

UST – FMS

RESEARCH MANUAL

AY 2017-2018

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I. Office for Research and Innovation

There are nine key areas in the University of Santo Tomas' Vision 2020 and one of which is Research and Innovation. The strategic objective for the Area of Research and Innovation for 2020 is:

To become internationally acknowledged expert in pioneering and innovative research in the culture, arts & humanities, social sciences, business management and education, health and allied sciences, science & technology and the sacred sciences.

The Office for Research and Development (ORD) was established last 1994 by the rector, Fr. Rolando V. de la Rosa, OP, Research was previously under the Office for Academic Affairs and Research. In 1998, Fr. Tamerlane Lana, OP the Rector of the University changed the ORD to the Office for Research, Planning and Development where research and university planning were placed in one office. This was short-lived because in 2000, Fr. Lana reverted back the office to ORD and created a separate office for planning.

In 2001, the ORD was moved to the newly built Thomas Aquinas Research Complex. But by 2007, Rev. Fr. Rolando de la Rosa, OP dissolved the Office for Research and Development and merged Research again with Academic Affairs to form the Office of Academic Affairs and Research. During the term of the incumbent Rector, Rev. Fr. Herminio Dagohoy, OP, research was again separated from the Office of Academic Affairs and Research. And the Office for Research and Innovation (ORI) was established on November 2012. It is headed by the Vice Rector for Research and Innovation to improve the research productivity of the faculty members of the University.

The specific objectives of the area for research and innovation are the following:

1. To increase faculty members with disciplinal research
2. To increase the number of faculty members with PhDs to engage in research.
3. To enhance research training program
4. To increase globally competitive research force
5. To improve the number of publications in national and international publications.
6. To improve the number of externally funded research projects.
7. To increase research productivity
8. To increase globally competitive research programs/projects
9. To strengthen partnerships between faculty members and students

The Research Centers of the University are the following:

1. Research Center for the Natural and Applied Sciences
2. Research Center for Education and Social Sciences,
3. Research Center for the Culture, Arts and Humanities
4. Research Center for Health Sciences
5. Center for Health Research and Movement Science
6. Center for Religious Studies and Ethics
7. Center for Creative Writing

The future plan is that the Research Center for Health and Allied Science will unify the Research Center for Health Sciences under the Faculty of Medicine and Surgery and the Center for Health Research and Movement Science under the College of Rehabilitation Sciences.

II. Key Result Area and Key Performance Indices

Key Results Areas with Key Performance Indices in which the different centers should contribute in the targets up to 2020 have been identified and these are as follows:

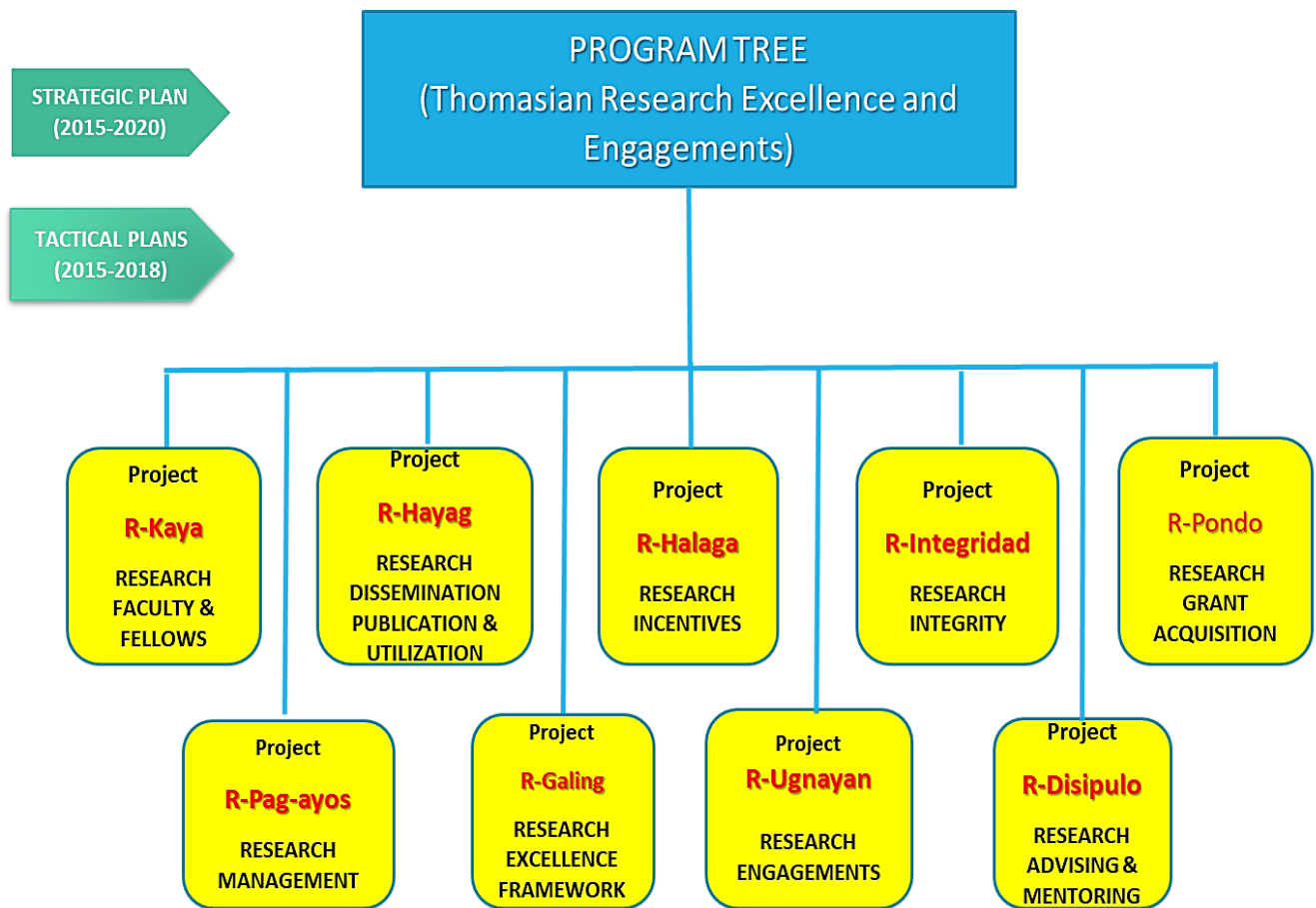
Key Result Area	Key Performance Index
1. A Globally Competitive Research Force in Residence	1. Number of faculty members involved in research project initiated/sponsored by the research centers.
	2. Percentage of faculty researchers with PhD
	3. Percentage of faculty researchers with published works in <u>peer-reviewed</u> journals/books/monographs a. National b. International
	4. Percentage of faculty researchers with externally funded projects a. National b. International
2. Active Research Involvement in a Broad Range of Disciplines	1. Number of externally-funded research projects a. National b. International
3. World Class and High Impact Research Projects	1. Number of publications in Thomas Reuters (formerly ISI)/SCOPUS indexed journals
4. Strong Links between Teaching and Research	1. Number of research outputs with student co-authors a. Publication b. Paper presentations c. Research-based exhibits
5. Effective Utilization of Research Output	1. Number of Patents
	2. Number of Utility Model
	3. Number of Research Output adopted for Policy & Decision making
	4. Number of Research Output on Teaching & Learning

Each research center should provide targets for the key performance index. The targets for the Research Center for Health Research are found in Appendix 1.

Every year, there is an annual planning workshop of the heads of the different research centers where targets are set, problems encountered during the past year are discussed and possible solutions are proposed. It also gives the different directors a venue where they could share best practices in their centers which other directors could adopt in their respective centers.

III. Program TREE (Thomas Research Excellence and Engagements)

With this the Program TREE (Thomas Research Excellence and Engagements) was launched by the Office of Research and Innovation. This program aims to guide the different research centers of the projects and activities they could engage in to further improve research profile of the University.



The ORI has launched several projects where each center could select their targeted programs for the each academic year. They are as follows:

PROJECT 1: R-GALING: RESEARCH GRANT PROGRAM (RGP) (for Thomasian researchers)

- This is the eligibility criteria in accepting researchers according to the Research Policy & Guidelines for those solely teaching in UST
- ACTIVITY 1: improve system for monitoring, benchmarking and reporting of research performance
- ACTIVITY 2: Seminars & Writeshops on Drafting the UST REF
- ACTIVITY 3: Seminars & Writeshops on Drafting the UST Research Agenda

PROJECT 2: R-KAYA: RESEARCH FACULTY AND FELLOWSHIP

- This aims to enhance the professional capability of the faculty
 - The funds will come from the external partners.
 - UST will provide the expertise and space.
 - Research fellow will be under a professor in the external partner and thus can act as an assistant professor.
 - All the projects must be aligned and in conformity with the Catholic teachings and stand of the University.
- ACTIVITY 1: Junior Research Fellowship
- ACTIVITY 2: Senior | Post-Doc Research Fellowship
- ACTIVITY 3: Engineering Externship
- ACTIVITY 4: Fellowship On Creative Studies
- ACTIVITY 5: Fellowship On Applied Social Sciences
- ACTIVITY 6: Fellowship On Applied Natural Social Sciences

- ACTIVITY 7: Program Training Fellowships
- ACTIVITY 8: International Fellowships
- ACTIVITY 9: Visiting professor

PROJECT 3: R-DISIPULO (RESEARCH ADVISING AND MENTORING)

- This aims to enhance the research capability and confidence of the junior faculty
- ACTIVITY 1: Faculty-led Research
- ACTIVITY 2: Seminars/symposia/Workshops on thesis/dissertation or twinning in adviserships

PROJECT 4: R-INTEGRIDAD: RESEARCH INTEGRITY

- This projects aims to develop a culture of integrity in performing research and for researches to follow the code of ethics
- ACTIVITY 1: Seminars/symposia on Research Ethics
- ACTIVITY 2: Authorship, Intellectual Property, Plagiarism, & Publication
- ACTIVITY 3: Orientations on Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Research Ethics Committee (REC) policies & guidelines
- ACTIVITY 4: Seminar on Predatory Journals and Conferences
- ACTIVITY 5: Formation of the Institutional ethics review committee for each college
- ACTIVITY 6: Formation of Institutional biosafety committee
- ACTIVITY 7: Formation of Institutional animal care and use committee

PROJECT 5: R-PONDO (RESEARCH GRANT ACQUISITION)

- This aims to improve the capability of researchers to apply for research grants.
- ACTIVITY 1: Organize regular research proposal writing workshops
- ACTIVITY2: Improvement of university research policies (research load, promotion, foster grant acquisition)
- ACTIVITY 3: Establish network of contacts to build database on and access to funding opportunities
- ACTIVITY 4: Develop and support multi-and interdisciplinary teams with capacity to avail of funding opportunities
- ACTIVITY 5: Develop a research office TO look and explore external funding opportunities
 - i. Source of funding: USAID stride, Newton Funds, CHED, DOH, AusAid

PROJECT 6: R-UGNAYAN (RESEARCH ENGAGEMENTS)

- This aims to foster exchanges for collaboration among faculty members
- ACTIVITY 1: Creation of multi-interdisciplinary research programs (British Council)
- ACTIVITY 2: Assignment of the composition of the committee

PROJECT 7: R-HAYAG (RESEARCH DISSEMINATION, PUBLICATION AND UTILIZATION)

- ACTIVITY 1: PANAYAM
 - Colloquium for new academic doctorate degree holders who have been funded by UST (paid study leave in collaboration with OVRAA)
- ACTIVITY 2: MEDIA dissemination
 - Social Media Bureau
 - UST Website
 - Academia
- ACTIVITY 3: Conferences and Forum
- ACTIVITY 4: Training & Workshops

PROJECT 8: R-HALAGA (RESEARCH INCENTIVES)

- This project aims to increase the incentives given to researchers for publication and presentation of papers
- ACTIVITY 1: Biennial Research Recognition
- ACTIVITY 2: Support For Paper Presentation Policies & Guidelines in harmony with OGEPH
- ACTIVITY 3: Conference support

PROJECT 9: R-PAG-AYOS (RESEARCH RESOURCE MANAGEMENT)

- This projects aims to improve the archiving of the researchers done in the university
- Data archiving – data and storage system
- Repository
- Data must be in the cloud

IV. Research Center for Health Sciences

The Research Center for the Health Sciences (RCHS) is one of the research centers under the Office for Research and Innovation (ORI). It is one of the two research centers in the University which are directly under the supervision of the college. The other research center is the Center for Health Research and Movement Science under the College of Rehabilitation Sciences.

Being such, it coordinates with the Dean of the UST Faculty of Medicine and Surgery and assists in the “preparation, conduct, monitoring, evaluation, reporting and publication” of completed researches from the different departments.

Mission

A research center imbued with Thomasian values engaged in medical research for the generation, dissemination, promotion and utilization of advanced health-related information.

Vision

The research center for the health sciences aims to be:

- A world-class research center in basic and clinical medicine
- A training ground for young medical scientists
- A major contributor to national and global health promotion

Each department is represented by a research coordinator which is recommended by the department chair and appointed by the dean. The responsibilities of the research coordinators are as follows:

1. Coordinate with Chief Program Officer of the Research Center for Health Sciences on the proper dissemination of information coming from the Office of the Vice-rector of Research and Innovation and the Office of Dean pertaining to research matters.
2. Help in the development of the research agenda of the Faculty of Medicine and Surgery.
3. Coordinate the research activities of the department.
4. Collate data pertaining to research for year-end report of the Faculty of Medicine and Surgery.

Communication pertaining to research matters, grants and programs from the Office for Research and Innovation is disseminated to the research coordinators through e-mail and/or viber messages.

Research Agenda of the Research Center for Health Science

The research agenda for the Faculty of Medicine and Surgery was formulated based on the research expertise of the faculty members of the college. This could be evidenced by the research topics of the papers that have published locally and internationally.

The yearly research agenda is disseminated through meetings with the research coordinators, viber group and the medical school website.

The research agenda will expand accordingly as more research projects will be endeavored by the faculty members. With the function of the Research Center of providing technical assistance to the faculty members interested in conducting research, more faculty members will be involved in research in their field of interests.

Furthermore, one of the major thrusts of the faculty of Medicine and Surgery is forming collaboration with the different colleges of the University to develop and support multi-interdisciplinary teams in research which will further expand the research agenda of the college.

Other projects that are being conceptualized in coordination with the Research Center for Health Sciences are the following:

1. Development of Health Registry for School Children in Dagat-dagatan: Department of Preventive Medicine
2. Development of an Mobile Application for the Performing Ultrasound in Pregnant Women: Lead Person: Dr. Leah Rivera, MD from the Department of Obstetrics and Gynecology in cooperation with Department of Preventive Medicine and Institute of Computer Science, College of Engineering
3. Development of an Insole Pressure Sensor for Patients with Diabetic Neuropathy: Lead Person: Consuelo B. Gonzalez-Suarez, Department of Rehabilitation Medicine in collaboration with Department of Medicine, College of Rehabilitation Sciences and Department of Electronical Engineering, College of Engineering.

Other functions of the Center in order to improve the culture of research in the Faculty of Medicine and Surgery are:

1. Providing lectures and workshop in research topics
2. Providing links, either from the Department of Statistics of the University of the Philippines or the Research Center for Social Sciences and Education, for statistical assistance

Relationship with the Department of Medical Education and Research of the University of Santo Tomas Hospital

The Department of Medical Education and Research (DMER) of the University of Santo Tomas Hospital is primarily responsible for the training of the medical interns, residents and fellows of the hospital. One integral part of training is research wherein a resident is required to submit a research that has been approved by the Institutional Review Board of the hospital. The DMER has appointed a research coordinator for the medical interns, residents and fellows who is responsible for the research program of the trainees of the hospital. Each department of the hospital also has a research head who is under the research coordinator.

All researches done by the residents/fellows are either advised or co-authored by consultants who are also faculty members of the Faculty of Medicine and Surgery. Therefore, researches whose primary authors are trainees of the hospital are provided technical support and ethical approval by the hospital.

Relationship with the Institutional Review Board of the University of Santo Tomas Hospital

In accordance with the policy of Philippine Health Research Ethics Board, ethical approval is site specific. It is, therefore, the policy of the Institutional Review Board (IRB) of the University of Santo Tomas Hospital (USTH) that all researches which will have patients of the USTH as their participants will have to seek ethical approval from the IRB of USTH.

Likewise, research proposals which involve students and the communities being served by the Faculty of Medicine and Surgery should seek ethical approval from the Ethics Review Board (ERB) of the college.

V: Guidelines for Application for Research Load

This guideline is based on the “Policies and Guidelines for Research” by the Office of Research and Innovation (2015) but was modified according to the requirements of the Faculty of Medicine and Surgery. Kindly refer to the “Policies and Guidelines for Research”.

I. Research Load

- A. Faculty members are allowed to have a minimum of 6 units research load and maximum of 15 units research load. This is equivalent to laboratory units.
- B. For faculty members who obtained grants for their research project, a 18 units research load may be allowed.
- C. For old faculty researchers
 1. AY 2016-2017: as per CBA, faculty members with ranks of Professor, Associate Professor, and Assistant Professor will carry full load of 21 units (combined teaching and research)
 2. AY 2017-2018: as per CBA, faculty members with ranks of Professor, Associate Professor, Assistant Professor, and Instructor will carry full load of 21 units (combined teaching +research)
 3. Proposed Combined Research Load and Teaching Load (Excluding Graduate School)
 - Without external grant: 15 units (30 hrs/wk) research load +6 units teaching load = 36 hrs/wk or more if teaching load assignment are laboratory courses.
 - With external grant: 18 units (36 hrs/wk) research load + 3 units teaching load = 39 hrs/wk or more if teaching load assignment is a laboratory course.
- D. For faculty Member with academic /administrative assignment
 1. Faculty member with academic/administrative assignment may carry research load of 3-6 units (6-12 hrs/week)
 - For Dean, 6 units research load means no teaching load = 42 hrs/wk
 - For Department Chairperson, 6 units research load + 6 units teaching load = 38 hrs/wk or more if teaching load are laboratory courses.
 - For Asst. Dean, College Secretary & Directors, 6 units research load + 3 units teaching load = 45 hrs/wk or more if teaching load is a laboratory course.
- E. FOR NEW FACULTY RESEARCHER
 - Qualifications
 - Tenured and non-tenured probationary track
 - “Satisfactory to VS” overall rating in the evaluation
 - Strongly endorsed by the Chairperson and Deans

- Proposal must be aligned to the expertise of the faculty and the research center's research programs.
- Research Load
 - MS/MA degree (with thesis) - 6 units research load
 - PhD – 9 units research load

II. Requirements to be considered for a research load

- A. Attended the Good Clinical Practice Workshop
- B. Attended the three Research Seminars conducted by the Faculty of Medicine and Surgery
- C. Research proposal is viable and will be a platform for further researches in the future

III. Procedure for application of research proposal/ research load

- A. Call for research proposal
- B. Submission of the research proposal to the Research Center for Health Sciences
- C. Screening of the research proposal by a Technical committee
- D. Acceptance of the Research Proposal
- E. Presentation of Research Proposal
- F. Letter to be written by the Chief Program Officer of the Research Center for Health Sciences which is endorsed by the dean to the Office of the Vice Rector of Research and Innovation stating that research proposal has been accepted
 - Will include the full research proposal and research capsule
- G. Signing of the Memorandum of Agreement between faculty member and OVRI.

IV. Forms to be submitted by the researcher

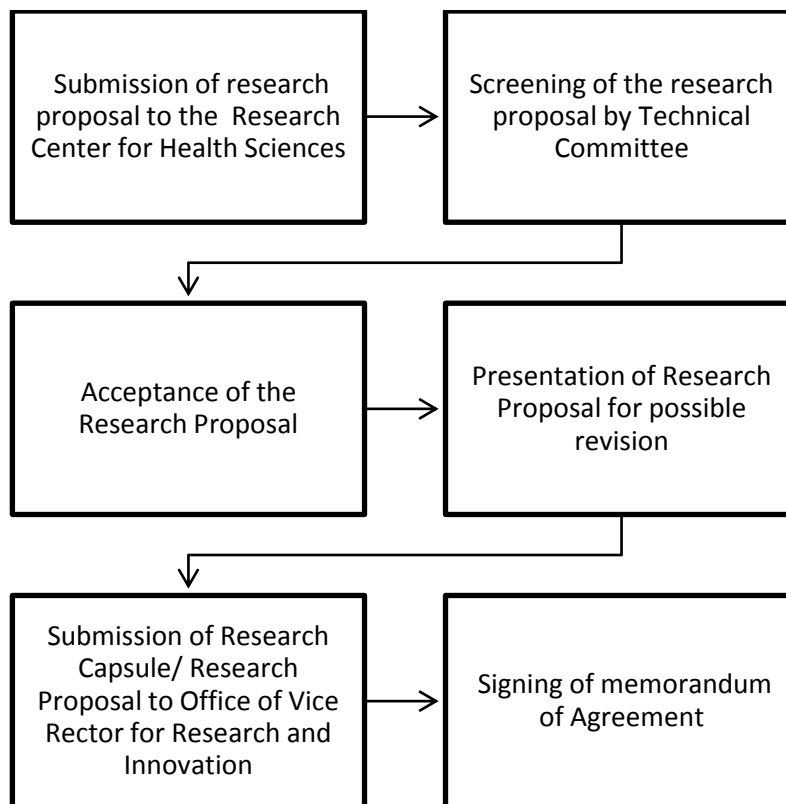
- A. Research capsule
- B. Research proposal
- C. Midyear progress report
- D. Final paper at end of second term
- E. Journal article of the final paper two months after submission of final paper

V. Guidelines for providing research load to faculty members as of June 2017

- A. Research load will be given according to the accomplishment for the past three academic years. (2014 -2016, 2015-2016, 2016-2017). Please make a performance records

1. No publication	No research load for AY 2017 -2018
2. 2 Publications + 2 paper presentations	12 units
3. 1 publication + 2 paper presentations	9 units
4. 2 paper presentations	6 units on the condition that publication will be generated for AY 2017-2018

VI. Flow Chart for Application for Research Load



VI. Student Research

Research is an integral component of the education of undergraduate and graduate students. As such, the Deans of the respective colleges shall formulate their own research policies, for students subject to the conditions stated in this policy and other applicable policies.

In the Faculty of Medicine and Surgery, a research project is a pre-requisite to graduation and is under the Department of Clinical Epidemiology.

Guidelines for Student Researches

1. Selection of Topic for Research

- a. Research topics should be in line with the Research Agenda of the Faculty of Medicine and Surgery.
- b. Research Agenda will be presented to the students by the faculty teaching Clinical Epidemiology 1 (CE1).
- c. Faculty members involved in research may provide research topics that are in line with his/her research specialty and/or interest. (**Appendix 2**)
- d. The faculty member will be the co-author and not an adviser.
- e. To provide mentoring, a faculty member in CE1 will be assigned to each group.
- f. The Research proposal will be formulated and written in Clinical Epidemiology 1. At the end of the school year the proposal (**Appendix 3**) will be presented to a technical panel for comment and revision. (**Appendix 4**)
 - i. The group will revise the proposal based on the comments of the technical panel

- ii. In the second year of medical school, the proposal will be followed up by a research coordinator. The group/s will meet the coordinator on a scheduled date twice during the school year. In the second meeting the students will be graded. Five (5) points will be added to the final grade in Clinical Epidemiology 2 if all research tasks for the 2nd year level are all accomplished, this includes IRB submission and approval. (**Appendix 5**).
 - iii. In the third year of medical school, the proposal will be followed up by a research coordinator. The group/s will meet the coordinator on a scheduled date twice during the school year. In the second meeting the students will be graded. Five (5) points will be added to the final grade in Clinical Epidemiology 3 if all research tasks for the 3rd year level are all accomplished, this includes faculty co-author. (**Appendix 6**).
 - iv. In the fourth year of medical school, the proposal will be followed up by a research coordinator. The group/s will meet the coordinator on a scheduled date twice during the school year. In the second meeting the students will submit and present the completed research. (**Appendix 7**) Selected papers from the batch will be chosen for poster presentation after the oral revalida. (**Appendix 8**).
2. Prior to initiation of research, a STATEMENT OF AGREEMENT FOR SUPERVISION OF RESEARCH STUDENTS (**Appendix 6**) will be signed by the faculty and student researchers of the group.
 - a. The agreement will define the roles and responsibilities of the research team.
 - b. It is an aid to planning and completing the project.
 - c. It will serve as the basis for authorship in the final paper.
 - d. The agreement is not intended to be legally binding.
 - e. Should the research question or methods change substantially, modify the contract, highlight the changes, and send copies to the appropriate people.
3. The proposal will be submitted to the Ethics Review Board for ethical approval
 Note: No research will be initiated if no ethical approval has been approved.
 - a. Requirements for ethical approval include the following:
 - i. Cover Letter addressed to Ethical Review Board signed by the Faculty Adviser
 - ii. Summary of comments and suggestions received from technical review and actions taken or clarifications by the students signed by faculty co-authors
 - iii. Official Receipt
 - b. Once with ethical approval, the research project could be started.
4. The progress of research will be assessed by the faculty member teaching Clinical Epidemiology. The progress will be reviewed at twice a year prior to submission of the research paper using two monitoring. (**Appendix 5**).
5. The research paper will be submitted on a designated date. It will be presented as an oral presentation and some maybe selected as poster presentation.
 - a. There are two guidelines for paper submission
 - i. GUIDELINES FOR SUBMISSION OF MANUSCRIPT (**Appendix 7**)
 - ii. GUIDELINES FOR POSTER PRESENTATION (**Appendix 8**)
6. After the oral presentation, the revised paper will be submitted to the Office of Clinical Epidemiology in paperbound copy. A guideline for submission is in (**Appendix 7**).
7. The students will be graded as follows: *presented or not presented* the research. This will be submitted to the Dean's office.

VII: Research Integrity

All research studies involving humans as participants/subjects shall be submitted to an Ethics Review Committee (ERC) for ethics review. This is in compliance with various international and national guidelines that have been developed for the protection of human participants in research. These include the following:

- a) Helsinki Declaration of the World Medical Association;
- b) Good Clinical Practice Guidelines as formulated by the World Health Organization;
- c) The International Conference on Harmonization and Council for International Guidelines Organization of Medical Students (CIOMS 2002);
- d) The National Ethical Guidelines for Health Research 2011 of the Philippine National Health Research System; and
- e) DOST Administrative Order No. 1 (2006).

The Ethical Review Board (ERB) of the Faculty of Medicine and Surgery has been organized by the Office of the Dean to review research proposals of the students and the faculty members.

1. MANAGEMENT OF PROTOCOL SUBMISSION

Purpose

To describe the initial review procedures of the Ethics Review Board (ERB) from the time that the ERB receives the protocol and related documents until the approval letter is sent by the ERB to the Principal Investigator

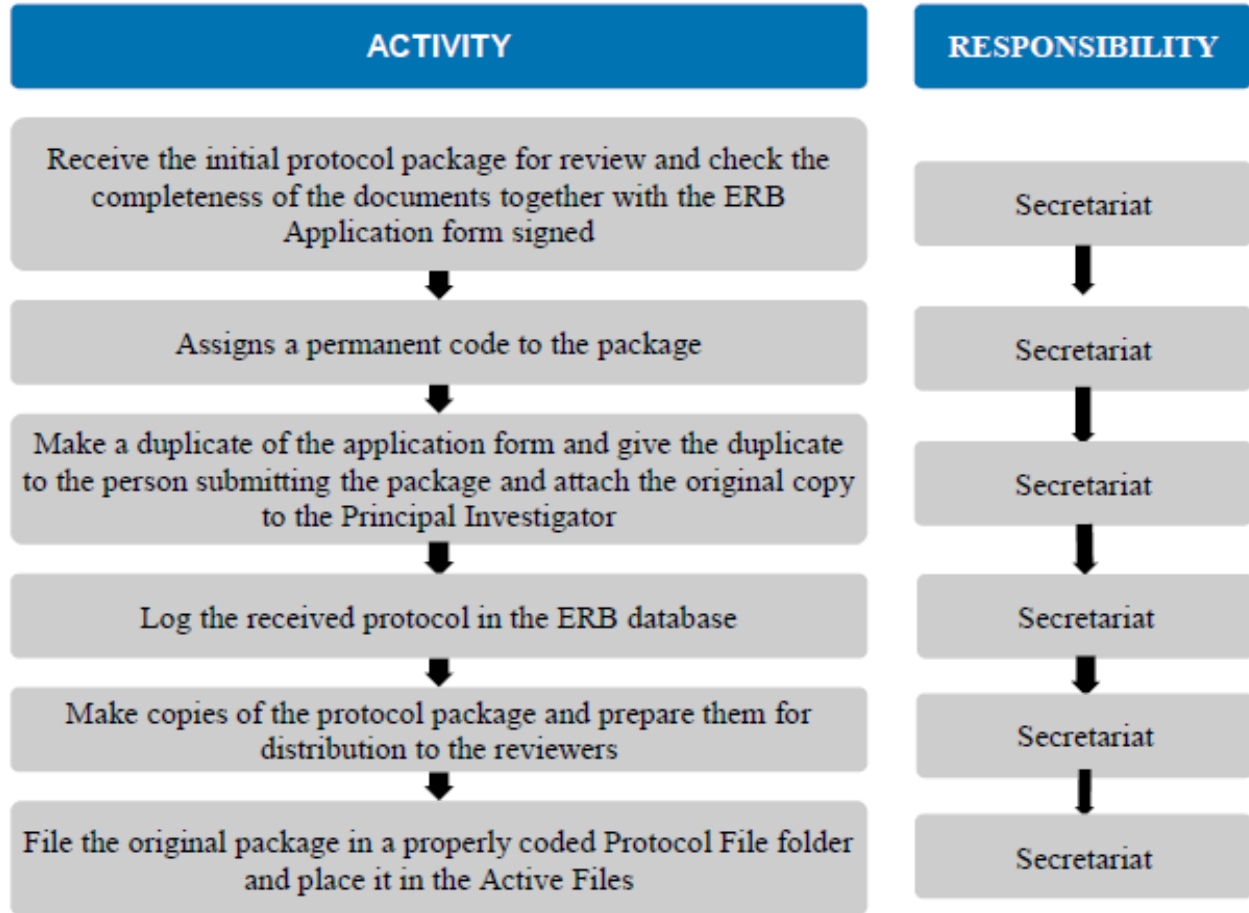
Scope

The USTFMS-ERB accepts the following protocols for review: (1) USTFMS-funded researches, (2) researches done by USTFMS faculty members, students and personnel and (3) researches done in other research sites provided they agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/institutions that accept USTFMS-ERB review.

Responsibility

The ERB Secretariat manages all protocol submissions to the ERB. It covers the actions to be done from the time of submission to the filing of the original protocol package in the Active Study File cabinet and the preparation of copies of the documents for distribution to the reviewers.

Process Flow/Steps



Note: Primary reviewers are selected on the basis of expertise related to the protocol. Research proposals are given to both medical and non-medical or lay members, institutional and non-institutional members for review. The medical/scientific members analyze the scientific and ethical procedures in the protocol while the lay/non-institutional members focus their assessment on the informed consent form.

2. USE OF STUDY ASSESSMENT FORMS

Purpose

To describe the procedures related to the use of study assessment forms in ethics review

Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to USTFMS-ERB for initial review and approval by the ERB. The ERB uses two study assessment forms. These two (2) USTFMS-ERB Assessment Forms for protocol review (see Annex for samples) are the following:

- a. Study Protocol Evaluation Form
- b. Informed Consent Evaluation Form

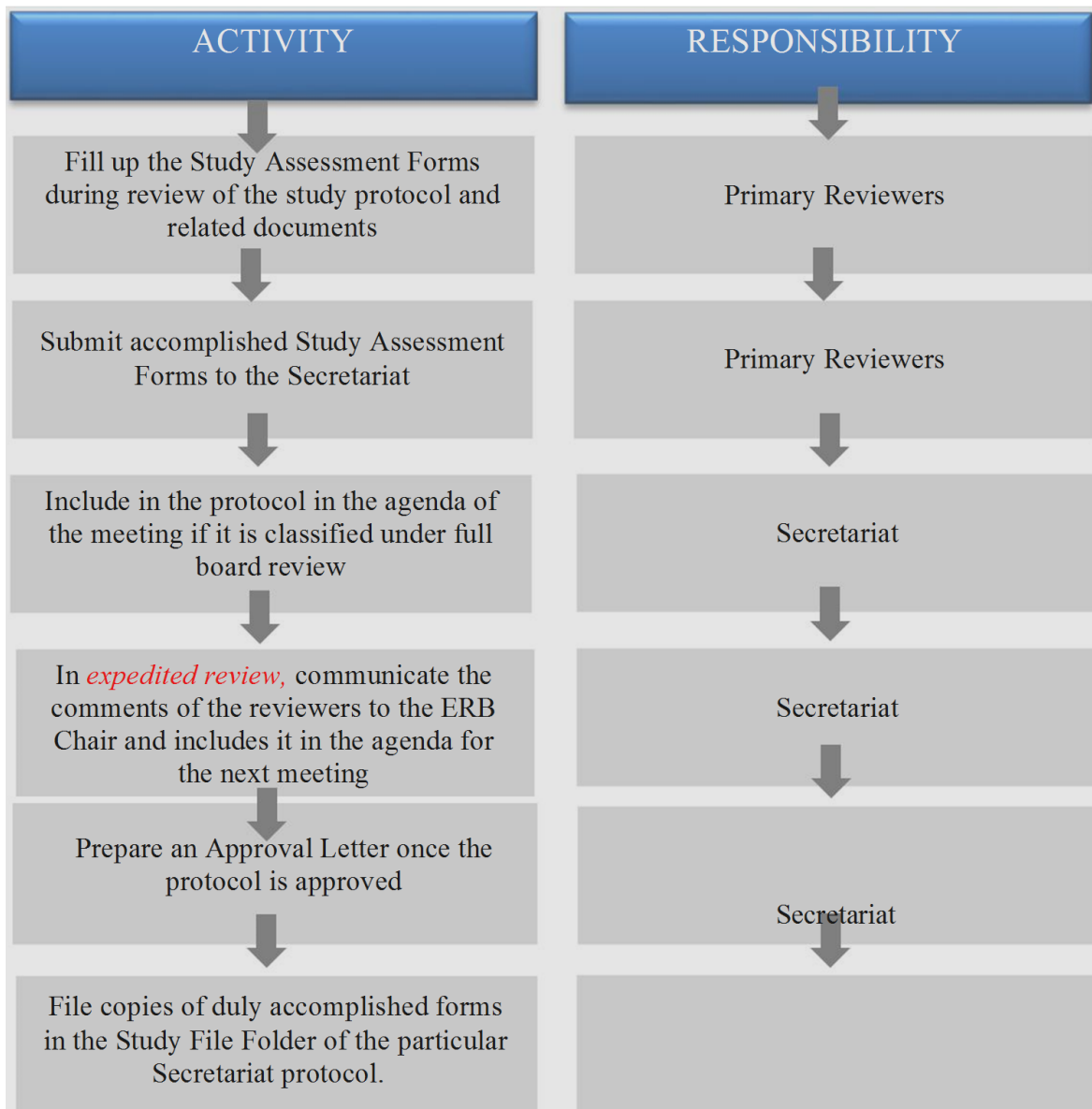
The two assessment forms are accomplished by individual reviewers. Any comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these two forms.

The Study Assessment Forms are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents.

Responsibility

It is the responsibility of the USTFMS-ERB reviewers to individually fill-in the assessment forms after reviewing each study protocol. The Secretariat is responsible for recording and filing the USTFMS-ERB's action, relevant points and deliberation about a particular protocol, including the comments for specific action. The consensus/agreements regarding the decisions on each reviewed protocol will be reflected in the Minutes of the Meeting.

Process Flow/Steps



3. Expedited Review

Purpose

To describe the procedures for the review of protocols that qualify for expedited review

Scope

This SOP applies to the review and approval of study protocols or amendments with minimal risk to study participants and minor revisions in the protocol or informed consent. The submission procedures are the same as first time submission.

The following are types of protocols which can be subjected to expedited review after initial submission:

- a. Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
- b. Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
- c. Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
- d. Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.
- e. Proposed continuing reviews, protocol amendments and end of study reports that have minor modifications and no significant risk to study participants.

Criteria for Expedited Review of Resubmissions/ Amendments/ Reports

- Administrative revisions, such as correction of typing errors
- Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
The research activity includes only minor changes from previously approved protocol. Minor protocol amendments that do not change the risk/ benefit assessment
- Progress/ Final reports that do not deviate from approval given by the ERB
SAEs from foreign sites – need not to review except if high mortality and if it happens in local site/your site then it should be reviewed.

Responsibility

Expedited review is the responsibility of primary reviewers appointed to assess any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the submitted documents and forward to the Chair or Member-Secretary	Secretariat
↓		
2	Determine that the protocol is for expedited review	Member-Secretary/ Chair
↓		
3	Assign reviewers for the expedited review	Member-Secretary / Chair
↓		
4	Do the expedited review and submit the comments to the Secretariat	Primary Reviewers
↓		
5a	Communicate the comments to the ERB chair and prepares a letter of approval or revision to be given to the PI	Secretariat to the Chair
↓		
5b	If modifications are required, revise the protocol or related document and resubmit to the ERB	Principal Investigator
↓		
5bi	Check and review revisions	Primary Reviewers
↓		
5bii	Communicate the decision to the principal investigators	Secretariat
↓		
6	Prepare an Approval Letter to be signed by the Chair and include Report results of expedited review during the board meeting	Secretariat and Chair
↓		
7	Keep copies of related documents in the files	Secretariat
↓		
8	Update the IRB database	Secretariat

4. Full Board Review of Submitted Protocols

Purpose

To describe the procedures when protocol submissions are classified for full board review

Scope

This SOP applies to the review and approval of study protocols or amendments with medium to high risk to study participants and major revisions in the protocol or informed consent. The submission procedures are the same as first time submission.

Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

It is the responsibility of the primary reviewers to review the protocol and related documents by using the assessment forms and make a recommendation for appropriate action.

The following are types of protocols that should undergo full board review after initial submission:

- Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
- Phase 4 intervention research involving drugs, biologics or device
 - Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm.
 - Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review.
- Protocols that involve collection of identifiable biological specimens for research
- Criteria for Full Board Review of Resubmissions/ Amendments/ Reports
- Major revisions of the protocol and informed consent after initial review
Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
Major amendments that change the risk/ benefit ratio
- Major protocol violations
- Progress/ Final reports that deviate from original approval given by the IRB
Onsite SAEs or SUSARs that may require protocol amendment or re-consent of participants

The Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version (if any) of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the USTFMS-ERB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated.

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments and put all of this in the Study Assessment Forms before returning the reviewed protocol and assessment form to the Secretariat on the due date.

Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the submitted documents and forwards to the Chair or Member-Secretary	Secretariat
↓		
2	Determine that the protocol qualifies for Full Board review	Member-Secretary/ Chair
↓		
3	Assign reviewers to review the protocol and related documents	Member-Secretary/ Chair
↓		
4	Review the protocol documents using the assessment forms and submit the decision/ recommendation to the Secretariat	Primary Reviewers
↓		
5	Include the protocol in the meeting agenda for discussion to arrive at a decision through full board	Secretariat/ Members
↓		
6	If modifications are required, revise the protocol or related document and resubmit to the ERB	Principal Investigator
↓		
7	Check and review revisions and refer to full board for decision	Primary Reviewers
↓		
8	After board approval, prepare the Approval Letter to be signed by the Chair and sent to the PI	Secretariat
↓		
9	Keep copies of all documents in the files	Secretariat
↓		
10	Update the protocol entry in the ERB database	Secretariat

5. Review of a Medical Device Protocol

Purpose

To describe procedures in the review of medical device protocols submitted to the ERB.

Scope

This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the USTFMS-ERB.

Medical device protocols are reviewed through full board procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non-Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the IRB. The IRB should make provisions to minimize the risks to human participants during review of the protocol and related documents.

Responsibility

It is the responsibility of the IRB members to review medical device protocols in accordance with international and national guidelines and regulations.

Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the submitted documents and forward to the Chair or Member-Secretary	Secretariat
↓		
2	Assign primary reviewers to review the protocol and related documents	Member-Secretary/ Chair
↓		
3	Conduct the review using the assessment forms and submit the decision/ recommendation to the Secretariat	Primary Reviewers
4	Full Board Review: Include the protocol in the meeting agenda for discussion and decision by full board	Secretariat
↓		
5	If modifications are required, revise the protocol or related document and resubmit to the IRB	Principal Investigator
↓		

6	Check and review revisions	Primary Reviewers
↓		
7	Prepare an Approval Letter to be signed by the Chair and sent to the PI	Secretariat
↓		
8	Keep copies of related documents in the files	Secretariat
↓		
9	Update the protocol entry in the IRB database	Secretariat

VIII. The Journal of Medicine – University of Santo Tomas (JMUST)

The Journal of Medicine, University of Santo Tomas (JMUST) is an open-access, peer-reviewed journal. It is a bi-annual planned publication. It is the official publication of the Faculty of Medicine and Surgery along with Santo Tomas University Hospital of University of Santo Tomas, Manila, Philippines.

JMUST is dedicated to provide healthcare practitioners with the best and most updated information in health science research and education. JMUST has a mission to assist healthcare practitioners through education, in delivering the best care to their patients.

JMUST follows a rigorous process of peer-review and editing process, to evaluate manuscripts for data fact check, plagiarism and scientific accuracy, prior to approval.

JMUST accepts qualitative and quantitative original research paper, review articles, commentary, letter to editor, research on medical education, and approved research proposals.

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COVER LETTER

Manuscript submission must have a cover letter addressed to the Editor-in-Chief. The letter must include the following:

- complete title of the paper
- intention for publication
- significance of the study

- all authors have contributed to the research undertaking, have reviewed the manuscript and have agreed for publication of the paper
- note that the manuscript has not been published elsewhere.

TYPES OF PAPERS

JMUST accepts qualitative and quantitative original research papers, review articles, commentary, letter to the editor, research on medical education, and approved research proposals. All submitted manuscripts must indicate proof of Institutional Review Board (IRB) approval.

MANUSCRIPT

Manuscript must be **double-spaced, Times New Roman style, 12 point, in A4** paper size. Double-spacing is required for the entire manuscript including the legends and references. Manuscript must be paginated (right top of page).

For the whole manuscript, except legends and references, we recommend at most 6000 words, with maximum of 5 tables, 5 figures and 30 references, except for a review.

Manuscript must page break for the following:

- title page (start of manuscript, title of the manuscript, authors with academic titles and addresses, correspondence, running title, five key words, number of words, number of tables, and number of figures)
- abstract (max 250 words)
- introduction (at most 2 pages)
- methodology
- discussion
- conclusion
- tables
- figures
- legends for figures and references.

REFERENCE CITATION

Vancouver style must be used for reference citation and reference writing. In manuscript citing of references must be, as follows

In brief, the citation numbers in Arabic, must be in line with the text (separated in a comma if >1 citation, example: "...in the review (1,5,6) or ...in the review (2-6, 11, 16)," and done chronologically as they appear in the manuscript (therefore not alphabetical); and NO parenthesis. In the Bibliography/List of References, the numbering is based on how the articles were cited in the manuscript. Author(s) appearance/s will be as follows:

-If 1-3 authors: include all.

-If 4-6 authors: only first 3 authors will be cited, and write "et. al."

-If 7 authors or more: only first 6 authors will be cited, and write "et. al."

FIGURES AND TABLES

Use Arabic numeral for figures for tables and figures. Both figures and tables are placed at the end of the manuscript. Tables must be in Word format with informative title related to the data being presented. Figures, charts and images must be in high resolution sent in JPEG. Legends will be separately placed after the references.

DISCLOSURE AND CONFLICT OF INTEREST

Full disclosure of potential conflict of interest of authors and any factor that may inappropriately influence bias in the execution of research and publication of the manuscript must be clearly stated. This must be written at the end of the manuscript after the references.

ACKNOWLEDGEMENT

Recognition of support, source of funding or any assistance in the completion of the research may be cited in this part written at the end of the manuscript after the references.

IX. Research Utilization

A. UST Intellectual Property Policy

1. Introduction

The University affirms research as one of its missions, and thereby encourages its faculty, students and staff to engage actively in the generation of new knowledge through research in the various fields of disciplines. Corollary to this mission, the University is committed to facilitate the dissemination and utilization of the knowledge acquired from research for societal benefit.

It is recognized that doing research may result in protectible inventions/conceptions that will bring benefits to:

- society, in terms of technology transfer and actual application;
- the university itself, in terms of enhanced reputation for excellence;
- the researchers, both faculty and students, in terms of professional advancement and achievements; and
- all three, through potential financial returns through commercialization.

The IP Policy can be viewed from the UST website through this link: <http://www.ust.edu.ph/research/office-for-research-and-innovation/the-innovation-andtechnology-support-office-itso/intellectual-property-policy/>

2. Purpose

The Provisions of this IP Policy have been established to manage and protect intellectual property generated at the University by its faculty, students and support staff, and where appropriate, facilitate its commercialization.

This policy is hence adopted to:

- facilitate patents and other intellectual property applications, licensing and the equitable distribution of royalties, if any;
- facilitate copyright application of forms of literary, scholarly, scientific and artistic creations;
- provide protection of the parties concerned through memoranda of agreement/understanding
- provide guidelines in patent and other intellectual property matters where the university has a right or equity;
- obtain appropriate benefits for the University from transfer of technology or commercial applications or research output and apply funds accruing to the University from such

applications for the support of research and other scholarly activities at the University and for sharing with the individual inventors and creators; and

- ensure that the rights and interests of all parties concerned are fairly established, with full consideration of the proper role of the University and the principles of academic freedom.

This policy shall be interpreted in a way consistent with all applicable Philippine Laws, including Intellectual Property Code of the Philippines (Republic Act No. 8293), the Philippine Plant Variety Protection Act of 2002 (Republic Act No. 1968), the Agriculture and Fishery Modernization Act (Republic Act No. 8435), the Philippine Fisheries Code of 1998 (Republic Act No. 8550), the Wildlife Act (Republic Act No. 9147), the Indigenous People Rights Law (IPRA Law), the Inventor's and Inventions Initiatives Act (Republic Act 7459), the Magna Carta for Scientists, Engineers, Researchers and other Science and Technology Personnel in Government (Republic Act No. 8439), the Administrative Code of 1987 (Executive Order No. 292), and the respective charters of agencies under the University and other relevant laws and their corresponding amendments, implementing rules and regulations.

B. Innovation and Technology Support Office (ITSO)

1. Background and History

The concept of Intellectual Property (IP) has already reached the consciousness of the University. In 2009, the University has promulgated its IP Policy and has established an IP Unit under the Office of the Vice- Rector for Academic Affairs and Research (OVRAAR). The task of the unit is to (1) assist faculty members, support staff and students register any IP that they have developed through the course of their employment or study; (2) inform faculty members, support staff, and students about IP through an on-going IP education program; and (3) be the forerunner in identifying possible IPs for possible commercialization and exploitation. With the numerous researches produced by both faculty and students, there is a wealth of technology waiting to be registered and used for public consumption. IP ensures that as the technologies are being used, the inventors and owners of it are given due recognition by the law.

In November 25, 2010, the University signed a Memorandum of Agreement (MOA) with IPOPhil to host a patent library called an Innovation and Technology Support Office (ITSO). The IP Unit also functions as the ITSO. Last March 22, 2012, the World Intellectual Property Organization (WIPO), headed by Director General Dr. Francis Gurry, and Intellectual Property Office of the Philippines (IPOPhil), headed by Director General Atty. Ricardo Blancaflor awarded the University the Official ITSO Glass Emblem, which signifies that the University is now an ITSO. As an ITSO the University will perform the following:

2. IP Creation by facilitating access to global science & technology information
 - Serve as a patent search facility & library for patent information
 - Provide skills training in patent searching
 - Render patent search services
 - Organize a community of patent information users
3. IP protection by promoting domestic and globally competitive innovations by providing general information on patents & patenting.
4. IP utilization by assisting commercialization of globally competitive innovations
 - Render IP audit and evaluations services
 - Provide licensing support to University Researches
 - Provide advice on IP management and commercialization strategies
 - Be a depository of patent-related documents, papers and statistics.

5. IPO Phil will be with the University throughout the duration of the project.

With the reorganization of research in the University, last November 4, 2012, the ITSO is now under the Office of the Vice Rector for Research and Innovation (OVRRI). This reorganization will further promote increase IP awareness as well as improve the caliber of research outputs made by both faculty and students.

The ITSO has two (2) technical experts and an administrative staff: Prof. Alice M. Aguinaldo, Ph.D., technical expert in the Sciences; Engr. Lourdes T. Baldelomar, MS, technical expert in Engineering; and, Mr. Christopher D. Purugganan, Admin Staff. It is being managed by Assoc. Prof. Michael Jorge N. Peralta, the ITSO Manager and the Executive Assistant for Intellectual Property and Research of the OVRRI.

6. Services Offered

- a. IP Advise: The ITSO offers IP advises to the faculty, students, support staff, or any client, who have developed an innovation, formulated a product, or written a creative work on how to protect their intellectual property.
- b. IP Education: The ITSO can conduct seminar-workshops on the basic intellectual property rights and hands-on training on patent searching.
- c. Basic IP: This module discusses the different Intellectual Property Rights, their characteristics and descriptions. This enhances the capacity of researchers to identify potential IPs that can be generated, protected and registered.
- d. Patent Searching: This module teaches how to use different search engines to look for prior arts in order to establish the novelty and patentability of an invention. It also educates on how to use patent information in relation to research development as well as identifies potential companies who are active in a particular technology.
- e. Patent Search: The ITSO can perform searches for a specific technology to establish its novelty and patentability. It can likewise perform a state-of-art-search which looks into what patents already exist in a particular field of technology. This prevents 're-inventing the wheel' thus saves the time, effort and resources of a researcher.
- f. Patent Drafting: The ITSO can draft patent specifications once novelty and inventive has been established through patent search.
- g. Assist in filing IP rights to the Intellectual Property Office of the Philippines (IPOPhil).
- h. Patent Drafting: Once novelty has been established by the patent search, the ITSO can assist in drafting the patent specifications of a given technology.
- i. Assists in IP filing: The ITSO can assist clients in filing the different kinds of IPs at the IPOPhil.

X: Research Incentives

A. GOLD AND SILVER SERIES AWARDS (2012–2014)

The GOLD AND SILVER SERIES are granted in recognition of the research productivity and leadership of faculty members in their respective fields of specialization within the period covered by the award.

These awards are based on the faculty member's research publications, ongoing research involvement, and tenure in the University.

Gold Series

A. Research Category

1. Tenured full-time faculty member with Ph.D. or M.D. with teaching load and exclusively teaching in UST except for faculty affiliates of the UST Graduate School;
2. Authored at least five (5) research papers published in refereed journals/scholarly books in the last five (5) years, with at least two (2) publications within the period covered by the award, one of which is an international (Thomson Reuters/ Scopus) publication, or has one (1) patent or utility model granted;
3. Or, authored at least two (2) scholarly books in the last five (5) years, with one (1) of these published within the period covered by the award;
4. With ongoing research under the Research Center or Research Unit;
5. And with at least one (1) research disciple*

B. Creative Works Category

1. Tenured full-time faculty member with Ph.D. with teaching load and exclusively teaching in UST except for faculty affiliates of the UST Graduate School;
2. Authored at least three (3) creative or critical works in the last five (5) years, with at least one (1) of these published within the period covered by the award;
3. With ongoing studies (creative projects) under the Research Center or Research Unit of the University

Silver Series

A. Research Category

1. Tenured full-time faculty member with M.Sc. or M.A. exclusively teaching in UST with teaching load;
2. Authored at least three (3) research papers published in refereed journals/scholarly books in the last five (5) years, with at least one (1) published, or has one (1) patent or utility model granted, within the period covered by the award;
3. Or, authored at least one (1) scholarly book in the last five (5) years, with one (1) of these published within the period covered by the award;
4. And, with ongoing research under the Research Center or Research Unit of the University

B. Creative Works Category

1. Tenured full-time faculty member with M.Sc. or M.A. exclusively teaching in UST with teaching load;
2. Authored at least two (2) creative or critical works in the last five (5) years, with at least one (1) of these published within the period covered by the award;
3. With ongoing studies (creative projects) under the Research Center or Research Unit of the University

*Research disciple refers to junior faculty members, graduate students, medical interns, and medical residents

B. INTERNATIONAL PUBLICATION AWARD (2012–2014)

The INTERNATIONAL PUBLICATION AWARD is presented to faculty members for their research productivity, as indicated by the publication of their work in refereed international (Thomson Reuters/Scopus) journals. Full-time faculty member teaching only in UST with research paper/s published, in a peer reviewed international journal with impact factor, or has a completed research project as a chapter of a book released by a prestigious publishing company or its equivalent (Author by-line should indicate the University of Santo Tomas as address in the publication).

XI: Guidelines for Conference Support

1. Eligibility

- A. Regular and probationary (on tenured track) full time faculty members including those with academic and administrative assignment and on **ACTIVE** duty at the time of seminar/conference may apply.
- B. A faculty member must
 - have served the University for at least 4 semesters
 - have an average teaching performance rating of at least “Very Satisfactory” for the past 2 academic years.
- C. A faculty member must present research paper derived from:
 - UST-funded research project conducted at the University Research Center/Unit.
 - Externally funded research project
 - Non-funded research project align to the research agenda of the Faculty/College.
 - Graduate thesis/dissertation defended a year earlier and has the name of the University of Santo Tomas as by-line.
 - Undergraduate theses align to the University/Faculty/College research programs.
 - Faculty member on official study leave with pay is not covered by the support for paper presentation.

2. General Policies

- A. An eligible faculty member shall avail of UST paper presentation support **only once** per academic year, **either for international or national** conferences, even if several of his/her papers have been accepted in different conferences.
- B. Request for paper presentation support shall be made once every Academic year subject to publication of previous presentation in ISI/SCOPUS indexed or CHED Category A Accredited Research journals. Copy of the publication must be attached with the letter of request.
- C. Financial support shall be provided to the presenting faculty member on a paper with multiple UST authors. A UST co-author may be supported subject to approval of the Dean and Faculty Council’s and availability of funds.
- D. Endorsement for travel grant application to Commission on Higher Education is provided by the Office of the Vice Rector for Research and Innovation (OVRRI).
- E. Non-funded or self-funded research paper intended for paper presentation must be align to the Faculty/College research agenda and is subject to review PRIOR to submission to the intended conference. It must secure approval from the Office of the Vice Rector for Research and Innovation for the use of the name of the University of Santo Tomas and for paper presentation support.
- F. Pre-departure expenses such as visa application fee, airport terminal fee and travel tax are of personal expense.
- G. All financial support is subject to UST regulations on disbursement, liquidation and oversight.
- H. No endorsement shall be issued by the OVRRI to papers that were already presented.
- I. Published paper cannot be presented in conferences/symposium etc.
- J. Research paper previously presented cannot be presented again.
- K. Research paper should carry the name of the University of Santo Tomas and use the template of the Faculty of Medicine and Surgery template.
- L. Registration fee will only be given to those who will attend the conference.

3. CONFERENCE SUPPORT:

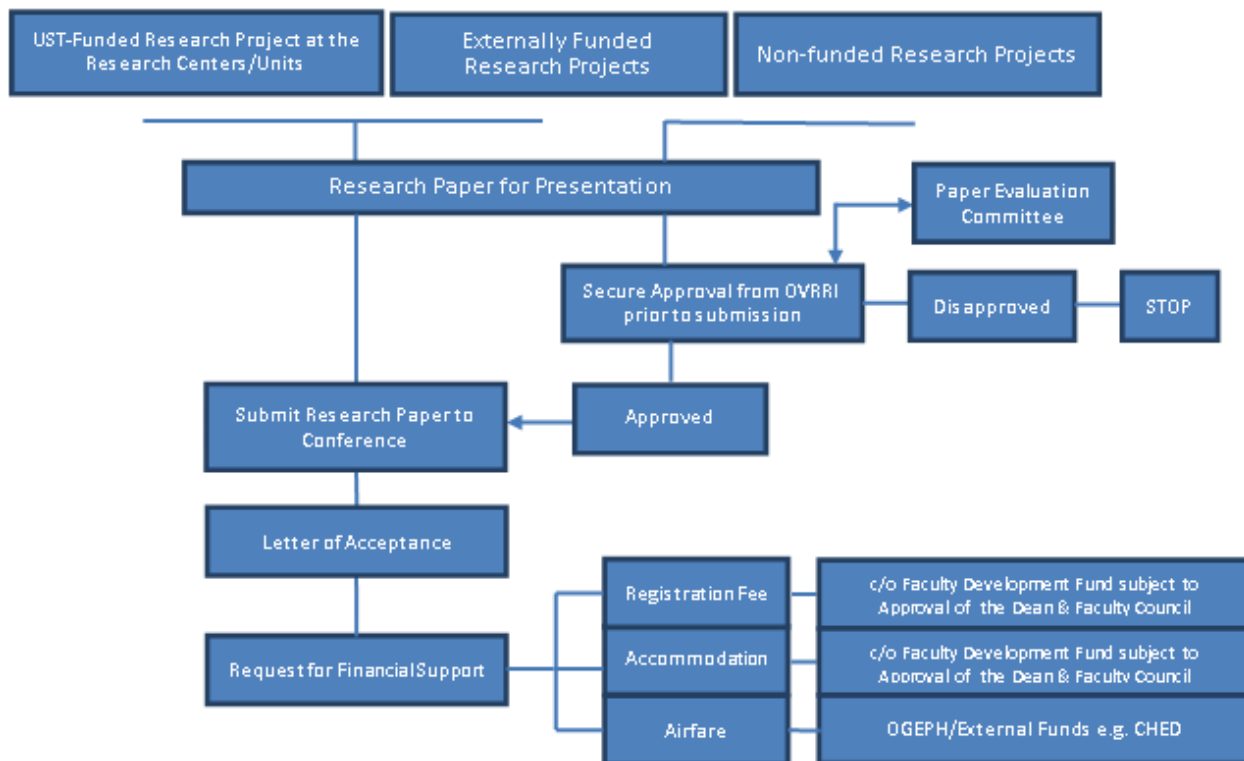
A. International conference

- Conference registration fee and accommodation up to a maximum of *P35,000.00* charged to Faculty Development Fund per Academic Year, subject to availability of funds.
- Conference registration fee, when not waived, at a maximum of P17,500.00 or US\$ 300
- Hotel accommodation, when not waived, at a maximum of *P4,500.00* or *US\$100* per night subject to Dean and Faculty Council's approval and availability of funds. The number of days is based on the duration of the conference plus one day or a maximum of 4 days.
- Return economy class airfare may be requested from the Research and Endowment Fund, Inc. (REFI) under the Office of Grants, Endowment and Partnerships in Higher Education (OGEP), subject to availability of funds. Please refer to REFI Guidelines on Travel Grant.
- Return economy class airfare, to be booked by the University, maybe provided at a maximum of *P35, 000.00* when conference registration fee and accommodation are waived.
- Per diem appropriated for food, local transportation and communication expenses may be provided when either conference registration fee or accommodation is waived. The number of days is based on the duration of the conference plus one day or a maximum of 4 days.
- Additional support up to a maximum of *US\$100*, maybe provided by the research center to affiliate faculty member presenting a paper in an international conference upon approval of the Research Center/Unit Director subject to availability of funds. The additional support shall be based on the productivity, performance, and active involvement of the faculty member in all research-related activities.

B. National Conference

- Conference registration fee and accommodation at a maximum of *P12,000.00* charged to Faculty Development Fund per Academic Year, subject to availability of funds.
 - Conference registration fee, when not waived, at a maximum of *P6,500.00*.
 - Hotel accommodation, when not waived, at a maximum of *P1, 500.00* per night subject to Dean and Faculty Council's approval and availability of funds. The number of days is based on the duration of the conference plus one day or a maximum of 4 days.
- Return economy class airfare, to be booked by the University, maybe provided at a maximum of *P10, 000.00* when conference registration fee and accommodation are waived.
- Per diem appropriated for food, local transportation and communication expenses maybe provided when either conference registration fee or accommodation is waived. The number of days is based on the duration of the conference plus one day or a maximum of 4 days. Per diem rate will be parallel to the rates implemented by the REFI and the Office of the Treasurer.

4. CONFERENCE SUPPORT process flow



IV. Documentary Requirements

- A. Letter of Request or accomplished application form recommended by the Dean/Unit Head.
- B. Abstract of the paper accepted for presentation
- C. Acceptance Letter or Letter of Invitation
- D. Conference flyers
- E. Copy of program
- F. Itemized budgetary requirements

V. Obligations of the Grantee

- A. Publication in ISI/SCOPUS indexed or CHED Category A Accredited Research journals for papers presented in an international conference.
- B. Publication in peer-reviewed national/international journals for papers presented in a national conference.
- C. Liquidation of financial support given subject to UST regulations on disbursement, liquidation and oversight.
- D. Submission of name and information of three new contacts established during the conference.

