Funding Research

Bertha deLanda
Training Specialist
September 2009
Introduction – Funding Research

...The American Cancer Society is the largest source of private, nonprofit cancer research funds in the US.

Donations and gifts to our center enable us to continue research of Alzheimer's disease.

...the Leukemia and Lymphoma Society relies on your support to fund our research initiatives...
Funding Process

1. Researcher has idea
2. Writes out study plan
3. Specifies research
4. Specifies costs
5. Applies for grant
6. Performs eProtocol submission; takes necessary training
7. IRB Approval
8. Scientific and scholarly review done/all approvals obtained
9. Matches scope of federal grant with scope in eP, & for human subject protection

Research Compliance Office
Different types of research funding

- Contracts/Grants
  - Industry sponsored
  - Federally sponsored
- Fellowships
  - Stipends
- Gifts/Endowments
- Department-funded

Federal

Research Compliance Office
Different types of research funding, cont.

Federal Grant

- An award of financial assistance from a federal agency to a recipient to carry out a public purpose of support or stimulation authorized by a law of the United States.

- NIH, NSF, Dept. of Defense, etc.
Why should the IRB look at funding source?

Because IRB has additional responsibilities related to the different types of funding,
Why should the IRB look at funding source?

45 CFR 46.103(f)

“Certification is required when the research is supported by a federal department or agency…(grant) applications must be approved and reviewed by the IRB”
Why should reviewers look at funding source?

HHS found numerous instances where:

- protocol description *was significantly different* than description in the grant application.
- important *elements were added* to the grant application that were implemented w/o IRB approval
- *e.g.*, targeting of vulnerable subjects
Why should reviewers look at funding source?

OPRR Letter May 31, 2000

- Grant application must be **approved** by IRB
- IRB must review the **actual grant application**
- Proposed research **must be consistent** w/grant application
- Entire grant application must be **attached**
“For federal projects, are the contents...as described in the proposal (grant) application?”

<table>
<thead>
<tr>
<th>Protocol Application Form</th>
<th>Protocol ID Title</th>
<th>12399 Measuring heartbeats while on Disney rides</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Medical</td>
<td></td>
<td>REGULAR</td>
</tr>
</tbody>
</table>

### Funding

- **Funding - Grants/Contracts**
  - SPO #: □
  - Grant #: □
  - Administered By: STANFORD
  - Funded By: NSF

### Funding - Fellowships

Please click on 'Add' to add Fellowships.
Funding Section, cont.

- IRB Manager ensures grant application is attached (in section 16 of “Protocol Information” for med, 11 for non-med)
- Reviewer verifies that scope of grant is consistent with the scope listed in eProtocol
Example: NIH Grant

- Grant application for NIH has specific format
- Electronic version will have TOC
- Specific Aims section has information re: research objective/scope
- Human Subject section has relevant information

2. SPECIFIC AIMS

Overview: Fragile X syndrome (FraX) is a common neurodevelopmental disorder associated with increased risk for serious cognitive and behavioral dysfunction including many features overlapping with autism spectrum disorders (ASD). Cognitive-behavioral dysfunction in FraX results from mutations of the FMR1 gene causing reduction in brain FMR1 protein (FMRP). In a much-anticipated “preview” of how specific risk factors for developmental disability and autism will eventually be addressed, intervention studies in humans with FraX and animal models have begun to target deficits. Though much initial attention was focused on mGluR5 dysregulation, it has become increasingly apparent that several important risk factors for development and autism will eventually be addressed, intervention studies in humans with FraX and animal models have begun to target deficits.
During IRB meeting, the reviewer states that the protocol objective is consistent with the grant objective.

Entire grant is attached to protocol; request assistance from Manager if it cannot be opened/found.

For significant protocol modifications or if there is a new grant, check to see that protocol and grant objective still match.