LOMA LINDA UNIVERSITY

<u>LLeRA Proposal Development</u>: a guide to developing and preparing proposals for electronic submission to NIH or other sponsors

<u>BEFORE YOU START:</u>

- Is your GENIUS profile / biosketch current?
- Are the profiles/ biosketch(es) for your Key Personnel current?

> ***TIP: Investigators can access the LLU – eRA Portal from off campus via webvpn.llu.edu. For assistance, contact x48611 or <u>lluhelpdesk@llu.edu</u>***

<u>LOGIN</u>
<u>FORGOT YOUR PASSWORD?</u>
REGISTER by emailing <u>osr@llu.edu</u>

> **<u>TROUBLE SAVERS - 1:</u>**
> - Follow instructions carefully and complete each step.
> - **SAVE** frequently. Use the "SAVE" button on the top-left corner of the LLeRA system, ***not*** your computer save command.
> - Use the "**BACK**" button on the top-right corner of the LLeRA system to go back to a previous page.
> - Be aware that the system **logs off** in 30 minutes if not in use.
> - <u>Have a question?</u>

If you wish to start the proposal yourself, follow the directions below to fill out the *<u>'New Proposal Questionnaire'</u>* and *<u>'Submission Mechanism/Form Information'</u>* sections. If you have sent the first page of the transmittal form to Sponsored Research and a record has already been started for you, skip to the *<u>'SF424 Tab'</u>* section of this document. *<u>Please note that the instructions below are for NIH proposals, the required information may vary by sponsor.</u>*

Once logged in, click on "Proposals" then "Create Proposal"

<u>NEW PROPOSAL QUESTIONNAIRE:</u>

Step 0: Verify your name is correct. "This Proposal will be created with **Last Name, First Name** as the PI." If not, click the 'Change PI' button to select the correct person.

Step 1: Choose 'Create a New Proposal' (Consult with Sponsored Research before preparing a proposal using the 'Copy from Existing Proposal' feature)

- *Continue to the next step.*

Step 1: Continued….
- Choose 'Select from Grants.gov Opportunities'
- *Continue to the next step.*

Step 1: Continued….
- Enter funding announcement number, e.g., PA-10-067 for a parent R01
- 'Select' the appropriate funding announcement from the search results

TIP: All submissions must be in response to a funding announcement.

Step 2: Select Proposal Type:
- New Proposal
- Resubmission (Revised Application)
- Renewal (Competing Continuation)
- Continuation (Progress Report)
- Revision (~'Competing Supplement')
- *Continue to the next step.*

Step 3: Select a Sponsor
- Select a Sponsor – **e.g. National Institutes of Health / DHHS**
- *Continue to the next step.*

Step 4: Automatic Numbering *(no input needed from investigator)*

Step 5: Enter the Proposal's Title
- *Continue to the next step*

Step 6: What are the project start and end dates? (For NIH, the earliest project start date must be ten months from the submission date, e.g. if the submission date is Feb. 5, 201x, the earliest project start date will be December 1, 201x).
- *Continue to the next step*

Step 7: How many years and/or budget periods would you like? (Your response to Step 6 will automatically fill this box. If you need additional years/periods beyond 7, add them inside the proposal.)
- *Continue to the next step*

Is all of the above information correct?
- If yes, click **'Yes, Create Proposal'** to show the final screen *(**Step 8**)* of questions that must be completed before you can work on your new proposal. You will be able to change the information once the proposal is created.
- If no, click on the "**Back**" button at the top-right corner to make changes.

<u>STEP 8: SET UP QUESTIONS</u> - All questions must be answered before you can **SAVE** to **CONTINUE!**

<u>Submission Mechanism/Form Information:</u>

- Is this a flow through Project? **No**
- Please select a Submission Mechanism/Screen Template – Choose **'424 R&R NIH (electronic submission')** from pull-down menu
- Is this a US federal sponsored project? **Yes**
- Will this be a proposal to PHS, NIH or one of the branches of NIH? **Yes**
- Is this an un-solicited application? **No**
- Opportunity Number – If not prepopulated, click on the **'Get Opportunity Number'** link to search for and select the funding announcement **(Questions? Contact either Sherie Donahue (sdonahue@llu.edu) or Wesley James (wjames@llu.edu)**

<u>Deadline Information:</u>

- Is there a Deadline for this Submission? **Yes**
- Fill in following information:
    - Deadline Type – Choose **Receipt** (from pull-down list)
    - Deadline Date – **mm-dd-yy** (e.g. 020511)
    - Deadline Time – (e.g. 5:00:00 PM)
    - Deadline Time Zone – Choose **(GMT 8:00) Pacific Standard Time (**from pull-down list)

<u>General Proposal Properties:</u>

- Choose "**Yes**" or "**No**" for each question.

<u>Because you indicated that this proposal is to PHS/NIH ...</u>

- Choose "**Yes**" or "**No**" for each question.

<u>Budget Setup Information</u> – (Questions? Contact your assigned Financial Analyst in Sponsored Projects Financial Management)

- What kind of budgeting model would you like to use? Choose **"Budget Period by Period"**
- Select the Program Type – it is usually **'Research Grants / R & D'** or **'Training'** or **'Program'**
- The majority of the research will be conducted **On** Campus

Cost Sharing Information

- Complete as appropriate

'Save and Continue' to generate the rest of the proposal

On each of the following pages you will see

- a menu on the left
- a box "□" next to the word 'Completed' (upper right corner)

Hereafter, you can click on any tab and work on that section.

- **SAVE:** frequently and often (top left-hand button)
- **COMPLETED:** When you have finished entering all the information in a particular section, check the 'Completed' box (upper right corner) to lock the information. To make changes to a particular item, first 'unlock' the section by un-checking the Completed box.
- **VIEW:** review generated PDFs of sections to confirm the content is correct.

Note: the proposal cannot be submitted until *all* sections have been marked completed.

SF424 TAB:

Much of the information on the SF 424 form is pre-filled. Below are the fields that may require investigator input:

1. ***Type of Submission:*** The default is listed as 'application.' If a proposal is corrected and re-submitted in the same grant round, this must be changed to 'changed/corrected application.'

4. Enter the ***federal identifier*** only when submitting a changed/corrected version of a new application, a resubmission or a competing continuation **(Questions? Contact either Sherie Donahue (sdonahue@llu.edu) or Wesley James (wjames@llu.edu)**

8. ***Type of Application:*** confirm that the correct submission type is selected

Is this application being submitted to other agencies? **Yes / No**

11. ***Descriptive title of applicant's project*** - Pre-filled from Setup Questions, Step 5, however, *it can be changed here.* ***(Maximum – 81 characters).***

15. ***Estimated funding*** – for NIH proposals, this is automatically populated when budget information is completed. For other sponsors, enter information manually.

16. If federal sponsor, click '**No** – Program is not covered by ***E. O. 12372***.' For other sponsors verify with instructions!

19. ***Authorized Representative***. Click on the box **(first name)** and it will open to a new page with a pull-down list of names. Select A J Zuccarelli → **Set** → **Save**. Click on the

"**Back**" button to return to the SF424 page. (At the time of submission, Research Affairs can change this information depending on availability of the AOR).

20. ***Pre-application*** – If submitting a pre-application, upload a summary description of the project in accordance with the announcement and/or agency specific instructions. (Unless specifically noted in a program announcement, NIH and other PHS agencies do not use pre-applications.)

PERFORMANCE SITES TAB: Provide **Organizational Name**, **DUNS# Congressional District** #, and **address** of associated organization(s) where the project will be conducted ***(required fields for all performance sites)***. (**Note:** *if associated organizations will be subawards, the basic site information will automatically be populated on this page. However, it should be confirmed that the DUNS # and Congressional District are filled in before submission.)*

OTHER PROJECT INFORMATION TAB: 1 & 2 are pre-filled from Setup Questions, Step 8. Answer questions 3 – 6.

TROUBLE SAVERS – 2:

- Prepare the Research Plan by following the page limits – e.g. R01 – 12 pages, R03 – 6 pages, R21 – 6 pages, etc.
- Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc.).
- Do **not** type Headers (PI Name) or Footers (page numbers) on documents. The system will generate these automatically.
- The application must be uploaded in segments. Whenever possible, convert each segment to '**PDF**' and view before uploading.
- Filenames - do not leave any space in between words of the file name (e.g. 'Project_Summary.pdf' **not** 'Project Summary.pdf' or 'Project-Summary.pdf'). Applications may not be accepted if the files are incorrectly named.
- Click on "Upload" icon, see box on the top right corner, identify file using the 'browse' button, upload.
- View and verify the images of each uploaded document; pay close attention to figures and special symbols.
- Once finalized, change the Research Plan status from "Draft" to "Final" (next to COMPLETED box).

PROJECT SUMMARY TAB: This project abstract should not be longer than 30 lines of text.

- Follow instructions for formatting this document. Identify the file using the "browse" button, upload, and view.

PROJECT NARRATIVE TAB: Describe the **relevance** of your research to public health in no more than two or three sentences.

- Follow instructions for formatting this document. Identify the file using the "browse" button, upload, and view.

REFERENCES CITED TAB:

- Follow instructions for formatting this document. Identify the file using the "browse" button, upload, and view.

RESOURCES TAB: Choose 'Upload Form' (preferred method) or 'Use the Database.'

- If you choose "Use the Database," type in all the relevant information. If you choose "Upload Form," identify the file using the "browse" button, upload, and view.

OTHER ATTACHMENTS TAB: Generally not used. *(Click* **COMPLETED** *and move on).*

PERSONNEL TAB: PI's name appears by default. To add more personnel, click on ***"Add"*** and select the person's name from the "pull down" list. (Personnel not affiliated with the institution nor on a subaward must be entered manually. For Loma Linda personnel, if the name is not in GENIUS - investigator database, contact Sponsored Research.) **(Questions? Contact either Sherie Donahue (sdonahue@llu.edu) or Wesley James (wjames@llu.edu)**

BUDGET TAB: contact your Financial Analyst at SPFM for assistance.

PHS 398 CHECKLIST TAB: (most information prefilled)

- Review and verify information

PHS 398 RESEARCH PLAN TAB:

1) Introduction to Application *(for resubmission or revision applications only)*
2) Specific Aims
3) Research Strategy
4) Inclusion Enrollment Report *(only for renewal or revision applications of a study that involves human subjects)*
5) Progress Report Publication List *(for renewal applications only)*

Human Subjects Section

Attachments 6-9 apply only if the question "are human subjects involved" is answered yes on the Other Project Information page. Read the Application Guide and/or the specific Funding Opportunity Announcement for instructions regarding attachments 6-9.

Other Research Plan Sections *(as applicable)*

10) Vertebrate Animals
11) Select Agent Research
12) Multiple PI Leadership Plan

13) Consortium / Contractual Agreements
14) Letter(s) of Support
15) Resource Sharing Plan
16) Appendix – no more than 10 documents

PHS 398 CHECKLIST TAB: Review and verify items **1-5**.

PHS 398 COVER LETTER TAB: Use this tab to upload a PDF of your **Cover Letter** if you indicated that it was going to be part of the proposal. *(If you do not wish to include a **Cover Letter** please visit the 'Setup Questions tab' to change your answer to the question.)*

APPROVALS TAB: Mark **COMPLETED**.

INTERNAL DOCUMENTS TAB: Mark **COMPLETED**.

FINALIZE TAB:

- Click on Build PDF/Form pages
- Click on Build Grants.gov application *(option available only after all tabs have been marked completed)*
- View PDF of the complete proposal

Transmittal Process:

- Complete the Transmittal Form with required signatures.
- Attach a hard copy of the complete proposal to the Transmittal form and bring it to Sponsored Research **at least five working days** before the submission date.
- The PI or the assistant must be available to answer questions during the whole pre-award application process until the time of submission to the sponsor.

Effective January 25, 2011, **No corrections can be made to NIH applications beyond the deadline.** However, proposals which follow our recommendation of submitting at least 2 days before the deadline will have 2 days or up until the deadline (whichever comes first) to make corrections. Those who wait to proposals the day before or day of the deadline will not have a cushion for electronic transmission issues. ***Due to the vagaries of electronic submissions (many of which are beyond our control), we cannot guarantee that a proposal submitted the day of or even the day before the deadline will make it fully through the system without errors.***

If you have any questions regarding your proposal after it is submitted to the sponsor, contact Sherie Donahue, x83911, sdonahue@llu.edu.