National Center for Advancing Translational Sciences

CTSA Clinical & Translational Science Awards Program

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

UM1 Awards

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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://grants.nih.gov/policy-and-compliance/policy-topics/public-access). The publications reported should be as a direct result of support from the CTSA hub 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.
- Recipient institutions are required to include information on UM1-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.
- 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
- 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 and 2:

Table 1: List of Appendices

Appendix	Title
1	Table of Institutional Collaborators
2	Pilot Project 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) and 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 the progress of each Element E research project as well as any major accomplishments during the year.

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; accomplishments and/or success stories during the year; achievement of last year's milestones.
- Detailed information about challenges encountered and plans for resolution.
- Plans for shifts in activities, if any, including a description and rationale for modifications; provide milestones and timelines for the coming year. Include changes made to provide support for improving capacity for new collaborative activities, if appropriate. **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.

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.**

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

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 Project Reports (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. All clinical trials must ensure they are compliant with NIH clinical trial reporting requirements regardless of the 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 is more than one PI. For investigators without an NIH Commons ID, write "N/A". The order of the usernames should match the order in the Investigator(s) field above.
- **Current 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** — Indicate whether the pilot involves an IND or IDE (IND, IDE, both, neither)
- **Vertebrate Animal Subjects** — Whether the pilot project involves vertebrate animal subjects
- **Research Category Terms** — Select one or more of the following high-level terms that characterize the pilot project:
    - **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
        - 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.

G.4.b: Inclusion Enrollment Data

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

ASSIST — Inclusion Enrollment Reports —

Guidance: https://www.era.nih.gov//erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/Incl_Enroll_Rprt.htm

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

G.10: Estimated Unobligated Balance

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

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

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

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

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

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

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

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).