



Yekatit 12 Hospital Medical College Research and Publication guideline and procedures

December, 2023

Addis Ababa, Ethiopia

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Research Guidelines and Procedures, Yekatit 12 Hospital Medical College

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Abbreviation

IRB: Institutional Review Board

PI: Principal investigator

Y12HMC: Yekaitit 12 Hospital Medical College

RERC: National Ethics Review Committee

RPO: Research and Publication Office

RPC: Research and Publication Committee

SET: survey, Experiment and Trial

1. Introduction

Yekatit 12 Hospital Medical College, abbreviated as Y12HMC, was established in 2004 E.C. Y12HMC is located at Addis Ababa, the capital city of Ethiopia, in Arada- sub-city and working under the supervision of Addis-Ababa Health Bureau. Currently, the college is organized into different departments which provide quality education and health care services in diversified fields of area ranging from undergraduate to master/ speciality level in regular and extension programs. Y12HMC is one of the fastest growing Medical and health sciences college in Addis-Ababa college the college has set its core responsibility with focus on producing competent, compassionate, and caring health workforce and healthcare leaders through excellence in system oriented teaching, patient care and problem solving medical research and community service. In according to core vision excellence in system oriented medical education and models in medical education ethics and quality medical research.

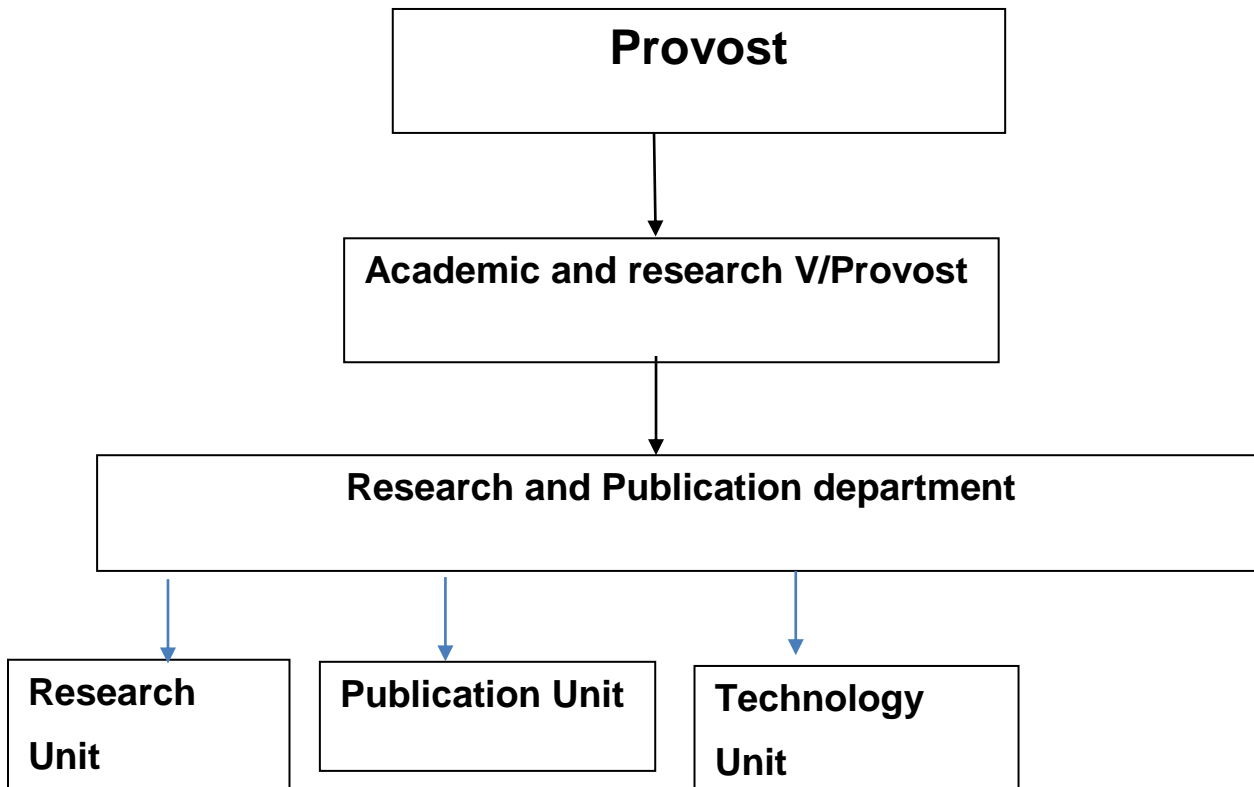
Within the context of academic institutions, it is evident that quality and relevant research contributes significantly to the search for excellence and to the ongoing efforts to ensure quality learning and teaching with the ultimate goal of cultivating and nurturing the new generation for the future of Ethiopia. The significance of research for changing the lives of the immediate and wider communities and improving their wellbeing is beyond doubt. Research projects initiated by the college can often yield very useful findings with direct bearings on policy initiatives, generation of new development insights, application of technologies and innovations, and ultimately on the quality of life of our citizens.

The major goals of the research and publication guideline are to enhance the research visibility of the college, to maximize the relevance and usefulness of its research programs and to determine the procedure and financial administration of research in Y12HMC.

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2. Organizational structure of Research and Publication office, Y12HMC

- i. The research and publication office is accountable to Academic and Research vice Provost of the college.
- ii. The research and publication office shall have Institutional Review Board and research & Publication Committee.
- iii. Under research and publication department there will be research, publication and technology transfer department



3. Accountability, Roles and Responsibilities of Different Functional Unit

3.1. the Research and Publication Office

Accountability: The Research and Publication Office is accountable to the academic and research vice provost

Appointment and terms of the RPO coordinator

RPO head appointment will be by competition with vacancy announcement every two years

The term of office of RPO coordinator shall be two years with possible extension for one more consecutive term

Roles and responsibilities:

- i. Supervise the overall research activities of the college
- ii. Prepare and submit action plan of research and publication to the college's Academic and Research Vice Provost;
- iii. Specify the calendar for submission of research proposals and research reports;
- iv. Supports the teams and other resourceful individuals to conduct research activities;
- iv. Directs and administers the research and publication activities;
- v. Designs ways and means of securing funds from external sources to undertake research and teaching material production
- vi. Set guidelines for the approval of research proposals
- vii. Prepare code of ethics governing/safeguarding research and intellectual property rights
- viii. Works with the college management, research and publication senate committee, chief librarian and information communication technology unit to have network of global information and access to newly introduced educational technology
- ix. Participate in appropriate academic and administrative committee of the college;
- x. Advise the academic commission on all matters pertaining to research and publications;

3.2. Research Unit

Accountability: Research unit is accountable to the Research and Publication Office

Roles and responsibilities:

- I. Prepare and submit progress reports of its activities as demanded by the college;
- II. Monitor the progress of research funded by the college
- III. Coordinate and facilitate the activities of research approval committee Establish award system for recognizing outstanding research;
- IV. Promote the publication of outstanding theses and dissertations;
- V. Issues internal regulation on procedures of its own meeting;

3.3. Publication unit

Accountability: Publication department is accountable to the research and publication office

Roles and responsibilities:

- i. Collect different published research and placed in the college library
- ii. Collect and facilitate different published research from international journal to be read by the academic staff
- iii. Ensure and facilitate the accessibility of publications such as: Bulletins, newsletters, proceedings, journals and other printed educational materials relevant to the college community;
- iv. Facilitate college approved research to be publish in different journal

3.4. Technology transfer unit

Accountability: Technology transfer unit is accountable to the Research and Publication Office

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Roles and responsibilities:

- i. Transferring research finding of the college by using different platforms: conference, seminars
- ii. Organize and facilitates workshops, symposia and seminars;
- iii. Coordinate with stakeholders to transfer new technology
- iv. Provide leadership for the development and adaptation of appropriate technology to significantly the improvement of the livelihood of community

Responsibilities of the research and publication office for ethical review

- i. Receives applications from applicants;
- ii. Makes preliminary screenings to ensure completeness of application;
- iii. Distributes proposals to all ethics committee members;
- iv. Calls regular and extra-ordinary meetings in consultation with the secretary of IRB;
- v. Communicates decisions of IRB to the applying institution with a copy to the principal investigator;
- vi. Documents all project related proposals, correspondences, decisions and minutes of IRB;
- vii. Receives periodic progress reports from investigators;
- viii. Facilitates registration and accreditation of IRB by national ethical review committee;
- ix. Establishes networking among all IRBs, NERC, and RERCs;
- x. Effects and facilitates monitoring and evaluation of ethical implementation of projects;
- xi. Organizes and conducts research ethics trainings at Institutional levels; and
- xii. Manages and facilitates all official correspondences of NERC

4. Committee and council

4.1. Research and Publication Committees

The college research and publication office works with 2 committees, both committees directly work with ARVP administratively and functionally with RPO

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1. Institutional Review Board (IRB)
2. Research and publication Committee (RPC)

xi. Research and Publication Committee (RPC)

The committee is a senate standing committee and composed of representatives of college management bodies, academic staff and librarian. The representatives will be elected by department and approved by academic and research vice provost

Members of the committee and respective responsibilities

AVP (Chairperson)

ADVP

One representative of Academic Units

Two senior researchers designated by the senate

College Librarian

Director for research and publication (Secretary)

Duties and Responsibilities PRC

- i. Formulates policies and strategies that foster research undertakings in line with national research priorities and for the development of science and technology. The Committee may involve concerned departments/institutes or resource persons in these processes.
- ii. Develop guidelines for implementation of research policies and strategies of the College;
- iii. Ensure coordination of research undertakings of the College in collaboration with the academic units.
- iv. Assists each Academic Unit in its efforts to secure grant or fund for research and development.

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- v. Establishes policies and procedures for visiting research scholars from other universities/colleges who seek formal association and collaboration with, and sponsorship, with the College.
- vi. Establishes and provides guidelines for technical committees which screen projects when deemed necessary.
- vii. Suggests to the Senate feasible options, including incentive to encourage the Academic Staff members to undertake research & development, and publication activities.
- viii. Reviews and recommends to the Senate the establishment and termination of research projects.
- ix. Ensures that certain minimum standards are maintained by all publications of the College.
- x. Organize and facilitate annual research conferences
- xi. Monitors and evaluates the research & development activities of the College.
- xii. Determines its own rules of procedures.
- xiii. Advise the senate on all matters pertaining to research and publication and performs any other duties as may be required.

4.2. Institutional Review Board (IRB)

The committee shall have members which includes research and publication coordinator and members selected from different programs and teams based on their research experience and educational background. The members shall be professionals from different academic backgrounds and one member from the community. The number of technical committee will be 7(seven) in number.

Members of the committee

- Research and Publication Office coordinator-----Chair person
- One among the IRB members-----Secretary
- Other selected academic staffs-----Members

Appointment and terms of the IRB members

- The IRB members shall be first select and nominate by department and then Academic Commission shall approve the appointment
- The term of IRB members shall be two years with possible extension for one more consecutive term

Duties and responsibilities of institutional review board members

The IRB shall have the following duties and responsibilities

- a. Evaluate and review research project proposals and teaching materials;
- b. Ethical review of research proposals;
- c. Send research proposals and teaching materials to external reviewers for review whenever needed;
- d. Send research proposals and teaching materials for funding and facilitate linkage with funding agencies;
- e. Identify thematic area for research and forward for the college research approval committee via research and publication coordinator for approval;

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- f. Monitor and evaluate research activities being effective;
 - g. Take part in dissemination of the research result;
 - h. Prepares and reviews terms of reference for research and teaching material qualification and ranking;
 - i. Build linkages with research institutions;
 - j. Prepare minutes for the committee and keep as record; and
 - k. Perform other duties to facilitate research activities in the college.

N.B. The committee shall use the FDRE Ministry of Science and Technology's National Research Ethics Review Guideline for ethical review.

5. Application and Review process of research proposals

The research process includes activities that pass through a series of steps in order to receive permission and funding to go ahead with a proposed research project. This process includes pre-award, post-award and termination phases.

5.1. Research thematic areas

Research and publication office in collaboration with other stakeholders shall develop n a research thematic area for the college with the consideration of the college's mission, vision, goal, strengths, and priorities and the national focus/priority areas. The office will perform the following activities to identify the thematic areas of the college:

1. Assess the national and the college Goals
2. Review Existing Research priority areas and practice
3. Conduct need assessment and analysis the current healthcare landscape
4. Engage Stakeholders
5. Prioritize Research Themes

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The college regularly reassesses and adapts the research thematic areas yearly to keep pace with scientific advancements, emerging healthcare needs, and institutional priorities. Engage in ongoing dialogue and collaboration with stakeholders to foster a vibrant research environment within the college.

College research thematic areas are:

1. Maternal, Neonatal and Child Health (MNCH),
2. Non-communicable Chronic Disease (public health important: Cardiovascular disease, DM, CKD, Asthma, Mental health, Cancer),
3. Communicable Disease (Tuberculosis, HIV/AIDS, Hepatitis B & C, Hospital acquired infection and other emerging Disease (COVID-19),
4. Health Care system development,
5. Burn, Trauma, Orthopedics disorder, operative and post-operative challenges and complication
6. Therapeutic and non-Therapeutic Drug uses (Drug Adherence, rational drug use, Drug resistance.

5.2. Conditions to initiate a research project

The following issues shall be considered, while developing/initiating project proposals,

- a. Research initiation shall be set based on the thematic and priority area of the colleges and priority for selection will be given to research proposals that have an effect on college service quality of care.
- b. All research grants applications shall be made following the format for application of research grant (Annex 1).
- c. The guideline for preparing proposal assisted by external sources shall be in line with the format of Y12HMC for proposal writing & the funding agency if available.

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5.3. Research proposal submission, review and declaration for funding

Guidelines to submit new project proposal for review and declaration of fund are:

- 5.3.1. There shall be calls for funding research on a competitive base in the month of July to September every year. The submission of research proposals shall be due three months after the call is posted.
- 5.3.2. Call for research proposals shall be announced by the Research and Publication office of the colleges.
- 5.3.3. Research proposals shall be submitted both electronically and in hard copy to the Research and Publication office of the colleges.
- 5.3.4. A research grant application shall not be considered from a person who is already receipt of a grant, unless and until which time the IRB has accepted a satisfactory progress report (reporting every six month based on the format and for allocated period) (**Annex 9**) for ongoing projects but the new submission from co-investigator can be consider by IRB
- 5.3.5. Research proposals presented by a single researcher shall not be accepted. The proposals should be prepared and submitted by two or more researchers to compete for funding.
- 5.3.6. The research project shall be evaluated based on guidelines for evaluation of research proposals (as stated in **Annex 3**).
- 5.3.7. The researchers shall present their proposal in open defense and the comments from the open defense shall be used as input in the decision to approve or reject the research proposal. No proposal is approved without research open defense for treasury funded projects.
- 5.3.8. The IRB will review all proposals presented in an open defense. In the case of a proposal being beyond the profession of a review board, expert(s) in the field –
- 5.3.9. shall be invited to join the team in ad-hoc bases for the specific project.
- 5.3.10. If ethical clearance is required to approve and run a project, the proposal could be administered based on guidelines as stated in **Annex 4**. The feedback from IRB shall be completed in one month's time from the final date of submission.

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- 5.3.11. The IRB shall complete the review process in consideration of Ethical and Technical matters of the proposal.
- 5.3.12. The IRB shall give its findings in writing directly to the researchers. The findings could be one of three responses: Approved, approved on conditions or rejected.
- a. Approved
 - b. Approved on conditions: If it needs *modification* the researchers shall submit the amended research proposal within 10 days, from the date on which comment was delivered. The complete proposal including adjusted modifications will be submitted to the colleges RPO coordinator.
 - c. Rejected: If the research proposal is *rejected*, the PI can request an oral or written clarification. If the researchers are not satisfied with the decision, they can appeal to the research and publication office studies. The director, upon review of the proposal will return to the research and ethical review board committee with recommendations or endorse the rejection. This is the sole method of appeal for rejected proposals.
- 5.3.13. The IRB shall check whether comments have been properly included. The board shall provide a certificate for incorporating the comments and recommend for registration of the research project.
- 5.3.14. The research and publication office issue a certificate of funding to the winning researchers and will send to ARVP for approval
- 5.3.15. The research grant will be released in two phases.
- 5.3.16. Phase I: 50% of the total fund requested will be released at the beginning of the project
- 5.3.17. Phase II: 50% of the total fund requested will be released following progress report submission which contains detailed activities conducted

5.4. Research proposal registration and publicity

- 5.4.1. There shall be entry workshops to inform and publicize the initiation of the research project (treasury and externally funded projects) or the projects that have been approved shall be made public to the college community.
- 5.4.2. There shall be a signing of project contract between researcher and Colleges/institutes/college using appropriate format (**Annex 5**).

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- 5.4.3. Collaborative research and research funded outside Y12HMC shall be registered and agreement shall be signed between PIs, donor and Y12HMC indicating the role of each parties, benefit sharing, and equipment ownership and patenting issues based on the guiding principles as stated in **Annex 6**.
 - 5.4.4. The research projects (external or internal funded) shall be registered at Y12HMC and given a serial number indicating colleges/institutes code, department code, registration year and project number **Annex 7**).
 - 5.4.5. The Research and Publication office coordinator shall submit the approved research project to ARVP for financial process and facilitate the finance the implementation of the project with all concerned units.

5.5. Research funding and follow up

- 5.5.1. Research funding shall be in two phases. The researcher shall be given half of the research funds allocated for the running and expendable costs in the first phase to operate the SET (survey, experiment and trial). The remaining fund shall be released based on the proper conduct of the SET half way between the duration of the project, as indicated in the proposal, when the progress report is approved by office of the research and publication office the college.
- 5.5.2. IRB shall arrange periodical monitoring and evaluations (M&E) of the project to know that the research is properly handled as planned in the research protocol. These M&Es are also an opportunity for the review boards to provide appropriate technical assistance to the project if needed (**Annex 8**).
- 5.5.3. The office of the research and publication office shall carry out an interim, post-evaluation or a monitoring mission. The researchers shall provide any document or information, including access to research protocol, to assist with the evaluation or monitoring mission and evaluation.
- 5.5.4. The M&E shall be done in a form of field visits, quarterly progress and terminal reports to ensure proper research conduct, as per the research protocol.
- 5.5.5. Once a research project is approved by the IRB and budget is secured, the researcher cannot change the place of work, work plan, methodology or objective of the study

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unless he/she informs the IRB in writing and the change is approved in writing from the board.

- 5.5.6. Research and publication office coordinator and other responsible bodies shall hold Annual or bi-Annual scientific conferences where results of research activities in all departments will be presented.
- 5.5.7. If a PI should leave Y12HMC, without completing his/her research work, he/she should delegate a co-investigator who can act as PI until the original PI returns.

5.6. Reporting of research progress

- 5.6.1. The PI shall submit a quarterly and terminal report that includes all technical and financial information regarding the research.
- 5.6.2. The PI shall produce a brief progress report (technical and financial) to get second round research funding using the appropriate format (**Annex 9**).
- 5.6.3. The PI funded by external sources is also obliged to present progress and terminal reports following appropriate format (**Annex 9**) or using a format developed by a funding agency. These reports shall be submitted to and reviewed by the Y12HMC Institutional Review Board.
- 5.6.4. The progress report shall be reviewed and evaluated by the research coordinators and Institutional Review Board based on the guidelines for reviewing (**Annex 10**).
- 5.6.5. The terminal report (including technical and financial information) shall be reported for evaluation and documentation using the appropriate format (**Annex 11**).
- 5.6.6. The terminal report shall be reviewed and evaluated by the research and Institutional Review Board or invited reviewers based on the guidelines for reviewing (**Annex 12**).
- 5.6.7. The feedback from the IRB on progress and terminal reports shall be communicated to the PI to accommodate comments and then submitted to the senior director or college's research and research and publication office coordinator.
- 5.6.8. Recommendations for continued funding of projects or the acceptance of the terminal report depends on previous satisfactory receipts of progress and quarterly reports as judged by colleges/institutes research and ethical review board or research and

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publication office. The externally funded projects which are accepted by the funding agency could be accepted for a continued funding.

- 5.6.9. The PI shall submit to the colleges/institutes three bound copies of the final result (terminal report) and settle financial matters. Failure to submit these documents may result in, the denial of future grants and the research will be denied clearance when leaving the college in any manner (scholarship, transfer, pension, etc).
- 5.6.10. The terminal report shall be registered and information shall be made public to staff, students and stakeholders.
- 5.6.11. In order to keep track and records of research activities at Y12HMC, projects funded by other funding agencies will also be required to submit terminal and progress reports to the respective colleges/ Research and publication office.
- 5.6.12. The PI shall acknowledge the financial assistance from the college or any other source and include this acknowledgment in an appropriate position in all related published works.
- 5.6.13. PIs failing to submit progress or terminal reports within one month for treasury funded projects after the required time of reporting will be notified (warned) by research office and then obliged to refund all funds used or supposed to have been used during the research period.
- 5.6.14. The research projects shall have a period to accomplish the project. The researchers have gone beyond the research period without justifiable reason will not have this work recognized as part of their research load. No extra funding or load extensions shall be given for a research project that has been extended without justifiable cause.
- 5.6.15. A project extension is allowed when there is justifiable reason and it is approved by the colleges/institutes IRB or research and publication office. The researcher should apply one month prior to the requested extension to allow time for processing and approval.

5.7. Exit mechanism of projects

- 5.7.1. The vehicles, equipment, chemicals and documents born from the research project shall be transferred to the department/college at the completion of the project to ensure the sustainability and support of research, the teaching and learning efforts of the college.
- 5.7.2. The Vehicle which are not bought in the name of the College, shall be decided by the pre-agreement made between the funder and the college as stimulated in the project document
- 5.7.3. The findings of the research projects upon project completion shall be presented to the appropriate research venue or to the annual research conference.
- 5.7.4. Any publications from the research project shall be registered, displayed and deposited in the respective college library. The publications that may arise from the research project shall be submitted to the research and publication coordinators deposited in the College library
- 5.7.5. The experience from the research project shall be documented and passed to the appropriate academic unit and serve as a learning ground.

5.8. Administration and management of research funding

Background: The PI is responsible in managing projects including: management of the project within the funding limit, adherence to reporting requirement, and assurance of the demands of sponsor. Y12HMC financial regulations will be notified when significant changes have been made to the project. The research fund shall be used effectively and efficiently and adhere to the following procedures:

- 5.8.1. Grants solicited by researchers, departments or college and non-treasury grant sources will be charged a flat rate of 20% of the total grant to meet overhead costs (expenses not immediately associated to goods and services) when it is appropriate.
- 5.8.2. The overhead cost will be used to cover administrative costs, to provide incentive for researchers, and to promote research capacity of the college.

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- 5.8.3. The PI is responsible for fiscal management of the awarded projects, including but not limited to the regular monitoring of the project budget throughout the life time of the project.
 - 5.8.4. Expendable items and compulsory expenses that happen in the field shall be available within two months of request to the researchers or the researchers shall be provided with cash to buy the expendable and compulsory expenses subject to liquidation in two phases.
 - 5.8.5. The research coordination office shall allocate purchasers dedicated to providing supplies to make sure the research inputs are timely availed
 - 5.8.6. Non-expendable items shall be purchased by college property management and be available to the research work within two months since request has been presented to the colleges.
 - 5.8.7. Y12HMC shall make available some expendable items (equipment, chemicals reagents, drugs, and stationery materials) which can be deducted from the project's budget to ensure that the researchers have access to the items on time.
 - 5.8.8. Y12HMC shall also outsource some expendable items and laboratory equipment to ensure the availability of the items on time.
 - 5.8.9. The researcher shall strictly adhere to the cost breakdown indicated in the approved project document. The transfer of moneys from one budget heading to another is not allowed unless the project gets permission from the colleges/institutes research and ethical review board or the funding agency.
 - 5.8.10. In cases when budget shortage may arises which hinders the progression of the activities, the investigator shall apply to the colleges/institutes research and ethical review board with concrete evidences and the board may allow for a maximum of 10% of a project budget heading to be transferred to the requested budget heading.
 - 5.8.11. Revenues generated from research activities, such as sales of research produce, shall be the revenue of the colleges and they will be used solely to enhance research.
- Y12HMC shall commit 10% of the research budget, such as treasury and internal revenue, to be distributed as annual research grants, training to improve research competitiveness and dissemination of research output.

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- 5.8.12. If, for any reason, a research project is discontinued and if the work is not properly carried out within the planned time table, the researcher is required to return all fixed assets purchased to run the project and the unutilized money to the college. All equipment purchased through research grants shall be the property of Y12HMC and must be returned to the college upon completion or termination of the project.
- 5.8.13. Equipment bought through college research grants or external sources (vehicles, equipment and any supplies) are the property of Y12HMC and shall therefore be entered in to the appropriate college record/ledger book.
- 5.8.14. Mega projects that have involved two or more departments shall have a project coordinator and an interdepartmental project implementation team. This coordinator and team will be supervised by the research and publication office.
- 5.8.15. Mega projects are externally funded project or thematic research project /program that involve more than 5 researchers and acquired more than 500,000 Birr. The researcher can acquire the fund from two or more projects
- 5.8.16. Projects shall be funded with no budget ceiling provided that the project has been properly planned and the research project activities are relevant to be funded. The researchers shall produce current price quotations for each of the project budget items allocated to the research activities.

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6. Engagement of staff in research, reward and remuneration mechanism

Background: A primary mandate of Y12HMC is to encourages staff and student research by ensuring that staff and students involved in research are rewarded materially and morally within the context of ‘scientific professionalism’. Placing a rewarding mechanism shall improve the quality of research and raise research culture contributing to the overall promotion of Y12HMC as a renowned research college. To do this, Y12HMC should adopt and mainstream different modalities including making research parameters part and parcel of various human resource development policies, setting and implementing enabling regulations and guidelines and providing rewards and recognition for outstanding, innovative, young and women researchers. This shall be addressed through adopting the following procedures:

6.2. Engagement of staff in research

- 6.2.1. All research staff should devote 62.5%, 25% and 12.5% of their work load in research teaching and community services respectively, as stipulated in senate legislation.
- 6.2.2. All academic staff should devote 20 % of their work time towards research and 40% and 40%% of their work time towards teaching and medical services as stated in senate legislation.
- 6.2.3. The academic and research vice provost of the college shall ensure that all staff of the college is fully involved in the research and maintains a good balance between teaching, research and community services.
- 6.2.4. The academic and research load of staff is as stipulated in senate legislation. If a staff member is not involved in research or not supervising research projects of post graduate or no justifiable reason not to initiate research projects, a letter of warning will be sent to academic and research vice provost for consultation and the provost can terminate the contract of any staff not abiding after two warnings.
- 6.2.5. The recruitment of expatriate staff shall also consider the research experience, merit and capacity of candidates for research to realize the research objective of the college.

6.3. Research allowance and load

- 6.3.1. Payment of subsistence allowance/per-diem to researchers shall be in line with the budget specified in the research grant and/or as agreed upon by the funding agency and Y12HMC.
- 6.3.2. Salary and per diem for research supportive staff shall be based on the pay list specified in the approved proposal by funding agency and Y12HMC.
- 6.3.3. The salary, per-diem and other payments shall be based on the financial regulation of the government for research projects funded by the Y12HMC
- 6.3.4. The members of Y12HMCstaff conducting research are not paid salaries from their research grants. However, there shall be summer payment from the research budget approved by the funding agency when a researcher is engaged on research work during their summer vacation period.
- 6.3.5. Researchers' credit load evaluation shall be made by considering the role of the academic staff in the respective project as well as the nature and time requirements of the research project. The workload for research will be implemented in consideration with **Annex 13**.

6.4. Reward, remuneration and recognition mechanism

- 6.4.1. Staff and students in a team or individual bases involved in research with outstanding research performance and merit will be awarded during the annual research symposium day or other venue as determined by the research and publication office.
- 6.4.2. The reward scheme shall, highlight four aspects of the Y12HMCresearch community: one best researcher in the college, one best female researcher in the colleges, one best department in running research in a college and one best PG student that has completed research in a college.
- 6.4.3. The application and nomination procedure for awards is indicated in a guideline (**Annex 14**).
- 6.4.4. The research reward shall be based on the relevance of research projects and the quality of research outputs (**Annex 15**).
- 6.4.5. The college IRB shall evaluate and select the outstanding researchers at college level to be rewarded during annual research conference and the best nominees in each

category will be presented to the college academic and research vice provost for final approval.

- 6.4.6. The awards shall be recognition certificates for the researcher. They will also provide material and financial rewards to enhance research culture **Annex 16**).
- 6.4.7. The academic/research staff with outstanding research merit shall also be sponsored to attend national conferences or sponsored to participate on local research related training (**Annex 16**).
- 6.4.8. The college shall also consider an extra-ordinary academic promotion to any of the academic ranks having successfully published in reputable journals (**Annex17**).
- 6.4.9. The award shall consider research outputs recorded in the previous budget year (From Hamle 1 to Sene 30 in Ethiopian Calendar)
- 6.4.10. Researchers involved in the critical reviewing of research proposals and reports (progress and terminal) shall be offered incentives. The incentive modalities are detailed in **Annex 18**.

5.5 . Follow up

All ethically approved projects should be followed to monitor the progress. The follow up review shall be done in the following manner:

- i. Ethics approval is valid only for one year; therefore, if the project life is more than one year, renewal application should be submitted to the Research and Publication Office for approval with full progress report and justification
- ii. Any amendment in the proposal such as methodology, study area, objectives etc, should be reported to the research and publication office and obtain approval from the IRB
- iii. Serious and unexpected adverse events related to the conduct of the research shall be immediately reported to the research and publication office; and
- iv. In case of premature suspension/termination of a study, the investigator should notify the research and publication office including the reasons and a summary of the results obtained.

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6.5. Responsibility and Accountability of Researcher, Host Institution and Donor/Sponsor

Researcher (s)

- 6.5.1. Adherence to basic ethics principles; and
- 6.5.2. Shall possess appropriate scientific and human ethics standards

Host institution(s)

- i. Ensure(s) that the study design is scientific and ethical;
- ii. Ensure(s) ethical implementation of the study;
- iii. Facilitates/provides support for ethical execution of the study;
- iv. Make sure that the result is properly disseminated;
- v. Ensure(s) that guidelines, principles of Ethics and related materials sent by the Research and Publication Office of IRB reach researchers;
- vi. Comply with local ethics regulation and legal requirements; and
- vii. Provides periodical report of ethical implementation of the project to the research and publication office.

Donor(s) sponsor(s)

Donors/Sponsors are responsible for providing an environment that promotes integrity, objectivity and the highest ethical standards of research, including standards for design, implementation and reporting. Particularly, sponsors must commit to protect the participants in all research studies. Sponsors can accomplish these goals in several ways:

- i. Ensure appropriate review, approval and supervision by an IRB;
- ii. Monitor the research according to a plan approved by the IRB;
- iii. Select qualified researchers and institutions;
- iv. Provide policies and procedures to all researchers before the research is initiated;
- v. Comply with the local ethical, regulatory and legal requirements;

-
- vi. Ensure the local relevance of the research by involving local partners in the development stages;
 - vii. Promote research integrity;
 - viii. Financing the study;
 - ix. Ensuring the safety and efficacy of investigational products if applicable;
 - x. Ensuring the investigational products to be manufactured following good manufacturing practice if applicable;
 - xi. Supplying and handling investigational products;
 - xii. Updating investigator's brochure as significant new information are made available;
 - xiii. Assigning clinical monitors if applicable; and
 - xiv. Providing insurance to study participants in case of injury.

Networking

IRB shall create networking among ethics review committees in the country especially with RERC and NERC for:

- i. Establishing strong data base system;
- ii. Facilitating coordination;
- iii. Building capacity and strengthening partnership among Ethics Review Committee;
- iv. Sharing of experiences;
- v. IRB establishes network with Regional, Institutional and National review committees shall basically include: activities performed, problems encountered, etc.;
- vi. IRB receives guidelines and other related information from RERC/NERC for updates on Ethical Review;
- vii. Ethics Review Committees IRBs shall send reports to RERCs biannually; and
- viii. For urgent matters IRB could seek information or technical help from NERC/RERC any time through its research and publication office.

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Information to investigators

An individual or group of staffs from the college is/are eligible to carry out any research project and have access to available facilities provided that he/she/ has got approval and ethical clearance from the college.

Investigators Mandate

- viii. In any case the principal investigator should be staff of the college;
- ix. The college encourages group research projects;
- x. An author of a research should have at least a Bachelor's Degree or above with relevant research methodology courses; all the principal and co-investigators are required to attach their CV with the project proposal; and
- xi. A Principal investigator should not submit more than one proposal at a time.

6.6. Roles, Responsibilities and obligation of principal Investigator

The principal investigator has

- i. Primary responsibility for the design; management, conduct, analysis and reporting of the study to the standards set out in the Research Guideline of the College;
- ii. Responsibility for coordinating the investigators who take the lead at each site involved in the study;
- iii. Responsibility for ensuring that research is conducted to an agreed proposal; the sponsor of the research and employer of the principal investigator are accountable to ensure this;
- iv. Principal investigator must ensure that research is carried out in accordance with the Research Governance and Research Guidelines of the College;
- v. Research proposal submitted to the Research and Publication Office should be original work and should be signed by the principal investigator;
- vi. Responsibility for submission of timely progress, final and financial reports according to the time schedule set by the IRB; and

-
- vii. Research projects that breach health ethics and or research ethics shall be liable to discontinue the research progress; without immediate corrective measures the principal investigator will be accountable for reimbursement of the research grant.

6.7. Conduct of the study

- 6.7.1. The research is conducted to high ethical standards;
- 6.7.2. The study is conducted according to a written protocol. The investigator will be fully conversant with the details of the study protocol, devices and procedures used in the study, and are satisfied that the objectives of the study are appropriate and the methods used are valid;
- 6.7.3. Each member of the research team, including data collectors, is qualified by education, training and experience;
- 6.7.4. Delegation of duties and responsibilities is formally recorded and reported;
- 6.7.5. Researchers have adequate supervision, support and training;
- 6.7.6. Arrangements are made for the management of financial and other resources provided for the study; and
- 6.7.7. All data and documentation associated with the study are available at the request of the internal or external inspectors or auditors.

6.8. Participant's involvement

- 6.8.1. Participant dignity, rights, safety and well-being are given priority at all times;
- 6.8.2. When the study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care;
- 6.8.3. When the research involves a social care service user or caregiver or child, looked after or receiving services under the auspices of the local authority, the agency director or the deputy agrees to the person (and/or their caregiver) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information; and

.....

- 6.8.4. Unless participants or the relevant Research Ethical Clearance Committee specify otherwise, participants' care professionals are given information specifically relevant to their care that arises in the research.

6.9. Data collection, analysis and publication

- 6.9.1. Procedures are in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage; Arrangements are made for the appropriate archiving of data when the research has finished;
- 6.9.2. Reports on the progress and outcomes of the work required by sponsors, funders and IRB are produced to time and to an acceptable standard;
- 6.9.3. Findings from the work, once critically reviewed through accepted channels, should be disseminated promptly and fed back as appropriate to participants; and
- 6.9.4. The investigator plays a key role in detecting a preventing scientific misconduct by adopting the role of guarantor on published outputs. `

6.10. Breach of agreement

Breach of agreement may be if the principal investigator,

- i. Utilization of the fund granted partially or wholly for purposes other than what is stated on the project document;
- ii. Failure in submission of progress, financial and final report; and
- iii. Failure in presentation of the output for the college community.

The undersigned has read and agree to accept role, responsibilities and obligation for the scientific, ethical and technical conduct of the research project and provision of required progress reports as per terms and conditions of the RPO of Yekatit 12 Hospital Medical College and did not submitted the project proposal elsewhere for financial support.

Name of investigator(s) ----- **Signature** ----- **Date** -----

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7. Financial Management

The college has recurrent seed money for research and publication activities. Other stake holders for research grant are Addis Ababa City Administration Health Bureau, other governmental and non-governmental organizations.

A researcher upon obtaining research grant from external source is required to fill the college grant data sheet approved by the Research and Publication Office.

This entitles the researcher to obtain financial, procurement and personnel service from the college.

7.2. Types of research project funded by Y12 HMC

7.2.1. Small scale research project

7.2.2. Grand research project

7.2.3. PhD student support research project

7.2.1. Small scale research project

- i. 50% of the research fund will be assigned for small research project
- ii. The maximum research budget allocated for small scale research project is 200,000 Ethiopian birr and the maximum reporting period are 2 years
- iii. These research project shall be based on already identified research thematic area
- iv. Under this research a minimum of two researchers from different principles/profession should be member

7.2.2. Grand research project

- i. Grand research project includes compressive and multidiscipline research project
- ii. 50% of the research fund will be assigned for grand research project
- iii. The maximum research budget allocated for grand research project is 5,000, 000 Ethiopian birr and the maximum reporting period are 5 years
- iv. The research project shall solve national, regional and community problems from different perspectives
- v. Under this research a minimum of five researchers from different principles should be member and two of them shall be senior researcher

7.2.3. PhD student support research project

- i. Y12HMC shall provide a budgetary support for PhD students sponsored by Y12HMC, attending their education in any of Ethiopian university and conducting their research in Ethiopia
- ii. In order to get support, the candidate shall be
 - a. Be academic staff of Y12HMC
 - b. Signed contractual agreement with the college
 - c. Be at least a second year PhD student
 - d. Registered their education in any of Ethiopian university and conducting their research in Ethiopia
 - e. Have research topic with the thematic area of the college
 - f. Provide a letter from hosting universities indicating the candidate required additional research budget and or have no research support from hosting university
 - g. Have signed the agreement to settle the budget within the budget year
 - h. Must agree to mention support from the college on the acknowledge of the dissertation

8. Research leave

Leaves are granted pursuant to the rules set out by the college legislation.

9. Working condition of an author

An academic staff engaged in approved research activities shall be given the right to obtain funds, time and other facilities.

10. Research output dissemination

The research output will be disseminated through conference in the college, report to stakeholders and publication on the journals

11. Preventing Academic misconduct

Preventing academic misconduct is of utmost importance in maintaining the integrity and credibility of research conducted by yekatit 12 hospital medical college's community. Yekatit 12 hospital medical college can create a robust framework to prevent academic misconduct during the research process by performing the following activities:

- Establishing clear policies and guidelines
- Research ethics training
- Institutional review boards (IRBs)
- Data management and record keeping
- Online Plagiarism detection software
- Collaboration and supervision
- Encouraging a culture of integrity
- Anonymous reporting mechanisms
- Regular audits and quality checks

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Annex I: Research Proposal Application Form

Instruction: Fill in the spaces and mark (x) wherever appropriate

A. General

1. Title of the project: _____

2. Name and address of the principal investigator(s)

Name

Father's Name

Grandfather Name

Region

Sub city

Woreda House Number

Tel. Number

Email

3. Name and address of the applying institution(s):

Region

Sub city/Zone

Woreda

House Number

4. Specific request of the application

A. Technical Review ☐

B. Ethics Review ☐

C. Renewal (extension) ☐

D. Termination ☐

E. Resubmission ☐

F. Specify if any other _____

.....

5. Number of submitted copies _____

6. Number of submitted pages excluding all attachments _____

7. Number of submitted pages including all attachments _____

8. Required annexes/attachments

8.1. Written informed consent form ☐

8.2 Information sheet ☐

8.3 Officially endorsed minutes of IRB ☐

8.4 Letter(s) of collaboration from all collaborating participating institution ☐

8.5 Ethics review letter from collaborating and host institution(s) ☐

8.6 CVs of the PI and relevant senior co-investigator(s) ☐

8.7 Specify if any other ☐

9. Name and signature of applying PI and host institution(s) as an expression of accountability, responsibility and authenticity of the request and prior commitment of ethical implementation of the project after approval.

_____	_____	_____
Name (PI)	Signature	Date

_____	_____	_____
Name, Research and Publication Office Coordinator	Signature	Date

.....

Annex III. Proposal Evaluation guideline to be filled by each review team member

Proposals are funded when they meet the set criteria. The criteria are listed below with its weight. Proposals with higher overall score are considered for funding. And the proposals that have scored below 50% may not be funded. Three reviewers shall be involved to review a project and the average of the three evaluators will serve to decide on the funding of the projects. The research and ethical board of the colleges/institutes shall provide weights to the projects by considering the open defence and the incorporation of the comments during open defence.

Title of the project-----

I. Relevance and degree of research priority in relation to Yekatit 12 list of research priority and themes that demonstrates responsiveness to national and regional needs (30 %)

----- Highly appropriate (25-30)

----- Moderately appropriate (15-24)

----- Inappropriate (< 15)

Score ----- ()

II. Scientific quality and contents of the project (25 %))

a. Justification, hypotheses, gaps and objectives- Is the objective and gap clearly stated, is the priority clear, and objective achievable, is the proposal well-reasoned out (6)

----- Highly appropriate (5-6)

----- Moderately appropriate (3-4)

----- Inappropriate (<3)

Score ----- ()

b. Methodology (Design, Method, Statistics, analyses), It should be proper, well designed and related to all objectives (10)

----- Highly appropriate (9-10)

----- Moderately appropriate (5-8)

----- Inappropriate (<5)

Score ----- ()

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c. Expected output, Indicates the anticipated outputs by running this project. Which research questions could be answered by doing this SET and what output is expected at the end of the project for dissemination and the beneficiaries from the project. The expected output should spell out and tally with the objectives that has been set (4)

----- Highly appropriate (4)

----- Moderately Appropriate (2-3)

----- Inappropriate (<2)

Score ----- ()

d. Technology/information/knowledge dissemination strategy (5)

----- Highly appropriate (4-5)

----- Moderately appropriate (2.5 -3)

----- Inappropriate (<2.5)

Score ----- ()

III. Technical feasibility (level of experience, availability of resources, time and budget and applicants are scientifically and technically capable and realistic in budgeting) (20%)

----- Highly appropriate (18-20)

----- Moderately appropriate (10-17)

----- Inappropriate (<10)

Score -----

IV. Degree of collaboration, multi-disciplinary and team (Institute, colleges/institutes, department) (15%))

----- Highly appropriate – Involved more than 4 disciplines (11-15)

----- Moderately appropriate –involved 2-4 (7.5-10)

----- in appropriate 1 discipline (<7.5)

Score ----- ()

V. Attainable within specified period (1-3 years) (10%))

----- Highly appropriate (8-10)

----- Moderately appropriate (5-8)

----- Inappropriate (<5)

Total score ----- ()

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If the total score is 50 and above and if you believe the project is worth funding with appropriate modifications, please give your comments to make improvement in the space provided;

a. Introduction and Objectives

Methodology -----

////////////////////////////////////

Expected output; -----

Project plan vis-à-vis implementation and budget

Technology dissemination strategy -----

Additional comments -----

Reviewer's Name -----Signature-----Date -----

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Annex IV. Ethical clearance guidelines

The ethical clearance shall follow a review guide developed by Ethiopian science & technology commission, national health science & technology council, and health department for health disciplines.

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12. Annex V: Grant Agreement Sheet

Yekatit 12 Hospital Medical College here after referred as the college and _____ here
in after referred as the researcher (principal investigator) on the project entitled

As _____

The college hereby agrees to pay the approved research budget of the study for the principal
investigator a total of _____Birr (_____)
in 2 phases.

It is agreed between and by the two parties as follows

The principal investigator is responsible for

1. Undertaking the project in accordance with the terms and conditions set in the research and publication guideline of the college.
2. Submission of timely progress, final and financial requests according to the time schedule set by the internal review committee.
3. Request for advance of project fund.
4. Use the entirely research grant for the research purpose as stated in the project proposal.
5. Present valid document on utilized fund for disbursement according to the financial proclamation of the Federal Democratic Republic of Ethiopia government.
6. Presentation of the research result.

Breach of agreement

- Utilization of the fund granted partially or wholly for purposes other than what is stated on the project document;
- Failure in submission of progress, financial and final report; and
- Failure in presentation of the output for the college community.

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Effective date

The effective date of this agreement shall be the date of signature of the agreement by

For the researcher:

For the college (RPO head):

Name_____

Name_____

Signature_____

Signature_____

Date_____

Date_____

Annex VI. Guiding principles to make contract agreement with other partner institutions

The contract agreement with partner institutions shall be developed by Yekatit 12 HMC and partner institution guided by the following principle,

- a. The project shall be under the thematic and priority areas of Yekatit 12 HMC and devoted in meeting the research strategic issues of Yekatit 12 HMC as stipulated in Yekatit 12 HMC strategic plan and research policy of Yekatit 12 HMC.
- b. The implementation of project shall be monitored and evaluated in both the university and partner institution system.
- c. The project shall commit to submit progress, annual and terminal reports to the colleges/institutes/ university and also present the findings in the annual research conferences of Colleges/institutes/university.
- d. The project shall commit to submit the publications, proceedings and other out puts aroused from the research project for respective colleges/institutes library and research coordination offices of the colleges/institutes/ Yekatit 12 HMC
- e. The financial administration shall be based on the project document agreed between Yekatit 12 HMC and partner institution.
- f. The data generated from the project shall be administered through the university system.
- g. Based on the above principles the university/colleges/institutes representative and the partner institution shall sign MOU

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Annex VII. Registration of the research project

The research projects be it funded from the treasury or non-treasury shall be registered at the colleges/institutes level with a serial number. The research proposals shall be serially coded and registered proceeded with colleges/institutes code, department code, year of registration (last two digits) and project number. The code shall be assigned in alphabetical order for colleges/institutes in departments in colleges/institutes. The title of the project shall be written in front of the serial code. The following could be an example to serially register a project.

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Annex VIII. Guidelines for M & E of research undertakings

M& E is mainly designed to play a supportive role in the conduct of research. The implementation of M& E in Yekatit 12 HMC is to verify the status of research activities, to identify problems encountered in the process of implementing research project, to take immediate measures, and to present challenges to the respective management for those not solved during field follow-up. The M&E is regularly done by the colleges/institutes research and ethical review board. The colleges/institutes RERB shall develop a check list for monitoring and evaluating a project that suites a discipline in question. The research and ethical review board shall undertake a periodical M&E in various forms such that;

- a. The board shall review quarterly, progress and terminal report and write a report whether the conduct of the research is in line with the project proposal and protocol of the project.
- b. The board shall arrange a field visit and check data log books, data record books and check the data collected as per the research proposal.
- c. The board also shall check whether the research project is undertaken in the time frame as documented in the proposal.
- d. The board shall monitor the management and utilization of financial and physical resources to the planned project
- e. The board shall write a report and provide a feed back to the researcher, the department where the research project is based and dean of the colleges/institutes
- f. The researcher shall send a response letter to department, dean of the colleges/institutes and RERB of the colleges/institutes stating the arrangements made to improve the research undertaking.
- g. The researcher failing to report as per the recommendations of the RERB shall not be getting a financial support to continue the project and will account the expenses born for the research.

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Annex IX. Format for Progress report

1. Code and title of the project:

a. Name of principal investigator/project coordinator (Department, Colleges/institutes).....

b. Research and team member (s) in the university (if any) and their specific role in the research project:

c. Other partner/collaborating organizations with addresses of contact person (s) and their role in the project:

3. Project duration and period:

4. Reporting period:

Funding

a. Source of funding.....

b. Amount (In phases if any).....

6. Fund utilized: indicate the amount of money utilized for the reporting period

Sr. No	Items	Amount brought forward ¹	Fund received ²	Total fund in this period ³	Fund expended ⁴	Balance
1	Expendable items					
2	Equipment					
3	Literature and stationery					
4	Local travel and communication					
5	Honorarium					
6	Personnel					
7	Other expenses (specify if any)					

.....

Objectives of the project

a. General.....

b. Specific objectives:

.....

8. Work plan used for the current reporting period (state briefly the work plan for the project until the current reporting is made).

Achievements/progress: Indicate also which objectives have been addressed: Project output description (give the highlights of the work done during the reporting period): Include detailed summaries of the work carried out and results obtained to permit informed critical scientific assessments of the work by the respective committee and peer reviewers. If possible the results could be presented in tabular or graph form. Summaries should be complete in themselves as brief as possible; consistent with clarity (a maximum of two pages is required). Interpret new findings (both positive and negative) in terms of the objective of the project and state if they are expected to increase (or decrease) the duration, total costs and/or the likelihood of the success of the project.

Annex X. Guideline for reviewing progress report (to be filled by the researcher)

A. General evaluation

Editorial quality

Quality of references

Comment -----

B. Administration information

1. Project title and code

2. Principal investigator and co-investigators and colleges/institutes/department

3. Project duration and period

i. Reporting period (Phase)

Sources of fund and amount in each phase

C. Technical

1. The extent of the objectives achieved as per the project document

The work plan: Is the future plan realistic and achievable?

Recommendations: What is recommendation of this report for future funding

Accept the report without change

Accept the report with minor change

Accept the report with major revision

Not accepted, that needs re-writing

9. Reasons for the recommendation

1. -----

2. -----

Reviewer----- Signatures -----Date -----