National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

2021 Supporting Instructions for Research Performance Progress Reports (RPPRs) for the Clinical and Translational Science Awards (CTSA) Program

UL1, KL2 and TL1 Awards

Released: September 2020

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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 awardees in the submission of CTSA specific information in their annual RPPR.

SUMMARY OF CHANGES 2020 TO 2021

The 2021 Supporting Instructions are being released earlier this year (September 2021). The earlier release should allow hubs with RPPR due dates at the end of the year to have time to review the guidelines before the submission of their RPPRs.

Below is the list of the main changes from 2020 to 2021 by section:

Introduction:
- Included NIH eRA technical assistance information

General Instructions:
- Removed Interim/Final RPPR instructions to avoid confusion. For more information refer to: https://era.nih.gov/erahelp/commons/Commons/status/closeout/Final_RPPR.htm.

List of Appendices:
- Removed Appendix 3 (Technology Transfer table)
- Training Individual Progress Report: Now Appendix 3
- Table of Institutional Collaborations: Now Appendix 4
- Pilot Project Report: Now Appendix 5

Section B. Accomplishments:
- Included Page limits on Section B2.
- Added COVID-19 to the Areas of Strong Public Health Interest
- Included specific examples of areas of strong public interest narratives as a guide for hubs on what to include in this section
- Clarified Evaluation section and its page limit

Section C. Products:
- Added information on C1. Publications
- IND/IDE information now on Pilot Project Table (Appendix 5)
- Removed the invention disclosure section.

Additional Updates to the Instructions:
- Added "COVID-19" as a reporting Catergory Term (2) to Pilot Projects (Page 17) and KL2 (Page 24)
- **G.4. Inclusion Enrollment Reports:** Added information about submitting Inclusion Enrollment Reports and helpdesk information for troubleshooting issues.

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/.

Since this may be the first time the RPPR is submitted for some new CTSA Program awards, the initial data to set up the current and subsequent submissions will have to be entered. For those who have previously submitted a RPPR, the RPPR will be pre-populated with the data from the first submission. It is recommended to start the process early and start by reviewing the general NIH instructions, http://grants.nih. gov/grants/rppr/rppr _instruction _guide.pdf.

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. You should also consult with your institution's Office of Sponsored Programs as needed.

IMPORTANT REMINDERS:

- NCATS will not be able to process a non-competing continuation application until all outstanding Federal Financial Reports (SF 425) have been submitted to, and accepted by, the NIH Office of Financial Management.
- Publications reported **must** comply with the NIH Public Access Policy (http://publicaccess.nih. gov/). The publications reported should be as a **direct result** of support from the CTSA 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**.
- Per NIH Grants Policy, prior approval requests must be submitted no later than 30 days before the proposed activity 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.
- Grantee institutions are required to include information on NCATS CTSA Program–funded pilot

studies in the annual Research Performance Project Report (RPPR) submission. See Prior Approval requirements for Pilot Projects involving Human Subjects and/or Animal Studies here: https://ncats.nih.gov/ctsa/funding/prior-approval-paga.

- Human Subjects pilot projects must adhere to the CTSA Program Prior Approval Guidelines: https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/new-projects-with-human-subjects-research/.

WHERE TO GO FOR ADDITIONAL HELP:
- General NIH RPPR Instructions: http://grants.nih. gov/grants/rppr/rppr_ instruction_ guide.pdf
- NCATS CTSA Program: Post-Award Grant Actions: Prior Approval and Reporting of Research with Human Subjects and/or Vertebrate Animals: https://ncats.nih.gov/ctsa/funding/prior-approval-paga
- NIH RPPR website: https://grants.nih.gov/grants/rppr/index.htm
- For technical assistance with your RPPR contact: https://grants.nih.gov/support/index.html
- CTSA Program RPPR FAQs: https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/rppr-faqs/
- For questions regarding the CTSA guidelines email: CTSARPPRQuestions@mail.nih.gov
- Contact your Office of Sponsored Programs for questions related to RPPR reporting and submission.
- Contact your NCATS Program Officer for grant-specific scientific or technical questions.
- Contact your 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 for 2021 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 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 RPPR applications 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 of required information. Please refer to Appendices 1 through 5:

TABLE 1: LIST OF APPENDICES

Appendix	Title
1	Training Roster
2	Training Diversity Report
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 (attachments) may not be more than 6 megabytes – 6MB.

Navigation

The online RPPR in eRA Commons consists of separate screens for each of the sections listed below:

A. Cover Page
B. Accomplishments
C. Products
D. Participants
E. Impact
F. Changes
G. Special Reporting Requirements
H. Budget
I. Outcomes (required for Interim/Final RPPRs)

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 Interim/Final RPPRs:

- Interim/Final-RPPR is due no later than **120 calendar days** from the project period end date. (See information about [Interim/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 RFA-14-009 should include pilot projects in the Research Implementation Plan (RIP) component. 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 (http://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 at the individual component level.

When the report is complete, applicants 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 UL1 component. When applicants are satisfied with the PDF version of their applications, they should save copies of them. 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 into the Commons.

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.** The following sections must be included:

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

The up to **5-page document** should address the progress of the overall program. 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 coming year. Include changes made to provide support for improve 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 Resources and Optional Modules" component for applications submitted in response to RFA-TR-14-009 or 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 in Section G. Special Reporting Requirements, G.1 Special Notice of Award and Funding Opportunity Announcement Reporting Requirements (Appendix 4. Table of Institutional Collaborators).
- 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 rationale for the proposed changes, including impact on programs. Shifts in funding between mechanisms should be well justified in the budget justification section of the relevant component and/or mechanism.
- For UL1 Interim/Final RPPRs 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. A progress report on implementation of the Common Metrics may be included in the relevant UL1 component, if appropriate.

Note: The External Advisory Committee report is submitted in section G.1.

Management of Participant and Clinical Interactions (PCI) Component (Limit: 1 Page)

The Participant and Clinical Interactions Management program replaces the previous voucher program as defined in RFA-TR-14-009 and PAR-15-304 or PAR-18-464 (see the following notice: https://grants.nih.gov/grants/guide/notice-files/NOT-TR-17-012.html).   If the hub has a PCI

Management program provide a description of the activities that are supported and the progress of these activities. Studies that are supported should not be listed or described. **Note: CTSA Program hubs that lack a PCI Management program and wish to implement one are required to submit a separate prior approval request.**

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

Include the title and a brief description about accomplishments in any of the current areas of strong public interest (e.g. health disparities, minority health, rural health outcomes, opioids, pain, American Indian/Alaskan Natives, COVID-19, etc.). Web links to the specific accomplishment can also be included. NCATS may use these accomplishments to describe how the program is addressing areas of urgent need. Examples of accomplishments can include (but are not limited) to: training and education such as conferences, meetings, working groups organized by the hub in areas of public health interest; clinical and translational projects (including clinical trials, observational cohort studies, biobank projects, registries, implementation science studies, etc.); community engagement research; accomplishments that helped streamline the translational science process at the hub in areas of public health interest. See the example of highlighted projects from CTSAs about rural health here: https://ncats.nih.gov/ctsa/projects/RuralHealth#people

Publications Resulting from Pilot Projects Funded via Voluntary Uncommitted Cost Share

For publications resulting from pilot projects funded via voluntary uncommitted cost share, grantee institutions may choose to follow the NIH guidance provided in NOT-OD-16-079—Reporting Instructions for Publications Supported by Shared Resources in Research Performance Progress Reports (RPPR) and Renewal Applications. **Per this Guide Notice, if an NIH award's only contribution to a publication is a shared resource, awardees 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 their shared resources developed through the CTSA Program hub award. Note: Grantee institutions are responsible for public access compliance of all publications listed in Section C.1 of an RPPR. More information: Post-Award Grant Actions: Prior Approval and Reporting of Research with Human Subjects and/or Vertebrate Animals

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 with the following exceptions:

The progress of competitive revisions/administrative supplements awarded to the UL1 with a total approved budget of **over $50,000 must be reported in Section G.1**. For those supplements 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. Please refer to instructions in G.1.

The progress of competitive revisions/administrative supplements awarded to the UL1 with a total

approved budget of **under $49,999 must be reported in Section B.3.** Each Administrative Supplement must be reported separately. For each report, include the complete award number including all suffixes (e.g., UL1 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 UL1 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.

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.

Training Roster (Appendix 1)

Include a training roster only for individuals funded who are supported by the UL1 grant for educational activities. Provide the full name and eRA Commons ID. (See Appendix 1 for a suggested format for reporting this information under the UL1).

Trainee Diversity Report (Appendix 2)

Provide aggregate information on sex/gender, ethnicity, and race as noted on form. Only include individuals who are supported by the UL1 grant for educational activities. The link to this table is here: https://grants.nih.gov/grants/funding/2590/2590.htm and a copy is in Appendix 2.

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

Grantees 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.

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.

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 (https://grants.nih.gov/sites/default/files/rppr_instruction_guide.pdf) Per NIH policy, NCATS cannot release the relevant Notice of Award until all publications are compliant with the Public Access Policy.

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 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. Pilot Project Table (Appendix 5) now 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

Please ensure the calendar months are included for all personnel devoting effort to the project. Additionally, please double check the Other Support documentation submitted. Effort listed in the other support documentation cannot exceed 12 calendar months.

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.

All Senior/Key personnel should be designated under S/K column and be according to the most current Notice of Award. 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 E. Impact

E.2: What is the impact on physical, institutional, or information resources?

Report the projected CTSA Program resource usage for the upcoming year in three categories: clinical trials, pediatric research, and AIDS research. For each of these areas, report the projections as a percentage of the entire CTSA Program activities. Each projection is separate and not mutually exclusive.

- Percentage projected to be directed to AIDS research – although the CTSA Program is not focused on any specific disease, percentage should reflect the projected CTSA Program-supported AIDS research
- Percentage projected to be directed to PEDIATRIC research – defined as involving research subjects under 18 years old
- Percentage projected to be directed to CLINICAL TRIALS – using the NIH definition of Clinical Trials which can be found at http://grants.nih.gov/grants/policy/hs/glossary.htm

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), and the names of CTSA Program staff who gave presentations. If ad hoc or special EAC reports were issued, include them, as well.

2) Pilot Projects (see Appendix 5)

Report **only** pilot projects supported with funds (direct funding and voluntary committed cost share) from the UL1 award during the reporting period. The pilot project activity may cross over budget periods. However, 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 follow: Post-Award Grant Actions: Prior Approval and Reporting of Research with Human Subjects and/or Vertebrate Animals

Include a separate, Pilot Project Report for each project. Suggested naming convention of each pilot: Pilot_Last Name of Pilot Project Investigator

Appendix 5 provides a suggested table format for reporting, including using a colon delimiter in the table, and should include the required following information:

- Project title
- Project Dates (Start and End Dates)
- Project Status (Yet to start, in progress, completed)
- Pilot project investigator(s) name(s)
- NIH Commons Username
- Current KL2 Scholar (Yes/No)
- Collaborating Institution (if applicable)
- Note whether human subjects are involved in the pilot project
- Indication of whether human subjects research is exempt
- Inclusion Enrollment Report (IER)
- Note whether animal subjects are involved in the pilot project
- 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: (For definitions please see the reference: https://ncats.nih.gov/translation/spectrum)
    - Pre-Clinical Research
    - Clinical Research
    - Clinical Implementation
    - Public Health
  - Research Category Term(s) 2:
    - Method or Process Development
    - Mechanistic Basic to Clinical

- • Biomedical Informatics / Health Informatics
- • Outcomes Research, Health Services Research, and Comparative Effectiveness
- • Clinical Epidemiology
- • Clinical Trial
- • Digital Health & Social Media
- • Pediatric
- • Rural Health Outcomes
- • Health Disparities
- • Covid-19
- • Source of funds (direct / voluntary committed cost share)
- • IND/IDE information (if applicable)
- • Did this pilot project receive NCATS prior approval (for HS or AS studies)? (yes / no)
- • Funds awarded for this pilot project
- • Funds expended for this pilot project
- • Abstract describing the pilot project (**less than 250 words**)
- • Description of progress during the reporting period (**less than 250 words**).
- • Impact Statement (describe the pilot project's impact in **50 words or less**)
- • Publications:
  - • Publications (if any) that resulted from the Pilot Project. Publications must also be reported under C.1 Publications in the RPPR and adhere to NIH Public Access Policy.

3) Table for Institutional Collaborators (see Appendix 4)

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 5: Table of Institutional Collaborators)

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)

cFunding Category (choose one)

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

4) Competitive Revisions/Administrative Supplements

Research Supplements to Promote Diversity and 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 Diversity in Health-Related Research (Admin Supp)
- Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp)

The reports on these supplements must use the provided template for the Training Individual Progress Report (Appendix 3) to report progress. The report should include a paragraph for the supplement awardee describing activities and progress during the reporting period. The following descriptive information will allow evaluation of the awardees' progress towards the goals of the supplement.

- Description of the supplement awardees' research project and progress
- Coursework
- Conference presentations
- A description of the supplement awardees' 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
- Independent funding received or applied for

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.

5) Workforce Development Externships

Report on opportunities for investigators, 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. Provide a description of the externship, number of participants within the requested budget period, sector that externship took place in (e.g. industry, government, nonprofit, other CTSA Program hub), skillsets to be learned from the externship. **Note:** Scholars and trainees supported by the KL2 or TL1 should report workforce development externships under the KL2 or TL1 and use the Trainee Individual Progress Report template (Appendix 4).

6) Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform (SMART IRB)

Under the current CTSA Program FOA, applicant institutions are required to comply with the NIH single IRB policy for multi-site research and to be willing to sign the CTSA Program SMART IRB Reliance Agreement.

Indicate the number of multisite clinical studies or trials initiated during the applicable grant year for which the SMART IRB Reliance Agreement has been used to designate an Institution Review Board covered under your institution's Federalwide Assurance (FWA) as:

- Reviewing _____ (number of studies where your institution's IRB is considered the reviewing IRB)
- Relying_____(number of studies where your institution's IRB is relying on another institution's IRB)

G.4.b: Inclusion Enrollment Data

To report on inclusion enrollment, use the Human Subjects link in eRA Commons that can be accessed via the RPPR tab in Section G.4.b. of the RPPR. Enrollment records must be updated as described: https://era.nih.gov/faqs.htm#XXIII11. For additional information regarding HSS or for assistance visit HSS at: https://era.nih.gov/hss_overview.cfm. Inclusion Enrollment Reports are only required for HS studies (except those under Exemption #4) of the UL1 award. KL2s do not require IER reporting at this point.

G.10 Estimated Unobligated Balance

Question G.10.a When answering the following: *Is it anticipated that an estimated unobligated balance (including prior year 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** is the current year authorization and any carryover approved in the current budget period through a revised notice of award. The **total amount available for carryover** is the total amount *available* for carryover from previous years associated with this grant award, which is any unobligated balance reported on the most recent FFR that has not been used via an approved carryover in the current budget period and any estimated unobligated balance from the current year that will not be obligated prior to the end of the current budget period. It is **NOT** only the current budget period authorization and the current budget period estimated unobligated balance.

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.

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/grantees/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 substantial change from the competing application. If there is no substantial change, the recipient may simply state "no substantial 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 of 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) overall budgets (as applicable) that were uploaded into each report.

Section H. is not applicable for Interim/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).

REMINDER – Scholar and Trainee appointment, re-appointment, and termination forms must be submitted timely. In accordance with NIH Grants Policy, appointment forms must be submitted before or at the start of each 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 award.

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 KL2 and TL1 funded training and professional development in their respective RPPR. Do <u>not</u> 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, Training Diversity Reports, or the reports in Table 8. Do not provide the name of these scholars in the RPPR.

Indicate whether the recipient 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.

TABLE 2: LIST OF TRAINING SPECIFIC APPENDICES

Appendix	Title
2	Training Diversity Report
3	Training Individual Progress Report

Trainee Diversity Report

Provide aggregate information on sex/gender, ethnicity, and race as noted on the form. Only include scholars and trainees, respectively, who are supported with a salary or stipend from the CTSA Program grant.

The Trainee Diversity Report is required and the template is found on the following website: https://grants.nih.gov/grants/funding/2590/2590.htm

Information and definitions of diversity categories used by the NIH is found in the following reference: Notice of NIH's Interest in Diversity: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html

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 for each trainee/scholar supported by the award describing activities and progress during the reporting period. Include the following information for each trainee/scholar, as applicable:

- Degrees working toward or held
- Mentor(s)
- 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 will be collected in Section C.1.
- Fellowships or other support
- Workshops attended
- Career development activities
- 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: (For definitions please see the reference:

https://ncats.nih.gov/translation/spectrum)
- • Pre-Clinical Research
- • Clinical Research
- • Clinical Implementation
- • Public Health
- Research Category Term(s) 2:
  - • Method or Process Development
  - • Mechanistic Basic to Clinical
  - • Biomedical Informatics / Health Informatics
  - • Outcomes Research, Health Services Research, and Comparative Effectiveness
  - • Clinical Epidemiology
  - • Clinical Trial
  - • Digital Health & Social Media
  - • Pediatric
  - • Rural Health Outcomes
  - • Health Disparities
  - • Covid-19

This description should be sufficient to allow evaluation of the appointees' progress towards the goals of the training grant.

Appendix 3 contains a suggested table format, including using a colon delimiter in the table, with the information that is described and requested in the NIH RPPR Instruction Guide that may be incorporated into an attachment for the Training Individual Progress Reports.

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)

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* |

Note the following information:

- 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.
- 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 (**250 word limit**).
- Progress Report: A description of the research project written by the trainee or scholar and the progress during the reporting period (**250 word limit**).
- A colon delimiter

Section C. Products

C.1: Publications

Report publications that resulted from the support of KL2/TL1 activities, respectively. 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 ad hoc or special EAC reports were issued, include them, as well.

G.10 Estimated Unobligated Balance

Question G.10.a is often misunderstood and incorrectly reported. When answering the following: *Is it anticipated that an estimated unobligated balance (including prior year 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** is the current year authorization and any carryover approved in the current budget period through a revised notice of award. The **total amount available for carryover** is the total amount available for carryover from previous years associated with this grant award, which is any unobligated balance reported on the most recent FFR that has not been used via an approved carryover in the current budget period and any estimated unobligated balance from the current year that will not be obligated prior to the end of the current budget period. It is **NOT** only the current budget period authorization and the current budget period estimated unobligated balance.

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.

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/grantees/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 KL2 or TL1 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. Research Supplements to Promote Diversity in Health-Related Research 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:

Use Table 8C from the data-tables: 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
- CTSA Program Administrators Group Meeting August 21, 2019 provides resources about how to use xTRACT (login required to access meeting materials: https://clic-ctsa.org/groups/administrators-group)

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 report should include a paragraph for the supplement awardee describing activities and progress during the reporting period. The following descriptive information will allow evaluation of the awardees' progress towards the goals of the supplement.

- Description of the supplement awardees' research project and progress
- Coursework
- Conference presentations
- A description of the supplement awardees' 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

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.

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. 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.

A separate, similar budget justification should be submitted for each subaward/consortium, if applicable. The budget justification should provide justification for those line items and amounts that represent a significant change from previously approved levels.

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
- CTSA Program Administrators Group Meeting August 21, 2019 provides resources about how to use xTRACT (login required to access meeting materials: https://clic-ctsa.org/groups/administrators-group)

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 should 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 should identify trainee slots as new appointments or re-appointments. 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.

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 rebudget funds from the UL1 or KL2 to cover any changes to the TL1 budget.

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.