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

STANFORD SCHOOL OF MEDICINE

Donations and gifts to our center enable us to continue research of Alzheimer's disease.
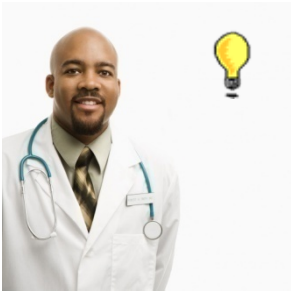
…the Leukemia and Lymphoma Society relies on your support to **fund our research initiatives**…

Funding Proce$$

Funding

Researcher has idea

Writes out study plan

Specifies research Specifies costs Applies for grant	✔ Scientific and scholarly review done/all approvals obtained → **GO**

IRB

Performs eProtocol submission; takes necessary training	✔ Matches scope of federal grant with scope in eP, & for human subject protection → **IRB Approval**

Different type$ of research funding

- Contracts/Grants
  - Industry sponsored
  - Federally sponsored

- Fellowships
  - Stipends

- Gifts/Endowments

- Department-funded

Federal Grants

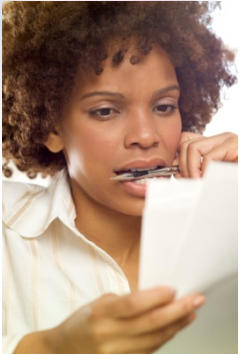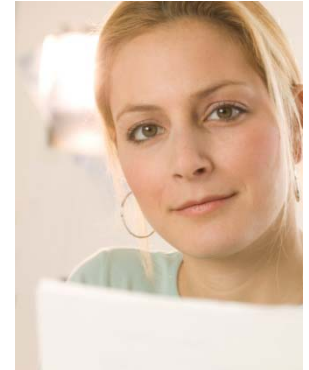# Different type$ of research funding, cont.

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.
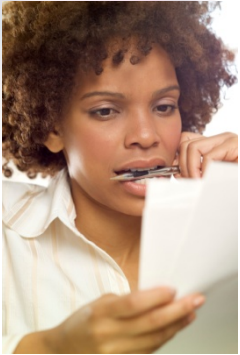
Why should the IRB look at funding source?

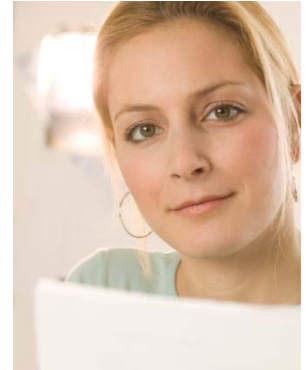Because IRB has additional responsibilities related to the different types of funding,

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 reviewer$ 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 reviewer$ look at funding source?

United States Department of Health & Human Services

OPRR Letter May 31, 2000

➡ Grant application must be <u>approved</u> by IRB

➡ IRB must review the <u>actual grant application</u>

➡ Proposed research <u>must be consistent</u> w/grant application

➡ Entire grant application must be <u>attached</u>

Funding $ection: eProtocol

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

Non-Medical **REGULA**

General Checklist

Funding

Resources

Protocol Information

~~Obligations~~

Info
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Checklist

Protocol Information
Obligations
IRB Return Notes

Funding

☐ NONE

Funding - Grants/Contracts

	SPO #	Grant #	Administered By	Funded By
☐			STANFORD	NSF

Funding - Fellowships

Please click on 'Add' to add Fellowships

◉ **"For federal projects, are the contents…as described in the proposal (grant) application?"**
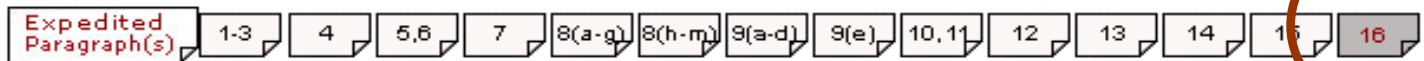
Funding $ection, cont.

- 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

16. Attachments

NOTE: For research done at or involving the VA, the <u>VA required questions</u> 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**

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