UNM HEALTH SCIENCES | UNM HEALTH

Contract & Grant Accounting Update

February 17, 2023

2023 Quarterly C&G Compliance Trainings

- February 24, 2023, 9-10 a.m.
- This meeting with focus on Business Purpose Documentation – Allowability and Allocability on Sponsored Projects
- Sign up - **https://app.smartsheet.com/b/form/8c55015bca4941fa853ceae7aed20af5**

NIH Updates - Stipends

Stipends

Effective with all Kirschstein-NRSA awards made on or after October 1, 2022, the following annual stipend levels apply to all individuals receiving support through institutional research training grants or individual fellowships.

Undergraduates: For institutional training grants supporting undergraduate trainees (T34, TL4), appointments for undergraduate candidates will continue to be made by distinct categories (i.e., Freshmen/Sophomores and Juniors/Seniors), but the stipend levels for the categories will be the same:

Career Level	Stipend for FY 2023	Monthly Stipend
Freshmen/Sophomores/Juniors /Seniors	$14,340	$1,195

Predoctoral Trainees and Fellows: For institutional training grants (T32, T35, T90, TL1) and individual fellowships (F30, F31), one stipend level is used for all predoctoral candidates, regardless of the level of experience.

Career Level	Years of Experience	Stipend for FY 2023	Monthly Stipend
Predoctoral	All	$27,144	$2,262

Postdoctoral Trainees and Fellows: For institutional training grants (T32, T90, TL1) and individual fellowships (F32), the stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the trainee or fellow must be paid at that level for the entire grant year. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.

Career Level	Years of Experience	Stipend for FY 2023	Monthly Stipend
Postdoctoral	0	$56,484	$4,707
Postdoctoral	1	$56,880	$4,740
Postdoctoral	2	$57,300	$4,775
Postdoctoral	3	$59,592	$4,966
Postdoctoral	4	$61,572	$5,131
Postdoctoral	5	$63,852	$5,321
Postdoctoral	6	$66,228	$5,519
Postdoctoral	7 or More	$68,604	$5,717

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-076.html

NIH Updates – Salary Cap

- January 1, 2023 through September 30, 2023 - $212,100

- For issued awards that were restricted to Executive Level II, including competing awards already issued in FY 2023, if adequate funds are available in active awards, and if the salary cap increase is consistent with the institutional base salary, recipients may rebudget funds to accommodate the current Executive Level II salary level.

https://grants.nih.gov/grants/policy/salcap_summary.htm
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-056.html

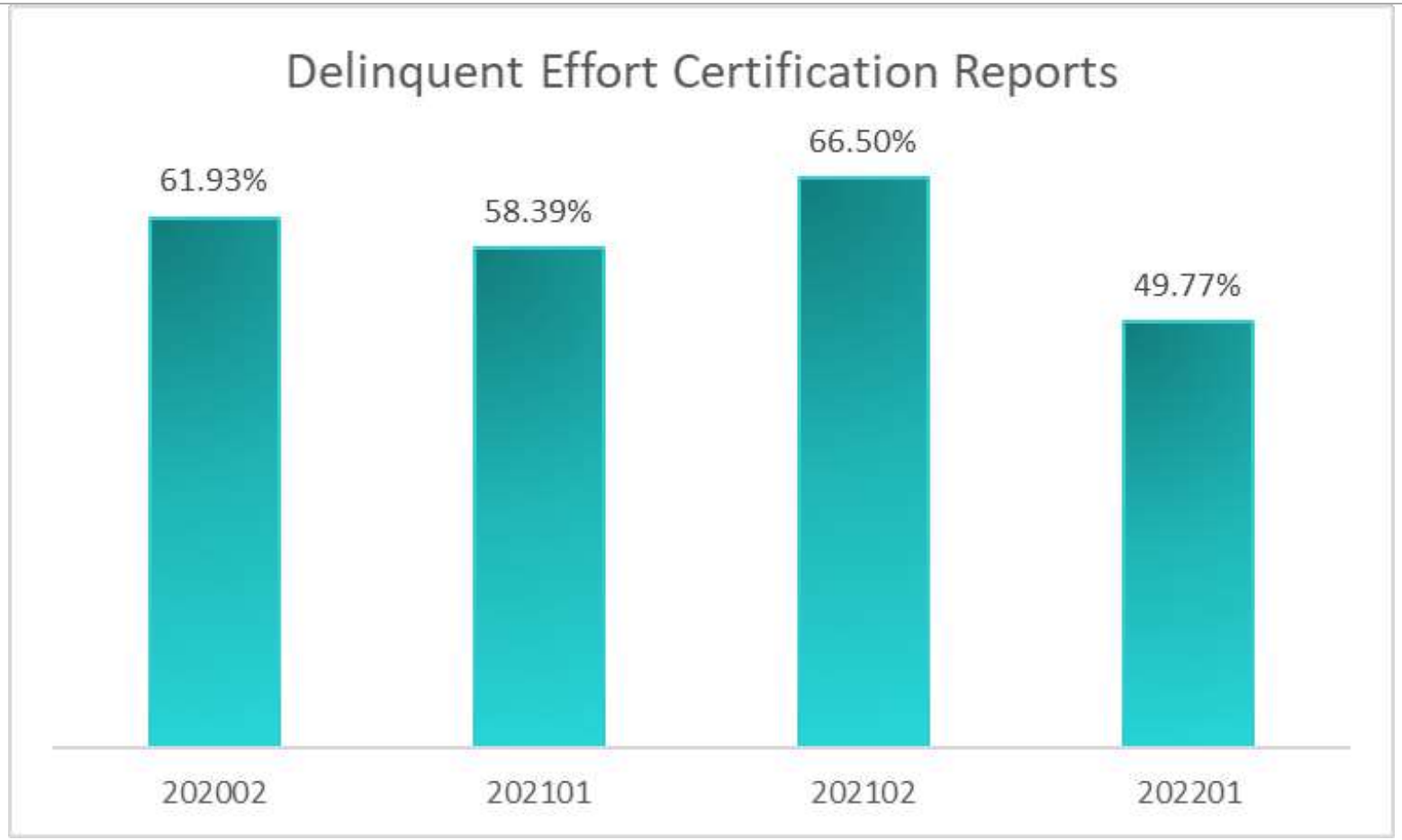
Signature Authorization Forms

- The current Signature Authorization Form used to declare members of a project who are authorized signatories for various aspects of the project is being transitioned to Click.

- We will add PI attestation to the - Submit For Department Review Endorsements

- A new activity will be added to all Click records for OEI

Effort Certification Update



- 202202 EC Period is not currently scheduled to kick off

Effort Certification Update

- Development of a new process to certify personnel and fringe allocations to sponsored project is underway.
- The new Payroll Certification will focus on certification of payroll charges at the fund level. (Not by individual)
- This process will be completed at the end of the budget period, or the anniversary of the budget period end date annually.
- Need departmental volunteers for testing.
- Estimated roll out of the new process will be Spring of 2023.

Questions

Research Administration Forum & Training Session

Sponsored Projects Office
February 17, 2023

SPO Reminder

- DHHS Salary Cap has increased to $212,100
  - IBWs have been updated and posted on our website
  - Please download a new copy of the IBW from our website: https://hsc.unm.edu/about/finance/sponsored-projects/forms-documents/
  - All forms, including IBW, are frequently updated and are announced in our weekly newsletter

SPO Reminder

- New NIH Biosketch Format required as of January 25, 2022
  - We are seeing quite a few grants and progress reports with the old forms
  - Latest NIH Biosketch template available on our website

SPO Reminder

- Award and/or Important Notices (Early Terminations, No-Cost Extensions, Award Notices, etc.) sent to the department/PI should be forwarded to the HSC-Preaward@salud.unm.edu as soon as possible
  - If notices are not addressed or processed promptly, it may cause financial loss to the department

SPO Reminder

- Cost Share, F&A Waivers and Timeline Waivers are all processed through SmartSheet
  - Request forms can be accessed through the SPO Department SmartSheet Dashboard, along with detailed instructions on how to submit these requests: https://hsc.unm.edu/about/finance/sponsored-projects/

SPO Reminder

- NIH Data Management and Sharing Plan must be submitted as part of the funding application for all new and competing proposals/renewals as of January 25, 2023
  - Lori Sloane, HSLIC Data Manager, can provide guidance and assistance in development of these plans

SPO Reminder

- Mass Salary Updates are due to SPO today by 5pm
- SPO RAFT Topics link added in our weekly newsletter
  - Submit your ideas or questions that you would like us to present

SPO Reminder

- Click Agreements/Outgoing Subawards
  - When you receive a Click notification to enter your subaward, please do this as quickly as possible since it initiates the outgoing subaward process

SPO Reminder

- When submitting an amendment, you will need to enter this off of your parent record
  - If you do not have access, please email your SPO contact for access
- If you have questions and need assistance submitting a subaward request, please contact Sean Gonzales, Marisa Sanchez, Madison Dow, Dean VonFox or Susan De Los Santos for assistance

SPO Reminder

- Next RAFT Session Topic – outgoing subaward process
- Effective March 1, 2023, new fees for external IRB Reviews for Pharma Clinical Trials
  - IRB will charge $2,500 for new protocols and $500 for modifications for all external IRB reviews for Pharma Clinical Trials

SPO Reminder

- 2023 Mentor/Mentee Health Sciences Mentorship Program
  - Applications will be accepted from March 13 – April 14
  - All staff are encouraged to apply

Questions

Reportable Events

What to report, what not to report, and the difference between Noncompliance and Unanticipated Problems

Unanticipated Problem

2009 GUIDANCE

HTTP://WWW.FDA.GOV/DOWNLOADS/REGULATORYINFORMATION/GUIDANCES/UCM126572.PDF

- FDA Guidance – An *Adverse Event* that occurs *during the conduct of the study* that is:
  - Unexpected;
  - Serious; AND
  - May Have Implications for the Conduct of the Study.
    - May results in safety related revision to the protocol, IB, monitoring requirements, Informed Consent Document, and/or Inclusion/Exclusion Criteria.

2007 GUIDANCE

HTTP://WWW.HHS.GOV/OHRP/POLICY/ADVEVNTGUID.HTML

- OHRP Guidance – Any *Incidence*, *Experience*, or *Outcome* that is:
  - Unanticipated;
  - Related or Possibly Related to participation in the Research; AND
  - Suggests that Human Subjects or Others are at Increased Risk for Harm.

Noncompliance

SERIOUS

- Serious noncompliance is any noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data and research. Apparent serious noncompliance describes an event that appears to constitute serious noncompliance, and so requires reporting to an appropriate IRB for consideration, but the IRB has not yet made a formal assessment of the event.

CONTINUING

- Continuing noncompliance is a pattern of repeated noncompliance which continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe. Apparent continuing noncompliance describes an event(s) that appears to constitute continuing noncompliance, and so requires reporting to an appropriate IRB for consideration, but the IRB has not yet made a formal assessment of the event.

UPIRHSO Vs. Noncompliance

- UPIRHSO
  - The protocol was followed.
  - Event represents new information that will require modification of the study design (updated IB, IC risk, protocol modification), and was not anticipated when the study was designed.
  - NOT the result of negligence or noncompliance with the protocol*.

- Noncompliance
  - The protocol was NOT followed.
  - Event does NOT present new information that will require modification of the study design.
  - Generally the result of negligence*.
  - Can be intentional or unintentional.

Responsibilities of the IRB

FDA

21 CFR 56.108(b)(2)

- In order to fulfill the requirements of these regulations, each IRB shall:

…(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others;

OHRP

45 CFR 46.103(b)(5)

- Assurances applicable to federally supported or conducted research shall at a minimum include:

…(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

Example UP Scenarios Provided by FDA

- A single occurrence of a serious, unexpected event that is uncommon and strongly associated with drug exposure.
- A single occurrence, or more often a small number of occurrences, of a serious, unexpected event that is not commonly associated with drug exposure, but uncommon in the study population.
- Multiple occurrences of an AE that, based on an aggregate analysis, is determined to be an unanticipated problem. There should be a determination that the series of AEs represents a signal that the AEs were not just isolated occurrences and involve risk to human subjects (e.g., a comparison of rates across treatment groups reveals higher rate in the drug treatment arm versus a control). **We recommend that a summary and analyses supporting the determination accompany the report.**

Example UP Scenarios Provided by FDA, Cont.

- An AE that is described or addressed in the investigator's brochure, protocol, or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations. **We recommend that a discussion of the divergence from the expected specificity or severity accompany the report.**
- A serious AE that is described or addressed in the investigator's brochure, protocol, or informed consent documents, but for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence (ordinarily, reporting would only be triggered if there were a credible baseline rate for comparison). **We recommend that a discussion of the divergence from the expected rate accompany the report.**
- Any other AE or safety finding (e.g., based on animal or epidemiologic data) that would cause the sponsor to modify the investigator's brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects. **We recommend that an explanation of the conclusion accompany the report.**

Examples of serious or continuing noncompliance

- Conducting non-exempt human subjects research without IRB approval.
- Conducting human subjects research without obtaining informed consent, when a waiver of informed consent was not approved by an IRB.
- Implementing a significant modification to IRB-approved research not needed to eliminate an immediate hazard without prior IRB approval.
- Failing to adhere to eligibility criteria, such that subjects were placed at increased risk of harm or their rights or welfare were adversely affected.
- Failing to perform safety assessments within protocol-specific time frames, such that subjects were placed at increased risk of harm or their rights or welfare were adversely affected.
- Failing to communicate new information to research subjects about study participation relevant to subject rights or welfare, such as new risks that could affect subjects' willingness to participate in the study.
- Violating any conditions of IRB approval that could adversely affect subject rights or welfare.

Potential UPIRHSOs, How Would you Vote?

- A staff member at a site manipulates data to ensure that a subject, who would not have otherwise been included in the study, meets the inclusion criteria per the protocol and is enrolled.
- An otherwise healthy subject develops Stevens-Johnson syndrome while participating in a phase 1 drug trial.
- A group of subjects experience spontaneous tendon rupture while participating in an allergy study.
- A sponsor for a renal cancer therapy study reports to the IRB that during review of aggregate data for the study, it was found that 400 out of 1000 subjects treated with the IP developed advanced renal cancer. 70 died.
- The Investigator's Brochure for an experimental drug lists hepatic injury as a potential risk. During participation in the study, a subject develops hepatic necrosis.
- A staff member at a site inadvertently injects a non-study patient with study drug instead of an influenza vaccination.
- A sponsor reports to the IRB that during review of aggregate data for a diabetes study, it was found that 21% of study subjects developed GI bleeding. The IB lists GI bleeding as a risk, with a 7% rate of occurrence.