National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

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

## UM1 Awards

**Released: September 2024**

# TABLE OF CONTENTS


Introduction ..... 3

Important Reminders ..... 3

Where To Go for Additional Help ..... 4

Forms and Uploads ..... 4

Table 1: List of Appendices ..... 4

UM1 Award ..... 5

Section B. Accomplishments ..... 5

B.2: What was accomplished under these goals? ..... 5

B.3: Competitive Revisions/Administrative Supplements ..... 7

B.4: What opportunities for training and professional development has the project provided? ..... 8

Section G. Special Reporting Requirements ..... 8

G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements ..... 8

G.10: Estimated Unobligated Balance ..... 16

# INTRODUCTION

Please visit the NIH RPPR website and review the general NIH instructions (PDF) for an overview and technical assistance for preparing and submitting reports. This document contains instructions regarding reporting specific to the CTSA Program UM1 grant. 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.** Appendices 1, 2, and 3 will assist in the submission of requested information; ***these appendices will be visible in the Supporting Instructions PDF once the instructions have been downloaded and saved to your computer.*** You should also consult the NIH Grants Policy Statement and your institution's Office of Sponsored Programs as needed.

## Important Reminders

- NCATS will not be able to complete the review of a non-competing continuation application until all outstanding Federal Financial Reports (SF 425) have been submitted via the Payment Management System and accepted by the NIH Office of Policy for Extramural Research Administration (OPERA).
- Publications reported **must** comply with the NIH Public Access Policy (https://sharing.nih.gov/public-access-policy). The publications reported should be as a **direct result** of support from the CTSA Hub grant award (UM1). If applicable publications are reported that do not comply with the NIH public access policy, NCATS will not be able to process non-competing applications until evidence of compliance is provided; **this will result in a delay in review and processing of the applicable Notice of Grant Award**. NCATS utilizes the NIH Public Access Support Center to assist with public access compliance issues; please comply with any requests received from the NIH Public Access Support Center. Questions or concerns may be sent to your assigned Program Officer and Grants Management Specialist.
- Per NIH Grants Policy, prior approval requests must be submitted ***no later than 30 days before the proposed activity, change or effective date occurs***. Failure to comply with the NIH terms and conditions of award may cause NIH to take one or more actions, including but not limited to disallowance of all or part of the costs of the activity or action not in compliance.
- Recipient institutions are required to include information on NCATS CTSA Program-funded pilot studies in the annual Research Performance Project Report (RPPR) submission. **It is recommended that pilot projects follow the pilot projects template specifications.** The template and instructions can be found below and attached to this PDF as Appendix 2.
- Human Subjects and Animal Studies pilot projects must adhere to the CTSA Program Prior Approval Guidelines. Prior Approval Requirements for Pilot Projects involving Human Subjects and/or Animal Studies can be found here: Human Subjects: https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/human-subjects-research; Animal Studies: https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/prior-approval
- Ensure you are carefully reviewing the instructions for section D. Participants and submitting only the required documentation. It is essential that other support and biosketch documents are submitted in accordance with NIH policies (https://grants.nih.gov/grants/forms/othersupport.htm). Failure to correctly submit these documents will result in delays. ***NOTE*** *– New Common Forms (biosketch and other support) will be required for RPPR submissions after May 25, 2025.* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html

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

## Where To Go for Additional Help

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

## Forms and Uploads

The following suggested table and report templates are intended to assist in reporting required information in the RPPR. Please refer to Appendices 1, 2, and 3:

### Table 1: List of Appendices

| Appendix | Title |
|---|---|
| 1 | Table of Institutional Collaborators |
| 2 | Pilot Project Report |
| 3 | Training Individual Progress Report |

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

# UM1 AWARD

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

## Section B. Accomplishments

### B.2: What was accomplished under these goals?

The goals in this question refer to the specific aims of the project. **Address this question in an external file and upload it as a PDF.**

In reporting on your accomplishments in this section, report on your progress in terms of impact, innovation, and significance – how did you advance your aims? The following sections must be included:

*Reporting on Element E Research Projects (Minimum: 1 Page per Element E Project)*

This section should have a general description of what the progress of each Element E research project has accomplished.

Reminder: new Element E projects will require prior approval if the project includes research with human subjects, vertebrate animals, and/or foreign components.

*Highlights, Milestones and Challenges Report (Limit: 14 Pages)*

The hub should address the progress of the overall program and each element/module (excluding Element E projects) in **no more than 14 pages.** Tables may be included. Please avoid redundancy between each element/module.

Specific areas to report for all element/modules include:

- Program integration and innovation; its significance/impact; achievement of last year's milestones.
- Detailed information about challenges encountered and plans for resolution.
- Plans for shifts in activities, if any, including a description and rationale for modifications; provide milestones and timelines for the coming year. Include changes made to provide support for improving capacity for new collaborative activities, if appropriate. **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 provided during the reporting period and confirmation of voluntary committed cost share in the upcoming budget period. **Note – reductions or changes in voluntary committed cost share indicated on the Notice of Award require NIH prior approval through a separate prior approval request.**
- Impact of the academic home on collaborator institutions and how the program facilitates multisite research of investigators in the academic home. List each collaborating institution that received support from the CTSA Program award. It is suggested this information be presented using the table provided as Appendix 1 (Table of Institutional Collaborators; see below Section G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements).

*Evaluation Report (Limit: 2 Pages)*

Describe the self-evaluation assessment of your CTSA; 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.

*Key Outcomes or Other Achievements (Limit: 3 Pages)*

Please include the title and a brief description about key outcomes or other achievements related to high-priority areas for the NIH.

Examples of information that has been previously requested from the CTSA Program:

- Addressing **Health Disparities** (description of definitions and parameters on the NIMHD website)
- **Minority Health** (e.g. address the significant disparities and burden of disease disproportionally affecting minority and special populations)
- **Rural Health** (e.g. delivery of innovative care, enhancing care)
- Response to **COVID-19**
- **Training** the next generation of physician-scientists and addressing physician **workforce shortage** issues
- **Community Engagement**

Trans-NIH Projects/Initiatives:

- **Opioid Abuse and Addiction** (see NIH Helping to End Addiction Long-term Initiative)
- **Pain** (see NIH Pain Consortium)
- **Tribal Health Research** (see NIH Tribal Health Research Office)
- **N3C** (see National COVID Cohort Collaborative)
- **Pediatric Health Research** (see NIH Pediatric Research Consortium)
- **Women's Health Research** (2019-2023 Trans-NIH Strategic Plan for Women's Health Research)
- **Behavioral and Social Sciences Research (BSSR)** (description of definition on the NIH Office of BSSR website)
- **Climate Change** and Health (see NIH Climate Change and Health Initiative)
- **Rare Diseases** (NCATS Rare Diseases Research and Resources)
- **Maternal Morbidity / Mortality** (see NIH Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative)
- **Conducting research in primary care settings** (see NIH Communities Advancing Research Equity for Health™ (CARE for Health™))
- **Engaging clinicians in quality improvement activities and building an evidence-based culture in primary care practice** (see Agency for Healthcare Research and Quality (AHRQ) Practice-based Research Networks)

Other:

- **Digital Health / Telehealth**
- **Diversity, Equity, Inclusion, Accessibility** (institutional enhancements in this space; e.g. hiring, promotion, student recruitment)
- **Clinical result** impacting clinical practice

*Publications Resulting from Use of CTSA Hub Resources*

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

### B.3: Competitive Revisions/Administrative Supplements

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

Each Competitive Revision/Administrative Supplement Report should include:

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

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

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

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

Use this section to report UM1-funded training and professional development such as workshops, conferences, and other training activities **directly supported** by the UM1 award.

## Section G. Special Reporting Requirements

Please include the following information in Section G.

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

*Internal Advisory Committee Report*

Report the date(s) that the Internal Advisory Committee (IAC) met during the reporting period, the roster of the committee and the names of the IAC members who attended the meetings(s). A brief summary of the meeting's outcome(s), topic(s), issues addressed and/or other information must be provided.

*Table for Institutional Collaborators (Appendix 1)*

The instructions are below and included in the Appendix 1 attachment.

Include a list and description of institutions functioning as collaborators with the CTSA Program hub. The following suggested table format may be incorporated into an attachment to fulfill this request. (See Appendix 1: Table of Institutional Collaborators). **In this table, do not include "Partners" as these are currently displayed and updated on the NCATS website: https://ncats.nih.gov/research/research-activities/ctsa/applicant-information/CPUBRT**

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

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

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

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

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

**[c]Funding Category (choose one)**

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

*Pilot Projects (Appendix 2)*

Report ***only*** pilot projects supported with direct funds from the UM1 award during the reporting period. The pilot project activity may cross over budget periods but, per NIH Grants Policy and the Notice of Award, the institution CANNOT carry over funds from one budget period to another without NIH prior approval. Repeated prior approval requests to transfer funds from one budget period to another for the same/similar program costs will be denied. Please work with your Office of Sponsored Programs to establish your pilot program in a manner that complies with NIH Grants Policy and avoids setting up a need for continual carryover requests for pilot program funds. For more information see: Prior Approval Requests for Vertebrate Animal Research and Prior Approval Requests for Human Subjects Research.

**NOTE: Once pilots complete their NCATS funded period, no reporting is required in the RPPR or HSS system. Once a K12 scholar terminates their appointment, no further reporting is needed in the RPPR or HSS.**

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

Appendix 2 provides a suggested table format for reporting, and should include the following information:

- **Project Title** – The name of the pilot project that received funding
- **Project Dates** – The first and last dates for which project funds were available in MM/DD/YYYY format
- **Project Status** – Whether the project funds will be available in the future, are currently available, or no longer available/the project has ended
- **Investigator(s)** – The name of every investigator associated with the project. All names should be listed last name followed by first name separated by a comma and using a semicolon to separate different PI names (e.g., Smith, John; Chu, Tim…). For multiple investigators, the order in this field should match the order in the NIH Commons ID(s) field below.
- **NIH Commons ID(s)** – The eRA Commons username for every PI associated with the project separated by commas if there are more than one usernames. For investigators without an NIH Commons ID, write "N/A". The order of the usernames should match the order in the Investigator(s) field above.
- **Current K12 Scholar** – Whether any of the associated PIs are K12 scholars (yes or no)
- **Collaborating Institution(s)** – The names of every institution outside the Recipient institution that is participating in the pilot project or K12 project with a semicolon separating institution names. This includes other CTSA hubs that are collaborating on a pilot or K12 project and collaborating institutions within a CTSA hub.
- **Human Subjects Research Exemption Number** – The NIH exemption number that applies to the study, if any.
- **Human Subjects System (HSS) Study ID Number** – The unique identifier assigned to the study by the eRA Human Subjects System.
- **Inclusion Enrollment Report in HSS/ASSIST** – Whether the pilot project's cumulative (actual) enrollment to date is appropriate, on target, and is up-to-date. In addition, inclusion enrollment records (IERs) and study records for non-exempt human subjects research must be uploaded in the Human Subjects System (HSS) as part of the RPPR submission. Fields that must be up-to-date include:
  - For clinical trials:
    - Enrollment start date
    - Enrollment end date
    - Cumulative enrollment (Actual)
  - Section 1 – Basic Information:
    - Question 1.5 NCT # (for clinical trials)
  - Section 2 – Study Population Characteristics (for clinical trials)
    - Question 2.6 Recruitment Status
  - Section 6 – Clinical Trial Milestone Plan (for clinical trials)
    - Question 6.1 Study Primary Completion Date
    - Question 6.2 Study Final Completion Date
    - Question 6.4 Completion of primary endpoint data analyses
    - Question 6.5 Reporting of results in ClinicalTrials.gov
- **Investigational New Drug/Device Exemption** – Whether the pilot involves an IND or IDE
- **Vertebrate Animal Subjects** – Whether the pilot project involves vertebrate animals
- **Research Category Terms** – Select one or more of the following high-level terms that characterize the pilot project for each Research Category Term:

- **Research Category Term(s) 1** (definitions)
  - Pre-Clinical Research
  - Clinical Research
  - Clinical Implementation
  - Public Health
- **Research Category Term(s) 2** (select one to three categories):
  - Method or Process Development – Develops/refines technical methods or procedures
  - Mechanistic Basic to Clinical – Applies a basic science discovery to clinical research
  - Biomedical Informatics / Health Informatics – Develops and applies computer and information sciences concepts, software, and tools to health-related application domains such as biology, behavioral science, health care, public health, and clinical research
  - Outcomes Research, Health Services Research, and Comparative Effectiveness – Measures or compares healthcare quality and outcomes
  - Clinical Epidemiology – Applies epidemiology or epidemiologic methods in a clinical setting
  - Clinical Trial – Studies one or more human subjects prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes
  - Digital Health & Social Media – Studies using digital health, mobile technologies and/or social media platforms.
  - Pediatric – Studies humans aged 0-21 (including college students) as well as the embryo/fetus or uses animal models to study processes in humans of that age group. All embryo/fetus studies are included except when the focus is on the pregnant mother.
  - Rural Health– Studies health and healthcare of rural populations
  - Health Disparities – Measures differences in access to or availability of medical facilities and services based on race, ethnicity, or other socioeconomic factors
  - COVID-19 – Studies the disease COVID-19 and/or its causative agent, SARS-CoV-2
  - Other – If none of the above categories encompass the pilot research, write in a category that defines the general field of study of the pilot research. If this field is used, no other category should be provided in this field.
- **Funds Awarded** – Funds provided from the CTSA hub for the pilot project
- **Funds Expended** – Expenditures against the funds provided by the CTSA hub for the pilot project (zero if no expenditures have been made)
- **Source of Funds** – The source of the project's funding. Can be direct (funds provided solely from UM1), voluntary committed cost share (if funds provided solely from institution), or both.
- **NCATS Prior Approval for HS or VAS** – Whether the pilot has been given approval by NCATS for human or vertebrate animal subject research.
- **Impact Statement** – A 250-character description of the impact or returns on investment associated with the results of the pilot research. Do not include graphical elements (plots, figures, etc.)
- **Publications** - Publications (if any) that resulted from the Pilot Project, listed as PMIDS with semicolons separating the PMIDs. These must also be reported under C.1 Publications in the RPPR and adhere to NIH Public Access Policy. For publications not indexed by the NLM/Medline system, please include an abbreviated citation in the Progress Report section.
- **Abstract** – The abstract provided in the pilot funding application, or text similar to the abstract required for an NIH grant. Limit text to 1200 characters and do not include graphical elements (plots, figures, etc.)
- **Progress Report** – The specific aims of the project and progress associated with each aim. Limit text to 1200 characters and do not include graphical elements (plots, figures, etc.).

***Pilot Project Report Formatting***

The Pilot Project Report template format for the RPPR submissions is recommended to help facilitate aggregation of pilot data from the RPPR. This information can be used to report on the impact of the CTSA Program. If Appendix 2 cannot be used, please email CTSARPPRQuestions@mail.nih.gov and CC your program officer so NCATS can assist with finding a suitable alternative for submitting pilot project data. To ensure that the information is efficiently and accurately extracted, pilot project reports are requested to adhere to the following guidelines:

- All pilot projects with human subjects should be entered first, followed by all pilot projects with vertebrate animals, and lastly by all projects involving neither human subjects nor vertebrate animals.
- Reports must only contain text. No images, scans, or other graphical objects should be included in a pilot project report as this is not recognized and disrupts efficient and accurate data collection.
- If multiple PIs from the same institution are collaborating on a pilot project, only one pilot project report should be included in that institution's RPPR. If PIs from different institutions are collaborating on a pilot project, each institution should report the pilot project using the exact same Project Title.
- Each pilot project report should start on a new page. No single page should contain information from more than one pilot project report.
- The table portion of a pilot project report (from Project Title to Publications) should not exceed one page in length. The free text portion of the report should start on the next page and also should not exceed one page in length.
- Each pilot project report table should retain the Appendix 2 heading as provided in the template: **Appendix 2: PILOT PROJECT REPORT**.

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

*Research Supplements to Promote Diversity and Re-Entry (Appendix 3)*

As indicated on the supplement Notice of Award, reports on supplements that have been awarded to the UM1 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 - Clinical Trial Not Allowed) (e.g. PA-18-906, PA-20-166, PA-20-222, PA-21-071, PA-23-189 and subsequent NOFOs)
- Research Supplements to Promote Re-Entry/Re-Integration into Biomedical and Behavioral Research Careers (Admin Supp - Clinical Trial Not Allowed) (e.g. NOT-OD-23-170 and subsequent opportunities.

The reports on these supplements may use the attached template for the Training Individual Progress Report (Appendix 3) to report progress. Include the following information for each diversity/re-entry/reintegration supplement recipient, as applicable:

- Description of the recipient's research project and progress
- Coursework

- Conference presentations
- A description of the recipient'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 recipient 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

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

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

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

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

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

8. **Mentor(s) and degree(s)**
9. **Project Title**
10. **Does the Project involve Human Subjects (Yes/No)**
11. **Does the Project involve Animals (Yes/No)**
12. **For TL1/T32 Trainees: Provide assurance that the project is covered under the TL1/T32 mentor's project (Yes/No)**

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

13. **Research Category Term(s) 1 (**definitions**)**
    a. Pre-Clinical Research
    b. Clinical Research
    c. Clinical Implementation
    d. Public Health
14. **Research Category Term(s) 2 (**select one to three categories**)**:
    a. Method or Process Development – Develops/refines technical methods or procedures
    b. Mechanistic Basic to Clinical – Applies a basic science discovery to clinical research
    c. Biomedical Informatics / Health Informatics – Develops and applies computer and information sciences concepts, software, and tools to health-related application domains such as biology, behavioral science, health care, public health, and clinical research
    d. Outcomes Research, Health Services Research, and Comparative Effectiveness – Measures or compares healthcare quality and outcomes
    e. Clinical Epidemiology – Applies epidemiology or epidemiologic methods in a clinical setting
    f. Clinical Trial – Studies one or more human subjects prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes
    g. Digital Health & Social Media – Studies using digital health, mobile technologies and/or social media platforms.
    h. Pediatric – Studies humans aged 0-21 (including college students) as well as the embryo/fetus or uses animal models to study processes in humans of that age group. All embryo/fetus studies are included except when the focus is on the pregnant mother.
    i. Rural Health– Studies health and healthcare of rural populations
    j. Health Disparities – Measures differences in access to or availability of medical facilities and services based on race, ethnicity, or other socioeconomic factors
    k. COVID-19 – Studies the disease COVID-19 and/or its causative agent, SARS-CoV-2
    l. Other – If none of the above categories encompass the pilot research, write in a category that defines the general field of study of the pilot research. If this field is used, no other category should be provided in this field.
15. **Training Partnership with other NIH IC?** – If the trainee is supported in partnership with another NIH Institute or Center (IC), please select that IC from the dropdown list. If the trainee is supported in partnership with multiple ICs, please specify them in the text, separated by semicolons. If no training partnership has supported the trainee, please select N/A from the dropdown list.

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

16. **Externship Report** – Report on opportunities for scholars and trainees to gain direct experience with key stakeholders of translational science through research externships in industry, regulatory agencies, nonprofit patient-advocacy groups, or other CTSA Program hubs with strengths different from the parent hub. For the externship report section of the Trainee Individual Progress Report, provide a description of the externship, sector that externship took place in (e.g., industry, government, nonprofit, other CTSA Program hub), skillsets to be learned from the externship.
17. **Other Support (applied for and/or received)** – Grants, Fellowships, K-awards, etc. This support can be NIH or non-NIH.
18. **Mentor Report** – This should be a concise statement written by the mentor(s) that describes the individual's progress and performance during the reporting period.
19. **Progress Report** – A description of the research project written by the trainee or scholar and the progress during the reporting period. Please include the following as appropriate:
    - Coursework
    - Conference presentations
    - A description of the trainee/scholar's role in any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment, analyzed data, drafted paper) Note that full citations of all publications arising from work conducted while the trainee/scholar was supported by the award should not be reported here, as they will be collected in Section C.1.
    - Workshops attended
    - Career development activities

***Training Progress Report Formatting***

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

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

## G.10: Estimated Unobligated Balance

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

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

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

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

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

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

$$\frac{\text{Total Amount Available for Carryover}}{\text{Current Year's Total Approved Budget}} = \frac{(A-B)+C}{B+D} \times 100$$

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