
Compliance 101 for the Research Administrator
Debra Schaller-Demers, MSOM
Senior Director, Research Outreach and Compliance
Memorial Sloan Kettering Cancer Center
Mary Schmiedel, JD, CPCM
Senior Director, Office of Research Oversight
Georgetown University
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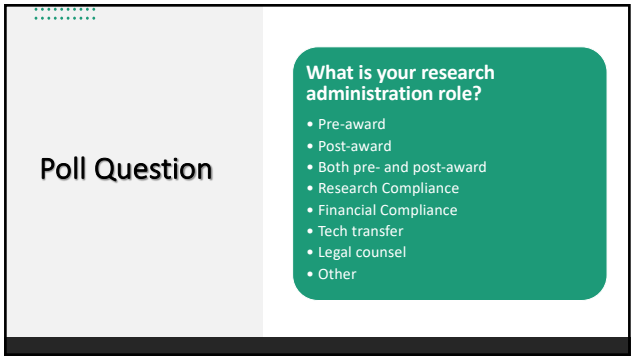
Poll Question
What is your research administration role?
• Pre-award
• Post-award
• Both pre- and post-award
• Research Compliance
• Financial Compliance
• Tech transfer
• Legal counsel
• Other

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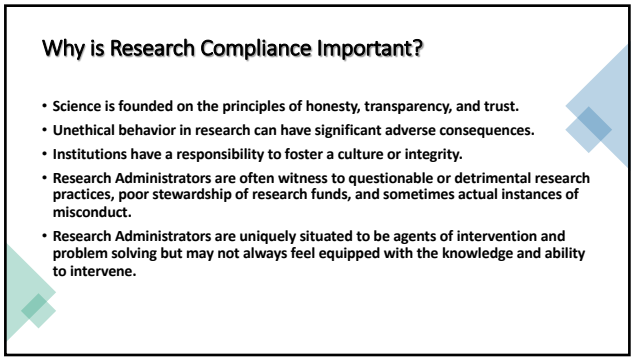
Why is Research Compliance Important?
• Science is founded on the principles of honesty, transparency, and trust.
• Unethical behavior in research can have significant adverse consequences.
• Institutions have a responsibility to foster a culture or integrity.
• Research Administrators are often witness to questionable or detrimental research practices, poor stewardship of research funds, and sometimes actual instances of misconduct.
• Research Administrators are uniquely situated to be agents of intervention and problem solving but may not always feel equipped with the knowledge and ability to intervene.

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Why is Research Compliance Important?

- Compliance requirements have become increasingly more complex and burdensome.
- Noncompliance and research misconduct does happen.
- Although instances of noncompliance differ in content and scale, an organized planned response is prudent.
- Protect the institution, IOs, and researchers/staff.
  - Protect the human subjects so individuals will be willing to engage in research.
- Increased reporting requirements to agencies: your response to noncompliance/misconduct must be complete and defensible.

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How Does Research Administration and Compliance Intersect?

- Research administrators must certify that certain compliance obligations have been met.
  - IRB (IACUC, IBC, EO, etc.) review and training
  - COI review and training
- IRB wants to know who is sponsoring a project, whether investigators are conflicted, and that safety and welfare of human subjects is being protected.
- IRB may refer concerns about conduct of human subjects research to research misconduct committee.
- Any missteps in the above processes could lead to reputational and financial implications.
- Do you all know who to contact in the various offices?

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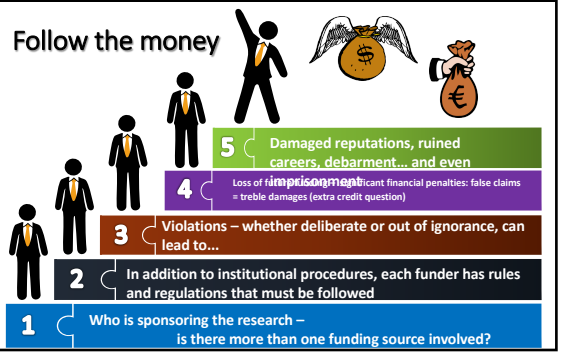
Follow the money



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Practicing a Culture of Compliance

Setting the bar high …

- Roles and responsibilities
- Policies and procedures
- Training and education
- Financial conflict of interest/commitment – publication ethics
- Financial management of sponsored programs
- Clinical trial data and safety reporting and monitoring
- Bayh-Dole Act/invention and patent reporting

You have all the elements – how do you make them work?

- Know your audience – communication is essential
  - Faculty (Physicians/Scientists), RSAs, Postdocs, Students, Clinical Nurses, Admins
- Accessibility – to information, advice, guidance
- Enforcement – Consequences

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Financial Conflicts of Interest

- Potential for personal gain could compromise the design, conduct or reporting of research or other University activity.
  - Individual
    - Advisory board service
    - Consulting
    - Stock ownership
    - Equity ownership – start ups
    - Spouse's employer
    - Subcontracting to spouse
  - Institutional
    - Patent holder
    - Equity holder in a start up
- Actual or perceived conflicts.
- Identify activities and provide reliable processes for managing the potential conflict.

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Financial Conflicts of Interest

- 42 CFR Part 50, Subpart F - Responsibility for Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors
  - Effective August 24, 2012
  - https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf
- PHS wants to ensure there is no reasonable expectation that design, conduct, or reporting of research will be biased by conflicting financial interests.
  - Disclosures must be on file at the time of proposal or protocol submission
  - Conflict of interest officer makes an independent determination of whether financial interest is a conflict
  - Conflicts must be managed and reported
  - Training requirement: at time of award and every 4 years thereafter
- Some private sponsors follow the PHS guidelines.
- Know your institutional policy.

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Research Misconduct - FFP

- DHHS Office of Research Integrity's definition is "fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion."
  - See 42 CFR § 93.
- Universities tend to broaden the definition as follows: "(1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, and reviewing research, or in reporting results from research, or (2) failure to meet material legal or University requirements governing research. This definition does not include honest error or honest differences in interpretations or judgments of data."
- Fabrication
  - Manufacturing or inventing something that never occurred or just "making it up" and reporting it
- Falsification
  - Falsifying information
- Plagiarism
  - Using someone else's ideas, results or words without the proper acknowledgement
  - Self plagiarism

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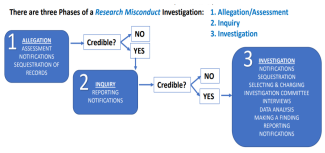
Research Misconduct

Why do individuals commit research misconduct?

- Promotion and tenure
  - Need to get (and keep) grant funding
  - Need to publish (or perish) – intense competition
- Want to prove an invention works
- Competition with colleagues
- Greed – money or fame
- Personal issues
- Reputation/arrogance – so sure of the outcome
- Cultural differences – values and definitions



Criteria for finding research misconduct

- Significant departure from accepted practices
- Committed knowingly, intentionally or recklessly
- Can be proven by a preponderance of the evidence

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Human Subject Research

- Fundamental Research Ethics Documents
  - Nuremberg Code
  - Declaration of Helsinki
  - Belmont Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research – 4/18/79
- Three Basic Ethical Principles
  - Respect for persons
    - Individual autonomy
    - Protection of individuals with reduced autonomy
  - Beneficence
    - Maximize benefits and minimize risks
  - Justice
    - Equitable distribution of research costs and benefits
- DHHS Office of Human Research Protections, https://www.hhs.gov/ohrp/
- 45 CFR Part 46
  - Pre-2018 and 2018 Revised Common Rule (2018 Common Rule) – Effective 1/22/19

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Definitions

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

Pre-2018 (45 CFR 46.102(f))

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information

2018 (45 CFR 46.102(e)(1))

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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Significant Changes in the Common Rule

- Activities not considered human research
  - Scholarly/journalistic activities that focus on the individuals about whom info is being collected
  - Public health surveillance activities
  - Criminal justice agency activities
  - Activities in support of intelligence, homeland security, defense or other national security
- Consent changes
  - Waiver of consent
    - New criteria that the IRB can waive the requirement or the elements of informed consent if the research could not be practically carried out without accessing info or biospecimens in an identifiable format
  - Waiver of documentation of consent
    - New criteria for international research if subject's signature on the consent form is not culturally appropriate
  - Broad consent – an optional, alternative consent process for use solely for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future unspecified research.
- Continuing review
- Some studies that require only expedited review will no longer require a continuing review

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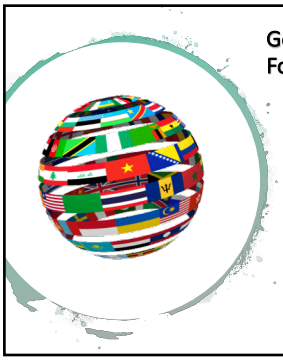

Government Scrutiny on Undue Foreign Influence

U.S. Government is concerned about the loss of U.S. intellectual property to foreign countries.

- Sharing confidential information received by peer reviewers with other countries/governments.
- Failure to disclose other support and other foreign government collaborations.
- Foreign government sponsored talent (recruitment) programs.

Result

- More disclosures to federal agencies.
  - Foreign collaborations and visiting, adjunct, and honorary appointments.
  - Study personnel who are volunteers or visitors paid by another organization.
- Conflict of interest disclosure may not match other support disclosures.

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Export Controls

- Export controls regulate the export of controlled information, software, materials, technologies and services to foreign persons, whether they are in the U.S. or abroad.
- Sanctions and embargoes restrict travel to or interactions with certain countries and individuals within those countries.
- Deemed exports are the release of controlled technology or source code (subject to export control regulations) to a foreign national while inside the U.S., e.g., on campus.
  - Deemed to be an export to the home country of the foreign national
  - Exceptions
    - Permanent residents, U.S. citizens, and those with status as a protected person

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Export Controls

- Fundamental Research
  - Per National Security Decision Directive (NSDD) 189 – fundamental research is defined as basic and applied research in science and engineering, the results of which are ordinarily published and shared broadly within the scientific community, as distinguished from proprietary research . . .
  - The fundamental research exclusion ("FRE") exempts GU from requiring a deemed export license for research performed on campus
  - Any agreement that restricts publications or the participation of foreign nationals negates the FRE
    - Side deals by the PI can negate the FRE
- Agreements in which the University is providing a service to a sponsor are not considered fundamental research and require additional review.

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Fundamental Research Exclusion and "Use"

- The fundamental research exclusion applies to the outputs, e.g., reports, but not to the inputs, e.g., access to controlled equipment, encryption, etc.
- "Use" is defined by the Export Administration Regulations as "operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing."
  - The International Traffic in Arms Regulations define use with an "or" instead of "and" so they are far more restrictive
- Many foreign nationals do not have access to information that will enable them to do all the activities that rise to the level of use.
- If they do, their "use" may require a license.

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Embargoed and Sanctioned Countries

- **Balkans**
- **Belarus**
- **Central African Republic**
- **Cuba**
- **Democratic Republic of Congo**
- **Iran**
- **Iraq**
- **Lebanon**
- **Libya**
- Mali
- Nicaragua
- **North Korea**
- Somalia
- Sudan and Darfur
- **Syria**
- Ukraine/Russia/Crimea
- Venezuela
- Yemen
- Zimbabwe

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Resources

- **Bayh-Dole Act:** https://grants.nih.gov/grants/bayh-dole.htm
- **Conflict of Interest**
  - **PHS FCOI Policy:** https://grants.nih.gov/grants/policy/coi/index.htm
  - **Georgetown Financial Conflicts of Interest Policy:** https://fcoi.georgetown.edu/
- **Human Subjects**
  - **Federal Policy for the Protection of Human Subjects ("Common Rule"):** https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html
  - **DHHS Office of Human Research Protections,** https://www.hhs.gov/ohrp/
  - **Nuremberg Code:** https://history.nih.gov/research/downloads/nuremberg.pdf
  - **Belmont Report:** https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
  - **GU IRB website:** https://ora.georgetown.edu/irb/#
- **Animal Subjects**
  - **Animal Welfare Act:** https://www.nal.usda.gov/awic/animal-welfare-act
  - **PHS Policy on Humane Care and Use of Laboratory Animals:** https://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf
  - **Guide for the Care and Use of Laboratory Animals:** https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
  - **Georgetown Institutional Animal Care and Use Committee (IACUC):** https://ora.georgetown.edu/iacuc/#
- **Research Misconduct**
  - **Federal Research Misconduct Policy:** https://ori.hhs.gov/federal-research-misconduct-policy
  - **Georgetown University Code of Procedure for Alleged Misconduct in Research:** https://facultyhandbook.georgetown.edu/section4/#4&_ga=2.268804729.920104998.1583005447-1486817733.1576103158

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Contact:

schalled@mskcc.org
Mary.Schmiedel@georgetown.edu

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