Advanced Administrative Topics: Post-Award

NIH Virtual Seminar on Program Funding and Grants Administration

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Presenters

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Quick logistics...

• You are all muted with no video
• You are welcome to put questions in the Q&A however...
  • This session relies heavily on case studies – real-life examples of issues that have occurred
  • We will be trying to cover a number of topics – directly and indirectly - throughout
  • We will most likely not have ample time to cover Q&A but we have some plans in the presentation...
  • You are welcome to enter questions in the chat – NIH Grants Officials will do their best to respond throughout!
  • Head to the NIH and/or individual IC booths to discussion your questions further!
What period of time is considered “Post Award?”

- Any time after the initial competing award is made
- Annual reports are considered a post-award period
- This is the time where much of the “action” happens!
NIH Perspective... a Few Things to Remember

• We must support federal policy, to enforce applicable laws, cost principles and administrative requirements
• We must act as stewards of federal funds
• Some IC’s have a relatively broad mission; others are (by comparison) relatively narrow
• Larger IC’s have more funds which can mean more flexibilities
• Not all IC’s fund the same grant mechanisms
• The correct answer often really is...“it depends”
NIH Perspective When Considering Challenging Complex Situations During Post-Award

- Have we "listened" enough to really understand all the issues and objectives of the situation?
- What is in the best interest of the science?
- What will best serve the investment of the taxpayer in the project?
- Do we have the necessary funds to support the proposed arrangements?
- How would this play if presented on the evening news or the front page of ......?
- Is there an opportunity for a 'win/win'?
- Can we get to a “yes”
Issues and Scenarios for Today’s Discussion

- Change in Scope
- NIH’s Human Subjects System (HSS) & you!
- Effort Changes
- Scientific/budgetary overlap
- Changes and delays in the research and large balances
The Basics – What is Scope?

• Ummm...maybe not what we have in mind here...
Scope in NIH Grants

- Scope is the direction, aims, objectives, purposes, or type of research training, identified in the project
- Stated/identified in the original, peer-reviewed application
- Is the basis for which the budget is requested and awarded
- Unless negotiated otherwise, is approved with the award
Change in Scope and Prior Approval

• As stated in the NIH Grants Policy Statement, section 8.1.2.5, a change in scope requires NIH prior approval

  In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope.

• It is the grant recipient’s responsibility to initially assess whether a plan will result in a change in scope that requires approval
What constitutes a change in scope?

- There are a number of potential indicators of a change in scope which are:
  - Change in the specific aims approved at the time of award
  - Substitution of one animal model for another
  - Change from the approved use of live vertebrate animals
  - Change from the approved involvement of human subjects that would result in an increased risk (which has a number of situations!)
  - Shift of the research emphasis from one disease area to another
  - A clinical hold by FDA under a study involving an IND or an IDE
  - Application of a new technology
  - Transfer of the performance of substantive programmatic work to a third party
  - Change in personnel
  - Significant rebudgeting
  - Incurrence of research patient costs that were not previously approved by NIH
  - Purchase of equipment exceeding $25K
More on “indicators”

• Change in scope may not be cut and dried
• Contact NIH IC Officials to discuss!
Who doesn’t love Human Subjects reporting???
One of the major issues with human subjects reporting that occurs on annual progress reports and drives NIH officials a bit batty... What is it?

A – IRB approval date is not included on the face page
B – The Human Subjects System (HSS) and CT.gov records do not match
C – Inclusion table is not included
D – Excessive use of memes and gifs (or is that just this presentation?)

ENTER IN THE CHAT!
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And the Answer is...
How to help make HSS and you easier...

- Check your records!
  - Ensure everything is matching up
- NIH has a great user guide out there!
  - [https://era.nih.gov/files/HSS_user_guide.pdf](https://era.nih.gov/files/HSS_user_guide.pdf)
- Best advice...remember to populate HSS with what you have in CT.gov before you submit the RPPR (see p.17 of the User Guide)
- IMPORTANT!!!! It is critical that the registration in CT.gov is done in compliance with the regulations!
A twist on a transfer situation...

- How about this...
  - Grant transferred in March 2019
  - Previous grant recipient relinquished $185K
  - Funds were moved from the old to the new recipient via Notices of Award issued by the IC
Transfer situation...(cont.)

- The previous recipient contacts the NIH IC saying they relinquished too much!
  - Rather than $185K being relinquished it should have been $150K
- What can the awarding IC do?
  A – Tell the previous recipient too bad so sad...
  B – Restore the funds by moving money back to the prev. recipient from the new recipient
  C – Start a gofundme page for the previous recipient
  D – It depends

ENTER IN THE CHAT!
And the Answer is...

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D – It depends
Why “It Depends”

- Timing matters a lot in these situations
  - If it is reasonably close (within a month or two) to the time of the transfer, a negotiation can be worked out with all parties
  - If it is too far removed (multiple months), it is highly likely that the new recipient already spent the funds
- Additionally, depending on the timing, it could bring into question the previous recipient’s financial management standards
• Let’s see if we have any questions in the chat...

• For the next 5 minutes, we will address as many questions as we can...

• If they are too involved, we may need to skip it. However, please feel free to contact us via e-mail (or attend one of the many Meet the Expert sessions!)
Change in Effort for Key Personnel

• The competing R01 application lists the PI with a 2.4 calendar month effort.

• PI’s effort on the subsequent RPPRs (as shown on the participant table):
  • Year 2 = 2.0 CM
  • Year 3 = 1.6

• TRUE OR FALSE – The recipient did NOT need to request prior approval for a reduction in effort of more than 25%?
  ENTER IN THE CHAT!
And the Answer is... FALSE
Why false?

- In this case, the approved level is the competing year.
- Year 2’s RPPR is not a “resetting” of the approved level.
  - Decreasing to 2.0 CM does not need prior approval – less than a 25% reduction.
- Year 3 however IS a greater than 25% reduction – goes from 2.4 CM in the competing year to 1.6 CM in year 3.
What would the NIH IC do?

- Contact the award recipient organization to confirm what is being reported
- If the report is accurate, NIH would address the retroactive request – Grants Management and Program would need an official request and would consider the change
- Grants Management would discuss the recipient organization’s policies/procedures for evaluating effort
You ready for something really good??

- Competing R01 is funded in Fiscal Year 2020 for Dr. Slick.
- The Year 2 RPPR comes in...the Other Support is showing some interesting items...
  - A previously unreported DOD grant that was funded in FY2020 is listed showing the same title as a P20 which was also funded in FY2020
  - Even better – there may be potential overlap between all three funded applications (R01, DOD and P20)
Oh wait...there is more...

• NIH Policy became involved in the conversation – Other Support is no joke!
• These grants crossed Awarding Agencies and Programs...
• Let’s sit back and hear what these conversations were like between the NIH Grants Management and Program Official...
Where did this one end up?

- NIH Program Officials conducted a thorough side-by-side analysis of all of the projects
  - A lot of exchanges occurred via e-mail between the NIH and the grant recipient.
- The recipient previously negotiated with the DOD to reduce the scope of that award to resolve the overlap with the two NIH grants
  - NIH obtained a copy of that negotiation
- However, there was still existing overlap between the two NIH grants – the R01 and P20
- The NIH IC decided to:
  - Fund the P20 per normal – it is a shorter project period and a multi-project grant
  - Delay funding on the R01 – an extension (for 3 months) was provided to allow the recipient time to address the overlap with the IC. A plan will need to be submitted by the deadline or the grant will be ended.
Important to note...

- Even with a complete mess, the NIH IC was still seeking to find a win/win!
Changes, Delays and Balances

Biomedical research is does not always proceed as planned

• Projects are delayed
• Balances accrue in the project
• Progress points the research in a different direction
• Changes in scope require prior approval per NIH GPS 8.2.1.5
Unanticipated Events
(aka Stuff Happens)

Most problems start out small....

Only when unaddressed and/or left unchecked can they grow into ugly monsters.

Can anyone think of some widespread something that happened in 2020 that may have caused issues??? We will give you .5 seconds!
Progress Issues

• Here is the situation...
• 5 Year grant
• No concerns with years 1 & 2...the accrual portion of the grant is set to begin in year 3
• Year 3’s progress report arrives...the Program Official notes that thus far, only 10 of the planned 100 patients have been accrued and a significant balance is reported
• Accrual was supposed to be completed by the end of year 4, but the RPPR indicates that the timeline is now showing completion of the accrual in year 5.
Let’s listen to a discussion between Grants Management and Program...
Progress Issues?
What can be done?

• First, get in touch with NIH – the sooner the better!
• There are options that can be considered:
  • Mid project period extensions
  • Interim reporting/milestones
  • Restructuring the budgets (accounting for the new timeline)
  • Worst case – phasing out the grant
• Future year funds in a grant are not guaranteed!
• However, NIH is here to help in any way we can.
Resources...

I. **Your Organization**
   - Sponsored Programs Office
   - Accounting Office
   - Internal Auditor
   - IRBs
   - IACUCs

II. **NIH**
   - Grants Management Specialist
   - Program Administrator

III. **HHS**
    - Office for Human Research Protections (OHRP)
Resources for Compliance

Tips, methods, what to do? So many resources, only a select few are named here.

• NIH Grants Compliance and Oversight – website has compendium of observations, and presentations
  http://grants.nih.gov/grants/compliance/compliance.htm

• NIH Grants Compliance Inbox
  grantscompliance@mail.nih.gov

• NIH Outreach Activities
  http://grants.nih.gov/grants/outreach.htm
Select Resources at the NIH

Grants Management Specialist on the Notice of Award
- If unknown, contact Chief GMO of IC:
  http://grants.nih.gov/grants/stafflist_gmos.htm

Program Official on the Notice of Award

Office of Extramural Research: http://grants.nih.gov/grants/oer.htm


NIH Grants Policy Inbox (policy questions not specific to the NoA):
  grantspolicy@mail.nih.gov

Division of Financial Advisory Services: http://oamp.od.nih.gov/dfas
Questions?? Feel free to contact us via e-mail:

Crystal Wolfrey -
crystal.wolfrey@nih.gov

Sean Hine –
sean.hine@nih.gov
We have a few minutes...

• Bring on the questions!!
• Enter your questions in the Q&A and we will address what we can!