

# Advanced Administrative Topics

NIH Regional Seminar on  
Program Funding and  
Grants Administration

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## Presenters

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## 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://ohrp.osophs.dhhs.gov/polasur.htm>
  - OHRP Telephone/E-mail
    - Assurances: 301-496-7041
    - Educations: 301-496-8101
    - Compliance: 301-402-5567

## 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-06-036, February 7, 2006  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-036.html>
- Multiple Principal Investigator Website:  
[http://grants.nih.gov/grants/multi\\_pi/](http://grants.nih.gov/grants/multi_pi/)

## 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.

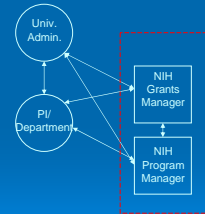
### To Whom Does the Policy Apply?

- 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/](http://grants.nih.gov/grants/policy/data_sharing/)

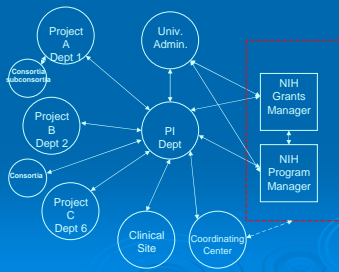
## Unique scientific resource – licensing, etc.

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

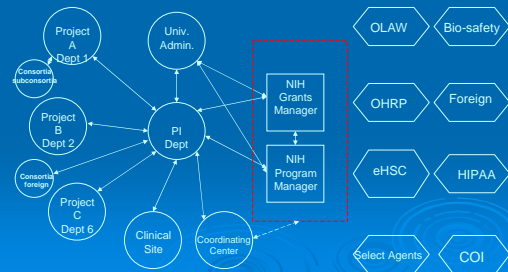
## Research Projects Business Model



## Research Projects Business Model (w/Complexity)



## Research Projects Business Model (w/Complexity)



## Resources...

### I. Your Organization

- 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>
- Office of Financial Management <http://ofm.od.nih.gov/ofs.htm>
- Office of Extramural Research <http://grants.nih.gov/grants/ger.htm>

### III. DHHS

- 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 of Grantee Organization (cont'd)

***A request for a change of grantee organization must be submitted to the GMO and include:***

- Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement)
- Final Invention Statement and Certification from the original grantee, as well as
- An application (PHS 398 or 416-1) from the proposed grantee or sponsoring organization.

## Change of Grantee Organization (cont'd)

- For awards using the PHS 398, the application from the proposed grantee should include, at a minimum, the following:
  - **Face page**
  - **Budget pages** (current and future years)
  - **Updated biographical sketches** for the PI and existing key personnel and biographical sketches for any proposed new key personnel
  - Updated “**other support**” page(s), if necessary
  - **Resources page**
  - **Checklist page**
  - Certification of **IRB/IACUC approval**, if applicable

## Change of Grantee Organization (cont'd)

- Mid-year transfer, new award held to total cost commitment of funds on relinquishing statement
- Anniversary transfer, new F&A applied to direct costs
- Any future years, new F&A applied to previously committed direct costs
- Carryover issues, automatic or not?
- Fiscal year issues, limited to five fiscal years inclusive

## 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. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.
- **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). An SII may result from legislative or other legal action, such as a merger or other corporate change.
- **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:

## SII Letter

- Stipulate that the transfer will be properly effected in accordance with applicable law and the transferor relinquishes all rights and interests in all of the affected grants.
- Request that the NIH awarding office(s) modify its (their) records to reflect the transferee as the grantee of record.
- Include a list of all affected NIH grants (active and pending) with the following information for each:

## SII Letter (cont'd)

- Complete grant # (e.g., 5 R01 GM 12345-04)
  - Name of PI
  - Current budget period and project period
- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization.
- Each face page must be signed by both the PI and the AOO at the transferee organization.

## 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 and domestic grants with foreign components.
- **Customs and import duties.** Unallowable under foreign grants and domestic grants with foreign components.
- **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.

## Foreign Recipients (cont'd)

- **Inclusion in SNAP is at the discretion** of the NIH awarding office and will be specified on the NGA.
- A **change in the performance site** within a foreign country or performance in a country other than that specified in the approved application requires NIH awarding office prior approval.
- A change of grantee organization that involves the transfer of a grant to or **between foreign institutions** or international organizations requires approval of the NIH awarding office and its National Advisory Council or Board.

## Foreign Recipients (cont'd)

- **Audit** - Foreign grantees are subject to the same audit requirements as for-profit organizations = >500K expended in its FY.
- **Reporting and Record Retention** - Foreign grantees must submit annual FSRs in U.S. dollars, whether or not they are under SNAP.

**Note:** The NIH will not award more funds to make up for fluctuations in the exchange rate.

## Foreign Recipients ~ Sub-Awards

Foreign collaborators may be experienced & knowledgeable (even so, *confirm*); however, some have little or NO experience.

**Be explicit about applicable regulations** and provide URL's (The NIH GPS, CFR's and OMB Circulars). Also tell them what does not apply.

**Discuss basic administrative requirements:**

**Co-mingling** – Confirm funds received will be set up in a separate account; commingling is common in many foreign entities.

**Time & Effort** – May have to provide informal advice on how to ensure appropriate measure of time and effort.

**Prior Approvals** – Specify that requests come to you, the prime, they are not sent directly to the NIH. Discuss what signatures are required and "who" signs.

**Audit requirement** – Threshold of \$500,000 or more expended under HHS awards during its fiscal year.

**Remember** – The prime is responsible for the performance of the subawardee in all ways. Some subawardees have systems similar to those used in the U.S. - others may not...

## 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.

## Clarifications from the 12/03 NIH GPS

- **Cost transfers:** policy now states that transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.
- **Cost overruns:** was further defined as: "Any amount charged in excess of the Federal share of costs for the project period (competitive segment)."

## Clarifications from the 12/03 NIH GPS

- **Consortium Written Agreements:** It is the responsibility of the grantee to include applicable requirements of the policy statement in written agreements; also agreements must also include a reference to the financial conflict of interest policy, intellectual property, and data sharing requirements.
- **Consortium participants and contractors under grants** are subject to the requirements of the cost principles otherwise applicable to their type of organization, AND to requirements placed on them by the grantee to be able to comply with the terms and conditions of the NIH grant.

## Resources for Compliance

Tips, methods, what to do? So many resources, only a select few are named here.

- Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards (11/28/05)  
<http://oig.hhs.gov/fraud/docs/complianceguidance/PHS%20Research%20Awards%20Draft%20CPG.pdf>
- 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\\_qmos.htm](http://grants2.nih.gov/grants/stafflist_qmos.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](mailto:grantspolicy@mail.nih.gov)  
NIH Helpdesk (technical questions)  
[nihhelppdesk@mail.nih.gov](mailto:nihhelppdesk@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 present 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 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 #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.

Thank You!

Questions?

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