Training Grant Administrators (TGA) Group

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SPA
November 13th, 2012

Agenda

• TGA Administrator list update
• New CourseWorks update
• T32 Deadline Review
• Revised NIH Grant Policy Statement (NIHGPS) review for T32s
• Overview of recent Federal Claims Act case (concerning a T32)
• COI Issues for Training Grants (Naomi Schrag and Michael Klein, ORCT)
TGA Group newCourseWorks Site

• Usage to date
  ▫ 5 Departments have uploaded their contact sheets
  ▫ 2 Departments have added files to Archived Deadlines
  ▫ 3 Departments have added files to May 2012 Deadline
• Is your department using the site? If not, why not?
• If yes, what is working?
• Should the TGA group continue to use the site?
• If yes, here are some proposed deadlines for uploading materials:
  ▫ All departments upload their contacts by Nov. 30th
  ▫ All departments upload final tables from latest grant submission by December 10th
  ▫ All up for discussion!

T32 Competitive Deadlines - a review

• Review current Parent Announcement (PA-11-184) carefully, in particular, the “Related Notices” section:
  ▫ Ex., various ICs may decide to stop accepting new T32s

• MUST review the table of IC Specific-Information
  ▫ Ex., NHLBI only accepts new and competing applications once a year, on January 25th

• The tables are not to be created equally for each IC
  ▫ Each IC has their own set of table requirements
Revised NIH Grants Policy Statement (NIHGPS)

- NIHGPS revised 10/1/2012
- Applicable to all NIH grants with budget periods beginning on or after 10/1/2012
- Doesn’t introduce new material, but incorporates notices issued over the last year, and clarifies some definitions and policies
- Specific to NRSAs:
  ▫ pilot the Research Performance Progress Report (RPPR) for non-SNAP awards during calendar year 2013
  ▫ NIH will announce when the RPPR is available for institutional training award progress reports

Revised NIH Grants Policy Statement (NIHGPS)

Section - 11.3.8.4 Training-Related Expenses
- Clarified the cost of meals
  ▫ “Meals. As stated in IIA, the cost of meals may be allowable if they are provided in conjunction with a meeting considered an ancillary activity to the training grant. A portion of such a cost could be charged as Training-related expenses.”
Article in NIH Extramural Nexus

Posted 10/24/12
Clearing Up Confusion about Postdoc Salaries and Training Activities

http://nexus.od.nih.gov/all/2012/10/24/clearing-up-confusion-about-postdoc-salaries-and-training-activities/

Purpose of an NRSA postdoctoral traineeship is to continue training for a career in research. All activities that contribute to this goal are permissible under these awards, including:

- laboratory research
- writing research reports, reviews and journal articles
- and attending and presenting at scientific conferences and seminars
- teaching or overseeing students on projects related to the fellow’s or trainee’s research training experience

Cornell University Loses False Claim Act Case Involving Federal Research Grants

- United States of America ex rel. Daniel Feldman v. Wilfred van Gorp and Cornell University Medical College, No. 10-3297 (Decided Sept. 5, 2012)

- Article summarizing what happened:

Cornell University Loses False Claim Act Case Involving Federal Research Grants

- T32 title, “Neuropsychology of HIV/AIDS Fellowship”
- Cornell applied in 1997

Dan Feldman, a postdoc fellow on the T32, complained to NIH that the actual training program deviated from what it was originally funded to do, and that Cornell failed to report to NIH these deviations (failed to report a change in scope)

1. some of the identified “key personnel” had no involvement with the fellowship;
2. the curriculum outlined in the grant proposal was never implemented;
3. the clinical training actually received materially differed from that described in the grant proposal; and
4. much of the research performed under the fellowship had no relation to HIV or AIDS.

Cornell University Loses False Claim Act Case Involving Federal Research Grants

- NIH asked Cornell to conduct an investigation of the complaint. Cornell’s investigation found no wrongdoing. NIH took no further action.

- In 2003, Feldman filed a *qui tam* complaint pursuant to the False Claims Act. Alleged that Cornell made false claims in both its initial grant application and all subsequent annual renewal applications.

- The case was tried to a jury for eight days in 2010

- Jury found liability based on the renewal applications for the third, fourth, and fifth years of the grant

- Damages added up to $1,519,596!!!
Lessons to be learned

- Need to constantly monitor program activities to see if there is a deviation from the original application versus what is really happening
- Competing renewals and progress reports should be carefully reviewed prior to submission for deviations from the original application
- Deviations need to be disclosed. Talk to your SPA Project Officer first, and plan on a subsequent conversation with the NIH Program Official with SPA
- Obtain Prior Approval from NIH before any anticipated change in scope, at least 30 days in advance of the change

What to do if someone raises a concern to you

- You (and the PI) may not retaliate against them
  - Means they must be treated the same way as any other similarly situated employee/trainee
- “The University does not tolerate retaliation against individuals who report compliance concerns in good faith.”
- Seek guidance from:
  - Office of General Council (OGC)
  - Office of Research Compliance & Training (ORCT)
  - Academic Affairs
Conflict of Interest issues

• New Public Health Service regulation on Financial Conflicts of Interest and research, effective Aug. 24, 2012

• NIH: “The regulation explicitly applies to research authorized under the PHS Act or other statutory authority, such as a research grant, career development grant, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.”

Conflict of Interest issues

• Institutions: The institution must review disclosures of significant financial interests by “investigators” on the grant to see if the disclosed interests “relate” to the grant.
  ▫ For a new award or continuation, potential COI issues must be resolved before funds can be expended.
  ▫ During the funding period, newly disclosed potential COI issues (e.g., newly acquired by existing investigator, or held by a newly added investigator) must be addressed within 60 days.

• Researchers: All “investigators” must:
  ▫ Have a current annual disclosure form on file (before proposal/progress report submission)
  ▫ Submit an updated disclosure within 30 days of acquiring new significant financial interest
  ▫ Complete online COI training (before engaging in the research)
Conflict of Interest issues

• Who is an “investigator” under the regulation?

“[T]he project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.”

Contact us!

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