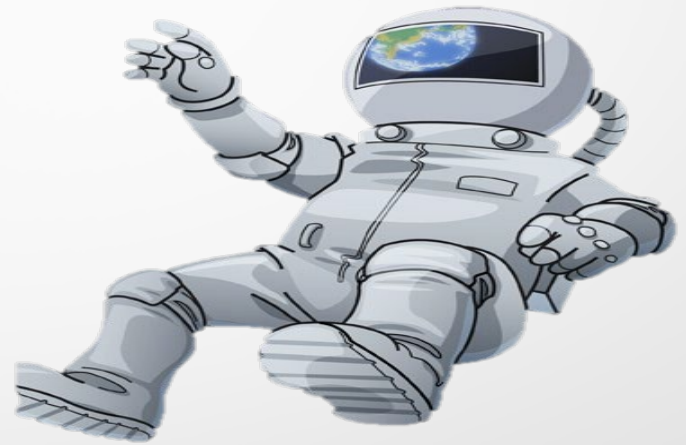


Houston, That NIH Grant Is in Trouble



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Thinking Like NIH: the NIH is Part of the Federal Government, Meaning...

- Must support federal policy, to enforce applicable laws, cost principles and administrative requirements
- Must support President's initiatives and policies.
- Stewards of federal funds

Thinking Like NIH: Second, the 24 Funding Institutes/Centers (IC's) Are Very Different

- Some IC's have a relatively broad mission; others have missions that are (by comparison) relatively narrow
- Larger IC's have more funds which can mean more flexibilities

NIH Perspective When Considering Challenging Complex Situations

Factors we consider critical in making decisions in 'tough' situations:

- Have we "listened" enough to really understand all the issues and objectives of the situation?
- What is best from a scientific or programmatic perspective (how will this impact the original scope/aims of the project)?
- What will best serve the investment of the taxpayer in the project?
- Could the action create issues for protection of human subjects?

What Are Some Aspects that Make Projects Complex and Create Post-Award Issues?

- Preaward change of recipient organization
- Project team at multiple institutions
- Consortium versus fee for service
- Delays in the project
- Significant changes in the research team
- Significant large balances accruing in the award
- Challenges ensuring compliance with terms of award
- Unexpected post award changes
- Close-out issues

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?
- 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?

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'?

Purely Hypothetical Situation - #1

Robbing Peter to Pay Paul

A PI has multiple NIH grants, 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?

- Is this allowable and/or does this present any issues?

Purely Hypothetical Situation - #2

Is It or Isn't It?

An investigator is not a VA employee, but is now on an Intergovernmental Personnel Act (IPA) with the VA. The MOU between the VA and the recipient states “joint appointment” but “without compensation.” The IPA reflects payment to university for the investigator’s “services.” Payment is based on monthly salary and number of months. The VA and recipient state this is not a joint appointment. The VA states they pay awardee for investigator’s services but do not pay the investigator directly.

- Is this a “joint appointment?”
- What should be provided to NIH to reconcile the discrepancies in the information?

Purely Hypothetical Situation - #3

It Was a Dark and Stormy Night

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 problems does this present?
- What would an NIH official do?
- What are some options?

Purely Hypothetical Situation - #4

Here Or There?

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?
- What are the options to continue?

Purely Hypothetical Situation - #5

She's Only Gone for a Month

The PI is taking a leave of absence for one month to deal with some personal matters. The department does not initiate a prior approval request because the PI will be back in a month.

- What problems does this present?
- What questions need to be asked?
- What might NIH do?

Purely Hypothetical Situation - #6

You've Been Voted Off the Island

A multi-PI project has been a productive team for years. One of the PI's moves in the 7th year, and a large subaward is issued to continue the collaboration. In the 8th year, the PI's have a falling out. The Contact PI sends a letter to NIH requesting to change the award to a single PI project. 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 questions will NIH ask?
- What are some option to resolve this?

Purely Hypothetical Situation - #7

How Much Is Too Much?

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 next steps are involved?

Purely Hypothetical Situation - #8

Does It Really Matter?

NIH has contacted the recipient several times for a delinquent Final RPPR for a particular grant. As there was no renewal (Type 2) application, there also was no Interim RPPR.

- What is Unilateral Closeout?
- How does this impact further chances of getting awards?
- What strategies can you use to ensure F-RPPRs are submitted?

Purely Hypothetical Situation - #9

Something's Broken

A piece of instrumentation, essential for the NIH-grant, has “blown up.” The PI wants to put the costs for the replacement on the NIH grant.

- Is this allowable?
- What needs to be considered?

Purely Hypothetical Situation - #10

How Can I Think About That at a Time Like This?

When you come into work, you learn that last night Dr. Cummings was in a freak car accident and killed. She was PI on an R01, an R21, and a K24.

- What will need to happen?
- What do you need to keep in mind?
- What are next steps?

Purely Hypothetical Situation - #11

Change of Scope

Everyone is excited by this innovative research grant focused on populations in Myanmar, but getting all of the permissions to do research in country has become complicated. As the PI is preparing her 3rd year RPPR, she is proposing a significant change of scope.

- Is this allowable?
- What questions will NIH ask
- What options are available?

Purely Hypothetical Situation - #12

Who's Responsible?

With a month left in a competitive segment, a PI changes institutions. Two months later the renewal application is submitted from the new institution.

- Is an I-RPPR required in this case and when?
- You say yes? Who was responsible for submitting?
- If yes, and the I-RPPR was overdue, what effect would the late report have on the new institution?

Purely Hypothetical Situation - #13

Catch Me If You Can

Dr. Johns works with his departmental administrator to set up payments for participant incentives and travel reimbursements on one of his 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 his 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?

Purely Hypothetical Situation - #14

It Doesn't Add Up

The completed Final FFR reflects less money expended than what is shown in the PMS as disbursed.

- What should happen at the time the FFR is completed?
 - What can be done if the PMS is correct and the FFR is wrong?
 - What can be done if the FFR is correct and the PMS is wrong?
- What happens if the funding agency closed out the grant?

Purely Hypothetical Situation - #15

Age Matters?

You had 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 a 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/problems does this pose?
- What are next steps?

Resources...

Your Organization

- Sponsored Programs/ Grants and Contracts Office
- Accounting Office
- Internal Auditor
- IRBs and IACUCs

NIH

- Grants Management Specialist noted in eRA Commons
- Chief GMO at IC http://grants.nih.gov/grants/stafflist_gmos.htm
- Program Official noted in eRA Commons
- NIH Policy & Compliance: <http://grants.nih.gov/grants/policy/policy.htm>
- Office of Financial Management <http://ofm.od.nih.gov>
- NIH Grants Policy Inbox (questions not specific to the NoA): grantspolicy@mail.nih.gov
- NIH Grants Compliance Inbox (questions not specific to the NoA): grantscompliance@mail.nih.gov

Questions?