What Am I Signing Anyway?
Proposal Review from an Institutional Point of View

Online Education Program

Friday, December 2, 2005
12:30 PM - 2:00 PM Eastern
11:30 AM - 1:00 PM Central
10:30 AM - 12:00 Noon Mountain
9:30 AM - 11:00 AM Pacific

Presented By:

Sally S. Tremaine
Joyce B. Freedman
Nancy J. Wray
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December 2, 2005
www.ncura.edu

Presenters

Sally S. Tremaine, Director, Corporate and Foundation Relations, Quinnipiac University

Joyce B. Freedman, Assistant Vice Chancellor, Office of Research, University of California, San Francisco

Nancy J. Wray, Director, Office of Sponsored Projects, Dartmouth College
Meet the presenters...

Sally Tremaine  Joyce Freedman  Nancy Wray

What Am I Signing Anyway?
Introduction
Authorized Signature – Why?

• Proposals are considered potential legal and financial commitments made by the submitting institution to a funding agency
• Authorized official (signatory) is held responsible by the sponsor to assure that the institution will meet the obligations
• Commitments offered in a proposal must be honored if an award is made

What Am I Agreeing To?

• Fringe benefit rates
• Indirect cost (F&A) rate
• Adequate costs to do the project
What Am I Agreeing To?

• Space
• Facilities
• Key personnel time and effort

What Am I Agreeing To?

• Conformance to Sponsor proposal guidelines
  – Format
  – Deadlines
  – Special terms and conditions
What Am I Agreeing To?

- Compliance with University policies/procedures
  - Waivers of overhead
  - Cost-sharing commitments
  - Documentation from subcontractors or consultants
  - Required internal signatures

What does the small print mean?
Assurances and Certifications

• When you sign a grant application do you really, really, really understand what your signature means regarding Assurances and Certifications?

• Where are your policies contained? Can you easily find them?
  – Human Resources Manual
  – Institutional Policy Manual
  – Research Administration Manual

Assurances and Certifications

What Are They?
  – Human Subjects
  – Research On Transplantation
  – Fetal Tissue
  – Women and Minority Inclusion Policy
  – Inclusion of Women Policy
  – Research Using Human Embryonic Stem Cells
  – Vertebrate Animals
  – Debarment and Suspension
Assurances and Certifications

– Drug-Free Workplace
– Lobbying
– Non-Delinquency on Federal Debt
– Research Misconduct
– Civil Rights
– Handicapped Individuals
– Sex Discrimination
– Age Discrimination

Assurances and Certifications

– Recombinant DNA and Human Gene Transfer Research

– Financial Conflict of Interest
  (except Phase I SBIR/STTR)
What Am I Signing Anyway?

In Section I, Page 8 of the NIH 398 Instructions for “PREPARING YOUR APPLICATION” Item 13. Official Signing for Applicant Organization.

“Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations.”

Human Subjects

- Applicant organization is responsible for safeguarding the rights and welfare of human subjects in DHHS-supported research
- Certify that you have a written Assurance of Compliance on file with OHRP (Office for Human Research Protections)
**Research on Transplantation of Human Fetal Tissue**

- Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c)
- Certify that if you do research on human fetal tissue you will make available for audit by Secretary, DHHS
  - physician statements & informed consents
  - or ensure access to those records if maintained by another entity

**Women & Minority Inclusion in Clinical Research Policy**

- Applicant must agree to comply with “NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research”
  - Women and members of minority groups must be included in NIH supported biomedical and behavioral research projects unless there is a clear and compelling rationale for not including
  - Must be addressed in developing research design appropriate to the scientific objectives of study
Inclusion of Children Policy

- Applicant must agree to comply with "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects"
- Requires that children must be included in all human subjects research conducted or sponsored by NIH unless there are clear and compelling reasons for exclusion.

Research Using Human Embryonic Stem Cells

- Applicant certifies that if research using human embryonic stem cells is proposed, the institution is in compliance with "Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells"
Vertebrate Animals

• Applicant certifies that they are in compliance with the Animal Welfare Act
• Have filed a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW)
• Applicant certifies that any animal research will be reviewed and approved by Institutional Animal Care and Use Committee (IACUC)

Debarment and Suspension

• Applicant certifies to the best of its knowledge and belief that it and its principals (including research personnel)
  — Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from any Federal agency
  — Have not within preceding 3-year period been convicted of fraud or criminal act
Debarment and Suspension (cont)

– offense in connection with
  • obtaining, attempting to obtain, or performing a public transaction or contract
  • violation of Fed or State antitrust statutes
  • commission of embezzlement, theft, or forgery, bribery, falsification or destruction of records
  • making false statements
  • receiving stolen property

Debarment and Suspension (cont)

– Are not presently indicted or criminally or civilly charged by a government entity with the commission of any of the offenses identified above
– Have not within a 3-year period preceding this application had one or more public transactions terminated for cause or default
• If applicant is unable to certify to any or all of the above – attach explanation
• Required to obtain cert from “Subs”
Drug-Free Workplace

• Applicant certifies “that it will continue to provide a drug-free workplace” by:
  – Notifying employees that it is unlawful to manufacture, distribute, dispense, possess, or use a controlled substance (the POLICY)
  – Specify actions that will be taken if violated
  – Establish and maintain a drug-free awareness program

Drug-Free Workplace (cont)

– Making it a requirement that those engaged in the performance of a grant be given a copy of the policy
– Require compliance to the policy as a condition of employment
– Notifying agency within 10 working days of a violation/conviction
Drug-Free Workplace (cont)

– Within 30 days of notification of a conviction
  • Taking appropriate personnel action
  • Require employee to participate in a drug abuse program
– Making good faith effort to continue to maintain a drug-free workplace

Lobbying

• Applicant certifies to the best of his/her knowledge and belief that:
  – No Federal funds have been paid or will be paid to influence or attempt to influence any Federal agency, employee, member of Congress, etc. in connection with the awarding of a grant
  – If funds other than Federal funds have or will be used to influence the awarding of a grant, applicant must complete and submit “Disclosure of Lobbying Activities” form
Non-Delinquency on Federal Debt

- Under “Federal Debt Collection Procedure Act” organizations and individuals that are indebted to the US are ineligible to receive Federal grants until debt is relieved
- Applicant certifies that institution is not delinquent in repaying any Federal debt

Research Misconduct

- Applicant certifies compliance with
  - “Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science” policy, and
  - “PHS Standards for the Protection of Research Misconduct Whistleblowers” policy
Research Misconduct (cont)

- Specifically requires
  - Institution will comply with policies
  - Institution has established policies and procedures of its own
  - Institution will provide policies and procedures to Office of Research Integrity (ORI) if requested
  - Institution will submit an Annual Report on Possible Research Misconduct

Civil Rights, Handicapped Individuals, Sex Discrimination, and Age Discrimination

- Organization certifies that it has filed with the DHHS Office for Civil Rights an Assurance of Compliance and has policies that prohibit discrimination on the basis of race, color, national origin, handicaps, sex, and age
**Financial Conflict of Interest**

- Applicant certifies that it is in compliance with the requirements of 42 CFR Part 50, Subpart F
  - Organization has written and enforced policies and procedures
  - Prior to expending any grant funds, organization will inform NIH of any conflicts
  - Organization will continue to make similar reports on subsequent identified conflicts

**Recombinant DNA and Human Gene Transfer Research**

- Applies to grants that propose gene transfer projects
  - Requires compliance with “NIH Guidelines for Research Involving Recombinant DNA Molecules” policy
  - Policy sets forth principles and standards for safe and ethical conduct of recombinant DNA research
What am I signing anyway?

- Considerations
  - Who is authorized to sign for an institution and why?
  - Why do some agreements have only one signature, some have two and possibly more?
  - When you sign an agreement what does it mean?
What am I signing?
Considerations (cont)

• Does the type of agreement signed make a difference to:
  – the institution?
  – the PI?
  – the agency?
• What type of agreements are appropriate for sponsored projects offices to sign?

Authorized Signature – who?

The person with
the official
delegation from
Board of
Trustees,
Regents, etc. to
make fiduciary
commitments for
the institution
**Signatures - how many and why?**

- Bi-lateral Agreements
  - two signatures required -- the proposer and the sponsor
  - only two parties to the agreement, the first (sponsor) and the second (proposer)
  - signatures are obtained at the final award stage
  - signatures indicate a fully executed agreement in which all parties agree to the terms and conditions of the award
  - normally used in contracts, co-operative agreements, sub-awards and other types agreements in which there are deliverables

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**Signatures -- when is two not enough?**

- Three or more signatures -
  - used when there are more than 2 parties to the agreement
  - signatures obtained at the final stages of the agreement
  - signatures indicate a fully executed agreement in which all parties agree to the terms and conditions of the award
  - often used with agreements when there is no funding involved
  - often used for joint ventures, collaborative agreements, teaming agreements
The type of agreement --
Does it make a difference?

How many signatures are needed and why?

- Unilateral agreements
  - one signature only
  - signature at proposal stage
  - signature indicates that institution can accept the terms and conditions of the award
  - conditions of the award are normally not negotiated
  - signature of institutional official is binding on the university
  - proposals for grants, scholarships, fellowships, training grants
Different Award Vehicles

- Grants
- Contracts
- Co-operative Agreements
- Material Transfers
- Unfunded Collaborations
- Joint Ventures
- Teaming Agreements
- Other Transaction Agreements (OTA)
- Fellowships, Scholarships
- Work-for-hire

A quick lesson on types of agreements – why they matter

A Grant
- a financial or other assistance award for the conduct of research or other programs as specified in an approved proposal
- often investigator initiated
- sponsor has no substantial programmatic involvement
- often only periodic technical reports are required
- terms and conditions are flexible, including fiscal management
- most common type of funding vehicle for universities
A lesson on agreements... cont

• A Contract
  – used when the principal purpose of the agreement is to provide tangible results or other “deliverables” to the sponsor
  – service is normally for the direct benefit and/or use of the sponsor
  – terms and conditions are usually strict and not flexible
  – milestone dates and due date deliverables are common
  – financial arrangements are usually cost-reimbursement but can be fixed-price

Another type of agreement

• A sub-contract, sub-grant, sub-award
  – an agreement under another agreement
  – original funding comes from a prime sponsor which is passed through to the subawardee
  – normally a collaboration with a third party for a part of the scope of work
  – it is under the authority of and consistent with the prime award
What Am I Signing Anyway?

Conclusions

Who has time to read this stuff?
Set Priorities

What is most important for you and your institution?

Watch what you sign, it makes a difference!
Questions??

• Please press *1 on your phone to ask a live question or submit them through the system

Thank you for attending today’s program!

Please send remaining questions to Marc Schiffman at schiffman@ncura.edu by December 9, 2005

To receive CEU's, please send an Excel spreadsheet with a list of all registrants to ceurequest@ncura.edu
Contact Us

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# National Council of University Research Administrators Evaluation

This form is electronically tallied. Please mark only one selection for each question, unless otherwise noted. Do not mark outside the boxes.

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**December 2, 2005**

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<th>Scale Definition: P - Poor</th>
<th>F - Fair</th>
<th>G - Good</th>
<th>VG - Very Good</th>
<th>E - Excellent</th>
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### Presenters: Overall Effectiveness

| **5. Sally S. Tremaine** | □ □ □ □ □ |
| **6. Joyce B. Freedman** | □ □ □ □ □ |
| **7. Nancy J. Wray** | □ □ □ □ □ |

**8. Would you participate in another virtual seminar?**

Y N

**9. What topic or issue would you like to see in a virtual seminar format?** (please check all that apply)

- [ ] Research Compliance
- [ ] Sponsor Agency Funding Opportunities
- [ ] Post-Award Accounting and Reporting
- [ ] Electronic Research Administration
- [ ] Pre-Award Administration
- [ ] Electronic Proposal Routing & Review
- [ ] Other: ___________________________________________

**10. Did the web component add to the value of the virtual seminar?**

Y N

What was your overall impression of the program and the virtual seminar format? Additional Comments?

Name: (optional) ____________________________

City: ____________________________ State: ______

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