College of Medicine
Research Proposal Submission Requirements and Guidance
Department – Research Administration and Compliance (RAC) – Division of Sponsored Programs (DSP)

**Department**

The department/unit should work closely with RAC and DSP personnel in order to prepare and submit an accurate and complete proposal. This will facilitate both a time efficient and compliant research process. See suggested department/unit procedures below. The department responsibilities include the review and/or preparation of general information and compliance documents (as applicable). These may include; COM and PI contact info, IRB/IACUC issues, Conflict of Interest Forms, Subcontracting approvals/budgets, Time/Effort Letters, Cost-Sharing Letters, PI User ID, PI/Other Roles for NIH and other grant requirements (e.g., page limits.)

1) Provide input and assistance to PI in preparing a completed proposal:
   - Create proposal in PeopleSoft.
     - Proposal with appropriate F&A allocations for COM projects
     - Budget Line Summary used to generate salary information [see #2 below]
   - Preparation of sponsor forms/electronic package
   - Conflict of Interest Forms
   - Time/Effort Reporting Letters
     - NIH Career Development K-Series
       - [http://www.med.ufl.edu/research/rac/proposal/forms/com-nih-k-award-compliance.doc](http://www.med.ufl.edu/research/rac/proposal/forms/com-nih-k-award-compliance.doc)
     - USD Veterans Administration
       - [http://www.med.ufl.edu/research/rac/proposal/forms/com-timecommitment-va.doc](http://www.med.ufl.edu/research/rac/proposal/forms/com-timecommitment-va.doc)
     - All Other Mechanisms [http://www.med.ufl.edu/research/rac/proposal/forms/com-timecommitment-general.doc](http://www.med.ufl.edu/research/rac/proposal/forms/com-timecommitment-general.doc)

2) Review and/or Preparation of Budget:
   - Modular
     - Preparation of budget using Budget Line Summary in PS [DSP strongly encourages the use of the RR Budget for all proposals that will be submitted via Cayuse. The College of Medicine will not require/review Budget Line Summary in PeopleSoft when Cayuse RR Budget is utilized. If the grant is not being sent via Cayuse and a detailed RR budget is not created, Budget Line Summary in PeopleSoft would still be required]
     - IDC (correct rate or upload of guidelines showing different rules for F&A)
     - Subcontracts (all documentation, with approvals and budgets, attached)
     - Cost-Sharing (Mandatory v Voluntary and appropriate letters)
     - Justification (PI roles, person/months of effort, and NO dollar amounts)

Detailed
   - Preparation of budget using Budget Line Summary in PS [DSP strongly encourages the use of the RR Budget for all proposals that will be submitted via Cayuse. The College of Medicine will not require/review Budget Line Summary in PeopleSoft when Cayuse RR Budget is utilized. If the grant is not being sent via Cayuse and a detailed RR budget is not created, Budget Line Summary in PeopleSoft would still be required]
   - IDC (correct rate or upload of guidelines showing different rules for F&A)
   - Subcontracts (all documentation, with approvals and budgets, attached)
   - Cost-Sharing (Mandatory v Voluntary and appropriate letters)
   - Justification (Mandatory, person/months effort, and dollar amounts)
   - Final budget to be sent to Sponsor/Agency
3) Approve in PeopleSoft:
   o When DSP must submit electronically, the submitting PI Department holds the proposal at their level until it is considered FINAL. Department approves FINAL proposal to advance to College level for review. In addition, if the proposal is submitted on the day of the deadline, the department must contact both the RAC and DSP by phone.

4) Clinical Research Compliance documentation
   This documentation is required at the time of submission for all industry sponsored research and investigator initiated research and before IRB submission. For federally funded grants, this documentation is required as follow-up to the RAC office once funding is imminent and before IRB submission.
   o Study Registration and Initiation Checklist for Research with Human Subjects (Completion of this form will identify which of the following forms are also required)
     http://media.news.health.ufl.edu/misc/rac/forms/RBC_Forms/Study_Registration_Initiation_Checklist.docx
     o Medicare Coverage Analysis Worksheet
     o Device Table (Include FDA Device Category Letter)
     o Drug Table
     o Shands/UFP Clinical Services Payment Grid
     o Confirmation of Services (COS) Form for all study-funded services
     o Budget (Detail or Limited)
     o Clinical Trial Agreement Checklist
     o Clinical Trial Agreement/Contract/Service Agreement/Award Letter
     o Informed Consent Form FINAL IRB01 or DRAFT WIRB
     o Protocol/Human Subject Plan/Scope/Statement of Work
   o A Financial Language Assessment (FLA) Form and a Study Initiation Letter (SIL) will be provided to the PI and the department contacts. A complete compliance packet is required in order to prepare a FLA form. This form is required by IRB and (W)IRB for all studies that involve human subjects and any drugs, devices, substances or clinical services.

**College of Medicine Research Administration and Compliance**

About the RAC: The Research Administration and Compliance (RAC) is a service-oriented office offering assistance to faculty and staff in the College of Medicine regarding research-related matters. As part of the College of Medicine’s research administration and compliance, RAC reviews and approves grant proposals to ensure compliance with University of Florida, UF Research Foundation, Health Science Center, College of Medicine, and sponsor agency rules and regulations.

The College of Medicine requires proposal approvals through PeopleSoft Workflow.

RAC REVIEW OF GRANT PROPOSAL DOCUMENTS: To assist PIs and departments with streamlining the grant review and approval process for external grant funding, RAC staff will review the following items in each grant proposal given sufficient time before a deadline (see Day of Deadline Submissions/Review Section below).

1) Review of Budget Information and Compliance Documents (as applicable); COM and PI Contact info, Clinical Services designations via scope of work and/or protocol, Subcontracting approvals/budgets, Time/Effort Reporting letter, Cost-Sharing letters. As DSP strongly encourages the use of the Cayuse RR Budget for all Federal proposals that will be submitted via Cayuse, the College of Medicine will not require/review Budget Line Summary in PeopleSoft when Cayuse RR Budget is utilized. RAC Staff will .PDF the approved Cayuse budget and upload to PS
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before approval. If the grant is not being sent via Cayuse and Cayuse RR Budget is not being used, Budget Line Summary in PeopleSoft will still be required.

RAC does not review budget details but will look at the following in general:

- Modular
  - IDC (correct rate and appropriate modifications)
  - Subcontracts (all documentation, with approvals and budgets, attached)
  - Cost-Sharing (Mandatory vs Voluntary and appropriate letters)
  - Justification (limit to personnel months of effort and dollar amounts for supplies, etc)
- Detailed
  - IDC (correct rate and appropriate modifications)
  - Subcontracts (all documentation, with approvals and budgets, attached)
  - Cost-Sharing (Mandatory vs Voluntary and appropriate letters)
  - Justification (limit to personnel months effort and dollar amounts for supplies, etc)
- Final budget to be sent to Sponsor/Agency
- Internal Budget changes in PeopleSoft (if applicable) will be required at time of Award

2) Approve in PeopleSoft:

- When proposal requires DSP to submit electronically, RAC approves FINAL proposal from PI/Dept.
- When Proposal will be submitted by PI or by paper, RAC approves upon general review of items 1) above.

3) Send email to DSP with notice of College approval and the FINAL proposal when DSP will submit electronically. Notation will be provided to indicate approval method (Workflow approval/or DSR 1 form approval) Cost-Sharing. The FINAL proposal will be sent with or without review depending on the circumstances to meet the deadline, see below.

4) Day of Deadline Submissions/Review:

- Submitting a proposal the day of the deadline significantly increases the risk of the proposal not being successfully transmitted through the electronic systems to your Sponsor to meet the deadline or rejected by your Sponsor for unacceptable submissions. If a proposal comes in on deadline day the review will consist of ensuring signatures are obtained and the application is final. RAC staff will approve your proposal WITHOUT any additional review in order to ensure that DSP has as much time as possible to submit your proposal. RAC will make every effort to identify and notify the PI/staff of any important budget issues that are noticed, however, they will not hold the proposal until those errors are corrected. RAC and DSP will communicate regarding any problems such as electronic system failures and late proposal submissions.

5) Follow-up Issues: Any elements of the proposal missing at time of submission including but not limited to the following:

- Cost-sharing commitment documentation; or time/effort reporting letter
- Clinical Research Compliance review and assessment
- Financial Language Assessment Form will be completed by the RAC and provided to the PI and dept contact. This form is required for all (W)IRB submissions for studies that involve human subjects and any drugs, devices, substances or clinical services
- Subcontracting information/approvals
Division of Sponsored Programs

DSP staff will review the following items for accuracy before a grant submission—given sufficient time—before a deadline and considering the number of proposals to be reviewed to meet the deadline:

1) Review of General Information and Compliance Documents (as applicable): Check for correct DUNS number, DSP contact info, IRB/IACUC issues, Conflict of Interest Forms, Subcontracting approvals/budgets, Time/Effort Reporting letter, Cost-Sharing letters, Grant guideline requirements (e.g., page limits) that if absent would cause proposal to be rejected, and other sponsor program-specific requirements.

2) Review of Budget: DSP does not review budget details but will look at the following in general:
   - Modular
     - IDC (correct rate and appropriate modifications)
     - Cost-Sharing (Mandatory v Voluntary and appropriate letters)
     - Justification (PI roles, person/months of effort, there should not be dollar amounts)
   - Detailed
     - IDC (correct rate and appropriate modifications)
     - Subcontracts (all documentation, with approvals and budgets, attached)
     - Cost-Sharing (Mandatory v Voluntary and appropriate letters)
     - Justification (PI roles, person/months effort, and dollar amounts)
   - Final budget goes to Sponsor/Agency
   - Budget changes in People/Soft will be done at time of Award
   - Provide input and assistance to PI/Dept: Email or call regarding any problems or missing items that would affect grant submission.

3) Obtain DSR authorized official signatures on proposal and DSR 1 forms.

4) Submit proposal through electronic or paper submission guidelines; or release back to PI or Department Staff for PI to submit, as appropriate.

5) Day of Deadline Submissions/Review:
   - For electronic submissions or other submissions via DSP: If a proposal comes in on deadline day, DSP staff may do a No-Review or very limited review. For electronic submissions, DSP will submit the FINAL version as provided by COM RAC staff. Deadline day proposals must get to DSP to move through the electronic system. RAC and DSP will communicate regarding electronic system problems, proposals coming late in the day, etc.
   - For PI submissions coming through on deadline day: DSP will consider walk-thrus to expedite getting a proposal submitted on time.
   - Follow-up Issues: DSP staff will follow up on missing items that did not delay timely submission of the proposal but that need to be included in the DSP file.
   - JIT will be completed as required.