

# 2020 Spring Regulatory Update and Hot Topics in Clinical Research

*COVID-19: The Virus, Preparedness in the time of Crisis, and Clinical Research*

PANEL 2

1:30pm – 2:15pm

Does this Relationship Need to be Managed:  
Conflicted Over Conflict of Interest



# DOES THIS RELATIONSHIP NEED TO BE MANAGED: CONFLICTED OVER CONFLICT OF INTEREST

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# GOVERNMENT SCRUTINY AND FOREIGN INFLUENCE

Katherine (Kate) Cohen

# GOVERNMENT SCRUTINY: SAFEGUARDING RESEARCH IN THE CONTEXT OF GLOBAL ENGAGEMENT

- Issue: 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 collaborations received from foreign governments
  - Foreign government sponsored talent (recruitment) programs
- Result
  - More disclosures to federal agencies
    - foreign collaborations and visiting, adjunct, honorary appointments, etc.
    - study personnel who are volunteers or visitors paid by another organization
  - Conflict of interest information will not match clinical trial proposal information

# INCREASED SCRUTINY: JUST LOOK AT THE HEADLINES!

- *Former West Virginia University Professor Pleads Guilty to Fraud that Enabled Him to Participate in People's Republic of China "Thousand Talents Plan"*, Department of Justice Press Release, March 10, 2020
- *Researcher at University Arrested for Wire Fraud and Making False Statements About Affiliation with a Chinese University*, Department of Justice Press Release, February 27, 2020
- *US Charges Target Alleged Chinese Spying at Harvard, Boston Institutions*, Reuters, January 29, 2020
- *Moffitt Cancer Center Details Links of Fired Scientists to Chinese Talent Programs*, Science, January 19, 2020
- *University of Florida Also a Target in Foreign Research Scandal*, Tampa Bay Times, January 13, 2020
- *Judge Mulls Fate of Kansas Researcher Who Denies Chinese Work*, Associated Press, January 6, 2020

# HOW WOULD YOU KNOW ABOUT FOREIGN INFLUENCE?

- Conflict of interest policy should state the requirement to disclose includes all work for or financial interests received from a foreign institution
- Consider requiring all foreign travel by employees, faculty be vetted by the Export Controls Office
- Communicate and educate researcher responsibilities related to foreign components often
- Evaluate disclosure points
  - Is there one central disclosure point for researchers or are there multiple?
  - Are all individuals who review disclosures familiar with foreign influence concerns in research and how to issue spot?

# CASE STUDY #1- HYPOTHETICAL

- A researcher at a University with multiple campuses is conducting an NIH sponsored study. The researcher is employed by campus A but he is conducting his study through a grant that was submitted and administered by campus B. Campus B's grant office requires COI disclosures with the grant application. Any disclosures that require management would be referred to Campus A, the researcher's employer. At the time of grant application, researcher indicated he had nothing to disclose. Grant was submitted to and funded by NIH.
- At some point after the grant had been funded, researcher plans a trip to China. Grant pays for the trip to China. Internally, grants accounting flags this as potentially inappropriate. Department Chair of researcher approves the trip and researcher travels.
- It is later discovered that prior to the submission of the grant, researcher had disclosed to campus A as part of his regular annual COI disclosure that he was traveling to China to obtain additional data for his NIH funded study. Campus A COI office does not recognize this as an issue.

# CASE STUDY #1- NOW WHAT?

- Investigation reveals that Campus A was aware of researcher's frequent travel to China. However, because campus A's COI office was not involved in the campus B grant submission process and campus B didn't communicate with campus A, this was never communicated to campus B's grants office.
- It was revealed that Department Chair and campus A COI office both had a knowledge gap about the risk of foreign influence and foreign components and how to issue spot because no widespread education or communication about the topic had occurred at the University.
- When asked, researcher indicated he didn't disclose the relationships with and frequent travel to Chinese universities to campus B grants office because he had already disclosed to campus A in a recent disclosure. "It's the same university- I had nothing new to disclose when campus B asked."



# CASE STUDY #1- NOW WHAT?

- Resolution would include:
  - Repayment of NIH grant
  - New leadership in COI office
  - Widespread education
  - New process to ensure communication between campus A and campus B related to COI disclosure, review and management

What else?

- Termination of researcher?
- Sanctions for Department Chair?

# GENERAL COI OBLIGATIONS, DISCLOSURE, AND MANAGEMENT

Mary Schmiedel

# COI - WHAT AND WHY?

- Regulatory obligation to disclose financial interests- Public Health Service COI regulations, 42 CFR 50, Subpart F
- Effects of Real or Perceived Conflicts
  - Public credibility for research community
  - Reputation of institution
  - Reputation of individual physicians and scientists
  - Legality/risk
  - Optimal training & research without exploitation...progress and fairness
  - Optimal translation of knowledge – add value and share benefits

# CONFLICTS THAT ARISE IN CLINICAL RESEARCH

- Individual Conflicts
  - Consulting
  - Advisory board service
  - Speaking engagements
  - Stock holder
  - Inventor
- Institutional Conflicts
  - Institution is the patent holder on the new use
  - Clinical trials testing the new use are being conducted at the institution
  - Financial interests of high level officials who have authority to act on behalf of the institution

# CONFLICT MANAGEMENT IN GENERAL

- Disclosure
- Restrictions – Individual Conflicts
  - No primary data analysis
  - No subject eligibility determinations
  - No consenting patients
- Restrictions – Institutional Conflicts
  - Inventor may write grant application, IND, and publications
  - Appoint clinical principal investigator
  - Secondary IRB review
  - Independent contract research organization
  - Independent verification of study results
  - DSMB

## CASE STUDY #2

- An inventor has discovered that an existing cardiac drug is useful to treat pancreatic disorders. He has filed his invention disclosure with the Technology Transfer Office and they filed a patent application. He is listed as the inventor and the inventor's institution is the patent owner. The inventor has received NIH clinical trial funding to test this drug on subjects with pancreatic disorders. The clinical trial will take place solely at the inventor's institution (not multi-center). If this drug is found to be safe and effective, the inventor and the institution stand to gain financially. As a result, the inventor has an individual conflict of interest and the institution has an institutional conflict. Both conflicts must be managed. What provisions must be in the management plan?

# MANAGING THIS CONFLICT

- Disclosure – to everyone and in all resulting publicly facing materials
- Inventor can write the grant application but may not be involved in any aspects of the clinical trial
- Clinical principal investigator (without a conflict) must be appointed
- Studies must be blinded
- External IRB review verifying the institution's recommendations
- External study monitor to ensure that all regulatory requirements are being met
- Biostatisticians perform data analysis and give blinded analysis to clinical principal investigator
- Clinical investigator interprets whether there is clinical significance to the results
- DSMB meets periodically throughout study but, at the conclusion of the trial, unblinds the data
- Unblinded data is given to the inventor to prepare a manuscript with clinical investigators as co-authors

# WHY CAN'T THE IRB HANDLE IT?

James (Jim) Boscoe



# IRB AND CONFLICT: WHAT DO THEY DO?

- Peripheral (primarily a research compliance function)
- Watch for red flags
- Refer to Research Compliance Office
- Facilitate communication
- In some cases the Committee may impose more strict requirements

## CASE STUDY #3

- A study involving the use of an FDA approved device is submitted for review by the IRB. The device will be modified with throughway wire and the Principal Investigator has obtained an Investigational Device Exemption from the FDA. Although the wire used to modify the device is available through multiple sources, the study protocol names a specific manufacturer for the wire that will be used. One sub-investigator on the study team has a significant financial interest in the named company.
- Does the sub-investigator's interest require a management plan?

# IS A MANAGEMENT PLAN NEEDED? IT ALL DEPENDS

- This is a supply chain issue:
  - If the individual with the financial interest is dictating the product to be used and they have selected the company with which they have an interest:
    - Yes: This may be considered a significant conflict that requires management.
  - If the product is made readily available in the operating room by an individual not associated with the study (meaning the sub-investigator is not selecting the product):
    - No: This most likely would not be considered a significant conflict that requires management.
- How was the IRB involved:
  - Facilitating communication between the study team and compliance office.

# COVID-19- TO BE FLEXIBLE OR NOT TO BE FLEXIBLE?

James (Jim) Boscoe

# CONFLICT MANAGEMENT IN COVID ENVIRONMENT

- Regulatory requirements
  - Human subjects research is highly regulated and we must still comply with sponsor and institutional policies and procedures
- Flexibility
  - Verbal agreement initially and catch up on the paperwork later
  - Is there additional flexibility that should be provided during this pandemic that wouldn't otherwise be provided?
- Communication
  - IRB, study teams, principal investigators, conflict officers

# NIH FUNDING DURING THE PANDEMIC

- NIH has provided a number of resources on their website related to flexibilities being granted to those receiving NIH funds during the public health emergency.
- Flexibility does not include a waiver of the COI obligations!
- **NIH FAQ:**
  - **Q: If a post doc on an active NIH grant must return home to a foreign country and work remotely due to COVID 19, must this be reported to NIH as a foreign component?**
  - **A: YES!**
- Do you need to educate your researchers or research administrators about this during the pandemic? Situations that may not have included a foreign component originally could become situations that suddenly do!

# QUESTIONS

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