NIH Regional Notes – Hot Topics

NIH Agenda and Slides

- 40 powerpoints over 2 days
- Recap a few hot topic updates and reoccurring items – please share your knowledge and experiences over the next hour
- NIH material will be distributed via email after the session
- If you have a question about a particular session, contact Susan, Chris or Marcel and we can find someone who attended the session to check their notes and help answer your question

ORCID Requirement and effective dates

- ORCID overview
- Important Dates:
  - October 2019:
    - T15, T32, T34, T35, T37, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, RL9
  - January 25, 2020
    - F05, F30, F31, F32, F33, F37, F38, F99/K00, FI2, K01, K02, K05, K07, K08, K18, K22, K23, K24,
      K25, K26, K38, K43, K76, K99/R00
- eRA system validations will check whether applicants have ORCID iDs and applications will not be accepted unless an ORCID iD is linked to the PD/PI's eRA Commons Personal Profile.

Career Development Awards (K award)

- To provide individual and institutional research training opportunities (including international) to trainees at the undergraduate, graduate, and postdoctoral levels.
  - https://researchtraining.nih.gov/programs/career-development
- Effort requirements – 75%→50%
  - https://nexus.od.nih.gov/all/2017/10/11/clarifying-percent-effort-and-support-for-career-development-k-awardees/
  - *Effort should be reviewed on semi annual effort reports against program requirements. SPCS annual review.*
- Discussion at NIH about a possible exception to 75% for clinical scientists

Post Award Reporting (RPPR)

- RPPR – Annual Research Performance Progress Report
- FRPPR - Final Research Performance Progress Report
  - Due within 120 days after the project period end date.
    - Unilateral closeout at 180!
  - Submit through eRA Commons
  - Project Outcomes should be written for lay public
- Analytics RPPR dashboard
- Problematic review points
  - Effort
  - Publications
  - Final reports for PI's who have left institution
  - Foreign component

xTrain

- xTrain is an eRA Commons module that allows program directors/principal investigators, university administrators, and trainees electronically prepare and submit PHS 2271 Statement of Appointment Forms and PHS 416-7 Termination Notices associated with institutional research training grants, institutional career development awards, individual fellowships, and research education awards.
- Although xTrain does not support the electronic submission of the PHS 6031 Payback Agreement, it makes it available for downloading/printing, with instructions for signing and submitting the agreement through postal mail. xTrain populates the basic information before printing.

Early Stage Investigator

- ESI definition now includes wider range of clinical training
- Can apply for extension of ESI status via a new portal in eRA Commons
  - Extensions are equal to time lost while away from research; automatic 1 year for females giving birth; spouses of females giving birth can receive extensions but need to submit request

Continuing Resolution/Fed Shutdown

- While under the Continuing Resolution, the official budget for the NIH is not yet released. So awards issued during this time are typically reduced to begin with, and are then increased later after the budget has been released.
  - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-003.html
- 11/19: House passed short term appropriations extension through 12/20. Onto Senate and President's office.
- 12/20: More uncertainty

NIH GPS

- What is the NIH GPS?
- NIH issues the GPS at the turn of the new fiscal year, which is Oct 1. Significant changes are (these will be published):
    - Human fetal tissue requirements
    - Other support language
    - ORCID requirements
    - Research misconduct language
    - SBIR.STTR level caps, IP, funding levels, and life cycle certifications.

Other support

- Foreign components
- Other changes

DUNS number transition

- NIH is transitioning from DUNS number to UEI (government-owned unique entity identifier) this will likely happen in Dec 2020. Any organization that currently has a DUNS number will automatically receive a new UEI.

Grant Transfers out/Relinquishments

- Unit and College determine whether to allow transfer or propose a replacement PI
- Grant Transfer Memo
  - Name of new institution
  - Effective date of xfr
  - Estimated unspent funds
  - Equipment
  - Dept/College approval
- Final progress report and financial report before transfer

eRA Commons Updates

- User interface changes
- 2 factor authorization through login.gov

Patent/invention reports

- Through NIH Commons
- PI initiate form, SPCS reviews and compares to Tech Launch Arizona records
- SPCS correspondence with PI and TLA for discrepancies
- Non-NIH agencies
  - SPCS fills out form with TLA data and sends to PI/dept for confirmation
  - SPCS submits

Notice of Awards

- Goal is for all HHS agencies to share a common NOA template on October 2020

Research/Financial Misconduct

RII - Scott Pryor
Interim Research Integrity Officer
Email: RIO@email.arizona.edu
Call Us: 520-621-0598

SPCS - Financial Compliance
Tara Gonzales
Tabatha Holan
Email: financialcompliance@email.arizona.edu
Call Us: 520-626-600

ETHICS & COMPLIANCE
HOTLINE
866-364-1908
hotline.arizona.edu

SBIR/STTR

- SBIR
- The NIH SBIR program funds early stage small businesses that are seeking to commercialize innovative biomedical technologies. This competitive program helps small businesses participate in federal research and development, develop life-saving technologies, and create jobs.
- STTR
- The NIH STTR program is similar to the NIH SBIR program, but requires that the small business formally collaborate with a research institution in Phase I and Phase II. Learn more about the NIH SBIR and STTR programs, including their critical differences.

Carryover

- When prior approval required, a bona fide need must exist for NIH to approve
- Prior approval module
- What is required – budget that matches unspent balance from FFR, justification, etc

NIH Rebudgeting

- 25% rebudgeting is a litmus test of scope change, not absolute
- The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.
- $25,000 purchase of equipment
- In these instances, document that change of scope is not occuring

NIH RePORT

- search for info on NIH funding by institution, principal investigator, and more;
- identify NIH funded projects and explain how this information can be helpful;
- find which institutes support research like yours
- identify study sections that review applications like yours

Training Grants and Fellowships

- Training Grants
  - Proper stipend levels
  - Annual financial reporting and including appointment obligations in correct period
- Fellowships
  - Stipends, not salary
  - Incidental additional employment that does not affect appointment

Other notes? NIH Q&A