Questions and Answers in Response to PAR-20-220

Trainees and TL1 Structure

1. How many trainees are expected to be supported by a single TL1?

The TL1 component functions similarly to the institutional T32. Your training budget request must include a <u>minimum of five slots each year</u> but may include more—there is no upper limit on the number of supported slots in a given year. For institutions currently supporting multiple T32s that are developing a single U2C/TL1 application, a reasonable starting point for determining the number of proposed training slots would be to add up the number of slots currently supported by the existing T32s in a given year. Of course, the number of proposed training slots must be well justified.

2. With fewer, larger awards (U2C/TL1) being made, will there be a reduction in the number of trainees who will be supported?

Although there may be fewer U2C/TL1 awards than T32 awards, each U2C/TL1 award will have a higher number of training slots (minimum of 5), compared to the average number of slots per currently active T32 (3.5 slots). In addition, it is worth noting that many of the currently available KUH T32 slots go unfilled every year, resulting in large unobligated (leftover) balances.

3. Does the TL1 need to support trainees in kidney, urology, AND hematology? How will this integration work?

Per <u>NOT-DK-21-018</u>, Clarification on the Inclusion of Kidney, Urologic, and Hematologic (KUH) Disciplines in Training Proposals:

Institutional Network Awards applications that engage trainees across all three K-, U-, and H- disciplines are encouraged and preferred. While equal representation across these disciplines is not required, NIDDK encourages applicants to leverage available resources -- to the extent possible -- to maximize the training opportunities across K-, U- AND H- research. This may be accomplished by partnering with other departments within a given institution or by partnering with other institutions in the Metropolitan Statistical Area (if feasible). Multi-institutional applications are not required, but they are encouraged if partnership enhances the training environment and experience. The FOA does not stipulate how many training slots should be dedicated to kidney, urologic, or hematologic research.

Training in such skills as scientific writing, leadership, and entrepreneurship is universally essential for trainees, independent of their chosen field of biomedical research. In addition, building an interdisciplinary community of scientists is an essential part of meeting the demands of the modern workforce.

4. Is it expected that there would be one combined application that would train both adult and pediatric physician-scientists? Or can an application for the Department of Pediatrics and an application from the Department of Internal Medicine be submitted separately?

Only <u>one</u> application per institution is permitted. This application is expected to support trainees across kidney, urology, and hematology research, and it can include both adult- and

pediatric-focused research programs, if desired. Separate applications from different departments within a single institution are **not** permitted.

5. In one large metropolitan area with multiple institutions, can institution A submit a multi-institution kidney application, institution B submit a multi-institution urology application, and institution C submit a multi-institution hematology application?

Per NOT-DK-21-018, Clarification on the Inclusion of Kidney, Urologic, and Hematologic (KUH) Disciplines in Training Proposals:

Institutional Network Awards applications that engage trainees across all three K-, U-, and H- disciplines are encouraged and preferred. While equal representation across these disciplines is not required, NIDDK encourages applicants to leverage available resources -- to the extent possible -- to maximize the training opportunities across K-, U-AND H- research. This may be accomplished by partnering with other departments within a given institution or by partnering with other institutions in the Metropolitan Statistical Area (if feasible). Multi-institutional applications are not required, but they are encouraged if partnership enhances the training environment and experience. The FOA does not stipulate how many training slots should be dedicated to kidney, urologic, or hematologic research.

Applications structured as exclusive to any one scientific discipline would be considered of lower programmatic priority.

6. Can a single TL1 support trainees across multiple institutions?

Yes. Although only one TL1 award will be issued with each U2C award, the TL1 can support trainees from multiple different institutions.

7. Can a single TL1 support predoctoral and postdoctoral trainees?

Yes, mixed predoctoral and postdoctoral programs are permitted.

8. Can the networking activities, and other career development activities supported by the U2C portion, include trainees or faculty who receive funding outside of NIDDK/KUH?

Yes, networking and other proposed career development activities can involve trainees or faculty who receive funding outside of NIDDK/KUH or who are engaged in research outside of the NIDDK/KUH mission. The immediate goal of the networking core is to create a community of interdisciplinary trainees. At a minimum, this community should bring together trainees across K-, U-, and H-mission area research, including those supported directly by the TL1, in addition to those supported by other mechanisms, such as Fellowships (F), Career Development Awards (K), or Research Experiences (R25). Applicants also are welcome to include other trainees outside of the NIDDK/KUH research areas in these networking efforts. For budget purposes, please justify your requests based on realistic projections of network participants.

As a reminder, trainees who are directly supported via the TL1 award must be engaged in research projects that would be considered mission relevant to NIDDK/KUH.

When to Apply

9. Our current KUH T32 lasts until 2022, and we would have submitted our renewal in 2021. Do we follow that schedule and submit our Institutional Network Awards (U2C/TL1) in 2021?

Applicants are welcome to submit at any of the three listed submission dates (having an active T32 does not affect your eligibility to apply for a U2C/TL1). Many institutions may choose to submit an application for a U2C/TL1 award earlier than when they may have planned to submit a T32 renewal to take advantage of the additional resources provided by this new mechanism, and/or to participate in a joint application with other institutions.

10. I currently have an active KUH T32. I would like to apply for a U2C/TL1 award. Will my application be considered a new application or a renewal?

Because PAR-20-220 is a new funding opportunity announcement, all incoming U2C/TL1 applications will be considered <u>new</u> applications, regardless of whether the applicant organization has been or currently holds a KUH T32. Resubmissions (A1s) of a U2C/TL1 application are permitted if the first application (A0) is not selected for funding.

11. If an Institution currently has an active KUH T32 and a U2C/TL1 application is submitted but not funded, will the KUH T32 still have to be relinquished?

KUH T32s will need to be relinquished only if a new U2C/TL1 is *awarded*. As mandated by NIH policy, NIDDK cannot fund overlapping projects. However, if the U2C/TL1 application is not selected for funding, the active KUH T32 will continue as planned in the original Notice of Award. Resubmissions (A1s) are permitted if the new U2C/TL1 application is not selected for funding.

12. If a U2C/TL1 is awarded and an active KUH T32 subsequently is relinquished, can the trainees who received support via the T32 continue to receive support via the U2C/TL1?

Yes, trainees who received support via a T32 are eligible to finish out their training with support via a TL1. Keep in mind that National Research Service Award (NRSA) aggregate support restrictions still will apply (i.e., a maximum of 3 years of aggregate NRSA support for postdoctoral students, and a maximum of 5 years of aggregate NRSA support for predoctoral students).

13. When are U2C/TL1 applications due?

Applications for the U2C/TL1 awards are due October 14, 2020, October 14, 2021, and October 14, 2022. These new application due dates were published in NOT-DK-20-038.

Multi-Institutional Applications & Metropolitan Statistical Areas

14. What is a Metropolitan Statistical Area (MSA)?

Further clarification of an MSA has been provided in NOT-DK-20-038:

Only one application per institution (normally identified by having a unique DUNS number or NIH IPF number) is allowed. A single, consolidated application from several institutions within the same MSA, as defined by the Office of Management and Budget

(https://www.whitehouse.gov/omb/information-regulatory-affairs/statistical-programs-standards) is strongly encouraged and preferred. An MSA consists of the county or counties (or equivalent entities) associated with at least one urbanized area of at least 50,000 population, plus adjacent counties having a high degree of social and economic integration with the core, as measured through commuting ties (https://www.census.gov/programs-surveys/metro-micro/about/glossary.html). To assist applicants in determining the boundaries of MSAs, please use the delineation files resource at the U.S. Census website (https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html) or contact the NIDDK program staff listed on this website.

15. What if there is only one university within an MSA? Can smaller programs/institutions still submit a competitive application?

We understand that not all metropolitan areas have access to the same number of institutions/or resources. For this reason, <u>consolidated applications representing multiple</u> institutions are *encouraged*—but they are not required.

What is driving this encouragement is the attempt to "de-silo" existing training programs, and to move away from the traditional "departmental" view of T32s toward building a stronger, multidisciplinary community of trainees. In past years, multiple KUH T32s have existed within a single metropolitan area (and, often, within a single institution), with very little crosstalk or collaboration between them. The mission at the heart of this FOA is to create a community of trainees and to provide them access to the best resources available in a given institution and/or metropolitan area. How applicants construct a program to best achieve this goal, including if/how to pair up with neighboring institutions, ultimately is up to them. The review criteria listed in PAR-20-220 do not include any sort of quantitative measure of the number of institutions included within a single application. There is no reason, a priori, that smaller institutions can't submit a competitive application.

16. Do applicants need to engage ALL institutions within an MSA on a U2C/TL1 application?

There are no requirements related to the number of institutions within an MSA that need to be included on the application. When considering which institutions to partner with in a single MSA, applicants are asked to identify what would be most beneficial to the *community of trainees* they intend to support. Often, this means pooling available resources and leveraging opportunities across institutions to provide the best training experience possible. However, the review criteria listed in PAR-20-220 do not include any sort of quantitative measure of the number of institutions included within a single application.

17. Given the recent expansion of teleconferencing and remote collaborations (with many universities opting for remote-only education this fall), what are the thoughts about awards that cover more than one metropolitan area?

Yes, applicants can engage institutions across different MSAs. The application should include a clear justification for this engagement and thoughtful plans for how interactions between participants will be facilitated (i.e., between trainees, or between trainees and training faculty). Applications also should include thoughtful plans for program leadership and communication when engaging multiple institutions, particularly those that are geographically separated.

18. How many U2C/TL1 applications will be funded?

The number of U2C/TL1 awards has not been predetermined. The number of applications selected for funding will depend on the number of competitive, meritorious applications submitted and the final congressional appropriations for each fiscal year. Notably, NIDDK's/KUH's commitment to supporting institutional training has not diminished.

19. If a U2C/TL1 award was already made to a different institution in my Metropolitan Statistical Area, can I still submit an application for the upcoming receipt date(s)?

Per the FOA, applicants are expected to submit only one application per institution (normally identified by having a unique DUNS number or NIH IPF number) per receipt date. A single consolidated, application from several institutions within the same metropolitan are strongly encouraged and preferred.

Therefore, as described above, a U2C/TL1 application from a **separate** institution would be permitted per the FOA. As with any application, a clear justification for the proposed program must be delineated, particularly if the proposed program is within close geographic proximity of currently funded U2C/TL1 program. We encourage all applicants to consider the mission of these programs – which is in large part to create a **community** of trainees prepared to excel in K, U, and H mission area research – and perhaps consider providing networking opportunities between trainees supported by different programs within a single MSA/geographic area.

We still encourage institutions that are in within a single MSA to work together towards a single U2C/TL1 application, assuming it is feasible and practicable.

Budget

20. Are there any specific instructions for the U2C/TL1 budget?

Per NOT-DK-21-018: Summary of Changes to Budget Instructions

The purpose of this program is to recruit, support, and retain as many talented trainees as possible into benign kidney, urologic, and hematologic (KUH) research disciplines, and to propel discovery forward in these fields. To this end, the majority of the total award budget should be used to directly support trainee costs (via the NRSA Training Core, or TL1). More specifically, the collective total cost of the U2C (Administrative Core, Networking Core, and Professional Development Core) should not exceed 70% of the total cost of the TL1 (NRSA Training Core).

In addition, the <u>maximum salary support that can be requested for all overall PI(s) and Core Director(s) effort combined is six calendar months per budget period</u>. This applies across all U2C cores and the TL1 core. Minimum effort requirements for PIs of the application will no longer be in effect, though effort commitment should ensure the success of the program. The six-months of salary support for all overall PI(s) and Core Director(s) effort can be divided amongst participating faculty as needed. There is no cap on other personnel effort, provided the total cost of the award adheres to the restrictions outlined above.

The budget for the NRSA Training Core should comply with the NRSA stipend levels and allowable costs. Applicants requesting \$500,000 or more in direct costs in any year must submit a proposed budget and justification memo to the scientific program contact (Victoria

Spruance, PhD) at least 6 weeks before submitting the application. We anticipate many U2C/TL1 applications will exceed this budget threshold.

21. What should I include in my prior approval request to submit an application that exceeds \$500,000 in Direct Costs? When should this be submitted?

Applicants requesting \$500,000 or more in direct costs in any year must submit a prior approval request to the scientific program contact (Victoria Spruance, PhD - victoria.spruance@nih.gov) at least 6 weeks before submitting the application. Requests should be submitted with institutional concurrence. Please include the following in these requests:

- Proposed Title of Application
- Proposed Contact PI of Application
- Commons ID of Contact PI
- Applicant Institute
- Proposed Budget
- Budget Justification (brief)

22. Can Principal Investigators (PIs) request salary support through the U2C/TL1? What about Core Directors or Mentors?

As a major benefit of the new Institutional Network Awards, a limited amount of salary support can be requested via the U2C funding mechanism. We recognize that the Project Director (PD)/PIs of the U2C will invest significant time and energy in creating and managing an Institutional Network Award that merits financial support. This support should be limited to the PD/PI of the overall U2C, and in some cases, Core Directors who will be involved heavily in the Institutional Network Award Activities. Of course, appropriate justification should be included with all budget proposals and will be subject to peer review. Mentors will not receive salary support via this mechanism.

Per NOT-DK-21-018: The maximum salary support that can be requested for all Overall PI(s) and Core Director(s) effort combined is six calendar months per budget period. This applies across all U2C cores and the TL1 core. Minimum effort requirements for PIs of the application will no longer be in effect, though effort commitment should ensure the success of the program. The six-months of salary support for senior key personnel effort can be divided amongst participating faculty as needed. There is no cap on other personnel effort, provided the total cost of the award adheres to the restrictions outlined in NOT-21-018 and PAR-20-220.

23. Is PI effort for the TL1 allowable in the TL1 budget, or should that be funded through the U2C?

As the TL1 award is subject to NRSA budget restrictions, PI effort should be requested via the U2C budget.

24. Is the indirect cost rate for the TL1 component set at 8%? What is the indirect cost rate for the U2C component?

As an NRSA-funded mechanism, the indirect costs for the TL1 award are capped at 8%. The indirect cost rate for the U2C component will be the standard negotiated rate for the applicant organization.

25. Do we need to include plans/budget for hosting an annual meeting? Will every U2C/TL1 awardee be expected to host a meeting?

To cultivate the K-, U-, and H-training community, all trainees supported by the U2C/TL1 awards across the country, in addition to PDs and Mentors, will be invited to attend an annual meeting. The responsibility of hosting this meeting will rotate among awarded institutions.

Therefore, each applicant (i.e., applicant institution) should propose plans for hosting the annual meeting and incorporate the associated costs into their proposed budgets. Ultimately, as the U2C awards will be Cooperative Agreements, all awarded institutions will work closely with NIDDK to finalize plans for how, when, and where each annual meeting will take place. It is possible there may be more U2C/TL1 awardees than there are annual meetings in a given project period, in which case some awarded institutions may not end up hosting a meeting at all. These types of logistical details will be determined once awards are made and Cooperative Agreements are formed.

The number of annual meetings in a project period is not meant to correlate with the number of awardees. The number of U2C/TL1 awards ultimately will be dependent upon available funds each fiscal year and the number of applications that are submitted and peer reviewed meritoriously.

PI/PD Eligibility

26. Do all PDs/PIs associated with a U2C/TL1 application need to be NIDDK-funded investigators?

There is an expectation that the overall PD/PI of the U2C and TL1 awards are established investigators with active research portfolios supported by NIDDK/KUH. For MPI applications, at least one of the multiple PDs/PIs should be an investigator with an active research program in basic, translational, or clinical science aligned with the mission of KUH, capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. Additional PDs/PIs, including individuals with experience in areas such as science education, program evaluation, mentoring, and career development and advancement for early-career scientists, may be included to achieve the training goals.

This requirement does <u>NOT</u> apply to other investigators associated with each U2C/TL1—including those who may serve as Core Directors, Mentors, Co-Sponsors, or other Faculty. That said, all trainees directly supported by the TL1 award must be engaged in KUH-mission area research.

27. Do the PD/PIs for the U2C award need to be different from the PD/PIs for the TL1 award? Are there separate applications for the U2C and TL1 components?

The proposed PD/PI(s) for the U2C award should be different from the PD/PI(s) for the TL1 award. Although there is a single application for the combined U2C-TL1, these components will be separated upon award. Each component will maintain its own budget. The person

named as the "Core Lead/Director" for the NRSA Training Core will become the PD/PI for the TL1 award.

Resubmissions

28. Are resubmissions allowed?

Resubmission (-A1) applications are permitted under this FOA.

29. Are Introductions allowed with resubmitted applications? What are the page limits?

For Resubmission applications, an Introduction to Application is allowed for each component. Each introduction should not exceed 1 page, including the introduction for the NRSA Training Core.

30. Do I need to submit a prior approval request to submit an application that exceeds \$500,000 in direct costs for a resubmission?

Yes, in order to submit a resubmission application that exceeds \$500,000 in Direct Costs in any year, prior approval is required. A new prior approval request must be submitted even if a prior approval request was granted for the original (A0) application. See [Q]21 for details about prior approval requests.