Responsible Conduct of Research (RCR) and the Office of Research Integrity and Assurance (ORIA)

Mark Hurwitz, Ph.D., P.E.
Chief Research Compliance Officer
Research Integrity Officer
Ithaca Campus Units: Ithaca, Cornell Tech, Geneva, and related field locations

Export Control

Weill Cornell Medicine: NYC, Qatar, Affiliate Hospitals

WCM IRB, IBC, IACUC, CAP, RIO

Hospital IRBs

Board of Trustees

President

Board of Fellows

Provost

Provost for Medical Affairs

Ithaca IRB, IBC, IACUC, FCOI, RIO
ORIA administers research compliance programs for all aspects of RCR:

- Integrity in reporting research results
- Conflict of Interest & Commitment
- Export and Import Control
- Human participants, Animal, r/sNA, and Biohazardous Materials
To the Researcher, Compliance can Appear as a Barrier...
To Sponsors, Compliance is Keeping Faith with the Public

National Pool of Research Scientists

Reliable Information
Patents, Start-ups, Jobs

Taxpayers

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Evolving Challenges in Innovation

How to enable entrepreneurship while protecting fundamental research?

Cornell University Spinout History
Harvard teaching hospital to pay $10 million to settle research misconduct allegations By Retraction Watch Apr. 27, 2017

Duke University settles research misconduct lawsuit for $112.5 million By Science News Staff Mar. 25, 2019

Former Newton Scientist Agrees to Pay $215,000 to Resolve Allegations of False Statements in NIH Grant Application By U.S. Department of Justice (Aug 6, 2021)

Department of Justice Reaches $1M Settlement With Van Andel Research Institute (VARI) To Resolve Allegations Of Undisclosed Foreign Ties To NIH Grants Second Settlement With VARI Brings Total Settlement Proceeds To $6.6 Million as NIH Imposes Specific Award Conditions On All VARI Grants By U.S. Department of Justice (Sep 1, 2021)
“Research Misconduct” is as defined in Federal Regulations:

- **Fabrication**: making up data or results and recording or reporting them.
- **Falsification**: 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**: the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

“Research Related Misconduct” in Policy 1.2:

- “Any act that violates the standards of integrity in the conduct of scholarly and scientific research and communication.”
- **Except**: Allegations are investigated under other Cornell policies, such as IACUC and IRB policies, where such policies apply.
Misconduct is Intentional

• A finding of misconduct requires:
  • Significant departure from accepted practices of the relevant research community; and
  • Committed intentionally, or knowingly, or recklessly; and
  • The allegations be proven by a preponderance of the evidence.

• Misconduct does not include unintentional error or honest differences in interpretations or judgements of data.
Data Management and Reproducibility are Critical to Integrity

• Fundamental principles*:
  • Sound stewardship of research data is required
  • Cornell must retain research data in sufficient detail to enable appropriate responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations.
  • Cornell asserts ownership of research data and related property rights arising from the activities of its researchers and others who use university resources.

*Policy 4.21 Research Data Retention:
https://policy.cornell.edu/policy-library/research-data-retention
Consult the Research Services Website

Starting point for Information on Compliance and RCR.

https://researchservices.cornell.edu
Financial Conflict of Interest (COI)
Bridget MacRae, [Chair: Chris Ober]

• Exists when opportunity for personal gain appears to compromise or influence research.

• Perception of conflict, real or not, can damage reputations, impugn research, and reduce funding.

• Scrutiny of possible COI and Conflict of Commitment is increasing due to federal concerns about Foreign Influence.

• Conflicts are not inherently bad: COI often arises in “real world” situations, Consulting, Entrepreneurship, etc..
The federal government is increasingly concerned about the role new technology plays in U.S. economic and national security. Recognizing that innovation and scientific collaboration are critical, scrutiny of possible threats continues to increase.

Key U.S. Emerging Technology Sectors*:
- Artificial Intelligence
- Quantum Information Science and Technology
- The Bioeconomy (biotechnology and the convergence of life and data sciences)
- Semiconductors
- Autonomous Systems

Some of the Recommended Basic Steps to Mitigate Counterintelligence Risks*:
- Know who you are doing business with
- Strengthen cyber security and hygiene
- Understand the risks involved in foreign government-sponsored talent recruitment programs
- Have no expectation of privacy when traveling abroad, especially on electronic devices.

*Protecting Critical and Emerging U.S. Technologies from Foreign Threats, The National Counterintelligence and Security Center, October 2021
Export Control Laws apply to Information not just Physical Goods
Sarah Schlagter, Export Control and Compliance Officer

• Typical Exclusions:
  • Fundamental Research (EAR & ITAR)
  • Educational Information (EAR)
  • Publicly Available/Public Domain (EAR/ITAR)

• Contractual Obligations can destroy Exclusions and require License:
  • Exclusion is lost if Sponsor has the right to approve or disapprove publications
  • Exclusion is lost if Sponsor Restricts participation in conduct of research:
    • For proprietary reasons
    • For national security reasons

• Proprietary technical information should always be treated as controlled: Access by certain foreign nationals in the U.S. is prohibited

• When in doubt, contact the Export Control Office!
• Currently recommended for all external contracts.
• Likely to be required before end of FY22.
• Recites and acknowledges pre-existing duties owed by the faculty member to Cornell:
• Intended to be non-negotiable. Clarifications, but not substantive revisions, are allowed.
• Exceptions are:
  • Sponsored research agreements (funds flow through Cornell);
  • Contracts with Cornell University or any of its units such as employment agreements and royalty agreements as an inventor of Cornell IP;
  • Contracts specifically about educational materials (e.g. book deals);
  • CU Part time faculty; and
  • Expert witness for court cases.
Anyone doing human participant research must have an approved IRB protocol or exemption.

Governing principles:

1. Respect for persons – use of informed consent
2. Beneficence - the benefit of the research outweighs any pain or discomfort each participant might experience
3. Justice – equal distribution of risks and benefits
Live Vertebrate Animal Use
Institutional Animal Care and Use Committee (IACUC)
Christine Bellezza / Rob Felt, [Chair: Ned Place]

- A research protocol must be approved by the IACUC before animal research can begin.
- Governing principles:
  - Replace animal use with alternatives such as cell cultures, when possible.
  - Reduce the number of animals needed as much as possible.
  - Refine the way procedures are carried out to minimize pain and/or improve animal welfare.
  - It is a privilege to work with animals. They deserve our care and respect.
• NIH regulations require the IBC review all research involving recombinant or synthetic nucleic acids.
• Cornell’s Ithaca Campus IBC also reviews all research with:
  • Infectious Pathogens (Risk Groups 2 and 3)
  • Biological Toxins (Lethal Dose for 50% less than 100 ug/kg)
  • Dual Use Research of Concern (DURC) Biological materials
  • Human embryonic stem cells (ESCRO).
• **Integrity Issues:** Mark Hurwitz (mfh37)  
  **Office Manager:** Allison Johnson (amw395)

• **Export Control Issues:** Sarah Schlagter (sms655)  
  **Export Mailbox:** exportcontrols@cornell.edu

• **Use of Human Participants in Research:** Myles Gideon (mbg223)  
  **IRB** Institutional Review Board  
  [https://researchservices.cornell.edu/compliance/human-research](https://researchservices.cornell.edu/compliance/human-research)

• **Use of Animals in Research, Teaching or Testing:** Christine Bellezza (cab37)  
  Robert Felt (rjf243)  
  **IACUC** Institutional Animal Care and Use Committee  
  [https://researchservices.cornell.edu/compliance/live-vertebrate-animal-research](https://researchservices.cornell.edu/compliance/live-vertebrate-animal-research)

• **Use of r/sNA and Biohazardous Agents:** Michael Betteken (mib46)  
  **IBC** Institutional Biosafety Committee  
  [https://researchservices.cornell.edu/compliance/rsna-or-biohazardous-research](https://researchservices.cornell.edu/compliance/rsna-or-biohazardous-research)

• **Responsible Conduct of Research:** Bridget MacRae (bm483)  
  **RCR** [researchservices.cornell.edu/compliance/research-integrity](https://researchservices.cornell.edu/compliance/research-integrity)

• **Financial Conflicts of Interest related to Research:** Bridget MacRae (bm483)  
  **FCOI** [https://researchservices.cornell.edu/compliance/conflict-of-interest](https://researchservices.cornell.edu/compliance/conflict-of-interest)
• **Cutting barbed wire:** (b/w photo), French Photographer, (20th century) / Private Collection / © Look and Learn / Bridgeman Images

• **U.S. Capital:** The Capitol (photo), / AA World Travel Library / Bridgeman Images
Principles Underlying Conflict of Interest Decisions for Entrepreneurs

Bridget MacRae, Conflicts and Education Supervisor

https://researchservices.cornell.edu/compliance/conflict-of-interest
Conflict of Interest Goals

Cornell is committed to fostering entrepreneurship by encouraging new company startups and enabling commercial use of technologies developed at Cornell through technology licensing. However, such entrepreneurial activities present the possibility of bias in research resulting from opportunities for personal gain. The appropriate management of these activities ensures that:

- Faculty do not exert undue influence over students and staff under their supervision
- Cornell facilities and resources are not used improperly
- Cornell IP ownership is not compromised
- Cornell’s not-for-profit status is not jeopardized
- Public and sponsor trust in Cornell research is not undermined
Responsibilities

Entrepreneurs, Research Administrators, and the Financial Conflicts of Interest Committee work together to facilitate appropriate management of entrepreneurial activities

- Entrepreneurs must report events that alter their opportunity for bias as they occur
- COI staff must implement a Conflict Management Plan (CMP) if needed
- CMPs must be reviewed and updated whenever opportunities for influence, or influence relations change significantly
- The FCOI Committee will make decisions about whether a CMP is needed and appropriate and to do so, must have access to the roles of startup company’s employees and members of the boards of directors and advisors.
- The Director of a Cornell incubator will be a part of any CMPs related to companies in that incubator, and they are managed by FCOI regarding enforcement of that CMP in a manner that allows relevant communications with the Conflict Manager and COI staff.
Lifecycle of a Company: Introduction

- Incorporation and building the framework for the company
- Conducting business, licensing, and funding
- Appropriate involvement of Cornell personnel at the company, or of company employees at Cornell
Lifecycle of a Company: Getting things off the ground

The beginning phases of forming a start-up include:

- Incorporation
- Applying for funding
- Negotiating licenses
- Seeking space in a Cornell business incubator
- Startups may have access to equipment in a faculty founders’ lab only with an approved CMP and a contract approved by OSP or University Counsel

In some cases, these events create opportunities for bias, so they must be reported. Usually, no conflict of interest is present.
Lifecycle of a Company: Conducting Business

After the preliminary stages of setting up a start-up company, such companies may:

- Be admitted into a Cornell incubator
- License IP from Cornell
- Obtain venture capital or SBIR/STTR funding
- Sub-contract funding to Cornell, to conduct work on behalf of the company
- Startups may have access to equipment in a faculty founders’ lab only with an approved CMP and a contract approved by OSP or University Counsel

These events can impact a faculty member’s opportunity for influence over Cornell personnel, complicate IP ownership, and present issues related to the appropriate use of Cornell resources. A COI now exists and must be managed.
Lifecycle of a Company: Leaves of Absence

In some cases, the role a faculty member takes with a company is incompatible with his or her obligations to Cornell.

**Going on a leave of absence**

- Faculty may not serve as President, Director, or in C-Suite roles (CEO, CSO, CTO) at a start-up. If an alternative individual is not identified to take on such roles, the faculty member must go on a leave of absence from Cornell.

**Returning from a leave of absence**

- When a faculty member returns from a leave of absence, s/he may serve as consultant, advisor, or a member of the Scientific Advisory Board or Board of Directors at the company.

Sufficient information about the roles of company employees are critical to making informed COI determinations and to confirming that the faculty member’s work at the company does not conflict with his or her pre-existing commitments to Cornell or sponsors.
In some cases, faculty and their research staff or students desire to engage in business activities together, or company employees seek appointments in a faculty founder’s lab. These arrangements present unique COI concerns.

**Postdocs and Research Staff**
- May be involved in under certain terms, for a limited period.

**Undergraduate or Graduate Students**
- May not work at a faculty member’s company. Doing so presents serious opportunities for coercion.

**Company employees working in the Cornell lab**
- Only allowable under an appropriate contract with clear separation between Cornell work and company business, for a limited time, under the approval of the Dean and Vice President for Research

Improper personnel involvement can create issues related to undue influence, IP ownership, and credibility of research. Careful steps must be taken to manage COIs and protect involved personnel.
Financial Conflicts of Interest Contact Information

General COI mailbox: coi@cornell.edu

For additional information, visit the FCOI website:
https://researchservices.cornell.edu/compliance/conflict-of-interest