Surgery Research Conference

Research Compliance: A Primer on Research Misconduct

Presented by Matt Richter, JD, MS

To receive 1.0 credit for this session, text the SMS code: NURSEF to 414-206-1776. This code will expire in 5 days.

ACCME Accreditation Statement: The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. AMA Credit Designation Statement: The Medical College of Wisconsin designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Hours of Participation for Allied Health Care Professionals: The Medical College of Wisconsin designates this activity for up to 1.0 hours of participation for continuing education for allied health professionals.
Research Highlights
Cardiovascular Center trainees, staff present posters at 2019 CVC Research Retreat

Medical Student:
1st – Melissa Anfinson (Surgery – Mentor-Aoy Mitchell, PhD -Congenital Heart)
2nd – Ayana Jamal (Cell Biology, Neurobiology & Anatomy)

Graduate Student:
1st – Wojciech Jankiewicz (Pharmacology & Toxicology)
2nd – Shi Fang (Physiology)

Postdoctoral Fellow:
1st – Yiliang Chen, PhD (BRI)
2nd – Shahram Eisa-Beygi, PhD (Cell Biology, Neurobiology & Anatomy)

Clinical Fellow/Resident:
1st – Rachel Sullivan, MD (Medicine)
2nd – Sakthi Sundararajan, MD (Medicine)

Research Support Staff:
1st – Katy Marie LaFond (Medicine)
2nd – Marcus James Weitekamper (Medicine)
Congratulations!

2019 CTSI Pilot Start Up Award

*Bioengineered heart tissue in congenital heart disease*

PI: [Brandon Tefft, PhD](mailto:brandon.tefft@uth.tmc.edu)
Biomedical Engineering

Co-PI: [Aoy Mitchell, PhD](mailto:aoy.mitchell@uth.tmc.edu)
Pediatric Congenital Cardiac

Co-I: [Mike Mitchell, MD](mailto:mike.mitchell@uth.tmc.edu)
Pediatric Congenital Cardiac
Congratulations!

2020-2025 George H.A. Clowes Career Development Award

The role of GLP-1 in cardiac recovery after bariatric surgery in obesity-induced heart failure.

Tammy Lyn Kindel, MD, PhD
Assistant Professor, General Surgery
15th Annual Academic Surgical Congress
February 4-6, 2020, Orlando, FL

REGISTER HERE

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>EARLY BIRD RATE (BY DEC 9, 2019)</th>
<th>LATE RATE (BY JAN 13, 2020)</th>
<th>ONSITE RATE (AFTER JAN 13, 2020)</th>
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<tr>
<td>AAS/SUS Member</td>
<td>$540</td>
<td>$640</td>
<td>$740</td>
</tr>
<tr>
<td>Non Member Surgeon</td>
<td>$675</td>
<td>$775</td>
<td>$875</td>
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<tr>
<td>Trainee or Allied Health</td>
<td>$350</td>
<td>$450</td>
<td>$550</td>
</tr>
<tr>
<td>Medical Students</td>
<td>$270</td>
<td>$270</td>
<td>$370</td>
</tr>
<tr>
<td>Active Duty Military</td>
<td>$270</td>
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<td>$270</td>
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Surgery Division of Research is collecting items for Keep Greater Milwaukee Beautiful

Science Supplies & Shoe Drive
October 14-November 27

These products help support our programming:

- School Supplies (Markers, colored pencils, glue sticks, card stock paper, etc.)
- Craft Supplies (Pipe cleaners, Puff Balls, tissue paper)
- Clear, plastic storage containers
- Tape (all types)
- Children's books with environmental themes
- Gently used SHOES
- NO flip flops (plastic), slippers, ski/winter boots, ice skates, roller skates/BLADES.
Surgical Oncology


Molecular Characteristics of Biliary Tract and Primary Liver Tumors. *Surgical Oncology Clinics of North America.* (Tsai S & Gamblin TC)

Molecular and Genetic Markers in Appendiceal Mucinous Tumors: A Systematic Review. *Annals of Surgical Oncology.* (Stein A, Strong E, Clark Gamblin T, Clarke C, Tsai S, Thomas J, George B, Mogal H)


Research


Pediatric Surgery


Trauma & Acute Care Surgery

Reply to Letter: Ketamine infusion for pain control in adult patients with multiple rib fractures. *The Journal of Trauma and Acute Care Surgery.* (Kugler NW, Juul J, Peppard WJ, Carver TW)

Pediatric Congenital Cardiac

Next Month:

December 11th, 2019

HUB A1015/1035
5:00-6:00pm

Please note the ROOM CHANGE

Christopher M. Dodgion, MD, MSPH, MBA
Assistant Professor
AGENDA

Agenda:

- Office of Research Compliance Overview
  - Office structure
  - Responsibilities
  - Assessing audit climate
  - Assessing audit risk

- Primer on Research Misconduct
  - Types of misconduct
  - Definition of research misconduct
  - Authority and MCW Policy
  - How is an allegation reviewed?
  - What do I do if I suspect research misconduct?
INTERNAL AUDIT

Mission:
The Internal Audit Office promotes operational effectiveness and efficiencies, ensures the College’s assets are safeguarded and assesses the adherence to regulations and College policies.

Contact:
Director: Tennille Sifuentes, CPA, CIA
Phone: 955-7366
Email: tsifuent@mcw.edu

Primary Functions:
- Risk Assessment
- Process Audits
  - Leadership/Governance
  - Administrative Support
  - Infrastructure and Environment
  - Clinical Practice
  - Education
  - Research
  - Community & Public Health
- Regulatory Audits
- Financial Transaction Audits
- Information Technology – Security Standards
- Policy Standardization and Implementation
- Document Retention
CLINICAL COMPLIANCE

Mission:

The mission of the Clinical Compliance Office is to ensure the College and its faculty physicians comply with the regulatory requirements of a group practice including but not limited to documentation, coding & billing of professional services, HIPAA, Fraud & Abuse Laws, EMTALA, Stark, and Anti-Kickback regulations.

This mission is accomplished through educational sessions, clarification of specific regulatory issues, and internal reviews/audits.

Contact:
Manager: Karen Rhyner
Phone: 955-3151
Email: krhyner@mcw.edu

Primary Functions:

• Departmental Retrospective Billing Audits
  - Medicare
  - Medicaid
• One-on-One New Provider Orientation
• Departmental Education/Training
  - Documentation Coding/Billing
  - HIPAA
• Inquiry Resource
• Privacy Investigation
  - Identity Theft
• Process Improvement
• Electronic Health Records
• Coding Reference and Resource
RISK MANAGEMENT

Mission:

The Risk Management Office helps MCW providers and staff respond to clinical adverse events in ways that reduce the risk of further injury, and works to improve the systems in which MCW providers practice to reduce the risk that clinical adverse events will occur.

Contact:
Director: Jonathan Wertz, JD, RN
Phone: 955-3152
Email: jwertz@mcw.edu

Primary Functions:

• Threat assessment guidance
• Clinical incident guidance and tracking
• Claims management
• Education and advisory services
• Administration of MCW malpractice liability trust fund
• Guidance regarding subpoenas and depositions
• Other
RESEARCH COMPLIANCE

Mission:

The mission of the Research Compliance Office is to provide the MCW Community with oversight of research compliance issues in a centralized, organized, and consistent manner.

Contact:
Manager: Matt Richter, JD, MA
Phone: 955-8243
Email: mrichter@mcw.edu

Primary Functions:

- Audit and review research risk areas:
  - Institutional Review Boards (IRBs) & Human Subject Research Protection
  - Institutional Animal Care and Use Committee (IACUC) & Animal Research
  - Financial Grants Management
  - Clinical Trial Billing
  - Research Conflicts of Interest
  - Research Misconduct: fabrication, falsification, plagiarism
  - Research Safety
  - Biological/Radiation/Chemical Safety
- Research and respond to questions regarding the interpretation of research policies, rules or regulations.
- Educate researchers and staff about regulatory research compliance.
- Provide information to the leaders of MCW so that they can make educated decisions regarding research conduct and to take appropriate actions to maintain the integrity and reputation of the College.
REPORTING COMPLIANCE CONCERNS

• Compliance hotline – an anonymous “hotline” number is available to report concerns

   Compliance hotline: 1-844-703-8171

• NEW online compliance portal for reporting concerns

   www.mcw.ethicspoint.com
RCO: RECENT ACTIVITY

• Revisiting audit strategy
• Reviewing Financial Conflict of Interest in Research policy / program
• Investigating potential HIPAA issues in research
• Conducting reviews for research misconduct
AUDIT CLIMATE

2019
• Oregon State U: NSF questioned $369k in research costs for consulting fees, equipment, and travel
• Ohio State U: NSF seeking $500k in research costs for unallowable expenses, unapproved subaward payments, and inappropriately applied indirect costs
• U of Texas Health Sciences Center: UTHSC settles with DOJ for $2.4m in unallowable costs upon NIH audit findings

2018
• MIT: NIH concluded that MIT used incorrect indirect cost rate and questioned $255k in inappropriate claims

2017:
• UC San Diego: NSF questioned $288k in research costs relating to equipment, materials and supplies, travel, and salary that were deemed unreasonable

2016
• Columbia: Settled with DOJ for $9.5m, findings included inappropriate indirect cost rate
• Columbia: NSF questioned $1.2m in costs: time / effort, unreasonable / late charges
• U of Washington: NSF questioned $2m in costs: time / effort
• U of Miami: NASA OIG questioned $264k in costs: inadequate documentation

(Sources: CHARLENE BLEVENS, costaccounting.org; HCCA Report on Research Compliance)
ASSESSING AUDIT RISK

Consider **impact** and **probability**

- **Impact**—what will the consequence be to the institution if the action(s) in question happens without policy or controls in place?
- **Probability**—how likely is it the action(s) in question will occur?

<table>
<thead>
<tr>
<th>Impact</th>
<th>Probability</th>
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</thead>
<tbody>
<tr>
<td>High</td>
<td>High Risk</td>
</tr>
<tr>
<td>Low</td>
<td>Low Risk?</td>
</tr>
<tr>
<td>High</td>
<td>Medium Risk?</td>
</tr>
<tr>
<td>Low</td>
<td>Low Risk</td>
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RESEARCH MISCONDUCT
TYPES OF MISCONDUCT

• Discrimination or Harassment
  - Anti-Harassment and Non-Discrimination (MCW Policy AD.CC.050)
  - Prohibition on Sex Discrimination and Related Misconduct (AD.CC.080); Investigations (AD.CC.090)

• Conflict of Interest
  - Conflict of Interest - General (AD.CC.030); Health Care Industry Product Interactions (AD.CC.040); Financial Conflicts of Interest in Research (RS.GN.020)

• Misappropriation of Funds and False Claims
  - Federal/State – NIH, CDC, Medicare, Medicaid, etc...
  - Institutional/College – personal use

• Safety and Environmental
  - Hazardous Chemical Safety (RS.GS.040); Biological Safety Program (RS.GS.030)
  - Occupational Health and Safety

• Human or Animal Research
  - Oversight of the Care and Use of Vertebrate Animals in Research and Education (RS.AN.010); Reporting and Investigating Animal Welfare Concerns (RS.AN.020)
  - Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010); Participation as Research Subject (RS.HS.030); Human Research Protection Program (RS.HS.040)

• Research Misconduct
  - Research Misconduct and/or Research Noncompliance (RS.GN.010)
WHAT IS RESEARCH MISCONDUCT?

• **Fabrication** is making up data or results and recording or reporting them.

• **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

• **Plagiarism** is the use of another person's ideas, processes, results, or words without giving appropriate credit.

• Research misconduct does not include honest error or differences of opinion.
## RESEARCH MISCONDUCT CRIMINAL ACTIONS ARE RARE, BUT THEY DO HAPPEN

<table>
<thead>
<tr>
<th>Name</th>
<th>Sentenced</th>
<th>Background</th>
<th>Criminal Charges</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>Scott Reuben</td>
<td>5/24/10</td>
<td>Anesthesiologist - Former Chief of acute pain at Baystate Medical Center, Springfield, MA</td>
<td>Falsified research studies, published in medical journals. Solicited and obtained research grants from pharmaceutical manufacturers but did not actually perform studies. Made up patient data and submitted data in various articles.</td>
<td>• Sentenced to 6 months in prison&lt;br&gt;• $361,923 in restitution to drug companies&lt;br&gt;• Forfeiture of $50,000 and a fine of $5,000</td>
</tr>
<tr>
<td>Richard Fleming</td>
<td>4/24/10</td>
<td>Cardiologist - President of Fleming Heart and Health Institute in Omaha, Nebraska</td>
<td>Submitted false research data about privately funded clinical study of benefits of soy chips to sponsor.</td>
<td>• Pled guilty to one count of mail fraud&lt;br&gt;• Sentenced to 5 years probation, 6 months of house arrest, 150 hours of community service&lt;br&gt;• Restitution in the amount of $107,244</td>
</tr>
<tr>
<td>James Holland</td>
<td>3/31/09</td>
<td>Oncologist - Physician and head of oncology at Stratton VA Medical Center, in Albany, NY.</td>
<td>Falsified histories of certain VA patients to allow them to be enrolled as participants in study who did not qualify; one unqualified patient died as a result.</td>
<td>• Pled guilty to one count of information&lt;br&gt;• Placed on 5 years probation&lt;br&gt;• Restitution of $502,925</td>
</tr>
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MCW CORPORATE POLICY RS.GN.010

MCW Corporate Compliance

MCW Corporate Policies
MCW Corporate Policies were designed to further the mission of the organization.

- Complete Alpha List of all Corporate Policies
- Administrative and Organizational (AD)
- Business and Finance (BF)
- Education (ED)
- Faculty (FC)
- Human Resources (HR)
- Information Technology (IT)
- The Knowledge Center

Clinical Compliance
The Clinical Compliance section lists its faculty physician requirements of documentation, cod reimbursement, HIF Stark, and Anti-Kickback through educational regulatory issues, etc.

Corporate Policies and Procedures
Research

Research Misconduct

Purpose
To maintain appropriate standards to ensure a healthy and compliant research environment at the Medical College of Wisconsin (MCW), to protect Public Health Service (PHS) funds from misuse by ensuring the integrity of all PHS supported work, and to outline the process for responding to and reporting allegations of Research Misconduct.


http://ori.hhs.gov/about-ori
RESEARCH MISCONDUCT: REVIEW PROCESS

• **Assessment of Allegation**
  - Performed by Corporate Compliance Office
  - Purpose: To determine whether allegation meets required criteria for further review

• **Inquiry**
  - Performed by Corporate Compliance Office
  - Purpose: To review evidence, conduct interviews, consult with scientific or other experts, to determine whether to recommend institutional investigation.

• **Investigation**
  - Performed by Institutional Investigation Committee (at least 3 individuals appointed by the Dean), in consultation with Office of General Counsel
  - Purpose: To determine whether research misconduct has been committed.
WHAT TO DO?

• Do I have to report it?
  - Anyone with credible knowledge or reasonable suspicion that an incident of research misconduct has occurred is required to report the incident.

• Where / to whom do I make a report?
  - Your Supervisor or Advisor
  - Department or Section Chief or Chair
  - Senior Associate Dean for Research, Dr. Ann Nattinger
  - Dean of Graduate/Medical School, Dr. Joseph Kerschner
  - Compliance Office (can always call if unsure what to do)
  - LAST RESORT – when nothing works, report it externally to the federal office charged with research misconduct oversight: ORI

• How do I make a report?
  - Oral or written
  - Anonymous allegations are accepted
WHAT TO DO?

- **Federal Whistleblower Protections**
  - *Research Misconduct* – rule requires that institutions have a policy that provides for some confidentiality and protections.

- **State Whistleblower Protections** *(WI Statute 146.997)*
  - State law prohibits retaliatory action by a *health care provider* *(e.g. MCW)* against an employee who in good faith reports:
    - Violation of state or federal law;
    - Violations of recognized clinical or ethical standards.

- **MCW Policy**
  - all parties involved with a report or review of possible research misconduct must keep identities confidential *to the extent allowed by law*. 
Thank you!

MCW Compliance Contact Information:
MCW Compliance hotline: 1-844-703-8171

NEW online compliance portal for reporting concerns: www.mcw.ethicspoint.com

Research Compliance Office:
Matt Richter, JD, MA
Manager, Research Compliance
(414) 955-8243
mrichter@mcw.edu

Ellen Manning, MA
Compliance Coordinator, Research
(414) 955-7374
elmanning@mcw.edu