



National Center
for Advancing
Translational Sciences

CTSA Clinical & Translational Science Awards Program

**2026 Supporting Instructions for Research Performance Progress
Reports (RPPRs) for the Clinical and Translational Science Awards
(CTSA) Program**

UL1, KL2 and TL1 Awards

Released: January 2026

Table of Contents

SUMMARY OF CHANGES	3
INTRODUCTION.....	4
General Instructions — Annual RPPR	5
Forms and Uploads.....	5
TABLE 1: LIST OF APPENDICES.....	5
Final RPPR Instructions.....	6
UL1 AWARD	7
Section B. Accomplishments	7
B.2: What was accomplished under these goals?.....	7
B.4: What opportunities for training and professional development has the project provided?	8
Section C. Products.....	8
C.1: Publications.....	8
Section G. Overall Special Reporting Requirements	9
G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements	9
G.4.b: Inclusion Enrollment Data	14
G.10 Estimated Unobligated Balance	14
KL2 AND TL1 AWARDS	16
Section B. Accomplishments	16
B.2: What was accomplished under these goals?.....	16
B.4: What opportunities for training and professional development has the project provided?.....	16
Section C. Products.....	19
C.1: Publications.....	19
Section G. Overall Special Reporting Requirements	20
G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements....	20
G.4.b: Inclusion Enrollment Data	20
G.10 Estimated Unobligated Balance	20
Section H. Budget.....	21
KL2:.....	21
TL1:.....	21

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](#) and [website](#) 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 current NOFOs (UM1, K12, T32) are considered NEW applications and *not* renewals.

SUMMARY OF CHANGES

This document has been shortened through the removal of information that was duplicative of the NIH RPPR Instructions, but there have not been any changes to the instructions that are specific to the CTSA UL1, KL2, and TL1 awards.

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.

Where the requested information does not pertain to the CTSA Program, you can indicate “Nothing to Report.” **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. ***The appendices 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:

- Publications reported **must** comply with the NIH Public Access Policy (<https://grants.nih.gov/policy-and-compliance/policy-topics/public-access>). 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.
- 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 project reports follow the pilot project report 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>

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

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 the list of appendices; Appendices 1 and 2 are no longer needed:

TABLE 1: LIST OF APPENDICES

Appendix	Title
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 Final RPPRs, *B.2: What was accomplished under these goals? 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. It is also important to discuss the primary outcomes from the grant. Suggested page limits in B.2 for the overall and for each component are the same as the page limits suggested in the Annual RPPR. The Final RPPR should also include sections C, D, E and G, including additional information under Section G.1 and corresponding Appendices/Tables.

For the 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).

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](#).

For more information about how to submit your Final RPPR please see:

<https://www.era.nih.gov/recipients/submit-final-rppr.htm>

UL1 AWARD

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.

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 each)

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; accomplishments during the grant year; 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 the 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.

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 are not required to be tracked and monitored for the purposes of public access compliance. There is no page limit. 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.

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

Use this section to report on 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.**

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.

Section G. Overall Special Reporting Requirements

The following special reporting requirements should be included 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 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 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 is more than one PI. 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 reported information in HSS is appropriate, on target, and up-to-date (yes or no). 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** — Indicate whether the pilot involves an [IND](#) or [IDE](#) (IND, IDE, both, neither)
- **Vertebrate Animal Subjects** — Whether the pilot project involves vertebrate animal subjects
- **Research Category Terms** — Select one or more of the following high-level terms that characterize the 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 describe 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 institution to the PIs 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 project has been given approval by NCATS for human or vertebrate animal subject research (yes or no).
- **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 that do not have a PMID, please include an abbreviated citation.
- **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.

G.4.b: Inclusion Enrollment Data

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 and TL1 RPPR section below.** For questions regarding Inclusion Enrollment Reports, email: inclusion@od.nih.gov. To ensure compliance with reporting requirements, refer to the [Steps to Compliance for NIH Awardees](#).

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

G.10.a 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 NIH-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:

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

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>).

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).

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.

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 respective grants.

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/databables/Instruc_RPPR_Postdoctoral_Training.pdf). Do not provide the names of these scholars in the RPPR.

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>
- 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.

Training Individual Progress Reports (see Appendix 3)

Appendix 3 provides a suggested table format for reporting trainee and scholar progress, 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
DAUD	Doctor of Audiology

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.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

G.10 Estimated Unobligated Balance

G.10.a 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>).

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. For the TL1 budget, be sure to select the PHS 398 Training Budget forms.

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.**

KL2:

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 the 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.**

TL1:

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.

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 or supplemental funds.

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.