

**Research Compliance
Office**



Funding Re\$earch

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Training Specialist
September 2009**



Introduction –Funding Re\$earch



...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.



Research Compliance Office

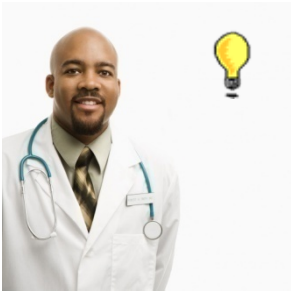


...the Leukemia and Lymphoma Society relies on your support to **fund our research initiatives...**



Funding Process

Researcher has idea



Writes out study plan

Funding

Specifies research
Specifies costs
Applies for grant

✓ Scientific and scholarly review done/all approvals obtained

IRB

Performs eProtocol submission; takes necessary training

✓ Matches scope of federal grant with scope in eP, & for human subject protection





Different types of research funding

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



Federal Grants



Different types of research funding, cont.

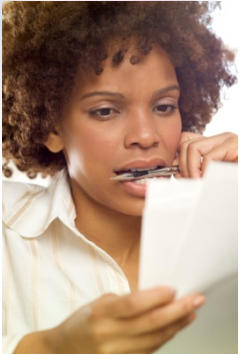


Federal Grant

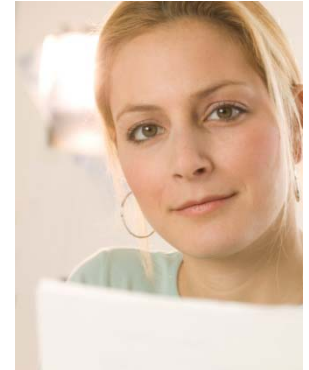
- An award of financial assistance from a federal agency to a recipient **to carry out a public purpose** of support or stimulation authorized by a law of the United States.
- NIH, NSF, Dept. of Defense, etc.



Why should the IRB look at funding source?

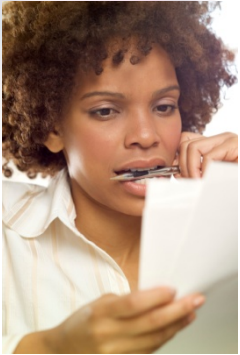


Because IRB has **additional responsibilities** related to the different types of funding,



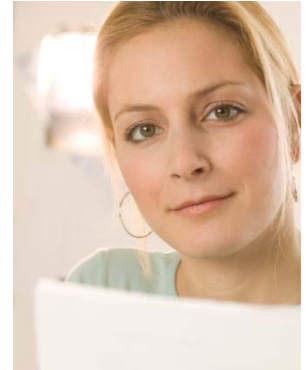


Why should the IRB look at funding source?



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?



United States Department of
Health & Human Services

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?



United States Department of
Health & Human Services

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

Funding Section: eProtocol

Protocol Application Form Protocol ID : 12399
Title : Measuring heartbeats while on Disney rides

Non-Medical REGULA

General Checklist

Funding

Resources

Protocol Information

Obligations

Funding - Grants/Contracts				
	SPO #	Grant #	Administered By	Funded By
<input type="checkbox"/>			STANFORD	<u>NSF</u>

Funding - Fellowships

Please click on 'Add' to add Fellowships

⦿ “For federal projects, are the contents...as described in the proposal (grant) application?”

Funding \$ection, cont.

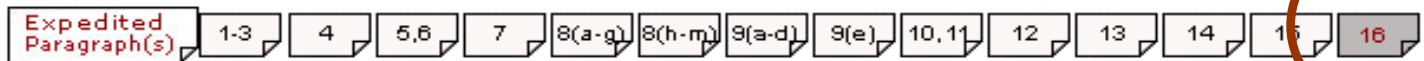
- IRB Manager ensures grant application is attached (in section 16 of “Protocol Information” for med, 11 for non-med)
- Reviewer verifies that scope of grant is consistent with the scope listed in eProtocol



Personnel Info

Participant Population

Study Location



16. Attachments

NOTE: For research done at or involving the VA, the [VA required questions](#) document must be saved to your computer, completed and attached. When attaching, set the attachment type to *VA required questions*.

Example : NIH Grant

- ❑ Grant application for NIH has specific format
- ❑ Electronic version will have TOC
- ❑ Specific Aims section has information regarding research objective and scope
- ❑ Human Subject section has relevant information

The screenshot displays the Adobe Acrobat Professional interface. The left sidebar shows a table of contents with the following items: Additional Justification, List of Research Plan Attachments, Introduction, Specific Aims, Background & Significance, Preliminary Studies/Progress, Research Design & Methods, and Protection of Human Subjects. The main content area shows the '2. SPECIFIC AIMS' section, which includes an 'Overview' paragraph discussing Fragile X syndrome (FraX) and its association with autism spectrum disorders (ASD). The text mentions mutations of the *FMR1* gene and the resulting reduction in brain *FMR1* protein (FMRP). It also notes that intervention studies in humans with FraX and animal models have begun to target deficits, and that although much initial attention was focused on mGluR5 dysfunction, it has become increasingly apparent that several important individuals with FraX (Curia, Papouin et al. 2008; Wang, V) have provided a body of evidence from our lab and others implicating dysfunction in the mGluR5 pathway.



IRB Responsibilities

- 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