

Advanced Administrative Topics

NIH Regional Seminar on
Program Funding &
Grants Administration

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Presenters

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What Are Some Aspects that Make Projects Complex?

- Multiple Projects funded through single award
- One project with multiple awards (cluster grants)
- Multiple institutions participating
- Clinical activities/trials
- Sub-contracted activities
- Unique scientific resources – licensing, intellectual property, etc.
- Cooperative Agreements – Science Officers
- Foreign involvement



What Are Some of the Issues and Changes that Make Projects Complex?

- Change of Grantee Organization
- Change of Legal Status of Grantee Organization
- Significant Changes (break-up) of Research Team
- Allocation of Costs to Closely Related Projects
- Compliance with Reporting Requirements
- Conflict of Interest
- Ethical issues on the conduct of research (examples: use of children or prisoners)
- Allegations of misconduct (scientific, administrative and fiscal)



Thinking Like a Fed

- NIH Perspective When Considering Challenging Complex Situations
- First remember NIH is a Federal Agency
 - Support Federal policy (Must enforce applicable laws, cost principles and administrative requirements)
 - Support President's Initiatives and policies.



NIH Perspective When Considering Challenging Complex Situations

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

- Have you "listened" enough to really understand the issues and objectives of the situation or issue?
- What is best from a scientific or programmatic perspective (how will this impact the scope of the project)?
- What best serves the investment of the taxpayer in the project?
- Will the action create issues for protection of subjects?

NIH Perspective When Considering Challenging Complex Situations (con't)

- 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? (NIH's large budget doesn't result in broad fiscal flexibility)
- How would this play if presented on the evening news or the front page above the fold on?



NIH Perspective When Considering Challenging Complex Situations Lower Level Considerations

- What is in the best interests of the PI(s)?
- What is in the best interest of the institution(s)?
- Is there an opportunity for a 'win/win'?
- Remember consultants, consortiums, subcontractors are not a direct party to the grant with the NIH

Clinical Trials

■ Pre-Start-Up

- IND
- IRB
- FWA – individual investigator agreements
- Data and Safety Monitoring Board (DSMB)

■ Pre Set up Costs

- Indemnification
- Insurance
- Cost of the IND and/or IRB review
- Consultant Costs/travel/per diem for the DSMB



Other Clinical Trial Expenses

- Professional Fees
- “Use of Hospital” Fees
- Incentive Costs
- Per Diem for visits.



Clinical Activities

- Multi-Center Clinical Trials
- Capitation Models
- Patient Recruitment Issues
- Patient Protection and Safety



Human Protection and Safety

- Informed consent
- IRB
- Conflict of Interest
- DSMB
- Safety Monitoring Plan
- Adverse Events

OHRP: 45 CFR 46 Protection of Human Subjects

■ Confused??

When in doubt – Consult-----

Local IRB

OHRP Guidance/Website:

<http://www.hhs.gov/ohrp/policy/index.html>

OHRP Telephone/E-mail

■ Assurances: 240-453-8138

■ Educations: 240-453-8227

■ Compliance: 240-453-8132

■ Main number: Toll-Free 866-447-4777 or 240-453-6900

Change of Grantee Organization

- NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project.
- The grant is awarded to the grantee institution – not to the PI.
- In addition, a change of grantee involving the transfer of a grant to or between a foreign institution requires the ICs' Council approval.
- A grant to an individual may not be transferred.
- A change of grantee organization may involve the transfer of equipment purchased with grant funds.

Change of Grantee Organization (cont.)

- Request must be made before the anticipated start date at the new organization and preferably several months in advance.
- A change of grantee request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds.
- A change may be made without peer review, provided the PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project.

Change in Grantee Organizational Status

Grantees must give NIH advance notice of the following types of change in organizational status

- ***Merger.*** Legal action resulting in the unification of two or more legal entities.
- ***Successor-in-Interest.*** Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s).
- ***Name Change.*** Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee.



Purely hypothetical situation #1

- The PI leaves in the middle of the night and takes data and critical parts of the research team with her. She wants to re-establish the project at a new institution. Your institution feels cheated and states they don't plan to relinquish the grant.
- What should you do, what are some options?

Purely hypothetical situation #2

- On a renewal the PI changes institution to a new organization, which has never received NIH support.
- The application receives a fundable score and is on the pay list.
- The Grants Management Specialist notices that the Signing Official is the same person who was involved in a 'Federal' case a few years ago.
- The case, resulted in a large financial settlement and criminal charges on this individual.
- The Dept. of Justice eventually closed the criminal charges in a negotiated agreement.
- Program is insistent that the science is top notch and funding is critical to the Institutes research program.
- What would you do?



Successor-in-Interest (SII)

For an SII, a letter signed by the Authorized Organization Officials (AOO) of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding office, following consultation with the GMO of that awarding office. The letter must do the following:



Name Changes

- For name changes, the grantee's written notification to the lead NIH awarding office must include the effective date of the change.
- Revised face pages are not required for name changes because name changes are processed with the next award action (e.g., non-competing continuation award) and the organization will submit a face page with the new information as part of that action.

Domestic Organizations with Foreign Components and Foreign Recipients

Allowable and Unallowable Costs - Costs that are generally allowable under grants to domestic organizations also are allowable under foreign grants.

- **A&R.** Revised DHHS policy now states that costs for minor A&R (\leq \$500,000) are generally allowed on grants made to foreign organizations or to domestic institutions with foreign components.
- ***Customs and import duties.*** Unallowable.
- **F&A costs.** NIH provides limited F&A costs (8 percent of total direct costs less equipment) to foreign institutions and international organizations to support the costs of compliance with NIH requirements.
- You need to be aware of some complexities involving foreign components other than cost concerns.



Multiple PIs

- The administration of applications under the multiple-PI model have some elements that differ significantly from the traditional single-PI model.
- It is essential that investigators and grantees consider all aspects of the funding mechanism before submitting an application.
- Multiple Principal Investigator Website:
http://grants.nih.gov/grants/multi_pi/



Purely hypothetical situation #3

- The PI and co-investigator have been a very productive team for years.
- They have a scientific (and personal?) falling out and want to go their separate ways.
- Both play a critical role in the project and so are 'named on the grant award'.
- What are some options to resolve this ?

Late and Incomplete Applications Impact NIH and Grantees

- Considerable IC resources are diverted chasing late applications and missing items on incomplete applications.
- Grantee resources are also diverted to responding to requests from NIH for missing documents.
- Delays in issuing awards creates a snowball of work rolling into the last quarters of the Federal Fiscal Year both for NIH and Grantees.





Timely Submission of Non-Competing Continuation Progress Reports (Type 5s)

- All grantees have access to a searchable list of due **progress reports**.
- NIH sends 2 progress report reminders via e-mail to the PI:
 - √ Two months prior to the due date
 - √ Two weeks after the due date for overdue reports

Checklist for Reporting Requirements



Does Your Institution...

- Submit Late Progress Reports?
- Submit Incomplete Reports?
- Submit Timely Close Out Documents?
- Submit FSRs within the Required 90 Days?

Do You Know Your Institution's Track Record?

What would you do?

- You receive letter from NIH stating that a progress report due on July 1 has not been received as of August 15.
- Your institution is required to submit a “complete” progress report in 7 days.
- Failure to submit the progress report may result in lose of funding.
- The PI says he\she is too busy to prepare the application and “not to worry, they will not reduce or eliminate my funding”

Intellectual Property

Intellectual property includes:

- Inventions and patents
- Copyrightable works





Inventions & Patents

- Invention reporting required by terms & conditions of NGA.
- NIH grantees may retain intellectual property rights to subject inventions provided they
 1. Report all subject inventions to NIH.
 2. Make efforts to commercialize the subject invention through patent or licensing.
 3. Formally grant the Federal government a limited use license to the subject invention.
- Bayh-Dole invention reporting requirements apply to all recipients.

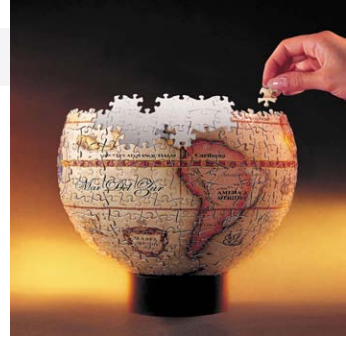
Rights in Data

(Publication & Copyrighting)



- In general, grantees own the rights to data resulting from a grant-supported project.
- NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals.
- Any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval.
- NIH must be given a royalty-free, nonexclusive, irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes.

Data Sharing Policy



What Obligations Exist Under the NIH Data Sharing Policy?

- Under NIH's Data Sharing Policy, investigators are requested to provide a plan to share final, non-restricted research data in a timely manner, usually upon publication of the main findings from the final dataset.

To Whom Does the Policy Apply?

- The Data Sharing Policy applies to all investigators applying for NIH research grants subsequent to October 1, 2003 that request at least \$500,000 in direct funds in any single year.
- http://grants.nih.gov/grants/policy/data_sharing/

Unique scientific resource – licensing, etc.

- Human Embryonic Stem Cell Research
- Bio-Safety Issues
- Select Biological Agents
- Model Organisms



Purely hypothetical situation #4

- The PI has developed an extremely valuable scientific resource on an NIH grant, but won't share with other investigators.
- He and his team has published extensively on the resource but continue to deny reasonable requests for sharing.
- Duplicating this resource, while not cost prohibitive, is not reasonable because the cost of duplicating is several times the 'reasonable' cost of sharing the resource.
- What should you do, what should the Fed do?

Closely Related Projects



A brilliant young PI has won two major awards to conduct research and perform motivational interventions on campus to combat alcohol abuse among college students. The Dept of Education grant focuses on issues relating to men and the NIH grant focuses on women.

Now the PI is close to running out of funds on one grant, so he proposes to bill "similar activities" to the other grant. He believes that since this is all government money and because the projects are essentially similar, it is permissible to pay for activities and personnel from one grant to another.

What do YOU tell him/her?

Allocation of Costs and Closely Related Work

NIH now applies the relatedness provision of OMB Circular A-21 (C., 4., d., (3)) to all NIH recipients which states

“if a specific cost can not be reasonably allocated to a specific project; it can be charged to any of the benefiting projects on any reasonable basis.”





American Recovery and Reinvestment Act (ARRA)

Special requirements apply to all projects receiving ARRA funding including:

- ❖ New type 1 awards
- ❖ Renewal type 2 awards
- ❖ Supplements both competing and administrative



ARRA Requirements

- ARRA fund recipients are required to submit reports within 10 days of the end of each federal quarter.
 - Reports must be submitted to www.federalreporting.gov (when the site is activated) and possibly to the awarding agency.
- Separate Accounts in Payment Management System (PMS)
 - ARRA funding will be accessed through a totally unique account from non-ARRA funding for each funded award.
- Separate Financial Reporting
 - Separate SF 272 and Financial Status Reports will be required to be submitted covering this additional funding.
 - These will be in addition to any required financial reports for the parent grant.



ARRA Requirements

- Separate closeout documents
 - Separate Final Progress Reports, Final Financial Status Reports, and Final Invention Statements will also be required to closeout the Recovery Act funding at the time the ARRA funding ends.
 - These closeout reports for the ARRA funding are required even when the parent grant continues.
- ARRA funds are not available for rebudgeting or carryover into the parent grant.
 - Any ARRA funding remaining at the end of the funding period for this award must be reported as an unobligated balance.

Communication Between Department and Sponsored Projects is Critical

- 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.
- If not, well... outcomes are not likely to be positive.

Resources...

I. Your Organization

1. Sponsored Programs Office
2. Accounting Office
3. Internal Auditor
4. IRBs
5. IACUCs

II. NIH

1. Grants Management Specialist
2. Program Administrator
3. Office of Laboratory Animal Welfare (OLAW)
<http://grants.nih.gov/grants/olaw/olaw.htm>
4. Office of Financial Management <http://ofm.od.nih.gov/frs.htm>
5. Office of Extramural Research
<http://grants.nih.gov/grants/oer.htm>

III. DHHS

1. 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://grants1.nih.gov/grants/compliance/compliance.htm>

- NIH Outreach Activities and Resources

<http://grants1.nih.gov/grants/outreach.htm>

Select Resources at the NIH

Grants Management Specialist on NGA

- If unknown, contact Chief GMO of IC

http://grants2.nih.gov/grants/stafflist_gmos.htm

Program Official on NGA

Division of Financial Advisory Services

<http://oamp.od.nih.gov/dfas/dfas.asp>

Office of Extramural Research

<http://grants.nih.gov/grants/oer.htm>

NIH Grants Policy Inbox

(policy questions not specific to NGA)

grantspolicy@mail.nih.gov

NIH Helpdesk (technical questions)

nihhelpdesk@mail.nih.gov or <http://support.nih.gov/>



Questions?

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