#### SCHOOL OF PUBLIC HEALTH Center for Health Research Proposal Development Guidelines for Research Proposals

**Title:** Proposal Development Timeline and Transmittal process for research proposal submission.

**Purpose:** The Proposal Development (PD) and Transmittal Process timeline is a guideline to promote successful grantsmanship that is in compliance with the institutional policies and sponsor's requirements.

The Principal Investigator (PI) initiates the PD process and will be responsible for the overall coordination, using the institutional resources, and management to ensure a timely submission to the sponsor. The PI will follow the recommended timeline and activities:

Timeline and activities:

### • Three months ahead of sponsor deadline:

- PI discusses the plan, concept, and aims with the **SPH Associate Dean for Research** and obtains approval to submit a proposal with CHR support.
- Decide on major items
  - Deadline to go for
  - Major topic (connected to title)
  - In general, what specific aims will be
    - Read
    - Look at your data
    - Talk to people in your laboratory
    - Talk to your colleagues
- o Do some research
  - Which study section? Who is on that study section? Who is likely to review your grant? What have they published? Do they have a favorite system, paradigm, cell type, etc.?
  - Network anything you need to know about the people on the study section? Are there telephone calls you should make?
  - Which institute? What have pay lines been for that institute? Do you know anyone with a project funded by that institute?
  - New criteria and reviewing approaches are being implemented on a time schedule; depending on your selected deadline, some or more of the changes may apply to you. Check the sponsor's web site.
- PI informs CHR (Pramil Singh, <u>psingh@llu.edu</u>, Wes James, <u>wjames@llu.edu</u>) and works with CHR to send page one of the Transmittal

Form, <u>http://www.llu.edu/assets/research-affairs/docs/llu-transmittal-form.pdf</u>, to Pre-Award @ Research Affairs. CHR enters the information in SPH Proposal Deadline Tracker to monitor progress.

- The PI must send the instructions / guidelines (if it is a non-NIH sponsor) as a link or as an attachment. In addition, the PI must provide the following information on page one of the transmittal form to proceed with the record set up:
  - Sponsor's name:
  - If NIH, proposal mechanism: R01 / R03 / R15 / R21 / Other:
  - Opportunity Number: R01 Parent PA-13-302, R03 Parent PA-13-304, R15 Parent – PA-13-313, R21 Parent – PA-13-303. (Expiration date: 9/08/2016)
  - Type of Proposal: New / Resubmission / Renewal
  - Proposal's Title: (not to exceed 81 characters for NIH applications)
  - Will the proposal include a cover letter? Yes / No
  - Does the project involve IRB? Yes / No
  - Does the project involve IACUC? Yes / No
  - Does the project involve multiple PIs? Yes / No
  - Does the project involve any sub-contract(s)? Yes / No
  - Does the project involve any international collaboration? Yes / No
  - Project start date:
  - Project end date:
  - Submission Deadline:
- Research Affairs will create a LLeRA record and e-mail a "Proposal Alert" with a timeline for the Transmittal Process and other information regarding the required administrative procedures to be followed.
- PI will continue with the Proposal Development process.

## • Two and a half months ahead of sponsor deadline:

- Write Specific Aims
  - Absolutely critical perhaps 70% of decision is made by the time reviewer gets through your abstract and SA
- o Try two or three different versions
- Between 2 and 5 aims; can have sub-aims
- Revise as often as needed constantly circle back around as your grant develops
- Show versions to trusted colleagues, mentors, Associate Dean for Research; and don't be afraid to completely redo more than once
- Make sure stuff at the beginning and throughout the aims provide strong evidence of:
  - Significance not just health impact; also how it will move field (and maybe other fields) ahead
  - Approach convince reviewer that it is appropriate and cutting-edge; will be a summary
  - Investigator you are the right one for this job; you have the experience, expertise, tools
  - Environment core facilities, collaborations
  - Innovation use buzz words novel, collaborative, cutting-edge, paradigm shifting, innovative, synergy

### • Two months ahead of sponsor deadline:

- Write individual sections
  - Background and Significance can be the easiest part to write, and you may be able to ask your students/postdocs to help with this
  - Preliminary Results can often borrow from your papers and manuscripts
  - Experimental Plan
    - An Aim at a time, but can jump back and forth
      - Why are you doing it? (Rationale and Overview)
      - How do you plan to do it? (Several sections)
      - What do you do if it doesn't work? (Anticipated Results, Possible Pitfalls and Alternative Approaches)
      - What will you do if it does work amazingly well? (Future Directions)
  - Abstract last thing

### • One month ahead of sponsor deadline:

- Finalize "respectable draft"
- Give it to "trusted" colleagues, mentors, etc. for review request for feedback within two weeks. Make arrangement with Associate Dean for Research and / or CHR Director for pertinent persons from SPH to give a

# comprehensive review of the science with results back within two weeks.

- Spend the next week working on other stuff
  - LLeRA (InfoEd) entries (Wes James)
  - Resource Page (example documents from Wes James)
  - Biosketch(es) (use current version with updated "personal statement")
  - Letters of collaboration (compiling and contacting investigators)
  - Budget PI will contact the SPH Grants Budget Coordinator (Rebecca Cannady) and the assigned RAFM Analyst for assistance with budget development, review and approval.
  - Personnel justification (be prepared to respond to all edits by Rebecca Cannady and Gordon Hewes)
  - Cover letter where you request a study section and an institute
- Give yourself a break and a chance to get "fresh eyes"
- Once the budget is finalized, get formal approval and signatures (SPH Associate Dean for Finance and RAFM Analyst) on the Transmittal Form at least *five* business days before the sponsor deadline.

## • Two weeks ahead of sponsor deadline:

- Incorporate comments from the scientific review by colleagues don't be afraid to take stuff apart if you need to - it can be very hard psychologically to do this!
- Rethink completely your Specific Aims logic, wordsmithing, consistency
- o Reread entire grant for logic flow
  - Abstract is it still relevant, connected, accurate and compelling?
  - Specific Aims are they still relevant, connected, accurate and compelling? Did you change your mind about something as you worked on the rest of the grant?
  - Background and Significance
    - Entry headlines by themselves should tell a story
    - Include paragraphs you need; delete those that are not absolutely essential
  - Preliminary Results
    - Entry headlines by themselves should tell a story
    - Include graphs, etc. that you need to show that your hypothesis is sound and that you can perform these experiments. Delete those that are not absolutely essential
    - Include some of what's already published, but not all. Include more of what is not published.
  - Research Design
    - Make sure everything makes sense check logic flow
    - Pay special attention to how you will interpret your possible results

- Connections between aims want them to fit into a logical, connected scheme, but you also don't want SA2 and SA3 to depend on absolute success in SA1
- Extra Stuff
  - Letters of collaboration
  - Human Subjects (meet with the IRB Director before you write this section *only* if your project involves Human Subjects).
  - Animals (meet with the IACUC Director before you write this section *only* if your project involves Animals).
- Ten business days ahead of sponsor deadline: (Receives technical assistance from Research Affairs Pre-award / CHR (James) as needed). During this period, extra administrative support can be requested through the CHR Director and is subject to final approval by SPH Finance.
  - PI will begin uploading the proposal documents into LLeRA or the recommended website.
- PI will send the signed Research Conflict of Interest (rCOI) disclosures to Sandra Figueroa, <u>researchcoi@llu.edu</u>, at least 10 business days before the deadline. ALL the investigators on the proposed project must complete and submit the "Research Conflict of Interest" disclosure form before submission of application. Please contact <u>researchcoi@llu.edu</u> for current rCOI forms.
  - PI will obtain the required signatures on *page two* of the Transmittal Form from:
    - Executive Director for PI's affiliated Center
    - SPH Associate Dean for Finances
    - SPH Dean (Alternates: 1. Associate Dean Academic Affairs, 2. Associate Dean – Financial Affairs)
    - Research Affairs Financial Management
    - (The PI must also obtain the respective signature(s) if the project includes personnel from a different School or entity, e.g. LLUMC, on campus).
    - PI sends Transmittal Form + proposal to Research Affairs Pre-Award for institutional review & approval. (The proposal will not be submitted without the signed Transmittal and rCOI forms).
    - Research Affairs Pre-Award informs PI that application has been reviewed and approved for submission
    - PI uploads all documents to LLeRA or recommended website, completes a final review, and requests Pre-Award to facilitate submission of electronic submission by the Institutional Official; or mails the application if required.
  - Five business days ahead of sponsor deadline:

- PI will submit the Transmittal Form along with the complete application to Preaward – Research for a complete review of the application prior to submission.
- PI will continue to review and edit as needed.
- Three business days ahead of sponsor deadline:
  - The PI must be available to respond to any issues Research Affairs may have.
  - Submit! The Institutional Official (Research Affairs) will submit the proposal electronically. (If it is a paper submission, the PI will submit the application via postal system and will e-mail a copy of the submitted proposal to Pre-Award which will be uploaded to the Proposal Tracking Module of LLeRA.)
  - After submission, the PI will check and make sure the application got into the system – using their **eRA Commons** account for NIH proposals. (If there is a problem, the PI must report to Research Affairs immediately to make necessary corrections and resubmit – only if it is before the submission deadline.)
- Post-submission:
  - You may wish to submit supplementary data exact rules and format will depend on your sponsor. You will probably get an email from the sponsor with specific instructions.
  - Study section will meet.
  - Scores will be entered in PI's eRA Commons account.
  - PI will need to respond to any JIT information (for NIH) if required.
  - o Council will make the final decision and inform the PI and Research Affairs.

(If you have a question or need assistance with the process, please contact Wes James, x15732 or <u>wjames@llu.edu</u>).