Overview

• Conflict of Interest
  • Mary Jeka, Akiyo Fujii, Seth Kornetsky, and Phil Hinds
  • Research, Financial / Personal, Institutional
• Regulatory and Safety Updates
  • Heather Cosier
• Funding Updates
STATUS UPDATE ON THE TUFTS CONFLICT OF INTEREST (COI) PROGRAM

Caroline A. Genco  
Vice Provost for Research

Mary R. Jeka  
Senior Vice President and General Counsel
Types of COI Policies

- **Financial and Personal COI Policy:**
  Addresses conflicts that may arise from business relationships outside of Tufts; personal relationships; other potential conflicts that are not research-related

- **Research COI Policy:**
  Addresses conflicts that may arise from research (whether or not federally funded)

- **Institutional COI Policy:**
  Addresses large donations or grants that seek to influence or may have the appearance of influencing Tufts’ academic programs, research or clinical work

- **Conflict of Commitment (not being modified):**
  Addresses how much time faculty members and other employees may spend on outside activities during regular business hours

- **Protocol:**
  New COI Questionnaire and how disclosures will be reviewed
Key Initiatives 2020-21

**Gap Analysis**
- Review of Existing Policies
- Review of Existing Protocols
- Review of Existing COI Questionnaire

**New Policies**
- Updating Financial Conflict of Interest
- Updating Research Conflict of Interest
- Institutional Conflict of Interest

**New Protocol**
- Appointment of Steering Committee
- Appointment of COI Advisors
- Appointment of Review Committees

**New Questionnaire**
- Combining multiple questionnaires that were being used for business, research and at TUSM
- Needed to address new questions that address foreign influence
Updating Financial/Personal COI Policy

• Greater details about what would constitute a conflict

• Clarifies that this policy applies whether the conflict arises from financial arrangements or personal or professional relationships/appointments

• Many faculty, staff and students have business relationships with each other outside of Tufts

• Review of what outside activities would cause a greater risk to Tufts (reputationally and otherwise)
Updating Research COI Policy

- Needed to address new regulations

- Acknowledge faculty members that own companies may be funding their research

- Old policy focused on faculty members with federal funding; now applies to all researchers regardless of source of funding

- NIH concerns regarding human trials

- On-going government enforcement regarding foreign influence
New Institutional Conflict of Interest Policy

• When the financial interests of Tufts, or individuals in a position to make decisions, pose a risk of undue influence on decisions involving Tufts’ primary interests.

• Many universities are moving toward adopting an institutional conflict of interest

• Stern Report recommendations

• Concerns about big donors or contractors influencing academic, clinical and research programs
Conflict of Commitment Guidelines

• Keeping current version

• Addresses situations where faculty and staff want to engage in work activities outside of Tufts

• 20% independent work allowed for full time faculty members

• No independent work allowed for full time staff during regular business hours. Exceptions for teaching, non-profit, approved activities
New COI Protocol

Next steps:

• List of faculty/staff subject to the annual questionnaire

• Establish committee review of the disclosures

• School/Division to review draft/approve management plan

• School/Division to implement management plan

• School/Division enforce management plan
2020-2021 Pilot Year

- Using the new questionnaire in Qualtrics (hoping for new software after the pilot year)
- Limited recipients
  - All faculty members
  - All researchers
  - Officers, Deans, Department Chairs, Center Directors
  - Staff in key business areas
- Communication Plan
- Appointment of COI Review Committees
- Review the protocol after this year for improvement
REGULATORY AND SAFETY UPDATES

Heather Gipson-Cosier
Sr Director
Research Safety & Regulatory Programs
March 20:
- On-campus research activities suspended
  
  Integrative Safety Committee formed

March 13:
- Ramp down of on-campus research began

March 16:
- Daily Research Council Meeting began

March 20:
- On-campus research activities suspended

March 27:
- Weekly Research Town Hall began

April 1:
- Planning for research ramp up

May 18:
- Gov Baker issued Phased Statewide Back-to-Work Plan

June 8:
- Remote and lab-based animal research ramp up began (Low Density)

August:
- Human Subject Research ramp up began (Low Risk)

December/January:
- Administration of vaccine began
Safety Unit Organization

Laboratory Safety (Melanie Marketon- Director)
- Biosafety
  - Sarah Augood- Medford Biosafety Officer
  - Brandon Linz- Boston Biosafety Officer
  - John Tonkiss- Grafton Biosafety Officer
  - Seema Bhalchandra- Biosafety Support Specialist
- Chemical and General Safety
  - Shaun Savage- Assistant Director
  - Kathy Craig- Chemical Hygiene Officer
  - Amanda Carey- Chemical Safety Officer
  - Kate Barry- Chemical Safety Officer
  - TBH- Lab Safety Support Officer
  - TBH- Lab Safety Support Officer
- Radiation and Laser Safety
  - Geoff Sirr- Radiation Safety Officer
  - Hector Gonzalez- Radiation Safety Specialist

Industrial Hygiene (Stephen Larson- Director)
- Workplace Safety & OSHA Compliance
  - TBH Medford Campus Manager
- Environmental Protection
  - TBH- Boston Campus Manager
- Industrial Hygiene
  - Jason Erbach- Environmental Manager
  - Simona Holacek- Industrial Hygienist

EHS webpage will be replaced with a Safety page - will guide you to Laboratory Safety or Industrial Hygiene.
In August 2020, President Monaco mandated the creation of the Institutional Chemical Safety Committee (ICSC).

- Chair: Prof. Clay Bennett, Chemistry (Clay.Bennett@tufts.edu)
- Purview: ICSC oversees the use, storage, and disposal of chemicals in all research, teaching, and training activities across the university.

Current Initiatives
- Developing policies, standards, and procedures for chemical use and storage- research, teaching, and training activities.
- University-wide Chemical Inventory: Chemical Safety Officers are working with PIs, Departments, and Central/Core facilities to complete the first inventory upload in a new university-wide electronic resource: BioRaft (the ChemTracker module).

For more information or to schedule an inventory, email ICSC@tufts.edu.
Human Subjects Research Considerations

Existing Considerations
- COVID-19 Status of Participant
- Risk Level of Target Population
- Research Location
- Duration and Type of Face-to-Face Contact
- Frequency of Contact and Number of People
- Research Setting
- Research Equipment
- Research Activities

New Considerations
- Travel
- Scholarly Activities
- Proof of Vaccine
- Exceptions for Medium Risk Studies may be submitted to the ISC through the school deans

Timeline:
- March 2020: State Issued Stay-at-Home Policy
- June 2020: Remote and Lab-Based Animal Research Ramp Up (Low Density)
- August 2020: Human Subject Research Ramp Up (Low Risk)
- March 2021: Medium Risk Research Exceptions
Avoiding Workplace Transmission of COVID-19

• **Avoid close contacts**
  - Close contact = less than 6 ft for more than 15 min
  - New strains are circulating which are more contagious.
  - Stagger work schedules and use alternate methods of communication (virtual meetings, etc)

• **Close contacts must be approved**
  - On campus, there should be no unapproved close contacts.
  - Close contacts – proximity must be approved by the ISC and will have specific safety protocols.

• **N95 Re-use**
  - Avoid re-using N95s if possible.
  - If you MUST re-use N95s, follow the steps outlined in the [GUIDE FOR N95 RESPIRATOR RE-USE](#).

• **If you have a positive COVID test,**
  - Share your contact info with the contact tracers.
  - Failure to cooperate with contact tracing puts us all at risk for workplace transmission.

• **If you are identified as a close contact,**
  - You MUST stay quarantined and not come to campus until you are cleared.
  - You will be notified if you are a close contact and will be given instructions about testing and quarantine based on public health guidelines.

• **Surveillance testing continuing throughout the summer.**
Funding Announcements & Research Event

Tufts Medical Center/Tufts University COVID-19 Seed Funding Program – Phase 2 Awards – 8 funded projects

Tufts Launchpad | Accelerator (TLA) Application
Deadline – March 15

Tufts Springboard
Application Deadline – May 15

COVID-19 Bridge Funding (Coming Soon)

Research Forum on March 30th
9:30am – 10:30am
Successes and challenges of the COVID-19 vaccine rollout in the global context (part of Tufts Global Month)
The ‘new normal’ is coming: Mass. set to enter final phase of reopening in March

By Andy Rosen, Anissa Gardizy and Diti Kohli Globe Staff and Globe Correspondent, Updated February 25, 2021, 7:44 p.m.

Governor Charlie Baker said Thursday that the moves on reopening were prompted by the improvement in COVID numbers. PAT GREENHOUSE/GLOBE STAFF

Governor Baker is right — schools must reopen

Children have fallen behind academically. Pediatricians report rising anxiety and depression among kids. Schools can reopen safely for in-person learning, and it’s past time they do.

By The Editorial Board, Updated February 25, 2021, 5:33 p.m.

Chelsea public school fifth-grader Ashley Mejia-Gargano takes her online class from inside the cafeteria at the Clark Avenue Middle School, Feb. 7. JESSICA RINA/GLOBE STAFF
Questions?