National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

2018 Specific Guidelines for Research Performance Progress Reports (RPPRs) for the Clinical and Translational Science Awards (CTSA) Program

UL1, KL2 and TL1 Awards

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Table of Contents

INTRODUCTION 4
General Instructions 5
Forms and Uploads 5
TABLE 1: LIST OF APPENDICES 5
Navigation 6
Due Dates 6
UL1 AWARD 6
Section B. Accomplishments 7
B.2: What was accomplished under these goals? 7
Highlights, Milestones and Challenges Report 7
Evaluation Report 8
Management of Participant and Clinical Interactions (PCI) Component 8
B.3: Competitive Revisions/Administrative Supplements 8
Supplements that support an individual's training, education and career development 9
B.4: What opportunities for training and professional development has the project provided? 9
Training Roster 9
Trainee Diversity Report 9
Section C. Products 9
C.1: Publications 9
C.4: Inventions, patent applications and/or licenses 10
C.5a: Other products and resources sharing 10
Section E. Impact 10
E.2: What is the impact on physical, institutional, or information resources? 10
Section G. Overall Special Reporting Requirements 10
G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements 11
External Advisory Committee Report 11
Pilot Projects (see Appendix 7) 11
IACUC and IRB Approval Table (see Appendix 5) 12
Table for Institutional Collaborators (see Appendix 6) 12

Research Supplements to Promote Diversity and Re-Entry (see Appendix 4) 13
Workforce Development Externships 13
G.4.b: Inclusion Enrollment Data 14
Section H. Budget 14
KL2 AND TL1 AWARDS 14
Section B. Accomplishments 14
B.2: What was accomplished under these goals? 14
B.4: What opportunities for training and professional development has the project provided? 14
TABLE 2: LIST OF TRAINING SPECIFIC APPENDICES 15
Trainee Diversity Report 15
Training Applicant Diversity Report (see Appendix 2) ..... **Error! Bookmark not defined.**
Training Individual Progress Reports (see Appendix 4) 15
IACUC and IRB Approval Table (see Appendix 5) 16
Section C. Products 17
C.1: Publications 17
KL2 AWARD 17
Section B. Accomplishments 17
B.3: Competitive Revisions/Administrative Supplements 17
Supplements that have been awarded to the KL2 to support an individual's training, education and career development 18
B.4: What opportunities for training and professional development has the project provided? 18
Section G. Overall Special Reporting Requirements 18
G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements . 19
Supplements that have been awarded to the KL2 to support an individual's training, education and career development 19
Section H. Budget 19
TL1 AWARD 20
Section B. Accomplishments 20
B.4: What opportunities for training and professional development has the project provided? 20
Section H. Budget 20

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.

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 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

The RPPR, essentially, requires the same information that has been requested in prior progress reports, only in a different format. 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 specific 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/). 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**.

WHERE TO GO FOR ADDITIONAL HELP:

- General NIH RPPR Instructions: http://grants.nih. gov/grants/rppr/rppr_instruction_guide.pdf
- NIH RPPR website: https://grants.nih.gov/grants/rppr/index.htm
- CTSA Program RPPR FAQs: https://ncats.nih.gov/ctsa/funding/rpprfaq
- Email: CTSARPPRQuestions@mail.nih.gov
- Contact your NCATS Program Officer or Grants Specialist listed in your Notice of Grant Award

General Instructions

General RPPR instructions are at http://grants.nih.gov/grants/RPPR/rppr_instruction_guide.pdf. The instructions below for 2018 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. Unlike the PHS 2590 process, 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 7:

TABLE 1: LIST OF APPENDICES

Appendix	Title
1	Training Roster
2	Training Diversity Report
3	Technology Transfer Report
4	Training Individual Progress Report
5	IACUC_IRB Approval Table
6	Table of Institutional Collaborators
7	Pilot Project Report

The entire RPPR package should be assembled according to the general, supplemental and CTSA Program Specific Instructions and submitted electronically via the eRA Commons accounts for the 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

Due Dates

All 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.

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**. Grantees who responded to RFA-14-009 should include pilot projects in the Research Implementation Plan (RIP) component. Grantees who responded to PAR-15-304 should include pilot projects in the Translational Endeavors component. For grantees responding to other RFAs, pilot projects should be included in the Overall UL1 Component (see section G.1 below). 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 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

The 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 and their management
- 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. **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 – shifts in activity may occur but changes and/or expansion in scope 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.

- If requesting to shift funds between the linked awards (UL1, KL2, or TL1), 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. The institution should **NOT** re-budget committed funds from the UL1 or KL2 to cover any applicable changes to the NIH NRSA established levels for FY2018. In the event any changes are applicable, NCATS staff will make the necessary adjustments at the time of award.

Evaluation Report

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. This document is limited to five (5) pages.

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

Management of Participant and Clinical Interactions (PCI) Component

The Participant and Clinical Interactions Management program replaces the previous voucher program as defined in RFA-TR-14-009 and PAR-15-304 (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.**

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., 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. 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 support an individual's training, education and career development

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)

Please refer to instructions in G.1. Research Supplements to Promote Diversity in Health-Related Research for specific instructions.

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

Use this section to report UL1-funded training and professional development. 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

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

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

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.

Publications reported must comply with the NIH Public Access Policy (http://publicaccess.nih. gov/). 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 for those publications; this will result in a delay in review and may delay any Notice of Grant Award. 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.

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 only for Pilot Projects directly supported by the CTSA Program grant. Since there is no ability to upload IND and IDE information in question C.4, please use the suggested table format in Appendix 3.

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 less than 21 years of age
- 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

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.

Pilot Projects (see Appendix 7)

Report **only** pilot projects supported with funds (federal funding and approved cost share) from the UL1 award during the reporting period. Include a separate, Pilot Project Report for each project.

Suggested naming convention of each pilot: Pilot_Last Name of Pilot Project Investigator

Appendix 7 provides a suggested table format for reporting and should include the required following information:

- Project title
- Pilot project investigator(s) name(s)
- NIH Commons Username
- Note whether human 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
- Funds awarded for this pilot project
- Abstract describing the pilot project (**less than 250 words**)
- Description of progress during the reporting period (**less than 250 words**).
- 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.

Appendix 7 provides a suggested table format for reporting and should include the suggested information:

- If applicable: Inclusion data record(s) (IDR) available in the eRA Inclusion Management System (IMS) for the pilot project. (Note: although inclusion enrollment data is required in Section G.4.b of the RPPR, reporting the IDR in this one-page report is suggested as it is necessary to link the IDR to a specific pilot project).

IACUC and IRB Approval Table (see Appendix 5)

Include information in the IACUC or IRB Approval Table for human subjects or live vertebrate animal subjects Pilot Project protocols directly supported by the CTSA Program grant (via federal CTSA Program grant funds or cost-share) during the reporting period. If not previously reported, include the most recent IACUC or IRB approval date or date of approval of continuing review. (See Appendix 6: IACUC_IRB Approval Table for a suggested table format)

Table for Institutional Collaborators (see Appendix 6)

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 6: Table of Institutional Collaborators)

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

[a]Relationship to the Clinical and Translational Science Award (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
- Other (please indicate)

[c]Funding Category (choose one)

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

Research Supplements to Promote Diversity and Re-Entry (see Appendix 4)

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)

These supplements must use the provided template for the Training Individual Progress Report (Appendix 4) 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

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 hubs with strengths different from the parent hub. Provide a description of the externship, number of participants in FY 2017 or applicable year, 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).

G.4.b: Inclusion Enrollment Data

Inclusion enrollment monitoring data is required for pilot projects and should be reported under Section G.4.b within the overall component of the RPRR. For guidance please see the following notice: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-078.html.

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).

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.

The institution should **NOT** re-budget committed funds from the UL1 or KL2 to cover any applicable changes to the NIH NRSA established levels for FY2018. In the event any changes are applicable, NCATS staff will make the necessary adjustments at the time of award.

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 as described in the NIH RPPR instructions. 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 not address the UL1 career development individuals or individuals sponsored

solely by the 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.

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
4	Training Individual Progress Report
5	IACUC_IRB Approval Table

Trainee Diversity Report (see Appendix 2)

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 template for this report is required and is found on the following website: https://grants.nih.gov/grants/funding/2590/2590.htm (See Appendix 2)

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-15-053.html

Training Individual Progress Reports (see Appendix 4)

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.

Appendix 4 contains a suggested table format 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 Trainee Individual Progress Report (see Appendix 5), 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**).

IACUC and IRB Approval Table (see Appendix 5)

Include information in the IACUC or IRB Table for protocols including human subjects or live vertebrate animals directly supported by the CTSA Program grant during the reporting period. If not previously reported, include the most recent IACUC or IRB approval date or date of approval of continuing review. Note: PHS Policy requires that IACUC approval occur within three years to be considered current.

Appendix 5 contains a suggested table format to assist with reporting this information for scholars/trainees.

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.

Publications reported must comply with the NIH Public Access Policy (http://publicaccess.nih.gov/). 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 may delay the receipt of the applicable Notice of Grant Award. 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.

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. These include:

- Limited Competition: NIDCR Supplements to NCATS CTSA Programs for Scholars Pursuing Dental, Oral and Craniofacial Clinical and Translational Research Career Development (Admin Supp) (RFA-DE-17-008)

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: Program Outcomes: Postdoctoral

References:
https://grants.nih.gov/grants/guide/notice-files/NOT-TR-16-009.html
https://grants.nih.gov/grants/forms/data-tables.htm
https://grants.nih.gov/grants/funding/datatables/Consolidated_Training_Tables.pdf

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

References:

- NIH Announces the Transition to New Research Training Tables Formats for 2016 and Upcoming Release of the xTRACT System: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-007.html
- Extramural Trainee Reporting and Career Tracking (xTRACT) User Guide: https://era.nih.gov/files/xTRACT_userguide.pdf

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. These include:

- Limited Competition: NIDCR Supplements to NCATS CTSA Programs for Scholars Pursuing Dental, Oral and Craniofacial Clinical and Translational Research Career Development (Admin Supp) (RFA-DE-17-008)

These supplements must use the provided template for the Training Individual Progress Report (Appendix 4) 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 institution should **NOT** re-budget committed funds from the UL1 or KL2 to cover any applicable changes to the NIH NRSA established levels for FY2018. In the event any changes are applicable, NCATS staff will make the necessary adjustments at the time of award.

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.

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:

https://grants.nih.gov/grants/guide/notice-files/NOT-TR-16-009.html
https://grants.nih.gov/grants/forms/data-tables.htm
https://grants.nih.gov/grants/funding/datatables/Consolidated_Training_Tables.pdf

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

References:

- NIH Announces the Transition to New Research Training Tables Formats for 2016 and Upcoming Release of the xTRACT System: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-007.html
- Extramural Trainee Reporting and Career Tracking (xTRACT) User Guide: https://era.nih.gov/files/xTRACT_userguide.pdf

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.

The institution should NOT re-budget committed funds from the UL1 or KL2 to cover any applicable changes to the NIH NRSA established levels for FY2018. In the event any changes are applicable, NCATS staff will make the necessary adjustments at the time of award.

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.