

Conflict of Interest in Research

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Objectives

- Define 'investigator'.
- Summarize requirements related to research conflict of interest (COI).
- Describe the process for monitoring investigator compliance with Geisinger's COI policy.

What's the Big Deal?

- Promotes **objectivity in research** by establishing standards that provide a reasonable expectation that the **design, conduct, and reporting of research** will be **free from bias** resulting from Investigator financial conflicts of interest.
- Geisinger Policy for *Investigator Conflicts of Interest (COI) in Research* complies with federal COI regulation¹.

¹42CFR Part 50, Subpart F

Investigator



Investigator defined as ...

“project director or principal Investigator and any other person, regardless of title or position, **who is responsible for the design, conduct, or reporting of research**, which may include, for example, collaborators or consultants.”¹

Investigator

- Geisinger employees
- Non-Geisinger employees
 - Follow either the COI Policy of their home institution or Geisinger.
 - Work with OSP to determine the appropriate designation.

Investigator Disclosure

- Investigators (includes family members) must **disclose** financial interests to Geisinger.
 - Annual FCOI Questionnaire
 - Update questionnaire throughout the year (**within 30 days**)
<https://geisinger.coi-smart.com/login.php>
 - Significant changes
 - Travel
- Investigators **attest** that there are no conflicts with proposed research at time of grant award and IRB submission.

Investigator Training

Must complete **FCOI training**:

- Before engaging in any research activities,
- At least every 4 years, and
- Immediately when:
 - Revised Geisinger FCOI policy/procedures
 - New Geisinger investigator
 - Investigator non-compliance with policy or management plan



Investigator Training

- CITI Training

- January 2013 - *Conflict of Interest in Research* included in your CITI Human Subjects Research Protection training required course list; or

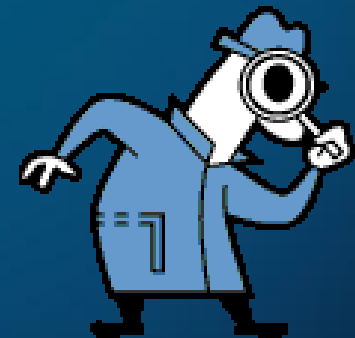
- Web-based NIH FCOI Tutorial

- View the NIH tutorial at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi/htm>
- Type your name and print Certificate of Completion
- Submit Certificate to the Office of Research Compliance (internal zip - 30-69 / email - orc@geisinger.edu)

How do we insure compliance?

Review by OSP and ORC:

- Funding Application
- Grant Award, Renewal, Continuation
- IRB Submission



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