

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NIH ADMINISTRATION OF THE
CLINICAL AND TRANSLATIONAL
SCIENCE AWARDS PROGRAM**



Daniel R. Levinson
Inspector General

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OBJECTIVES

1. To determine the extent to which the National Institutes of Health (NIH) administered the Clinical and Translational Science Award (CTSA) program in accordance with Federal regulations and Department of Health and Human Services (HHS) and NIH policies for:
 - monitoring awardee progress in achieving the goals and milestones of the program (awardee progress),
 - ensuring timely submission of reports, and
 - maintaining official files.
2. To determine whether CTSA program staff provided substantial involvement to awardees in accordance with Federal regulations and HHS and NIH policies.

BACKGROUND

In 2006, NIH's National Center for Research Resources (NCRR) established the CTSA program to provide external research awards for expediting scientific research for new medical treatments. As of March 2011, NCRR had awarded CTSA research awards to 55 domestic graduate schools, with planned 5-year funding of more than \$2.2 billion. The role of NIH grants management staff, including CTSA program staff, is to oversee awardees to ensure that they follow all applicable Federal regulations, departmental and agency policies, and terms and conditions of awards. CTSA program staff must ensure that awardees submit annual progress reports and financial status reports and must determine whether awardee progress remains satisfactory before awardees receive continued funding.

NIH uses three funding mechanisms for research awards: grants, cooperative agreements, and contracts. The CTSA program uses cooperative agreements. Under cooperative agreements, NIH staff provide assistance to awardees above and beyond the levels usually required for program stewardship of grants. This level of stewardship is known as substantial involvement. CTSA program staff assign NIH Project Scientists to awardees to provide substantial involvement through technical assistance, advice, and coordination. Names of substantially involved staff and an annual summary of staff involvement should be documented in the official files.

We reviewed files for the 38 CTSA cooperative agreements awarded in fiscal years (FY) 2006 through 2008 to determine whether CTSA program staff administered the program in compliance with Federal requirements and HHS and NIH policies and whether they provided substantial involvement to awardees.

FINDINGS

Despite completing basic checklists, CTSA program staff did not document awardees' progress in compliance with NIH policy. For only 1 of 38 awardees, CTSA program staff documented a comparison of accomplishments to research objectives. Although reviews for six awardees' files mentioned an inability to fulfill goals, only one file included a note from CTSA program staff regarding resolution. Similarly, plans for the upcoming year were noted in only one file.

Awardees were frequently late in submitting required reports; CTSA program staff did not take action to address timeliness. Most progress reports and one-half of financial status reports were late, yet the CTSA files contained no evidence that staff tried to obtain delinquent reports. Also, despite widespread report delinquency, no enforcement actions were documented in official files.

Official CTSA files were not maintained in accordance with HHS policy. Official CTSA files were incomplete, were not current, were often not separated by budget period, and did not enable third-party review.

No files contained evidence that CTSA program staff provided substantial involvement to awardees in accordance with Federal regulations and NIH policy. The CTSA files contained no evidence of expected substantial involvement by Project Scientists. Additionally, the files contained no other evidence of substantial involvement by any CTSA program staff beyond usual program stewardship activities.

RECOMMENDATIONS

For better oversight of the CTSA program, we recommend that NIH ensure that CTSA program staff:

Document their monitoring of awardee progress. NIH must ensure that staff document awardee accomplishments toward meeting project goals; reasons for not meeting project goals, if applicable; and plans for activities during the coming year.

E X E C U T I V E S U M M A R Y

Ensure timely submission of required reports. NIH should ensure that staff document correspondence with awardees as they act to obtain delinquent progress reports and financial status reports.

Maintain official files in accordance with HHS policy. NIH must establish a single comprehensive filing system in which files are complete, current, easy to identify, easy to access, and separated by budget period. This would promote a coordinated approach to oversight for NIH staff and third-party reviewers.

Provide substantial involvement to CTSA awardees. At a minimum, staff must clearly list the Project Scientists involved and include the annual summary of involvement within the award files.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH concurred with our recommendations. NIH stated that it (1) will issue specific guidance on documentation requirements for monitoring awardee progress and obtaining delinquent reports, (2) has already implemented the recommendation to maintain official files in accordance with HHS policy, and (3) will work with NCRR to revise its cooperative agreement terms of award.

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OBJECTIVES

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 - monitoring awardee progress in achieving the goals and milestones of the program (awardee progress),
 - ensuring timely submission of reports, and
 - maintaining official files.
2. To determine whether CTSA program staff provided substantial involvement to awardees in accordance with Federal regulations and HHS and NIH policies.

BACKGROUND

The National Center for Research Resources (NCRR) is one of the funding institutes or centers within NIH.¹ NCRR established the CTSA program to provide external research awards for scientists to transform basic research and patient observations into clinical practice and new treatments.² As of March 2011, NCRR had awarded CTSA research awards to 55 domestic graduate schools, with planned 5-year funding of more than \$2.2 billion.³

Previous Office of Inspector General (OIG) reviews of award programs administered by NIH and other agencies highlighted opportunities for improvements in the oversight of grantee funds and compliance.⁴

¹ NIH, *Institutes, Centers, and Offices*. Accessed at <http://www.nih.gov> on April 25, 2011. See also NIH, *Scientific Management Review Board Report on Translational Medicine and Therapeutics*. Accessed at <http://smrb.od.nih.gov> on April 12, 2011.

² NCRR, *Clinical and Translational Science Awards Fact Sheet*. Accessed at <http://www.ncrr.nih.gov> on August 26, 2010. NIH, "Request for Applications RM-06-002: Institutional Clinical and Translational Science Award."

³ NCRR, *Clinical and Translational Science Awards and Five-Year Funding Amounts by Institution*. Accessed at <http://www.ncrr.nih.gov> on March 30, 2011.

⁴ OIG, *National Cancer Institute's Monitoring of Research Project Grants* (OEI-07-07-00120) and *Agency for Healthcare Research and Quality: Monitoring Patient Safety Grants* (OEI-07-04-00460).

Award oversight is a top management challenge for the Department of Health and Human Services (HHS), as award programs are at risk of fraud, waste, abuse, and ineffectiveness without proper controls to ensure the appropriate use of Federal funds.⁵ Moreover, expansion in the number and size of awards, such as that occurring in the CTSA program, will magnify oversight vulnerabilities.⁶

Federal Requirements and Departmental Guidance for Award Administration

Federal regulations establish uniform administrative requirements governing HHS awards to institutions of higher education, hospitals, and other nonprofit organizations.⁷ Guidance in implementing these regulatory requirements is contained in the HHS *Grants Policy Directives (GPD)*, which apply to all organizational levels within HHS; the NIH *Policy Manual*, which applies to internal operations of NIH; and the CTSA Consortium *Governance Manual*, which is specific to the CTSA program.

The role of NIH grants management staff, including CTSA program staff,⁸ is to oversee awards to ensure that awardees use funding properly and prudently and follow all applicable laws, regulations, and policies.⁹ Grants management staff are responsible for usual program stewardship, including the business administration of award programs and resolving questions regarding the applicability of departmental and agency policies.¹⁰

If awardees materially fail to comply with the terms and conditions of an award, the Grants Management Officer may take one or more of the following enforcement actions:

- temporarily withhold payments pending the correction of deficiencies,
- disallow funds on the cost of the activity not in compliance,

⁵ OIG, *FY 2010 Top Management and Performance Challenges Identified by the Office of the Inspector General*. Accessed at <http://oig.hhs.gov> on March 30, 2011.

⁶ Ibid.

⁷ 45 CFR pt. 74.

⁸ For the purposes of this report, CTSA program staff are the staff responsible for both the business and programmatic aspects of the CTSA awards, including Grants Management Officers, Grants Management Specialists, Program Officials, and Project Scientists.

⁹ See Appendix A for a listing of specific responsibilities of grants management staff, including Grants Management Officer business responsibilities and Program Official programmatic responsibilities.

¹⁰ HHS, GPD, pt. 1.02; NIH, *Policy Manual*, ch. 54444.

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- suspend or terminate the current award, and/or
- withhold further awards.¹¹

Ensuring Submission of Required Reports

All NIH awardees¹² must submit annual performance reports and financial status reports (FSR).¹³ The Grants Management Officer should not release continued funding until required reports are submitted.¹⁴

For many NIH research awards, including CTSA awards, annual progress reports are due 2 months before the beginning of the next budget period.¹⁵ Awardees must provide a comparison of the accomplishments during the progress period to the goals and milestones and, if applicable, reasons that the goals and milestones were not met. If an awardee is delinquent in submitting a progress report, the Grants Management Officer must:

- send an initial request letter to the awardee 30 days beyond the due date,
- send a second request letter to an official at the awardee institution 60 days beyond the due date,
- send a third request letter to the head of the awardee institution 90 days beyond the due date, and
- refer the matter to the designated NIH official if there is not an acceptable response 120 days beyond the due date.¹⁶

All NIH awardees, including CTSA awardees, must submit an FSR no later than 90 days after the close of the budget period.¹⁷ The FSR shows the status of awarded funds for that budget period. When FSRs are 4 months overdue (i.e., when 7 months have elapsed since the end of the budget period), the Grants Management Officer must:

¹¹ 45 CFR § 74.62.

¹² For the purposes of this report, the term “all awardees” refers to those subject to the Streamlined Noncompeting Award Process, including CTSA awardees.

¹³ 45 CFR §§ 74.51 and 74.52. NIH refers to the annual performance reports as “progress reports.” NIH, *Grants Policy Statement*, pt. 1.

¹⁴ NIH, *Policy Manual*, ch. 55806. CTSA awards may include continued funding for 4 years after the initial award year, for a total of 5 years. NIH, “Request for Applications RM-06-002: Institutional Clinical and Translational Science Award.”

¹⁵ Office of Management and Budget, *U.S. Department of Health and Human Services Public Health Service Non-Competing Grant Progress Report (PHS [Public Health Service] 2590)*. Accessed at <http://grants.nih.gov> on December 6, 2010.

¹⁶ NIH, *Policy Manual*, ch. 55806.

¹⁷ 45 CFR § 74.52; *NIHGPS*, pt. 2, pt. II-87.

- send a request letter to the awardee requesting submission of the report within 30 days,
- send a letter to the head of the awardee institution if there is no reply to the initial request within 30 days (i.e., 5 months beyond the due date),
- not make continuation awards until required reports have been received, and
- refer the matter to the designated NIH official if an awardee institution is consistently delinquent in submitting FSRs.¹⁸

Monitoring Awardee Progress

Grants management staff must identify programmatic and financial deficiencies, if any, throughout the award period.¹⁹ This includes reviewing the annual progress reports to ensure that awardees achieve the goals and milestones of the program. Staff must also review FSRs to monitor awardees’ expenditures and compliance with financial reporting requirements. When reviewing awardee progress, grants management staff must include, at a minimum, the following:

- evidence of accomplishments toward meeting project goals,
- reasons for not meeting project goals (if applicable), and
- plans for activities during the next year.²⁰

Grants management staff use award checklists to document their review of annual progress as reflected in the Award Worksheet Reports.²¹

Official File Maintenance

As part of a coordinated approach to postaward administration, awarding offices, such as NCRP, must create and maintain files that enable a third party (e.g., auditor or other reviewer) to follow the life of the award, from initiation through closeout.²² A third-party reviewer should be able to view information regarding decisions made and actions taken throughout the entire award. An individual official file

¹⁸ NIH, *Policy Manual*, ch. 55806. The *Manual* does not define the term “consistently delinquent.”

¹⁹ HHS, *GPD*, pt. 3.06; NIH, *Policy Manual*, ch. 54815 and 54444.

²⁰ NIH, *Policy Manual*, ch. 55808.

²¹ NCRP staff use the same Award Worksheet Reports to document review of each awardee’s annual progress report and FSR. NIH, *Grants Management User Guide*, System Version 2.16.0.0. Accessed at <http://era.nih.gov> on August 11, 2010.

²² HHS, *GPD*, pt. 3.06.

must be created for each award and must contain the following documentation:

- signed copies of applications and all documentation that supports the review and approval of the applications;
- Notices of Award;
- performance and financial reports and evidence of review and acceptance by the awarding agency;
- site visit reports, records of telephone calls, and documents to support postaward technical assistance provided; and
- documentation related to enforcement actions, including any award appeals.²³

Official file contents must be current, easy to identify, easy to access, and separated by budget period to the extent possible.²⁴ Official files must also include hardcopies of electronically created or transmitted documents, including email, or be referenced to a separate file or repository.²⁵

Cooperative Agreement Award Mechanism

NIH uses three funding mechanisms for research awards: grants, cooperative agreements, and contracts. The CTSA program uses the cooperative agreement award mechanism. Federal requirements for award administration are generally the same for grants and cooperative agreements. Under cooperative agreements, however, NIH facilitates the awardees' performance of the funded activity in a "partnership" role.²⁶

In such a partnership, NIH staff provide assistance to awardees above and beyond the levels usually required for program stewardship of grants, but without dominating the relationship.²⁷ This increased NIH staff involvement with awardees is known as substantial involvement.²⁸ The NIH *Policy Manual* states that substantial involvement could include:

²³ HHS, *GPD*, pt. 3.06; NIH, *Policy Manual*, ch. 55806.

²⁴ HHS, *GPD*, pt. 3.06.

²⁵ *Ibid.*

²⁶ NIH, *Policy Manual*, chs.1820 and 54815.

²⁷ *Ibid.*

²⁸ The Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. § 6305; HHS, *GPD*, pts. 1.02 and 2.02.

- cooperation, coordination, or participation in assisting awardees in performing project activities (e.g., development of research protocols; data collection, analyses, and interpretations; or reestablishment of objectives during the course of a project);
- an option to halt a project activity if technical performance requirements are not met;
- review or approval of one stage of a project before work may begin on a subsequent stage during a current approved project period;
- assistance with, or approval of, the selection of contractors or subawardees and of key project personnel other than principal investigators of projects or subprojects;
- technical monitoring to permit specified directions of the work, including approval of changes in experimental approaches; and
- participation on committees or in other functions responsible for helping to guide the course of long-term projects or activities.²⁹

The NIH *Policy Manual* states that the names of substantially involved staff and an annual summary of staff involvement in the award must be documented in the award files.³⁰

For the CTSA program, the *Governance Manual* indicates that at least one Project Scientist is assigned to each CTSA awardee to provide substantial involvement through technical assistance, advice, and coordination.³¹ Project Scientists are not responsible for usual program stewardship. Instead, Project Scientists are responsible for reviewing and commenting on critical stages in implementation of the awards and for promoting collaboration among awardees.³² See Appendix A for a listing of all responsibilities for Project Scientists (as well as the responsibilities of grants management staff).

METHODOLOGY

Scope

This evaluation reviewed NIH's administration of the 38 CTSA research awards funded in fiscal years (FY) 2006 through 2008.³³ NIH awarded \$606 million to these awardees during our 3-year review period. Since

²⁹ NIH, *Policy Manual*, ch. 1820.

³⁰ NIH, *Policy Manual*, ch. 54815.

³¹ CTSA Consortium, *Governance Manual*, Working Document, Version 2008.8.14. Accessed at <http://www.ctsaweb.org> on June 22, 2009.

³² *Ibid.*

³³ The required reports for these awards were due during FYs 2007 to 2009.

all awardees requested 5 years of support, a total of 74 budget periods were reviewed for the 38 cooperative agreements during our review period—12 awardees were in the third year of operation (36 budget periods), 12 were in the second year (24 budget periods), and 14 were in the first year (14 budget periods). See Table 1 for a description of the number of awards and budget periods by award year.

Table 1: CTSA Award Summary

Fiscal Year	Budget Periods Reviewed	Number of Awardees	Total Budget Periods
2006	3	12	36
2007	2	12	24
2008	1	14	14
Total		38	74

Source: OIG analysis of CTSA files, 2009.

We did not review the research or scientific outcomes described in the progress reports or the appropriateness of the information reported in FSRs. However, we did determine the extent to which CTSA program staff documented their own review of research or scientific outcomes when evaluating awardee progress.

Data Sources

NCCR staff scanned their official files for the 38 CTSA awards into an electronic format for our review. NCCR staff stated that the electronic files contained both the scanned versions of the paper files and supplemental information from NIH’s electronic grants management system, Information for Management, Planning, Analysis, and Coordination (IMPAC II). For the purposes of our review, we refer to these scanned files as the official files.

If documents were missing from the official files, we consulted two additional sources to complete our review: IMPAC II via direct access and electronic copies of the Award Worksheet Reports not present in IMPAC II.

Data Collection and Analysis

We reviewed the following documents when present in the CTSA files, regardless of data source:

- CTSA applications;

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- Award Worksheet Reports;
- Notices of Award;
- progress reports;
- FSRs; and
- any documentation of postaward assistance in emails, telephone records, reports, or other documents.

We developed a checklist to conduct our review of these files to determine compliance with Federal regulations and HHS and NIH policies. We determined whether any CTSA program staff performed the following activities, regardless of which staff were charged with responsibility for each activity:

Ensuring Submission of Required Reports. We reviewed the CTSA files to determine whether required progress reports:

- were submitted 2 months before the beginning of the next budget period;
- contained a self-reported comparison of accomplishments with awardee goals and milestones³⁴ established for the budget period; and
- explained the reasons that goals and milestones were not met, if applicable.

We determined whether required FSRs were received within 90 days after the close of the budget period and whether they reflected the status of funds. We determined whether CTSA program staff ensured the submission of required progress reports and FSRs through correspondence with awardees to obtain delinquent reports and enforcement actions in the event of continued delinquency.

Monitoring Awardee Progress. We reviewed Award Worksheet Reports to determine whether CTSA program staff reviewed annual awardee progress for continued funding. Specifically, we determined whether the following were documented:

- awardee accomplishments toward meeting project goals;
- reasons for not meeting project goals, if applicable; and
- plans for activities during the coming year.

Award Worksheet Reports contain a yes/no option that enables grants management staff to indicate whether awardee progress was

³⁴ See Appendix B for an example of the goals and milestones section of an application.

satisfactory. The Award Worksheet Reports also contain a narrative field for staff comments.

Maintaining Official Files. We determined whether official files enabled a third party to follow the life of CTSA awards. Specifically, we determined whether file contents were current, easy to identify, easy to access, and separated by budget period. We also determined whether files were complete, containing the following documentation specified in HHS and NIH policy:

- signed copies of applications and documentation that supports the review and approval of the applications (e.g., Award Worksheet Reports);
- Notices of Award;
- progress and financial reports and evidence of review and acceptance by the awarding agency;
- site visit reports, records of telephone calls, and documents to support postaward technical assistance provided; and
- documentation related to enforcement actions, including any award appeals.

Providing Substantial Involvement. We reviewed the CTSA files for evidence of substantial involvement by CTSA program staff, including technical or scientific assistance from Project Scientists regarding program implementation³⁵ and any other assistance beyond usual program stewardship. We determined whether files contained the names of substantially involved staff and the annual summaries of staff involvement specified in agency policy.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

³⁵ See Appendix A for information from the *CTSA Governance Manual* regarding Project Scientists' responsibilities with regard to programmatic involvement.

► FINDINGS

Despite completing basic checklists, CTSA program staff did not document awardees' progress in compliance with NIH policy

We reviewed Award Worksheet Reports to determine whether CTSA program staff documented the following when reviewing

awardees' progress: awardee accomplishments toward meeting project goals; reasons for not meeting goals, if applicable; and plans for activities during the coming year. For all but one file, a simple "yes/no" checklist item on these reports indicated that progress was satisfactory each year. However, CTSA program staff largely failed to document the support for their answers as specified in NIH policy.

CTSA program staff documented their comparison of awardee accomplishments from the prior year to project goals for only 1 of the 38 files. For two other files, the section of the application outlining the goals and milestones was missing altogether, which prevented annual comparisons of progress to milestones. For the remaining 35 files, the goals and milestones sections of the application were present; however, comparisons to annual accomplishments were not documented.

In the 38 files, 8 Award Worksheet Reports noted awardees' inability to fulfill project goals. CTSA program staff attributed most of these deficiencies to budget cuts, although one file indicated that the goal was too ambitious, and another did not provide a reason. Moreover, only one of these six files contained a plan for resolution. In this case, the awardee was producing less than other awardees and developed an advisory committee to address this concern. CTSA program staff noted that this strategy was likely to bring this awardee's production in line with that of the other awardees.

Similarly, CTSA program staff noted only one awardee's plans for the upcoming year. In this case, the Award Worksheet Report narrative included a copy of an email from the awardee that described activities that occurred after the submission of the annual progress report and plans for the upcoming project period.

F I N D I N G S

Awardees were frequently late in submitting required reports; CTSA program staff did not take action to address timeliness

Awardees commonly submitted progress reports and FSRs late. Despite frequent delinquencies in the

submission of required reports, CTSA program staff did not take action to address the noncompliance.

Most progress reports and half of FSRs were late

During our study period, 66 of the 74 (89 percent) progress reports were late. Progress reports were late an average of 12 days. Table 2 summarizes the number of progress reports received late during each year of our review period.

Table 2: Timeliness of Progress Reports Submitted From 2007 to 2009

Year	Total CTSA Awards	Progress Reports Received	Number Received Late	Percentage Received Late
2007	12	12	11	92%
2008	24	24	20	83%
2009	38	38	35	92%
Total	74	74	66	89%

Source: OIG analysis of CTSA files, 2010.

During our study period, 36 of 74 FSRs (49 percent) were late. FSRs were late an average of 113 days. One report was not submitted within the period of our review. Table 3 summarizes the number of FSRs received late during each year of our review period.

Table 3: Timeliness of FSRs Submitted From 2007 to 2009

Year	Total CTSA Awards	FSRs Received	Number Received Late	Percentage Received Late
2007	12	12	6	50%
2008	24	24	13	54%
2009	38	37	17	45%
Total	74	73	36	49%

Source: OIG analysis of CTSA files, 2010.

Staff did not ensure timely submission of required reports

The NIH *Policy Manual* instructs CTSA program staff to document correspondence with awardees to obtain delinquent reports; however, no such documentation was present in the files.

NIH policy requires CTSA program staff to send notices to awardees regarding delinquent reports when progress reports are 30, 60, 90, and 120 days late and when FSRs are 4 and 5 months late. None of the files contained these reminder notices. However, files contained 8 progress reports that were more than 30 days late; 4 of those were more than 60 days late.³⁶ Similarly, files contained 11 FSRs that were more than 4 months late and 9 of those FSRs were more than 5 months late.

For all of the research awards, only one file contained documentation of an instance when CTSA program staff contacted an awardee about a late report, but this request was late and therefore was not in compliance with the NIH *Policy Manual*. To illustrate, the CTSA program staff member emailed the awardee to request an FSR that was due 9 months earlier. The awardee finally submitted the FSR to CTSA program staff 3 months after the request, nearly a year after the original due date.

NIH policy also instructs CTSA program staff to document enforcement actions taken to address continued delinquency. Despite widespread report delinquency, no enforcement actions were documented. For example, one awardee's FSRs were 67 days late in 2007, 351 days late in 2008, and 184 days late in 2009. This awardee's progress reports were also late each year. Even though these reports were repeatedly late, no evidence in the files documented any of the enforcement actions that CTSA program staff could have taken to address this awardee's violation of the terms and conditions of award.

³⁶ None of the progress reports were more than 90 days late.

F I N D I N G S

Official CTSA files were not maintained in accordance with HHS policy

Official files must be complete, current, easy to identify, easy to access, and separated by budget

period. Official award files must also enable third-party review in order to provide a coordinated approach to award oversight. Official CTSA files maintained by NCRP did not meet these criteria.

NCRP staff stated that the official files for the CTSA awards contained scanned versions of their paper files and supplemental information from IMPAC II. However, at least 1 required document was missing from the official file for each of the 38 awards. Table 4 provides a summary of the missing documents.

Table 4: Summary of Documents Missing From Official CTSA Files

Award Year	Number of Awards	Document	Number Missing From Official File Source
Prior to Award	38	Entire application	7
		Implementation and Milestones Section of application	21
Year 1	38	FSR	6
		Progress Report	17
		Award Worksheet Report	16
		Notice of Award	12
Year 2	24	FSR	8
		Progress Report	15
		Award Worksheet Report	8
		Notice of Award	12
Year 3	12	FSR	5
		Progress Report	4
		Award Worksheet Report	1
		Notice of Award	6

Source: OIG analysis of official CTSA files, 2009.

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Official CTSA files were also not current. All CTSA awards were into the second quarter of a new budget period at the time of our request, and for this reason, the Notice of Award for the new budget period should have been filed by that time. However, none of the files contained information from that budget period (e.g., Notices of Award, site visit reports, records of telephone calls, or emails).

Official CTSA files were often not separated by budget period. Files were not consistently separated by budget period for 16 of the 38 CTSA awards. Files for 13 awards combined 2 or more years into 1 section, while files for the other 3 awards divided single award years into multiple small sections.

Additionally, official CTSA files do not enable third-party review. Because the official files maintained by NCRP are incomplete, a third-party review would be inaccurate if it relied solely on these files. To complete a comprehensive review of CTSA files, we consulted two additional file sources. Table 5 summarizes the file sources used and the extent to which they complied with Federal policy from a third-party perspective.

Table 5: Extent to Which File Sources Met Requirements of Federal Policies for File Maintenance

Access Date	Data Source	Files Are Complete	Files Are Current	Files Are Easy to Identify	Files Are Easy to Access	Files Are Separated by Budget Period
October 2009	Official files	No	No	No	Yes	Sometimes
March 2010	IMPAC II	No	Yes	Yes	No	Yes
April 2010	Electronic Award Worksheet Reports	No	Yes	Yes	No	Yes

Source: OIG analysis of CTSA files, 2010.

No single file source met all the requirements of the Federal policies for maintaining files. IMPAC II contained all documents missing from the official file except the Award Worksheet Reports. NCRP could not locate four Award Worksheet Reports electronically; however, these reports were present in the official files for the respective awards.

No files contained evidence that CTSA program staff provided substantial involvement to awardees in accordance with Federal regulations and NIH policy

According to Federal statute, cooperative agreements necessitate substantial involvement³⁷ by the awarding agency in partnership with the awardee throughout the life of the

award. NIH policy states that the names of substantially involved staff and annual summaries of substantial staff involvement in the cooperative agreements must be documented in the files. According to the CTSA Consortium *Governance Manual*, Project Scientists are responsible for providing substantial involvement for CTSA cooperative agreements. However, file documentation contained no evidence of this type of involvement by Project Scientists or any other CTSA staff.

The CTSA files contained no evidence of substantial Project Scientist involvement

The award files contained no documentation of technical assistance from Project Scientists regarding program implementation for any of the cooperative agreements. Additionally, files had no evidence that Project Scientists did any of the following:

- assisted awardees in performing project activities,
- halted a project activity if technical performance requirements were not met,
- reviewed or approved stages of a project,
- approved the selection of contractors or subawardees or key project personnel,
- conducted technical monitoring to permit specified directions of the work, or
- participated on committees.

None of the files listed names of Project Scientists, and only two files contained any mention of a Project Scientist. In one instance, the Project Scientist emailed his intent to attend a teleconference with CTSA program staff and the awardee regarding restructuring of the CTSA program. However, the file contained no documentation explaining what, if any, technical advice the Project Scientist contributed during that meeting or documentation of any other

³⁷ Substantial involvement includes activities beyond those usually required for program stewardship.

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involvement. In the other instance, a Program Official with the title “Scientific Project Officer” in her email signature emailed the Grants Management Specialist to inquire about the status of an awardee’s request to purchase equipment.

The CTSA files contained no other evidence of substantial involvement

We searched for documentation of any involvement beyond usual program stewardship by CTSA program staff. A checklist item on Award Worksheet Reports indicates whether the annual summaries of substantial staff involvement in the awards were present in the file. Despite the fact that checklists for all but one of the files indicated that these summaries were present for at least 1 year of the project, they were not in the files.

In 11 of the files, the annual summary consisted of a brief note from CTSA program staff stating that only usual program stewardship was provided or describing usual program stewardship activities, such as correspondence with awardees. In two other files, the brief note from the CTSA program staff instead described the awardees’ level of involvement rather than NIH staff involvement. For the rest of the files, such notes were not provided.

Throughout our review of the files, we were able to identify only documentation from CTSA program staff related to usual program stewardship, such as correction of financial information. Some of the documentation of usual program stewardship that had the potential to include evidence of substantial involvement was not present. For example, a few of the files indicated that site visits occurred, which is considered usual program stewardship. However, these same files contained no site visit reports. Consequently, we could not determine whether CTSA program staff provided involvement beyond usual program stewardship during these site visits.



R E C O M M E N D A T I O N S

Our review of files for FYs 2006 to 2008 demonstrated that administration of the CTSA program was noncompliant with the following: monitoring awardee progress, ensuring timely submission of required reports, and maintaining official files. Also, no files contained evidence that CTSA program staff provided substantial involvement to awardees in accordance with the cooperative agreement funding mechanism.

For better oversight of the CTSA program, we recommend that NIH ensure that CTSA program staff:

Document Their Monitoring of Awardee Progress

When staff review awardee progress, NIH must ensure that they document awardee accomplishments toward meeting project goals; reasons for not meeting project goals, if applicable; and plans for activities during the coming year. To assist staff in documenting these elements of annual progress, NIH may consider revising the Award Worksheet Report to require a narrative related to awardee accomplishments. NIH also may consider formally tracking awardee goals and milestones from the time that they are submitted in the application through the life of the award, which would facilitate a streamlined comparison of accomplishments to goals and milestones when evaluating annual awardee progress. This could be accomplished through IMPAC II or another mechanism.

Ensure Timely Submission of Required Reports

NIH should ensure that staff document correspondence with awardees as they act to obtain delinquent reports.

Maintain Official Files in Accordance With HHS Policy

NIH must establish a single comprehensive filing system for the CTSA program in which files are complete, current, easy to identify, easy to access, and separated by budget period. This would promote a coordinated approach to award oversight by better enabling third-party review.

Provide Substantial Involvement to CTSA Awardees

NIH involvement may include collaboration, participation, and/or intervention in cooperative agreement activities. At a minimum, staff must clearly list within the award files the Project Scientists involved and include the annual summary of involvement.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH concurred with our recommendations. In response to our first and second recommendations, NIH stated that it will issue specific guidance on documentation requirements for monitoring awardee progress and obtaining delinquent reports. NIH stated that it has already implemented our third recommendation by using electronic grant files. In response to our fourth recommendation, NIH stated that NCRP will revise its cooperative agreement terms of award to identify the names and titles of program staff who will provide substantial involvement as CTSA Project Collaborators. We did not make any changes to the report based on NIH's comments. For the full text of NIH's comments, see Appendix C.

▶ A P P E N D I X A

Responsibilities of Clinical and Translational Science Awards Program Staff

Usual Program Stewardship (all awards)	Substantial Involvement (cooperative agreements only)
<p>Grants Management Officers:</p> <ul style="list-style-type: none"> • All business management matters associated with the review, negotiation, award, and administration of grants and cooperative agreements • Interpret grants administration policies and provisions • Sign Notices of Award • Change the funding, duration, or other terms and conditions of award 	<p>Project Scientists</p> <ul style="list-style-type: none"> • Coordinate activities at the designated CTSAs with other ongoing studies supported through NCRR to avoid duplication of effort and encourage sharing and collaboration in the development of new clinically useful agents and methodologies • Review and comment on critical stages in the implementation of the program • Assist in the interaction between the awardee and investigators at other institutions to promote collaborations • Coordinate access to other resources available through CTSAs including access to specialized technology cores • Assist with technical monitoring to permit kinds or directions of work • Participate on committees as voting members as needed or in other functions to guide the course of long-term projects or activities • Retain the option of recommending termination of support if technical performance or implementation falls below acceptable standards, or when specific key resources cannot be effectively implemented in a timely manner • Retain the option to recommend additional infrastructure support within the constraints of the approved research and negotiated budget; • Coordinate activities for the CTSA institutions to participate in the national program evaluation and work with NIH evaluation officials and other evaluation staff • Call additional meetings/workshops of CTSAs to address emerging areas of high priority
<p>Grants Management Specialists:</p> <ul style="list-style-type: none"> • Evaluate applications for administrative content and compliance with regulations and guidelines • Negotiate awards • Provide consultation and technical assistance to recipients • Post-award administration • Close out awards 	
<p>Program Officials:</p> <ul style="list-style-type: none"> • Approve awardee plans prior to award, or review performance after completion • Evaluate progress by reviews of technical or fiscal reports or by program visits, to determine that performance is consistent with objectives, terms and conditions of the award; this may include external reviewers • Provide technical assistance requested by awardees, or unanticipated procedures to correct programmatic or financial deficiencies in awardee performance • Conduct scientific and technical discussions with awardees, or actions to facilitate or expedite interactions between awardees; e.g., organizing and holding meetings of investigators 	

Source: National Institutes of Health, CTSA Consortium *Governance Manual*, version 2008.08.14; Department of Health and Human Services, *Grants Policy Directives*, pt. 1.01.

Note on acronyms used in the table: CTSA is Clinical and Translational Science Award. NCRR is the National Center for Research Resources (NCRR). NIH is the National Institutes of Health.

▶ APPENDIX B

Example of Awardee Goals and Milestones*

II.E. Design and Biostatistics (Center for [REDACTED])																				
Aims and Key Activities	Year 1				Year 2				Year 3				Year 4				Year 5			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Provide advice on design of studies and preparation of grant proposals																				
• Recruit permanent Director																				
• Establish procedures and priority criteria																				
• Prepare [REDACTED] webpage																				
• Work with [REDACTED] members on study design																				
• Help with grant applications																				
• Help with IRB approvals																				
Provide statistical analyses for [REDACTED] studies																				
• Analyze data from [REDACTED] studies																				
• Assist with manuscript preparation																				
• Involve Biostat Consulting Class.																				
Provide biostatistics training to [REDACTED] investigators and trainees																				
• Deliver weekly Biostatistics Workshop																				
• Prepare online training courses/																				
• Add modules to Summer Institute																				
Engage in methodological research																				
• Identify methodological issues.																				
• Prepare methodological manuscripts.																				
• Submit methodology grant applications.																				
II.I. Translational Technologies and Resources Core																				
Aims and Key Activities	Year 1				Year 2				Year 3				Year 4				Year 5			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Existing technologies and resources: Create a database of existing, relevant technologies																				
• Complete survey of current resources																				
• Create web-based portal to existing resources																				
• Annual review/update of posted resources																				
Existing technologies and resources: 'technology application' seminars or short courses																				
• Identify all planned courses for coming year																				
• Prioritize needs for new training areas																				
• Develop content / identify speakers for new technology applications courses																				
• Review and evaluate past year's courses																				
Existing technologies and resources: [REDACTED] Committee																				
• Hold quarterly meetings																				
• Oversee implementation of recommendations																				
• Evaluate new tech areas for development,																				
Existing technologies and resources: Provide continued support for existing core technologies and resources																				
• Support for Nutrition Services																				
• Support for Cell Therapeutics Facilities																				

Source: Excerpts from one Clinical and Translational Science Award application on file, accessed by the Office of Inspector General in October 2009.

Note: Potentially identifying information (e.g., names of centers, studies, and committees) has been redacted.

Note on acronym used in the table: IRB is Institutional Review Board.

* Shaded areas under Years 1–5 indicate the quarter(s) in which the awardee intends to complete the listed activity.

▶ A P P E N D I X C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

SEP 11 2011

TO: Stuart Wright
Deputy Inspector General for Inspection and Evaluations, OIG, HHS

FROM: Director, NIH

SUBJECT: NIH Comments to the Draft Office of Inspector General Report, *NIH Administration of the Clinical and Translational Science Awards Program* (OEI-07-09-00300)

Attached are the National Institutes of Health's comments on the draft OIG report entitled, *NIH Administration of the Clinical and Translational Science Awards Program* (OEI-07-09-00300).

We appreciate the opportunity to review and comment on this important topic. Should you have questions or concerns regarding our comments, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

/S/

Francis S. Collins, M.D., Ph.D.

Attachment

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF INSPECTOR GENERAL'S (OIG) DRAFT REPORT ENTITLED, NIH ADMINISTRATION OF THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM (OEI-07-09-00300)

The National Institutes of Health (NIH) appreciates the review conducted by the OIG and the opportunity to provide comments on this draft report.

OIG Recommendation: Document Their Monitoring of Awardee Progress

NIH Response: NIH concurs with the OIG's finding that National Center for Research Resources (NCRR) program staff are not consistently and comprehensively documenting their assessments of awardees' progress. However, NCRR program staff are reviewing all grants for progress before making subsequent awards; although their documentation is provided in various forms (e.g., required checklists, e-mails, and reports), which are part of the official grant file.

NCRR will issue specific guidance on documentation requirements and communicate these requirements through a written standard operating procedure (SOP), frequently asked questions (FAQs), and staff training. The NCRR Director will issue a transmittal memo relaying the training requirements to NCRR program and grants management staff. NCRR will post the written SOP and FAQs on their intranet for ready accessibility. The SOP will include, but will not be limited to, procedures for reviewing progress against stated goals, identifying and providing for corrective action/resolution when goals are not met, and comparing plans for the upcoming year against proposed goals. The SOP will include specific guidance regarding where this review should be reflected in the Program Checklist so that it will appear in the Award Worksheet Report (AWR). Guidance will also specify what constitutes an acceptable method of documenting progress reviews. NCRR plans to develop the SOP and FAQs and conduct staff training by March 1, 2012.

OIG Recommendation: Take Action to Assure Timely Submission of Required Reports

NIH Response: NIH concurs with the OIG's recommendation that grants management staff document correspondence with awardees as they act to obtain delinquent reports.

The current NIH awards process provides tools, such as the standardized checklists and the AWR, for NCRR staff to document actions when following up on delinquent reports. NCRR will train its program and grants management (GM) staff to utilize, consistently and fully, these tools that were developed and incorporated into the Information for Management, Planning, Analysis, and Coordination (IMPAC II)¹ Program and GM Modules in 2007. The checklist is composed of standardized questions as well as NIH Institute or Center (IC)-specific questions, which program and GM staff address prior to issuing an award. The checklists are reviewed by

¹ The IMPAC II system is an Oracle-based online information system that contains application and award information on extramural programs.

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF INSPECTOR GENERAL'S (OIG) DRAFT REPORT ENTITLED, NIH ADMINISTRATION OF THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM (OEI-07-09-00300)

the Grants Management Specialist and the Grants Management Officer. The checklist ensures that certain programmatic and administrative requirements are addressed consistently across the NIH ICs prior to issuing the grant award and that awards are issued in compliance with NIH, HHS, and other applicable regulations and policies. The checklists are included as part of the AWR and provide a means for staff to document their comments, award, and follow-up actions. The AWR is stored in the Grant Folder of the IMPAC II system. As stated above, by March 1, 2012, NCRR will establish and communicate to staff an SOP to promote consistency in the documentation of NCRR actions to obtain delinquent reports.

It is the responsibility of the grantee to submit timely and accurate reports. Nonetheless, NIH has developed several tools for grantee use to assist them in this effort. In 2004, NIH established centralized receipt and initial processing of all NIH noncompeting progress reports. The Division of Extramural Activities Support (DEAS), Office of Extramural Research, receives paper progress reports and scans these reports into the IMPAC II system. DEAS is also responsible for following up on delinquent noncompeting progress reports and maintaining the associated file documentation, which is part of the official grant file. Once progress reports are received and scanned into the system, they are available in the Grant Folder of the IMPAC II system for use by program and GM staff. However, images are generally not available for viewing until several business days after receipt of the progress report. There are numerous instances in the OIG's sample where progress reports were received by the due date but were not available for review until a later date, which appears to have contributed to the OIG's conclusion that most progress reports were late.

Additionally, NIH continues to develop, refine, and implement its electronic grant systems. NIH instituted a new submission policy that requires all progress reports for awards subject to the Streamlined Noncompeting Award Process (SNAP) that were due on/after August 1, 2010, to be submitted electronically through the NIH electronic research administration (eRA) Commons² (eSNAP Module). NIH anticipates that grantee performance on timely submission of progress reports will improve with continued deployment of electronic systems.

To address the issue of late annual progress reports, eRA utilizes automatic monthly e-mails and/or late notifications as reminders to grantees. The system sends the e-mail reminders to the project director/principal investigator (PD/PI) two months before the annual progress report due date. The PD/PI and the applicable NIH awarding IC receive the e-mail notifications when the progress report is late. The late notification e-mails serve as the official grant file documentation when saved to the official grant file repository established by the IC (e.g., paper file, eAdditions in IMPAC II). The OIG reported that these automatic late notifications were absent from the

² eRA Commons is an online interface where grant applicants, grantees, and Federal staff at NIH and other grantor agencies can access and share administrative information relating to research grants.

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF INSPECTOR GENERAL'S (OIG) DRAFT REPORT ENTITLED, NIH ADMINISTRATION OF THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM (OEI-07-09-00300)

official grant file; however, late notifications are available only in the eRA GM Module, to which the OIG did not have access.

To enable grantee organizations to fulfill their responsibilities in monitoring and meeting progress reporting deadlines, NIH continues to maintain a publicly accessible Web site, (http://era.nih.gov/userreports/pr_due.cfm) from which grantees can access progress report due date information. PD/PIs and grantee administrative officials can also monitor due date information in the eRA Commons Status system.

NIH has also made system enhancements to promote timely submission of financial expenditures reports. Beginning October 1, 2007, NIH required all grantees to submit Financial Status Reports (FSRs) through the eRA Commons using the FSR Module. Beginning February 1, 2011, NIH implemented the expenditure data portion of the Federal Financial Report (FFR). The FFR expenditure data is also submitted through the eRA Commons using the updated FSR/FFR Module. The eRA Commons FSR/FFR system allows grantees to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. The FFR expenditure data submitted to NIH is initially reviewed and accepted by the Office of Financial Management (OFM), NIH. IC staff have the ability to monitor the receipt and acceptance of submitted reports through a query tool in IMPAC II. Once the FSR/FFR is accepted by OFM, it is available for viewing by NIH staff in the Grant Folder of IMPAC II. Reporting requirements for the FSR and FFR are different. The awards issued under the NCRRTSA program are subject to annual FSR/FFR reporting. Annual FSRs were due within 90 days following the end of the budget period, whereas annual FFRs are due within 90 days after the end of the calendar quarter in which the budget period ends. Since the due date of the annual financial report (e.g., for year 01) is after the next year's budget period start date (e.g., for year 02), the IC staff monitor the receipt and acceptance of the annual FSR/FFR when preparing the following year's Notice of Award (NoA) (e.g., for year 03). Therefore, if a required FSR/FFR is delinquent (e.g., year 01 report), IC staff will generally delay the issuance of the current fiscal year NoA (e.g., year 03) until the FSR/FFR is received and accepted by OFM. GM staff will document any follow-up actions taken at this time in the official file. We have provided this information as clarification of the financial reporting process and when FSRs/FFRs are due and available for review. Lack of clarity in this process may have influenced the OIG's assessment and led them to conclude that NCRRTSA should have restricted the awardee from receiving continued funding until they received and accepted all outstanding FSRs/FFRs.

NCRRTSA does not issue subsequent awards until the required FSRs/FFRs are received and accepted, except in unique circumstances. In those exceptional cases where an award is made in the absence of a received and accepted FSR/FFR, the award will include a restrictive term indicating that funds awarded may not be expended until the required report(s) are received and accepted. The Grants Management Specialist documents the reason for the restricted award in the comments section of the GM checklist, which is subsequently reflected in the AWR.

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Further, NIH takes additional actions to augment its electronic systems development by continuing to address the importance of timely submission of progress reports and annual financial reports in outreach sessions with the grantee community.

NIH also takes additional measures to promote timely submission of required final closeout documents (FFR [expenditure data], Final Progress Report, and Final Invention Statement and Certification). In 2008, NIH established a centralized processing center that is responsible for receiving all nonfinancial closeout documents (Final Invention Statement and Certification and the Final Progress Report). Within this centralized processing center, DEAS is responsible for the administration of grants closeout in accordance with SOPs for all NIH awarding components. DEAS sends out reminder notices to inform grantees about the requirement for submitting final closeout documents as soon as the project terminates. If the required documents have not been submitted within 90 days following the end of the project period, additional reminder notices are sent.

Through its outreach efforts and publication of the NIH Grants Policy Statement and NIH Guide Notices (e.g., NOT-OD-08-061 and NOT-OD-09-128), NIH continues to inform and remind the extramural grantee community of the requirement to submit closeout documents in a timely and accurate fashion.

OIG Recommendation: Maintain Official Files in Accordance with HHS Policy

NIH Response: NIH concurs with OIG's recommendation; however, NIH has already fully implemented this recommendation through the establishment and use of electronic grant files. In 2005, NIH began receiving electronic grant applications through Grants.gov; it now receives approximately 98 percent of all applications electronically. NIH still receives paper applications for complex award mechanisms, including the CTSA program. As previously discussed, grantees submit non-SNAP annual progress reports on paper to a centralized mailing address. NIH then scans the progress reports into the IMPAC II system.

During the OIG review, NCRP was transitioning from paper files to electronic files (in 2003, NIH recognized electronic files as an official grant file repository; however, there is no requirement for ICs to convert fully to electronic files at this time). Today, the NCRP utilizes a system within the IMPAC II system known as Electronic Additions for Review (eAdditions). eAdditions provides a means to ensure documentation and organization of the official grant file. The GM staff have the ability to upload additional materials in the IMPAC II system to a centralized location (the Grant Folder). The uploaded information is also available for viewing by Program Officials (POs). eAdditions provides major categories and subcategories for establishing a standard method for filing documents within the IMPAC II system for those who have access rights to the system.

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We would like to make it clear that the OIG was not provided the official paper grant file for its review but rather was provided the documentation they requested from paper and/or scanned files at the point in time it was requested. The scanned portion of the files was a "bulk" scan of all information residing in the paper files. It was not parsed out into budget periods, or type of documentation (e.g., correspondence, application, FSR) nor was it requested to be provided in that manner. Therefore, the data provided to the OIG may have appeared incomplete as the file material reflected the contents of the official paper file from the day it was scanned by NCRP and did not include information not yet due or not yet uploaded.

During the audit, the OIG was unable to find four AWRs in IMPAC II. NCRP, along with Office of Policy for Extramural Research Administration and eRA staff, investigated this finding. They determined the finding resulted from an eRA system processing error at the time of award, which ultimately prevented the system from storing the four AWRs correctly in the IMPAC II grant folder. NIH eRA developed the following documentation and placed it into every affected grant's AWR record.

Award Worksheet Report not available

eRA is issuing this notice to document that the Award Worksheet Report (AWR) for this grant is not available due to a system processing error that occurred at the time of award. The Notice of Award (NoA) that was generated was not affected and is available in the Grant Folder for reference. The NoA will serve as the documentation for this record. For more information, please see below.

eRA discovered that prior to the hardware upgrade in May 2009, a number of AWRs were not stored correctly in the Grant Folder. The system's inability to store the AWRs correctly was due to an intermittent issue with connecting to the Oracle hardware that produces the reports. Less than 1.5% of AWRs were affected by this system error.

It is important to note that although some AWRs were affected, all changes or updates to the grant data are correct in the Grant Folder and the Notice of Award reflects all the accurate information. Unfortunately, the AWR for this record cannot be recovered.

It is important to note that since the hardware upgrade last year, there have not been any failed AWRs. To safeguard against a recurrence of this problem, eRA is implementing an enhancement to the report generation procedure that will detect any errors immediately. This new feature will generate an automatic re-run for any failed AWRs and is scheduled for deployment in the eRA July 2010 system-wide release.

The OIG stated in its draft report that "official CTSA files were incomplete, were not current, were often not separated by budget period, and did not enable third-party review." As discussed,

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF INSPECTOR GENERAL'S (OIG) DRAFT REPORT ENTITLED, *NIH ADMINISTRATION OF THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM (OEI-07-09-00300)*

OIG based this conclusion on a specific situation rather than a comprehensive view of NIH's grants process and electronic systems.

OIG Recommendation: Provide Substantial Involvement to CTSA Awardees

NIH Response: NIH concurs with the OIG's finding that NCRP files contained no evidence that Project Scientists or CTSA POs provided substantial involvement beyond usual program stewardship activities. Substantial involvement of NCRP program staff exists, and basic documentation of this involvement is reflected in the program checklist. However, substantiated documentation is neither consistently nor adequately included in the official file. NCRP will revise its cooperative agreement terms of award to identify the name and title of program staff who serve as CTSA Project Collaborators so that one NCRP scientist provides both functions (as defined by NIH policy).

Under the CTSA cooperative agreement mechanism, the NCRP guides, coordinates, or participates in project activities and is involved substantially with CTSA award recipients. The NCRP supports and stimulates the awardees' activities by working jointly in a partner role but does not assume direction, prime responsibility, or a dominant role. The specific tasks and activities in carrying out project activities will be shared among the awardees and the NCRP project scientists and/or NCRP POs. Those aspects of the cooperative agreement partnership between the awardees and the NIH are also applicable to activities of the national CTSA consortium.

NCRP POs are scientists who provide the scientific expertise for the typical programmatic stewardship of assigned CTSA and are named in the award notice.

Typical PO stewardship includes:

- Approval of awardee plans prior to award and review of performance after completion
- Evaluation of progress by reviews of technical or fiscal reports or by program visits, to determine that performance is consistent with objectives, terms, and conditions of the award (this may include external reviewers)
- Technical assistance requested by awardees, or correcting programmatic or financial deficiencies in awardee performance
- Scientific and technical discussions with awardees, or actions to facilitate or expedite interactions between awardees; e.g., organizing and holding meetings of investigators

Additionally, the POs may recommend the termination or curtailment of an investigator or project/program (or an individual award) in the event the partnerships fail to evolve within the intent and purpose of this initiative.

Additional activities of CTSA POs include the following:

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- Participate as nonvoting members of relevant CTSA consortium committees
- Serve as coordinators of CTSA consortium Key Function Committees (KFC) and/or Strategic Goal Committees (SGC), providing liaison to NCCR; supporting committee activities and meetings; and coordinating approaches, projects and programs between CTSA committees
- Assist the partnership efforts by facilitating access to fiscal and intellectual resources provided by NIH, industry, private foundations, and Federal funding agencies
- Ensure that activities proposed for development or implementation at CTSA's do not financially overlap or duplicate activities supported by Research Centers at Minority Institutions Infrastructure Grants, Minority Biomedical Research Support Grants, or other peer-reviewed funding mechanisms
- Interact with each CTSA, coordinate approaches between CTSA's, and contribute to the adjustment of projects/programs or approaches as warranted
- Provide assistance in reviewing and commenting on all major transitional changes of an individual CTSA's activities prior to implementation to ensure consistency with the goals of the Request for Applications (RFA)
- Link the approaches developed from these partnerships to each other and to other NIH-supported Centers and Consortia to ensure that information is shared and utilized on the widest basis possible
- Monitor institutional commitments and resources to ensure that the partnership receives the maximum chance of stabilization and success
- Retain the option of recommending termination of support if technical performance or implementation falls below acceptable standards, or when specific key resources cannot be effectively implemented in a timely manner
- Retain the option to recommend additional infrastructure support within the constraints of the approved research and negotiated budget
- Coordinate activities for the CTSA institutions to participate in the national program evaluation and work with NIH evaluation officials and other evaluation staff

NCCR Project Scientists have substantial scientific involvement during the conduct of this activity, through technical assistance, advice, and coordination beyond normal program stewardship for grants.

Additional activities of CTSA Project Scientists include the following:

- Coordinate activities at the designated CTSA's with other ongoing studies supported through NCCR to avoid duplication of effort and encourage sharing and collaboration in the development of new clinically useful agents and methodologies
- Review and comment on critical stages in the implementation of the program
- Assist in the interaction between the awardee and investigators at other institutions to promote collaborations

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF INSPECTOR GENERAL'S (OIG) DRAFT REPORT ENTITLED, NIH ADMINISTRATION OF THE CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM (OEI-07-09-00300)

- Coordinate access to other resources available through CTSA's, including access to specialized technology cores
- Assist with technical monitoring to permit kinds or directions of work
- Participate on CTSA consortium committees as needed to guide the course of long-term projects or activities
- Call additional meetings/workshops of CTSA's to address emerging areas of high priority

Proposed Action Plan Summary:

- NCRP will issue specific guidance on documentary assessments of awardee's progress.
- A written standard operating procedure (SOP), frequently asked questions (FAQs), and staff training will be implemented for documenting monitoring of awardee progress.
 - The SOP will include, but will not be limited to, procedures for reviewing progress against stated goals, identifying and providing corrective actions/resolution when goals are not met, and comparing plans for the upcoming year against proposed goals.
 - The SOP will include specific guidance regarding where this review should be reflected in the Program Checklist so that it will appear in the Award Worksheet Report (AWR). Guidance will also specify what constitutes an acceptable method of documenting progress reviews. NCRP plans to develop the SOP and FAQs and conduct staff training by March 1, 2012.
- NCRP will revise its cooperative agreement terms of award to identify the name and title of program staff who will serve as CTSA Project Collaborators. Concurrently, and by March 2012, NCRP will develop and conduct training on an SOP incorporating the NIH policy requirements related to the award and administration of cooperative agreements.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Brian T. Pattison, Regional Inspector General for Evaluation and Inspections in the Kansas City regional office, and Deborah K. Walden, Deputy Regional Inspector General.

Julie Dusold Culbertson served as the project leader for this study. Other principal Office of Evaluation and Inspections staff from the Kansas City regional office who contributed to the report include Perry Seaton and Dennis Tharp; central office staff who contributed include Pamela J. Langer and Talisha Searcy.

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

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The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

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