Gabriella Neff
Research Compliance Officer
H. Lee Moffitt Cancer Center and Research Institute, Inc.

Research Compliance Fundamentals

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Your Courage Inspires Ours

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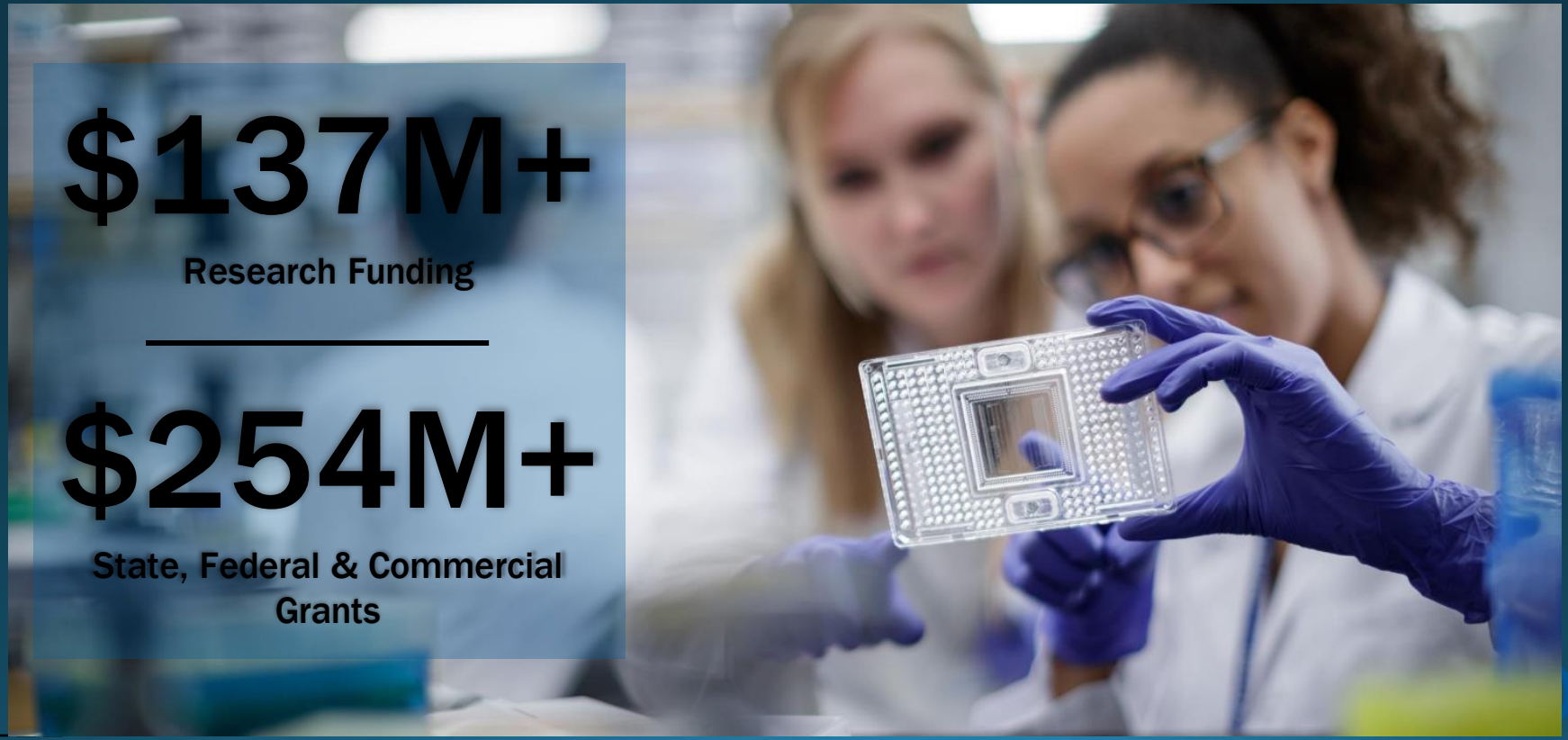
Research

Moffitt's research focuses on cutting-edge discoveries that can be rapidly translated into improved diagnostic, preventive and therapeutic advances.



$137M+

Research Funding

$254M+

State, Federal & Commercial Grants

Clinical Trials

More than

1,900

Clinical Trial Accruals Annually

700+ Active Interventional Trials

212+ Trials initiated by Moffitt researchers

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Expanding Industry Alliances

Advancing Moffitt discoveries by forging partnerships with startups and industry to bring cutting edge ideas and discoveries to the marketplace.

Office of Innovation and Industry Alliances

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Research Compliance 101

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Research Compliance Issues & Regulations

- Human Subjects & Research Safety
- Federal Awards & Grant Expenditures
- Stem cells & DNA
- Animal Use & Care
- Research Integrity
- Foreign Influence & Export Controls
- Conflicts of Interest
- Research Information Privacy & Security
- Clinical Trial Billing

- HHS (Department of Health & Human Services)
- OMB (Office of Management & Budgets)
- OHRP (Office of Human Research Protection)
- OLAW (Office of Laboratory Animal Welfare)
- FDA (Food & Drug Administration)
- OBA (Office of Biotechnology Activities)
- ORI (Office of Research Integrity)
- OCR (Office for Civil Rights)
- ICH-GCP (International Conference on Harmonisation & Good Clinical Practice)

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Human Subjects Research

Historical Perspective

- The Nuremberg Code (1947)
- The Declaration of Helsinki (1964)
- The Belmont Report (1979)

- International Conference on Harmonisation – ICH-GCP
- Code of Federal Regulations – The Common Rule

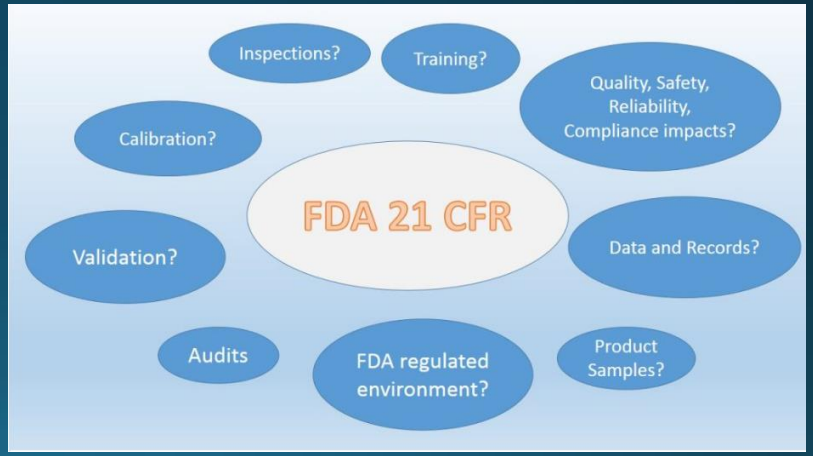
FDA Regulations

The Code of Federal Regulations (CFR): Rules published in the Federal Register by the Executive Departments and agencies of the Federal Government.

Divided into 50 titles that represent areas subject to Federal regulations.

Title 21 CFR is administered by the FDA and covers regulations related to Food & Drugs

- Part 11 –Electronic Records & Signatures
- Part 50 – ICF (Protection of Human Subjects)
- Part 54 – Financial Disclosure
- Part 56 – IRB
- Part 312 – IND Application
- Part 812 – IDE
- Part 814- Premarket Approval of Medical Devices



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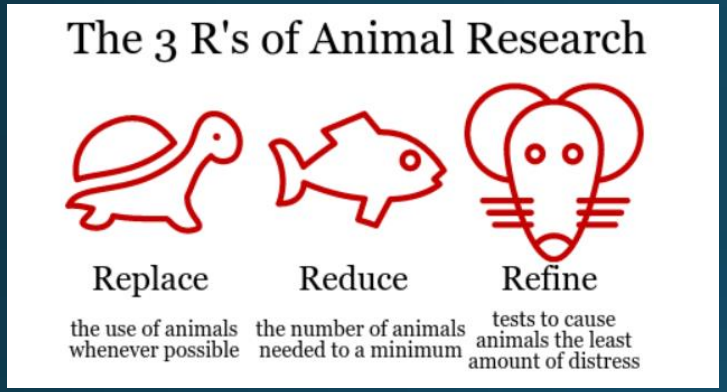
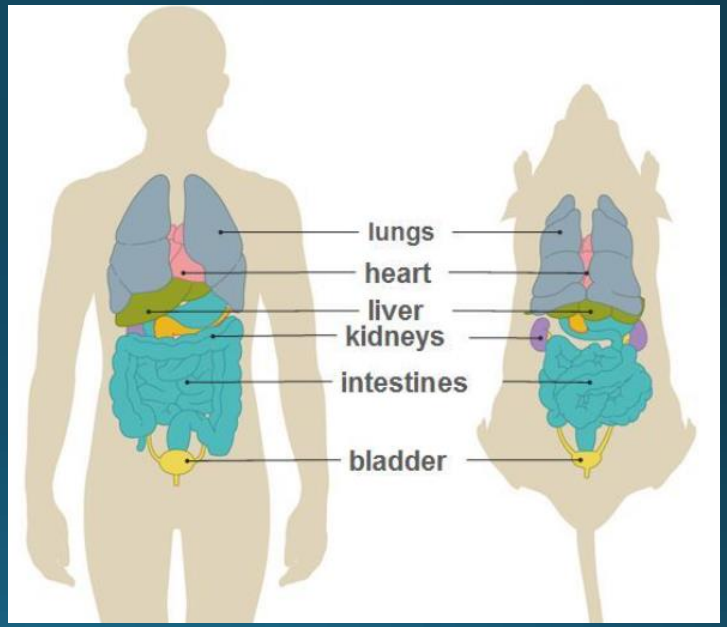
Animal Use & Welfare





Office of Laboratory Animal Welfare
OLAW

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Federal Awards & Grant Expenditures

Overcharging Grants

UW-Madison to pay $1.5 million to settle claim with U.S. government, DOJ reports

Foreign/Other funding or support

OIG Outlines Multiple Probes Into NIH, PIs Who May Have Failed to Disclose All Support

Time and Effort Reporting

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Foreign Influence

NIH Investigates Foreign Influence at U.S. Grantee Institutions

Concerns:

- "Shadow laboratories" & substantial funding for research conducted abroad
- Conflicts of Interest
- Time commitment (>100% effort)

> In order for NIH to make informed assessments of possible overcommitment and/or scientific or budgetary overlap, we will need to see complete copies (in original and in English translation) of foreign grants and employment contracts.

Benefits : Sign-on bonuses , additional salary, housing, laboratory, equipment, personnel
Deliverables: training personnel, papers, patents/IP

100s of investigator removals, terminations, repayments, and False Claims Act payments

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Foreign Influence, continued

Moffitt Cancer Center CEO, Center Director Resign after Compliance Review

December 18, 2019

Sacked Moffitt Officials Didn't Report Chinese Financial Ties

— Not clear what was done in exchange for payments

by Crystal Phend, Senior Editor, MedPage Today January 23, 2020

Hospitals

Top exec, researchers resign from Moffitt Cancer Center over concern of IP theft by China

House Select Committee begins query into Chinese interference in public research

The group will investigate Chinese involvement with UF and Moffitt.

By **Janelle Irwin Taylor** on January 22, 2020

The House Select Committee on the Integrity of Research Institutions kicked off Tuesday with its first meeting as the day was wrapping up in Tallahassee.

House Speaker **Jose Oliva** **convened** the committee to investigate foreign interference in United States publicly funded research, particularly by China.

Oliva launched the **committee** in response to situations at two Florida research institutions, Moffitt Cancer Center in Tampa and the University of Florida in Gainesville.

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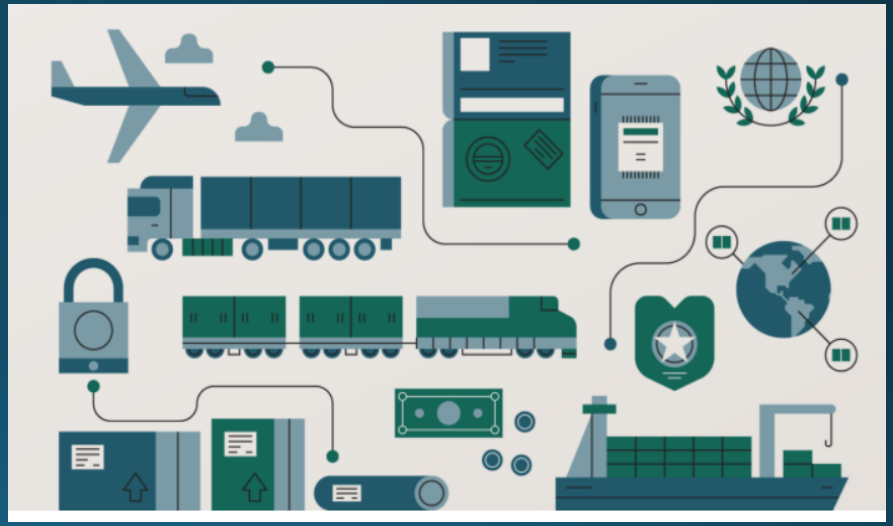
Export Control

What is Affected by Export Controls?

- Foreign students and researchers' participation in research associated with a controlled technology
- Ability to provide services to foreign nationals
- Ability to send controlled equipment internationally
- Disclosure of proprietary information



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Research Integrity & Misconduct

Duke University settles research misconduct lawsuit for $112.5 million

www.pubpeer.com
www.retractionwatch.com

Harvard and the Brigham call for more than 30 retractions of cardiac stem cell research

Cancer researcher retracts 19 studies at once

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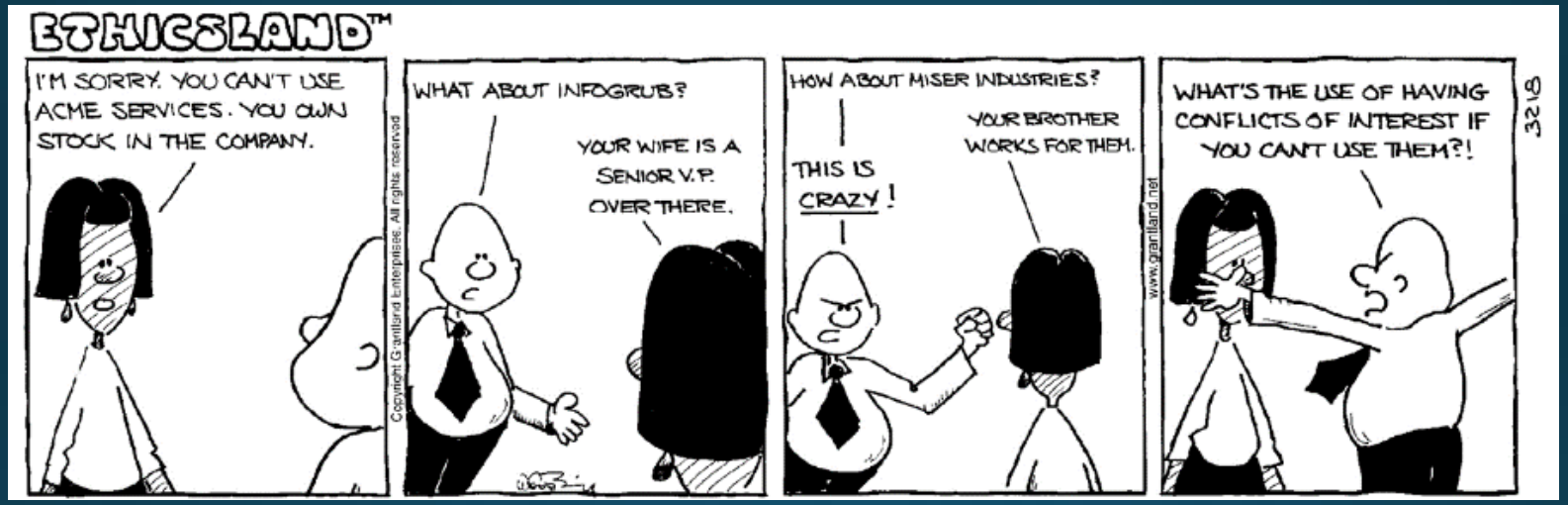
Conflicts of Interest (COI) & FCOI



Memorial Sloan Kettering, you've betrayed my trust

"A seed of doubt now exists: Could those recommendations be colored by a physician's extra-curricular financial entanglements?"

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Conflicts of Interest - Management

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institution Review Board, etc.);
- For research projects involving human subjects, disclosure of financial conflicts of interests directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); &
- Severance of relationships that create financial conflicts.

Clinical Trial Billing

- National Coverage Determinations (NCDs)
- Local Coverage Determinations (LCDs)
  - Medicare Administrative Contractor (MAC) – First Coast - has special device coverage rules
- Medicare Advantage Plans - cannot be billed as primary payer for qualifying drug trials

- Two federal statutes prohibiting waivers of co-payments:
  - Beneficiary Inducement Statute 42 U.S.C. 1320a-7a
  - Medicare Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)
- Medicare coverage and off-label use:
  - Off-Label use for non-cancer – MAC Determination
  - Off-label use for cancer –NCCN Drug Compendia

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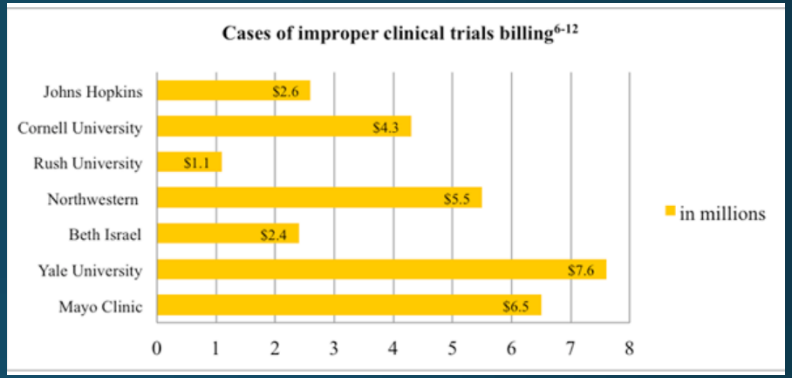
Clinical Trial Billing continued

Getting it ‘Right” – Why is it important?



Not managing clinical research billing risks may lead to:

- Billing for services already paid for by the sponsor
- Billing for services promised free in the informed consent
- Billing for services that are for research only that are not allowable to bill under the CMS Clinical Trial Policy (CTP)

December 2005 Rush University Medical Center Settlement: Improper Medicare Billing in Clinical Trials under September 2000 NCD

Medicare ‘double billing’ has been a focus and the subject of numerous OIG/DOJ investigations/settlements

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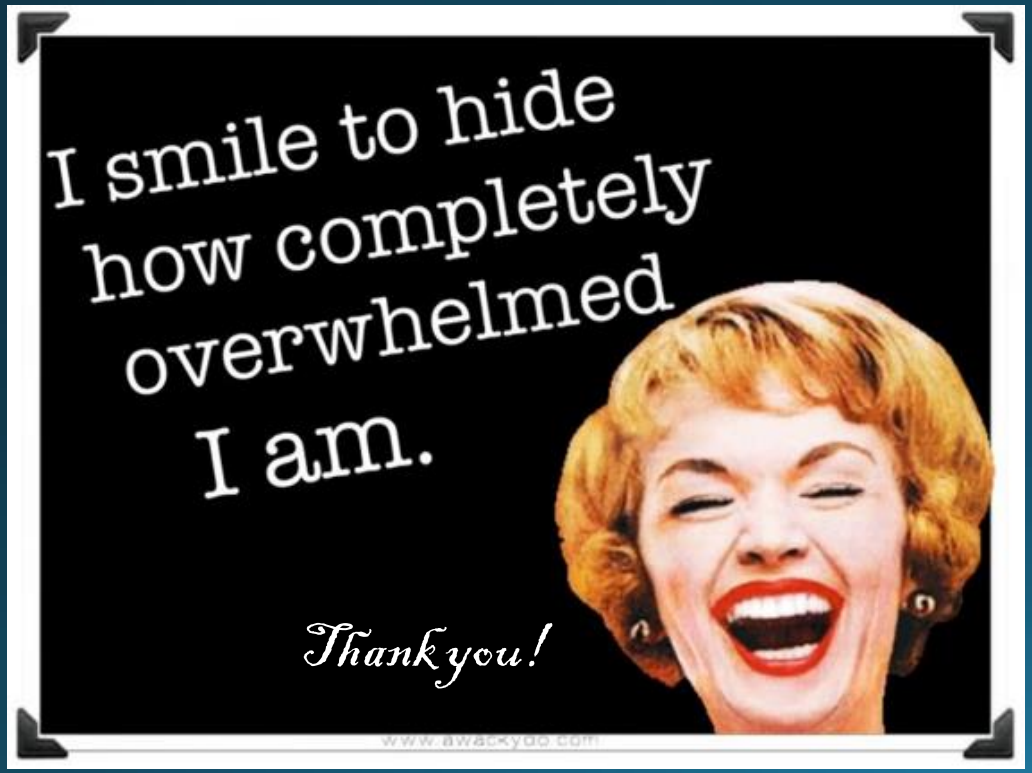
Are You Having Fun Yet?



Questions?

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