

Questions and Answers for Applicants who are Submitting P01 Applications using the ASSIST Application “Package” in Response to [PAR-15-023](#)

Q1: Where is the electronic application form for creating a P01 application in response to [PAR-15-023](#)?

A1: There is no form per se. You must either create and submit your P01 application through the NIH web-based system called [ASSIST](#) or a valid system-to-system solution in use at your institution. On the first page of [PAR-15-023](#), see the hyperlinked “Apply Online Using ASSIST” button that brings applicants to the [ASSIST](#) application package. P01 applications generated and submitted via [ASSIST](#) or a system-to-system solution come through the [Grants.gov](#) portal and then through the [eRA Commons](#) to the NIH (as do applications created using the Standard Form 424 [SF 424]).

Q2: How do I use ASSIST?

A2: For instructions, go to NIH's [ASSIST](#) portal, then open and read (or at least refer to) the **Application Guide** and **ASSIST User Guide**.

Q3: If I find that a section of the application has been accidentally omitted or not uploaded correctly, may I correct the information after the submission has been completed?

A3: You may resubmit corrected files up until the submission deadline. However, no changes can be made or accepted after this deadline. As a result, it is strongly recommended that you begin the uploading process several days before the deadline so there is sufficient time to carefully review the electronically assembled document.

Q4: In [PAR-15-023](#), no instructions are given about a Project Abstract/Summary and Project Narrative for the Overall component, yet they appear to be required in the associated ASSIST application package. What are the instructions?

A4: You should upload a Project Abstract/Summary (data item #7) and a Project Narrative (data item #8) under the tab Other Project Information in the Overall Component. The abstract for the Overall component of the application should summarize the overall goals of the Program Project as a whole, including why the integrated program is expected to have a greater impact than the individual components.

Q5: Both the Project Summary/Abstract and the Project Narrative are required (*) for the Program Integration and Management component under the tab Other Project Information in ASSIST, but the [PAR-15-023](#) contains an explicit statement not to include a Project Narrative. We know that the funding opportunity announcement (FOA) is supposed to take precedence, but this is difficult to do when ASSIST denotes it as required. May we omit both of these items from the Program Integration and Management component of the application?

A5: Although applicants must upload the Project Summary/Abstract, applicants can follow the FOA instructions to not include the Project Narrative attachment. The Project Narrative attachment is only systematically required for the Overall component. ASSIST does have an ‘*’ by the field; however, there is a help tip at the top of the screen that reiterates it is optional for other components. The FOA template for

multi-projects includes this additional text which seems to have been removed for this FOA “Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.”

Q6: Similar to above (Q3), incomplete/insufficient instructions are given about a Project Abstract/Summary Project for each Project and Core, yet they appear to be required in the associated ASSIST web-based application. What are the instructions?

A6: You should upload a Project Abstract/Summary (data item #7) and a Project Narrative (data item #8) under the tab Other Project Information in each Project and each Core. The Project Abstract of each Project or Core should summarize its rationale and purpose (hypothesis or hypotheses, aims, purposes, expected/possible outcomes, connection/service to other parts of the Program Project, etc.). Separate and distinct, a Project Narrative is also required for each Project and Core, and brief instructions on what is needed for it in either a Project or Core are provided in [PAR-15-023](#).

Q7: In the Project Abstract/Summary for an individual Project or Core, should I address the integration of that Project or Core into the Program Project (i.e., its role in the whole Program Project including its interactions with other Projects and Cores) in addition to describing the Project or Core itself?

A7: You may wish to briefly describe any critical relationship(s) of the individual Project with other Projects and Cores in the Project Abstract/Summary to show additive and synergistic interactions, possibilities, and effects. You should also describe interactions in the Research Plan for each Project and in the Overall section of your application, but this aspect should be presented in greatest detail in the Program Integration and Management component.

Q8: Can the public health relevance statement (i.e., the Project Narrative) for a Project or Core be the same as that for the Overall (Program Project)?

A8: The public health relevance statement (i.e., the Project Narrative) should be tailored to the individual Project or Core.

Q9: Should I describe the interactions of the Project(s) and Core(s) as a flow chart or in a detailed paragraph?

A9: You may describe Project-Core interactions in the best way to meet the needs of your program. The more information you provide, the better, since peer reviewers will use this in assessing the utility and feasibility of proposed Cores. When including images and/or figures, check your application image in your Commons account after its successful submission to confirm that they look right.

Q10: Should I prepare a detailed budget, and where does it go?

A10: You will need to prepare a detailed budget for each Project and each Core. Budgets are also required for each consortium (subcontract) project if they are part of any Projects or Cores. With regard to a budget (or no budget) request for Program Integration and Management, see **Q24/A24** below. The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover. A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

Q11: If we are preparing a P01 application in which one Core is using either animals or human subjects to generate cell lines that will be used by multiple projects, which sections on the face page should be “Yes” for Vertebrate Animals or Human Subjects?

A11: Each Project and Core using either human subjects and/or vertebrate animals needs a Human Subjects (item 5) and/or Vertebrate Animals (item 8) section under the Research Plan tab, respectively, unless the project and/or core is using cell lines only. Under the Other Project Information tab for any Project and/or Core, indicate “Yes” or “No” for human subjects and/or “Yes” or “No” for vertebrate animals, as appropriate. If the Projects and/or Cores involve human subjects (“Yes”) and/or vertebrate animals (“Yes”) in research, then “Yes” must also be indicated in the Overall component and the appropriate human subject and vertebrate animal attachments must be included in the Overall Research Plan. This is systematically enforced. Generally, the Administrative Core (if proposed) does not need a Human Subjects or Vertebrate Animals section. Basically, any component of the application that involves humans in research must have a Protections of Human Subjects section and any component of the application that uses animals must have a Vertebrate Animals section. These are scorable aspects of the application.

Q12: Where should I put the biosketches?

A12: Overall component: Include only the PD/PI and any multi-PD/PI for the entire application. A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall Section of the assembled application image in eRA Commons will be generated upon submission. Under the R&R Senior/Key Person Profile for Program Integration and Management, Projects, and Cores: Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. The Biosketch can be included in any one component, i.e., only one biosketch per person is allowed in the entire application.

Q13: Should biosketches include research support? What about other support?

A13: Biosketches should include research support. [PAR-15-023](#) does not ask for Other Support at time of submission; this information is typically part of the Just-in-Time (JIT) information that would only be required when an award is being negotiated.

Q14: Do I need to use the new NIH biosketch format in my P01 application?

A14: Yes, the new biosketch format is required for all applications submitted beginning with the May 2015 receipt date (see [NOT-OD-15-032](#)).

Q15: Does the Overall component need to include a Resources section in addition to the ones written for individual Projects and Cores?

A15: Overall Program Environment and Resources should be addressed in item “10. Facilities and Other Resources” under the tab entitled “Other Project Information” -- it should contain a description of the features of the environment that will contribute to the success of the program as a whole. This information should not, however, simply be a repetition of the information provided about Resources in the other components of the application. Essential resource information should be provided in the individual Projects and Cores of the

application. Resources should be addressed in detail for each Project and each Core in item “10. Facilities and Other Resources” under the tab entitled “Other Project Information.” Separately (but tangentially related), a Resource Sharing Plan should be provided as the last subsection under the Research Plan tab for each Project and Core.

Q16: In [PAR-15-023](#), it is stated that any of the leaders of the individual Projects or Cores of the P01 can serve as an additional PD/PI (i.e., as one of the multiple PDs/Pis) of the overall P01. Does the one PD/PI or each of the multiple PDs/Pis of the overall P01 have to be the PI (i.e., Leader or Director) of any of the individual Projects or Cores?

A16: No, the PD/PI or any one of the PDs/Pis of a P01 application does not have to be the Leader of any Project or Core. Obviously though, the applicants should present a strong case in the application to the peer reviewers about the critical leadership roles and responsibilities that the person in question would have as a PD/PI of the Program Project and how s/he would fulfill them successfully.

Q17: Should information about a program advisory committee be presented in the application?

A17: It depends. For a new (type 1) application, if advisory members have been selected and participated in evaluating the application prior to submission, then yes, you should provide their information. If you have individuals in mind but the committee has not yet been assembled or met, then there is no need to list their names. For a renewal (type 2) application, you must provide names of your current program advisory committee members (since they cannot serve as reviewers for your application) as well as a description of their expertise and responsibilities.

Q18: Are publications to be listed only once in the Overall section of the application?

A18: No, relevant publications should be listed at the end of each component (i.e., as attachments at the end of Overall, Program Integration and Management [optional], each Project, and each Core).

Q19: Is the Research Strategy page limit for ALL components 12 pages?

A19: No. For specific limitations for each component of the application, please refer to the table of Page Limitations in Part 2, Section IV, of [PAR-15-023](#).

Q20: Are cited publications considered part of the Research Strategy page limit?

A20: No. Publications are separate from the Research Strategy and do not count against the specified page limits.

Q21: Where do letters of support belong? Are they being entered in the Overall component or do they go into each Project or Core?

A21: Letters of support can be provided as attachments to Item 12. Letters of Support, under the tab Research Plan for each component (i.e., for Overall, each Project, and each Core).

Q22: Is there a limit on the number of letters of support that can be included in a P01 application?

A22: There is no limit. Letters of support can be attached to any of the individual components of the application. However, letters of support should be limited to what is appropriate and justified (considering especially what the peer reviewers might find to be useful). Even when a letter of support is attached to a specific project or core, the relevance of the support to that specific Project or Core should be clearly stated in the letter.

Q23: Must a budget be requested for Program Integration and Management?

A23: A budget page must be uploaded for this part of the application. If your team does not need and/or want to have an actual budget for Program Integration and Management (which is appropriate in many instances), you will need to specify a minimal possible level of effort for a Principal Investigator (e.g., .01 month effort for the component lead, even if \$0 requested), and provide a budget justification stating that the costs of dealing with Program Integration and Management are subsumed into the budgets of the other components (and are not/cannot be usefully separated from them) and that the \$1 is just a symbolic cost. If a real budget is needed and requested, provide a budget justification.

Q24: How might the roles and responsibilities of an Administrative Core be similar, different, shared, and/or overlapping with those of the Program Integration and Management component?

A24: Many or most of the administrative items (e.g., office support, travel, conferences, and more) can be described in and funded through an Administrative Core. Aspects of management and leadership can also be described in and funded through an Administrative Core. Applicants have the flexibility to request funds for integrative and management efforts of the Program Project in either the Program Integration and Management component or an Administrative Core; please note that the former is required whereas the latter is not. Nevertheless, P01 applications submitted to the NCI usually have Administrative Cores. However, even if most of the funds for integrative, management, and leadership efforts are requested in the Administrative Core only, the narrative of the Program Integration and Management component must still describe the integrative and management efforts for the entire Program Project.

Q25: Is it still true that individual Projects in a P01 can each only have one Project Leader and that individual Cores in a P01 can only have one Core Director? What should be the role given to an additional faculty member who is a significant contributor to a project or core?

A25: Individual Projects and Cores in a P01 can each have only one Project Leader or Core Director, respectively. Other significant contributors are listed as Co-Investigators, and those with minor roles are listed as Collaborators.

Q26: If I change some of the Projects in my P01, is my submission a renewal (and/or resubmission) or a new grant application?

A26: It depends on the level or degree of change. If the change is minimal (e.g., only one new Project added to three prior Projects or one of four Projects replaced with a new one), then a renewal application would be appropriate. If the change is substantial (e.g., two of three or four Projects are replaced with new ones), then a new application would be appropriate. Note that per [NOT-OD-14-074](#), applications submitted and peer reviewed once, but not funded, do not have to come back in as resubmission applications but can come back

in as new applications. However, if such an application comes back in as new, the applicant(s) cannot openly address any of the critiques from the initial peer review in the application. Contact the assigned NCI Program Officer to discuss your changes and their impact(s) on your Program Project.

Q27: For figures, tables, photographs, etc., included in the Research Strategy of any component of the application, can we include larger versions as Appendices to the application?

Q27: No.

Q28: Can I include a video clip or movie in my application?

A28: For information about including video clips or movies with your application, see [NOT-OD-13-030](#). Please also check with the responsible NCI Program Officer and assigned Scientific Review Officer.

Q29: What is the allowable requested budget level (increase) for a renewal (type 2) P01 application submitted in response to [PAR-15-023](#)?

A29: See NIH Guide Notice [NOT-CA-08-028](#).

Q30: If my/our type 1 (new) P01 application is not selected for funding (i.e., awarded), is my/our only option to resubmit the application?

A30: See NIH Guide Notice [NOT-OD-14-074](#).

Q31: What are the policies with regard to concurrently submitting other applications that overlap in part with a P01 application (e.g., an R01 application corresponding to a P01 Project)?

A31: Although in most cases NIH does not allow two or more applications that have scientific overlap to be submitted concurrently, subprojects of a P01 application can be submitted as research applications (R01, R21, R03, R15, etc.) in the same cycle.

Q32: Letters of Intent (to submit a P01 application) are not required so why are they requested and how are they useful?

A32: First, if the applicant(s) have not already communicated with NCI program director(s) about the planned P01 application submission, the information in the Letter of Intent (LOI) helps the NCI Referral Officer find the best program person(s) to advise you about your proposed application submission. Second, the information provided in the typical LOI is used by NCI staff in order to gain clearance for the receipt and log-in of a (\geq \$500K direct cost/any year) P01 application to the NCI. Without enough information, the interested NCI program officer(s) would not be able to determine if the application fits with the program's mission and priorities and he/she/they would not be able to gain approval from his/her/their leadership to have the application logged-in if submitted. Often, after provision of an LOI, applicants and NCI program (and review) staff members will have discussions to determine if and when a program project is warranted. Third, the information in the LOI helps the NCI Referral Officer plan for the receipt and referral of the application at the NCI and it helps the Scientific Review Officers plan for the peer review of the application.

The informational items in a typical LOI (of several pages in length) include:

- Overall title;
- Overarching research theme;
- Name(s) and affiliation(s) of Principal Investigator(s);
- Name of the applicant institution;
- Site(s) of performance;
- Project titles;
- Names of Project Leaders (only one per project);
- Brief summary of each project (with an indication of approximate degree to which the proposed research is basic, translational, and/or clinical in focus);
- Core title(s);
- Name(s) of Core Director(s)(only one per core);
- Brief summary of each Core;
- Estimated first-year direct costs (not including any consortium F&A costs); and
- Estimated total-year (i.e., all-years) direct costs (not including any consortium F&A costs).

LOIs for P01 applications should be e-mailed to the NCI Program Director (if known) and the NCI Referral Officer (ncirefof@dea.nci.nih.gov). If additional information is needed for the submission/receipt clearance process, the Program Director will request it.

Q33: Can a Foreign institution submit a P01 application and/or hold a P01 award?

Q33: No.

Q34: Can a Foreign institution be substantially involved in a P01 application and award?

Q34: Yes, via a consortium arrangement/subcontract, a Project or Core can be based at a Foreign institution. However, there should be sufficient justification for the unique resources/expertise/services provided at the institution that are not readily available in the United States.

Q35: If a P01 application and award will have multiple Program Directors/Principal Investigators (PDs/Pis), can one or more of the PDs/Pis be located at a Foreign institution?

A35: Yes, as long as any Foreign Multi-PD/PI on the P01 application and award is not and will not become the Contact Multi-PD/PI (as specified in the Leadership Plan), and his/her/their inclusion is sufficiently justified.