



# Q&A

## Orientation Presentation Formula 2019

- Q:** The cover letter e-mail that we received stated that “Based on previous RFA processing time, we require that the term of the grant agreement be at least two years in length.” In the provided Instructions document, section 2 (Effective and Termination Dates), the text indicates that the “applicant must determine the direction of the Grant award” and that the “Grants may be awarded for a period not to exceed four years.” On the webinar this morning, it sounded as if we are required to have at least 1 project that lasts for the full 4 years.
- A:** Due to the receipt of multiple no cost extension requests which require the Health Research Office (HRO) and other offices’ processing times, the decision was made to make grants for the full four years permitted by the Tobacco Settlement Act Chapter 9. An early end to a grant does not require any additional processing. One project in the 2019 RFA 67-87 submission must be identified to last for four years in the grant application. This requires no changes to the Cover Page as the updated version sent to applicants includes the ending date of May 31, 2024. The four-year project must have May 31, 2024 listed as the “anticipated end date” and the milestones must be identified for each fiscal year.
- Q:** I want to confirm that the salary cap is staying at \$189,600 and not increasing to the most current NIH salary cap of \$192,300. (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-099.html>)
- A:** The salary is based on the maximum federal hourly rate as identified in the 2019 RFA 67-87. At the time the RFA was developed, the salary had not changed from the 2018 rate of \$97.23/hour or yearly rate of \$189,600. The salary cap identified in the 2019 RFA 67-87 is to be used.
- Q:** If you had more than \$5,000 in reagents, would that go into "Equipment" even though it isn't a piece of equipment?
- A:** Equipment is defined in the budget as an item that costs \$5,000 or more. If the item is over \$5,000, it is to be under the heading of “Equipment” with the quantity and unit cost identified.
- Q:** Will it be possible to have leniency with regard to the number of projects? We have been and are in the process of doing internal reviews for what we understood to be an unlimited number of projects. Even being able to have 20 projects would be a huge benefit to us. Our process for identifying projects that we would like to support, is to put out Funding Opportunity Announcements for various mechanisms that we have determined to be both responsive to the spirit of the TSF Formula Program and beneficial to the research at the College. These mechanisms include: a Bridge Grant for investigators who have submitted to NIH and were scored but unfunded – to allow them to improve the competitiveness of their subsequent submission; a Junior Faculty Research Scholar Award that provides critical funding to early stage investigators; an Innovation and Impact Pilot Grant that supports exciting new projects to allow them to obtain preliminary data for external grant proposal submissions; a Grant that promotes cross-college interdisciplinary team research; and a Fund for Innovation Grant that stimulates critical research along the early stages of the commercialization pipeline. As an example, for the 22 projects submitted in response to the Yr 18 RFA, we put out five announcements that resulted in the submission of 61 proposals that were reviewed by an average of 3 reviewers, the majority of whom, in addition to providing a detailed written critique, participated in a face to face discussion of the proposals. The rigor of this process takes considerable time both administratively and from our faculty reviewers. We take our stewardship of the Tobacco Settlement Funds very seriously.

**A:** The internal review process listed above is for identifying research projects to submit. The number of projects within the 2019 RFA 67-87 is limited to 15. The goal is to lessen the amount of time for review of an institution's submission and this limit is above the average number of projects submitted for Formula grants. The HRO has been reviewing applications and providing multiple correction requests. The number of projects submitted is limited to focus on the application process. The applications received by the HRO include multiple errors that can be corrected by extending the internal process to a review once the applications are completed and before sending it to the HRO.

**Q:** **You said at least one project must be the full four years. Can a second project be two or three years? The 8/1 notification letter from the DOH states that "the term of the grant agreement be at least two years in length." Please clarify.**

**A:** If an institution is submitting multiple projects for the 2019 RFA 67-87, one project must be the full four-year length of the grant. Other projects submitted may be less than four years.

**Q:** **Just to be clear, there must be two IRB approvals submitted with this application? One for PA Department of Health and Institutional IRB?**

**A:** The Formula grant requires all human subjects research be reviewed by the institution's IRB and documentation be submitted to the Pennsylvania Department of Health's (department) IRB. There is an application to accompany the submission of the institution's IRB documentation to the DOH's IRB. This can be found on the department's IRB website at: <https://www.health.pa.gov/topics/Research/Pages/IRB.aspx>. Please review the process in the 2019 RFA 67-87 Appendix D Attachment 4, or you can email the department IRB at: [ra-dhirb@pa.gov](mailto:ra-dhirb@pa.gov). The IRB submission should be sent to the department IRB prior to or at the same time the application is submitted to the HRO. The institutional IRB process should have been performed prior to submitting the application. It is recommended that Grant Coordinators take the CITI training for IRB Administrators which may cover many of the IRB questions.

**Q:** **Related to the project budget period. Our organization has selected 1 application for our funding. Is it possible to close out the project before the full 4-year period if work wraps up sooner? The project was originally selected based on initial email communication indicating the award period was required to be a minimum of 2 years.**

**A:** If a single project is submitted for the 2019 RFA 67-87 and the work is finished prior to the May 31, 2024 end date, the institution will submit a final report within 60 days of the actual end date of the grant.

**Q:** **Is there any limit to the amount of outside support that is allowed for a project? For example, if there is a protocol that will receive 75% support from industry, will the PA DOH have any issues with providing funds for just 25% of a project?**

**A:** The 2019 RFA 67-87 is for department funded project(s). The example provided raises issues on the level of control the Principal Investigator has if an industry has 75% investment in the outcome of the research. The amount of additional funding should be identified and referenced in the grant outlining its purpose and how it supports the department project(s). The application should provide transparency regarding the amount of additional funds, where they are used, how they are used, and how it impacts the project(s). This would be reviewed on a case by case basis.

**Q:** **I was on the conference call this afternoon and wanted to clarify a period of performance question. I mentioned we've already selected an application to move forward that was operating under the assumption that the budget would need to be at least 2 years in length. If we submit for the full 4-year period as required but revise once funding is received to complete the work early, is that an issue? The project is one that crosses two research groups here at our organization and the budget allotted for our site will not cover 4 years' worth of work. If revising timelines to a shortened date is ok, we may look at doing so to adequately cover our costs. If not, we may advise the team to plan to start after the earliest 6/1/2020 date.**

**A:** A revision to a fully executed grant is not permitted. If a single project is submitted for the 2019 RFA 67-87 and the work is finished prior to the May 31, 2024 end date, the institution will submit a final report within 60 days of the actual end date of the grant. The four-year project must have the May 31, 2024 “anticipated end date” and the milestones must be identified for each fiscal year.

**Q:** You state the formula grant should be four years in length. We are certified for ~\$8,900. This amount does not reasonably map across four years. How do you suggest we handle the reporting/mapping of "objectives" across such a lengthy period with so few funds?

**A:** Due to the small amount of funds, please follow the directions on the 2019 RFA 67-87 with a minimum of two years for the submitted application. However, please be aware that a no-cost extension will not be an option if there are delays for the department or the institution.

**Q:** Is an institution eligible to submit a single project in response to a Formula RFA? Or is a minimum of 2 projects required? What are the criteria that determines the number of projects that can be proposed in an application?

**A:** An institution that receives more than \$500,000 should submit at least two projects. This is to set the Formula grants apart from the much larger Non-formula grants that are peer reviewed.

**Q:** Can a PI who served on a previous Formula or Non-Formula award serve as a PI on another Formula or Non-Formula submission?

**A:** A Principal Investigator is not limited to a single Formula or Non-formula award; however, poor performance in a review can lead to the request that the PI not be used on future awards.

**Q:** How is an institution informed about the release of RFA for a Non-Formula grant application?

**A:** This orientation was for the 2019 RFA 67-87 Formula grant application. The non-formula grant application process is competitive and posted in the PA eMarketplace.

**Q:** IRB/IACUC/IBC approvals: Should the application include approvals for the applicant institution only or should it include approvals for the sub-award institutions?

**A:** The primary institution is responsible for the human subject IRB review for all projects. It is recommended that Grant Coordinators take the CITI training for IRB Administrators which may cover many of the IRB questions. Additionally, the department’s IRB website and the email address as listed previously are available for any inquiry.

**Q:** We will have only one project since we are receiving \$108k. I was told via email the end date must be four years, and there is no penalty for ending earlier. However, in the Orientation it sounded as though we must go the full four years. Please clarify.

**A:** One project in the 2019 RFA 67-87 submission must be identified to last four years in the grant application. This requires no changes to the Cover Page as the updated version sent to applicants includes the ending date of May 31, 2024. The four-year project must have May 31, 2024 listed as the “anticipated end date” and the milestones must be identified for each fiscal year. If there is only one project and it ends earlier than the four years, there is no penalty if the work does not take the full four years.

**Q:** If a project is clearly identified in the milestones as being less than four years, will we be able to submit a final project report at our end date as opposed to waiting the full four years?

**A:** Projects are different than grants. The grant end date is the last date of the longest project. If there is one project for the 2019 RFA 67-87, that project should be identified as a four-year project. This is shown in the “anticipated end date” and the milestones. Annual and final reports are for all projects in a grant. If a project ends prior to the grant end date, the annual report notes that the project has ended. The final report is completed for all projects at the end of the grant term.

**Q: You mentioned that paper forms being sent via Fed-Ex are held in a 'warehouse' and it takes an additional two days to be delivered to your office. Are these packages not date-stamped at the holding place? I do not believe it is fair to have a due date of the 27th on your RFA, and now tell us the due date must really be the 25th? (It will be next to impossible for our office to have the Fed-Ex package sent out on the 24th due to the schedule of our Grant Coordinator). It would be appreciated to have some leeway here and not be rejected without review.**

**A:** The potential delays due to the involvement of the processing center were reviewed with our procurement office. Clarification was received as to how it is to be handled. If a submission is received by the processing center by the deadline, it is to be accepted.

**Q: You indicated in your webinar that one of the projects must be at least 4 years, but can end early. We have a single project being submitted this year, and we are eligible to apply for \$55,423. Our PI believes that the project will likely end in two years, not four.**

**Questions:**

- **The cover page indicates the start and end dates from 6/1/20 to 5/31/24 and is not able to be revised. Can/should we revise this somehow?**
- **Under the Research Plan, Section I (c) should we indicate that the Anticipated Project Duration will end 5/31/22?**
- **Under (4) Time Frame and Milestones – Can we indicate Not Applicable for years 7/1/22 through 6/30/23 and also 7/1/23 – 5/31/24?**

**A:** One project in the 2019 RFA 67-87 submission must be identified to last four years in the grant application. This requires no changes to the Cover Page as the updated version sent to applicants includes the ending date of May 31, 2024. The four-year project must have May 31, 2024 listed as the “anticipated end date” and the milestones must be identified for each fiscal year. If there is only one project and it ends earlier than the four years, there is no penalty if the work does not take the full four years.

**Q: If an organization proposes a project with a sub-award to another institution in the Commonwealth of PA with no Human Subjects Research at the organization but with Human Subjects Research at the sub-award site, how do we handle the following?**

- **Do we report sub-site IRB information in the AppD,Att2\_Cert\_Human Subjects\_2019F?**
- **If so, should the organization’s Authorized Official sign this form?**
- **Should the organization submit the application for secondary IRB review for the sub-site’s protocol?**
- **If so, should the organization’s Authorized Official sign this form?**

**If the organization proposes a project with a sub-award to another institution in the Commonwealth of PA with Human Subjects Research at the organization and at the sub-award site, how do we handle the following?**

- **Do we submit only one AppD,Att2\_Cert\_Human Subjects form and IRB application for secondary review with the organization and sub-site’s IRB information incorporated?**
- **If so, should the organization’s Authorized Official sign this form?**

**OR**

- **Do we submit two separate AppD,Att2\_Cert\_Human Subjects forms one for the organization and one for the sub-site signed by the respective institution’s Authorized Officials?**

**Similarly, should two separate IRB applications for secondary review be submitted to the State IRB?**

**OR**

**Do we submit only one AppD,Att2\_Cert\_Human Subjects form and IRB application for secondary review with the organization’s IRB information?**

**In other words, the organization should not submit the sub-site’s IRB information as part of the application but will ensure by obtaining necessary documentation from the sub-site that it is following the State’s requirements before the application is submitted?**

**A:** The primary institution is responsible for the human subject IRB review for all projects. In the cases presented, the Principal Investigator for the project is responsible for addressing these issues with the primary institution's IRB, as the projects are the responsibility of the primary institution. It is recommended that Grant Coordinators take the CITI training for IRB Administrators which may cover many of the IRB questions. Additionally, the department DOH IRB website and the email address as listed previously are available for any inquiry.

**Q:** 1. **Will the RFA be revised to include the requirement that one of the projects span 4 years? Our institution's budget plan includes this funding to last two years and the funds are allocated to the specific investigators for each project. At this point, it will be difficult to revise projects and reallocate funds to meet this requirement.**

2. **Will on time submission be documented by the upload of the electronic documents or the delivery of the original documents? The State's package delivery process described in the 8/19 webinar includes an uncertain delivery timeline that is difficult to account for from our perspective. While we intend to send the required original documents well in advance of the deadline, we want to be certain that our application will not be penalized by circumstances that are beyond our control.**

**A:** One project in the 2019 RFA 67-87 submission must be identified to last four years in the grant application. This requires no changes to the Cover Page as the updated version sent to applicants includes the ending date of May 31, 2024. The four-year project must have May 31, 2024 listed as the "anticipated end date" and the milestones must be identified for each fiscal year.

The potential delays due to the involvement of the processing center were reviewed with our procurement office. Clarification was received as to how it is to be handled. If a submission is received by the processing center by the deadline, it is to be accepted.

**Q:** I learned that the application for RFA for the 2019-2020 Formula funds will be for 4 years. We anticipate that our research project will be done within 2 years. My questions are as follows:

**Can we leave the milestones for the period from 7/1/22 to 5/31/24 on the attached form blank? This is due to the fact that we will complete the project by 6/30/22.**

**We understand the official ending date of the grant will be 5/31/24. If we finish the project by 6/30/22, can we submit the same financial and/or progress reports that we submit for the period ending 6/30/22 in the later years?**

**When the new online grant submission platform becomes available, do we have the option to submit either via Fed Ex and/or the new online platform?**

**A:** One project in the 2019 RFA 67-87 submission must be identified to last for four years in the grant application. This requires no changes to the Cover Page as the updated version sent to applicants includes the ending date of May 31, 2024. The four-year project must have May 31, 2024 listed as the "anticipated end date" and the milestones must be identified for each fiscal year. If there is only one project and it ends earlier than the four years, there is no penalty if the work does not take the full four years.

Projects are different than grants. The grant end date is the last date of the longest project. If there is one project for the 2019 RFA 67-87, that project is to be identified as a four-year project. This is shown in the "anticipated end date" and the milestones. Annual and final reports are for all projects in a grant. If a project ends prior to the grant end date, the annual report notes that the project has ended. The final report is completed for all projects at the end of the grant term.

The submission process online is for the electronic documents. The original and copies of the signature forms will be submitted as directed in the 2019 RFA 67-87.

**Q:** 1. **Will Commonwealth require annual project budgets or just the cumulative project budgets?**

2. **If annual budgets are required, does it matter if actual dollars expended in a project year differ from the annual budget, but the project's total budget never changes?**

3. **Can funds be realigned within a project or between projects based upon changes in timeline and scientific need or results?**

**A:** 1. The Budget is based on the cumulative costs of each project over the course of the four- year grant.

2. N/A

3. No, funds are not permitted to be realigned between projects or Budget Categories.

**Q: In light of the webinar is it feasible to consider proposing projects that have funds from NIH already? That would help us to be able to meet the IRB requirement.**

**A:** The connection between an already funded project and the IRB process is unclear. The department should be the primary funder of the 2019 RFA 67-87 project(s) and it is to be new research. If human subjects are involved, a review by the institution's IRB with an application to the department's IRB should be submitted for review. It is recommended that Grant Coordinators take the CITI training for IRB Administrators which may cover many of the IRB questions.