CAYUSE (S2S) NIH REVIEW CHECKLIST

Revised June 19, 2018

PI Name: ___________________________ Due Date: ____________
Agency/Type: ___________________________ FOA/PA #: ____________
Fund Manager ___________________________

RFA/PA Special Instructions:

✓ Checkmark = No issues, item completed correctly.
☐ Circled Item = Issue. Read checklist item, and/or please see notes.
− Dash = Not Applicable.

Getting Started

☐ As soon as you are notified of a proposal submission, send an email to DOM DRA with the following information:
  ○ PI Name, Agency Name, RFA/PA#, Due Date

☐ Ensure the correct Validation type is chosen. Generally, it will be “NIH”. If the FOA/PA has non-standard instructions, choose “NIH – Opt Out”.

☐ 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-18-484, R01 Heart Study

☐ Verify that you are using the correct FOA/PA/ package in Cayuse by checking the Electronic Submission/Proposal Details/Opportunity Number section of the proposal.

☒ Professional Profiles will need to be created for each UCLA Key Personnel before you start the proposal, unless a profile already exists under the People tab
  ○ Under the Salary & Fringe Worksheet, enter "12" in the Calendar Months field
  ○ For non-UCLA Key Personnel, use the Non-UCLA PI #1-23 profile already established. Do NOT set up a Professional Profile for Non-UCLA personnel.

SF424 R&R

☐ Field 4a – For Resubmissions & Renewals, must contain the NIH grant #, e.g. HL123546.
☐ 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 FOA/PA.
☐ Field 14 – Change the PI Org Name to “UCLA David Geffen School of Medicine”.
☐ Field 14 – Zip code should be 9-digits, e.g. 90095-1736.
☐ 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** should be physical street address (e.g. 10833 Le Conte Avenue).
- **Street2** should be building and room number. To find a UCLA street address, see page 2
- Enter a 9-digit **Zip/Postal Code** for each Performance Site. 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 PI’s.
  - To find the **Congressional District**, enter the Institution’s 9 digit zip, **UCLA = CA-033**
  - To find the **DUNS number**, search for the Institution’s registration in the CCR
- Complete the **Performance Site** section in the **PI’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 7 – Verify Abstract is no more than 30 lines (not including Abstract Heading).
- Field 8 – Verify Project Narrative contains 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 description of how the scientific environment will contribute to the probability of success of the project, unique features of the environment.
- 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 – If Equipment is not applicable to the research, upload a PDF so stating.
Senior/Key Person Profile

Profiles
- Change Org Name for all SOM 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.
- Include Prefix, Suffix, Position/Title, AND verify data matches BioSketch.
- Street1 should be physical street address (e.g. 10833 Le Conte Avenue).
- Street2 should be building and room number. To find a UCLA street address, see pg. 2.
- If NIH, enter the Commons user name into the Credential field (required for PI). Check 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.
- Section B: Positions & Honors in chronological order concluding w/ present.
- Section C:
  - Describe up to 5 most significant contributions to science.
  - Cite up to 4 publications per contribution.
  - A publication list URL is optional but, if provided, must be a government website (.gov) like myNCBI.
- Section D: Additional Information: Research Support and/or Scholastic Performance:
  - Ongoing – all dates are current, NOT expired.
  - Completed – contains grants completed ONLY w/i last 3 years.
  - Assure $ amounts or % effort/calendar months are NOT included in either section.
  - Include the title, project period, agency grant #, role & goal for each Ongoing or Completed award.
    - Change any “Co-PI” roles to “MPI” aka Multiple PI.
    - Pending proposals and Overlap statements should NOT be included.
  - Include both Ongoing and Completed sections even if there are “None”.

- Verify Project Roles for all key personnel are appropriate. [Definition of Key Personnel](#).
- 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.

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<th>KEY PERSONNEL</th>
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Research and Related Budget

Detailed Budget

- **Sections A & B - Project Role matches Key Person Role & Budget Justification.**
  - Section A – Salary information is entered in the Base Salary AND the Cal. Salary ($) fields.
    - If you do not enter the salary in both fields, the auto-calculation will not work!
  - Sections A & B – Benefit Rate:
    - Use composite benefit rate (CBR).
    - Enter the rate as a PERCENTAGE (e.g. 34%). This will enable the reviewer to easily determine the rate used when the box is clicked on.
- 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 Grad Fees** in the benefits in Section B. Instead, add to Section F8-10, so that the fees can be excluded from the Indirect Cost Base.
- Section F, Fields 8, 9, or 10 – TIF charges are included in the Other Direct Cost section.
  - Reminder: Cost shared effort and Summer Months effort are not subject to TIF.
- Escalation Rate for future years: Current NIH Policy allows for a 0% overall escalation, unless otherwise specified in the FOA/PA.
  - Do NOT escalate salaries where the NIH Salary Cap was used in year 01.
- **Budget Justification:**
  - 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.
- 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 your numbers 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).
  - **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 estimate of **TOTAL COST** (direct + F&A) for each year, rounded to the nearest $1,000.
    - Justify ALL personnel, including level of effort (in person months) and roles on the project. No other categories justified.
  - **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.

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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 Subrecipient Commitment Form, Subrecipient Letter of Intent (only for FDP Pilot Institutions) or Multi-Campus (MCA) Commitment Form (other UCs), and Subrecipient vs. Contractor Determination Checklist for each Sub to the Documents section PRIOR to deadline.

PHS Human Subjects and Clinical Trials Information

- **If “NO” to Human Subjects**
  - If the research involves human specimens and/or data, an explanation of why the application does not involve human subjects research must be attached. The remainder of the PHS Human Subjects and Clinical Trials Information can be skipped.

- **If “YES” to Human Subjects**
  - A study record must be added for each proposed Human Subject Study
  - Field 1.1 – Study Title is limited to 600 characters. Each study must have a unique title
  - Field 1.3 – Verify that an exemption number is selected, if applicable. Verify that exemption 7 or 8 were not selected
  - Field 1.4 – Verify Clinical Trial Questionnaire is completed. All sections of the PHS Human Subjects and Clinical Trials Information must be completed if all answers to questionnaire are “yes.” If one answer is “no,” only Sections 2 and 3 are required.
  - Field 2.1 – At least one entry is required, up to 20 entries are allowed. Each entry is limited to 255 characters.
  - Field 2.2 – Text entry is limited to 15,000 characters. To provide a bulleted list, use a dash followed by a space at the start of each bullet
  - Field 2.3 – Verify numerical value is entered and unit of time. If no upper limit or unknown, enter “N/A (No Limit)” and do not enter a unit of time.
  - Field 2.4 – Verify attachment has two sections (1. Inclusion of Women and Minorities, 2. Inclusion of Children)
  - Field 2.5 – Required unless “Exemption 4” applies or no human participants
  - Field 2.6 – Required unless “Exemption 4” applies or no human participants
  - Field 2.7 – Required unless “Exemption 4” applies or no human participants. Verify timeline does not include specific dates (For example, “one year after notice of award.”)
  - Field 2.8 – Required unless “Exemption 4” applies or no human participants. Verify date format is MM/DD/YYYY

- **Inclusion Enrollment Reports** – required for all human subjects studies unless Exemption 4 applies. Each proposed study must have at least one Inclusion Enrollment Report. A maximum of 20 IERs per study record are allowed (can be a combination of planned and cumulative reports)
  - Fields 1 and 2 are required.
  - Field 5 is limited to 500 characters
  - **Planned Enrollment Tables** are required if study will not use an existing dataset or resource
  - **Cumulative Enrollment Tables** are required if study will use an existing dataset or resource

- **Section 3** is required for all studies involving human subjects
  - If you selected an exemption number for the study record, justify why the research meets the criteria for the exemption(s) claimed

For proposed non-exempt human subjects studies, a Protection of Human Subjects attachment is required and must include the following: 1. Risks to Human Subjects; 2. Adequacy of Protection Against Risks; 3. Potential Benefits of the Proposed Research to Research Participants and Others; 4. Importance of the Knowledge to be Gained.

Field 3.2 – Verify Single IRB Plan attachment is included if “yes” was selected. “N/A” should only be selected if the study is exempt, you are a career development applicant, a training applicant, or a fellowship applicant.
- Field 3.3 – Verify Data and Safety Monitoring Plan was uploaded if all answers to Clinical Trial Questionnaire Section are “yes”
- Field 3.4 – required if all answers to Clinical Trial Questionnaire Section are “yes”
- Field 3.5 – Verify “Overall Structure of the Study Team” attachment was uploaded if all answers to Clinical Trial Questionnaire Section are “yes”
- **Section 4 is only required if all answers to Clinical Trial Questionnaire Section are “yes”**
  o Field 4.1 – verify no more than 5,000 characters
  o Field 4.2.a – verify no more than 32,000 characters
  o Field 4.2.b – if “other” is selected, verify no more than 255 characters
  o Field 4.2.c – if “other” is selected, verify no more than 200 characters. Verify no more than 2 interventions. The description of the intervention is limited to 1,000 characters.
  o Field 4.2.d – if “other” is selected, verify no more than 255 characters.
  o Field 4.2.e – if “other” is selected, verify no more than 255 characters.
  o Field 4.3 – Verify no more than 50 outcome measures. Brief description is limited to 999 characters.
  o Field 4.5 – enter the time (e.g. in months). If duration is unknown or not applicable, write “unknown” or “not applicable.” Duration is limited to 255 characters
  o Field 4.7 – Dissemination Plan must be uploaded for each study within the application. All file names within the application must be unique.
  o **Section 5 should only be completed if all answers to the Clinical Trials Questionnaire are “yes” and only if the FOA requires or permits the attachment.**

**Research Plan**
- Field 1 – Introduction, 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
  o 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.
  o This file should include the following information for each Subaward:
    ▪ 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 be required.
- Field 11 – **Authentication of Key Biological and/or Chemical Resources** If this section is not applicable to the research, upload a PDF so stating.
- Field 16 – **Appendix**
  o Use file names for attachments that are descriptive of the content.
A summary sheet of all items included in the Appendix is encouraged. Include in the front of first attachment of the Appendix.

Complies with NIH Policy **NOT-OD-07-018**.

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**PHS Assignment Request**

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

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**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 no headers/footers on any documents.
- Verify NIH approved font size 11 point or larger, ½ inch margins, 8.5" x 11" sized paper, and black font color have been used.
- **Internal Documents** – [eDGE Economic Disclosure](#) for ALL UCLA Key Personnel, EPASS, PI Responsibility (for projects with human subjects), PI Exception (if applicable), Subaward docs, & other required documents have been uploaded to the Documents section of the proposal before submission.
  - If multiple PIs involved, ALL UCLA PIs must complete internal documents, including signature on the EPASS.
  - EPASS common issues:
    - 3. Proposal Title should match Cayuse Proposal title.
    - 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 – Add:
      - “Submitted via DOM DRA”.
      - List all subaward Institutions, if applicable.