Compliance and Conflicts of Interest

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Disclosures

- I have no actual or potential conflicts of interest in relation to this presentation

Objectives

- Recognize the key components of a research compliance program
- Define what is considered research misconduct and how to report any potential concerns
- Apply the policies & procedures in place in regard to research conflicts of interest

Agenda

Research

- Compliance
- Integrity & Misconduct
- Conflict of Interest

Research Compliance

Illustration by David Parkins

Regulatory Acts & Agencies

FDA
IRB
NSF
USDA
IACUC
CLIA
ORI

IBC
CDC
OCR
RDRC
DSMB
OHRP
COI

GCP
NIH
OSP
OIG
SAMHSA
HIPAA
FERPA

Just to name a few…

Role of Compliance in Research

Research Oversight Committee:

- Research & Development (R&D)
- Institutional Review Board (IRB)
- Health Analytics Research Team (HART)
- Organizational Integrity & Compliance (OIC)

Areas of OIC Responsibility

- Privacy/HIPAA
- Information/Data Security
- Auditing & Monitoring
- Protocol Non-Compliance
- Research Integrity
- Research Misconduct
- Conflicts of Interest

Research Integrity

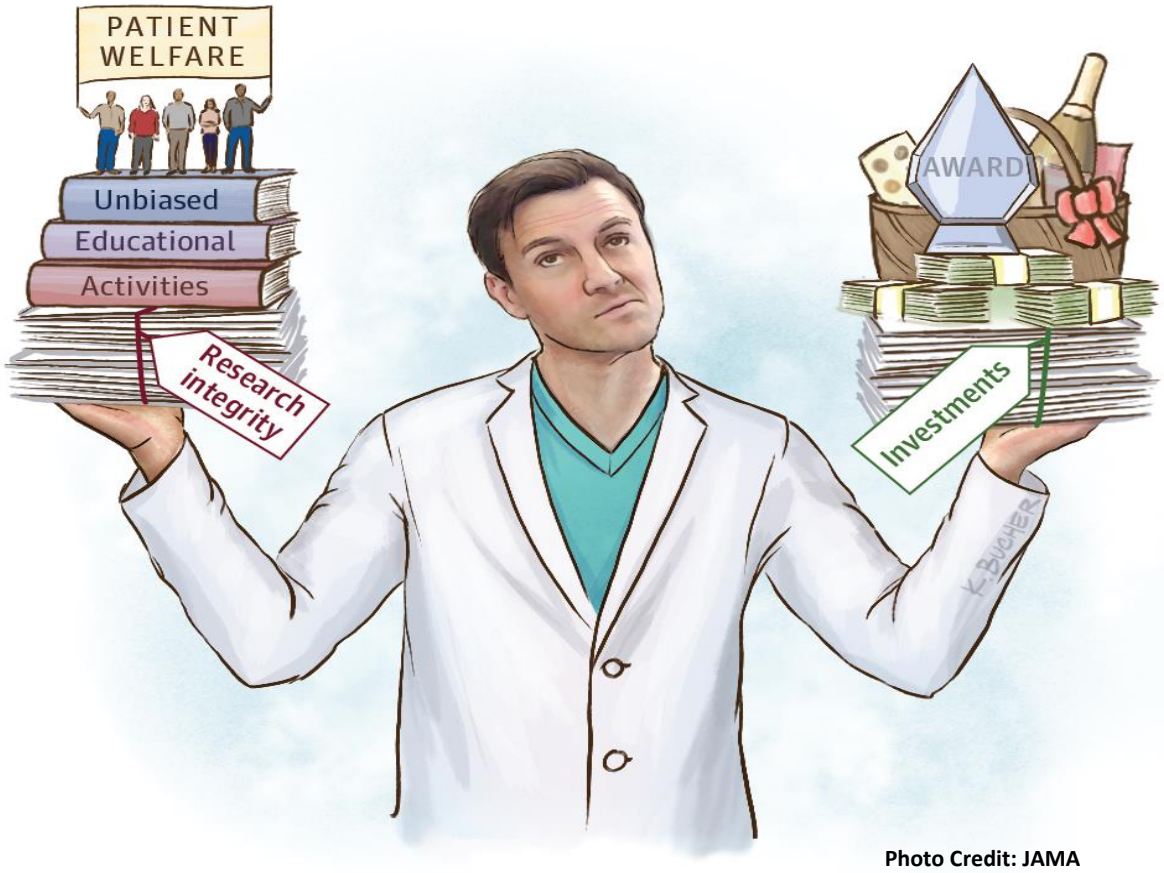


Photo Credit: JAMA

Examples of Research Integrity

- Reporting both positive & negative results
- Providing true, accurate, and complete costs related to your research grant/sponsored funding
- Providing credit where credit is due

Research Misconduct

Office of Research Integrity (ORI) Definition of Research Misconduct

Fabrication, **falsification**, or **plagiarism** in proposing, performing, or reviewing research, or in reporting research results.

*Research misconduct does not include honest error or differences in opinion.

Credit: University of Southern Maine

Examples of Misconduct

- Taking authorship credit for research participation that was in name only
- Failure to provide validation for your research
- Self-plagiarism

“If you see something say something”

- Your supervisor/department chair
- Compliance@carilionclinic.org
- Integrity Help Line: (844) 732-6232
- http://CarilionClinicIntegrity.org

Conflict of Interest

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."

What is a Conflict of Interest?

A situation in which an Investigator's, and/or their family members, financial, professional, or other personal considerations may directly or indirectly affect, or reasonably appear to affect, the Investigator's professional judgement in performing a Carilion Clinic-related duty or responsibility.

A Conflict of Interest may be actual, apparent, or potential.

Who needs to disclose a potential COI?

Key Research Personnel:

The project director or principal investigator, and ANY other person, regardless of title or position, who is responsible for the design, conduct, or reporting of actual or proposed research, or proposed funding for research.

When do I need to disclose a COI?

- Annually
- No later than 30 days after discovery of a new financial interest, potential conflict, or change in information
- When adding new personnel to an already existing protocol

How do I know if I need to disclose?

- ANY externally funded OR supported research needs to be disclosed
  - Regardless of sponsor
  - Regardless of monetary value

- R&D collaboration:
  - -Feasibility meetings
  - -Grants
  - -External institutions

What needs to be disclosed?

- Employment
- Consulting services (e.g. advisory board, speaker’s bureau)
- Proprietary interest (IP, patents, copyrights, royalties)
- Financial benefits
- Incentives
- Reimbursement for travel

Where do I go to disclose a COI?

COI Smart:

For Carilion Clinic AD account holders:

https://carilionclinic.coi-smart.com

For External Collaborators:

https://carilionclinic-nonshib.coi-smart.com

Why do I need to disclose?

- Requirement of all PHS-funded research
  - 42 CFR Part 50
  - 45 CFR Part 94
- FDA Requirement
  - 21 CFR Part 54
- Carilion Clinic Policy

Seriously, why for every study?

- Study specific, not sponsor specific
- Better transparency
- Confirmation of role/responsibilities
- Complies with timeframe requirements
- Complies with external affiliations
- New method, not a new concept

How is my disclosure reviewed?

- Evaluated by Chief Compliance Officer (or designee) to determine if COI exists
- If potential COI, key stakeholders (e.g. Department Chair, Chief Legal Counsel, Institutional Official), will be informed and may be consulted as part of the development of a management plan.

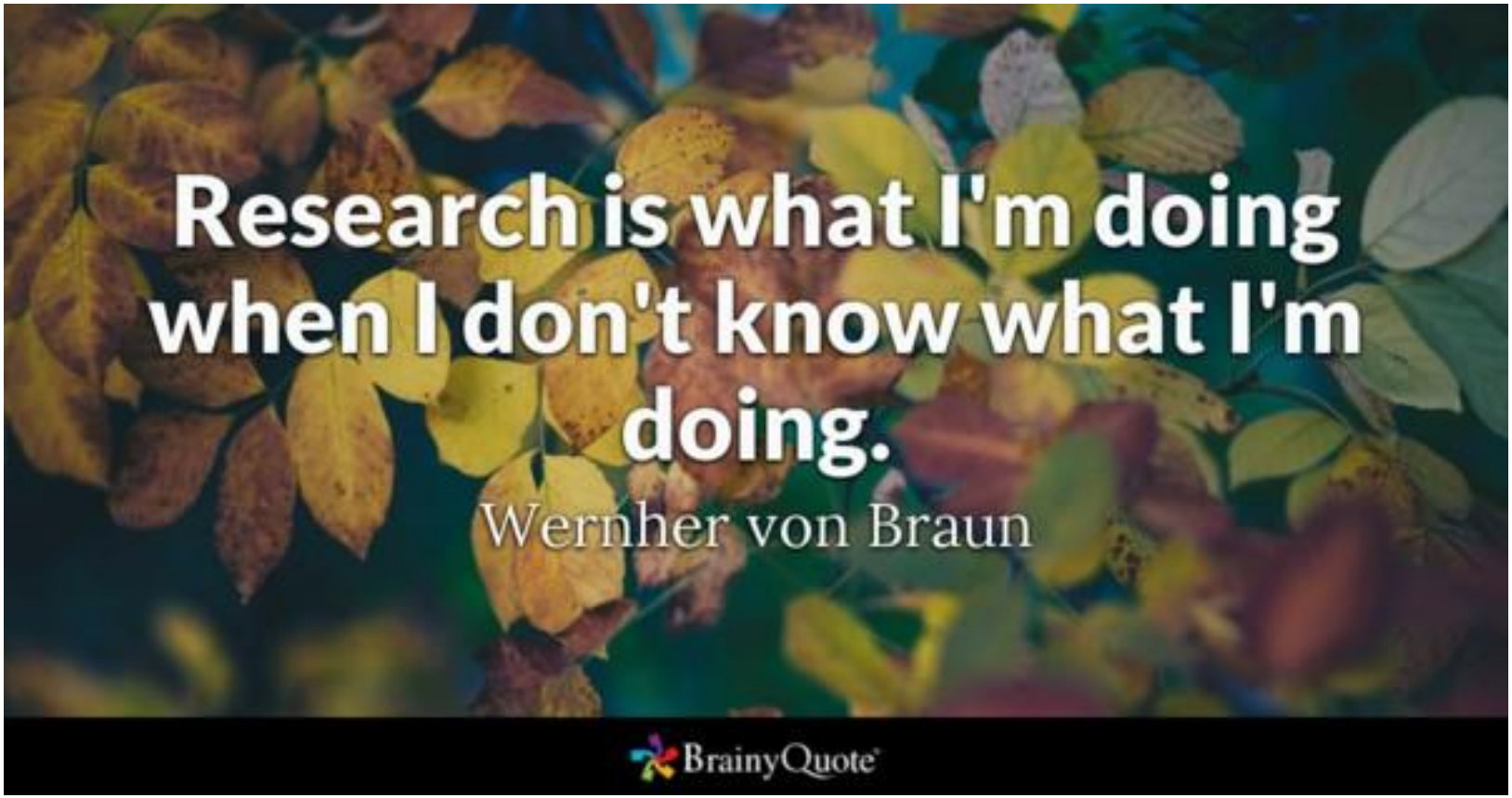
Management Plan Examples

- Public disclosure of the COI
- Disclosure included in consent form to potential research subjects
- Modification of research study
- Change of personnel or responsibilities
- Reduction or elimination of the financial interest
- Severance of relationships

Key Takeaway Regarding Disclosures

It is important to remember that the mere disclosure of an interest or relationship **does not** necessarily mean a conflict exists, or that it is adverse to complying with regulatory requirements.

Questions?


Research is what I'm doing when I don't know what I'm doing.
Wernher von Braun
BrainyQuote