National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

2025 Supporting Instructions for Research Performance Progress Reports (RPPRs) for the Clinical and Translational Science Awards (CTSA) Program

UL1, KL2 and TL1 Awards

Released: April 2025

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Please read these instructions completely before you begin entering information. Failure to do so could lead to errors that might require you to restart your work, thus losing the data you already entered. The Supporting Instructions contained herein are not in replacement of the NIH RPPR instruction guide but only as an aid to CTSA Program UL1, KL2, and TL1 award recipients in the submission of CTSA specific information in their annual RPPR.

***Note:* All UL1, KL2 and TL1s are required to submit a final RPPR at the end of their project period; the new suite of NOFOs is all considered NEW applications and *not RENEWALS*.**

SUMMARY OF CHANGES 2024 TO 2025

Overall, changes to this version have been minor. Most edits were in response to inquiries received from CTSA hubs through our CTSA RPPR mailbox. Below is the list of the main changes from 2024 to 2025 by section:

General Instructions:

- Highlighted additional sentences (in **bold** and/or in RED font) throughout the instructions to emphasize key areas of attention for hubs.
- Updated URLs throughout the document.
- Removed references to Interim RPPRs as these are no longer relevant to UL1, KL2, and TL1 award recipients.

List of Appendices:

- Appendices 1 & 2: Removed — these are not required for the UL1.

Section B. Accomplishments:

- Section B.2: Removed text related to Management of Participant and Clinical Interactions (PCI) Component.
- Section B.2: Updated Reporting on Current Areas of Strong Public Interest section (added new terms).

NOTE — New Common Forms (biosketch and other support) will be required for RPPR submissions after May 25, 2025. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html

INTRODUCTION

The NIH Guide Notice, NOT-OD-15-014, requires that all Grant Progress Reports for the CTSA Program UL1, KL2 and TL1 mechanisms be submitted electronically using the Research Performance Progress Report (RPPR) format. Please visit the NIH RPPR website for an overview and technical assistance for preparing and submitting reports: http://grants.nih. gov/grants/rppr/.

The following may serve as a reference for the NIH instructions:

- Chapter 6: Instructions for RPPR Sections A–I
- Chapter 7.4: Supplemental Instructions for Specific Grant RPPR Types — Training RPPRs
- Chapter 7.6.1: Supplemental Instructions for Specific Grant RPPR Types — Multi-Project RPPRs and Single-Project RPPRs with Complicated Structure — Overall
- Chapter 7.6.2: Supplemental Instructions for Specific Grant RPPR Types — Multi-Project RPPRs and Single-Project RPPRs with Complicated Structure — Component Instructions

Where the requested information does not pertain to the CTSA Program, you can indicate "Nothing to Report." Please refer to the general NIH instructions along with the CTSA Program supporting instructions, in this document, as you prepare the submission. **Please pay attention to page limits and save your work regularly since there is no automatic save. The UL1, KL2, and TL1 Progress Reports must be submitted separately. This document contains instructions for all three mechanisms.** The Appendices will assist in the submission of required information. ***Appendices 3, 4, and 5 will be visible in the Supporting Instructions PDF once the instructions have been downloaded and saved to your computer*.** You should also consult with your institution's Office of Sponsored Programs as needed.

IMPORTANT REMINDERS:

- NCATS will not be able to complete the review of a non-competing continuation application until all outstanding Federal Financial Reports (SF 425) have been submitted via the Payment Management System, and accepted by, the NIH Office of Policy for Extramural Research Administration (OPERA).
- Publications reported **must** comply with the NIH Public Access Policy (https://sharing.nih.gov/public-access-policy). The publications reported should be as a **direct result** of support from the CTSA Hub Program. If applicable publications are reported that do not comply with the NIH public access policy, NCATS will not be able to process non-competing applications until evidence of compliance is provided; **this will result in a delay in review and processing of the applicable Notice of Grant Award**. NCATS utilizes the NIH Public Access Support Center to assist with public access compliance issues; please comply with any requests received from the NIH Public Access Support Center. Questions or concerns may be sent to your assigned Program Officer and Grants Management Specialist.
- Per NIH Grants Policy, prior approval requests must be submitted ***no later than 30 days before the proposed activity, change or effective date occurs***. Failure to comply with the NIH terms and conditions of award may cause NIH to take one or more actions, including but not limited to disallowance of all or part of the costs of the activity or action not in compliance.
- Recipient institutions are required to include information on NCATS CTSA Program-funded pilot studies in the annual Research Performance Project Report (RPPR) submission. **It is recommended that pilot projects follow the pilot projects template specifications.** The template and instructions can be found below and attached to this PDF as Appendix 5.
- Human Subjects and Animal Studies pilot projects must adhere to the CTSA Program Prior Approval Guidelines. Prior Approval Requirements for Pilot Projects involving Human Subjects and/or Animal Studies can be found here:
    - Human Subjects: https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/human-subjects-research;
    - Animal Studies: https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/prior-approval

- Ensure you are carefully reviewing the instructions for Section D Participants and submitting only the required documentation. It is essential that other support and biosketch documents are submitted in accordance with NIH policies. (https://grants.nih.gov/grants/forms/othersupport.htm). Failure to correctly submit these documents will result in delays.

Per the NIH Grants Policy Statement, failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions.

WHERE TO GO FOR ADDITIONAL HELP:

- General NIH RPPR Instructions: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf
- NIH RPPR website: https://grants.nih.gov/grants/rppr/index.htm. For technical assistance with your RPPR, contact: https://www.era.nih.gov/need-help
- CTSA Program RPPR FAQs: https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/rppr-faqs
- NIH Grants Policy Statement: https://grants.nih.gov/policy/nihgps/index.htm
- For questions regarding the CTSA supporting instructions, email: CTSARPPRQuestions@mail.nih.gov
- NCATS CTSA Program Guidelines for Recipients: Prior Approval and Reporting of Research with Human Subjects and/or Vertebrate Animals: https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-guidelines
- Human Subjects System (HSS) guidebook: https://era.nih.gov/files/HSS_user_guide.pdf
- Recipients can contact their Office of Sponsored Programs/Authorized Organization Representative for questions related to RPPR reporting, RPPR submission, and NIH policy.
- Recipients can contact their NCATS Program Officer for grant-specific scientific or technical questions.
- Recipients can work with their Office of Sponsored Programs/Authorized Organization Representative to contact the NCATS Grants Management Specialist for grant-specific administrative or financial questions.

General Instructions — Annual RPPR

General RPPR instructions for annual RPPRs are at http://grants.nih.gov/grants/RPPR/rppr_instruction_guide.pdf. The instructions below are limited to describing the reporting of *only* CTSA Program specific information that is not captured by the general RPPR instructions. Section titles refer to the RPPR Sections A–H (see Navigation below).

Each CTSA Program award is composed of linked UL1 and KL2 awards and may also include a linked TL1 award. These individual awards resulted from a single U54 application in response to a CTSA Program solicitation. At the time of funding, successful applications were disaggregated into individual grants, which are linked as specified in the Notice of Grant Award. Separate RPPRs must be prepared and submitted electronically for each CTSA Program mechanism.

Forms and Uploads

These CTSA Program specific instructions include suggested tables and report templates that will be helpful in completing the progress report. Note that the tables and reports are suggested templates for reporting required information. Please refer to Appendices 1 through 5:

TABLE 1: LIST OF APPENDICES

Appendix	Title
1	Training Roster *(removed — this is no longer needed)*
3	Training Individual Progress Report
4	Table of Institutional Collaborators
5	Pilot Project Report

The entire RPPR package should be assembled according to the NIH instructions and CTSA Program Supporting Instructions. RPPR packages must be submitted electronically via the eRA Commons accounts for each award — UL1, KL2 and TL1 — separately.

All uploads must use a PDF format; the PDF uploads do not have page limits, but each PDF file upload (attachment) may not be more than 6 megabytes (6 MB).

Final RPPR Instructions

There are no components for Final RPPRs. For UL1 recipients Final RPPRs *B.2: What was accomplished under these goals? Including Highlights, Milestones and Challenges Report* should be uploaded under the Overall section and encompass the main progress (including progress on each component/core) during the final year of the award. Suggested page limits in B.2 for the overall and for each component are similar to the page limits suggested in the annual RPPR (up to 5 pages for highlights, milestones and challenges plus up to 2 pages for evaluation). The final RPPR should also include sections C, D, E and G, including additional information under Section G.1 and corresponding Appendices/Tables.

Differences between Final RPPR and the annual RPPR are few:

- In the Final RPPR, only Section D.1 is required in the Participants section
- Section F: Changes and Section H: Budget are not part of the Final RPPR
- Section G: For UL1 Final RPPR, in addition to the requested information, Section G should also include Appendix Tables 4 (Table of Institutional Collaborators) and 5 (Pilot Project Reports).
- Section I: Outcomes is required for both the Final RPPR

Recipients should be aware that the NIH will make the Project Outcomes Section of all Final RPPRs publicly available via NIH RePORTER. The narrative of the Project Outcomes section must be written for the general public in clear and comprehensible language, without including any proprietary, confidential information or trade secrets. For more information see NOT-OD-18-103.

Program Officers and/or Grants Management Specialists may request additional information as part of their official review for Final RPPRs. The Final Progress Report Additional Materials (FRAM) feature provides a means for the recipient to enter, review, route, and submit information in response to specific request(s) by the Program Official (PO) for additional information related to the Final RPPR (including requests to revise Outcomes Section I). When additional information is required, the PO will submit a request for this information referred to as a FRAM request. For more information about how to submit FRAM: https://www.era.nih.gov/erahelp/commons/Commons/status/closeout/fram.htm. After the review is completed, the final RPPR must be accepted by the assigned Program Officer in the system.

For more information about how to submit your final RPPR please see:
https://www.era.nih.gov/recipients/submit-final-rppr.htm

Due Dates

For Annual RPPRs:

Annual RPPRs for CTSA Program awards are due 60 days before the budget period ends.

For the initial RPPR, the reporting period:

- Starts with the initial Notice of Grant Award budget period start date.
- Ends 2 months before the budget period end date.

For subsequent years, the reporting period for RPPR:

- Starts two months before the budget period start date.
- Ends 2 months before the budget period end date.

For Final RPPRs:

- The Final RPPR is due no later than **120 calendar days** from the project period end date. (See information about Final RPPR Instructions)

Late submission of a grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

UL1 AWARD

WHEN CREATING THE INITIAL RPPR for the UL1, ANSWER "YES" TO THE QUESTION, "DOES THIS PROJECT HAVE COMPONENTS?"
If you answer "NO," contact the eRA Help Desk, and restart the process.

To comply with these instructions and the RPPR general instructions, create the following separate components in the report for the UL1 Award: one for the **overall CTSA Program** project and one for each **key function/resource/service**. Recipients who responded to PAR-15-304, PAR-18-464, or PAR-18-940 should include pilot projects in the Translational Endeavors component. **Please reference the original RFA the submitting institution was funded under for the specific components that should be included.**

Follow the NIH RPPR instructions for creating multiple components within the UL1 Award: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf.

RPPR items for which there are no CTSA Program-specific supporting instructions have been intentionally omitted. Use the Instructions for RPPR Sections A–I (Chapter 6) or the Supplemental Instructions for Specific Grant RPPR Types (Chapter 7) of the NIH RPPR instructions for the items not included here.

Each component within the CTSA Program should be reported as a separate component with its own sections A through H. Please follow the NIH RPPR instructions carefully. Note that some of the sections and questions do not apply to the individual component level.

When the report is complete, submitters are encouraged to print a PDF version and review carefully to ensure that the budget figures are consistent with the composite budget spreadsheet uploaded in the U L1 component. When submitters are satisfied with the PDF version of their RPPR, they should save a copy. The finished report should be submitted electronically.

The eRA system will convert the submission data into a PDF document, which will be visible after submission.

Section B. Accomplishments

B.2: What was accomplished under these goals?

The goals in this question refer to the specific aims of the project. **Address this question in an external file and upload it as a PDF.** In reporting on your accomplishments in this section, report on your progress in terms of impact, innovation, and significance — how did you advance your aims? The following sections must be included:

Highlights, Milestones and Challenges Report (Limit: 5 Pages)

The hub should address the progress of the overall program and each core/component in **no more than 5 pages each.** Tables may be included. Please avoid redundancy between reports. Specific areas to include are:

- Program integration and innovation; its significance/impact; achievement of last year's milestones
- Detailed information about challenges encountered and plans for resolution.
- Plans for shifts in activities, if any, including a description and rationale for modifications; provide milestones and timelines for the coming year. Include changes made to provide support for improving capacity for new collaborative activities, if appropriate. For example, a description of the proposed Trial Innovation Network Liaison Team would be included under the "Network Capacity" component for applicants responding to PAR-15-304 or PAR-18-464. ***Note — Shifts in activity may occur but changes and/or expansion in scope require NIH prior approval through a separate prior approval request*.**
- Information on the type and level of institutional support (including voluntary committed cost share) provided during the reporting period; also include any proposed modification for the institutional support in the coming year. ***Note — Reductions or changes in voluntary committed cost share indicated on the Notice of Award require NIH prior approval through a separate prior approval request*.**
- Impact of the academic home on collaborator institutions and how the program facilitates multisite research of investigators in the academic home. List each collaborating institution that received support from the CTSA Program award. It is suggested this information be presented using the table provided as Appendix 4 (Table of Institutional Collaborators; see below Section G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements).
- **Shifts in funding between the UL1 and KL2 can only occur via the RPPR (type 5) submission.** Shifts in funding are ONLY permitted between the UL1 and KL2. If requesting to shift funds between the linked UL1 and KL2 awards, include the dollar amounts and relevant component(s) and/or mechanism and rationale for the proposed changes, including impact on programs. Justification must be included for any deviations from the originally approved budget especially when shifting funds. Shifts in funding between mechanisms must be **well justified in the budget justification sections** of both the UL1 and the KL2. Shifts in funding are made at a total cost level, inclusive of F&A costs.
- For UL1 Final RPPR, the Highlights, Milestones and Challenges Report in the Overall section should encompass the main progress of the UL1 during the final year of the award.

Evaluation Report (Limit: 2 Pages)

Describe the self-evaluation assessment of your CTSA Program; include its conceptual framework, objectives, milestones, metrics, and type of data collected. Summarize findings; include specific changes you have implemented or that you plan to implement based on those findings; the metrics you will use to document impact, and future timelines for implementation, reassessment, and adjustment.

Reporting on Current Areas of Strong Public Interest (Limit: 3 Pages)

Include the title and a brief description about accomplishments in any area(s) of strong public interest. A point of contact for additional information for the areas of strong public interest, reference to other sections of the RPPR for more information, and/or web links to the specific accomplishment are encouraged to be included. NCATS may use these accomplishments to describe how the program is addressing areas of urgent need. See rural health example of how NCATS compiles data on areas of strong public health interest: https://ncats.nih.gov/research/research-activities/ctsa/projects/rural-health

Publications Resulting from Use of CTSA Hub Resources

For publications resulting from pilot projects funded via voluntary uncommitted cost share or other uses of hub resources, recipient institutions may choose to follow the NIH guidance provided in NOT-OD-16-079—Guidance for Publications Supported by Shared Resources in RPPRs and Renewal Applications. **Per this Guide Notice, if an NIH award's only contribution to a publication is a shared resource, award recipients can opt to list and/or summarize these publications in Section B.2 of the RPPR with the subtitle "Shared Resources."** Publications listed or summarized in this section will not count against the section's two-page limit and are not required to be tracked and monitored for the purposes of public access compliance. Pilot projects without publications but supported via voluntary uncommitted cost share may also be reported in this same manner in order to document the value of the shared resources developed through the CTSA Program hub award. NOTE: Recipient institutions are responsible for public access compliance of all publications listed in Section C.1 of an RPPR. More information: Prior Approval Requests for Vertebrate Animal Research and Prior Approval Requests for Human Subjects Research

B.3: Competitive Revisions/Administrative Supplements

Refer to the instructions in the RPPR instruction guide (Chapter 7.6.1) and competitive revision/administrative supplement terms of award for how to report on any Competitive Revision/Administrative Supplement(s) awarded during the reporting period.

Each Competitive Revision/Administrative Supplement Report should include:

- Revision/Supplement Title
- Specific Aims
- Accomplishments
- Challenges
- Status of milestones (if applicable)
- Supplement budget page(s) and budget justification(s) must be included in the specific project or core (identify the component) budget section for each individual supplement.

If publications resulted from the supplement, cite the PMCIDs in the UM1 report using MyNCBI.

NOTE: Under B.3 the user is provided with 700 characters to describe the specific aims for each Revision/Supplement, and 700 characters to describe the accomplishments for each Revision/Supplement. These descriptions will of necessity be brief, and NIH strongly encourages concise responses. Attach information in G.1 if the report goes beyond 700 characters.

Recipients should refer to the Competitive Revision/Administrative Supplement terms of award to ensure proper reporting procedures are followed.

B.4: What opportunities for training and professional development has the project provided?

Use this section to report UL1-funded training and professional development such as workshops, conferences, and other training activities directly supported by the UL1 hub award. **Do not report training and professional development for KL2 scholars or TL1 trainees in the UL1 report.** This section includes descriptions and formats for attachments that should be uploaded to address question B.4. Tables, charts, diagrams, and other non-text material may be included in the attachment. Concise, clear, and complete narratives facilitate the review of non-competing applications.

Section C. Products

C.1: Publications

Include all publications, along with the PMCID (Pubmed Central ID) found in MyNCBI, that were directly resulting from the funds provided in the UL1 component and/or any UL1 revision/administrative supplements. Publications directly resulting from the KL2 scholars or TL1 trainees must be reported separately in the corresponding KL2 or TL1 report. If the publication cites multiple grants (UL1, KL2, and/or TL1) then the publication should be reported in each of those corresponding reports.

What to Report

Recipients must report publications in section C.1 if:
(1) The publication was accepted for publication or made public during the reporting period; **and**
(2) The publication directly arises from the award (e.g., the award supported personnel activity that contributed to the publication, such as authorship, consulting with authors, preparing manuscripts, running analyses reported in the publication). Publications listed in other parts of the RPPR will not be tracked as award products. For additional information about the importance of accurately acknowledging NIH grants in publications: https://loop.nigms.nih.gov/2017/02/why-is-it-important-to-accurately-acknowledge-nigms-grants-in-publications/

Information that will enable you to use My BIBLIOGRAPHY in MyNCBI may be found at: http://www.ncbi.nlm.nih.gov/books/NBK3843/. Please refer to the NIH RPPR instructions for additional guidance on using My BIBLIOGRAPHY and MyNCBI.

For information on the public access policy, how to cite your publication and the Public Access Compliance codes in the RPPR and My NCBI report follow: https://sharing.nih.gov/public-access-policy/reporting-publications-to-nih

NOTE: **Non-compliant publications will need to be brought to compliance following the process described in Public Access Progress Report Additional Materials (PRAM) section of the NIH RPPR Instructions Guide. Per NIH policy, NCATS cannot release the relevant Notice of Award until all publications are compliant with the Public Access Policy. NCATS utilizes the NIH Public Access Support Center to assist with public access compliance issues; please comply with any requests received from**

the NIH Public Access Support Center. Questions or concerns may be sent to your assigned Program Officer and Grants Management Specialist.

C.4: Inventions, patent applications and/or licenses

Please indicate any inventions, patent applications and/or licenses that resulted from the support of UL1 activities. Report any inventions or patents in the i-EDISON database as required and **include the i-EDISON invention report number in this section.**

C.5a: Other products and resources sharing

Information about INDs or IDEs held by the investigator or participating institution should be included for pilot projects directly supported by the CTSA Program grant. The Pilot Project Report template (**Appendix 5**) includes a question regarding studies that are under IND/IDE. Other IND/IDE enabling activities, such as regulatory support, can be included in the corresponding component section milestones/activities.

Section D. Participants

Reminder: You are required to report effort in accordance with the NIH RPPR instructions. Please read the instructions under each question in section D carefully.

Provide or update the information for: (1) program director(s)/principal investigator(s) (PDs/PIs); and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort).

The RPPR instructions permit recipients to request a reduction in the level of effort of the PD/PI or other key personnel named in the Notice of Award for the upcoming budget period. **This is the only prior approval request that can be submitted via the RPPR and does not include reductions in level of effort that occurred during the RPPR reporting period. These reductions must receive NCATS prior approval prior to the reduction in effort.** Recipients are reminded to review the relevant FOA for effort level requirements. Instructions for documentation requirements for changes in key personnel are available on the NCATS website: https://ncats.nih.gov/funding/grantee-information/prior-approval.

As a reminder, follow NCATS prior approval instructions for key personnel changes of > 25% effort (https://ncats.nih.gov/funding/grantees/approval#change-in-key-personnel) that are not occurring in conjunction with the annual RPPR submission as stated above.

Section G. Overall Special Reporting Requirements

The following special reporting requirements should be under the Overall component of the RPPR.

G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements

1) External Advisory Committee Report

Provide the complete text of the External Advisory Committee (EAC) report(s). In addition, include a roster of all the members of the EAC including their terms of office (if applicable), the date(s) of the EAC meeting(s) during the reporting period, the names of EAC members who attended the meeting(s), the agenda(s) for the meeting(s), the names of CTSA Program staff who gave presentations and *confirm no Type 1 competing application planning/writing occurred during any EAC meetings*. If ad hoc or special EAC reports were issued, include them, as well.

REMINDER: **Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of data necessary to support the non-Federal entity's bids or proposals. Based on Uniform Guidance 200.460 and the NIH Grants Policy Statement, proposal costs cannot be charged as direct costs to federal grants, except in specified scenarios outlined in the scope of work (ex. development of independent research proposals for scholars/trainees). Use of current grant funds for the preparation or development of proposals in response to active solicitations for new grant funding is considered unallowable as a direct cost.**

Awarded CTSA Hubs cannot use current federally funded grant activities to support the development or preparation of a grant application to a new solicitation. **The new CTSA UM1, K12, T32, and related NOFOs are considered new solicitations.** The costs of the activity as well as the salary support/effort for the individuals involved in the development, planning or participation in the activity are unallowable as direct costs. During an EAC meeting the following are:

Allowable:

- Broad discussions of lessons learned, best practices and how to move the field forward
- Evaluation of the current grant funded activities
- Discussions on the strengths/weaknesses of the currently funded grant

Unallowable:

- Discussions and recommendations for preparation of applications for the new grant solicitations
- Development of data to support the new grant applications

2) Table for Institutional Collaborators (see Appendix 4)

The instructions are below and included in the Appendix 4 attachment.

Include a list and description of institutions functioning as collaborators with the CTSA Program hub. The following suggested table format may be incorporated into an attachment to fulfill this request. (See Appendix 4: Table of Institutional Collaborators). **In this table, do not include "Partners" as these are currently displayed and updated on the NCATS website: https://ncats.nih.gov/research/research-activities/ctsa/applicant-information/CPUBRT**

#	NAME OF COLLABORATOR	RELATIONSHIP [a]	TYPE [b]	FUNDING CATEGORY [c]

[a] Relationship to the Clinical and Translational Science Award Program (CTSA) hub (Choose one)

- Subaward
- Memorandum of understanding (MOU)
- Reliance or other authorization agreement with the CTSA Program hub relevant to multi-site clinical research
- Other (provide descriptor)

[b] Type of institution (include all that apply to this institution)

- Academic Medical Center
- College/School/University
- Community Practice/Clinic
- Community Hospital
- Community Organization
- Pediatric Hospital
- State/Local Health Department
- Specialty Hospital/Center (other than listed)
- Research Institute/Organization
- Veteran's Affairs Clinic/Hospital
- Nonprofits with or without 501c3 status
- Other Institutions of Higher Education such as:
    - Hispanic-serving Institutions
    - Historically Black Colleges and Universities (HBCUs)
    - Tribally Controlled Colleges and Universities (TCCUs)
    - Alaska Native and Native Hawaiian Serving Institutions
    - Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)
- Other (please indicate)

[c] Funding Category (choose one)

- Private
- Not-for-profit
- State, local, or federally funded
- Other (provide descriptor)

3) Pilot Projects (see Appendix 5)

Report ***only*** pilot projects supported with funds (direct, voluntary committed cost sharing, or both) from the UL1 award during the reporting period. The pilot project activity may cross over budget periods but, per NIH Grants Policy and the Notice of Award, the institution CANNOT carry over funds from one budget period to another without NIH prior approval. Repeated prior approval requests to transfer funds from one budget period to another for the same/similar program costs will be denied. Please work with your Office of Sponsored Programs to establish your pilot program

in a manner that complies with NIH Grants Policy and avoids setting up a need for continual carryover requests for pilot program funds. For more information see: Prior Approval Requests for Vertebrate Animal Research and Prior Approval Requests for Human Subjects Research.

NOTE: **Once pilots complete their NCATS funded period, no reporting is required in the RPPR or HSS system. Once a KL2 scholar terminates their appointment, no further reporting is needed in the RPPR or HSS.**

All clinical trials must ensure they are compliant with NIH clinical trial reporting requirements regardless of the time period of award.

Appendix 5 provides a suggested table format for reporting, and should include the following information:

- **Project Title** — The name of the pilot project that received funding
- **Project Dates** — The first and last dates for which project funds were available in MM/DD/YYYY format
- **Project Status** — Whether the project funds will be available in the future, are currently available, or no longer available/the project has ended
- **Investigator(s)** — The name of every investigator associated with the project. All names should be listed last name followed by first name separated by a comma and using a semicolon to separate different PI names (e.g., Smith, John; Chu, Tim…). For multiple investigators, the order in this field should match the order in the NIH Commons ID(s) field below.
- **NIH Commons ID(s)** — The eRA Commons username for every PI associated with the project separated by commas if there are more than one usernames. For investigators without an NIH Commons ID, write "N/A". The order of the usernames should match the order in the Investigator(s) field above.
- **Current KL2 Scholar** — Whether any of the associated PIs are KL2 scholars (yes or no)
- **Collaborating Institution(s)** — The names of every institution outside the Recipient institution that is participating in the pilot project or KL2 project with a semicolon separating institution names. This includes other CTSA hubs that are collaborating on a pilot or KL2 project and collaborating institutions within a CTSA hub.
- **Human Subjects Research Exemption Number** — The NIH exemption number that applies to the study, if any.
- **Human Subjects System (HSS) Study ID Number** — The unique identifier assigned to the study by the eRA Human Subjects System.
- **Inclusion Enrollment Report in HSS/ASSIST** — Whether the pilot project's cumulative (actual) enrollment to date is appropriate, on target, and is up to date. In addition, inclusion enrollment records (IERs) and study records for non-exempt human subjects research must be uploaded in the Human Subjects System (HSS) as part of the RPPR submission. Fields that must be up to date include:
  - For clinical trials:
    - Enrollment start date
    - Enrollment end date
    - Cumulative enrollment (Actual)

    - Section 1 — Basic Information:
        - Question 1.5 NCT # (for clinical trials)
    - Section 2 — Study Population Characteristics (for clinical trials)
        - Question 2.6 Recruitment Status
    - Section 6 — Clinical Trial Milestone Plan (for clinical trials)
        - Question 6.1 Study Primary Completion Date
        - Question 6.2 Study Final Completion Date
        - Question 6.4 Completion of primary endpoint data analyses
        - Question 6.5 Reporting of results in ClinicalTrials.gov
- **Investigational New Drug/Device Exemption** — Whether the pilot involves an IND or IDE
- **Vertebrate Animal Subjects** — Whether the pilot project involves vertebrate animals
- **Research Category Terms** — Select one or more of the following high-level terms that characterizethe pilot project for each Research Category Term:
    - **Research Category Term(s) 1** (definitions)
        - Pre-Clinical Research
        - Clinical Research
        - Clinical Implementation
        - Public Health
    - **Research Category Term(s) 2** (select one to three categories):
        - Method or Process Development — Develops/refines technical methods or procedures
        - Mechanistic Basic to Clinical — Applies a basic science discovery to clinical research
        - Biomedical Informatics / Health Informatics — Develops and applies computer and information sciences concepts, software, and tools to health-related application domains such as biology, behavioral science, health care, public health, and clinical research
        - Outcomes Research, Health Services Research, and Comparative Effectiveness —
        - Measures or compares healthcare quality and outcomes
        - Clinical Epidemiology — Applies epidemiology or epidemiologic methods in a clinical setting
        - Clinical Trial — Studies one or more human subjects prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes
        - Digital Health & Social Media — Studies using digital health, mobile technologies and/or social media platforms.
        - Pediatric — Studies humans aged 0–21 (including college students) as well as the embryo/fetus or uses animal models to study processes in humans of that age group. All embryo/fetus studies are included except when the focus is on the pregnant mother.
        - Rural Health — Studies health and healthcare of rural populations
        - Other — If none of the above categories encompass the pilot research, write in a category that defines the general field of study of the pilot research. If this field is used, no other category should be provided in this field.
- **Funds Awarded** — Funds provided from the CTSA hub for the pilot project
- **Funds Expended** — Expenditures against the funds provided by the CTSA hub for the pilot project (zero if no expenditures have been made)

- **Source of Funds** — The source of the project's funding. Can be direct (funds provided solely from UL1), voluntary committed cost share (if funds provided solely from institution), or both.
- **NCATS Prior Approval for HS or VAS** — Whether the pilot has been given approval by NCATS for human or vertebrate animal subject research.
- **Impact Statement** — A 250-character description of the impact or returns on investment associated with the results of the pilot research. Do not include graphical elements (plots, figures, etc.)
- **Publications** — Publications (if any) that resulted from the Pilot Project, listed as PMIDS with semicolons separating the PMIDs. These must also be reported under C.1 Publications in the RPPR and adhere to NIH Public Access Policy. For publications not indexed by the NLM/Medline system, please include an abbreviated citation in the Progress Report section.
- **Abstract** — The abstract provided in the pilot funding application, or text similar to the abstract required for an NIH grant. Limit text to 1200 characters and do not include graphical elements (plots, figures, etc.)
- **Progress Report** — The specific aims of the project and progress associated with each aim. Limit text to 1200 characters and do not include graphical elements (plots, figures, etc.).

Pilot Project Report Formatting

The Pilot Project Report template format for the RPPR submissions is recommended to help facilitate aggregation of pilot data from the RPPR. This information can be used to report on the impact of the CTSA Program. If Appendix 5 cannot be used, please email CTSARPPRQuestions@mail.nih.gov and CC your program officer so NCATS can assist with finding a suitable alternative for submitting pilot project data. To ensure that the information is efficiently and accurately extracted, pilot project reports are requested to adhere to the following guidelines:

- All pilot projects with human subjects should be entered first, followed by all pilot projects with vertebrate animals, and lastly by all projects involving neither human subjects nor vertebrate animals.
- Reports must only contain text. No images, scans, or other graphical objects should be included in a pilot project report as this is not recognized and disrupts efficient and accurate data collection.
- If multiple PIs from the same institution are collaborating on a pilot project, only one pilot project report should be included in that institution's RPPR. If PIs from different institutions are collaborating on a pilot project, each institution should report the pilot project using the exact same Project Title.
- Each pilot project report should start on a new page. No single page should contain information from more than one pilot project report.
- The table portion of a pilot project report (from Project Title to Publications) should not exceed one page in length. The free text portion of the report should start on the next page and also should not exceed one page in length.
- Each pilot project report table should retain the Appendix 5 heading as provided in the template: **Appendix 5: PILOT PROJECT REPORT**.

Failure to follow the recommended formatting guidance will not impact the review and/or funding determinations for the RPPR.

4) Competitive Revisions/Administrative Supplements

Research Supplements to Promote Re-Entry (see Appendix 3)

Reports on supplements that have been awarded to the UL1 to support an individual's training, education and career development must provide additional information and be uploaded as an attachment in G.1., Special Notice of Award and Funding Opportunity Reporting Requirements. These include:

- Research Supplements to Promote Re-Entry/Re-Integration into Biomedical and Behavioral Research Careers (Admin Supp - Clinical Trial Not Allowed) (e.g. NOT-OD-23-170 and subsequent opportunities.

The reports on these supplements must use the attached template for the Training Individual Progress Report (Appendix 3) to report progress; see instructions for Appendix 3 below on page 26. The report should include a paragraph for the supplement award recipient describing activities and progress during the reporting period.

All other Competitive Revisions / Administrative Supplements

Progress should include a description of:

- Revision/Supplement Title
- Specific Aims
- Accomplishments
- Challenges
- Status of milestones (if applicable)
- Plans for the next funding period/grant year (if applicable)

If publications resulted from the Administrative Supplement, cite the PMCIDs in the UL1 report using MyNCBI.

Recipients should refer to the Competitive Revision/Administrative Supplement terms of award to ensure proper reporting procedures are followed.

G.4. b: Inclusion Enrollment Data

The Planned Enrollment Table in the Inclusion and Enrollment Report (IER) ASSIST 2.9 must be accurate (number of participants, racial categories, and ethnic categories) and must match the described project and all supporting documentation. The Actual (Cumulative) Enrollment Table must be updated in the IER (ASSIST 2.9) at the time of submission of the annual RPPR, including age at enrollment.

IER is not required for Category 4 Exempt HSR projects. **For specific information on the requirement for IER for KL2 independent clinical research, please refer to the KL2 RPPR section below.** For questions regarding Inclusion Enrollment Reports, email: inclusion@od.nih.gov.

ASSIST — Inclusion Enrollment Reports — Guidance: https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/Incl_Enroll_Rprt.htm

Inclusion Policies: https://grants.nih.gov/policy/inclusion.htm

G.10 Estimated Unobligated Balance

Question G.10.a When answering the following: *Is it anticipated that an **estimated unobligated balance (including prior year(s) carryover)** will be greater than 25% of the **current year's total approved budget**? If yes, provide the estimated unobligated balance.*

- The **current year's total approved budget** equals the current year authorization and any carryover approved in the current budget period through a revised notice of award (denominator).
- The **estimated unobligated balance** (cumulative unobligated balance over the current project period) **equals** (numerator) the **total amount *available* for carryover which includes:**
    - The amount of current budget period funds that are expected to remain unobligated at the end of the current budget period, AND
    - The **unobligated balance reported on the most recent OFM-accepted FFR** minus the sum of all approved carryover funds in the current budget period.
- **A response that only includes the current budget period authorization and the current budget period estimated unobligated balance is considered an inaccurate calculation and therefore is not an adequate response to this question**.

Using the **total amount available for carryover** as the numerator and the **current year's total approved budget** as the denominator will provide an accurate percentage of the current unobligated balance associated with this award and will allow for proactive planning through the life cycle of the CTSA.

EXAMPLE: NCATS University is going into Year 4. To determine whether the estimated unobligated balance will be greater than 25% of the current year's estimated total approved budget for G.10.a, NCATS University will gather the following information:

- The unobligated balance reported on the Year 2 FFR **(A)**
- The sum of all approved carryovers in Year 3 **(B)**
- The amount of Year 3 funds that are expected to remain unobligated at the end of Year 3 **(C)**
- The total amount of Federal funds authorized for Year 3 **(D)**

NCATS University will then enter those four numbers into the following formula to determine the percentage needed to answer the questions in Section G.10:

$$\textit{Total Amount Available for Carryover} = \frac{(A-B)+C}{B+D} \times 100$$

Current Year's Total Approved Budget

Please note that the answer to G.10.c (*If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent.*) is not a prior approval request. Carryover of unobligated balances must be requested in accordance with standard post award prior approval actions (https://ncats.nih.gov/funding/grantee-information/prior-approval#unobligated-funds-carryover).

Section H. Budget

The UL1 Award is a multi-component award. The eRA Commons system will automatically generate an overall budget from the individual components of the UL1 entered into the RPPR. A separate budget for each component of the CTSA UL1 award and a separate budget for each subaward should be reported. The eRA Commons system automatically creates a PDF version of the overall budget. Note that if a subaward budget is completed for any component of the UL1, the system will not calculate these for the overall budget. The total subaward/consortium costs for the overall budget must be computed and entered manually into the appropriate budget line (as indicated in the Supplemental instructions, section 7.6.1).

A detailed budget justification is only required if there is significant change from previously recommended levels (e.g., total re-budgeting greater than 25 percent of the total award amount for this budget period); any change in the approved voluntary committed cost share must be submitted as a prior approval request. If there is no significant change, the recipient may simply state "no significant change" for the relevant direct costs budget categories. Note the RPPR instructions require an itemized breakdown of costs for budget line items over $1,000.

If "To Be Named/Determined" personnel are included in the budget, the recipient must provide a budget justification that includes the anticipated role and responsibility for the individual(s), the level of effort requested, and the estimated time needed to fill this position.

Recipients who have received multi-year Revision/Administrative Supplements must include the subsequent budget request in the **Administrative Core budget**. The budget justification documentation should separate and clearly identify those costs related to the Revision/Administrative Supplement.

Applicants are responsible for checking carefully to ensure that the completed overall budget reflects all the UL1 components and subawards. It should also include all individual cost categories. The overall budget for the UL1 should be consistent with the composite budget spreadsheet containing the UL1, KL2 (and TL1, as applicable) overall budgets that was uploaded into each report.

Section H is not applicable for Final RPPRs.

KL2 AND TL1 AWARDS

RPPR sections for which there are no CTSA Program specific instructions have been intentionally omitted. Use the general instructions (Chapter 6) or the supplemental instructions for KL2 and TL1 Awards (Chapter 7.4 Training RPPRs) of the NIH RPPR instructions for these sections (https://grants.nih.gov/grants/RPPR/rppr_instruction_guide.pdf**).**

REMINDERS:

- Scholar and Trainee appointment, re-appointment, and termination forms must be submitted in xTRAIN in a timely manner. In accordance with NIH Grants Policy, appointment forms *must be submitted before or at the start date of each scholar/trainee's appointment or reappointment.* Failure to submit timely appointment, re-appointment and termination forms is a compliance concern and violation of the terms and conditions of the award. Failure to appoint a scholar/trainee prior to payment may result in a return of funds.
- Recipients *must request the actual tuition and fees in the budget and include a statement confirming that the actual tuition and fees amount is being requested and the NIH reduction has not been applied*. Trainee tuition and fees must be identified as in-state, out-of-state, single degree, dual degree, and specify the tuition and fee rate for pre-doctoral and post-doctoral trainees.
- Review the xTRAIN roster prior to RPPR submission — *Please ensure that you have included a report for each appointed/terminated trainee in the RPPR.*

Section B. Accomplishments

B.2: What was accomplished under these goals?

Use this section to report KL2 and TL1 accomplishments. All information provided must be relevant to KL2 and TL1-funded scholars and/or trainees receiving support directly from the grant. Report any scholars or trainees that have terminated the program early and provide the reason(s) why.

B.4: What opportunities for training and professional development has the project provided?

Use this section to report on KL2- and TL1-funded training and professional development in their respective RPPR. Do *not* address the UL1 career development individuals or individuals sponsored solely by the recipient institution. All information provided must be relevant to KL2- and TL1-funded scholars and/or trainees receiving support directly from the grant.

Activities of scholars that are supported on institutional funds may be reported in the RPPR as part of your institution's career development program environment and accomplishments. If including these scholars in the RPPR, clearly indicate they are institutionally funded and do not include these scholars in the Training Individual Progress Reports or the reports in Table 8C (see https://grants.nih.gov/grants/funding/datatables/Instruc_RPPR_Postdoctoral_Training.pdf). Do not provide the names of these scholars in the RPPR.

Table 8C, Part II allows for reporting of clearly affiliated scholars; these are post-doctorates who have been supported by NIH funds other than this training grant. Provide the information described in Part I, items 1–9, for each. "Clearly associated" post-doctorates are those with a training experience identical to those appointed to this training grant, but who are supported by other forms of NIH or HHS funding (e.g., fellowships or research grants). Note that, for some postdoctoral programs, Part II may not be applicable; this includes those funded by the institution.

Indicate whether the scholar/trainee organization uses Individual Development Plans (IDPs), and if so, describe how they were used in this reporting period to help manage the training and career development of the trainees/scholars (do not include actual IDPs).

This section includes descriptions and formats for the attachments that should be uploaded to address question B.4. Tables, charts, diagrams, and other non-text material may be included in the attachment. Concise, clear, and complete narratives facilitate the review of the application.

Aggregate information on training programs should be provided in the suggested table forms as noted below.

Training Individual Progress Reports (see Appendix 3)

Adhere to the instructions in 7.4 Training RPPRs (B.4) in the NIH RPPR Instructions. This document includes sponsor's (mentor's) progress reports for each appointee listed in the respective KL2 and TL1 Tables provided in B.4. It is expected that each scholar/trainee progress report will be concise and complete and include a paragraph describing activities and progress for each trainee/scholar supported by the award during the reporting period. Include the following information for each trainee/scholar, as applicable:

- Description of the trainee/scholar's research project and progress
- Coursework
- Conference presentations
- A description of the trainee/scholar's role in any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment, analyzed data, drafted paper) Note that full citations of all publications arising from work conducted while the trainee/scholar was supported by the award should not be reported here, as they should be reported in Section C.1.
- Fellowships or other support
- Workshops attended
- Career development activities

Appendix 3 provides a suggested table format for reporting, and should include the following information:

1. **Last Name** — The last name of the trainee
2. **First Name** — The first name of the trainee
3. **Middle Initial** — The middle initial of the trainee
4. **eRA Commons ID** — The eRA Commons username of the trainee
5. **Degree(s) held (acquired to date)** — Degrees that the trainee has already acquired
6. **Degree 1 working toward (degree seeking)** — Note the following Degree(s) that should be reported:

DEGREE 1 SOUGHT	
Abbreviation	**Description**
PhD CTS	PhD in Clinical and Translational Science (or equivalent depending on institution)
MS CTS	MS in Clinical and Translational Science (or equivalent depending on institution)
PhD non-CTS	PhD (in any other field)
Masters non-CTS	Masters (in any other field)

7. **Degree 2 working toward (degree seeking)** — Note the following Degree(s) that should be reported:

DEGREE 2 SOUGHT	
Abbreviation	**Description**
MD	Doctor of Medicine
DDS	Doctor of Dental Surgery
DMD	Doctor of Medical Dentistry
DO	Doctor of Osteopathic Medicine
PHAR	Doctor of Pharmacy
ND	Doctor of Naturopathy
DNP	Doctor of Nursing Practice
DVM	Doctor of Veterinary Medicine
DPT	Doctor of Physical Therapy — ***NCATS Approval required***
DAUD	Doctor of Audiology — ***NCATS approval required***

8. **Mentor(s) and degree(s)**
9. **Project Title**
10. **Does the Project involve Human Subjects (Yes/No)**
11. **Does the Project involve Animals (Yes/No)**
12. **For TL1 Trainees: Provide assurance that the project is covered under the TL1 mentor's project (Yes/No)**

Research Category Terms — Select one or more of the following high-level terms that characterize the trainee's research focus for each Research Category Term:

13. **Research Category Term(s) 1 (**definitions**)**
    a. Pre-Clinical Research
    b. Clinical Research
    c. Clinical Implementation
    d. Public Health
14. **Research Category Term(s) 2 (**select one to three categories**)**:
    a. Method or Process Development — Develops/refines technical methods or procedures
    b. Mechanistic Basic to Clinical — Applies a basic science discovery to clinical research

c. Biomedical Informatics / Health Informatics — Develops and applies computer and information sciences concepts, software, and tools to health-related application domains such as biology, behavioral science, health care, public health, and clinical research
d. Outcomes Research, Health Services Research, and Comparative Effectiveness — Measures or compares healthcare quality and outcomes
e. Clinical Epidemiology — Applies epidemiology or epidemiologic methods in a clinical setting
f. Clinical Trial — Studies one or more human subjects prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes
g. Digital Health & Social Media — Studies using digital health, mobile technologies and/or social media platforms.
h. Pediatric — Studies humans aged 0–21 (including college students) as well as the embryo/fetus or uses animal models to study processes in humans of that age group. All embryo/fetus studies are included except when the focus is on the pregnant mother.
i. Rural Health— Studies health and healthcare of rural populations
j. COVID-19 — Studies the disease COVID-19 and/or its causative agent, SARS-CoV-2
k. Other — If none of the above categories encompass the pilot research, write in a category that defines the general field of study of the pilot research. If this field is used, no other category should be provided in this field.

15. **Training Partnership with other NIH IC?** — If the trainee is supported in partnership with another NIH Institute or Center (IC), please select that IC from the dropdown list. If the trainee is supported in partnership with multiple ICs, please specify them in the text, separated by semicolons. If no training partnership has supported the trainee, please select N/A from the dropdown list.

The free text section (items 16–19) should not exceed two pages in length, total. The information included here should be sufficient to allow evaluation of the appointees' progress towards the goals of the training grant.

16. **Externship Report** — Report on opportunities for scholars and trainees to gain direct experience with key stakeholders of translational science through research externships in industry, regulatory agencies, nonprofit patient-advocacy groups, or other CTSA Program hubs with strengths different from the parent hub. For the externship report section of the Trainee Individual Progress Report, provide a description of the externship, sector that externship took place in (e.g., industry, government, nonprofit, other CTSA Program hub), skillsets to be learned from the externship.
17. **Other Support (applied for and/or received)** — Grants, Fellowships, K-awards, etc. This support can be NIH or non-NIH.
18. **Mentor Report** — This should be a concise statement written by the mentor(s) that describes the individual's progress and performance during the reporting period.
19. **Progress Report** — A description of the research project written by the trainee or scholar and the progress during the reporting period. Please include the following as appropriate:
    - Coursework
    - Conference presentations
    - A description of the trainee/scholar's role in any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment,

analyzed data, drafted paper) Note that full citations of all publications arising from work conducted while the trainee/scholar was supported by the award should not be reported here, as they will be collected in Section C.1.
- Workshops attended
- Career development activities

Training Progress Report Formatting

The Appendix 3 Training Individual Progress Report template format for the RPPR submissions is recommended to help facilitate aggregation of training progress report data from the RPPR by NCATS. This information can be used by NCATS to report on the impact of the CTSA Program. If Appendix 3 cannot be used, please email CTSARPPRQuestions@mail.nih.gov and CC your program officer so NCATS can assist you with finding a suitable alternative for submitting training progress report data. To ensure that the information is efficiently and accurately extracted, Training Individual Progress Reports are requested to adhere to the following guidelines:

- Reports must contain only text. No images, scans, or other graphical objects should be included in a Training Individual Progress Report as these are not recognized and disrupt efficient and effective data collection.
- Each Training Individual Progress Report should start on a new page. No single page should contain information from more than one Training Individual Progress Report.
- The table portion of the Training Individual Progress Report (from Last Name to Training Partnership with other NIH IC?) should not exceed one page in length.
- The free text portion (from Externship Report to Progress Report) should start on a new page (the page immediately following the table portion) and should not exceed two pages in length.

Section C. Products

C.1: Publications

Report publications or manuscripts accepted for publication during the reporting period resulting directly from this award. If there are publications from the UL1, report those publications separately in the corresponding UL1 RPPR.

Section G. Overall Special Reporting Requirements

G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements

External Advisory Committee Report

Some KL2 and TL1 programs conduct External Advisory Committees (EAC) separate and distinct from the UL1 or overall grant EAC. Separate and distinct may be defined as the committee members and the date of the meeting being different from the UL1 or overall EAC. If applicable, provide the complete text of the EAC report(s). In addition, include a roster of all the members of the EAC including their terms of office (if applicable), the date(s) of the EAC meeting(s) during the reporting

period, the names of EAC members who attended the meeting(s), the agenda(s) for the meeting(s), and the names of CTSA Program staff who gave presentations, if applicable. If ad hoc or special EAC reports were issued, include them, as well.

G.10 Estimated Unobligated Balance

Question G.10.a When answering the following: *Is it anticipated that an **estimated unobligated balance (including prior year(s) carryover)** will be greater than 25% of the **current year's total approved budget**? If yes, provide the estimated unobligated balance.*

- The **current year's total approved budget** equals the current year authorization and any carryover approved in the current budget period through a revised notice of award (denominator).
- The **estimated unobligated balance** (cumulative ($) over project period) **equals** (numerator)**:**
  - the **total amount *available* for carryover includes** any estimated unobligated balance from the current year that will not be obligated prior to the end of the current budget period **AND**
  - **any unobligated balance reported on the most recent FFR** that has not been used via an approved carryover in the current budget period.
- **A response that only includes the current budget period authorization and the current budget period estimated unobligated balance is considered an inaccurate calculation and therefore is not an adequate response to this question**.

Using the **total amount available for carryover** as the numerator and the **current year's total approved budget** as the denominator will provide an accurate percentage of the current unobligated balance associated with this award and will allow for proactive planning through the life cycle of the CTSA.

Example: NCATS U is going into grant year 4. To calculate the estimated unobligated balance, NCATS U will gather the following information:

A. Unobligated Balance reported on the most currently accepted FFR (i.e., grant year 2 FFR)
B. The amount of the Year 3 NoA plus any approved carryover in Year 3
C. How much NCATS U will report unobligated on Year 3 FFR (Year 3 total approved budget less Year 3 obligations/expenditures)

- Estimated UOB = (A+C)/B (NCATS U's response to G.10 and associated questions)

Please note that the response given to G.10.c (*If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent*) does not constitute an acceptable prior approval request. Requests for carryover of unobligated balances must be submitted in accordance with standard post award prior approval actions (https://ncats.nih.gov/funding/grantee-information/prior-approval#unobligated-funds-carryover).

KL2 AWARD

The following instructions are for the KL2 award only.

RPPR sections for which there are no CTSA Program specific instructions have been intentionally omitted. Use the general instructions (Chapter 6) or the supplemental instructions for KL2 Awards (Chapter 7.4 Training RPPRs) of the NIH RPPR instructions for these sections (https://grants.nih.gov/grants/RPPR/rppr_instruction_guide.pdf**).**

Section B. Accomplishments

B.3: Competitive Revisions/Administrative Supplements

Refer to the instructions in the RPPR instruction guide (Chapter 7.6.1) for how to report on any Administrative Supplement(s) awarded during the reporting period. Each Administrative Supplement must be reported separately. For each report, include the complete award number including all suffixes (e.g., KL2 TR012345-01S2) in the text box provided.

Each Administrative Supplement Report should include:

- Revision/Supplement Title
- Specific Aims
- Accomplishments
- Challenges
- Status of milestones (if applicable)

If publications resulted from the Administrative Supplement, cite the PMCIDs in the C.1 Publications section of the KL2 report using MyNCBI.

NOTE: Under B.3 the user is provided with 700 characters to describe the specific aims for each Revision/Supplement, and 700 characters to describe the accomplishments for each Revision/Supplement. These descriptions will of necessity be brief, and NIH strongly encourages concise responses. If more extensive reporting is required by the Revision/Supplement award, additional information may be uploaded as an attachment in G.1., Special Notice of Award and Funding Opportunity Announcement Reporting Requirements. If reporting additional information in G.1., there must be a note in B.3. reporting the administrative supplement award number, revision/supplement title and a note to see G.1. for the full progress report.

Supplements that have been awarded to the KL2 to support an individual's training, education and career development

Supplements that have been awarded to the KL2 to support an individual's training, education and career development must provide additional information and be uploaded as an attachment in G.1., Special Notice of Award and Funding Opportunity Reporting Requirements. Please refer to instructions in G.1.Special Notice of Award and Funding Opportunity Announcement Reporting Requirements for specific instructions (below).

B.4: What opportunities for training and professional development has the project provided?

Provide updated information reflecting new appointments and other changes over the reporting period.

This section must include Table 8C from the data tables: Program Outcomes: Postdoctoral in the user guide: https://era.nih.gov/files/xTRACT_userguide.pdf

Hubs that have "clearly associated" scholars, information about these individuals are to be entered in Part II of Table 8C. "Clearly associated" scholars are those with a training experience identical to those appointed to this grant, but who are not supported by the KL2 and are not appointed on xTRACT. The data entry for the "clearly associated" scholars may require a manual entry.

References:

- Required Use of the xTRACT System to Prepare Data Tables for Training Grant Research Performance Progress Reports in FY 2020: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-108.html
- https://grants.nih.gov/grants/forms/data-tables.htm
- https://grants.nih.gov/grants/funding/datatables/Consolidated_Training_Tables.pdf
- Extramural Trainee Reporting and Career Tracking (xTRACT) User Guide: https://era.nih.gov/files/xTRACT_userguide.pdf

As per NIH Grants Policy Statement "individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status." This is a reminder to email your NCATS Grants Management Specialist a notarized statement verifying possession of permanent residency documentation for the trainees and scholars who are not US citizens when the Statement of Appointments (PHS Form 2271) were submitted via xTRAIN.

Section G. Overall Special Reporting Requirements

G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements

Supplements that have been awarded to the KL2 to support an individual's training, education and career development

Supplements that have been awarded to the KL2 to support an individual's training, education and career development must provide additional information and be uploaded as an attachment in G.1., Special Notice of Award and Funding Opportunity Reporting Requirements.

Supplements must use the provided template for the Training Individual Progress Report (Appendix 3) to report progress. The Appendix 3 template is attached, and the instructions are included above on page 24.

G.4. b: Inclusion Enrollment Data

Inclusion Enrollment Reports are not required for KL2 Scholar projects. *For studies that are not covered under the mentor's IRB approval and use KL2 research funds to support the clinical study (including clinical trials),* the Program Officer should be alerted ahead of time and the institution must follow NCATS guidelines for Human Subject Research prior approvals. Inclusion Enrollment Reports must be updated at the time of the RPPR.

For questions regarding Inclusion Enrollment Reports email: inclusion@od.nih.gov

Section H. Budget

For the KL2 budget, be sure to select the SF424 R&R Budget forms from the drop-down menu in this section.

Please review a PDF copy of the application and ensure the budget figures are consistent with the composite budget spreadsheet uploaded in the UL1 component. Once you are satisfied with the PDF application version, please save and submit the application.

The recipient should ***NOT*** re-budget committed funds from the UL1 or KL2 to the TL1. **Any changes between the UL1 and KL2 must be clearly identified and justified in the budget justifications of both the UL1 and KL2.**

Recipients who have received multi-year Revision/Administrative Supplements must include the subsequent budget request in the budget form. The budget justification documentation should separate and clearly identify those costs related to each Revision/Administrative Supplement. Use the Budget Justification section to provide justification for those line items and amounts that represent a significant change from previously approved levels. Information for personnel should include the name, role, associated level of effort, salary, fringe benefits, and total for each individual.

The budget justification should identify scholar slots as new appointments or re-appointments. The KL2 program requires a minimum of two years of support; include duration of recipient K scholar program. **The recipient must clearly specify in the budget justification how any new appointments in the last year of a project period will be supported in the future.**

Include a justification for any significant increases or decreases from the initial or prior budget years. Only one file may be attached.

TL1 AWARD

The following instructions are for the TL1 award only.

RPPR sections for which there are no CTSA Program specific instructions have been intentionally omitted. Use the general instructions (Chapter 6) or the supplemental instructions for KL2 Awards (Chapter 7.4 Training RPPRs) of the NIH RPPR instructions for these sections (https://grants.nih.gov/grants/RPPR/rppr_instruction_guide.pdf**).**

Section B. Accomplishments

B.4: What opportunities for training and professional development has the project provided?

Provide updated information reflecting new appointments and other changes over the reporting period:

For TL1s, depending on the program, include one or more of the following:

- **Table 8A: Program Outcomes: Predoctoral**
- **Table 8B: Program Outcomes: Short-Term**
- **Table 8C: Program Outcomes: Postdoctoral**

References:

- Required Use of the xTRACT System to Prepare Data Tables for Training Grant Research Performance Progress Reports in FY 2020: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-108.html
- https://grants.nih.gov/grants/forms/data-tables.htm
- https://grants.nih.gov/grants/funding/datatables/Consolidated_Training_Tables.pdf
- Extramural Trainee Reporting and Career Tracking (xTRACT) User Guide: https://era.nih.gov/files/xTRACT_userguide.pdf

The use of the Extramural Trainee Reporting and Career Tracking (xTRACT) system is required to generate training tables for the TL1.

As per NIHGPS "Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status." This is a reminder to email your NCATS Grants Management Specialist a notarized statement verifying possession of permanent residency documentation for the trainees and scholars who are not US citizens when the Statement of Appointments (PHS Form 2271) were submitted via xTRAIN.

Section H. Budget

For the TL1 budget, be sure to select the PHS 398 Training Budget forms from the drop-down menu in this section.

Recipients ***must*** reflect the actual tuition and fees for all trainees. **Do not apply the NIH reduction on the training budget form**. The reduction will be applied by NIH in accordance with the applicable NRSA Levels. Recipients should include a statement in the budget justification confirming that their budget reflects the actual tuition and fees for all trainees.

Recipients who have received multi-year Revision/Administrative Supplements must include the subsequent budget request in the budget form. The budget justification documentation should separate and clearly identify those costs related to each Revision/Administrative Supplement.

The budget justification **must identify trainee slots as new appointments or re-appointments. Trainee names must be included in budget justification for reappointments.** For multi-year training programs, the recipient must clearly specify in the budget justification how any new appointments in the last year of a project period will be supported in the future without expectation of a carryover, supplemental funds or a type 2 competing renewal.

The recipient should submit the training budget form request with the current NRSA Stipend Levels in effect at the time of the RPPR submission. In the event any changes are applicable, NCATS staff will make the necessary adjustments at the time of award. The recipient should NOT re-budget funds from the UL1 or KL2 to cover any changes to the TL1 budget.

In Section G.1 of the RPPR, recipients must upload a PDF named "Childcare_Costs.pdf" (without quotation marks). The attachment must specify the number of trainees who used childcare costs in the reporting period. Refer to NOT-OD-24-116 for more information on how to report childcare costs (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-116.html)

Please review a PDF copy of the application and ensure the budget figures are consistent with the composite budget spreadsheet uploaded in the UL1 component. Once you are satisfied with the PDF version, please save and submit the RPPR.