

**Research Compliance
Office**



Funding Re\$earch

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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



Different types of research funding, cont.

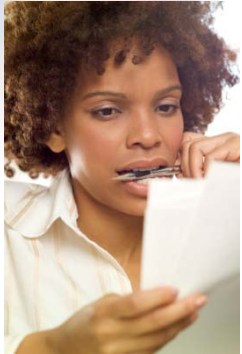
Federal Grant

- 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.

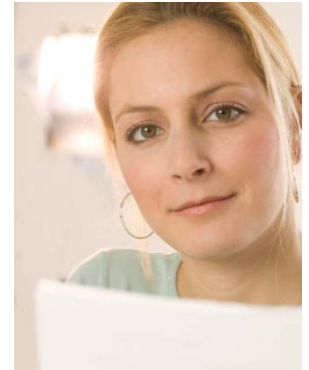




Why should the IRB look at funding source?

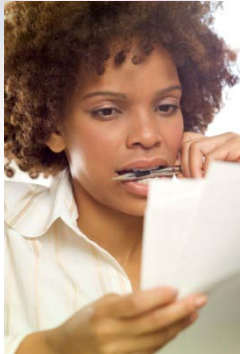


Because IRB has **additional responsibilities** related to the different types of funding,



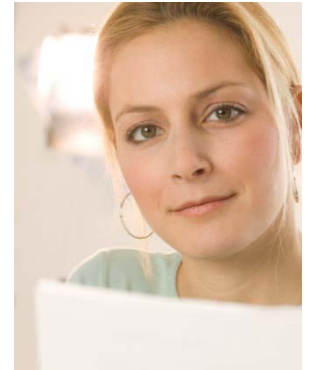


Why should the IRB look at funding source?



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 REGULAR

General Checklist

Funding

Resources

Protocol Information

Obligations

Protocol Information

Obligations

IRB Return Notes

Funding

NONE

Funding - Grants/Contracts

	SPO #	Grant #	Administered By	Funded By
<input type="checkbox"/>			STANFORD	NSF

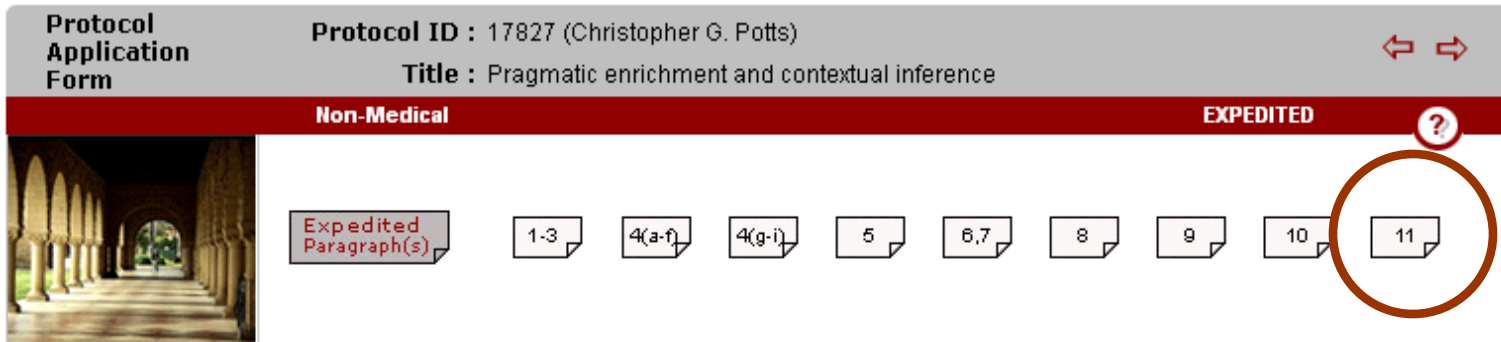
Funding - Fellowships

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



The screenshot displays the eProtocol system interface for a protocol application. At the top left, it says "Protocol Application Form". To the right, the "Protocol ID" is 17827 (Christopher G. Potts) and the "Title" is "Pragmatic enrichment and contextual inference". Below this, a red bar indicates the protocol is "Non-Medical" and "EXPEDITED". A navigation bar at the bottom shows a sequence of numbered tabs: "Expedited Paragraph(s)", "1-3", "4(a-f)", "4(g-i)", "5", "6,7", "8", "9", "10", and "11". The "11" tab is circled in orange, and a question mark icon is visible above it. A small image of a hallway with arches is visible on the left side of the interface.



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

The screenshot displays a PDF viewer interface. On the left, a table of contents is visible with the following items: Additional Justification, List of Research Plan Attachments, Introduction, Specific Aims (highlighted with a blue box), Background & Significance, Preliminary Studies/Progress, Research Design & Methods, and Protection of Human Subjects (highlighted with a blue box). Below this, a secondary list of contents is shown, including: List of Research Plan Attachments, Introduction, Background & Significance, Preliminary Studies/Progress, Research Design & Methods, Protection of Human Subjects (highlighted with a blue box), Women & Minorities, Planned Enrollment Table, Children, References Cited, and Letters of Support. The main content area on the right shows the text of the '2. SPECIFIC AIMS' section, which includes an overview of Fragile X syndrome (FraX) and its association with autism spectrum disorders (ASD).

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 dysfunction, it has become increasingly apparent that several important individuals with FraX (Curia, Papouin et al. 2008; Wang, V. body of evidence from our lab and others implicates dysfu



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