Cayuse NIH Review Checklist DOM Fund Manager's Manual

# **CAYUSE (S2S) NIH REVIEW CHECKLIST**

Revised January 18, 2022

PI Name: Agency/Type: Fund Manager  RFA/PA Special Instructions:	Due Date:	
	FOA/PA #:	

### **Getting Started**

- □ As soon as you are aware of a proposal submission, complete the <u>Proposal Notification Form</u>.
- Cayuse Proposal Title should be formatted at follows:
   Signing Official's Initials, PI Last Name, First Initial, FOA/PA/#, then add grant short name.
   EXAMPLE: RGM, Bruin, J., PA-20-185, R01 Heart Study
- □ Verify that you are using the correct FOA package **and** form set (i.e. Forms-G) in Cayuse by checking the Electronic Submission > Opportunity Details section of the proposal.
- Professional Profiles will need to be created for each <u>UCLA</u> Key Personnel (KP) before you start the proposal, unless a profile already exists under the People tab.
  - o Under the Salary & Fringe Worksheet, enter "12" in the Calendar Months field.
  - Ensure UEI # RN64EPNH8JC6 is listed under performance site field for existing and new KPs being added to Cayuse. Request access for your division PIs so the UEI # can be added.
  - For non-UCLA Key Personnel, use the "Non-UCLA, PI #1-23" profile already established. <u>Do NOT</u> set up a <u>Professional Profile for Non-UCLA personnel.</u>

#### SF424 R&R

- □ Field 4a Resubmissions, Revisions & Renewals must contain the NIH grant #, e.g. HL123546.
- □ Field 5 Person to be contacted should be OCGA C&G Analyst. Do **not** edit any of the auto-filled fields.
- □ Field 11 Title = max 200 characters\*, including spaces & punctuation.
  - \* Revision & Renewal applications should have the same title as the previous grant application, unless the specific aims have significantly changed. In these instances, choose a new title.
- □ Field 12 Project dates are based on NIH award cycles or dates specified in the FOA.
- □ Field 14 Change the PI Org Name to "UCLA David Geffen School of Medicine".
- □ Field 15d Enter 0, if no Program Income. Otherwise, add appropriate amount.

#### **Project/Performance Site Locations**

- Change Org Name for primary site = UCLA David Geffen School of Medicine/Division
   Name.
- Street1: Physical street address (e.g. 10833 Le Conte Avenue).
   Street2: Building and room number. To find a UCLA street address, see page 2
- □ Enter a **9-digit Zip/Postal Code** for each Performance Site, e.g. 90095-1736. Zip Code lookup can be found here.

- □ List a Performance Site for each subaward, or location where work will be performed, e.g. additional departments and/or laboratories at UCLA other than the Pl's.
  - To find the Congressional District, enter the Institution's 9 digit zip, UCLA = CA-033
  - To find the UCLA's UEI # RN64EPNH8JC6 go to OCGA's Standard Information Site. To search for other Institution's UEI # try FDP Clearinghouse website or email DOM DRA.
- Complete the Performance Site section in the Pl's Professional Profile (People tab) and check "Active", so information is auto-filled for future proposals.

#### **Other Project Information**

- □ Field 1a & 2a If applicable, mark YES to Human & Animal Review Pending, unless current approval will be active at start date of award.
- □ Field 6 If proposal has international collaboration checked yes to 6a, complete 6b **and** include foreign justification in section 12. Other Attachments.
- □ Fields 7-12 Use of URLs/hyperlinks in documents uploaded in these sections is not allowed.
- □ Field 7 Abstract should be no more than 30 lines (not including Abstract Heading).
- □ Field 8 Project Narrative should contain no more than 3 sentences.
- □ Field 9 Include a full reference, and the Pub Med Central ID # (PMCID) for each publication where the PD/PIs are authors, as per the Public Access Policy.
- □ Field 10 **ALL Resources** require a <u>description</u> of <u>how the scientific environment</u> will <u>contribute</u> to the probability of <u>success of the project</u>, & unique features of the environment. Described any special facilities used for working with biohazards. Also double check <u>additional instructions for various activity codes</u>.
- □ Field 10 **Early Stage Investigators ONLY** Require a description of the institutional investment in the success of the investigator (e.g. resources, classes, etc.).
- □ For proposal with subawards, include the Facilities and Other Resources, and Equipment information for each subaward within sections 10 & 11.
- □ Field 11 Equipment is required. If not applicable to the research project, upload a PDF so stating.

# Senior/Key Person Profile

#### Profiles

- Change Org Name for all DGSOM faculty = UCLA David Geffen School of Medicine.
  - List of DGSOM Departments, Institutes & Centers.
  - If KP is not in DGSOM, change Org Name to appropriate School or College, e.g. UCLA School of Public Health, UCLA College of Letters & Science, etc.
- o Include Prefix, Suffix, Position/Title AND verify data matches BioSketch.
- Street1: Physical street address (e.g. 10833 Le Conte Avenue).
   Street2: Building and room number. To find a <u>UCLA street address, see pg. 2</u>.
- If NIH, enter the Commons user name into the Credential field (required for ALL Key Personnel). Should match eRA Commons User Name field of the BioSketch.
- □ **BioSketches** (5 pages max)
  - No graphics, figures and tables allowed.
  - Section A: Personal Statement can include up to 4 citations. May include ongoing & completed research projects from the past 3 years that you want to draw attention to Do not use hyperlinks or URLS to cite these items.
    - Ongoing: All dates are current, NOT expired.
    - Completed: Contains grants completed ONLY within last 3 years.
    - Do NOT include \$ amounts or % effort/calendar months in either section.

- For each Ongoing or Completed Award include: Title, Project Period, Agency Grant #. Role & Goal.
  - For NIH grants: Change any "Co-PI" roles to "MPI" aka Multiple PI.
- Do NOT include any Pending proposals and Overlap statements.
- Section B: Positions, Scientific Appointments and Honors in reverse chronological order (current/newest on top to oldest on bottom)
  - All positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).
- o Section C: Contributions to Science
  - Describe up to 5 most significant contributions to science.
  - Cite up to 4 publications per contribution. Do not use hyperlinks or URLS to cite these items.
  - A publication list URL is optional but, if provided, must be a government website (.gov) like myNCBI.
- Section D: Scholastic Performance solely present on the fellowship applications (i.e. Fs, R36 dissertation research grants). Otherwise, section D needs to be removed.
- o Additional Information: Research Support and/or Scholastic Performance:
- Verify Project Roles for all key personnel are appropriate. <u>Definition of Key Personnel</u>.
- Enter Key Personnel (KP) in the order you would like them to appear in the detailed budget.
   Once all KP have been entered, hit the blue Sort Personnel button to alphabetize your KP.

# Research and Related Budget Detailed Budget

- □ Sections A & B Verify Project Role matches Key Person Role & Budget Justification.
- □ Section A Salary information is entered in the Base Salary **AND** the Cal. Salary (\$) fields.
  - o If you do not enter the salary in both fields, the auto-calculation will not work!
- □ Sections A & B Benefit Rate:
  - Use UCLA composite benefit rate (CBR).
  - Enter the rate in Fringe Benefit fields as a PERCENTAGE (e.g. 39.3%), not \$ amount.
     This will enable the reviewer to easily determine the rate used.
- □ Section B Cal/Acad/Sum. Months enter the **TOTAL** number of months for all personnel in each category. Example, 2 SRAs at 6.0 Cal. Months/each = 12 Calendar Months Total.
- □ **Do NOT include** <u>Grad Fees</u> in the benefits in Section B. Instead, add to Section F8-17, so that the fees can be excluded from the Indirect Cost Base.
- □ Section F, Fields 8-17 TIF charges are included in the Other Direct Cost section.
  - Reminder: Cost shared effort and Summer Months effort are not subject to TIF.
  - Reminder: IF Human Fetal tissue is used follow instructions <u>NIH-Human-Fetal-Tissue-Proposals</u>.
- Escalation Rate for future years: NIH does not have a policy regarding <u>future years escalation</u>, unless otherwise specified in the FOA/PA.
  - Request actual costs needed for the project. Request escalation only if escalation is consistent with institutional (UCLA) policy.
  - Do NOT escalate salaries beyond any years where capped rates are reached. i.e. <u>NIH</u>
     Salary Cap
- Budget Justification:
  - o All personnel justified, person months used. All categories justified.

- Justification includes how future years' escalation was calculated (if applicable).
- Justification includes how benefit rates were calculated.
- If NIH cap used, so state, and also state actual TNS is greater than the cap.
- Names and categories are listed in the same order as they appear in the detailed budget!
- All subtotal amounts add up to the totals, AND the total amounts match amounts listed in the detailed budget.
- Budget justification reference guide.
- □ If you override an auto-calc field (indicated with a red star), explain to DOM DRA what you did and why. Remember Cayuse will auto-calculate for you. There should be VERY few reasons why an over-write is necessary (e.g. effort w/o salary). Do not over-write an auto-calc field unless you are 100% positive.

#### Modular Budget

- Section A Cayuse will only auto-calculate the "Direct Cost less Consortium F&A" if the Detailed RR Budget is completed within Cayuse (which is best practice!). Otherwise, the requested module will have to be manually entered.
- □ Section B Verify MTDC base & IDC math calculated correctly. **Cayuse will auto-calculate** these fields.
- □ Section C.2 Budget Justifications
  - Personnel Justification: All personnel justified, person months used. NO other categories justified (e.g. escalation, benefits, supplies, travel).
  - o Consortium Justification (if applicable) From the NIH SF424 Guide:
    - List the name of the subaward institution at the top of the page.
    - Indicate whether the subaward institution is foreign or domestic.
    - Provide project period for subaward.
    - Provide an <u>estimate of TOTAL COST</u> (direct + F&A) for <u>each year</u>, <u>rounded to</u> the nearest \$1,000.
    - Justify ALL personnel, including level of effort (in person months) and roles on the project. No other categories justified.
  - o Additional Narrative Justification. Required under the following circumstances:
    - To explain any variations in the number of modules requested annually.
      - REMINDER: Additional Narrative Justification is NOT needed in applications to FOAs/PAs with direct cost limits that do not spread evenly across budget periods (e.g. R21s).
    - To describe any direct costs that were excluded from the total direct costs (e.g. equipment, tuition remission, rent, etc).
    - To describe any work being conducted off-site, especially if it involves a foreign study site or an off-site F&A rate.

## **R&R Subaward** (see Cayuse (S2S) NIH Subaward Checklist for detailed instructions)

- Detailed Budgets with Subawards
  - Verify Subaward Budget box is checked to include with submission to NIH.
  - Complete all sections in the linked Subaward (Performance Sites, Key Persons, Budget, Budget Justification), not in the prime proposal. When the Subaward is linked to the prime, all sections of the Subaward will auto-fill into the prime. If they do not auto-fill, de-link the sub, and then re-link it. Key Persons in prime proposal may need to re-alphabetize.

- Subaward Budget Justification list the name of the Subaward Institution at the top of the Budget Justification. e.g. "Budget Justification for University of Michigan"
- Subaward Budget Justification should include escalation rates for future years (if applicable) and benefit rates used.

### Modular Budgets with Subawards

- Verify Subaward Budget box is **NOT** checked. Add a **Worksheet Row** for each Subaward Institution. This section will only be used for budget calculation purposes.
- Verify UCLA Indirect Cost calculated correctly, e.g. exclude all but the first \$25K EXCEPT for subs to another UC, then total subaward amount is excluded.
- Upload Signed UCLA <u>Subrecipient Commitment Form</u>, <u>Subrecipient Letter of Intent</u> (only for <u>FDP Pilot Institutions</u>) or <u>Multi-Campus (MCA) Commitment Form</u> (other UCs), and <u>Subrecipient vs. Contractor Determination Checklist</u> for each Sub to the Supporting Documents section **PRIOR** to deadline.

### PHS Human Subjects and Clinical Trials Information (HSCTI)

NIH Human Subjects Decision Tool: This tool will help PIs in determining if study includes Human Subjects, falls under Exemption #4, or is NO to Human Subjects, but YES to human specimens and/or data.

- If NO to Human Subjects, but YES to Human Specimens and/or Data
  - o Provide an explanation of why the application does not involve human subject research.
- If YES to Human Subjects, and YES to Exemption #4
  - Under Study Records, add a new study.
  - o In the HSCTI form, complete the following:
    - Answer sections 1.2, 1.3, and 1.4
    - 3.1: Add Attachment: Provide justification as to why the study falls under Exemption #4.
- If YES to Human Subjects, NO to Exemptions, but NOT a Clinical Trial
  - In the HSCTI form, complete the following:
    - Section 1: All items, except 1.5
    - Section 2: All items
    - Section 3:
      - 3.1: Required
      - 3.2: Complete only if applicable
      - 3.3, 3.4, 3.5: Optional
- If YES to Human Subjects, NO to Exemptions, and YES to Clinical Trial
  - o In the HSCTI form, complete all 5 sections.

#### **PHS 398 Cover Page Supplement**

- □ Complete items 1-4
  - #4: NIH-Human-Fetal-Tissue-Proposals
- □ Field 5 only required if it is a Renewal application
- □ Field 6 only if a change in PI/Institute

#### Research Plan – Do not use hyperlinks or URLS to cite items in any of these documents.

- □ Field 1 Introduction to Application, if applicable, is limited to 1 page, unless otherwise noted in FOA/PA. If changes in Research Strategy are marked (*no longer required*), include how edits are indicated. i.e. brackets, change in font, etc.
- □ Field 2 Specific Aims is limited to 1 page.

- □ Field 3 Research Strategy includes: **(3a) Significance**, **(3b) Innovation**, **(3c) Approach**, and needs to meet page limit requirements.
  - o Confirm section conforms to new rigors and transparency in research requirement.
- □ Field 5 If Animal Subjects marked YES on Other Project Info page, then ensure Item 5 contains only the following 3 bullet points: 1) Description of Procedures, 2) Justifications, 3) Minimization of Pain and Distress.
- □ Field 7 **REQUIRED** if more than one PD/PI is named.
- ☐ Field 8 Consortium/Contractual Arrangements
  - NIH SF424 Guidelines state: Explain the programmatic (statement of work), fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.
  - This file should include the following information for each Subaward, as best practice:
    - Name of Subaward Institution
    - Name of Subaward PI
    - Project period dates for Subaward
    - Total Cost for each year
    - Scope of Work
- □ Field 9 It is recommended that you include a Letter of Support from each subaward PI. Be sure all Letters of Support are 8" x 11".
- □ Field 10 Resource Sharing Plan is required.
- □ Field 11 Authentication of Key Biological and/or Chemical Resources is requested. If this section is not applicable to the research, suggest uploading a PDF so stating. **Limit to 1 page**.
- □ Field 16 Appendix
  - A summary sheet of all items included in the Appendix is encouraged. Include as first page of the Appendix.
  - Use filenames for attachments that are descriptive of the content.
  - Complies with NIH Policy NOT-OD-07-018.
    - Only allowable items: blank data collection, survey or questionnaire forms; simple
      list of interview questions; blank informed consent/assent forms; other items only
      if they are specified in the FOA as allowable appendix materials.

# **PHS Assignment Request**

- PIs may request institute and/or study section assignment via the <u>PHS Assignment Request</u>
   Form. PIs may also list individuals who should not review the application and why.
  - No longer include these requests in the cover letter!

#### Other Miscellaneous Items

- Cover Letter If included, verify it is printed on official letterhead with PI signature and a current date. Verify proposal title referenced in Cover Letter matches Proposal Title on SF 424 RR.
- Proposal contains no Errors (see Error/Warning/Info button at bottom of proposal).
  - If submitting to DOM DRA for administrative review only (i.e. awaiting Research Plan sections from PI), it is okay to have Errors related to the scientific sections only.
- □ Verify all NIH Font & Line Spacing policies were followed:
  - Font: 11 point or larger
  - Type Density: No more than 15 characters per linear inch (including characters & spaces).

Cayuse NIH Review Checklist DOM Fund Manager's Manual

- Line Spacing: No more than 6 lines per vertical inch.
- General: at least ½" margins, no headers, no footers, 8.5" x 11"
- □ Internal Documents all should be uploaded into Supporting Documents section of the Cayuse prior to submission.
  - o **EPASS** 
    - EPASS common issues:
      - 4. Current Sponsor Award/ID # complete this for Resubmissions, Renewals, and Revisions. Add "N/A" for new proposals. Do NOT use FOA #.
      - 8. Verify budget figures match actual budget.
      - 9. Remarks List all subaward institutions and PATS # if, if applicable.
  - eDGE Economic Disclosure for ALL UCLA Key Personnel (not required for Other Significant Contributors (OSCs))
  - DOM PI Responsibility (for projects with human subjects)
  - PI Exception (if applicable)
  - Subaward docs, & other required documents
  - If multiple PIs involved, ALL UCLA PIs must complete internal documents, including signature on the EPASS.