Post-Review Process for an S10 Grant: Q&A Session

FAQs
Thursday, November 14, 2024
1:00 p.m. – 2:00 p.m.

Q: Will you send a copy of this presentation?

A: The slides and Q&A for today's webinar will be posted on ORIP's website.

Q: We received a reviewer comment that our Accessible Usage Time (AUT) was too low, and the reviewer used 8,760 hours, which is 24/7 365. Is this a valid AUT assessment?

A: Because we have not read your summary statement, it is not clear why you received that criticism. Using 24/7 365 does not sound realistic, but it is up to the applicant to describe how many hours the instrument will be used on an annual basis. The applicant should provide detailed information about the typical daily, weekly, or annual available access time for the instrument for the reviewers to evaluate. Provide the reviewer with information about instrument downtime. For example, the system may need time for maintenance or services. Factor this in when calculating a realistic available time for the instrument to be used for research.

Q: While you cannot tell us right now what the fundable score will be this time around, can you provide us with historical data? For example, what was the fundable range for the past several years for each of the S10 solicitations? We understand that this is just historical data and might not be indicative of this year's results.

A: Currently, ORIP does not have any information about the budget. Each year, ORIP receives a different number of applications, and these applications vary based on the types of instruments requested and their pricing. Each year, ORIP tries its best to obtain co-funding from other NIH institutes, centers, and offices. The amount of co-funding received varies by year. Previously, it has been scores in the upper 20s to upper 30s that were fundable, depending on factors including the budget situations and subprograms.

Q: How should one respond when it is suspected that a reviewer used a large language model to provide their peer review? Is this strictly forbidden in the NIH review process? What recourse might one have?

A: NIH prohibits abuse or egregious use of artificial intelligence for applications and the review process. If the applicant has a way to identify this, please reach out to the program officer (PO) for consultation. The Research Integrity Officer at NIH will be informed of the situation. The outcome depends on the results of a future investigation.

Q: Can you explain more about "even distribution of awards among geographical areas"?

A: ORIP considers many factors when making funding decisions, including geographic distribution, subprograms, and institution type. ORIP wants to ensure that resource access is provided widely across the United States. However, other factors besides geographic distribution affect the final consideration for a funding recommendation.

Q: Regarding Just-in-Time (JIT), eRA Commons sometimes automatically sends JIT requests. I understand that we should ignore those and instead, respond only to the JIT requests sent directly from the PO. Is that correct?

A: As of October 2024, the eRA system no longer automatically sends applicants JIT requests. If a JIT request is received, the applicant will see that it is specifically from the ORIP system with the following email address: s10reports@od.nih.gov.

Q: Regarding resubmission, we can do only one round of resubmission, correct? For example, if an A1 application is not funded, will it have to start as a new application?

A: That is correct.

Q: When is the earliest a JIT request might be received?

A: January.

Q: My application was not discussed during the review. One of the comments I received was that I had only three major users. I believed that having three major users with NIH funding—provided they cover the required percentage of the AUT—would be sufficient. Since my proposal was not discussed, if I were to revise it based on reviewer comments and resubmit, would that be considered a new submission, or is it classified as a resubmission? What is the optimal number of major users for an S10 proposal?

A: It is up to the applicant on how to proceed. The applicant may resubmit it as a resubmission addressing the critiques, or they may submit it as a new application. As previously mentioned, only one round of resubmission is allowed; after resubmission it must be submitted as a new application. The eligibility requirement is having three major users with active NIH research grants at the time of application.

Q: Is it a weakness that the principal investigator (PI) group has 38% of the allotted AUT?

A: ORIP would not see this as a weakness. If the usage time is dominated by the PI, it may be construed as a bias. S10 encourages collaboration and shared use of instruments. If one group of investigators is dominating use of the instrument, it may not be portrayed well as a shared-use

instrument. The reviewers may consider this to be a weakness if minor users do not have fair access to the system. In this situation, it depends on how well the applicant justifies the usage. The AUT requirement for major users for the Basic Instrumentation Grant (BIG) program is 25% in total, and 55% of AUT should be dedicated to NIH research.

Q: What level of NIH funding is the PI required to have to be awarded the S10 BIG grant?

A: S10 BIG is a limited competition program. It still requires three major users with active research grants, but the limitation is that it is only eligible for the institutions that have received less than $500,001 in S10 awards in the past three fiscal years. If this requirement is met, the other requirements are the same. The PI is not required to have an NIH grant.

Q: We received a comment that the hourly rate of the device is too high, although we offered one-third of what the cores charge investigators for other imaging devices. How can we address this review?

A: Please reach out to the PO and schedule a meeting to discuss this issue.

Q: What happens if an emergency or other life event prevents you from submitting the JIT request within 2 weeks? What should you do?

A: ORIP understands that life is unpredictable and that circumstances do arise. As soon as the applicant becomes aware of the situation, please consult with the PO.

Q: What are the considering factors that lead to an S10 grant not getting discussed?

A: The scientific review groups consider the scientific and technical merit of the grant application. Generally, the applications that are in the top half of scores are discussed, so if the grant falls within this score range, it will be discussed.

Q: Reviewers 1 and 3 gave me much stronger scores than reviewer 2 in my summary statement (i.e., on technical expertise, I got 2:4:2, on research projects I got 3:6:3, and on institutional commitment I got 1:4:1). How would I know if there was no bias or maybe that reviewer 2 was not familiar with the instrument/technology?

A: Reviewers may receive different assignments so the scoring basis may be different; it's common for reviewers to have differing opinions when completing the scientific evaluation on the same application. If you feel the review is biased, please reach out to the PO to discuss this in a personal meeting.

Q: What level of NIH funding is required for major users and other users to be eligible at the time of the S10 BIG award?

A: A minimum of three major users with a minimum use of 35% (for the Shared Instrumentation Grant [SIG] and High-End Instrumentation Grant [HEI] programs) and 25% (for the BIG program) of AUT is required. The total AUT for all NIH projects should be at least 65%, 75%, or 55% for SIG, HEI, and BIG, respectively. The Program Directors/PIs are not required to have an NIH research grant at the time of application, but they are expected to be experts on the instrumentation being requested. Additional information can be found here: PAR-24-326: Limited Competition: Basic Instrumentation Grant (BIG) Program (S10 Clinical Trial Not Allowed)

Q: Am I qualified if I resubmitted an application by the regular deadline (June 2) and not in May, as suggested for resubmissions?

A: To clarify here, we recommend you make the decision for submission by May. The next submission deadline remains June 2, 2025.

Q: We received a poor review from one panel member that appears to be the result of a technical misunderstanding or misreading. How do you suggest that we handle this? Would it be advisable to discuss this with a PO?

A: Yes, please reach out to the PO to discuss the reviewer's critique.

Q: If an S10 grant is not discussed, will the PI get a statement that explains why the grant was not discussed?

A: All grants under review will receive three critiques in the summary statement, whether it is discussed or not.

Q: What is the minimum number of major users with NIH funding required for the S10 BIG?

A: Three major users are required.

Q: Is the availability of the instruments at the institution taken into consideration? For example, it might be a situation where the instrument in the institution is not supported by the manufacturer anymore, so the institution is losing the possibility of doing NIH-funded research. On the other hand, the situation may be that newer instruments are being added or the institution already has several similar instruments, so the possibility of doing research is not necessarily compromised by the institution.

A: Explicitly explain in the application the necessity for this instrument because justification of need is an important criterion. If an existing instrument is no longer supported by the vendor, provide this documentation with the application for the reviewers to examine. If a neighboring

institution has the instrument that the applicant is requesting, clearly state its availability and justify the need for the instrument. Geographical distribution is considered when reviewing and making funding decisions.

Q: Are NIH grants that are under a no-cost extension (NCE) or NIH grant proposals under review considered acceptable funding to determine eligibility as a major user?

A: NIH-supported research is considered at the time of application, so an NCE is considered active. A grant application that has not yet been awarded would not qualify as a research project and would not be considered an active grant. However, an application that received a favorable score would be worth mentioning and may be positively received by reviewers.

Q: If you are resubmitting a not-discussed application as an A1, is it likely to go back to the same reviewers?

A: A review panel typically has some level of continuity, so it is possible to receive one or two reviewers from the prior review panel, but the applicant should not expect the exact same set of reviewers for the resubmission.

Q: The summary we received showed that the reviewers may not have enough expertise or knowledge of the device. What is the best way to address such comments and avoid delay and resubmission?

A: If an applicant feels that the panel lacks technical expertise, please reach out to the PO to discuss the situation.

Q: If we already have more than three major users with NIH funding, can an individual serve as an additional major user without NIH funding?

A: Anyone can serve as a major user to support the research. What ORIP counts is NIH-supported major users and NIH-supported research, which need to meet certain criteria.

Q: Are S10 applications from Core Facility Directors in support of multiple investigators handled differently?

A: No, there is no distinction between a PI who is a laboratory investigator and a PI who is a Core Director. This should not affect the review of the application.

Q: How is the study section recruited? Is the experience breakdown of the S10 study section available to grant submitters? Can you please describe the study section review process?

A: The Scientific Review Officer (SRO) decides whom to recruit. The recruitment takes place after the applications have been submitted. It starts with an administrative review to determine the technical areas of science that need to be covered and how many individuals to recruit based

on the number of applications received. To minimize conflict of interest, the SRO recruits individuals whose applications are not in the current applicant pool.

Q: Can a PI resubmit their S10 grant application, as well as a new S10 grant application for a different instrument?

A: Yes, if the instruments are distinct and not the same type, an institution can apply for multiple S10 grants in the same cycle, but the instruments must be completely different. The exception is for the S10 BIG program, which is restricted to one application per institution.

Q: What will be the start date of the S10 BIG when awarded next year?

A: The earliest possible date would be January, and this process will go through August.

Q: Can an S10 grant application that was not discussed be resubmitted, or should it be considered as a new grant?

A: As discussed previously, this is a decision for the investigators to make. One resubmission is allowed, so if the applicant feels that their edits will be sufficient for successful funding, then they can try to resubmit. If the applicant thinks another application round as a new grant will receive a better response, then they can proceed that way.

Q: Can a Small Business Innovation Research project count as a major or minor user?

A: ORIP has a specific requirement for major users to account for a certain amount of AUT and for NIH-supported research projects to account for the major user AUT. The applicant can group minor users or other users together in the application when justifying their needs because their use of time is limited. Because the S10 program is designed to support research conducted by NIH-funded investigators, the applicant needs to satisfy those eligibility categories.

Q: If a flaw in the review is found, it is not going to result in a score change. What is the point of submitting it? What if the review is found to be flawed? Can the grant be awarded based on that?

A: Please read the entire summary statement and consult with the PO to discuss the options available.

Q: Do we need to address the review criteria at the time of submitting JIT request? If so, how many pages or in what form?

A: The applicant must address the weaknesses that are listed by the reviewers in the summary statement. If additional information is needed, the applicant will be asked for a revision by the PO. A typical JIT should use two pages to address the weaknesses.

Q: Can someone with technical expertise but without an NIH grant qualify as a major user?

A: A major user is a PI whose project has a substantial instrument usage. Anyone can be a major user if the other criteria for minimum usage by the major NIH-funded researchers and the NIH-supported research are met.

Q: What does "Pending IRG Review" mean on the S10 grant status, and what is the review process?

A: This means the review meeting has not taken place yet. Review the S10 grant status in your eRA Commons to check for the meeting date. The applicant should be able to see when the meeting will take place. A few days after the review meeting, the applicant should see a score. Within 30 days following the review meeting, the applicant should see a summary statement.

Q: If an S10 grant application is being resubmitted, does the PI have to submit a new letter of support or can they keep the same support letters?

A: New letters of support are recommended. An old letter of support that was written over a year ago may not be well received by the reviewers.

Q: Do we need to get an updated quotation with a January date for applications that received a JIT request?

A: When the applicant receives the JIT request, obtain an updated quote from the vendor. The expiration date needs to be at least 45 days out so that ORIP can process the JIT request and pass it on to grants management for further review. ORIP will reach out for an updated quote if its effective date expires during the time of review.