GUIDELINES FOR PREPARING RESEARCH PROPOSALS

Each application should have one Principal investigator (PI) and, as needed, one Co-PI and one or more co-investigators. Co-PI(s) make(s) major contributions to the project and assume(s) the project responsibilities during the absences of the PI. Co-Investigator(s) on the proposal make(s) also significant contribution to the project. By signing the cover page, the Co-PI(s) and Co-Investigator(s) indicate they have reviewed and approve the proposal.

The research proposal should cover the following sections. Sections 1 through 8 should not exceed 15 pages.

1. **Abstract**: (up to 350 words).

Briefly state the background and aims of the project; describe the methodology and the analytical plan; and state the significance of the project.

2. **Specific Aim(s)**: (up to 1 page).

Enumerate and describe concisely the specific research aim(s) of this application and utter the hypotheses to be tested.

3. **Background:** (1-2 pages).

Describe the background to the present proposal, critically evaluating the existing knowledge on the topic, and identify any gaps in knowledge the project is intended to fill.

4. **Preliminary Studies**- *if applicable*: (1-2 pages).

This section maybe used to report on preliminary pertinent studies and/or information that help in appraising the experience and competence of the investigator.

5. **Research Design and Methods**: (up to 6 pages) integrated with each specific aim.

Describe the research methods and procedures to be used to accomplish the specific aims of the project. Comment critically on them. This section should include, where appropriate:

- Study design
- The methods used to accomplish the specific aims of the project
- The number of subjects per group, and its justification (for Basic/translational research specify the number of vertebrate animals to be used and its justification)
- Data management and statistical analysis
- Recruitment methods
- Eligibility criteria
- Description of the intervention, if applicable (surgical procedures, protocols for drug dosage regimen)
- Definition of outcomes (primary, secondary and other outcomes)
- Definition of outcome measures and the specific data to be collected (the parameters to be measured), for each specific aim
- Tentative time-table for the specific aims of the project
- Description of procedures and materials that maybe hazardous to personnel and the precautions to be exercised

- **Human Subjects:**
  It is recommended to submit all IRB forms **after the initial RC review** when you receive the notice for rebuttal. For IRB forms/ applications and appendix please visit:
  http://www.aub.edu.lb/irb/Pages/index.aspx
  IRB Appendix

- **Vertebrate Animals:**
  For IACUC forms/ applications and appendix please visit:
  http://www.aub.edu.lb/fm/medicalresearch/Pages/AnimalCareFacility.aspx#IACUC
  IACUC appendix

6. **Significance:** (up to 1 page).

State the importance and relevance of the proposal to health care and medical sciences.
Describe how the methodology and approach proposed will indeed give the answers to the questions posed, and explain how the data collected will be analyzed and interpreted. If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

7. **Innovation**: (up to 1 page).

Describe the innovative aspects of the proposed project.

8. **Feasibility of the study and Potential pitfalls** (up to 1 page):

A discussion of difficulties and potential limitations of the work and possible alternatives. To assess whether the study is deemed feasible, it is advisable to consider a range of criteria:

- Research methods/ technique (done at AUB or outside)- methodological approach
- Availability of in vivo and in vitro models or animal models needed for the study
- Availability of sufficient number of potential participants or samples, based on the expected recruitment and retention rates, and alternative plans in case of slow recruitement
- Expected duration required to recruit the sample size
- Expected duration of study completion
- Feasibility of testing procedures and data collection methods, including completion rates
- Letter of support from relevant company (reagents, equipment...)

9. **Literature Cited:**

Provide the authors' names, title, journal, volume and page numbers and year of publication, in this order. For books, mention in addition the book title, editors' names (if applicable), publisher, and generate a list of references.

10. **Budget:**

This should be itemized and detailed enough to allow judgment of its appropriateness based on the description of the research design and methods. A separate justification section may be included if necessary. The budget may be divided into 5 parts:

- Personnel. Indicate the percent of time that will be allocated to the proposal. Include salaries

and benefits in the budget.

- Supplies/Equipment. (For supplies and equipment, make sure that the 35% - 60% shipping expenses for foreign orders are accounted for in the budget). No more than 25% of the proposed budget should be used for purchasing equipment. Justification for any equipment is needed. Final decision for approving purchase of equipment will be made by the RC.
- Others, e.g.: animal costs, token compensation for human subjects, including transportation costs. However, hospitalization, extended hospitalization or any another form of medical intervention that is a potential consequence of participation of the subject in a MPP/URB-funded study CAN NOT be covered by any MPP/URB- funded grant. The premiums for an insurance policy that is issued to cover for such events can, however, be paid for by MPP/URB-funded grants.
- MPP-funded grants can be used to pay for personnel and reagents needed to carry on a given project.
- External technical services are covered provided three conditions are satisfied:
    - *The service is not available at AUB*
    - *A clear explanation of the necessity of performing this outside service is included in the proposal and accepted by the RC committee*
    - *The total cost of all external services does not exceed 25% of the total fund allocated*
    - *For services AUB already offers, a justification is required and needs approval from the RC chair. Also please remember that no more than 25% of your MPP funds may be used to pay for external services.*
- All study-related clinical services paid for from MPP/URB-funded grants should be performed at AUBMC. Exceptions require prior approval by the RC chair.
- Travel expenses are not covered by the MPP/URB-funded grants.
- Statistician fee should not be included in the budget
- Funds provided by the URB will be available for one fiscal year (as of July1 - June 30 of the following year).
- No duplicate funding will be approved for projects with significant overlap among separate applications submitted by different PIs or same PI.
- Any proposal submitted for additional funding beyond its originally approved funding period will not be considered by the RC.
- MPP accounts that are **dormant** for more than three years will be retrieved by the Dean's office.

11. Progress Reports:

A progress report is required for all renewals and should include the following:

- Project Information: Title, PI/co-PI/co-I, Date of approval, Amount of Fund, Estimated date of completion.
- Brief description of the research proposal and aims of the study.
- The report should include a narrative of accomplishments during the last year. Organize the summary by the aims listed in the original submitted proposal, using separate section for each aim. Describe the obtained data, including tables and figures where appropriate. For clinical research this section should include the number of subjects recruited to date.
- Include a section of what is planned for the next year in order to accomplish the aims of the study.
- Include any significant publication or presentation that resulted from this project.
- Include a section where investigators can list any changes made to their existing research plans or protocols.
- Include a budget justification if there is a major change from the previously approved

budget.

- In case of deviation from the timeline related to unavailability of reagents or slow recruitment of subjects, the PI needs to describe the strategies that would be used to accomplish the Aims during the time remaining, with a rationale and adjustments in the corresponding budget for the next year as applicable.
- If there is significant delay in study initiation due to IRB/ IACUC, patient recruitment process or MOH then the PI may ask for a no cost extension by informing the RC administrator. This needs to be done in writing. ***The PI should include any problem/ obstacle encountered that withhold completing the specific aim within timeline.***

12. Timeframe for the Study:

Describe the duration of the proposed work and the division of labor during that time- period. Set landmarks for accomplishment of tasks or specific aims for the duration of the study. It is important that the budget remains in line with the proposed timeframe. Request for a deferment use of funds or a no-cost extension of a study period beyond the originally approved duration will need approval from the RC chair/co-chairs.

Time Commitment and Funds Available:

The investigator must clearly state the percent of his/her time he/she will spend on this proposal. Mention other sources of funds for the proposal being now submitted and the amounts provided. Also, a list of other research projects under way should be provided indicating percent time allocated to them, the granting agencies, the funds available and the dates they will expire.

13. Co-investigators:

This section should include a description of the role of the co-PI and each co-investigator, and his/her contribution to the accomplishment of the proposed work. Co-PI and all co- investigators should indicate the percent of their time to be spent on the project.

14. Online Submission:

It is imperative that all sections are included in the proposal before submission.
All applications need to be submitted via the online system. No application will be accepted in paper form or after the set deadline. It is important for the PI to ensure that there is a full match between the names of Co-PI and Co-investigators entered in the online submission system and listed on the full proposal. Any mismatch may result in excluding of the proposal from the review process.

15. Responsibilities of PI and co-PIs and co-Investigators

The PI is responsible to adhere to all RC guidelines and policies as well as the university guidelines and policies pertaining to research conduct. Deviations may jeopardize current and future funding. All applicants are required to sign online their acceptance to serve on the proposal. Electronic signature implies that all applicants have read and agreed with the contents of the application.