LESSONS LEARNED

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RESEARCH INTEGRITY PROGRAM:
LESSONS LEARNED
Research Integrity
Some Thoughts…

“Integrity is doing the right thing when no one is watching.”

- C.S. Lewis
It is a challenge for research leaders to foster a culture of integrity and excellence, with defined systems, transparent processes, and clear accountability, while meeting the varied requirements and expectations in a dynamic research environment.
Research Integrity

Integrity Definition

- Firm adherence to a code of especially moral or artistic values
- An unimpaired condition
- The quality or state of being complete or undivided

http://www.merriam-webster.com/dictionary/integrity
Research Integrity
The Canadian Context

• **Research Integrity in Canada**
  – No central oversight body
  – No federal regulations
  – Requirements are specified by funders
  – Oversight is managed by institutions
UHN Research Integrity Program

Our Context

- Tri-agency (CIHR/ SSHRC/ NSERC)
- US Department of Health & Human Services
- University of Toronto
- Agreement, contracts
- Journals
- Regulations, legislations
UHN Research Integrity Program
Mandate

Responsible Conduct of Research

- Support local and systemic improvements
- Facilitate management of concerns of research conduct
- Promote a culture of quality and integrity
UHN Research Integrity Program

Program Elements

**Research Integrity Team**
- EVP Science & Research
- Research Integrity Advisors
- Research Quality Integration

**Internal Collaboration**
- EVP Clinical Programs, Safety & Quality
- Area VP
- Department/Division Heads
- Institute Directors
- General Counsel
- Public Affairs

**External Accountability**
- University of Toronto
- Tri-agency SRCR
- Office of Research Integrity (DHHS)
- Journals
- Funders
UHN Research Integrity Program
Policy & Process

Policy 40.90.001 Responsible Conduct of Research

Consistent with Tri-agency, ORI, U of T requirements

Defines Research Misconduct
- Fabrication
- Falsification
- Plagiarism
- Material failure to comply with accepted standards

Outlines Process for the Management of Allegations
- Complaints intake
- Evaluation by EVPs
- Inquiry
- Investigation
- Appeal
- Remedial Actions
- Reporting
Key Lessons
Case Complexities

**People**
- Complainants
- Respondents
- Role of co-authors
- Confidentiality vs. Disclosure – who/when/internal/External
- Data availability/access/sequestration

**Processes**
- Jurisdiction
- Regulatory & funder reporting
- Committee membership
- Operations & logistics
- Ownership/access to data
- Scope of investigation

**Systems**
- Lack of consistent harmonized standards, definitions, requirements
- Varying institutional practices
Key Lessons
Example: Anonymous Allegations

Anonymous allegations

Case Complexities

• Multiple sources of complaints/concerns
• ‘Good faith’ – responsible allegation
• Complaint intake process, validation
Key Lessons
Example: Cross-Allegations

Allegations made by two parties, both of whom act as both respondent and complainant

Case Complexities

• Complainant & respondent roles
• Committee membership/ conflict of interest
• Scientific validity vs. Research conduct
Key Lessons

Example: Jurisdiction

Multiple concerns involving both clinical and research conduct in a multi-centre trial.

Case Complexities

- Jurisdiction
- Communication, information sharing, reporting
- Confidentiality vs. disclosure
Key Lessons
Example: Changing Scope

Concerns raised regarding image irregularities in multiple publications spanning years.

Case Complexities

• Data – ‘ownership’, access, and retention
• Multiple funding sources, requirements
• Role of co-authors
• Confidentiality vs. disclosure
• Changing scope, additional allegations
Key Lessons
What We’ve Learned

People
- Researchers want to do a good job
- Leadership is important – the institutional, Program and PI levels

Processes
- Establish best practices
- Tools and training
- Principles based, adaptive approach

Systems
- Alignment with growing and changing environment
- Being a leader, sharing knowledge
Key Lessons

Institutional Risk Assessment

- Patient Safety
- Financial
- Compliance
- Legal
- Reputational
Key Lessons
No Two Cases are the Same

- Establish policy and standards as a foundation
- Monitor environment, requirements
- Develop (and follow) a transparent process
- Be adaptable, making principles based-judgments
- Involve counsel
Key Lessons

Communication

Eats shoots and leaves

Eats, shoots, and leaves

- Be clear and specific in communication
- Know your audience and purpose
- Treat everything as if it will be public
Key Lessons

Document Management

• Know the requirements
  – Privacy
  – Confidentiality
  – Privilege

• Establish a file naming convention, process

• Create a document log
Key Lessons
Some Final Thoughts...

“The only real mistake is the one from which we learn nothing.”

-Henry Ford