I. PURPOSE

The purpose of this operating procedure is to outline the process of developing and submitting a research proposal, which could include grants, contracts, or clinical trials, to an external sponsor. This SOP will enable the Research Administration Services (RAS) units to support Principal Investigators (PI) in the proper development and submission of a research proposal in accordance with sponsor guidelines.

II. INTRODUCTION

Most external sponsors have defined guidelines and procedures for proposal submission and may require the use of specific application forms or systems. RAS units are expected to assign a Pre Award Administrator to work on the proposal with the PI. PIs are responsible for developing the components of the proposal that are required by the sponsor, with support from the Pre Award Administrator. Pre Award Administrators are expected to support the preparation of the highest quality materials and work closely with the PI to submit proposals to agencies that are compliant with both sponsor and institutional guidelines. All proposals to external sponsors must be routed to the Office of Sponsored Programs (OSP) in the Emory Proposal Express system (EPEX) prior to sponsor and institutional deadlines. OSP will review all proposals as soon as possible after receipt and within sponsor deadlines. As the Institutional Official (IO) for Emory, OSP will review all proposals, approve on behalf of Emory, and submit proposals to the sponsor in most cases. With certain Sponsors the PI or RAS may be responsible for submitting.

Timing:
The timing of proposal submission is critical to the success of Emory University’s research enterprise. Thorough preparation, review, and correct processing are essential to support research aims of Investigators. To allow for a thorough review of each proposal, the draft proposal, including completed administrative and budget components, should be submitted through EPEX (Emory Proposal Express, Emory’s internal routing system) and received at OSP at least 5 business days before the sponsor deadline. Though these guidelines are strongly encouraged, it is the intent of Emory University that all completed grants received prior to the sponsor’s deadline will be submitted.

Note: Please make sure the PI and relevant staff have access to internal (i.e., EPEX) and external proposal
submission systems (e.g., Cayuse).

Please contact local Departments and/or School/Unit for guidance on internal deadlines (for example: due at department 10 days prior to sponsor’s due date) for EPEX routing, as timelines vary by Departments and Schools/Units.

Late proposal routing in EPEX may jeopardize successful submission of the proposal to the sponsor and may impact the fundability of the proposal.

- If a late proposal is funded and is found to contain financial or administrative inaccuracies, OSP and the School/Unit reserve the right to renegotiate and/or rebudget the award, and if necessary return the funding to the sponsor.

III. PROCEDURE

1. Proposal Preparation
   a. PI identifies funding opportunity and notifies RAS of intent to submit (See Notification of Intent to Submit SOP # 1001 - Refer to Notification of Intent Checklist or Submit online via REDCap as well as the associated form to guide through the process).

   b. Upon notification of intent to submit, a Pre Award Administrator is assigned to work on the proposal and the proposal assignment is documented in REDCap or is added to a list of proposals in process within the RAS unit.

   i. The Pre Award Administrator provides continuous support to PI in terms of understanding the timeline and submission process.

   c. The Pre Award Administrator will contact the PI to set up an initial meeting to discuss and develop a plan for completing elements of the proposal (see Associated Documents 1. Research Proposal Application Process Checklist, 2. Sample Proposal Template/Job Tool and 3. Sample Proposal Timeline Template) including, but not limited to:

      i. Confirm that PI is eligible and has sufficient effort (available) to complete research (based on local School/unit guidelines)

      ii. Confirm that the PI is listed as PI eligible in the EPEX system (please note that PI eligibility in the EPEX system may be different from School/Unit definitions of eligibility). The easiest way to complete this verification is to navigate to the EPEX search page, click on the PI ID lookup, and search for the PI’s name. If the individual is not found, they are not currently PI Eligible.

      iii. If PI is not listed as eligible in EPEX, submit EPEX PI Eligible Access Form (http://www.osp.emory.edu/ra-systems/epex1/EPEX/PIEligibleAccess.pdf)

      iv. Identify whether proposal is a limited submission and if so, contact OSP and/or School/Unit for further instructions and action on limited submission

      v. Identify general proposal information (name, title, sponsor, proposal type, project period, due date, etc.)

      vi. Review sponsor requirements and restrictions (please note that these are often listed in a funding announcement, request for proposal guidelines and/or sponsor website)

      vii. Determine if prior approval from sponsor is necessary (please note that prior approval is
required for some applications of significant direct costs in any year. Please see part e below and review the RFP or funding guidelines for clarity.

viii. Identify and discuss proposal specific information (for example: methodology, location, gathering collaborative splits, submission deadlines, professional resources (e.g., subcontracts), proposed effort percentage, F&A distribution, cost sharing requirements)

ix. Identify any subcontractors/subawardees

tax. Define budget elements needed to accomplish research (i.e. personnel and effort, non-personnel, sub-contracts, and any cost shares)

xi. Prepare Proposed VA MOU for all faculty named in the proposal with a VAMC appointment as per associated job aid.

xii. MOU disclosure statement must be included in the budget/personnel justification disclosing the amount of effort on this proposal in relationship to the faculty member's total professional effort, along with the statement that no VA time will be used.

xiii. Determine timeline and assignment of responsibility for completing the necessary proposal components, including uploading to sponsor system

**Note: The following is strongly suggested; nonetheless the use of the document listed in section d is not required.**

d. The Pre Award Administrator should prepare and compile elements of the proposal (see Associated Documents 1. Research Proposal Application Process Checklist, which could include, but are not limited to:

i. For projects that cross multiple units/Schools, Pre Award Administrator will work with other PIs, RAS units, and Departments/units to gather needed/requird information (See Complex Award Management – Pre Award SOP # 1003)

ii. Support development of budget and budget justification (note: PI primarily responsible for budget justification) (See Budget Development SOP # 1004 for more details)

iii. Complete non-scientific sections of proposal and all other proposal elements as appropriate.

iv. Assist PI in compiling all proposal documents required for routing and ensuring documents are in proper format

1) For contracts and clinical trials (with a Clinical Trial Agreement), a draft, editable copy of the sponsor-provided contract should be obtained from the sponsor. If a clinical trial, the sponsor-provided budget, and protocol/informed consent documents, if applicable, need to be included in proposal routing for OSP review and negotiation

v. Track the exchange of these documents (see Associated Document 3. Sample Proposal Timeline Template) and communicate with the PI via email when documentation or elements are considered past due based on the agreed upon timeline

vi. Review proposal data and application materials. Pre Award Administrator will communicate any required and suggested changes to the PI via email (clearly indicating which changes are required and which are suggested).

1. Required Changes: It is expected that the Pre Award Administrator and PI will make all required changes.
2. **Suggested Changes**: It is the PI’s decision if the suggested changes should be made (depending on the type of change, either the PI or the Pre Award Administrator may make the changes). If the PI chooses not to make the suggested changes, the Pre Award Administrator will route the proposal “as-is” and document this information in the “Other Comments” Box (Question 19) in EPEX to make sure OSP is aware of the decision not to make the suggested changes.

**Note**: OSP is the Institutional Official (IO) for Emory and will make a final determination of required and suggested changes during its review. If PI or Pre Award Administrator needs clarification regarding required changes during proposal preparation process, they can contact OSP for guidance or route proposal as-is and notify OSP to make final determination during its review.

Examples of Required and Suggested Changes are listed in the chart below. Please note that this is not an exhaustive list.

<table>
<thead>
<tr>
<th>Examples: Required Changes</th>
<th>Examples: Suggested Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(Changes that must be completed prior to submission of proposal to sponsor)</em></td>
<td><em>(Changes that will not jeopardize the submission, but may ultimately affect the acceptance or review of the proposal)</em></td>
</tr>
<tr>
<td>• Proposal elements that are in direct violation of the sponsor guidelines, institutional policies, or state and federal regulations</td>
<td>• Section headings different than suggested</td>
</tr>
<tr>
<td>• Data entry mistakes on the sponsor application that will cause submission errors</td>
<td>• Spelling errors</td>
</tr>
<tr>
<td>• Budgetary miscalculations or incorrect F&amp;A rate selection</td>
<td>• Format of biosketches</td>
</tr>
<tr>
<td>• Incomplete proposal eCOI form for any person responsible for the design, conduct, or reporting of the proposed research</td>
<td>• Minor budget errors</td>
</tr>
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<td></td>
<td>• Weak budget justifications</td>
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<td></td>
<td>• Et al. use in references</td>
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</tbody>
</table>

vii. Assist PI in entering proposal elements into sponsor’s electronic system (if applicable)

e. If a Letter of Intent for proposal is required, the Pre Award Administrator will assist in obtaining institutional signatures, if required by sponsor, from OSP. Pre Award Administrator will submit sponsor requirements and Letter of Intent to OSP for review and approval.

i. If space commitments or cost shares beyond what is typical (e.g., cost share other than over-the-salary-cap, or full /partial F&A waivers – See Cost Share and F&A Waiver Approval Process SOP # 1005) are being requested by the institution, the
letter must be reviewed and approved by the CBO or Dean of the School (or other appropriate official) of the PI or Co-PI making the commitment

ii. If Institutional Official signature is required, please allow 5 business days for processing

f. The Pre Award Administrator works with the PI and their Investigators in obtaining commitments, cost share commitments (which must be approved by Department and/or School/Unit - See Cost Share and F&A Waiver Approval Process SOP # 1005), requests for space, Veterans Affairs Memorandum of Understandings (VA MOUs), and any commitment letters from subawardees / subcontractors, as needed. The Pre Award Administrator:
   i. Confirms required approvals have been obtained, if applicable
   ii. Obtains VA MOUs and any commitment letters from subawardees / subcontractors, if applicable

Note: Pre Award Administrator is not responsible for obtaining approvals; however, they may assist the PI and/or study coordinator in these processes, as requested by the PI

g. Conflict of Interest (COI) Forms (PFIRR, IFIRR)
   (see Emory Policy for Investigators Holding a Financial Interest in Research http://www.policies.emory.edu/7.7)
   i. Pre Award Administrator initiates and submits a new Proposal Investigator Financial Interest Related to Research Report Form (PFIRR – hereafter referred to as eCOI forms) found at: http://www.ecoi.emory.edu . Enter the following information about the proposal: title, funding source, Investigators, and IRB, IACUC, EPEX identifiers, if known
      1) A pdf copy of the summary of eCOI forms indicating the status of Investigators’ completion of forms is attached in EPEX and submitted with the proposal to OSP
      2) For PHS proposals that include subawards with Investigators, Pre Award Administrator must obtain a consortium letter from the proposed subawardee that indicates whether the subawardee has policies and procedures that are compliant with the current PHS regulations. If the subawardee cannot certify that it has such policies and procedures, the Investigators on the subaward must complete the eCOI form, External Investigator Report of Financial Interest in Research http://www.coi.emory.edu/COI_documents/External%20Investigator%20Disclosure%20Form.pdf
         These forms are submitted with the consortium letter and the proposal to OSP

h. Investigators receive an automated email from the eCOI system to login at: http://www.ecoi.emory.edu to complete and submit the Proposal for Investigator Financial Interest in Research Report (PIFIRR) Please note: A Proposal Investigator Financial Interest Related to Research Report Form is completed for each new proposal submitted and updated at time of award and then annually through award end date. This is different from the annual Investigator Financial Interest in Research Report (IFIRR)
which each faculty member submits annually to disclose all research activities.

i. The Pre Award Administrator and PI ensure all eCOIs are complete prior to submission of the proposal to the routing process

ii. In accordance with federal regulations, OSP cannot submit proposals until all required COI forms have been completed

i. Enter proposal into EPEX for routing (See Associated Documents 5.Job Aid: Entering Simple Proposal and 6.Job Aid: Entering Supplement Proposal)

   i. The Pre Award Administrator is responsible for ensuring that the proposal is entered into EPEX. This includes creating a new proposal record in EPEX and uploading necessary attachments, including but not limited to: budget, statement of work, draft research plan, resources, commitments, and eCOI summary page (see Associated Document 4.Sample Checklist for Entering Proposal into EPEX for list of required fields and potential attachments)

      1) Answer all required questions and fields in EPEX.
         - For Clinical Trials or Contracts, also include the contact information of the sponsor representative that will be responsible for contract review and approval.

      2) Ensure that proposal projects and respective budgets are entered correctly (including multiple budgets for more complex proposals with multiple projects or collaborative splits – See Complex Award Management – Pre Award SOP # 1003).

      3) Ensure that the proper HR record and roles are selected for the named Investigators (please note, many Investigators have more than one HR record; it is important that the one selected represents where the work will be done so that the proper approvals are obtained). Workflow needs to include all entities where the work will be performed.

      4) Confirm that proposal data and relevant attachments have been properly entered or attached. If the proposal is a contract or Clinical Trial Agreement, include an editable draft of the contract or Clinical Trial Agreement.

      5) In the “Other Comments” Box in EPEX (Question #3 or #19), write the name and phone number of the Pre Award Administrator who should be contacted for questions regarding the proposal.

ii. Preview proposal workflow: Workflow will automatically populate based on the named Investigators, the HR record selected, and answers to initial EPEX screen questions. If the proposal needs to be seen by the RAS unit again, add the RAS unit as an additional reviewer/approver.

   1) It is critical to preview and verify certifiers listed in the workflow to ensure that the proper individuals and units will be reviewing (including mentors or sponsors of students/fellows, if applicable). Refer to School/Unit guidelines regarding who needs to certify proposals in EPEX. Once routed, the only way to correct workflow for certifiers is to deny the proposal and start workflow over, which results in obtaining ALL certifications again.

   2) Also, please verify that anyone who is listed on the proposal and needs to certify
has a role that triggers workflow (Other Role: PI, Co-PI, Co-Investigator, Multi-PI, Named Investigator, Key Personnel, or Mentor/Sponsor)

3) To confirm whether personnel on the proposal should certify, please contact a School Level approver to verify before saving and routing. If all certifiers are not listed in the workflow preview, please contact PSGrants@emory.edu for assistance before saving and routing.

4) Verify that VA, Yerkes, or Office of Clinical Research (OCR) approvals are included within the workflow, if applicable.

   iii. If proposal must be entered into sponsor systems, ensure that all proposal data and relevant attachments have been properly entered into the correct sponsor system prior to OSP review and verify that the data in the sponsor system matches the data entered into EPEX.

2. Proposal Review and Routing:
   a. The Pre Award Administrator ensures that the proposal data has been properly entered into EPEX and the correct sponsor system(s), that the budget is correct and prepared correctly (including any subawardee/subcontractor budget documents), that all internal Emory requirements are met, all relevant commitments have been approved (cost shares, space, subcontractors, etc.), and any relevant compliance approvals are obtained or pending (IACUC, IRB, Environmental Health and Safety Office (EHSO), etc), prior to EPEX routing.

   b. The RAS Pre Award Manager or other senior team member in the RAS unit will review the EPEX entry created by the Pre Award Administrator assigned to the proposal prior to saving and routing the proposal in EPEX. (See Associated Document 4. Sample Checklist for Entering Proposal into EPEX for checklist of items to be checked).

   c. Pre Award Administrator will save and route the EPEX record to begin the routing process. Proposal should be routed with sufficient time for review. Refer to local School/Unit for guidance on deadlines for standard and complex proposals. For grants with deadlines, routed proposals should reach OSP at least 5 business days in advance of the sponsor due date.

   d. Proposal will follow the EPEX workflow which will include:

      i. Certification in EPEX by the Principal Investigator (PI) and all key personnel. This indicates to OSP the accuracy of the proposal materials and also includes the mandatory PI Federal assurance statement.

      ii. Department Administrator and Chair or designee approval indicates that the scientific aspects of the proposal have been reviewed, that adequate Departmental space and resources/commitments are available for completion of the project at the level of PI effort requested, and that any projected clinical trial deficits can be covered by departmental funds.

      iii. If required for the proposal, Schools/Units review for atypical cost share, other resources/commitments, and collaborative splits.

      iv. If applicable, OCR, VA, and Yerkes (based on OCR, VA and Yerkes review guidelines) will also review and approve proposal.

      v. OSP review and approval (see section e below).
e. The Office of Sponsored Programs (OSP) will conduct the overall final review of the proposal. Proposals received after internal deadline may not receive a thorough review.

f. Pre Award Administrator will monitor proposal approval workflow in EPEX, including OSP approval; follow-up if an approver has not approved quickly; respond to questions from approvers, review changes with PI, and make adjustments, as necessary.

g. For grant proposals (see section h below for contracts and clinical trials), once the proposal reaches OSP in EPEX, Pre Award Administrator will notify OSP when the proposal is final and ready for OSP review. OSP reviews the final proposal. OSP will communicate required and suggested changes to the Pre Award Administrator via email, and the Pre Award Administrator will work with the PI to make the changes. (See section III.1.d.vi. for examples of Required and Suggested Changes)

h. For contracts and clinical trials, OSP will negotiate contract language with the sponsor. The Pre Award Administrator will monitor the progress of contract negotiation and approval until contract is fully executed.

3. Submission
   a. Upon completion of final OSP review and no further changes are required, OSP will submit to the sponsor.
   b. OSP will email the Pre Award Administrator and PI when the proposal is submitted or, in the case of submission by the PI, when required review and/or signatures are complete and/or ready for pickup.
   c. Proposal submission to sponsor will occur as follows:
      i. Grants.gov Electronic Submissions: OSP will submit the final proposal package to the sponsor.
      ii. Other Electronic Submissions: Many foundations and other agencies require Institutional submission through their own electronic system. Pre Award Administrator will determine if proposal submission is to be completed by OSP or PI. If PI submission necessary, OSP will notify and provide required documentation to Pre Award Administrator and PI when the proposal has been approved.
      iii. Paper submissions: OSP will provide institutional signature(s) on the appropriate sponsor form page(s) and return to the Pre Award Administrator for their submission to the sponsor.

IV. RESPONSIBILITY

School/Unit:

- Determines PI eligibility policies/criteria
- Approves cost share or other resource commitments and /or collaborative splits as needed, prior to submission
- Reviews proposal and provides approval as necessary

Department:
• Reviews scientific aspects of the proposal and ensures that adequate Departmental space and resources/commitments are available for completion of the proposal.
• Reviews and approves any projected budget deficits

Office of Sponsored Programs (OSP):

• Reviews each proposal application to ensure compliance with all sponsor and institutional guidelines and regulations
• Ensures completion of eCOI forms
• Ensures cost share has been approved
• Confirms cost share commitments / collaborative splits
• Approves / signs proposals, prior to submission
• Submits proposal (where applicable) to sponsor
• Provides assistance with interpretation of sponsor guidelines
• Negotiates contracts and clinical trial agreements with sponsor

Principal Investigator (PI) or PI Staff:

• Reviews sponsor guidelines
• Develops research plan, budget justification, biosketch and other proposal components required by sponsor
• Provides guidance to Pre Award Administrator in the completion of the budget, biosketches, and other proposal components assigned to the Pre Award Administrator
• Provides relevant proposal documents to RAS unit
• Obtains and maintains compliance approvals (e.g. IRB, IACUC, Radiation Safety, etc), as needed
• Obtains atypical cost share and other resource commitments and approvals, as needed
• Obtain commitment letters from subawardees, as needed
• Identifies need for and requests additional space, as needed
• Certifies proposal in EPEX
• Completes PIFIRR (eCOI) forms
• Ensures collaborators (e.g. subcontractors or other Emory faculty) are providing appropriate information for the project
• Works with Pre Award Administrator to submit proposal as determined by sponsor system and guidelines
• Obtains editable, draft copy of contracts, if applicable, from sponsor
• Obtains clinical research protocols and/or informed consent documents, if applicable

Pre Award Administrator:

• Reviews sponsor requirements, identifies proposal elements that must be completed and determines, with PI, who is responsible for each component
• Ensures PI meets School/Unit eligibility requirements and has sufficient effort to complete research
• If proposal involves multiple PIs or units, coordinates with other RAS units, as necessary
• Assists PI with proposal elements as requested (e.g. budget development, biosketch)
• Ensures subawardee documentation is complete and supports PI in obtaining subawardee information, as needed
• It is the responsibility of the RAS unit that supports the prime Contact PI to ensure that information and approvals relating to all projects within the proposal are obtained – regardless of which RAS units support the faculty on those projects.
• Develops budget in standard template with proper F&A rate calculation
• Ensures budget justification matches budget
• Compiles proposal elements from PI and follows-up with PI if components are missing
• Puts proposal elements into proper format (i.e. PDF), as needed
• Confirms compliance approvals have been obtained
• Confirms cost share or resource commitment approvals have been obtained, as needed
• Obtains VA MOU, if necessary (for all faculty in the proposal, regardless of which RAS units normally support those faculty)
• Submits proposal in eCOI system (PFIRR) and ensures Investigator eCOI forms are completed
• Enters proposal into EPEX
• Assists PI in entering proposal elements into sponsors’ electronic systems or submitting paper submissions
• Monitors proposal approval workflow in EPEX, including OSP approval, and follows-up as necessary; makes corrections, if requested
• Monitors progress of contract negotiations, as needed for clinical trials and contracts
• At time of award, the Proposed VA MOU should be updated to reflect any changes in awarded effort in the event a revised budget was necessary due to agency’s reduction in the total amount awarded. The corrected Proposed MOU would then be routed as a Revised VA MOU and all signatures must be obtained. (PI, Dept, VAMC and OSP)

***************************************************************************END OF SOP***************************************************************************