

# Hot Topics in Research Compliance

Donnetta Horseman, Chief Compliance Officer

# History of Leadership & Innovation

- Established by the Florida Legislature in 1981.
- Named after H. Lee Moffitt, former Speaker of the Florida House.
- Opened in 1986, quickly earning its NCI-designation through innovative, breakthrough research.
- Received our highest score ever by the National Cancer Institute in 2021.
- In 2021, we celebrated 35 years of providing patient care and hope to countless patients and families.





# Moffitt Partnerships



Moffitt Outpatient Satellite at AdventHealth's Wesley Chapel Campus (AH West Division)



Moffitt Radiation Oncology at Morton Plant Hospital- BayCare Health System

Clinical Trials at James A. Haley and Bay Pines VA Hospitals



Moffitt | AdventHealth Celebration CRU & Infusion Center (AH Central Division)



Moffitt Malignant Hematology & Cellular Therapy at Memorial Healthcare System



# Unparalleled Research Impacts

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

No other institution in the region is making research contributions at this level of scale or quality.

**\$150M**

In Active Total Grant  
Funding in FY21

**\$588M+**

State, Federal &  
Commercial Grants Since FY13  
(Excludes Clinical Trials)



Moffitt currently has over

**600**

active treatment  
clinical trials

Moffitt has accrued nearly **1,100**  
Patients in treatment trials in FY21



# Collaborative Reach



Once Upon A Time...

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# Where the story begins – Pre -2015



**A “ Brotherhood Institutionship” Agreement between Moffitt Cancer Center and TMUCIH was signed in November 2008**



**Moffitt Cancer Center  
Tampa, Florida**

**Tianjin Medical University  
Cancer Institute & Hospital**



- April 2014
  - Moffitt enters into Collaboration Agreement with Tianjin China Taishan Cancer Hospital (IPCC).

# Chapter 1 – The New CCO & What Are We Doing in China?







# What are export controls?

Export controls are laws and regulations put in place by the federal government to control the release of equipment, chemical or biological materials, information, technology, software code or services to foreign countries



# Activities that are Subject to Export Controls



Proprietary  
Research



Development



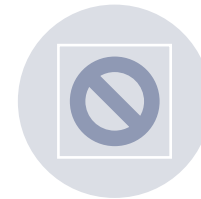
Use Technology



International  
Agreements



Defense Services



OFAC prohibited  
Activities



International  
Shipping



International  
Travel

# U.S. Agencies Responsible for Export Controls

- **Department of State** – Directorate of Defense Trade Control (DDTC)
  - International Traffic in Arms Regulations (ITAR)
  - Controlled technologies are listed on the US Munitions List (USML)
- **Department of Commerce** – Bureau of Industry and Security (BIS)
  - Export Administration Regulation (EAR)
  - Controlled technologies are listed on the Commerce Control List (CCL)
  - Also maintains the “entity list” for those entities where a license would be required
- **Department of Treasury** – Office of Foreign Asset Controls (OFAC)
  - Foreign Asset Control Regulations
  - Comprehensively sanctioned countries – Cuba, Iran, North Korea, Syria and the Crimea region of Ukraine



# Controlled List of Items and Technological Info

- The regulations include comprehensive lists of items and technological information that are “controlled”
  - Meaning items and information which cannot be exported to foreign countries without authorization or “license” from the U.S. government





# What is an export?

- An export is the controlled transfer of technology, information, equipment, software, or services to a foreign person in the U.S. or abroad.
- Two main types of exports
  - Physical
    - Hand Carrying
    - Shipping
    - Transmitting technical data or technology to another country
  - Deemed Export
    - Release is visual or other inspection or oral or written exchanges that reveal EAR-controlled technology or source code to a foreign person regardless of location (15 CFR 734.15)





# Deemed Exports and Research

- Fundamental Research – EAR 15 CFR 734.8(c)
- “Fundamental research means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons.”
- The research is NOT fundamental research if:
  - Sponsor approval is required prior to publication
  - Publication of the results of the project are restricted
  - Other access and dissemination restrictions are in the agreement
  - Project dictates citizenship of project team members

# Office of Foreign Asset Controls



Comprehensively sanctioned countries – Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine

Any export to any of the comprehensively sanctioned countries will require a license

There are many other countries of concern that are affected by OFAC embargoes, sanctions and regulations, but not as completely as the above countries.

# Office of Foreign Asset Controls



Prohibits payments and providing value to nationals of sanctioned countries and specified entities/organizations. Assets are blocked and U.S. persons are generally prohibited from dealing with them.

Specially Designated Nationals and Blocked Persons List (SDN) – Transnational Criminal Organizations, Non-proliferation, War crimes, Drug trafficking

# Export Control Compliance Risk Assessment



Risk	Recommendation	Risk Level
<b>Foreign National on site (visas)</b>	Conduct a review of all Moffitt sponsored visas using Visual Compliance.	High
<b>International Shipping</b>	Monitor international shipping daily to ensure compliance.	High
<b>Research Collaborations</b>	Review all grants and contracts that contain export control language or that have an international component. Screen all international parties using Visual Compliance.	High
<b>Agreements</b>	Review all agreements with export control language or international parties and screen using Visual Compliance.	High
<b>Equipment</b>	Review access to equipment and technology by foreign nationals. Comprise a list of Moffitt owned equipment and its associated export classification.	High
<b>Access to Moffitt Systems</b>	Enact a policy to block access to Moffitt systems from comprehensively sanctioned countries.	High
<b>Biologicals</b>	Review all biological protocols to ensure compliance	Medium
<b>International Travel</b>	An International Travel Authorization form was introduced in Spring of 2020. It has been effective in creating oversight of international travel. Update the form and require clean laptop loaners for Team Members traveling to specific countries of concern. Implement and enforce specific compliance activities for Team Members traveling to Cuba.	Low

# Chapter 2 – The NIH and Foreign Talent Programs







# National Landscape – Foreign Influence

## Foreign Interests & Activities

- Disclosure and reporting requirements clarified, expanded or newly added into existing policies

Please review these issues and confirm that these investigators and AWARDDEE complied with the policies cited above. If any instances of non-compliance are identified or suspected, please also provide a detailed description of the issue and corrective actions taken.

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.

I ask that you submit your written response with a copy to the NIH Office of Policy for Extramural Research Administration, [ComplianceReview@mail.nih.gov](mailto:ComplianceReview@mail.nih.gov), within the next 30-60 days.

Sincerely,  
Michael S. Lauer, MD  
cc: IC|

'THIS IS REAL THEFT'

### NIH Investigates Foreign Influence at U.S. Grantee Institutions

BY ERIC BOCK

### *Universities Face Federal Crackdown Over Foreign Financial Influence*

By Erica L. Green

Aug. 30, 2019



# WHAT IS CHINA'S THOUSAND TALENTS PLAN?

*The nation's bid to lure back ex-pat scientists and recruit highly-skilled foreign researchers is now in its tenth year.*

BY HEPENG JIA

<https://www.nature.com/articles/d41586-018-00538-z>

Nature January 17, 2018



# Undisclosed Foreign Employment, Teaching & Affiliation Agreements

Concerns include:

- “Shadow laboratories”
- Time commitment – sometimes full-time or substantial part time
- Substantial funding for research abroad (including start-up funds)
- Laboratory, equipment, personnel
- Signing bonus, salary, housing, other benefits
- Deliverables: training personnel, papers, patents/IP
- Creates conflicts of commitment (>100% effort), interest
  
- NIH inquiries include 100s of investigators, resulting in investigator removals, terminations, repayments, and False Claims Act payments

# Chapter 3 – Peeling the Onion



VP, Clinical Research  
Discloses 1000 Talent “Award”  
from Tianjin



Key Research Leader “A”  
Discloses has employee  
working full-time from China



THE UNIVERSITY OF TEXAS  
MD Anderson  
~~Cancer Center~~

MD Anderson  
Ousts 3  
Scientists Over  
Chinese Data  
Theft Concerns

“...and by the way, our CEO and EVP/Center Director also received the “award”

# Defining Conflicts of Interest and Commitment



## Financial Conflict of Interest (FCOI)

- Financial interests that may create or give the appearance of creating bias or affecting decision-making

## Research Financial Conflict of Interest (RFCOI)

- When an individual's personal financial interests could directly and significantly affect the design, conduct, or reporting of research.

## Conflict of Commitment (COC)

- When an individual's commitment of time and effort to outside activities is inconsistent with the individual's commitment to the institution and/or the institution's interests

## Institutional Conflict of Interest (ICOI)

- When the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, could affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution





# Defining COI and COC

- Research Financial Conflicts of Interest
  - Grounded in Public Health Service (PHS) regulations promulgated in 2011
  - Key components in the regulations include:
    - Defining significant financial interests (SFI)
    - Mandating disclosure and review of SFIs
    - Requiring publication of a COI policy
    - “Publishing” COI management plans
    - Requiring training for Investigators

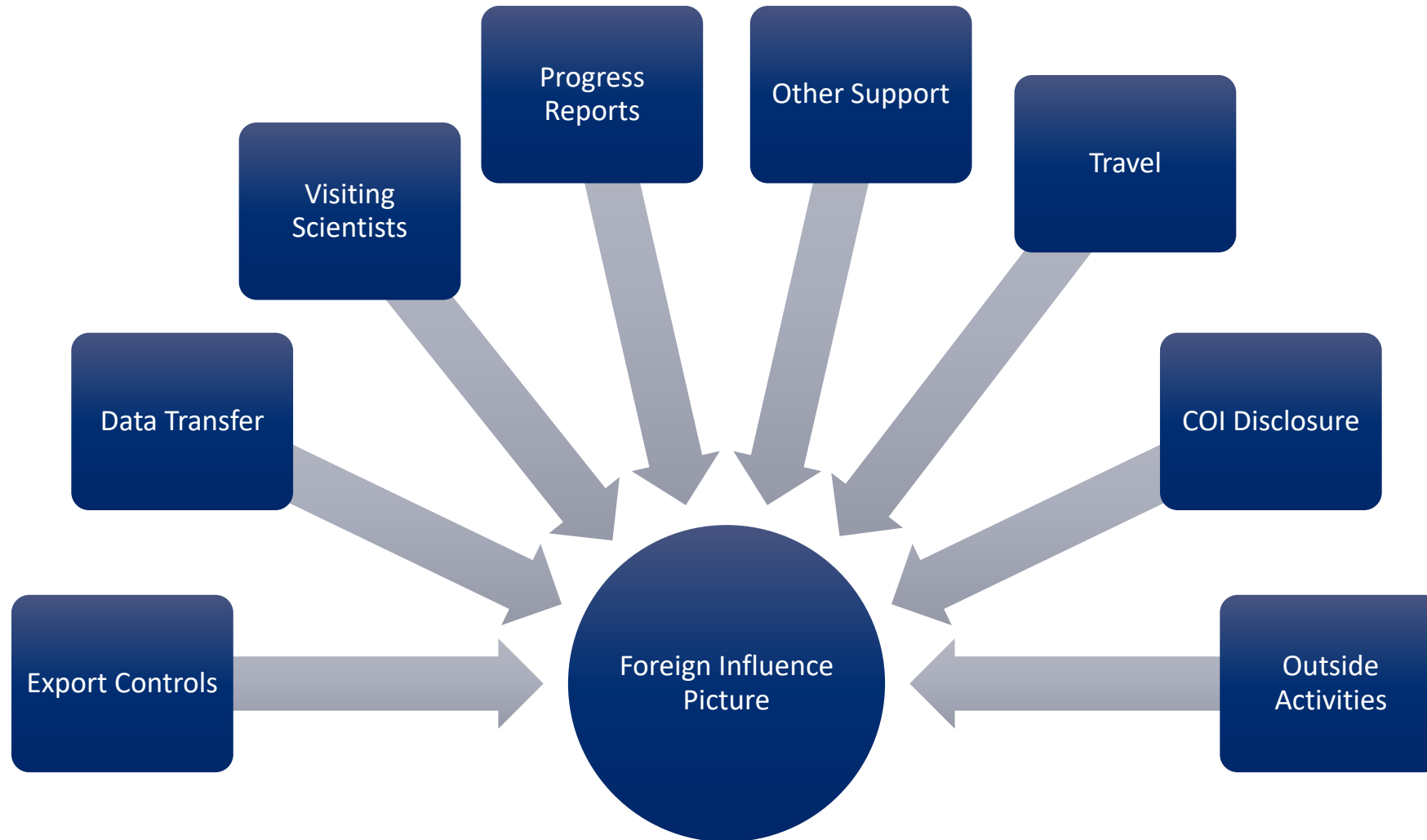
## Conflicts of Commitment

- There is no unifying federal regulation governing COC
- Institutions are subject to varying requirements under state laws and system/board policies
- Common components of COC include:
  - Outside Activities / Time Away from Work
  - Incidental Use
  - Prior Approvals
  - Foreign Relationships & Activities

# Managing COI and COC



- Foreign Influence Information





# Managing COI and COC

## Disclosures

- Individual interests should be disclosed
  - Upon joining the organization
  - Annually
  - Upon obtaining new interests (for researchers: within 30 days of acquisition)
  - For researchers: no later than the time of application for PHS funded research
- Institutional interests disclosed by relevant offices to COI office on a regular cadence (e.g., quarterly) and as new interest arise



# Managing COI and COC

## Disclosure Review

- COI
  - Disclosures received and reviewed by COI office
  - COI Committees review and determine if potential conflict exists – often specific committees for RFCOI and ICOI
- COC
  - Outside activities and prior approval requests review can vary - sometimes centralized, often at the departmental level



# Managing COI and COC

## Conflicts Determination

- COI
  - RFCOI regulations: could the interest “significantly and directly affect the design, conduct or reporting of the research”
  - ICOI: considerations usually like individual research disclosures
    - Responsible conduct of research (e.g., participant safety);
    - Research integrity;
    - The appropriate allocation of institution resources;
    - The dissemination of research results;
    - Related educational activities, including non-exploitation of students or trainees;
    - Managing and licensing intellectual property resulting from research activity;
    - The independence of professional practice judgment.
- COC
  - Conflict determination based on time commitment or nature of the outside activity

# Chapter 4 – Uncovering the Evidence



- Compliance performs preliminary email search and finds talent applications for CEO, EVP/Center Director and VP, Clinical Research (including commitments to do future research).
- Discovers long time Moffitt physician-researcher and close collaborator of CEO is the connection between Moffitt and Tianjin and the recruiter for foreign talent programs
- Moffitt engages outside counsel for criminal law assistance.
- Compliance email search locates evidence of talent program involvement for other faculty members.



# Talent Program Application



## 国家“千人计划”外专项目（短期项目）申报书 Application Form for Short-term Recruitment Program of Foreign Experts

- Outlined benefits to the “expert”
  - Position title (Director)
  - 300 sq meters of space for experiments
  - Professional team of 10 researchers, assistant researchers and techs
  - Full-time translators with a dedicated office area
  - Residential apartment of 150 sq meters and work vehicle
  - Living allowance provided during term of work = RMB 50,000 per month (~\$7,800 USD)
  - First-class tickets for work trips

# Example of Contract Provision – Work/Time Commitment



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本人以上信息均真实有效。

本人郑重承诺：被批准纳入“千人计划”半年内到岗，在华连续工作至少3年，每年不少于2个月。

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The above information is true and correct. I promise to start working full time in China within six months after my application is approved. The minimum employment term is three consecutive years, with at least nine months working in China for each year.

# Credit Card Issued by China Bank



# Chapter 5 – The Disclosures



# Chapter 6 - The Fallout

Hospitals

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

by Tina Reed | Jan 6, 2020 7:10am

NEWS / HEALTH

### Moffitt Cancer Center shakeup: CEO and others resign over China ties

The actions come amid a widening federal investigation of foreign attempts to take advantage of U.S.-backed medical research.

### Major Cancer Center's CEO, Staff Resign over Chinese Payments

A Call for Moffitt to 'Come Clean'

Nick Mulcahy  
December 20, 2019

# Select Committee on Integrity of Research Institutions

- Special House Committee convened to investigate safety of tax-payer funded research, intellectual property theft and gifts from foreign entities
- New legislation requires all institutions of higher education and public entities to disclose foreign gifts, contracts, grants and anything of value worth more than \$50k
- Research institutions must screen all foreign applicants for research positions and monitor foreign business travel

Florida House speaker forms panel to investigate foreign influence in taxpayer-funded research

By NEWS SERVICE OF FLORIDA  
NEWS SERVICE OF FLORIDA | DEC 30, 2019 AT 2:41 PM



Governor Ron DeSantis and House Speaker Chris Sprowls Highlight Proposed Legislation to Combat Foreign Influence and Corporate Espionage

*On March 1, 2021, in News Releases, by Staff*

SCIENCE & SCIENTIFIC COMMUNITY

**Florida joins U.S. government in probing foreign ties of researchers**

Firings at Moffitt Cancer Center trigger investigation by state legislators





# Chapter 7 - The Recovery

- Increased education for all Faculty and Staff
- Reviewed and revised internal policies: COI, COC, grants management, travel
- Created new internal guidance regarding disclosure requirements, FAQs and educational resources
- Added info about International Compliance to internal and public facing webpages
- New question added to COI disclosure form specific to involvement in foreign talent recruitment programs
- Established new Export Control/International Compliance division within Corporate Compliance
- Overhaul of Team Member reporting of outside professional activities

# Chapter 8 – Implementing Foreign Influence Legislation

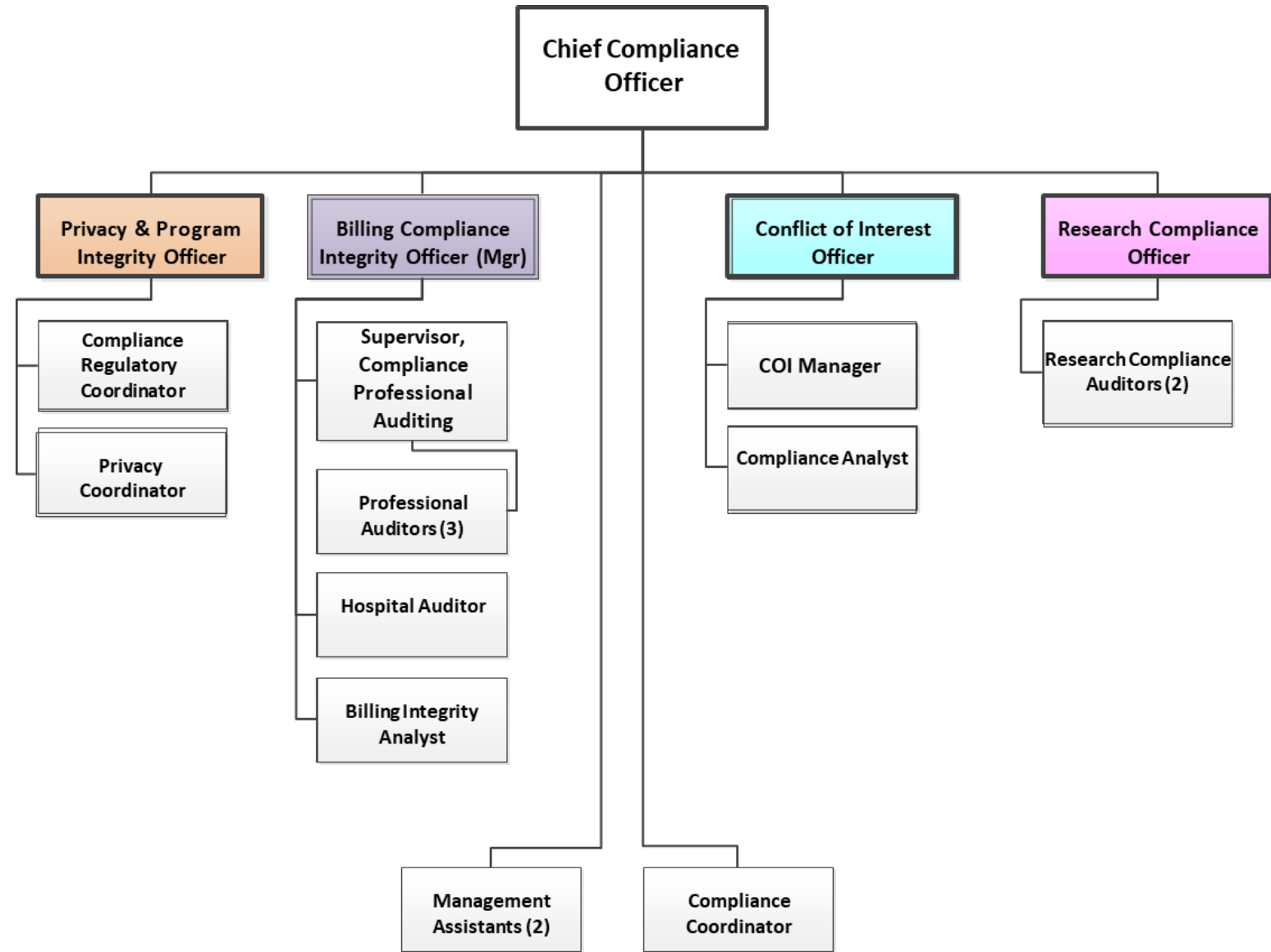
- [Florida House Bill 7017 – Foreign Influence](#)
  - All State agencies required to report any gift, grant, money or anything of value over \$50,000 from a foreign source to the Department of Financial Services within 30 days of receipt.
  - Private entities that apply for grants or want to do business with a State agency must disclose financial ties worth more than \$50,000 with China, Cuba, Iran, North Korea, Russia, Syria, Venezuela, or their agents.
  - Requires creation of a research integrity office to oversee compliance
  - Requires an even more rigorous screening of foreign applicants prior to interview, including review of all publications, grants, employment, education.
  - Requires monitoring of international business travel and provision of detailed annual report listing travelers and foreign institutions visited.
  - Random audits by the Inspector General are required to ensure compliance

# 2020 Compliance Program Improvements

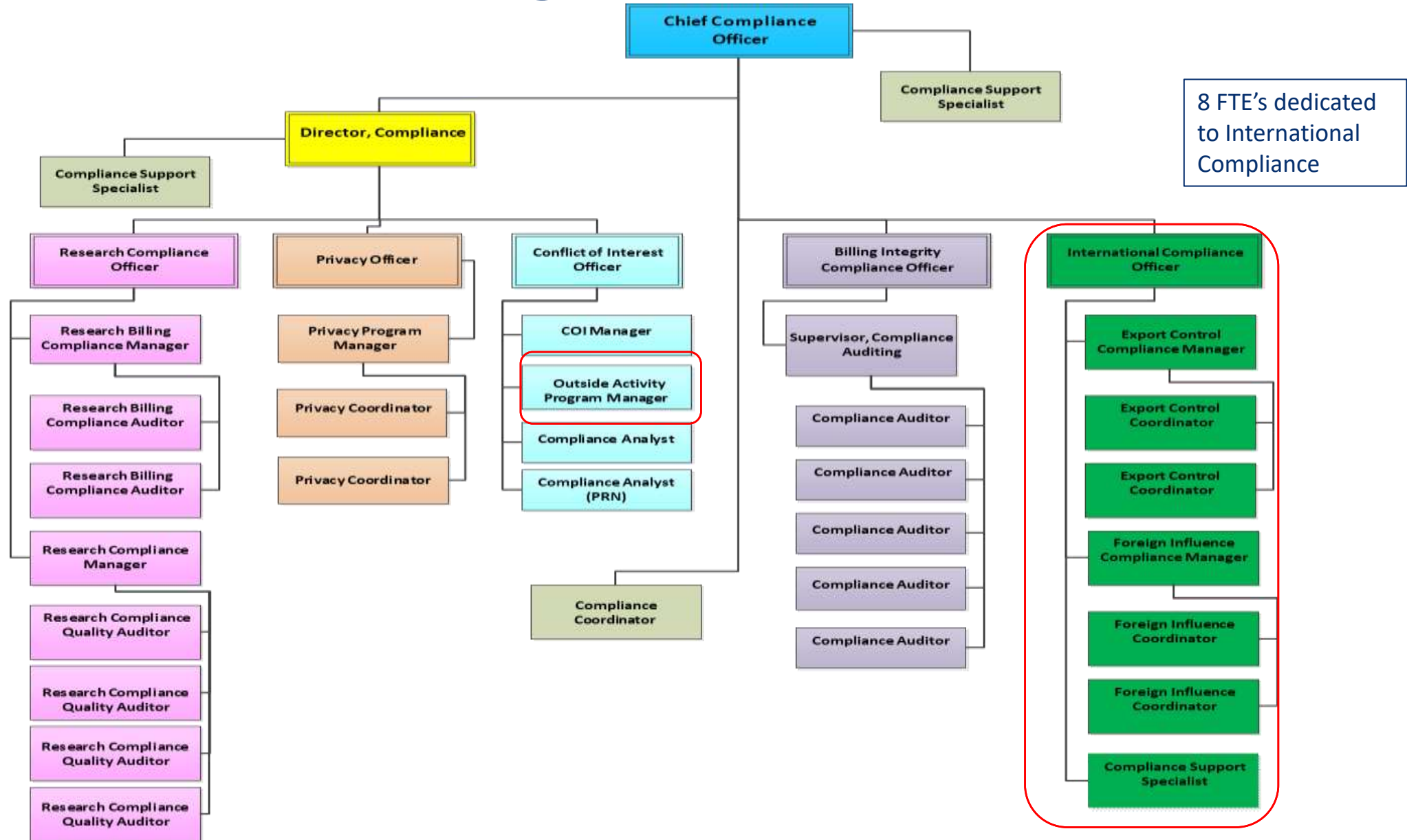


- Revised Conflict of Interest in Research policy and disclosure forms
- Launched system-wide re-education effort on foreign influence and conflicts of interest
- Hired International Compliance Officer and Export Control Compliance Manager
- Conducted export controls risk assessment
- Implemented international travel pre-approval process
- Improved processes for visa review
- Implemented review of international agreements and research collaborations
- Initiated development of an electronic outside professional activity reporting system

# 2019 Compliance Program Structure



# Current Compliance Program Structure



# Contact Information



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# Appendix



# Resources/References

- [Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components \(NOT-OD-19-114, July 10, 2019\)](#)
- [NIH FAQ – Other Support and Foreign Components \(August 6, 2019\)](#)
- [NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More \(OEI-03-19-00150, September 2019\)](#)
- [The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations \(A-03-19-03003, September 2019\)](#)



# Resources/References

- [JASON Report: Fundamental Research Security \(December 2019\)](#)
- [GAO-21-30: Agencies Need to Enhance Policies to Address Foreign Influence \(December 2020\)](#)
- [JCORE Report: Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research \(January 2021\)](#)
- [Presidential Memorandum on United States Government-Supported Research and Development National Security Policy \(January 14, 2021\)](#)
- [National Institutes of Health Notices NOT-OD-21-0733 \(March 2021\) and NOT-OD-21-110 \(April 28 2021\)](#)
- [Foreign Interference in National Institutes of Health Funding and Grant Making Processes: A Summary of Findings From 2016 to 2021](#)

# U.S. Senate Committee on Homeland Security & Governmental Affairs Report



- [Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans](#)
- CHINA'S TALENT RECRUITMENT PLAN CONTRACTS  
<https://www.hsgac.senate.gov/imo/media/doc/2019-11-18%20PSI%20Staff%20Report%20-%20Appendix%20A%20-%20China's%20Talent%20Recruitment%20Plans.pdf>
- CHINA'S TALENT RECRUITMENT PLAN CASE STUDIES  
<https://www.hsgac.senate.gov/imo/media/doc/2019-11-18%20PSI%20Staff%20Report%20-%20Appendix%20B%20-Chinese%20Talent%20Recruitment%20Examples.pdf>