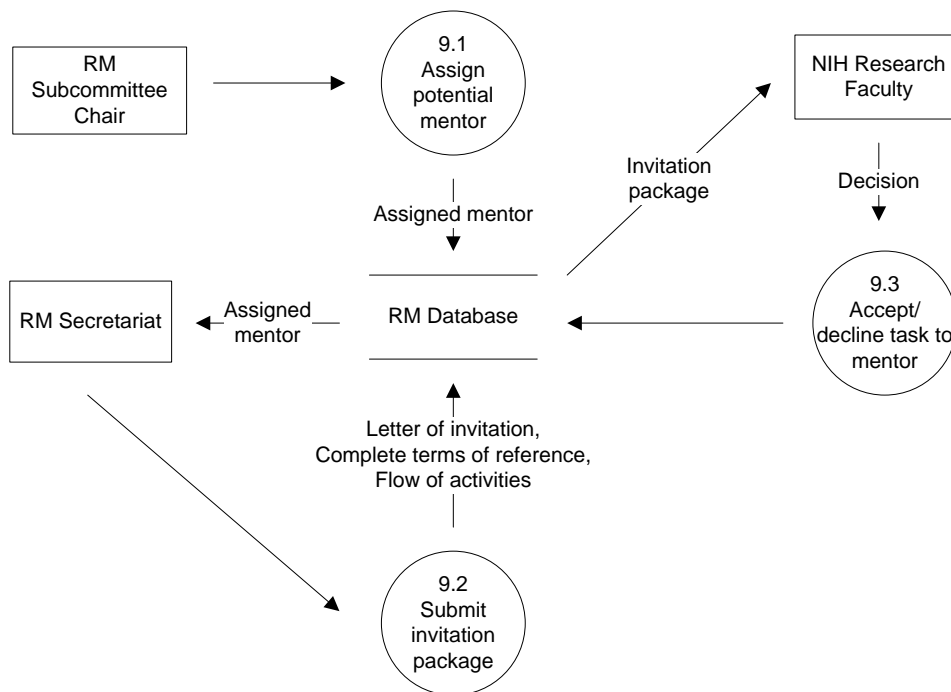


Figure 11: Sub-explosion of Process 9.0 Assign research mentor

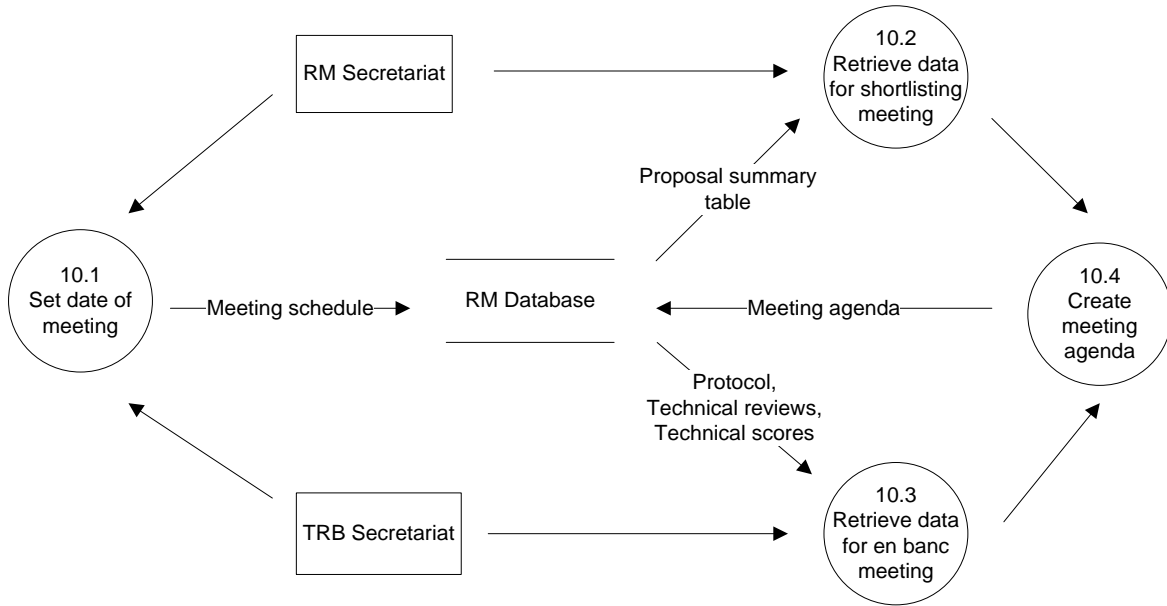


Figure 12: Sub-explosion of Process 10.0 Manage meetings

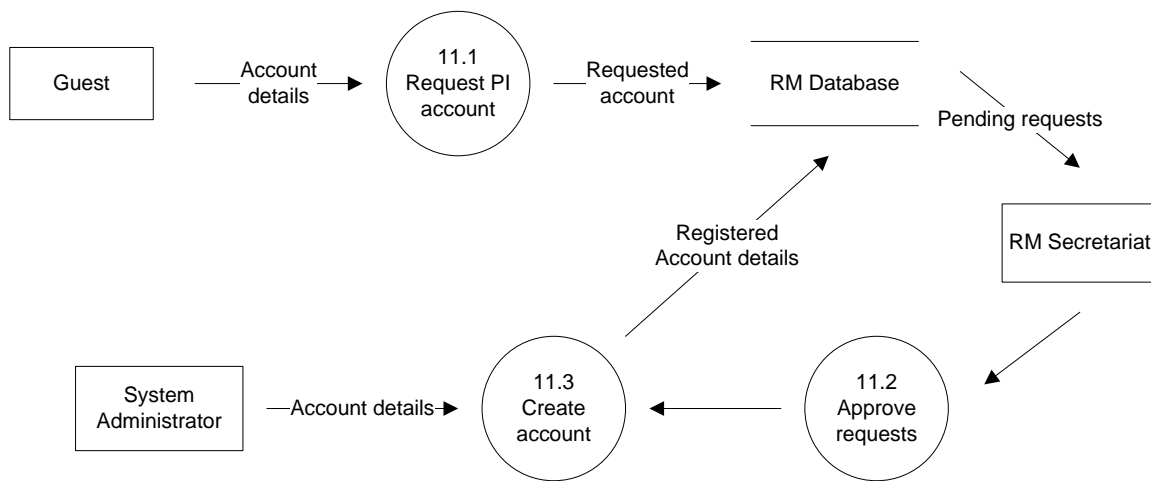


Figure 13: Sub-explosion of Process 11.0 Manage user accounts

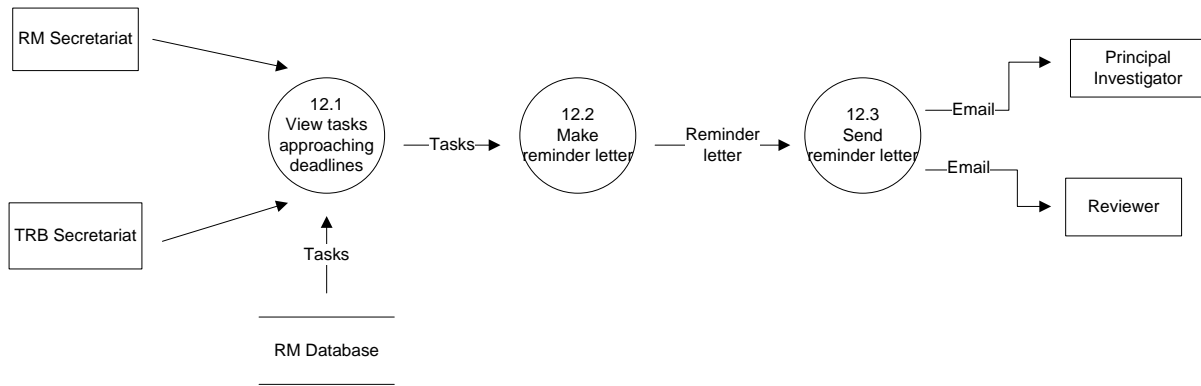


Figure 14: Sub-explosion of Process 12.0 Manage notifications

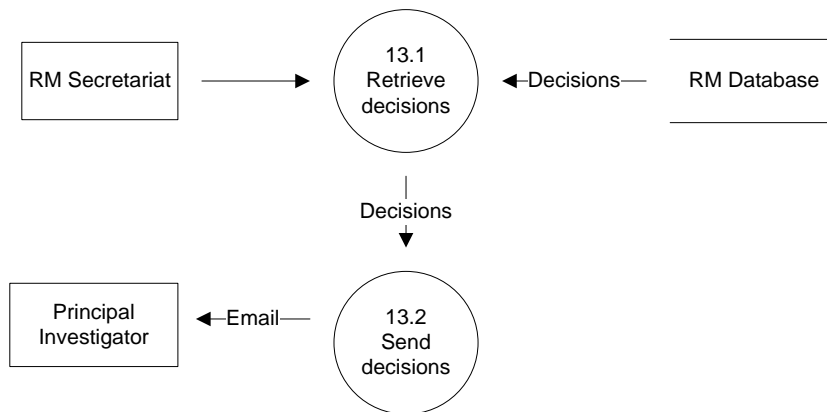


Figure 15: Sub-explosion of Process 13.0 Communicate results to PI

C. Entity Relationship Diagram

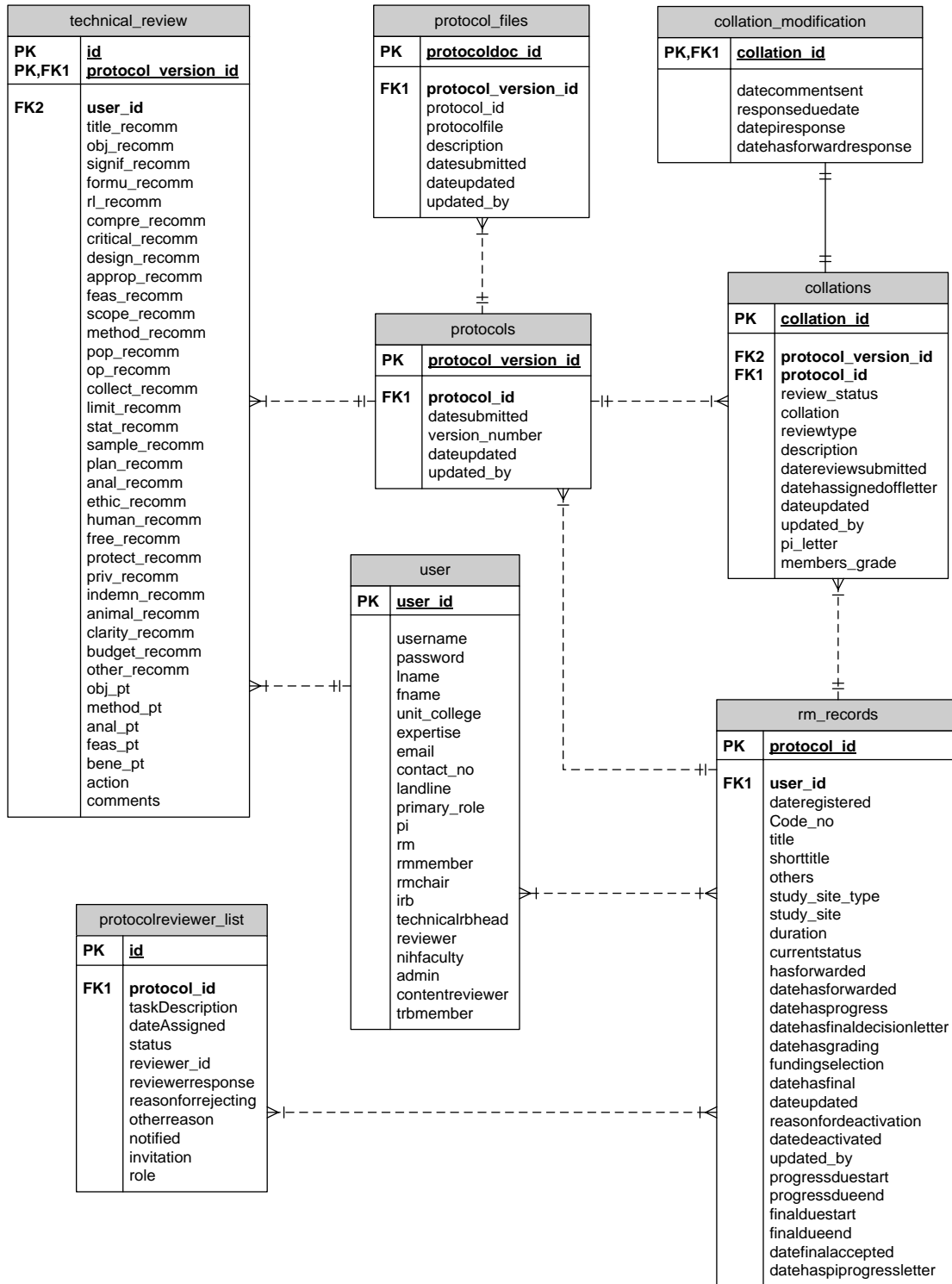


Figure 16: Entity Relationship Diagram, NIH-TRB Research Monitoring and Tracking Information System (ReMTIS 2.0)

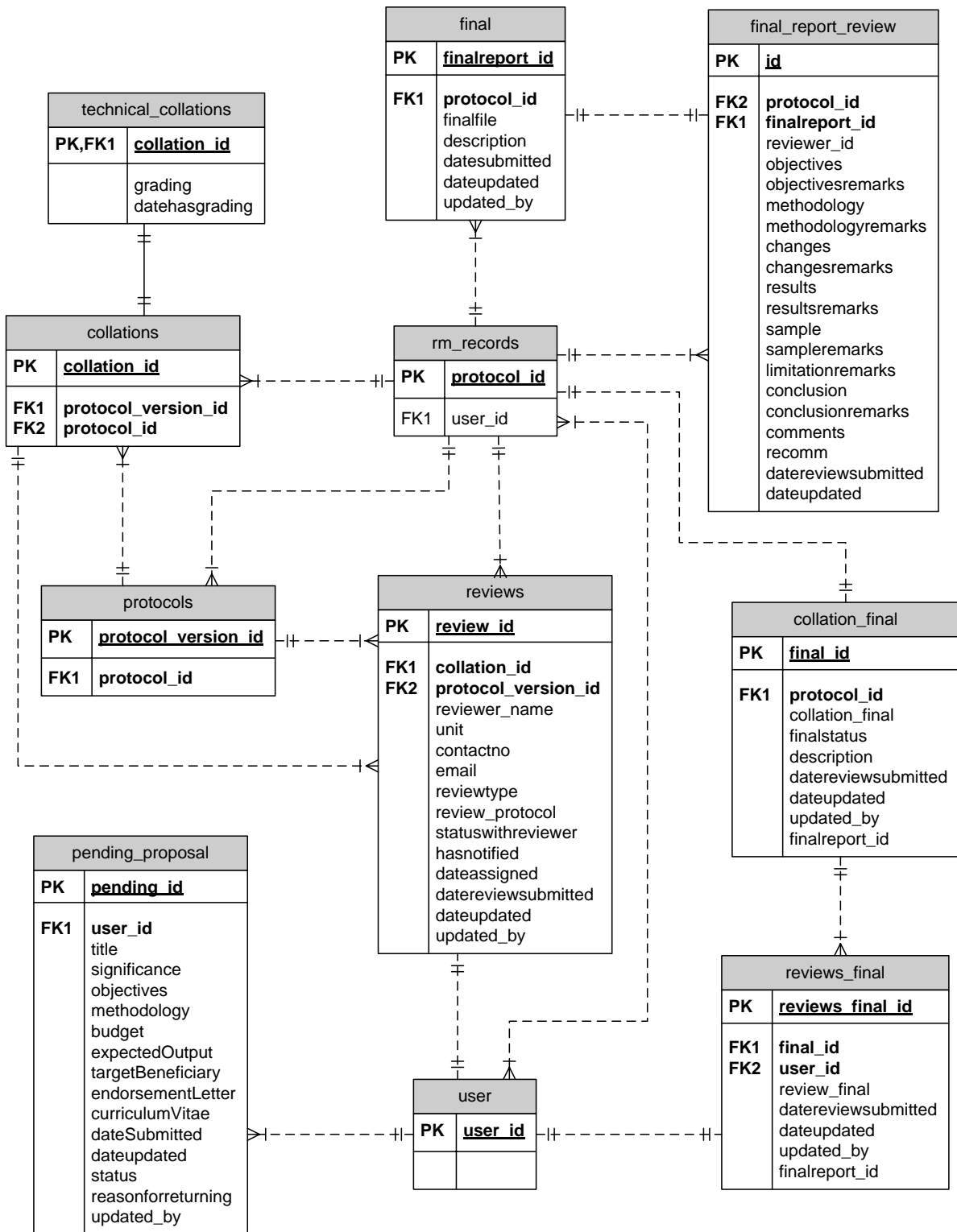


Figure 17: Entity Relationship Diagram, NIH-TRB Research Monitoring and Tracking Information System (ReMTIS 2.0)

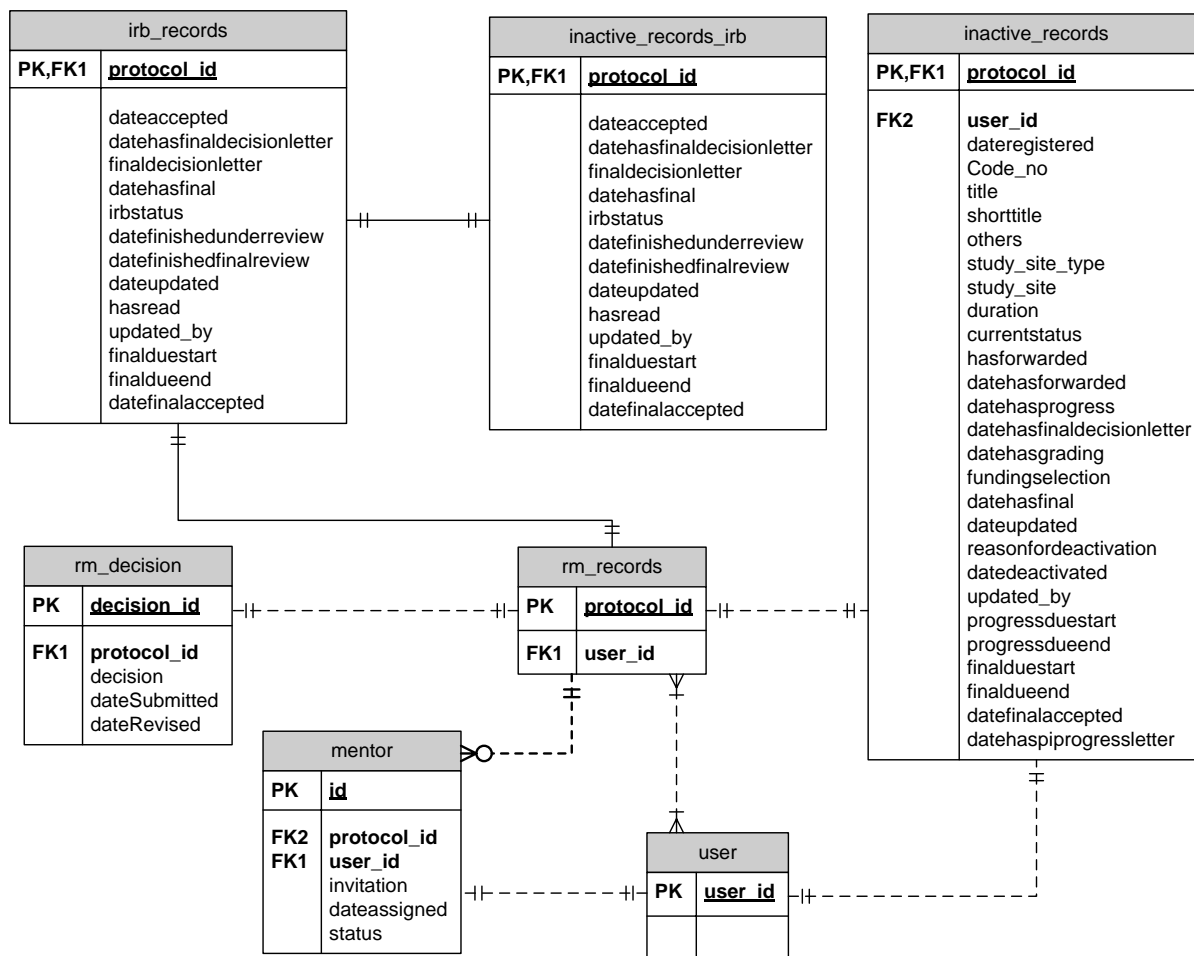


Figure 18: Entity Relationship Diagram, NIH-TRB Research Monitoring and Tracking Information System (ReMTIS 2.0)

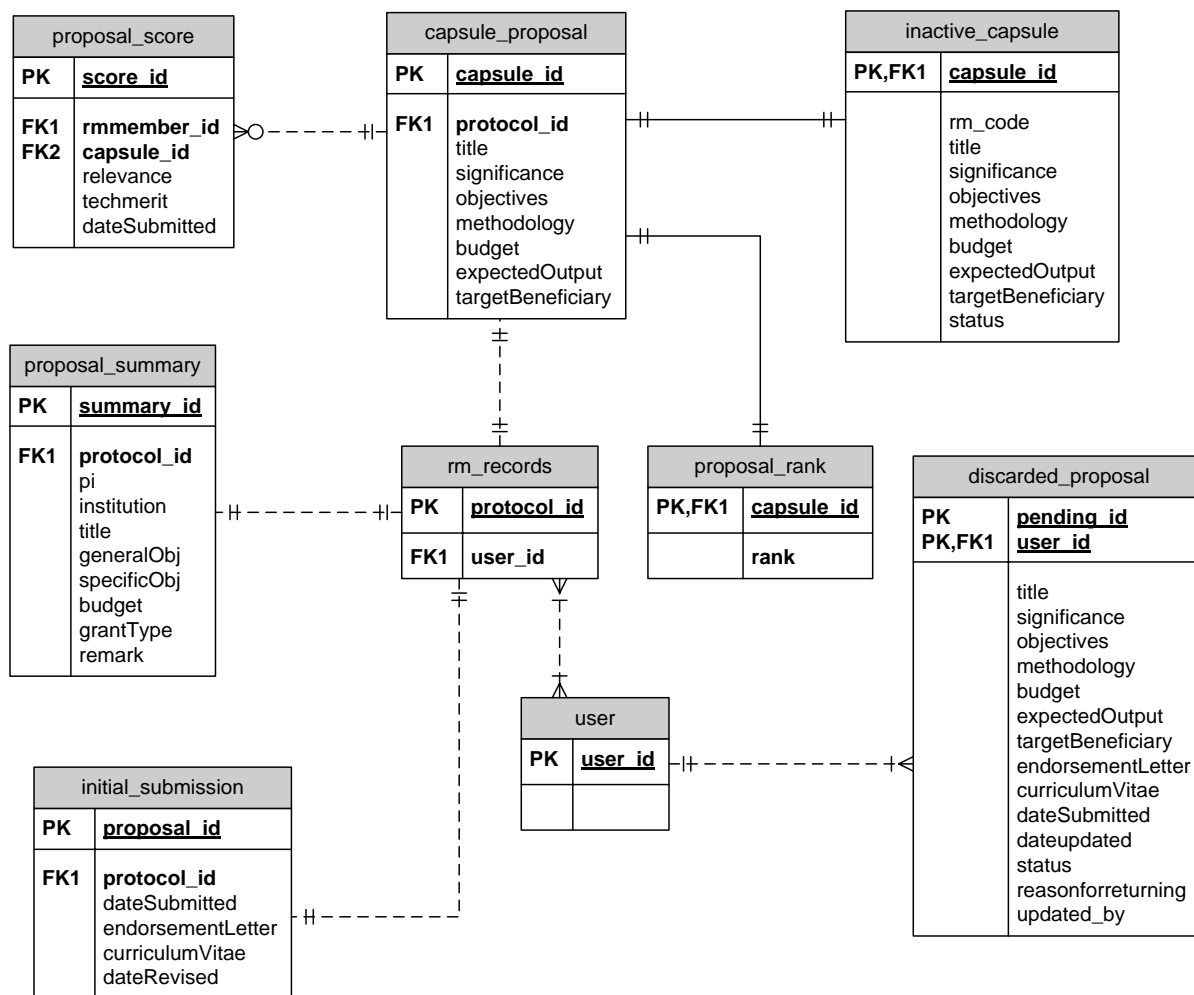


Figure 19: Entity Relationship Diagram, NIH-TRB Research Monitoring and Tracking Information System (ReMTIS 2.0)

D. Data Dictionary

DATA FIELD	DATA TYPE	DESCRIPTION
user_id	tinyint(4)	User identifier
username	varchar(50)	Username of user
password	varchar(50)	Password of user
fname	varchar(50)	First name of user
lname	varchar(50)	Last name of user
unit_college	text	College of user
expertise	text	Expertise of user
email	varchar(50)	Email of user
landline	varchar(15)	Landline number of user
contact_no	varchar(15)	Contact number of user
primary_role	enum('rm', 'irb', 'pi', 'reviewer', 'ethicsrbhead', 'erbmemberr', 'technicalrbhead', 'funder', 'nihadmin', 'vcr', 'admin', 'rmmember', 'rmchair', 'nihfaculty')	Primary role of user
pi	Boolean	1 if user is Principal Investigator, 0 otherwise
rm	Boolean	1 if user is RM Secretariat, 0 otherwise
rmmember	Boolean	1 if user is RM Subcommittee member, 0 otherwise
rmchair	Boolean	1 if user is RM Subcommittee chair, 0 otherwise
irb	Boolean	1 if user is TRB Secretariat, 0 otherwise
reviewer	Boolean	1 if user is reviewer, 0 otherwise
nihfaculty	Boolean	1 if user is NIH research

		faculty, 0 otherwise
admin	Boolean	1 if user is system administrator, 0 otherwise
contentreviewer	Boolean	1 if user is content reviewer, 0 otherwise
trbmember	Boolean	1 if user is TRB member, 0 otherwise

Table 1: USERS

DATA FIELD	DATA TYPE	DESCRIPTION
protocol_id	int(11)	RM Records identifier
user_id	tinyint(4)	Users identifier
dateregistered	date	Date protocol registered
Code_no	varchar(20)	Unique code of protocol
title	text	Title of protocol
shorttitle	text	Short title of protocol
study_site	varchar(100)	Study site of protocol
duration	varchar(100)	Duration of study
currentstatus	enum('Under Review', 'Ongoing', 'Disapproved', 'Completed', 'Discontinued', 'Withdrawn', 'Deferred','Others')	Current status of protocol
hasforwarded	int(11)	1 if protocol forwarded to TRB, 0 otherwise
datehasforwarded	date	Date protocol forwarded to TRB
datehasfinaldecisionletter	date	Date final decision letter is uploaded by TRB
datehasgrading	date	Date final grading is given by TRB
datehasfinal	date	Date final report is submitted
fundingselection	int(11)	Funding selection protocol

dateupdated	date	Date updated
reasonfordeactivation	text	Reason for deactivation of protocol
datedeactivated	date	Date of deactivation
updated_by	int(11)	User id of last updated
finalduestart	date	Start date of final report submission
finaldueend	date	End date of final report submission
datefinalaccepted	date	Date final report is accepted by RM

Table 2: RM_RECORDS

DATA FIELD	DATA TYPE	DESCRIPTION
protocol_id	int(11)	RM Records identifier
dateaccepted	date	Date protocol is accepted
datehasfinaldecisionletter	date	Date final decision letter is uploaded by TRB
finaldecisionletter	text	File path of final decision letter
datehasfinal	date	Date final report is uploaded
irbstatus		Status of protocol in IRB
datefinishedunderreview	date	Date finished TRB proposal review
datefinishedfinalreview	date	Date finished TRB final report review
dateupdated	date	Date record is updated
updated_by	int(11)	User id of last updated
finalduestart	date	Start date of final report submission
finaldueend	date	End date of final report submission
datefinaleaccepted	date	Date final report is accepted by

		RM
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Table 3: IRB_RECORDS

DATA FIELD	DATA TYPE	DESCRIPTION
protocol_id	int(11)	RM Records identifier
dateaccepted	date	Date protocol is accepted
datehasfinaldecisionletter	date	Date final decision letter is uploaded by TRB
finaldecisionletter	text	File path of final decision letter
datehasfinal	date	Date final report is uploaded
irbstatus		Status of protocol in IRB
datefinishedunderreview	date	Date finished TRB proposal review
datefinishedfinalreview	date	Date finished TRB final report review
dateupdated	date	Date record is updated
updated_by	int(11)	User id of last updated
finalduestart	date	Start date of final report submission
finaldueend	date	End date of final report submission
datefinaleaccepted	date	Date final report is accepted by RM

Table 4: INACTIVE_RECORDS_IRB

DATA FIELD	DATA TYPE	DESCRIPTION
review_id	int(11)	Reviews identifier
collation_id	int(11)	Collations identifier
protocol_version_id	int(11)	Protocols identifier
protocol_id	int(11)	RM Records identifier
reviewer_id	int(11)	User id of reviewer
reviewer_name	text	Reviewer name

unit	varchar(50)	Reviewer unit
contactno	varchar(50)	Reviewer contact number
email	varchar(50)	Reviewer email
reviewtype	int(11)	Review type of the collation 1 – Technical,2- Ethics, 3 – IACUC, 4 –IBC
review_protocol	text	File path of review file
statuswithreviewer	enum('pending', 'accepted', 'rejected')	
hasnotified	int(11)	1 if reviewer is notified,0 otherwise
dateassigned	date	Date when task is assigned
datereviewssubmitted	date	Date when review is submitted
dateupdated	date	Date recorded last updated
updated_by	int(11)	User id of last updated

Table 5: REVIEWS

DATA FIELD	DATA TYPE	DESCRIPTION
reviews_final_id	int(11)	Finals identifier
final_id	int(11)	Collation Final identifier
reviewer_id	int(11)	User id of reviewer
review_final	text	File path of final report review
datereviewssubmitted	date	Date of submission
dateupdated	date	Date record is updated
updated_by	int(11)	User id of latest update
finalreport_id	int(11)	Final report ID

Table 6: REVIEWS_FINAL

DATA FIELD	DATA TYPE	DESCRIPTION
collation_id	int(11)	Collation identifier

grading	int(11)	Final grading of protocol
datehasgrading	date	Date final grading is set

Table 7: TECHNICAL_COLLATIONS

DATA FIELD	DATA TYPE	DESCRIPTION
id	tinyint(4)	Protocol Reviewer List identifier
protocol_id	int(11)	RM Records identifier
reviewer_id	varchar(20)	User id of reviewer
taskDescription	text	Task description of protocol reviewer
dateAssigned	date	Date of task assignment
status	varchar(100)	Status of task
reviewerresponse		Response of reviewer
reasonforrejecting	int(11)	Reason for rejecting task
otherreason	text	Other reason for rejecting
notified	int(11)	1 if notified, 0 otherwise
invitation	text	File path of invitation letter
role	text	Role of reviewer

Table 8: PROTOCOLREVIEWER_LIST

DATE FIELD	DATA TYPE	DESCRIPTION
id	int(11)	Technical Review identifier
protocol_id	int(11)	RM Records identifier
protocol_version_id	int(11)	Protocols identifier
reviewer_id	int(11)	User id of reviewer
title_recomm	text	Recommendation
obj_recomm	text	Recommendation
signif_recomm	text	Recommendation
formu_recomm	text	Recommendation
rl_recomm	text	Recommendation
compre_recomm	text	Recommendation

critical_recomm	text	Recommendation
design_recomm	text	Recommendation
approp_recomm	text	Recommendation
feas_recomm	text	Recommendation
scope_recomm	text	Recommendation
method_recomm	text	Recommendation
pop_recomm	text	Recommendation
op_recomm	text	Recommendation
collect_recomm	text	Recommendation
limit_recomm	text	Recommendation
stat_recomm	text	Recommendation
sample_recomm	text	Recommendation
plan_recomm	text	Recommendation
anal_recomm	text	Recommendation
ethic_recomm	text	Recommendation
human_recomm	text	Recommendation
free_recomm	text	Recommendation
protect_recomm	text	Recommendation
priv_recomm	text	Recommendation
indemn_recomm	text	Recommendation
animal_recomm	text	Recommendation
clarity_recomm	text	Recommendation
budget_recomm	text	Recommendation
obj_pt	int(11)	Objectives score
method_pt	int(11)	Methodology score
anal_pt	int(11)	Analysis score
feas_pt	int(11)	Feasibility score
bene_pt	int(11)	Beneficiary score
action	text	Recommended action
comments	text	Other comments

Table 9: TECHNICAL_REVIEW

DATA FIELD	DATA TYPE	DESCRIPTION
collation_id	int(11)	Collations identifier
protocol_version_id	int(11)	Protocols identifier
protocol_id	int(11)	RM Records identifier
collation	text	File path of collation
review_status	int(11)	Status of review collation
reviewtype	int(11)	Type of review
description	varchar(100)	Description of collation
datereviewsubmitted	date	Date of review submission
datehassignedoffletter	date	Date decision letter is signed off
dateupdated	date	Date record is updated
updated_by	int(11)	User id of last updated
pi_letter	text	Decision letter to PI
members_grade	int(11)	Average score of TRB members grade

Table 10: COLLATIONS

DATA FIELD	DATA TYPE	DESCRIPTION
collation_id	int(11)	Collations identifier
datecommentsent	date	Date comments sent to PI
responseduedate	date	Due date of PI response to comments
datepireponse	date	Date PI responded
datehasforwardresponse	date	Date TRB forwarded response to reviewers

Table 11: COLLATION_MODIFICATION

DATA FIELD	DATA TYPE	DESCRIPTION
final_id	int(11)	Collation Final identifier
protocol_id	int(11)	RM Records identifier
collation_final	text	File path of final report review collation

finalstatus	text	Final status of collation
description	text	Description of collation
datereviewsubmitted	date	Date of review submission
dateupdated	date	Date record is updated
updated_by	int(11)	User id of last update
finalreport_id	int(11)	Final report ID

Table 12: COLLATION_FINAL

DATA FIELD	DATA TYPE	DESCRIPTION
proposal_id	tinyint(4)	Initial Submission identifier
rm_code	varchar(20)	Code No of proposal
dateSubmitted	date	Date of initial submission
endorsementLetter	text	File path of endorsement letter
curriculumVitae	text	File path of curriculum vitae
dateRevised	date	Date of revision

Table 13: INITIAL_SUBMISSION

DATA FIELD	DATA TYPE	DESCRIPTION
capsule_id	tinyint(4)	Capsule Proposal identifier
rm_code	varchar(20)	Code No of proposal
title	varchar(100)	Title of proposal
significance	text	Significance of proposal
objectives	text	Objectives of proposal
methodology	text	Methodology of proposal
budget	varchar(50)	Budget of proposal
expectedOutput	text	Expected output of proposal
targetBeneficiary	text	Target beneficiary of proposal
status	text	Status of capsule proposal

Table 14: CAPSULE_PROPOSAL

DATA FIELD	DATA TYPE	DESCRIPTION
capsule_id	tinyint(4)	Capsule Proposal identifier
rm_code	varchar(20)	Code No of inactive proposal
title	varchar(100)	Title of inactive proposal
significance	text	Significance of inactive
objectives	text	Objectives of inactive
methodology	text	Methodology of inactive
budget	varchar(50)	Budget of inactive proposal
expectedOutput	text	Expected output of inactive
targetBeneficiary	text	Target beneficiary of inactive
status	text	Status of inactive proposal

Table 15: INACTIVE_CAPSULE

DATA FIELD	DATA TYPE	DESCRIPTION
capsule_id	tinyint(4)	Capsule Proposal identifier
rank	int	Rank of proposal

Table 16: PROPOSAL_RANK

DATA FIELD	DATA TYPE	DESCRIPTION
capsule_id	tinyint(4)	Capsule Proposal identifier
rm_code	varchar(20)	Code No of discarded
title	varchar(100)	Title of discarded proposal
significance	text	Significance of discarded
objectives	text	Objectives of discarded
methodology	text	Methodology of discarded
budget	varchar(50)	Budget of discarded
expectedOutput	text	Expected output of discarded
targetBeneficiary	text	Target beneficiary of discarded
endorsementLetter	text	File path of endorsement letter of discarded
curriculumVitae	text	File path of curriculum vitae of discarded proposal

dateSubmitted	date	Date of submission of discarded proposal
dateupdated	date	Date discarded updated
status	text	Status of discarded proposal
reasonforreturning	text	Reason for returning discarded proposal
updated_by	int(11)	User id of last update

Table 17: DISCARDED_PROPOSAL

DATA FIELD	DATA TYPE	DESCRIPTION
protocol_version_id	int(11)	Protocols identifier
version_number	int(11)	Protocols identifier
protocol_id	int(11)	RM Records identifier
datesubmitted	date	Date protocol submission
dateupdated	date	Date record updated
updated_by	int(11)	User id of last update

Table 18: PROTOCOLS

DATA FIELD	DATA TYPE	DESCRIPTION
finalreport_id	tinyint(4)	Final identifier
protocol_id	int(11)	RM Records identifier
finalfile	text	File path of final report
description	text	Description of final report
dateupdated	date	Date record updated
updated_by	int(11)	User id of last update

Table 19: FINAL

DATA FIELD	DATA TYPE	DESCRIPTION
summary_id	tinyint(4)	Summary Table identifier
rm_code	varchar(20)	Code No of proposal
pi	varchar(100)	Principal Investigator

institution	varchar(100)	Institution of PI
title	varchar(100)	Title of proposal
generalObj	text	General objectives of proposal
specificObj	text	Specific objectives of proposal
budget	varchar(50)	Budget of proposal
grantType	varchar(100)	Grant type of proposal
remark	text	Remark of proposal

Table 20: PROPOSAL_SUMMARY

DATA FIELD	DATA TYPE	DESCRIPTION
score_id	tinyint(4)	Proposal Score identifier
rmmember_id	tinyint(4)	User id of RM member
techmerit	int	Technical merit score
relevance	int	Relevance score
dateSubmitted	date	Date of submission

Table 21: PROPOSAL_SCORE

DATA FIELD	DATA TYPE	DESCRIPTION
table_id	tinyint(4)	Summary Table identifier
finalizedTable	text	File path of summary table
dateSubmitted	date	Date of submission
finalizedDueDate	date	Due date of finalized summary table
dateFinalized	date	Date of finalized summary table

Table 22: SUMMARY_TABLE

DATA FIELD	DATA TYPE	DESCRIPTION
user_id	tinyint(4)	User identifier
username	varchar(50)	Username of user
password	varchar(50)	Password of user
fname	varchar(50)	First name of user

lname	varchar(50)	Last name of user
unit_college	text	College of user
expertise	text	Expertise of user
email	varchar(50)	Email of user
landline	varchar(15)	Landline number of user
contact_no	varchar(15)	Contact number of user
datesubmitted	date	Date of submission

Table 23: PENDING_USERS

DATA FIELD	DATA TYPE	DESCRIPTION
id	int(11)	Final Report Review identifier
protocol_id	int(11)	RM Records identifier
finalreport_id	int(11)	Final report ID
reviewer_id	int(11)	User id of reviewer
objectives	int(11)	1 if yes, 2 if no
objectivesremarks	text	Remarks
methodology	int(11)	1 if yes, 2 if no
methodologyremarks	text	Remarks
changes	int(11)	1 if yes, 2 if no
changesremarks	text	Remarks
sample	int(11)	1 if yes, 2 if no
sampleremarks	text	Remarks
liquidationremarks	text	Remarks
conclusion	int(11)	1 if yes, 2 if no
conclusionremarks	text	Remarks
comments	text	Review comments
recomm	int(11)	Recommendation for publication
datereviewsubmitted	date	Date of review submission
dateupdated	date	Date updated

Table 24: FINAL_REPORT_REVIEW

DATA FIELD	DATA TYPE	DESCRIPTION
meeting_id	tinyint(4)	Meeting Agenda identifier
task	text	Task
agenda	text	File path of meeting agenda
year_id	int(11)	Current year
place	varchar(100)	Place of meeting
date	date	Date of meeting

Table 25: MEETING_AGENDA

DATA FIELD	DATA TYPE	DESCRIPTION
meeting_id	int(11)	IRB Meeting Agenda identifier
task	text	Task
date	text	Date of meeting
agenda	text	File path of meeting agenda
attendees	text	List of meeting attendees

Table 26: IRB_MEETING_AGENDA

DATA FIELD	DATA TYPE	DESCRIPTION
id	tinyint(4)	Mentor Invite identifier
protocol_id	varchar(20)	RM Records identifier
mentor_id	tinyint(4)	User id of NIH Faculty
invitation	text	File path of invitation
dateassigned	date	Date of assignment
status	status	Status of invite

Table 27: MENTOR

DATA FIELD	DATA TYPE	DESCRIPTION
pending_id	tinyint(4)	Pending Proposal identifier
user_id	tinyint(4)	User identifier
title	text	Title of pending proposal
significance	text	Significance of proposal

objectives	text	Objectives of proposal
methodology	text	Methodology of proposal
budget	varchar(50)	Budget of pending proposal
expectedOutput	text	Expected output of proposal
targetBeneficiary	text	Target beneficiary of proposal
endorsementLetter	text	File path of endorsement letter
curriculumVitae	text	File path of curriculum vitae
dateSubmitted	date	Date of submission
dateupdated	date	Date updated
status	text	Status of pending proposal
reasonforreturning	text	Reason for returning
updated_by	int(11)	User id of last update

Table 28: PENDING_PROPOSAL

DATA FIELD	DATA TYPE	DESCRIPTION
task_id	tinyint(4)	RM Task identifier
task	text	Task of RM members
startDate	date	Start date of task
endDate	date	End date of task

Table 29: RM_TASK

DATA FIELD	DATA TYPE	DESCRIPTION
decision_id	tinyint(4)	RM Decision identifier
rm_code	varchar(20)	Code No of proposal
decision	text	File path of RM decision
dateSubmitted	date	Date of submission
dateRevised	date	Date of revision

Table 30: RM_DECISION

E. Activity Diagram

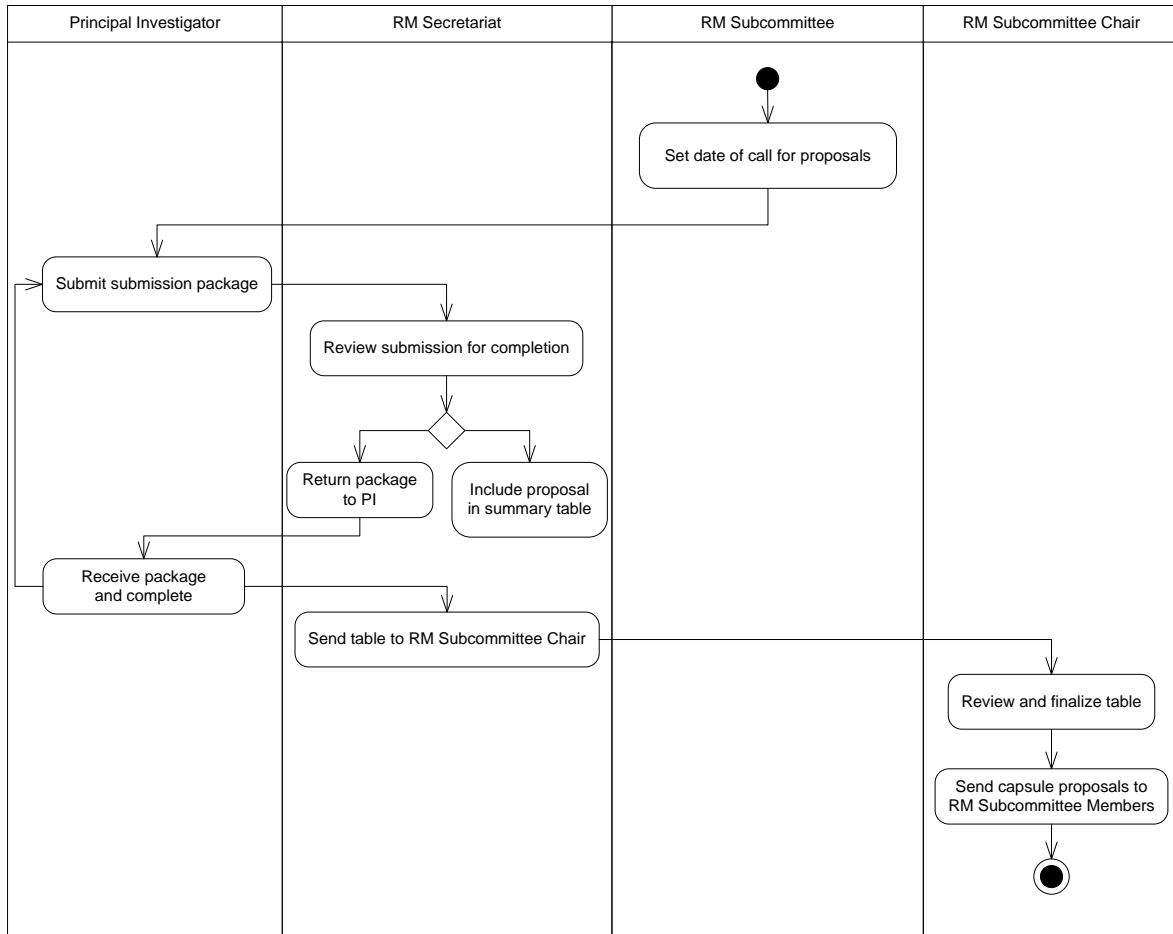


Figure 20: Activity Diagram of Initial Submission

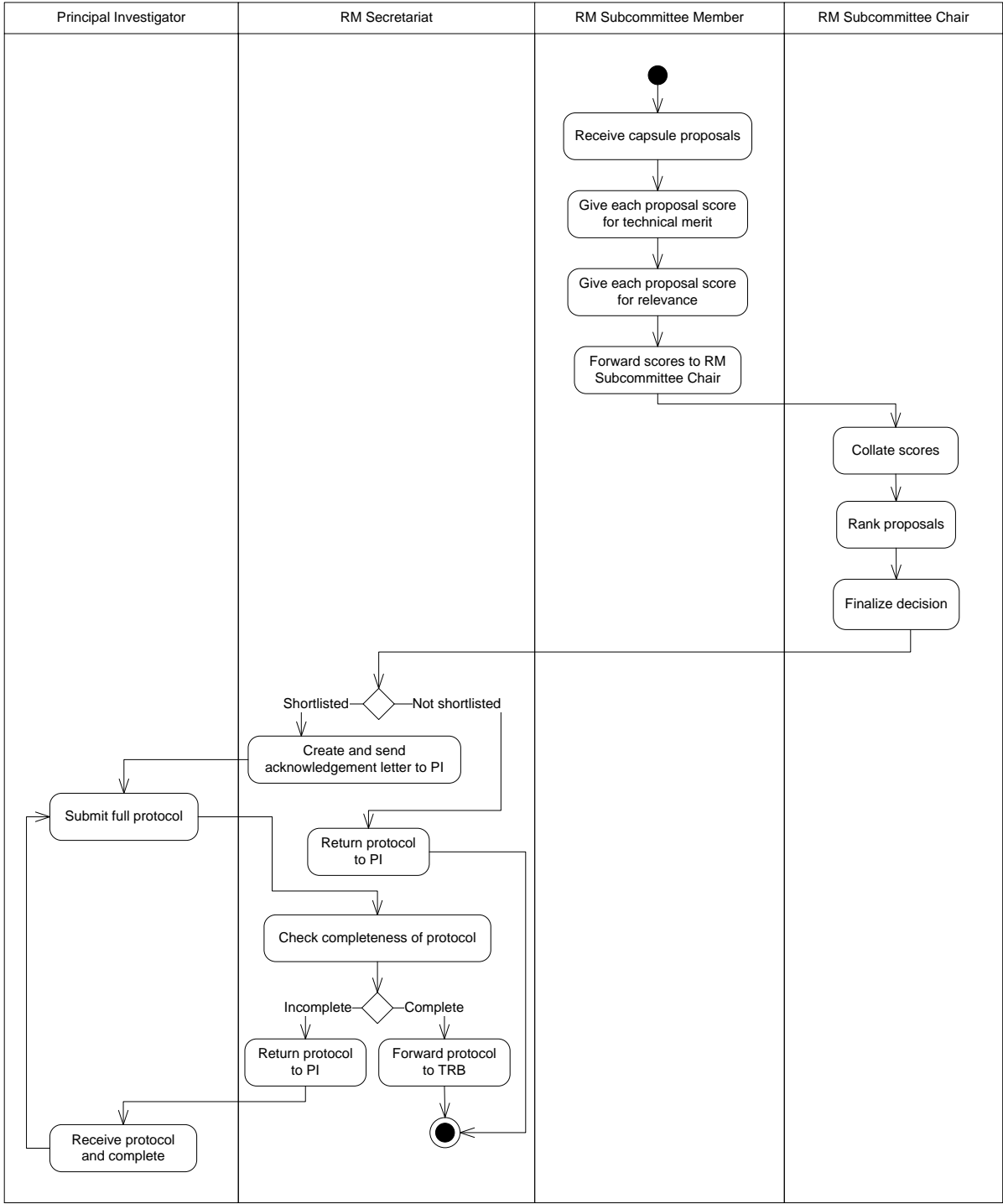


Figure 21: Activity Diagram of Proposal Shortlisting

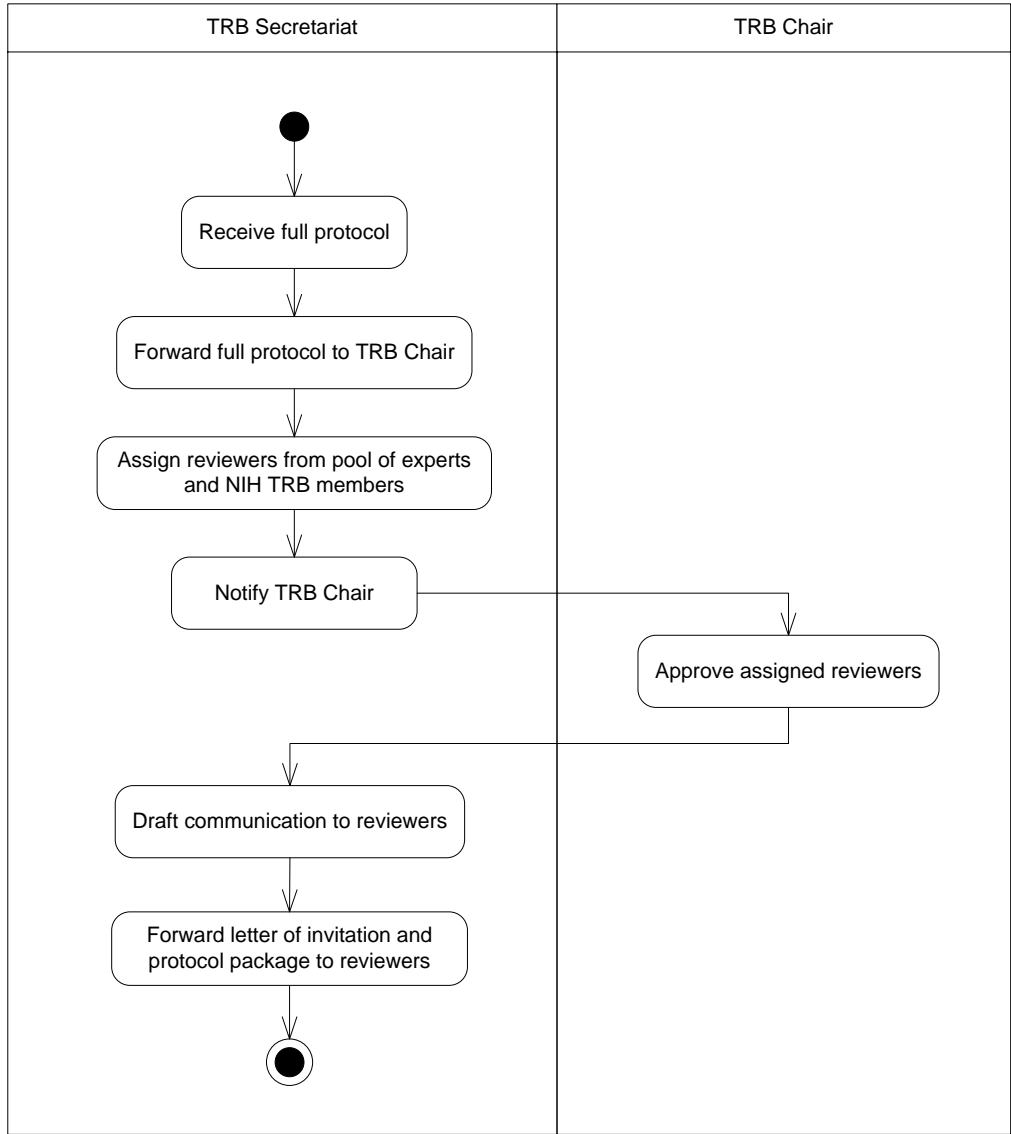


Figure 22: Activity Diagram of Assignment of Reviewers

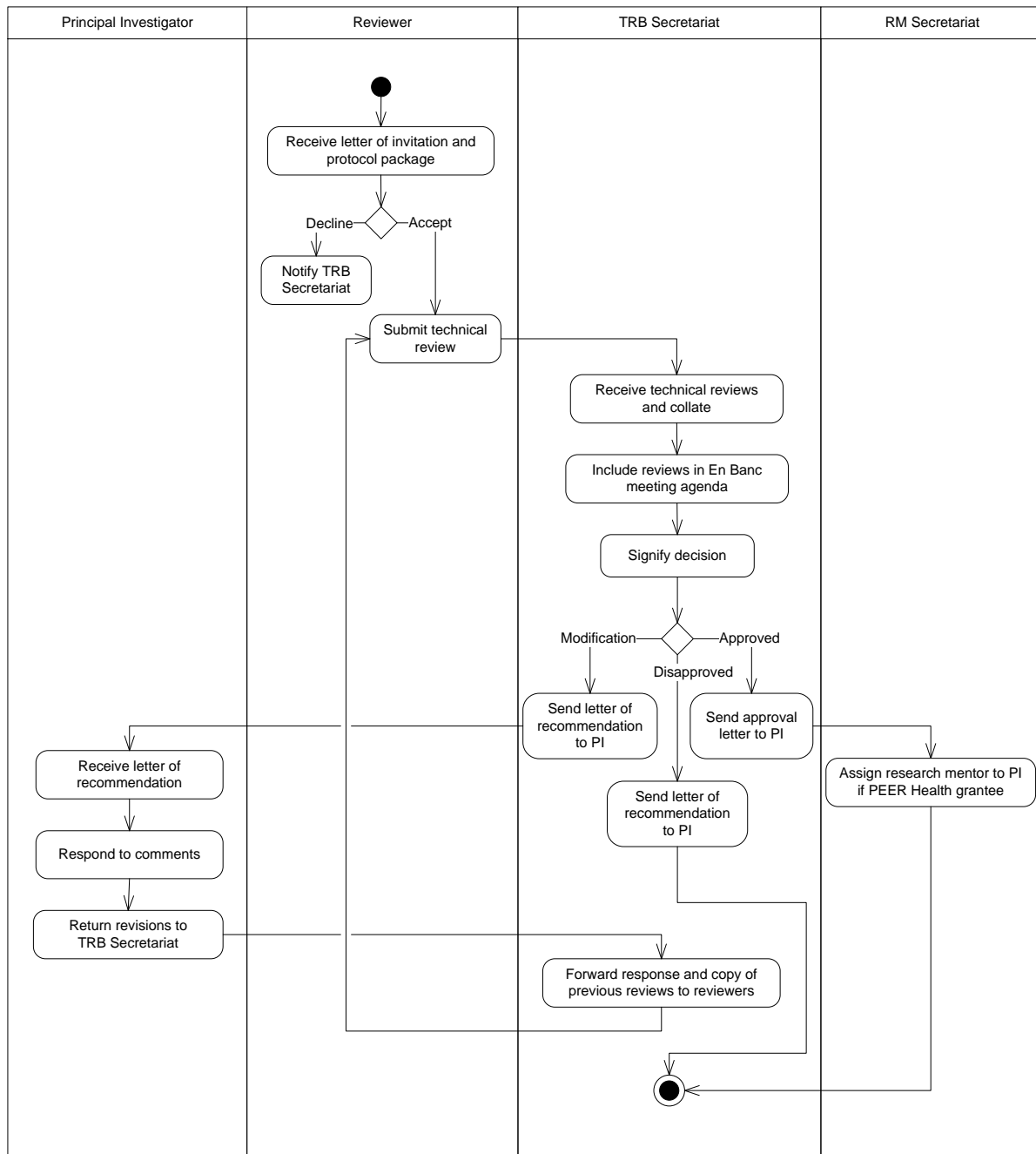


Figure 23: Activity Diagram of Protocol Review

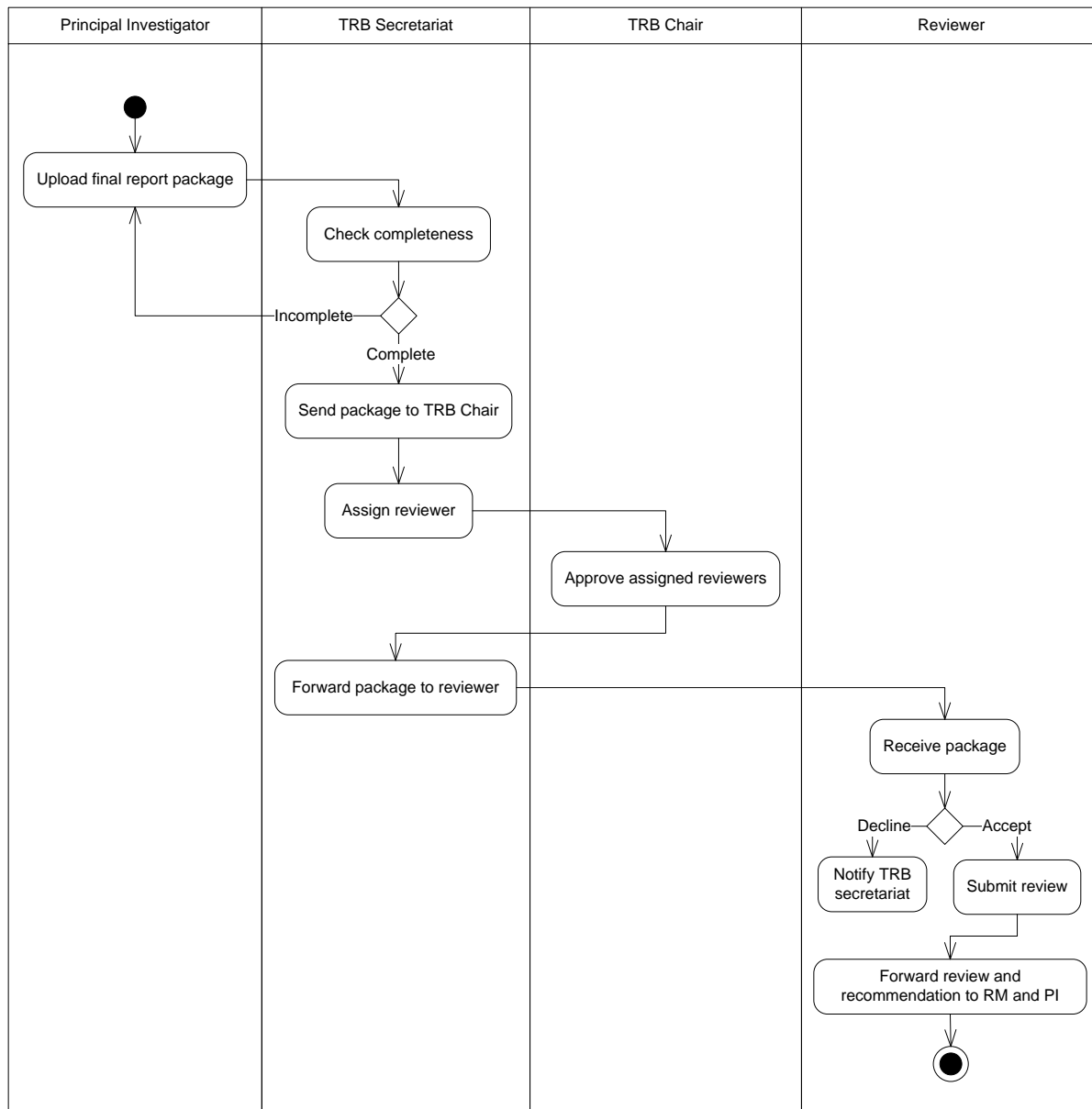


Figure 24: Activity Diagram of Final Report

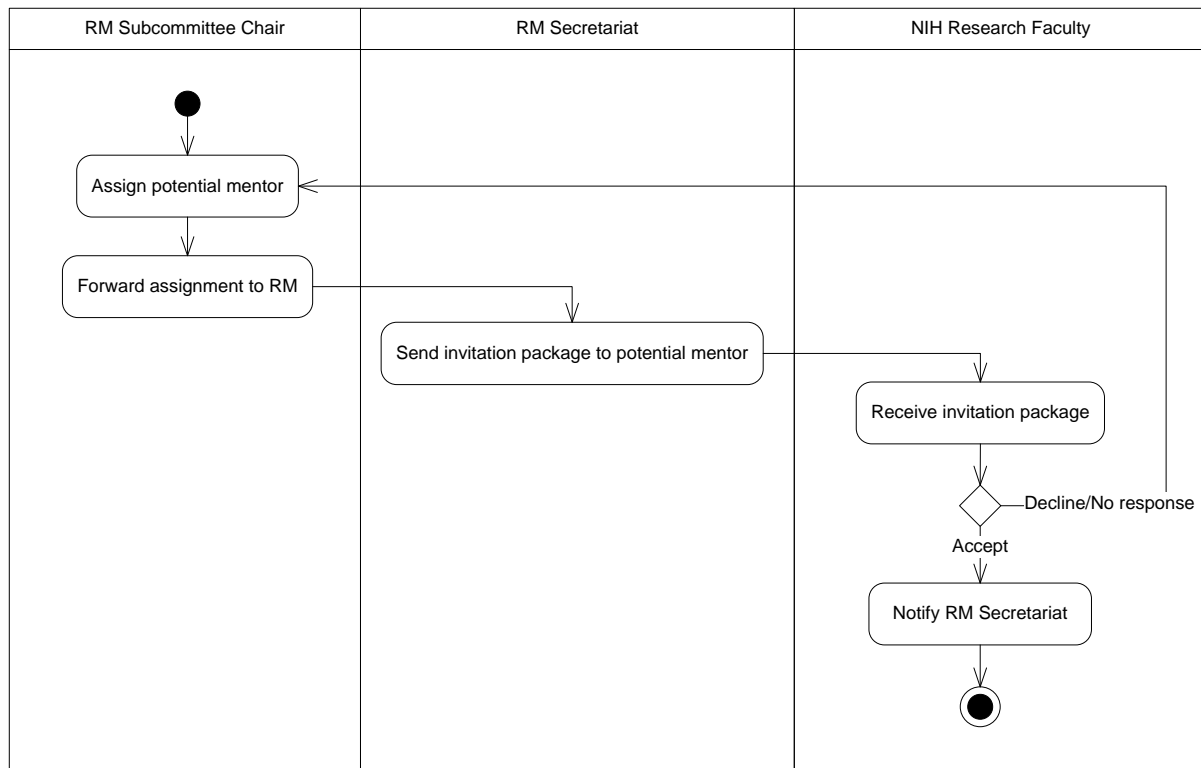


Figure 25: Activity Diagram of Assignment of Research Mentor

V. Architecture

A. System Architecture

Model–view–controller (MVC) is a software pattern for implementing user interfaces. It divides a given software application into three interconnected parts. The central component, the *model*, contains functions that help you retrieve, insert, and update information in your database. A *view* is the information that is being presented to a user. It is normally a web page. The third part, the *controller*, serves as an intermediary between the model, the view, and any other resources needed to process the HTTP request and generate a web page.

CodeIgniter is an open source rapid development web application framework, for use in building dynamic web sites with PHP. CodeIgniter is loosely based on the Model-View-Controller development pattern with model classes being optional. CodeIgniter also enables the incorporation of existing scripts, or even develop core libraries for the system.

ReMTIS 2.0 is based on the CodeIgniter MVC PHP framework. The system also has modules separated by their specific roles and functions.

1. Login. This module allows the users to access their system accounts by entering their username and password.
2. Protocol Registration. This module allows the RMD Secretariat and Principal Investigators to submit proposals and their information to the system. It is the first step in the tracking and monitoring of protocols submitted to NIH.
3. RM Management. This module allows the RMD Secretariat and other members of the Research Management and Development Committee of NIH to view and update information of protocols

monitored by the RMD. The information is also used for the report generation feature of the module.

4. TRB Management. This module allows the TRB Secretariat and other members of the Technical Review Board to view and update information of protocols and their corresponding review statuses monitored by the TRB. The information is also used for the report generation feature of the module.
5. Protocol/review Submissions. This allows the Secretariats, Principal Investigators and Reviewers to submit necessary requirements needed by the RMD and TRB.

B. Technical Architecture

NIH-TRB Research Monitoring and Tracking Information System (ReMTIS 2.0) follows the client-server architecture. The following is the minimum requirements:

Client Side

- Microsoft Windows or Linux
- Internet connection
- Web browser preferably Mozilla Firefox or Google Chrome

Server Side

- 700 MB memory
- XAMPP or LAMPP
- Internet connection

VI. Results

ReMTIS 2.0 has 3 additional users to the original 12 users of the earlier version of the system. The main users for the latest version that are included in the original 12 users include RMD Secretariat, IRB Secretariat renamed to TRB Secretariat, Principal Investigator, Reviewer, TRB Head, System Administrator and Guest. Additional users include RMD Chair, RM Member, NIH Research Faculty.

Registered users may log in (<http://agila.upm.edu.ph/~maduldulao/nih>) by entering their username and password (Figure 26). Each user may have more than one role. The user can change the logged-in role by selecting the desired role from the dropdown list at the left side of the webpage (Figure 27).



Figure 26: Log-in using username and password



Figure 27: Change role using dropdown menu

The RMD Secretariat sets important dates such as the Call for Proposals and the annual meeting of shortlisting (Figure 28). The TRB Secretariat also sets important dates such as the monthly en banc meeting (Figure 29).



Figure 28: Set important dates

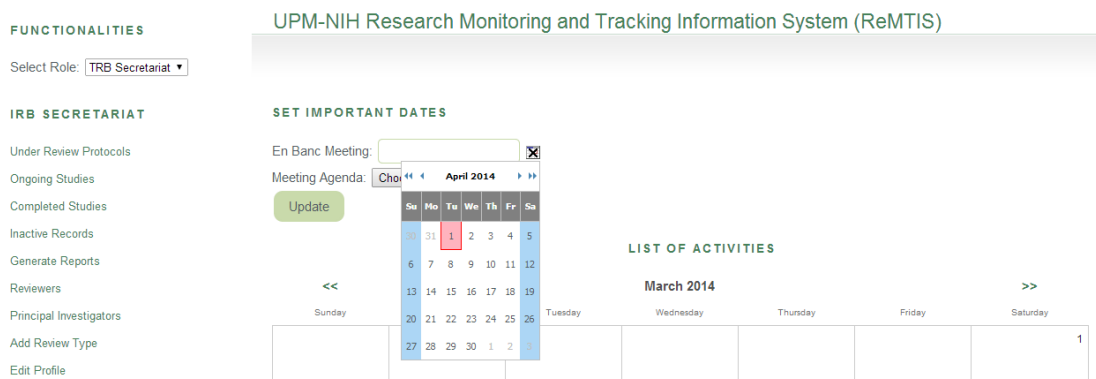


Figure 29: Set important dates

The system allows the RMD Secretariat and Principal Investigator to submit proposals seeking financial aid from the university.

PIs are only allowed to submit capsule proposals within the time frame set by the RMD Secretariat (Figure 30, 31).

FUNCTIONALITIES

Select Role: Principal Investigator ▼

PRINCIPAL INVESTIGATOR

- Submit a Protocol
- Pending for Registration
- Capsule Proposals
- Under Review Protocols
- Disapproved Protocols
- Ongoing Studies
- Completed Studies
- Discarded Protocols
- Edit Profile
- Change Password

CREATE CAPSULE PROPOSAL

* required fields

Name of the investigator: Myna Mendoza

Unit/College: Dept. of Medicine, CM

*Title of the Study

*Significance

*Objectives

Figure 30: Submit capsule proposals

*Target Beneficiary

*Endorsement Letter

*Curriculum Vitae

Choose File No file chosen

Choose File No file chosen

Submit Proposal

Figure 31: Submit capsule proposals

Those submitted by PIs are subject to the approval of RMD Secretariat (Figure 32).

LIST OF PENDING PROTOCOLS

Show entries Search:

Title ▲	Principal Investigator ↕	Status ↕	Date Submitted ↕
Prevalence of Birth Defects Among Newborns	Laurie S. Ramiro, PhD	pending	2014-03-05
Prevalence of CYP2D6 and CYP2C19 polymorphisms associated with extensive, intermediate and poor metabolism of Tamoxifen in Filipino Breast Cancer Patients admitted at Philippine General Hospital (PGH)	Myrna Mendoza	returned	2014-03-05
Prevalence of Parasitic Infection and Colonization in HIV-Infected Persons at the Philippine General Hospital	Raul Destura	returned	2014-03-05
Reinforcing Knowledge and Case Management Skills of Primary Health Care Workers on the Expanded Program on Immunization (EPI) through the Use of an Educational Video Game	Portia Grace Fernandez-Marcelo	pending	2014-03-05
Sputum AFB Smear Microscopy on the Second Month of Treatment as Predictor of Multi-drug Resistant Tuberculosis	Raul Destura	pending	2014-03-05

Showing 1 to 5 of 5 entries ◀ Previous Next ▶

Figure 32: Pending protocols for registration

RMD Secretariat has the option to register the proposal after giving it a Code No. or return to PI after stating his/her reason for returning (Figure 33).

STATE REASON FOR RETURNING

Reason for returning:

[back](#)

Code No.

[back](#)

Figure 33: State reason for returning proposal

Principal Investigators can view the status of their pending proposals. They may resubmit their proposal if RMD returns it (Figure 34).

VIEW PENDING PROPOSAL

Title of the Study: Prevalence of CYP2D6 and CYP2C19 polymorphisms associated with extensive, intermediate and poor metabolism of Tamoxifen in Filipino Breast Cancer Patients admitted at Philippine General Hospital (PGR)

Status: returned

Reason for returning: Submit again

Significance: breast sig

Objectives: breast obj

Figure 34: View status of proposal

RMD Secretariat has the authority to submit a protocol under the name of a registered PI (Figure 35). After selecting the PI, the secretariat is directed to filling up the capsule proposal form and adding the Code No.

LIST OF PRINCIPAL INVESTIGATORS

Show entries Search:

Principal Investigator	Email Address	Unit
Abadingo, Lourdes	inb.10.belle@gmail.com	College of Arts and Sciences
Abong, Jovilla	jabong@yahoo.com	College of Arts and Sciences
Acuin, Cecilia Mae	inb.10.belle@gmail.com	Institute of Clinical Epidemiology, NIH
Agrasada, Graci	g.agrasada@gmail.com	Department of Pediatrics, CM
Balabagno, Araceli O.	abalabagno@yahoo.com	CN-UPM
Banaag, Cornelio	cbanaag@yahoo.com	College of Medicine
Bandong, Aila Nica J.	abandong@gmail.com	Dept. of Physical Therapy, CAMP
Caoili, Salvador	scaoili@gmail.com	College of Medicine
Chua, Richard Bryann	rbchua@upm.edu.ph	CAS
Co, Elisa L.	elisaco@yahoo.com	Dept. of Biology, CAS

Showing 1 to 10 of 45 entries ◀ Previous Next ▶

Figure 35: View list of registered principal investigators

Once the proposals are registered, they are included to the list of capsule proposals (Figure 36).

FUNCTIONALITIES

LIST OF CAPSULE PROPOSALS

Select Role: **RMD Secretariat**

RMD SECRETARIAT

- Register a Protocol
- Pending for Registration
- Capsule Proposals**
- Under Review Protocols
- Ongoing Studies
- Completed Studies
- Inactive Records
- Generate Reports
- Principal Investigators
- Add Protocol Type
- Add Funder Type
- Edit Profile
- Change Password

RMD ALERTS

Proposal Summaries

Show **10** entries

Search:

Rank	Title of Study	Principal Investigator	Date Registered	Status	Proposal Summary
12	Potential Antioxidant Effects of Crude Syzygium aromaticum Bud Extract to Cadmium-Induced Hepatotoxicity in Adult Male Mus Musculus L.	Aida M. Salonga, MD	2014-03-05	Not Shortlisted	Yes
5	A Framework for the Costing of Nursing Services: Towards the Development of a System for Reimbursement	Arnold V. Hallare	2014-03-04	Shortlisted	Yes
11	Assessing the Ecotoxicological Impacts and Changes in Microbial Community Structure Induced by Aquaculture Activities in Taal Lake	Graci Agrasada	2014-03-04	Under Review	Yes
10	A Cognitive-Behavioral Intervention for the Prevention of Dengue among School Children (Phase 1)	Isidro Sia	2014-03-04	Under Review	Yes
2	Application of a loop-mediated isothermal amplificatio (LAMP) method for the diagnosis of typhoid fever in the	Jovilla Abong	2014-03-04	Shortlisted	Yes

Figure 36: View list of registered capsule proposals

After choosing any title, the RMD Secretariat is redirected to another page that shows the capsule proposal and its review section (Figure 37, 38).

Review Section

POTENTIAL ANTIOXIDANT EFFECTS OF CRUDE SYZYGIUM AROMATICUM BUD EXTRACT TO CADMIUM-INDUCED HEPATOTOXICITY IN ADULT MALE MUS MUSCULUS L.

Aida M. Salonga, MD
2014g
Not Shortlisted

Title of the Study

Potential Antioxidant Effects of Crude Syzygium aromaticum Bud Extract to Cadmium-Induced Hepatotoxicity in Adult Male Mus Musculus L.

Significance

cadmium sig

Figure 37: Capsule proposal

REVIEW SECTION

Date of RM Meeting: March 5, 2014

RM DECISION

Proposal Rank:

Status:

RM Decision Letter: March 12, 2014 is the deadline of sending decision to PI
 No file chosen

PROPOSAL SCORES

Show entries Search:

RM Member	Relevance	Technical Merit	Date Scored
Leticia Barbara Gutierrez	5	4	2014-03-06
Maan Duidulao	0	0	2014-03-05
Rachelle Anne Barcelona	2	1	2014-03-06

Showing 1 to 3 of 3 entries ◀ Previous Next ▶

[back](#)

M
E
N
U

Figure 38: RM review section of proposal

RMD Secretariat creates summary for each proposal (Figure 39). Once he/she finishes creating proposal summaries, the secretariat notifies the RM Chair of the deadline of the finalized summary table (Figure 40).

PROPOSAL SUMMARY

POTENTIAL ANTIOXIDANT EFFECTS OF CRUDE SYZYGIUM AROMATICUM BUD EXTRACT TO CADMIUM-INDUCED HEPATOTOXICITY IN ADULT MALE MUS MUSCULUS L.

Aida M. Salonga, MD
2014g

*required fields

*General Objectives

*Specific Objectives

Budget: 8908

*Type of Grant:

Remarks

Figure 39: Create summary table

LIST OF CAPSULE PROPOSALS

Deadline of finalized summary table

Figure 40: Notify RM Chair of finalized summary table deadline

The system allows the RMD Chair to view the registered capsule proposals, their corresponding review sections and the proposal summaries. He/she can edit the proposal summaries to finalize the summary table. Once the proposal summaries are finalized, the RMD Chair sets the deadline of proposal scores and notifies the RM Members (Figure 41).

LIST OF CAPSULE PROPOSALS

Deadline of proposal score

Show entries Search:

Rank	Title of Study	Principal Investigator	Date Registered	Status	Proposal Summary
1	A Qualitative Study on the Readiness of South Manila Inter-Institutional Consortium (SMIC) Universities during Emergencies and Disasters	Myrna Mendoza	2014-03-05	Shortlisted	Yes
10	A Cognitive-Behavioral Intervention for the Prevention of	Isidro Sia	2014-03-04	Under	Yes

Figure 41: Set deadline of proposal scores

RM Members can view the capsule proposals where they give scores for merit and relevance (Figure 42).

PROPOSAL SCORES (0-100)

** Merit - Objectives and methods are sound and feasible.*
- Plan for data analysis is appropriate for the design.
- Proposal is feasible.

Technical Merit:

** Relevance - Potential impact to policy and practice*
- Benefits to target population
- Significance of proposal, in reference to NUHRA 2012-2016

Relevance:

Figure 42: Give proposal scores

After RM Members score the proposals, the RMD Chair ranks each proposal based on the scores given. This is done before the set date for the annual meeting for shortlisting (Figure 43).

Endorsement Letter
Curriculum Vitae

Endorsement Letter
Curriculum Vitae

REVIEW SECTION

Proposal Rank:

PROPOSAL SCORES

Show entries Search:

RM Member	Relevance	Technical Merit	Date Scored
Araceli O. Balabagno	3	4	2014-03-06
Elisa L. Co	5	5	2014-03-06
Leticia Barbara Gutierrez	5	5	2014-03-06
Maan Duldulao	5	2	2014-03-05
Rachelle Anne Barcelona	4	2	2014-03-06

Showing 1 to 5 of 5 entries ◀ Previous Next ▶

M
E
N
U

Figure 43: Rank proposal

After the annual meeting, RMD Secretariat changes the status of the capsule proposals based on the decision made during the meeting (Figure 44). The status may be “Shortlisted” or “Not Shortlisted.” The secretariat also uploads the decision letter for the PI and set the deadline for the submission of full protocols for those shortlisted proposals.

REVIEW SECTION

Date of RM Meeting: March 5, 2014

RM DECISION

Proposal Rank:

Status:

RM Decision Letter: No file chosen

Deadline of full protocol submission: April 1, 2014

March 12, 2014 is the deadline of sending decision to PI

Figure 44: Change status of proposal

Shortlisted proposals are included in the list of Under Review Protocols (Figure 45). These are forwarded to the Technical Review Board once the required submissions are completed.

FUNCTIONALITIES

Select Role: **RMD Secretariat**

RMD SECRETARIAT

- Register a Protocol
- Pending for Registration
- Capsule Proposals
- Under Review Protocols**
- Ongoing Studies
- Completed Studies
- Inactive Records
- Generate Reports
- Principal Investigators
- Add Protocol Type
- Add Funder Type
- Edit Profile
- Change Password

LIST OF UNDER REVIEW SHORTLISTED PROTOCOLS

Deadline of full protocol submission:

Show entries Search:

Title of Study	Principal Investigator	Date Registered	Status
A Framework for the Costing of Nursing Services: Towards the Development of a System for Reimbursement	Arnold V. Hallare	2014-03-04	Forwarded to TRB
Application of a loop-mediated isothermal amplificatio (LAMP) method for the diagnosis of typhoid fever in the Philippines	Jovilla Abong	2014-03-04	Forwarded to TRB
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Portia Grace Fernandez-Marcelo	2014-03-05	Not yet forwarded to TRB
Profiling of the Distal Gut and Vaginal Microflora among Pregnant and Non-pregnant Filipino Women in Angeles University Foundation Medical Center	Aida M. Salonga, MD	2014-03-05	Forwarded to TRB
Status of Geriatric Education in Philippine Nursing Schools	Laurie S. Ramiro, PhD	2014-03-04	Forwarded to TRB

Showing 1 to 5 of 5 entries

Figure 45: List of under review protocols

Principal Investigators can view the list of capsule proposals registered by the RMD Secretariat (Figure 46) as well as their corresponding review status (Figure 47). If at least one of the submitted proposals is shortlisted, the deadline of full protocol submission is displayed.

FUNCTIONALITIES

Select Role: **Principal Investigator**

PRINCIPAL INVESTIGATOR

- Submit a Protocol
- Pending for Registration
- Capsule Proposals**
- Under Review Protocols
- Disapproved Protocols
- Ongoing Studies
- Completed Studies
- Discarded Protocols

LIST OF CAPSULE PROPOSALS

Show entries Search:

Title of Study	Date Registered	Status
A Qualitative Study on the Readiness of South Manila Inter-Institutional Consortium (SMIC) Universities during Emergencies and Disasters	2014-03-05	Shortlisted
Preformulation Studies on Local Materials for Use as Excipients: 4 Pigments	2014-03-05	Shortlisted

Showing 1 to 2 of 2 entries

Figure 46: List of capsule proposals

REVIEW SECTION

RM DECISION

Status	Shortlisted
RM Decision Letter	Not yet uploaded
Deadline of full protocol submission	April 1, 2014

[back](#)

Figure 47: Proposal review section

Their shortlisted proposals are included in the list of Under Review Protocols where they must update their protocol information before undergoing technical review (Figure 48). Updating of protocol information can be done by the RMD Secretariat as well. The PI and secretariat may upload the full protocol in this section (Figure 49).

Figure 48: Update protocol information

Figure 49: Upload full protocol

Once protocols are updated, the RMD can forward the protocol to TRB (Figure 50).

Figure 50: Forward to TRB

The system allows the TRB Secretariat to view the forwarded protocols. They are listed in the Under Review Protocols (Figure 51).

FUNCTIONALITIES

Select Role: **TRB Secretariat**

IRB SECRETARIAT

- Under Review Protocols**
- Ongoing Studies
- Completed Studies
- Inactive Records
- Generate Reports
- Reviewers
- Principal Investigators
- Add Review Type
- Edit Profile
- Change Password

LIST OF UNDER REVIEW PROTOCOLS

Show **10** entries

Search:

Title of Study	Principal Investigator	Date Forwarded
A Framework for the Costing of Nursing Services: Towards the Development of a System for Reimbursement	Arnold V. Hallare	03/19/2014
Application of a loop-mediated isothermal amplificatio (LAMP) method for the diagnosis of typhoid fever in the Philippines	Jovilla Abong	03/27/2014
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Portia Grace Fernandez-Marcelo	03/31/2014
Profiling of the Distal Gut and Vaginal Microflora among Pregnant and Non-pregnant Filipino Women in Angeles University Foundation Medical Center	Aida M. Salonga, MD	03/20/2014
Status of Geriatric Education in Philippine Nursing Schools	Laurie S. Ramiro, PhD	03/14/2014

Showing 1 to 5 of 5 entries

◀ Previous Next ▶

Figure 51: Under review protocols

TRB Secretariat assigns a primary reviewer and a secondary reviewer each protocol to accomplish the technical reviews (Figure 52). If a primary reviewer/secondary reviewer cannot be selected from the list due to lack of expertise, the TRB Secretariat chooses from the Content Reviewer list (Figure 53).

Protocol Files

VERSION 1

[Protocol File 1 .xdp protocol1](#)

No review files uploaded

[+ Add reviewers](#)

LIST OF REVIEWERS

PRIMARY REVIEWER

Reviewer	Collge/Unit	Area of Expertise	Email Address
● Destura, Raul	IMBB-NIH	Biotechnology	rdestura@gmail.com
● Fabella, Terence Diane F.	IHG-NIH	Human Genetics	tfabella@yahoo.com

SECONDARY REVIEWER

Reviewer	Collge/Unit	Area of Expertise	Email Address
● Destura, Raul	IMBB-NIH	Biotechnology	rdestura@gmail.com
● Fabella, Terence Diane F.	IHG-NIH	Human Genetics	tfabella@yahoo.com

Figure 52: Assign reviewers

CONTENT REVIEWER

	Reviewer	College/Unit	Area of Expertise	Email Address
<input type="radio"/>	Bunoan, Pebbe	CAS/DPSM	Health Informatics	maduldulao@gmail.com
<input type="radio"/>	Malabanan, Vennedy	CAS	Health Informatics	maduldulao@gmail.com
<input type="radio"/>	Narvaza, Allen	CAS		maduldulao@gmail.com
<input type="radio"/>	Vitor, Maurus	CAS	Health Informatics	maduldulao@gmail.com

Search by:

▾

Figure 53: Content Reviewer list

After selecting the reviewers, the list is forwarded to the TRB Chair for approval (Figure 54).

ADD REVIEW

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

*REVIEW TYPE ▾

SELECTED REVIEWERS

Reviewer	Area of Expertise	Status with TRB Chair	Status with Reviewer	Date Assigned
Raul Destura	Biotechnology	Forwarded to TRB Chair	Pending	2014-03-31
Terence Diane F. Fabella	Human Genetics	Forwarded to TRB Chair	Pending	2014-03-31

Figure 54: Forward list to TRB Chair

The TRB Chair approves or disapproves the selected reviewers (Figure 55). If he/she disapproves, he/she may choose a different reviewer. The TRB Secretariat can also assign new reviewers (Figure 56).

Protocol Files						
VERSION 1						
Protocol File 1_xdp protocol1						
Review Collation		Status				
No review files uploaded						
SELECTED REVIEWERS						
A	D	Reviewer	Role	Area of Expertise	Status	Date Assigned
<input type="radio"/>	<input type="radio"/>	Raul Destura	Primary Reviewer	Biotechnology	Pending	2014-03-31
<input type="radio"/>	<input checked="" type="radio"/>	Terence Diane F. Fabella	Secondary Reviewer	Human Genetics	Pending	2014-03-31
FINAL DECISION LETTER						
Not yet uploaded						

Figure 55: Approve/disapprove reviewers

SELECTED REVIEWERS				
Reviewer	Role	Area of Expertise	Status	Date Assigned
Raul Destura	Primary Reviewer	Biotechnology	Disapproved	2014-03-31
Terence Diane F. Fabella	Secondary Reviewer	Human Genetics	Approved	2014-03-31

Add Reviewer/s

Figure 56: Assign new reviewers

Since a primary reviewer is disapproved, only the list of possible primary reviewers and list of possible content reviewers are shown (Figure 57).

PRIMARY REVIEWER			
Reviewer	Collge/Unit	Area of Expertise	Email Address
<input type="radio"/> Gregorio, Jr., Ernesto R.	Department of Health Policy and Administration , CPH	Health Promotion and Education	egregorio@yahoo.com
<input type="radio"/> Mendoza, Myrna	Dept. of Medicine, CM	Internal Medicine	maduldulao@gmail.com
<input type="radio"/> Ong, Rafaelita	IMBB-NIH	Health Promotion and Education	rafaelita.ong@gmail.com
<input type="radio"/> Ong, Janus P.	College of Arts and Sciences	Internal Medicine	janusong101@gmail.com
<input type="radio"/> Pasco, Paul Matthew	Dept. of Neurosciences, CM	Neurology	paulpasco@gmail.com
<input type="radio"/> Salvana, MD, Edsel Maurice T.	IMBB-NIH	Internal Medicine	esalvana@gmail.com
<input type="radio"/> Sia, Isidro	Institute of Clinical Epidemiology, NIH	Pharmacology and Toxicology	mad13_smiley@yahoo.com
<input type="radio"/> Silva, Ma. Esmeralda	Department of Health Policy and Administration , CPH	Public Health	e.silva@gmail.com
CONTENT REVIEWER			
Reviewer	Collge/Unit	Area of Expertise	Email Address

Figure 57: Possible new reviewers

After the approval of the TRB Chair, the TRB Secretariat notifies the reviewers after generating the invitation letter (Figure 58).

VIEW REVIEWER

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

Type of Review	Technical Review
Name of the reviewer	Terence Diane F. Fabella
Unit/College	IHG-NIH
Area of Expertise	Human Genetics
Status	Approved
Role	Secondary Reviewer
Notify Reviewer?	+Generate invitation letter

Notify Reviewer

Figure 58: Notify reviewers

Choosing the +Generate invitation letter enables the TRB Secretariat to choose an image for the e-signature required to generate the invitation letter. A password is also required to generate the letter (Figure 59).

GENERATE INVITATION LETTER

* Choose an image file (jpg/png) in your file system to add your e-signature.
Note that your e-signature will only be used once and for this transaction only.

Choose File No file chosen

Enter your password to confirm identity:

Submit

Figure 59: Generate invitation letter



March 31, 2014

Terence Diane F. Fabella
IHG-NIH

Dear Terence Diane F. Fabella:

May we request you to do initial review of the research proposal entitled **Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)** by Portia Grace Fernandez-Marcelo

As a reviewer, you are given two weeks lead time to review the aforementioned protocol.

For questions, you may contact the undersigned through the NIH-TRB Secretariat at telephone number (02) 528-4041.

Thank you very much.

telephone number (02) 528-4041.

Thank you very much.

Sincerely,

GODOFREDA V. DALMACION, MD
Chair
Technical Review Board

Figure 60: PDF file of invitation letter

The system allows reviewers to see the list of pending review assignments (Figure 61) where they can reject or accept the review task (Figure 62). Emails are also sent out to them once the TRB Secretariat chooses the Notify Reviewer button.

FUNCTIONALITIES

Select Role:

REVIEWER

- Pending Assigned Reviews
- Under Review Protocols
- Ongoing Studies
- Completed Studies

LIST OF PENDING REVIEWS

Show entries

Search:

Title of Study	Principal Investigator	Task	Date Assigned
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Portia Grace Fernandez-Marcelo	Review Invitation	2014-03-31

Showing 1 to 1 of 1 entries

◀ Previous Next ▶

Figure 61: List of pending review assignments

VIEW PENDING REVIEW

***Enclosed herewith is a copy of the study and the letter of invitation**

Title of the Study	MUTATION SCREENING OF DYT3 IN FILIPINO PATIENTS WITH X-LINKED DYSTONIA PARKINSONISM (XDP)
Name of the investigator	Portia Grace Fernandez-Marcelo
Study Site	xdp study site
Protocol Type	NIH full-funded
Technical Grading	Yes
Role	Secondary Reviewer
Invitation Letter	Invitation File

Protocol files:

VERSION 1

[Protocol File 1_xdp protocol1](#)

Accept Task Reject Task

Figure 62: Accept or reject task

If the reviewer chooses to reject the task, he/she should state the reason for rejecting the task (Figure 63). This prompts the TRB Secretariat to assign new reviewers.

STATE REASON FOR REJECTING

Please refer to another reviewer because of possible conflict of interest.

Please refer to another reviewer because the topic is not my expertise

Other reason/s

Submit

Figure 63: State reason for rejecting task

Once the reviewer accepts the task, the protocol is listed in Under Review Protocols (Figure 64).

FUNCTIONALITIES

Select Role: Reviewer

REVIEWER

- Pending Assigned Reviews
- Under Review Protocols**
- Ongoing Studies
- Completed Studies
- Edit Profile
- Change Password

LIST OF UNDER REVIEW PROTOCOLS

Show 10 entries

Search:

Title of Study	Principal Investigator	Date Assigned
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Portia Grace Fernandez-Marcelo	2014-03-31

Showing 1 to 1 of 1 entries

◀ Previous Next ▶

Figure 64: List of under review protocols

VIEW RECORD

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

Study Site: XDP STUDY SITE
 Technical Grading: YES
 Role: SECONDARY REVIEWER

Protocol Files

VERSION 1

[Protocol File 1 .xdp protocol1](#)
 + Accomplish Review

Figure 65: View under review protocol

The reviewer accomplishes the technical review upon choosing +Accomplish Review (Figure 65). At the end of the form, the reviewer assigns the score and the corresponding action of the protocol. The reviewer may submit the review as draft or create the PDF that can be viewed by the TRB Secretariat (Figure 67). Once the review is submitted, the reviewer comments may be viewed by the other reviewer for comparison (Figure 68).

ACCOMPLISH TECHNICAL REVIEW

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

Other reviewer not yet responded

TECHNICAL REVIEW BOARD
 Project Proposal Evaluation Form

TO THE REVIEWER: For clarity, please write your comments in complete sentences. Please refer to Review Guide Questions (Form 1A) in answering the evaluation form.

COMPONENTS	Page/s	Comments	Recommendations
• Title	<input type="text"/>	<input type="text"/>	<input type="text"/>
• Research Question/	<input type="text"/>	<input type="text"/>	<input type="text"/>

Figure 66: Accomplish technical review

SCORING SYSTEM

In the table below, please give a score (with 1 as the lowest) for each parameter based on the result of your evaluation. Each parameter has been given corresponding points as shown below.

Role	Objective (5 pts)	Methods (8 pts)	Analysis (5 pts)	Feasibility/Significance (2 pts)	Benefit/Impact (5 pts)
Secondary Reviewer	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

ACTION

- Approval / Favorable opinion (Score = 25)
- Minor modifications required prior to approval (Score 20-24)
- Major modifications required prior to approval (Score 10-19)
- Disapproval/Negative opinion (Score < 10)

Reason for disapproval/negative opinion:

Submit Draft

Create PDF

Figure 67: Score and submit review

[Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia
Parkinsonism \(XDP\)
2014i
Portia Grace Fernandez-Marcelo](#)

[View other reviewer's comments](#)

TECHNICAL REVIEW BOARD

Figure 68: View other reviewer's comments

If the reviewer chooses to create PDF, he/she chooses an image for the e-signature of the technical review. A password is also required to generate the PDF (Figure 69).

GENERATE TECHNICAL REVIEW PDF


* Choose an image file (jpg/png) in your file system to add your e-signature.
Note that your e-signature will only be used once and for this transaction only.

Choose File signature.jpg

Enter your password to confirm identity:


Create PDF

Figure 69: Generate PDF file of technical review



University of the Philippines Manila
National Institutes of Health

TECHNICAL REVIEW BOARD
Project Proposal Evaluation Form




PROJECT TITLE: Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)
PROJECT NO: 2014i
PRINCIPAL INVESTIGATOR: Portia Grace Fernandez-Marcelo
DURATION:

SCORING SYSTEM

Role	Objective	M
Primary Reviewer		

ACTION: 0


Ernesto R. Gregorio, Jr.

March 31, 2014

COMPONENTS	Pages	Comments	Recommendations
• Title			
• Research Question & Objectives & Hypothesis			
- Significance			
- Formulation			
• Review of Literature			
- Tracking Method and Comprehensiveness of Review			

Figure 70: PDF file of technical review

Once the two reviewers have accepted the review task, the TRB Secretariat can add a technical collation (Figure 71).

Protocol Files

VERSION 1

[Protocol File 1 xdp protocol1](#)

No review files uploaded

[+ Add a technical review collation](#)

TECHNICAL REVIEW

Selected Reviewers

Reviewer	Area of Expertise
Terence Diane F. Fabella	Human Genetics
Ernesto R. Gregorio, Jr.	Health Promotion and Education

*REVIEW TYPE Technical Review ▼

SELECTED REVIEWERS

Reviewer	Area of Expertise	Status with TRB Chair	Status with Reviewer	Date Assigned
Terence Diane F. Fabella	Human Genetics	Approved	Accept	2014-03-31
Ernesto R. Gregorio, Jr.	Health Promotion and Education	Approved	Accept	2014-03-31

Add Review

Figure 71: Add technical collation

Once the TRB Secretariat adds a technical collation, it is redirected to a page that allows the secretariat to view the review status of the protocol and review files of each reviewer (Figure 72). The TRB Secretariat can also upload the review file of reviewers (Figure 73). After the en banc meeting, the secretariat provides the average of TRB members' scores, the final score and the final status of the protocol based from the decision made during the en banc meeting. The secretariat can also upload the collation of the reviews which is forwarded to the PI and RM Secretariat once the decision letter has been signed off (Figure 72).

Selected Reviewers	
Reviewer	Date Assigned
Ernesto R. Gregorio, Jr.	2014-04-01
Terence Diane F. Fabella	2014-04-01

Review Status		
Reviewer	Score	Status
Ernesto R. Gregorio, Jr.	24	Minor modifications required prior to approval
Terence Diane F. Fabella	23	Minor modifications required prior to approval

En Banc Decision

Average of TRB members scores:

Average of reviewers scores:

Final Score

Final Status

RM Record

Collation file :

Change File No file chosen

File Description :

Has signed off letter?

Figure 72: Review status of protocol

VIEW REVIEW

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014!

Portia Grace Fernandez-Marcelo

Type of Review	Technical Review
Technical Grading	Yes
Role	Primary Reviewer
Name of the reviewer	Ernesto R. Gregorio, Jr.
Unit/College	Department of Health Policy and Administration , CPH
Review file :	Review File
	Change File <input type="button" value="Choose File"/> No file chosen

Figure 73: Upload review files

If the final status is for modification, the TRB Secretariat generates a recommendation letter for the PI (Figure 74). Generation of decision letter prompts a page to upload an e-signature. After generating the letter, the TRB Secretariat informs the RM Secretariat and PI of the decision after choosing Inform PI?. An email is also sent out to the PI.

RM Record	
Collation file :	Collation File
File Description :	<input type="text"/>
Date letter is signed off:	<input type="text"/>
Has comment been sent to PI:	+Generate decision letter
PI's response due date:	Not yet
Has PI sent modification?	Inform PI?
Date forwarded PI's response to reviewer:	Modification not yet submitted
	<input type="text"/>
<input type="button" value="Update"/>	

Figure 74: Generate recommendation letter

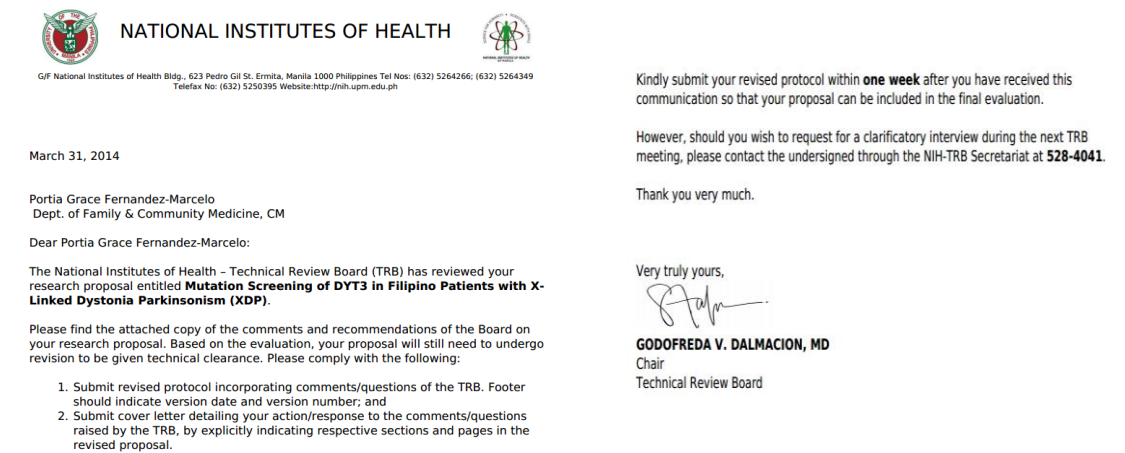


Figure 75: PDF file of recommendation letter

The PI can view the review status of protocol and the collated comments of the reviewers (Figure 76). If the protocol is for modification, the PI is allowed to add another version of his/her protocol based on the recommendations of the TRB (Figure 77). The same functionalities are also available for the RMD Secretariat.

Protocol Files Submitted:

VERSION 1	
Protocol File 1_xdp protocol1	2014-03-31
REVIEWS UNDERTAKEN	
Review Type	Status
Technical Review	Minor modifications required prior to approval See comments
Collated Technical Review 1	

Figure 76: Review status and collated review comments

VIEW COMMENTS

MUTATION SCREENING OF DYT3 IN FILIPINO PATIENTS WITH X-LINKED DYSTONIA PARKINSONISM (XDP)

2014i
XDP

PROTOCOL TYPE:	NIH FULL-FUNDED
REVIEW TYPE:	TECHNICAL REVIEW
Collation file:	Collation File Recommendation Letter
Status of the Review:	Minor modifications required prior to approval

CREATE ANOTHER PROTOCOL:

[+ Add protocol file](#) [x Delete recently added browse file](#)

Figure 77: Submit protocol modifications

After uploading a new version of the protocol, the new protocol is forwarded to TRB (Figure 79) and the reviewers (Figure 80). PIs are only allowed three revisions of protocols. If their protocols remain in the status of For Modification after three revisions, the PI forfeits his/her funding opportunity.

VERSION 1	
Protocol File 1_xdp_protocol1	2014-03-31
REVIEWS UNDERTAKEN	
Review Type	Status
Technical Review	Minor modifications required prior to approval
	See comments
Collated Technical Review 1	
VERSION 2	
Protocol File 1_xdp_protocol2	2014-04-01
Change file	
Add more files?	
No review files uploaded	
No collation uploaded	

Figure 78: PI view of protocol versions

Protocol Files	
<hr/>	
VERSION 1	
Protocol File 1_xdp_protocol1	
Review Collation	Status
Collated Review (Technical Review)	Minor modifications required prior to approval
VERSION 2	
Protocol File 1_xdp_protocol2	
Review Collation	Status
Collated Review (Technical Review)	Ongoing
+ Add a technical review collation	
TECHNICAL REVIEW	
Selected Reviewers	
Reviewer	Area of Expertise
Terence Diane F. Fabella	Human Genetics
Ernesto R. Gregorio, Jr.	Health Promotion and Education

M
E
N
U

Figure 79: TRB view of protocol versions

Protocol Files	
<hr/>	
VERSION 1	
Protocol File 1_xdp_protocol1	
Protocol 1 Review file	
VERSION 2	
Protocol File 1_xdp_protocol2	
+ Accomplish Review	

Figure 80: Reviewer view of protocol versions

After finishing all the reviews and signing of all decision letters for each protocol version, the TRB Secretariat uploads the final decision letter and sets the date of end of protocol TRB review (Figure 81). He/she may also change the final TRB status once the final decision is uploaded (Figure 82).

End of Protocol TRB Review: 04/01/2014

Final decision letter: Final Decision Letter

Change File: No file chosen

04/01/2014

Figure 81: Upload final decision letter and set date of end of TRB review

Other investigators involved: None

TRB status:

Start of Protocol TRB Review:

Figure 82: Change TRB status

The final decision letter is forwarded to RMD Secretariat and the PI. After the RMD Secretariat receives the decision letter, he/she assigns the funding selection status of the protocol based on the final TRB status (Figure 83).

FINAL DECISION LETTER: Final Decision Letter

Date final decision letter is released: 04/01/2014

REVIEW SECTION

Start of technical review: 03/31/2014

End of technical review: 04/01/2014

Date when final decision letter is uploaded: 04/01/2014

Final decision letter: Final Decision Letter

TRB Status: Approval / Favorable opinion

Date when grading by technical reviewers is set: 04/01/2014

Funding Selection Status:

Figure 83: View final decision letter and assign funding selection

The RMD Secretariat can now change the status of the protocol to Disapproved or Ongoing depending on the final TRB status (Figure 84). Disapproved protocols are listed under the Inactive Records (Figure 85). The secretariat may choose the Ongoing option if the protocol is approved by TRB. All protocols changed to Ongoing are listed under Ongoing Protocols (Figure 86).

Code No. 3: _____
 Current Status: _____
 Remarks: _____

Under Review ▾
 Under Review
 Disapproved
 Ongoing

Figure 84: Change status of protocol

FUNCTIONALITIES

Select Role: RMD Secretariat ▾

RMD SECRETARIAT

- Register a Protocol
- Pending for Registration
- Capsule Proposals
- Under Review Protocols
- Ongoing Studies
- Completed Studies
- Inactive Records
- Generate Reports

LIST OF INACTIVE RECORDS

Show 10 ▾ entries Search:

Title of Study	Principal Investigator	Date Deactivated	Status
Long-Term Effects of Separation on the Children of Overseas Contract Workers	Myma Mendoza	2014-03-16	Disapproved

Showing 1 to 1 of 1 entries ◀ Previous Next ▶

Figure 85: List of inactive records

FUNCTIONALITIES

Select Role: RMD Secretariat ▾

RMD SECRETARIAT

- Register a Protocol
- Pending for Registration
- Capsule Proposals
- Under Review Protocols
- Ongoing Studies
- Completed Studies

LIST OF ONGOING REGISTERED PROTOCOLS

Show 10 ▾ entries Search:

Title of the Study	Principal Investigator	Registration Date
A Qualitative Study on the Readiness of South Manila Inter-Institutional Consortium (SMIC) Universities during Emergencies and Disasters	Mendoza, Myma	03/05/2014
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Fernandez-Marcelo, Portia Grace	03/05/2014

Showing 1 to 2 of 2 entries ◀ Previous Next ▶

Figure 86: List of ongoing protocols

If the grant type of the approval protocol is PEER Health, the RMD Chair assigns a research mentor (Figure 87).

Assign research mentor

[back](#)

Figure 87: Assign research mentor

LIST OF NIH FACULTY

Reviewer	College/Unit	Area of Expertise	Email Address
Barcelona, Rachelle Anne	CAS	Computer Science	mad13_smiley@yahoo.com
Duldulao, Maan	CAS/DPSM	Computer Science	mad13_smiley@yahoo.com
Khu, Patricia	IHG-NIH	Ophthalmology	khu.patricia@gmail.com
Lago, Leonor	IHPDS-NIH	Dentistry	leonor.lago@yahoo.com
Lorenzo, Marilyn	IMBB-NIH	Health Policy and Development Studies	mlorenzo@yahoo.com
Nevado, Jr., MD, PhD, Jose B.	IHG-NIH		jnevado@yahoo.com
Oliveros, Mildred	Institute of Clinical Epidemiology, NIH	Pharmacy	moliveros@yahoo.com
Salcedo, Janel	CAS	Health Informatics	maduldulao@gmail.com

[Add reviewer/s](#)

Figure 88: List of possible mentors

VIEW MENTOR

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

SELECTED MENTOR

Research Mentor	Area of Expertise	Status
Rachelle Anne Barcelona	Computer Science	Pending

[Forward to RM](#)

Figure 89: Forward selected mentor to RM

After the RMD Chair forwards the selected mentor (Figure 89), the RMD Secretariat notifies the assigned mentor (Figure 90).

VIEW MENTOR

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

Name of the mentor	Rachelle Anne Barcelona
Unit/College	CAS
Area of Expertise	Computer Science
Status	Forwarded to RM
Notify Mentor?	<input checked="" type="checkbox"/> Yes
Invitation letter	Choose File 3_BS ComSc...gelica.pdf

[Update](#)

Figure 90: Notify assigned mentor

Pending mentor invitations are listed under Pending Mentor Invitations (Figure 91).

FUNCTIONALITIES

Select Role: **NIH Research Faculty**

NIH RESEARCH FACULTY

- Pending Mentor Invitations**
- Ongoing Studies
- Completed Studies

LIST OF PENDING REVIEWS

Show **10** entries Search:

Title of Study	Principal Investigator	Date Assigned
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Portia Grace Fernandez-Marcelo	2014-03-31

Showing 1 to 1 of 1 entries ◀ Previous Next ▶

Figure 91: List of pending review invitations

The assigned mentor may reject or accept the task (Figure 92). If the task is rejected, the RMD Chair assigns a new mentor.

VIEW PENDING MENTOR INVITATION

Title of the Study	MUTATION SCREENING OF DYT3 IN FILIPINO PATIENTS WITH X-LINKED DYSTONIA PARKINSONISM (XDP)
Name of the investigator	Portia Grace Fernandez-Marcelo
Study Site	xdp study site
Protocol Type	NIH full-funded
Invitation Letter	Invitation File

Protocol files:

VERSION 1
[Protocol File 1](#) xdp protocol1

VERSION 2
[Protocol File 1](#) xdp protocol2

Figure 92: Reject or accept mentor invitations

The TRB also handles the review of final reports submitted by PIs. Submission of final reports can be done if the protocol is under Ongoing status. Both the RMD Secretariat and PI can upload final reports (Figure 93, 94).

Final Report/s Submitted:

No final report uploaded.

3_BS ComSc...gelica.pdf

[+ Add final report](#) [x Delete recently added file](#)

Figure 93: PI view of final report submission

FINAL REPORT/S:

Terminal Report Due: Start:

End:

Starting date of submission of final report:

Final Report file/s:

[Final Report File 1](#) *final report*

[Change file](#)

No review files uploaded

[Recommendation for Publication](#)

No Reviews Yet.

[+ Add final report](#) [x Delete recently added file](#)

Figure 94: RMD Secretariat view of final report submission

Once the final report is uploaded, it is forwarded to TRB (Figure 95). TRB Secretariat assigns one reviewer for each final report.

Final Report Section

Terminal Report Due:	Start:
	End:
Date of receiving final report:	04/01/2014
Final Report file/s:	Final Report File 1 <i>final report</i>
	Add final report review
Start of Final Report TRB Review:	04/01/2014
End of Final Report TRB Review:	<input type="text"/>
Date of Final Report's Acceptance:	

[Update](#)

Figure 95: TRB Secretariat view of final reports

The list of reviewers is both from TRB members and content reviewers (Figure 96). After assigning a reviewer, the TRB Chair approves or disapproves the selected reviewer (Figure 97). The reviewer is notified once approved by TRB Chair (Figure 98). An email is also sent out to the reviewer.

LIST OF REVIEWERS

Reviewer	College/Unit	Area of Expertise	Email Address
Bunoan, Pebbe	CAS/DPSM	Health Informatics	maduldulao@gmail.com
Destura, Raul	IMBB-NIH	Biotechnology	rdestura@gmail.com
Fabella, Terence Diane F.	IHG-NIH	Human Genetics	tfabella@yahoo.com
Gregorio, Jr., Ernesto R.	Department of Health Policy and Administration , CPH	Health Promotion and Education	egregorio@yahoo.com

Figure 96: List of final report reviewers

Final Reports

Final Report: [Final Report File 1_final report](#)
No review files uploaded

SELECTED REVIEWER

Reviewer	Expertise	Status	Date Assigned
PebbeBunoan	Health Informatics	Approved	2014-03-31

Figure 97: Approve or disapprove reviewer

VIEW REVIEWER

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014i
Portia Grace Fernandez-Marcelo

Type of Review	Final Report Review
Name of the reviewer	Pebbe Bunoan
Unit/College	CAS/DPSM
Area of Expertise	Health Informatics
Status	Approved
Notify Reviewer?	Invitation File

Figure 98: Notify reviewer

Final report invitations are listed under Pending Assigned Reviews (Figure 99). The invitation includes the invitation from TRB, the history of reviews and the final report (Figure 100).

FUNCTIONALITIES

Select Role: **Reviewer**

REVIEWER

- Pending Assigned Reviews**
- Under Review Protocols
- Ongoing Studies
- Completed Studies
- Edit Profile
- Change Password

LIST OF PENDING REVIEWS

Show **10** entries Search:

Title of Study	Principal Investigator	Task	Date Assigned
Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	Portia Grace Fernandez-Marcelo	Final Report Invitation	2014-03-31

Showing 1 to 1 of 1 entries ◀ Previous Next ▶

Figure 99: List of pending assigned reviews

Study Site	xdp study site
Protocol Type	NIH full-funded
Invitation Letter	Invitation File

Protocol files:

VERSION 1

[Protocol File 1_xdp protocol1](#)

[Collated Technical Review 1](#)

VERSION 2

[Protocol File 1_xdp protocol2](#)

[Not uploaded](#)

Final Report files:

[Final Report File 1_final report](#)

Figure 100: Review invitation

If the reviewer chooses to reject the task, the TRB Secretariat is notified and he/she assigns a new reviewer. If the reviewer chooses to accept the task, he/she can accomplish the final report review form (Figure 101).

Final Reports

[Final Report File 1_final report](#)

+ Accomplish Review

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014j
Portia Grace Fernandez-Marcelo

TECHNICAL REVIEW BOARD

Final Report Evaluation Form

Items Reviewed

Yes No Remarks

- Were all the objectives met? If no, which objective/s were not met?

 Yes No

Items Reviewed	Yes	No	Remarks
• Were all the objectives met? If no, which objective/s were not met?	<input type="radio"/>	<input type="radio"/>	

Figure 101: Accomplish final report review

At the end of the form, the reviewer chooses his/her recommendation for publication. He/she may submit the review as draft or create the PDF file to be viewed by the TRB Secretariat (Figure 102).

Generation of PDF requires password and e-signature as well.

COMMENTS:

Items Reviewed	Yes	No	Remarks
• Were all the objectives met? If no, which objective/s were not met?	<input type="radio"/>	<input type="radio"/>	

Would you recommend publication of study?

 Strongly agree Agree Maybe with minor revisions Not at its present form Disagree

Submit Draft

Create PDF

Figure 102: Submit as draft or create PDF

The TRB Secretariat has the authority to submit a final report review for the assigned reviewer. Once the review files have been submitted, the TRB Secretariat uploads a comments file for RM and the PI. The TRB Secretariat also assigns the final recommendation for publication (Figure 103). After the review, the TRB Secretariat sets the date for end of final report TRB review (Figure 104).

VIEW FINAL REPORT REVIEW

Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP) 2014
 Portia Grace Fernandez-Marcelo

REVIEWER

Reviewer Name Pebbe Bunocan	Review File Final Report Review 1 Change File: <input type="button" value="Choose File"/> No file chosen
---------------------------------------	---

Comment File : No file chosen

File Description :

Recommendation for Publication:

Under Review ▼

Under Review

Strongly Agree

Agree

Maybe with minor revisions

Not at its present form

Disagree

Figure 103: Upload comments file and assign final recommendation for publication

End of Final Report TRB Review:

Date of Final Report's Acceptance:

Figure 104: Set date for end of final report TRB review

Once the recommendation has been assigned, the PI and RMD Secretariat can view the recommendation and comments (Figure 105, 106).

Final Report/s Submitted:

Final Report File 1 <i>final report</i>	04/01/2014
Change file	

Final Report Review Comments 1 <i>comments</i>	Recommendation for Publication
	Strongly Agree

Figure 105: PI view of final report review recommendations

FINAL REPORT/S:

Terminal Report Due: Start: End:

Starting date of submission of final report:

Final Report file/s:

Recommendation for Publication
Strongly Agree

[Final Report File 1](#) *final report*
Change file

[Final Report Review Comments 1](#) *comments*

[+ Add final report](#) [x Delete recently added file](#)

Start of final report TRB review:

Finished?

Date of Final Report's Acceptance:

Figure 106: RMD Secretariat view of final report recommendations

Both the RMD Secretariat and TRB Secretariat have functionalities of generating reports.

Aside from the existing report generation options, the RMD Secretariat can generate the summary table of capsule proposals and the capsule proposal scores (Figure 107).

FUNCTIONALITIES **GENERATE REPORT**

Select Role:

- GENERATE SUMMARY REPORT
- RESEARCH MANAGEMENT PROTOCOLS UPDATE
- CAPSULE PROPOSALS SUMMARY TABLE
- CAPSULE PROPOSALS SCORES

RMD SECRETARIAT

Register a Protocol

Pending for Registration

Capsule Proposals

Under Review Protocols

Ongoing Studies

Completed Studies

Inactive Records

Generate Reports

Figure 107: RM Secretariat report generation

	A	B	C	D	E	F	G	H	I	J	K	L	M
1			RMD Members										
2			Araceli O. Balabagno		Jose B. Nevado, Jr., MD, PhD		Allan Raymund S. Tenorio, MD		Elisa L. Co		Leticia Barbara Gutierrez		Maan
3	No	Code No	Technical Merit	Relevance	Technical Merit	Relevance	Technical Merit	Relevance	Technical Merit	Relevance	Technical Merit	Relevance	Technical Merit
4	1	2014a	4	3					4	1			0
5	2	2014b	5	5									5
6	3	2014c	5	5							2	0	4
7	4	2014d	0	1							2	3	3
8	5	2014e						0	5				5
9	6	2014f											5
10	7	2014g									4	5	0
11	8	2014h									3	3	4
12	9	2014i							3	2			4
13	10	2014j											2
14	11	2014k	4	3					5	5	5	5	2
15	12	2014m							1	3	3	5	4

Figure 108: Excel file of capsule proposal scores

	B	C	D	E
1	Principal Investigator	Institution/Academic Unit	Project Title	General Objectives
2	Isidro Sia	Institute of Clinical Epidemiology, NIH	A Cognitive-Behavioral Intervention for the Prevention of Dengue among School Children (Phase 1)	phase 1 general objectives
3	Arnold V. Hallare	Dept. of Biology, CAS, UPM	A Framework for the Costing of Nursing Services: Towards the Development of a System for Reimbursement	nursing gen
4	Myrna Mendoza	Dept. of Medicine, CM	A Qualitative Study on the Readiness of South Manila Inter-Institutional Consortium (SMIIC) Universities during Emergencies and Disasters	smiic gen
5	Jovilla Abong	College of Arts and Sciences	Application of a loop-mediated isothermal amplification (LAMP) method for the diagnosis of typhoid fever in the Philippines	lamp gen
6	Graci Agrasada	Department of Pediatrics, CM	Assessing the Ecotoxicological Impacts and Changes in Microbial Community Structure Induced by Aquaculture Activities in Taal Lake	taal gen
7	Myrna Mendoza	Dept. of Medicine, CM	Long-Term Effects of Separation on the Children of Overseas Contract Workers	separation gen
8	Myrna Mendoza	Dept. of Medicine, CM	Preformulation Studies on Local Materials for Use as Excipients: 4 Pigments	pigments gen
9	Portia Grace Fernandez-Marcelo	Dept. of Family & Community Medicine, CM	Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	xdp gen
10	Raul Destura	IMBB-NIH	Development of a PCR-based Assay and Molecular Genotyping of Schistosoma japonicum Isolated from Different Geographical Areas in the Philippines	pcr general

Figure 109: Excel file of summary table

The TRB Secretariat can generate reports regarding the activities of TRB members and the status of proposals being reviewed (Figure 110).

FUNCTIONALITIES

Select Role: TRB Secretariat

TRB SECRETARIAT

- Under Review Protocols
- Ongoing Studies
- Completed Studies
- Inactive Records
- Generate Reports

GENERATE REPORT

- TRB MEMBERS ACTIVITIES
- PROPOSAL STATUS

Figure 110: TRB Secretariat report generation

TRB Secretariat may choose specific dates to be reported (Figure 111).

TRB ACTIVITIES

Proposals Reviewed:

From

To

Final Reports Reviewed:

From

To

En Banc Meeting Attended:

From

To

Generate Excel

PROPOSAL STATUS

Proposal Submission:

From

To

Final Report Submission:

From

To

Generate Excel

Figure 111: Choose specific dates

Proposal Status has two spreadsheets – proposals and final reports (Figure 112, 113).

Proposals from							
No	RM Code	Principal Investigator	Title of Proposal	Version Number	Date of Submission	Date Finished TRB Review	
			A Qualitative Study on the Readiness of South Manila Inter-Institutional Consortium (SMIIC) Universities during Emergencies and Disasters	1	03/06/2014	03/09/2014	
				2	03/09/2014	03/10/2014	
1	2014k	Myrna Mendoza			3	03/09/2014	03/09/2014
2	2014c	Laurie S. Ramiro, PhD	Status of Geriatric Education in Philippine Nursing Schools	1	03/06/2014	03/15/2014	
			Preformulation Studies on Local Materials for Use as Excipients: 4 Pigments	1	03/06/2014	03/23/2014	
3	2014m	Myrna Mendoza			1	03/06/2014	03/22/2014
					2	03/22/2014	03/22/2014
			A Framework for the Costing of Nursing Services: Towards the Development of a System for Reimbursement	3	03/22/2014	03/22/2014	
4	2014b	Arnold V. Hallare			3	03/22/2014	03/22/2014
					4	03/22/2014	03/22/2014
5	2014h	Aida M. Salonga, MD	Profiling of the Distal Gut and Vaginal Microflora among Pregnant and Non-pregnant Filipino Women in Angeles University Foundation Medical Center	1	03/06/2014	03/20/2014	
6	2014a	Jovilla Abong	Application of a loop-mediated isothermal amplificatio (LAMP) method for the diagnosis of typhoid fever in the Philippines	1	03/06/2014		
7	2014i	Portia Grace Fernandez-Marcelo	Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	1	03/31/2014	04/01/2014	
				2	04/01/2014	04/01/2014	

Figure 112: Proposal spreadsheet

Final Report from							
No	RM Code	Principal Investigator	Title of Proposal	Final Report ID	Date of Final Report Submission	Date Finished Final Report Review	
			A Qualitative Study on the Readiness of South Manila Inter-Institutional Consortium (SMIIC) Universities during Emergencies and Disasters	1	03/08/2014	03/11/2014	
					2	03/11/2014	03/11/2014
					3	03/12/2014	03/12/2014
					4	03/12/2014	03/12/2014
					5	03/16/2014	03/16/2014
					6	03/16/2014	
1	2014k	Myrna Mendoza			8	03/25/2014	
2	2014c	Laurie S. Ramiro, PhD		Status of Geriatric Education in Philippine Nursing Schools			
3	2014m	Myrna Mendoza	Preformulation Studies on Local Materials for Use as Excipients: 4 Pigments	7	03/23/2014	03/23/2014	
4	2014b	Arnold V. Hallare	A Framework for the Costing of Nursing Services: Towards the Development of a System for Reimbursement				
5	2014h	Aida M. Salonga, MD	Profiling of the Distal Gut and Vaginal Microflora among Pregnant and Non-pregnant Filipino Women in Angeles University Foundation Medical Center				
6	2014a	Jovilla Abong	Application of a loop-mediated isothermal amplificatio (LAMP) method for the diagnosis of typhoid fever in the Philippines				
7	2014i	Portia Grace Fernandez-Marcelo	Mutation Screening of DYT3 in Filipino Patients with X-Linked Dystonia Parkinsonism (XDP)	9	04/01/2014	04/01/2014	

Figure 113: Final report spreadsheet

TRB Activities has three spreadsheets – proposals reviewed, final reports reviewed and en banc meetings attended (Figure 114, 115, 116).

	A	B	C	D	E
	No	Name of Reviewer	No. of Proposals	Proposals Reviewed	Date Reviewed
1	1	Pebbe Bunoan	0		
2	2	Raul Destura	1	2014m Version 1	03/23/2014
3				2014i Version 1	04/01/2014
4	3	Terence Diane F. Fabella	2	2014i Version 2	04/01/2014
5				2014i Version 1	04/01/2014
6	4	Ernesto R. Gregorio, Jr.	2	2014i Version 2	04/01/2014
7	5	Vennedy Malabanan	0		
8	6	Myrna Mendoza	0		
9	7	Allen Narvaza	0		
10				2014k Version 2	03/09/2014
11				2014b Version 1	03/22/2014
12				2014b Version 2	03/22/2014
13	8	Rafaellita Ong	4	2014m Version 1	03/23/2014
14				2014k Version 1	03/08/2014
15	9	Janus P. Ong	2	2014k Version 3	03/09/2014
16	10	Paul Matthew Pasco	0		
17	11	Edsel Maurice T. Salvana, MD	0		
18	12	Isidro Sia	1	2014c Version 1	03/15/2014
19				2014b Version 1	03/22/2014
20	13	Ma. Esmeralda Silva	2	2014b Version 2	03/22/2014
21	14	Maurus Vitor	0		
22					
23					
24					
25					

Figure 114: Proposals reviewed spreadsheet

Final Reports Reviewed from to						
No	Name of Reviewer	No. of Final Reports	Final Report ID	RM Code	Date Reviewed	
1	Pebbe Bunoan	1	9	2014i	04/01/2014	
2	Raul Destura	0				
3	Terence Diane F. Fabella	0				
			1	2014k	03/11/2014	
			2	2014k	03/11/2014	
			4	2014k	03/12/2014	
			3	2014k	03/12/2014	
			5	2014k	03/16/2014	
4	Ernesto R. Gregorio, Jr.	6	6	2014k	03/16/2014	
5	Vennedy Malabanan	0				
6	Myrna Mendoza	0				
7	Allen Narvaza	0				
8	Rafaelita Ong	1	7	2014m	03/23/2014	
9	Janus P. Ong	0				
10	Paul Matthew Pasco	0				
11	Edsel Maurice T. Salvana, MD	0				
12	Isidro Sia	0				
13	Ma. Esmeralda Silva	0				
14	Maurus Vitor	0				

Figure 115: Final reports spreadsheet

A	B	C	D
No	Name of Reviewer	No. of Meetings Attended	En Banc Meeting
1	Pebbe Bunoan	0	
2	Raul Destura	1	03/28/2014
3	Terence Diane F. Fabella	2	03/28/2014 02/19/2014
4	Ernesto R. Gregorio, Jr.	2	03/28/2014 02/19/2014
5	Vennedy Malabanan	0	
6	Myrna Mendoza	2	03/28/2014 02/19/2014
7	Allen Narvaza	0	
8	Rafaelita Ong	2	03/28/2014 02/19/2014
9	Janus P. Ong	2	03/28/2014 02/19/2014
10	Paul Matthew Pasco	2	03/28/2014 02/19/2014
11	Edsel Maurice T. Salvana, MD	2	03/28/2014 02/19/2014
12	Isidro Sia	2	03/28/2014 02/19/2014
13	Ma. Esmeralda Silva	1	02/19/2014
14	Maurus Vitor	0	

Figure 116: En banc meetings attended spreadsheet

Each user has a notification and calendar system.

The calendar system allows each user to view important deadlines as well as view protocols with the deadlines (Figure 117).

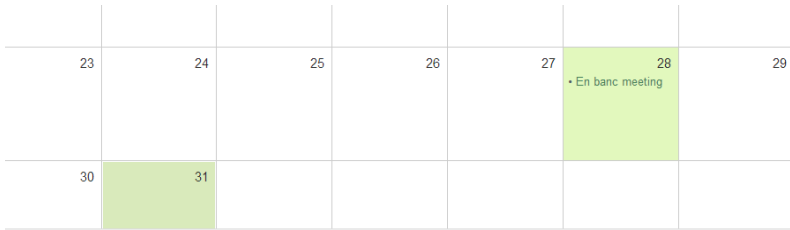
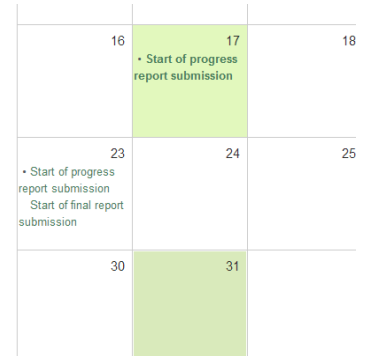
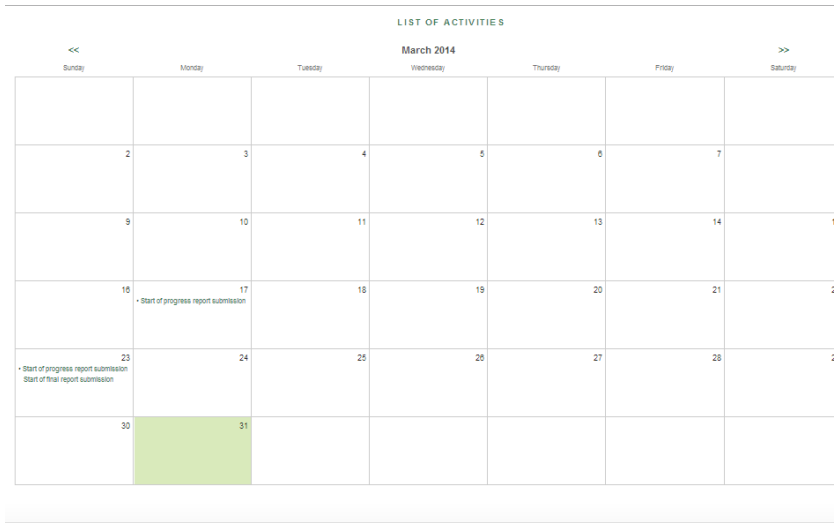


Figure 117: View important deadlines

Choosing the links on the calendar cell prompts another page listing the activities for that particular day (Figure 118).

EN BANC MEETING

En banc meeting

Meeting Agenda

Change file No file chosen

SELECT THOSE WHO ATTENDED

Check all Uncheck all

	TRB Member	Collge/Unit	Area of Expertise
<input checked="" type="checkbox"/>	Destura, Raul	IMBB-NIH	Biotechnology
<input checked="" type="checkbox"/>	Fabella, Terence Diane F.	IHG-NIH	Human Genetics
<input checked="" type="checkbox"/>	Gregorio, Jr., Ernesto R.	Department of Health Policy and Administration , CPH	Health Promotion and Education
<input checked="" type="checkbox"/>	Mendoza, Myrna	Dept. of Medicine, CM	Internal Medicine
<input checked="" type="checkbox"/>	Ong, Rafaelita	IMBB-NIH	Health Promotion and Education
<input checked="" type="checkbox"/>	Ong, Janus P.	College of Arts and Sciences	Internal Medicine
<input checked="" type="checkbox"/>	Pasco, Paul Matthew	Dept. of Neurosciences, CM	Neurology



Figure 118: List of activities

The notification system allows each user to view important tasks. All notifications are viewed in the home page of each user (Figure 119). The list can also be viewed on a separate page (Figure 120).

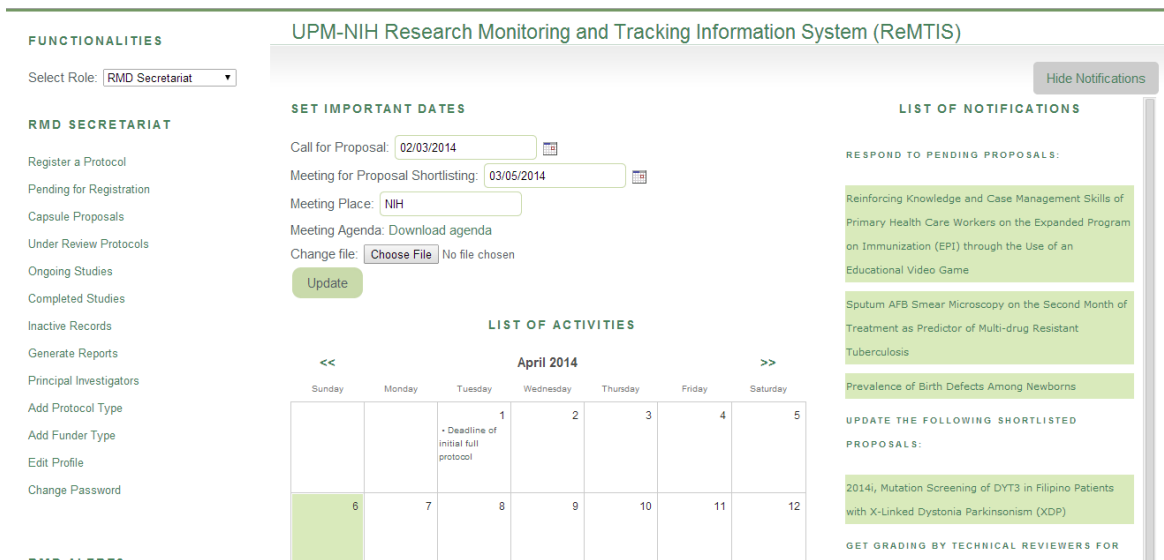


Figure 119: Side notifications

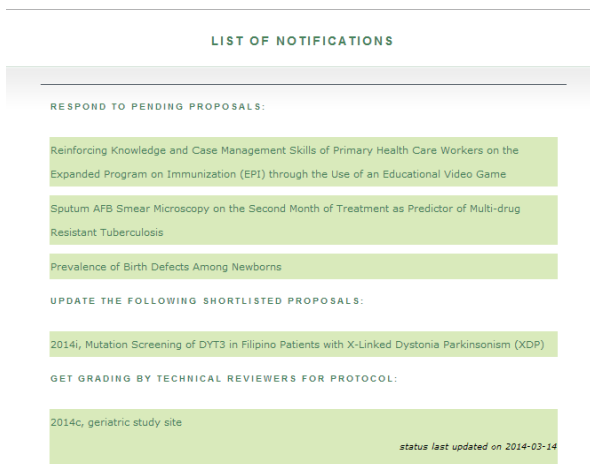


Figure 120: Notifications

VII. Discussion

ReMTIS is a web-based system that manages study protocols submitted to the National Institutes of Health. From the 12 original types of users, the RMD Secretariat handles the monitoring and tracking of the study protocols. The TRB Secretariat, on the other hand, handles the monitoring of reviews needed by the study protocols.

Before study protocols are qualified for funding by the University, the Principal Investigators and the RMD Secretariat submit capsule proposals. After the set deadline of submission of capsule proposals, the RMD Secretariat creates a summary for each capsule proposal, and then forwards them to the RMD Chair. The RMD Chair is responsible for finalizing the proposal summaries as well as the forwarding of capsule proposals to RMD members for the proposal scores. After the RMD Chair finalizes and forwards the capsule proposals to RMD members, each member scores the proposals on merit and relevance. The RMD Chair receives all the scores to which the proposal ranks are based upon.

After the meeting for shortlisting, the RMD Secretariat uploads the decision letters addressed to the Principal Investigators. Once a proposal is shortlisted, PIs are expected to submit the full protocol within the set time frame set by the RMD Secretariat.

Once all the requirements are completed by the PI, the RMD Secretariat forwards the protocols to the Technical Review Board. The TRB Secretariat receives all the forwarded protocols. He is also responsible for the monitoring of the review status of each protocol. Both the TRB Secretariat and TRB Chair decide on the assignment of reviewers needed for the technical review. Assigned reviewers have the option to accept or reject task. Rejection of task requires the reviewer to state the reason for rejection.

Acceptance of task allows the reviewer to submit a review file that contains comments, recommendations and technical scores. Approval of protocols depends on the recommendation of TRB.

The TRB is also responsible for the review of final reports submitted by approved protocols.

Collated reviews uploaded into the server allow a single repository of reviews which can be viewed consistently at any time. TRB Secretariat can indicate the status of protocol based on the review processes. The status is reflected back in RMD Secretariat's record. Decisions are also reflected back in the Principal Investigator's record. This feature prevents inconsistencies and delays.

These processes are accompanied by a calendar system and a notification system. The TRB Secretariat also receives alerts of those review assignments with no response. These features addressed the problems of delays and serve as a convenient way of monitoring and tracking the status of a protocol.

Features such as the processes before the submission of full protocols, the accomplishment of technical review forms and the calendar system were added to the current version of ReMTIS.

VIII. Conclusion

ReMTIS 2.0 allows a more convenient way in the management of study protocols submitted to the National Institutes of Health. The existing module for the Technical Review Board in ReMTIS is improved by adding checking to ensure correct flow of data within the Board, as well as the online accomplishment of technical review forms. Other important processes before the submission of full protocols are also included in this version to ensure systematic flow of all data needed by the Research and Management Development Committee. Having incorporated these additional features in the system reduced problem of redundancy and inconsistencies as all needed information are already stored in a central repository.

The system also allows different users to view protocols and dynamically displays information needed for a certain user. This allows not only sharing but also distinction and confidentiality among the records.

The system also as a monitoring and tracking system helps prevent time management issues with the use of the notification system and the calendar system.

IX. Recommendations

It is recommended that the system be extended to the submission of study protocols to Research Grants Administration Office (RGAO) for registration. After protocols are approved by the Technical Review Board, the RMD is expected to forward the approved protocols to RGAO. RGAO then facilitates the endorsement of protocols to other review boards such as the UPM Research Ethics Board (UPMREB) and Institutional Animal Care and Use Committee (IACUC).

A separate system for the UPMREB is currently being developed so it is also recommended to use the data of ReMTIS in the UPMREB system since RGAO-registered protocols may come from RMD.

X. Bibliography

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XI. Appendix

A. Forms

1. Form 3.1(A) 2010: Research Project Proposal Form

Form 3.1 (A) 2010
Research Project Proposal Form

NATIONAL INSTITUTES OF HEALTH
UNIVERSITY OF THE PHILIPPINES MANILA

RESEARCH PROJECT PROPOSAL FORM

ATTENTION:

1. The original form (with original signatures) should be submitted to the National Institutes of Health Ethics Review Committee with 15 additional copies.
2. All items must be filled-out (printed or typed) properly, otherwise it will not be accepted.

PART I. ADMINISTRATIVE INFORMATION

A. Research Project Title <i>(The distinctive name given to the project describing the work scope in specific, clear and concise terms)</i>			
B. Principal Investigator and Co-investigators <i>(Name of principal proponent and co-investigators, designation/ title and affiliate institution)</i>	Name of Principal Proponent/ Co-investigators	Designation / Title	Institution Affiliation (if applicable)
C. Proponent Institute / College <i>(Declaration of institutional endorsement)</i>	I confirm that I have read this application and that, if support is granted, the work will be accommodated and administered in the Department/Institution in accordance with the general conditions. I also confirm that the Principal Investigator has a full-time appointment in this institution.		
	_____ Institute/College /Unit	_____ Institute Director/Dean /Director (Signature over printed Name)	
D. Authorization and Acknowledgment of Review <i>(Administrative certification from the study site when the PI is not from UP Manila and the study site is outside UP Manila)</i>	This is to certify that the research site has no local Institutional Review Board/ Independent Ethics Committee (IRB/IEC) and that the research site authorizes and acknowledges the University of the Philippines-Manila National Institutes of Health – Institutional Review Board (UPM NIH-IRB) , located in the National Capital Region (NCR) with address at the Ground Floor, NIH Building, 623 P.Gil St. Ermita, Manila, to perform the ethical review of the study entitled, "TITLE OF PROTOCOL", in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse even monitoring, and site visits.		
	_____ On-site Administrative Authority (Signature over printed name, indicate position)		
E. Research Project Duration <i>(The length of time in which the specific project activities shall be accomplished)</i>			

F. Cooperating Agencies/ Research Links <i>(The agency/ies which is/are expected to cooperate/contribute to the research work. Collaboration with other scientist/s and research institutions or links with other research projects)</i>		
G. Research Classifications 1. Type of Scientific and Technological Activities	<i>(Please put appropriate letter)</i> _____	<i>(Note: If applying for ethical clearance ONLY, that is, without an application for NIH Grant, you may skip this section and move on to G.2)</i> a. RED – Research and Experimental Development b. STS - Scientific and Technological Services c. STET – Scientific and Technical Education and Training
2. Category of Research or Project	_____	a. Basic Research <i>(Acquiring new knowledge through experimental and theoretical work)</i> b. Applied Research <i>(Acquiring new knowledge with a specific application in mind, determining possible uses for basic research findings or determining new ways of achieving objectives)</i> c. Experimental Development Research <i>(Using existing knowledge to produce new materials, products, or devices; installing new processes, systems, and services; or improving current production of installation substantially)</i>
3. Purpose of Research	_____	a. Thesis b. Ph.D. Dissertation c. Postdoctoral work d. Independent work e. Others, please specify _____
4. Area of Interest	_____	a. Clinical b. Social Science c. Public Health d. Molecular Biology and Biotechnology e. Others, please specify _____
C. Summary of the Research Project	<i>Please write a summary of the research project in the space provided below based on the components itemized on the left, and indicate where such components may be found in the full protocol. Attach the full protocol to this form.</i>	

<ol style="list-style-type: none"> 1. Objectives 2. Study Population 3. Inclusion/ Exclusion Criteria 4. Study Design 5. Sample Size 6. Diagram of procedures 7. Data Collection Tools 8. Data Analysis 	
<p>D. Ethical Considerations <i>(Required if the proposal involves research on human subjects, including collection of human blood or other human tissue samples. If data is to be stored in electronic databases, ensure that all steps to protect confidential data are properly followed; eg: Anonymization of patient data, removal of personal identifiers, security of databases ensured, etc.)</i></p>	<p>(Please provide the following information)</p> <ol style="list-style-type: none"> 1. Subject Profile: <ol style="list-style-type: none"> a. Who are the human subjects? b. How will they be recruited? c. What information will be given to them? d. What intervention will they be subjected to? 2. Include a consent form containing all prerequisites of informed consent written in the language of the subject using the informed consent checklist provided.
<p>E. Declaration of Conflict of Interest <i>(Formal disclosure from investigator of information regarding funding, sponsors, institutional affiliations, etc)</i></p>	<p><i>Enumerate individual and institutional conflicts of interest such as funding in various forms and institutional affiliations relevant to this application</i></p>

PART II. RESEARCH PROJECT WORKPLAN SCHEDULE (Project year _____)

ACTIVITIES	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOURTH QUARTER

PART III. RESEARCH PROJECT WORKPLAN OUTPUT (Project year _____)

FIRST QUARTER	SECOND QUARTER
THIRD QUARTER	FOURTH QUARTER

PART IV. BUDGET BREAKDOWN (NOTE: This section should be filled out if applying for funding under the NIH Research Grant. Please indicate other source/s of funding, if applicable)

(For projects of 1-year duration or less AND 1st/_____ year of multi-year duration)

Program/Project	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter	TOTAL
Personal Services					
Salaries					
Honoraria					
MOOE					
Travel Expenses					
Supplies and Materials					
Sundry					
Laboratory Exams					
Equipment Outlay					
TOTAL					
Other sources					
TOTAL					
GRAND TOTAL					

(For projects of more than 1-year duration)

Program/Project	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter	TOTAL
Personal Services					
Salaries					
Honoraria					
MOOE					
Travel Expenses					
Supplies and Materials					
Sundry					
Laboratory Exams					
Equipment Outlay					
TOTAL					

Other sources					
TOTAL					
GRAND TOTAL					

DETAILED FINANCIAL REQUIREMENTS:

ITEM	BASIS	QUANTITY	UNIT	RATE/UNIT PRICE	AMOUNT
Personal Services	PI				
	Co-I				
	RAs				
	Sub-total				
MOOE	1 st release				
	2 nd release				
	3 rd release				
	Sub-total				
	TOTAL				

PART V. APPENDICES (If applicable please include the following)

1.	Informed Consent Form
2.	Patient / Case Report Forms
3.	Flow Chart of Activities
4.	Questionnaires

PART VI. BIBLIOGRAPHY (this section may be expanded as needed)

1.	
2.	
3.	
4.	

**PART VII. CURRICULUM VITAE OF PRINCIPAL INVESTIGATOR AND CO-INVESTIGATORS
(1 page maximum for each)**

1. Name College/Institute Contact Numbers Email Address
2. Degree(s) Subjects, university or school, year
3. Training Certifications of successful completion of protocol-related training, research ethics training, and Good Clinical Practice (GCP) training, as applicable
4. Present Posts / Positions held Type of post, institution/faculty/ department, dates
5. Recent Publications List only the five (5) most important publications or papers most relevant to this proposal over the last 5 years (papers in press or submitted or publication are also acceptable). Please give full bibliographic references (author/s, title, journal, volume, page numbers, years). If applicable, please attach copies of papers in press or submitted if these contain background material relevant to this proposal.
6. Concurrent Projects Enumerate all on-going projects and projects that will commence within the next three months. Indicate project involvement (PI, Co-I, Sub-I, Consultant, etc.), start dates, and expected completion dates.

Signature:

Date:

2. Letter to PI Request for Revised Paper Template



NATIONAL INSTITUTES OF HEALTH

G/F National Institutes of Health Bldg., 623 Pedro Gil St. Ermita, Manila 1000 Philippines

Tel Nos: (632) 5264266; (632) 5264349 Telefax No: (632) 5250395 Website: <http://nih.upm.edu.ph>



<Date>

<NAME OF PRINCIPAL INVESTIGATOR>

Principal Investigator

<Institution/ College>

Dear <Name of Principal Investigator>:

The National Institutes of Health – Technical Review Board (TRB) has reviewed your research proposal entitled <Title of Research Proposal>.

Please find the attached copy of the comments and recommendations of the Board on your research proposal. Based on the evaluation, your proposal will still need to undergo revision to be given technical clearance. Please comply with the following:

- B. Submit revised protocol incorporating comments/questions of the TRB. Footer should indicate version date and version number; and
- C. Submit cover letter detailing your action/response to the comments/questions raised by the TRB, by explicitly indicating respective sections and pages in the revised proposal.

Kindly submit your revised protocol within **one week** after you have received this communication so that your proposal can be included in the final evaluation.

However, should you wish to request for a clarificatory interview during the next TRB meeting, please contact the undersigned through the NIH-TRB Secretariat at **528-4041** or <NIH- TRB email address>.

Thank you.

Very truly yours,

GODOFREDA V. DALMACION, MD

Chair

Technical Review Board

3. Letter for Initial Review (Content Reviewer) Template



NATIONAL INSTITUTES OF HEALTH

G/F National Institutes of Health Bldg., 623 Pedro Gil St. Ermita, Manila 1000 Philippines

Tel Nos: (632) 5264266; (632) 5264349 Telefax No: (632) 5250395 Website: <http://nih.upm.edu.ph>



<DATE>

<NAME OF REVIEWER>
<Position/ Designation>
<College/ Institution>

Dear <Name of Reviewer>:

As a member of the UP Manila NIH- TRB Pool of Experts, may we request you to do initial review of the research proposal entitled <Title of Research Proposal> by <Name of Principal Investigator>.

Enclosed herewith is a copy of the study protocol and assessment forms for your comments and signature. As a reviewer, you are given two weeks lead time to review the aforementioned protocol. We would appreciate receiving your review on or before <Date of Deadline for Review>.

In the meantime, kindly indicate your response to this request in the section below by ticking the appropriate reply. Please return your reply slip as soon as possible. For questions, you may contact the undersigned through the NIH-TRB Secretariat at telephone number **(02) 528-4041** or <email address of NIH-TRB>.

Thank you very much.

Sincerely,

<NAME OF TRB CHAIR>
Chair, Technical Review Board

Reply Slip – NIH Technical Review Board

- Thank you. I will send my review by <Date of Deadline>
- Thank you but give me extra time for review. I will give it on _____ (*new date*).
- Please refer to another reviewer because of possible conflict of interest.
- Please refer to another reviewer because the topic is not my expertise.
- Other reason/s: _____.

Signature over printed name

Date

4. Letter to Reviewer (Initial Review) Template



NATIONAL INSTITUTES OF HEALTH

G/F National Institutes of Health Bldg., 623 Pedro Gil St. Ermita, Manila 1000 Philippines

Tel Nos: (632) 5264266; (632) 5264349 Telefax No: (632) 5250395 Website: <http://nih.upm.edu.ph>



<Date>

<NAME OF REVIEWER>
 <Position/ Designation>
 <Institution/ College>

Dear **<Name of Reviewer>**:

May we request you to do initial review of the research proposal entitled **<Title of the Project Proposal>** by <Name of Principal Investigator>.

Enclosed herewith is a copy of the study. The proposal evaluation form and guide questions can be found at the following links:

<https://www.dropbox.com/s/b83dkvc3mpdnvba/PPE%20Form.doc> <https://www.dropbox.com/s/5y3nivr9g3xtz0i/PPGQ.doc>

As a reviewer, you are given two weeks lead time to review the aforementioned protocol. We would appreciate receiving your review on or before <Date of Deadline>.

In the meantime, kindly indicate your response to this request in the section below by ticking the appropriate reply. Please return your reply slip as soon as possible. For questions, you may contact the undersigned through the NIH-TRB Secretariat at telephone number **(02) 528-4041** or **<NIH- TRB email address>**.

Thank you very much.

Sincerely,

GODOFREDA V. DALMACION, MD
 Chair, Technical Review Board

Reply Slip – NIH Technical Review Board

- Thank you. I will send my review by <Date of Deadline>.
- Thank you but give me extra time for review. I will give it on _____ (*new date*).
- Please refer to another reviewer because of possible conflict of interest.
- Please refer to another reviewer because the topic is not my expertise.
- Other reason/s: _____.

 Signature over printed name

 Date

5. Project Proposal Evaluation Form

**University of the Philippines Manila
 National Institutes of Health**

**TECHNICAL REVIEW BOARD
 Project Proposal Evaluation Form**

PROJECT TITLE: _____

PROJECT NO.: _____

PRINCIPAL INVESTIGATOR: _____

DURATION: _____

START DATE: _____ END DATE: _____

TO THE REVIEWER: Please accomplish this form electronically as much as possible. For clarity, please write your comments in complete sentences. Please refer to Review Guide Questions (Form 1A) in answering the evaluation form. Thank you.

COMPONENTS	Page/s	Comments	Recommendations
1. Title			
2. Research Question/ Objectives/ Hypothesis			

a. Significance			
b. Formulation			
3. Review of Literature			
a. Tracking Method and Comprehensiveness of Review			
b. Critical Appraisal			
4. Research Design			
a. Appropriateness			
b. Feasibility			
c. Scope and Delimitations			
5. Methodological Issues			
a. Subjects/ Patient population			
b. Operational definition of variables			
c. Data collection			
d. Limitations of the Study			
6. Data Management and Other Statistical Issues			
a. Sample size calculation			
b. Plans for statistical analysis			
c. Proposed analytic techniques			
7. Ethical Considerations			
A. Studies involving human subjects			
a. Free and prior informed consent			
b. Patient protection			
c. Privacy and confidentiality			
d. Indemnification			
B. Studies involving use of animals, chemicals and in vitro (please see Guide Questions)			
8. Organization and Clarity			
9. Budget			

10. Other matters			
-------------------	--	--	--

Scoring System

In the table below, please give a score (with 1 as the lowest) for each parameter based on the result of your evaluation. Each parameter has been given corresponding points as shown below.

Role*	Title of the Proposal	Objective (5 pts)	Methods (8 pts)	Analysis (5 pts)	Feasibility/Significance (2 pts)	Benefit/Impact (5pts)
Total						

*Legend

Reviewer 1- Primary Reviewer
 Reviewer 2- Secondary Reviewer
 Member- TRB Member

ACTION

Approval / Favorable opinion (Score >15)

Major modifications required prior to approval

Minor modifications required prior to approval

Disapproval/Negative opinion (Score <5)

Reasons for disapproval/negative opinion:

Signature _____

Date _____

Name of Reviewer _____

6. Review Guide Questions

**University of the Philippines Manila
 National Institutes of Health**

**TECHNICAL REVIEW BOARD
 Review Guide Questions**

1. Title
 - a. Is the title stated in the fewest possible words that adequately described the contents of the paper?
 - b. Does the title have "waste words" such as "Studies on;" "Investigations on"; a, an or the are also considered waste words
 - c. Is the title specific? For example "Action of Antibiotics on Bacteria" is too general. "Inhibition of growth of mycobacterium tuberculosis by streptomycin" is more specific
 - d. Is the syntax correct? For instance "Mechanism of suppression of non-transmissible pneumonia in mice induced by Newcastle disease virus." Did the virus induce the mice? "Mechanism of suppression of non-transmissible pneumonia induced in mice by Newcastle disease virus" is better

2. Research Question/Objectives/Hypothesis:
 - a. Significance
 - a. Does the research question address an issue of national or international significance?
 - b. Will the research question be useful in tackling a diagnostic or therapeutic problem in clinical practice? Is it of public health importance?
 - c. Will new knowledge and methods be generated through this research which will be helpful in drafting policies, processes, strategies and programs?

 - b. Formulation: Are the objectives stated in clear, specific and measurable terms?

3. Review of Literature
 - a. Applicability of the Literature
 - a. Is the literature supporting the study contain timely information?
 - b. Is the literature retrievable?
 - b. Association to the Objective
 - a. Is the literature related to the study objectives?
 - c. Critical Appraisal
 - a. Are the gaps, limitations and future areas of investigation mentioned in the review of literature?
4. Research Design
 - a. Appropriateness: Is the proposed study design appropriate to attain the objectives of the study?
 - b. Feasibility: Is the study doable according to time frame, available resources to include budget and human resources, and client population?
 - c. Were the scope and delimitations of the research stated?
5. Methodological Issues
 - a. Subjects/Patient population:
 - i. Are the inclusion and exclusion criteria well stated?
 - ii. Are the methods of selecting subjects clearly described?
 - iii. If the study is an experimental study, is the randomization process adequately described?
 - b. Operational definition of variables:
 - i. Are the variables (dependent, independent and confounding variables) operationally (rather than conceptually) clearly defined in measurable terms?
 - ii. If it is a drug trial, is the dose as well as the duration of treatment stated?
 - c. Data collection:
 - i. Are the methods of data collection clearly discussed?
 - ii. Are the proposed methods and tools for data collection suitable for the attainment of the research Objectives?
 - d. Limitations of the Study: Are the limitations of the study, particularly the possible sources of selection, information and confounding bias identified and addressed?
6. Data Management and Other Statistical Issues
 - a. Is the formula for computation of minimum sample size appropriate for the proposed study design?
 - b. Are the plans for data processing and statistical analysis included?
 - c. Are the proposed analytic techniques appropriate?
 - d. Are the methods of data extraction included?
7. Ethical Considerations
 - a. If study involved human participants, were the following ethical considerations included in the proposal?
 - a. Free and prior informed consent
 - b. Patient protection
 - c. Privacy and confidentiality
 - d. Indemnification
 - b. If the study involved use of animals, were the following considerations included in the proposal?
 - a. Housing and Environment
 - b. Animal Care Requirements
 - c. Procurement of Animals
 - d. Blood Collection
 - e. Use of Anesthetics
 - f. Euthanasia
 - g. Disposal of Animal Carcass and Non- carcass Waste
 - h. Scientific Procedures Involving Hazards
 - c. If the study involved use of in vitro, etc., were the following considerations included in the proposal?
 - a. Risk Assessment
 - b. Biosafety Level
 - c. Disinfection and Sterilization
 - d. Mitigation Controls
 - e. Management of Biohazardous Wastes
 - f. Accidents and Emergency Response Procedures
 - g. Biosecurity Policies of appropriate institutions
8. Organization and Clarity
9. Budget
10. Other matters

7. Letter to REB Template



NATIONAL INSTITUTES OF HEALTH

G/F National Institutes of Health Bldg., 623 Pedro Gil St. Ermita, Manila 1000 Philippines

Tel Nos: (632) 5264266; (632) 5264349 Telefax No: (632) 5250395 Website: <http://nih.upm.edu.ph>



Technical Review Board

<Date>

<NAME OF RESEARCH ETHICS BOARD CHAIR>

<Chair>

<Research Ethics Board>

Dear <Name of REB Chair>:

This is to respectfully endorse the project proposal entitled <Title of Research Proposal> by <Name of Principal Investigator>, for evaluation of the Research Ethics Board under your chairmanship.

The research proposal has undergone the following:

- D. Review by the Technical Review Board (TRB) with comments forwarded to the proponent; and
- E. Revision of the proposal done by the proponent based on the comments of the TRB.

Thank you very much.

Very truly yours,

<NAME OF TRB CHAIR>

Chair
Technical Review Board

8. Letter Final Report Template



NATIONAL INSTITUTES OF HEALTH

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Technical Review Board

<DATE>

TO: <NAME OF REVIEWER>
<Department/ Office>
<College/ Institution>

FROM: <NAME OF TRB CHAIR>
Chair, Technical Review Board

SUBJECT: EVALUATION OF FINAL REPORT

Dear <Name of Reviewer>:

As a member of the UP Manila Pool of Experts, we request you to review the final report of the study entitled <Title of Proposal> by <Name of Principal Investigator>.

Enclosed herewith are the (1) copy of the final report, (2) assessment form for your comments and signature, and (3) copy of the approved research proposal. As a reviewer, you are given one week lead time to review the aforementioned final report. We would appreciate receiving your review on or before <Date of Deadline of Return of Review>.

You may contact the NIH- TRB Secretariat at <telephone no. of NIH> or <e-mail address of TRB> if you have any concerns.

Thank you for your kind support.

9. Final Report Evaluation Form Template

University of the Philippines Manila
National Institutes of Health

TECHNICAL REVIEW BOARD
Final Report Evaluation Form

PROJECT TITLE: _____

PROJECT NO.: _____

PRINCIPAL INVESTIGATOR: _____

DURATION: _____

DATE SUBMITTED: _____

TO THE REVIEWER: Please accomplish this form electronically as much as possible. Make sure that all your comments are in complete sentences. Thank you.

Items reviewed	YES	NO	Remarks
1. Were all the objectives met?		If no, which objective/s were not met?	
2. Was the original methodology followed as described?			
3. Were there any changes made in the conduct of the research ?	If yes, was this reflected in the informed consent or in the final report?		
4. Was the results clearly described and appropriately analyzed?		If no, please mention why?	
4. Was the sample size satisfied?		If no, what was the explanation given?	
5. What are the limitation of the study mentioned by the author?			
6. Was the conclusion appropriate and supported by the findings ?			

COMMENTS: _____

	Strongly agree	Agree	Maybe with minor revisions	Not at its present form	Disagree
Would you recommend publication of the study?					