

Office of Research Administration (ORA)

Proposal Processing and Submission

To be eligible to serve as a principal investigator, an individual must hold one of the following titles: *professor, associate professor, assistant professor, research professor or other designated full-time, benefited professional position*. Individuals holding other than professor titles must obtain approval of the Provost or his designee to submit research, public service or training proposals to an extramural sponsor.

The principal investigator develops the proposal in accordance with agency and University requirements. The principal investigator completes the "Proposal Information Worksheet" in order for ORA to generate the internal routing form. The principal investigator obtains the necessary signatures on the internal routing form and obtains any necessary approvals concerning the use of animals, human subjects, and recombinant DNA. Once approved by the respective chair and dean, the principal investigator should send the form to ORA. If subcontracts are to be issued to other institutions, the principal investigator obtains proposals from the other institution.

Certifications and Endorsements

Ideally, the principal investigator should obtain the signature of the department chair or center director and the dean on the internal form before the final proposal submission by ORA. By signing the internal form, each person indicates the proposed research or sponsored activity will be beneficial to all concerned (department, university, sponsor) and that the respective campus offices assume responsibility for commitment of resources or persons under their jurisdiction as indicated by the proposal. The endorsement of the principal investigator certifies to authorship of the proposal and to proper arrangement of workload of other research or teaching so that the project can be undertaken and the requested time, facilities, equipment, and funding are sufficient to accomplish the proposed task.

Responsibilities of the Principal Investigator in the Proposal Submission Process

In addition to preparation of the proposal, there are various certifications that are required for all proposals submitted to a federal agency. Each principal investigator must certify that:

1. He or she is not delinquent on the repayment of any federal debt;
2. He or she is not presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by any federal department or agency;
3. No federally appropriated funds have been paid or will be paid, by or on behalf of the principal investigator, to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with the making of any federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal grant or cooperative agreement;

4. If any funds other than federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of a member of Congress in connection with a federal grant or cooperative agreement, the principal investigator shall complete and submit Standard Form - LLL, Disclosure Form to Report Lobbying, in accordance with its instructions. In addition, the principal investigator's signature indicates current and pending support and the conflict-of-interest issues, among others, have been appropriately addressed.

Responsibilities of the Chair and Dean in the Proposal Submission Process

The endorsement of the department chair certifies to the review and endorsement of the proposal and concurrence in the representation of the principal investigator; the principal investigator's teaching load will be compatible with the time requirements of the project; adequate space, equipment and facilities are either already available or required modifications or new additions have been approved and funding sources identified; to the best knowledge, there will be no other resource requirements generated by the award which are not accounted for in the proposal; and all other departmental requirements have been complied with. The endorsement of the dean certifies to concurrence in the representations of the principal investigator and the department chairperson and attests that the proposed activity contributes to the attainment of the university goals.

Responsibilities of the Office of Research Administration (ORA) in the Proposal Submission Process

ORA verifies that the proposal has been properly reviewed, has the appropriate prior approvals, meets the requirements of the sponsoring agency as well as the University, and includes maximum allowable indirect costs, except in those cases where the sponsor has limited the University's indirect cost recovery, or acceptance of a lower indirect cost rate has been justified by the principal investigator and approved by appropriate institutional officials as being in the best interest of the University. In addition, the certifications required from the principal investigator for federal proposals must also be made on behalf of the University. Finally, this endorsement certifies that the proposal is a valid offer by the University to undertake the proposed work under the terms defined by the proposal.

ORA will assist the Principal Investigator in the preparation of proposal forms, the development of the proposal budget and will copy, mail or electronically submit the proposal in accordance with the solicitation.

Other Relevant Items in the Proposal Submission Process

Because ORA processes many proposals each week and changes often must be made to those proposals necessitating communication between ORA and the principal investigators or dean, ideally **principal investigators should submit proposals five working days before the proposed sponsor's deadline**. Last-minute review can cause problems particularly for those proposals requiring submission electronically. Should changes be required on a proposal submitted close to the deadline date, timely submission may be endangered.

In some instances, sponsors accept only a limited number of proposals from each university. If interested in applying to such a program, consult the ORA website for the listing of limited-submission solicitations and the deadline for submitting preliminary materials to ORA. If the solicitation of interest is not included on the ORA list, notify ORA immediately before proceeding with preparation of the proposal.

Proposal Checklist

The following items are important points to consider when conducting the final review and evaluation of your proposal:

1. Are proposed personnel available within the department? If not, what arrangements for personnel are anticipated? If these involve another department, has this need been cleared with the department?
2. Are proposed salaries and benefits within the University ranges and appropriate to the anticipated effort? Are reasonable increases budgeted from year to year?
3. Has the application been reviewed and approved by the appropriate department chair, dean, and the ORA.
4. Is review and approval of protocol for animal care required?
5. If the research involves human subjects, has it been reviewed and approved by the appropriate human subjects committee?
6. If the research involves hazardous or potentially hazardous biological agents, has the approval of the appropriate hazardous substances committee been secured?
7. Is the financial stability of the sponsor a potential risk to the University? If so, ORA must be informed.
8. Is there any type of conflict of interest (personal, organizational, financial, etc.)?

Regulatory Committee Review: Review and Approval by the Human Subject, Animal Subject and Biohazard Safety Committees

When an investigator at UML wants to conduct research, she or he develops a **protocol**, which is the plan of a scientific experiment. If the protocol involves the use of **humans**, it must be reviewed and approved by the **Institutional Review Board for the Protection of Human Subjects (IRB)**. If it involves **animal subjects**, it must be reviewed and approved by the **Institutional Animal Care and Use Committee (IACUC)**. If it involves the use of **biohazard or recombinant DNA**, it must be reviewed by the **Institutional Biosafety Committee (IBC)**.

To obtain IRB, IACUC or IBC approval, the investigator must send the protocol to the appropriate committee. The IRB, IACUC or IBC will review the materials and will not approve the project unless it has determined that the project complies with applicable federal regulations and the University policies developed to implement these federal regulations.

Federal law states that research involving humans, animals, or RDNA **must** be approved by the appropriate committee before any work can begin on the project. The IRB, IACUC, and IBC can require changes in the research protocol to ensure compliance with applicable law. If the respective committee approves the research, it will notify the Office of Research Administration. Approvals are issued for **one year**

from the date of approval, and the researcher must file a continuation application for each subsequent year.