Advanced Administrative Topics: Pre-Award

NIH Virtual Seminar on Program Funding and Grants Administration

November 1, 2021
Presenters

Crystal Wolfrey
Chief Grants Management Officer
National Cancer Institute

Sean Hine
Branch Chief
National Cancer Institute
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 discuss your questions further!
NIH Perspective... a Few Things to Remember

• Must support federal policy, to enforce applicable laws, cost principles and administrative requirements
• 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
NIH Perspective: Additional Considerations

Additional considerations we consider in making decisions in 'tough' situations:

• Will an action create a precedent which will limit flexibility in the future?
• Is an action consistent with NIH, HHS or other Federal policy?
• How would this play if presented on the evening news or the front page of ......?
Questions We Ask When Considering Challenging Complex Situations

• What is in the best interest of the science?
• What is in the best interest of the recipient?
• What is in the best interests of the PI(s)?
• Is there an opportunity for a ‘win/win’?
• Can we get to a “yes?”
Situations we will explore involving...

- Human Subjects – Single IRB
- Changes prior to award
- Understanding the FOA before Submission
- Submitting a competitive renewal
- Brand new applicants to NIH...what to expect!
Human Subjects – Single IRB

Today, a Grants Management Specialist is reviewing a competing R01 which has 3 performance sites and human subjects research involved as a multi-site study. How many performance sites will need to provide certification of IRB approval to NIH for the award to be issued?

0
1
2
3

ENTER IN THE CHAT!
Drumroll please....

• The answer is 1!
• This is due to the single IRB policy – one IRB serving as the IRB of record for a multi-site study.

Only one site is conducting multiple, unique studies? Each of the participating sites are conducting unique studies? The answer change if...
Human Subjects - sIRB

- See the NIH’s sIRB webpage which includes all kinds of information:
The Research Plan for an application describes pre-clinical research that must be completed before the human subject’s research can be fully planned and described. What is this called? **ENTER IN THE CHAT**

A - Delayed Start of Human Subjects Research
B - Delayed Onset of Human Subjects Research
C - Nuts and the application should not be submitted
And the Answer is...

- The Research Plan for an application describes pre-clinical research that must be completed before the human subject’s research can be fully planned and described. What is this called?

  A - Delayed Start of Human Subjects Research

  B - Delayed Onset of Human Subjects Research

  C - Nuts and the application should not be submitted
Can an Award be Issued?

- While the PI is conducting the pre-clinical studies, NIH will issue the award indicating that no human subject activities should be initiated in the study until their involvement can be fully described.
- This restriction will allow the release of award funds and allow the PI to start working without the need for an FWA or IRB review and approval.
- Once the PI is prepared to begin research involving human subjects, the PI must submit to the IC the completed Protection of Human Subjects section, the FWA number, the IRB approval date and documentation of human subjects education by the key personnel.
How is this award different from delayed start of HS research?

- Because the application did not include definite plans for human subjects research – NIH must review and approve those plans post award.
- Awardees must submit a new or revised human subjects section that clearly describes risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities.
- The initiation of the human subjects research requires NIH prior approval – if not approved the award would require renegotiation or phase-out.
- Not just submission of the IRB when it has been approved
SWITCHING GEARS
Changes Prior to Award

- There are approximately nine months between the submission of an application and the NIH making an award.
- In those nine months – things can change – PI’s move, get new jobs, plans change.
Close your eyes...and imagine the following...

- Don’t fall asleep on us...yet!
Here is the situation...

- PI submits a competing application to an R01 Request for Application from Exemplary University in New Jersey...
- Six months later, the PI lands a dandy job on the West Coast...
- The PI tells all in his lab about the move and the grant is going with them!
- The PI contacts NIH’s Program Official...let’s listen in on that call...
Can a PI move prior to making a competing award...

Sure-ish...

• Typically, it is possible to change a grant recipient prior to award
• Important to understand what is allowed per the funding opportunity announcement (FOA)
• Also, important to consider what the grant will be doing!
• It is important to contact NIH Program and Grants Management Officials early in the process
• The applicant MUST relinquish their interest
• A transfer application MUST be submitted
What if the move is outside the U.S.?

• Possible... but it is complicated
  • Needs to be permitted by the Funding Opportunity Announcement
  • Grant still needs to be relinquished by the original applicant
  • Prior approval requirement – change of recipient organization AND adding a foreign component
  • Need to consider the scope of the originally submitted application
  • Must go to the IC’s Council for review and approval
• It can take a while so sooner it is known, the better to start discussing
• 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!)
Let’s get into some details...

• Application is submitted in response to an NIH Funding Opportunity Announcement (FOA) with very specific requirements
  • Example – NCI’s Outstanding Investigator Award

• Application is reviewed and scores well – meets the IC’s funding policies for the program

• The application is being reviewed by the Grants Management Specialist...who reaches out to the AOR to discuss.
SO IT BEGINS

THE GREATEST NEGOTIATION OF OUR TIME
What did we learn from this??

- Many FOAs have very specific requirements for the award – things like a requirement to relinquish other funding or requirements for time and effort of the investigator, limitations on foreign components, requirements for attendance at meetings, etc.
- Cooperative Agreements also have special terms and conditions
- The IC will not be able to ignore or waive those requirements at the time of award
A recipient has received an award to support their last year of the competitive segment in FY2021 – start date was December 1\textsuperscript{st}. However, they are anxious to not have a gap in funding...So, can they submit a competing renewal early knowing that if it reviews well it would be in the wrong fiscal year?

Enter Yes or No in the Chat...
And the Answer is...

• YES...But...there are somethings to consider...
• Funding a Type 2 in the same year the Type 5 was funded would be funding more than 12 months from one appropriation – not generally allowed.
• Typically, the IC should allow the support for the type 5 to continue and consider the type 2 in the following Fiscal Year.
• But as we said at the outset – not all ICs work the same – so...
• The applicant should contact the IC to discuss the potential impact of submitting a competing renewal early.
What if you are a new NIH applicant?

- There is a LOT to know and consider...
  - Need to know a lot of different things...DUNS, SAM, eRA, FWAs, Animal Assurances, IRB, IACUC, and on, and on, and on...
  - All of the policies that may potentially apply to you
  - Reporting requirements IF you get an award
Purely Hypothetical Situation...;)

- Applicant is a small-business concern
- Will be applying to the NIH Small Business Program
- Brand new company got up and running in 2020 – but feeling good about the success and the research they are proposing.
Moving along...

- Application is reviewed and receives a good score!
- Meets the IC’s funding policy for SBIRs
- No issues with the IC’s council review
The application now arrives to the Grants Management Specialist...

• A Grants Management Specialist is responsible for evaluating the applicant’s ability to manage the Federal award.

• New NIH applicants and awardees do not have any track record with NIH therefore, they inherently have higher risk to the Federal Government as award recipients.

• Let’s listen in on the call that takes place between the Specialist and the Authorized Organizational Official...
How does this get resolved...

• Requires a LOT of communication between the NIH Officials (Program and Grants Management) and the AOR

• The applicant putting together policies and procedures that can be followed in their management of the award
  • NIH does not need to “approve” the documents – but they do need to available if requested

• Financials may be limited or not available at all – that is ok!

• NIH may consider special award conditions to mitigate the risk for all involved
New Applicant – Additional Considerations

• NIH is required to assess not only the merit of the application but also to consider the ability of the applicant to manage the grant funds

• Main items that would be considered:
  • Financial management standards – policies, audits
  • Will request financial records to assess capital ratio
  • Documentation on the organizational structure
  • Other policies and procedures that may be dictated based on the nature of the grant application

• All other requirements for NIH applications would still apply
Take comfort though...

- NIH IC Officials are here to help!
  - There are a lot of resources available
  - Technical assistance site visits (in-person or virtual) can be conducted
  - Templates are out there!
- We want to get to a win-win for all involved!
Resources...

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

II. NIH
- Grants Management Specialist
- Program Administrator
- Office of Laboratory Animal Welfare (OLAW)
  http://grants.nih.gov/grants/olaw/olaw.htm
- Grants Policy & Guidance
  http://grants.nih.gov/grants/policy/policy.htm

III. DHHS
- 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 or in eRA; as backup contact the 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 Information:
http://grants.nih.gov/grants/giwelcome.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
Haven’t had enough of us??

• Join us tomorrow (11/2) at 4:00 as we conduct an Advance Administrative Topics: Post-Award
• Yep...that was just a shameless plug 😊
We have a few minutes…

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