

Advanced Administrative Topics



NIH Regional Seminar on
Program Funding and
Grants Administration

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Presenters

Joe Ellis

Director, Office of Policy for Extramural Research
Administration (OPERA)
Office of Extramural Research, OD, NIH

Eileen Natoli

Grants Management Officer
National Cancer Institute, NIH

What Are Some Things 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
- Conflict of Interest
- Ethical issues on the conduct of research (examples: use of children or prisoners)
- Allegations of misconduct (scientific, administrative and fiscal)

Clinical Research Network (multiple awards)

- Data Coordinating Center
- Clinical Coordinating Center
- Recruiting Sites
- Core Laboratories

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

Subject Enrollment

- Necessary for scientific objectives
- Source of cost-over runs
- Pro-active plan
- Suitable quality and number of sites
- Inclusion Policies
- Monitoring

Multiple PIs

Establishment of Multiple Principal Investigator Awards for the Support of Team Science Projects

- NOT-OD-07-017, November 20, 2006
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html>

Multiple Principal Investigator Website:

http://grants.nih.gov/grants/multi_pi/

Multiple PIs

- NIH Policy on Late Submission of Grant Applications – Clarification for Multiple PI Applications and New Submission/Receipt dates.

- NOT-OD-07-026 December 7, 2006
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-026.html>

Intellectual Property

- Information on reporting requirements and policy, as well as electronic systems to fulfill reporting requirements, may be found at Interagency Edison: <http://www.iedison.gov>
- All foreign grantees, contractors, consortium participants and/or subcontractors are reminded that they must comply with Bayh-Dole invention reporting requirements

Data Sharing Policy

What Obligations Exist Under the NIH Data Sharing Policy?

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

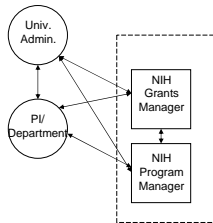
To Whom Does the Policy Apply?

- 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/

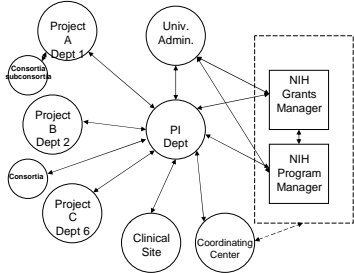
Unique scientific resource – licensing, etc.

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

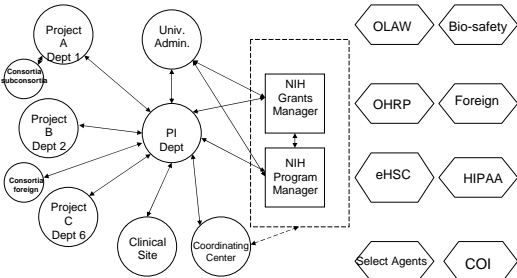
Research Projects Business Model



Research Projects Business Model (w/Complexity)



Research Projects Business Model (w/Complexity)



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)

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'd)

- 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.

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.

That's A Good Question



Foreign Recipients

Allowable and Unallowable Costs - Costs that are generally allowable under grants to domestic organizations also are allowable under foreign grants, with the following exceptions:

- **A&R.** Unallowable under foreign grants.
- **Customs and import duties.** Unallowable under foreign grants.
- **F&A costs.** With the exception of American University of Beirut and the World Health Organization, **full** F&A costs will not be allowed. However, 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.

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?

Allocation of Costs and Closely Related Work

With the 12/03 NIH GPS, 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.

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>

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.
- One must know and understand the rules to be able to comply.
- If not, well.....

Challenging Individual Interactions

- Principal Investigators
- Office Colleagues
- Departmental Administration
- Sponsored Projects Administration
- NIH Staff (grants management and program)
- Other Institutions' Staff
- Foreign consortia staff
- Other Federal Agencies (FDA , CMS, CDC)

Resources At Your Organization

Departmental Advisors
Sponsored Programs Office
Accounting Office
Institutional websites
Internal Auditor
IRBs
IACUCs

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](mailto:.nihhelpdesk@mail.nih.gov) or <http://support.nih.gov/>

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

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. The old institution feels cheated and states they don't plan to relinquish the grant.

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. In the final administrative review, the Grants Management Specialist notices that the Signing Official is the same person who was involved in a 'Federal' case a few years ago. This case involved the Institute's grant, 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 (see peer review) and funding is critical to the Institutes research program. What would you do?

Purely hypothetical situation #3

- The PI is traveling outside of the U.S. to make a grant-related presentation and the estimated travel time is 15 hours. The PI requests to fly first class because of the lengthy trip. Is this permissible? Additionally, she must fly from one foreign country to another to make the same presentation. Is she required to use a U.S. carrier when traveling between the two foreign countries?

Purely hypothetical situation #4

- 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 of the options?

Purely hypothetical situation #5

- 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.

Purely hypothetical situation #6

- Under a multi-project grant, the PI needs to replace a Project Leader because he is leaving. The current Project Leader was identified in the grant application, but is not listed in the Notice of Grant Award. Does the organization need to obtain prior approval from the IC for the replacement Project Leader?

Thank You!

Questions?

Joe Ellis
GrantsPolicy@mail.nih.gov

Eileen Natoli
natolie@mail.nih.gov
