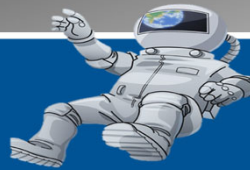


Houston, This (NIH) Grant's in Trouble



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Thinking Like a Fed

- Consider NIH perspective when considering challenging or complex situations
- First, remember NIH is a Federal agency
 - Supports Federal policy (must enforce applicable laws, cost principles and administrative requirements)
 - Supports President's initiatives and policies



NIH Perspectives When Considering Challenging, Complex Situations

Factors NIH Institutes and Centers (IC's) consider:

- Do we really understand all the issues and objectives of the situation (have we listened and asked enough questions)?
- What is best from a scientific or programmatic perspective (how will this impact the scope of the project)?
- Is the action consistent with NIH, HHS or other Federal policy?



NIH Perspectives When Considering Challenging, Complex Situations

- Will the action create issues for protection of human subjects?
- What best serves the investment of the taxpayer in the project?
- How would this play if presented on the evening news or the front page of ...?



NIH Perspectives: Secondary Considerations

- What is in the best interests of the institution?
- What is in the best interest of the PI?
- Is there an opportunity for a “win/win”?

Remember consultants, consortiums, subcontractors are not a direct party to the grant with the NIH.



Essential Documents

- The awarded application and the FOA it was submitted to.
- Complete copies of all of the Notices of Award.
- The NIH Grants Policy Statement (NIH GPS)



How We Should Administer Grants

If I told you to jump off of a six-story building, would you?

Would you jump off if I added that the bottom four floors were on fire?

Statements from an effective research administrator ALWAYS have a context in (NIH) policy.



Most Problems Start Out Small...

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



Three Blind Mice (or Is That Rats?): Purely Hypothetical Situation #1

- A PI's awarded grant involves the use of mice.
- His progress report describes an experiment using rats.

What issues—if any—does this raise?



Robbing Peter to Pay Paul: Purely Hypothetical Situation #2

- A PI has multiple NIH grants from one IC, all involving work with mice.
- One of the grants has not yet been competitively renewed.
- A small portion of the colony needs to be maintained, so the PI charges the animal care costs to one of her other NIH grants?

Does this present any issues?



Mmmmm. Donuts.... Purely Hypothetical Situation #3

A PI asks you to stop at an office supply store on your way to work to pick up some needed office supplies. The PI also asks you to pick up donuts for a lab meeting. When you arrive at work he tells you the items should be charged to his NIH grant.

Is this allowable?



Something's Broken Purely Hypothetical Situation #4

The PI's piece of instrumentation, essential for the NIH-grant, has "blown up." She wants to put the costs for the replacement on the NIH grant.

Is this allowable?

What needs to be considered?



Don't You Wish PI's Didn't Move: Purely Hypothetical Situation #5

The newly transferred PI walks into your office wanting to prepare a transfer (change of institution) application. There is just one catch: the start date for budget period was last month.

What do you do (besides scream)?



It Was a Dark and Stormy Night: Purely Hypothetical Situation #6

The PI leaves in the middle of the night and takes data and critical parts of the research team along with critical equipment with him. He wants to re-establish the project at a new institution.

What would an NIH official do?
What are some options?



How Can You Be In 2 Places at Once: Purely Hypothetical Situation #7

The PI moves from one institution to another institution across the country. All of her grants except one were relinquished and transferred to the new institution. When questioned, the original recipient indicated that it was in the best interest of the grant not to transfer due to the multiple consortium agreements. The PI retained an adjunct position at the original institution.

What problems does this present?



Show Me the Money: Purely Hypothetical Situation #8

The PI has prepared and submitted her RPPR before Year 3. You realize after-the-fact that she has checked “no” to the question about large unobligated balance: her logic was that she didn’t want to lose money that she will eventually need. You know that draw downs have only just begun on Year 2 funds.

What problems does this present?

What are the next step involved?



Is That “Milestones” or “Millstones”?: Purely Hypothetical Situation #9

A grant involving recruitment got off to a rough start, but by the time the RPPR was being submitted at the end of year 2, things were moving along. Yet as you look at the terms and conditions of the Year 3 Notice of Award, you see milestones spelled out and a requirement for an interim progress report.

Should we be concerned?

What does this mean?



You Have Been Voted Off The Island! Purely Hypothetical Situation #10

- A multi-PI project has been a productive team for years. One of the PI's moves in the -07 year, and a large consortium award is issued to continue the collaboration.
- In the -08 year, significant scientific, budgetary, (and personal?) differences arise. The PI's have a falling out and the consortium PI is voted out of the project.
- The consortium PI is notified of the decision by email and is told no consortium costs will be covered as of the date of the email.
- The consortium PI contacts NIH, hinting at possible budget mismanagement and scientific misconduct, and demanding NIH hold the prime grantee to the terms of the peer reviewed Leadership plan.

What issues and options are involved?



Catch Me If You Can: Purely Hypothetical Situation #11

- Dr. Johns works with her departmental administrator to set up payments for participant incentives and travel reimbursements on one of her grants.
- When the materials are ready for approval, the administrator asks Dr. Johns' project manager (in the PI's absence) to preview the payment materials, so that Dr. Johns could sign-off upon her return.
- The project manager points out that one participant for which payments are being made has not been part of the grant in question; in fact, no one by that name has been a participant in any of Dr. Johns' five grants.
- The administrator checks records and finds that this participant has received two prior payments.

What issues are at play? What checks are needed? Who needs to be involved?



Does Age Really Matter?: Purely Hypothetical Situation #12

You added to the grant file a copy of the institutional letter sent to the Office of Human Research Protections (OHRP) and copied to the funding-IC about an adverse event that happened to a 10-year old on the pediatric study. The only reason it sticks with you is that two weeks later the institution is submitting the RPPR application and the grant's abstract talks about patients 13-16 years of age.

What concerns does this raise? What problems may this pose?



Early Communication Between Department and Grants Office is Essential

- Many solutions are organizationally-, culture-driven. For example, if good communication is part of the culture, then it is more likely to support good management practices, such as work groups across departmental boundaries.
- Current, written, and accessible policies and procedures are a must.
- All parties involved must know and understand and comply with the rules, policies guidelines.
- Don't avoid contacting the IC or NIH, as appropriate



Resources....

- Your Institution
 - Department Chairman/Dean or Division Head
 - Sponsored Research/VP for Research
 - Financial Management/Internal Audit
 - IRB/IACUC
- NIH
 - Grants Management Specialist/Chief Grants Management Officer
 - Grant Program Administrator
 - grantspolicy@nih.gov
 - grantscompliance@nih.gov
 - Office of Financial Management <http://ofm.od.nih.gov>



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>



Questions???

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