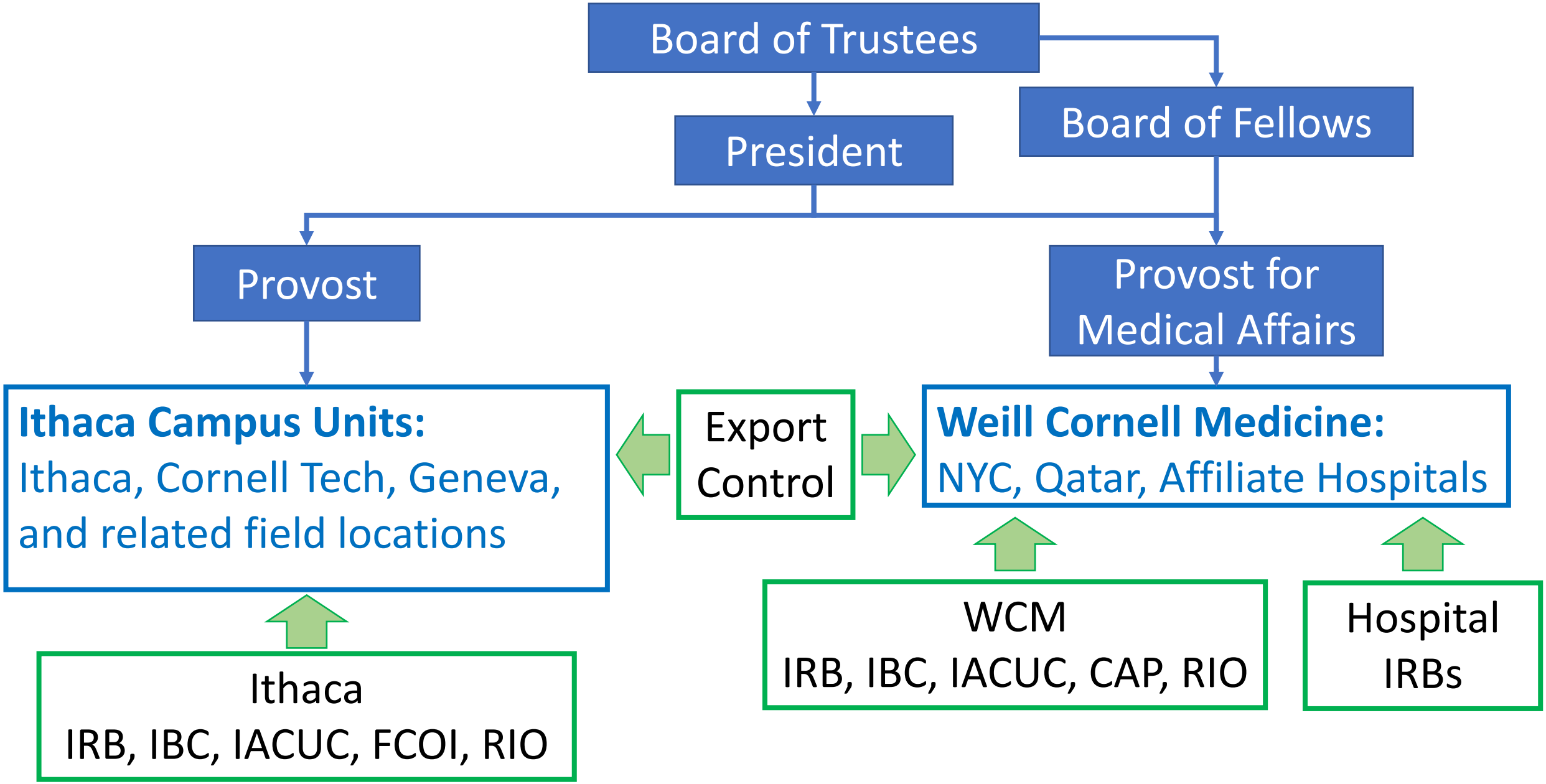
Responsible Conduct of Research (RCR)
and the
Office of Research Integrity and Assurance (ORIA)

Mark Hurwitz, Ph.D., P.E.
Chief Research Compliance Officer
Research Integrity Officer

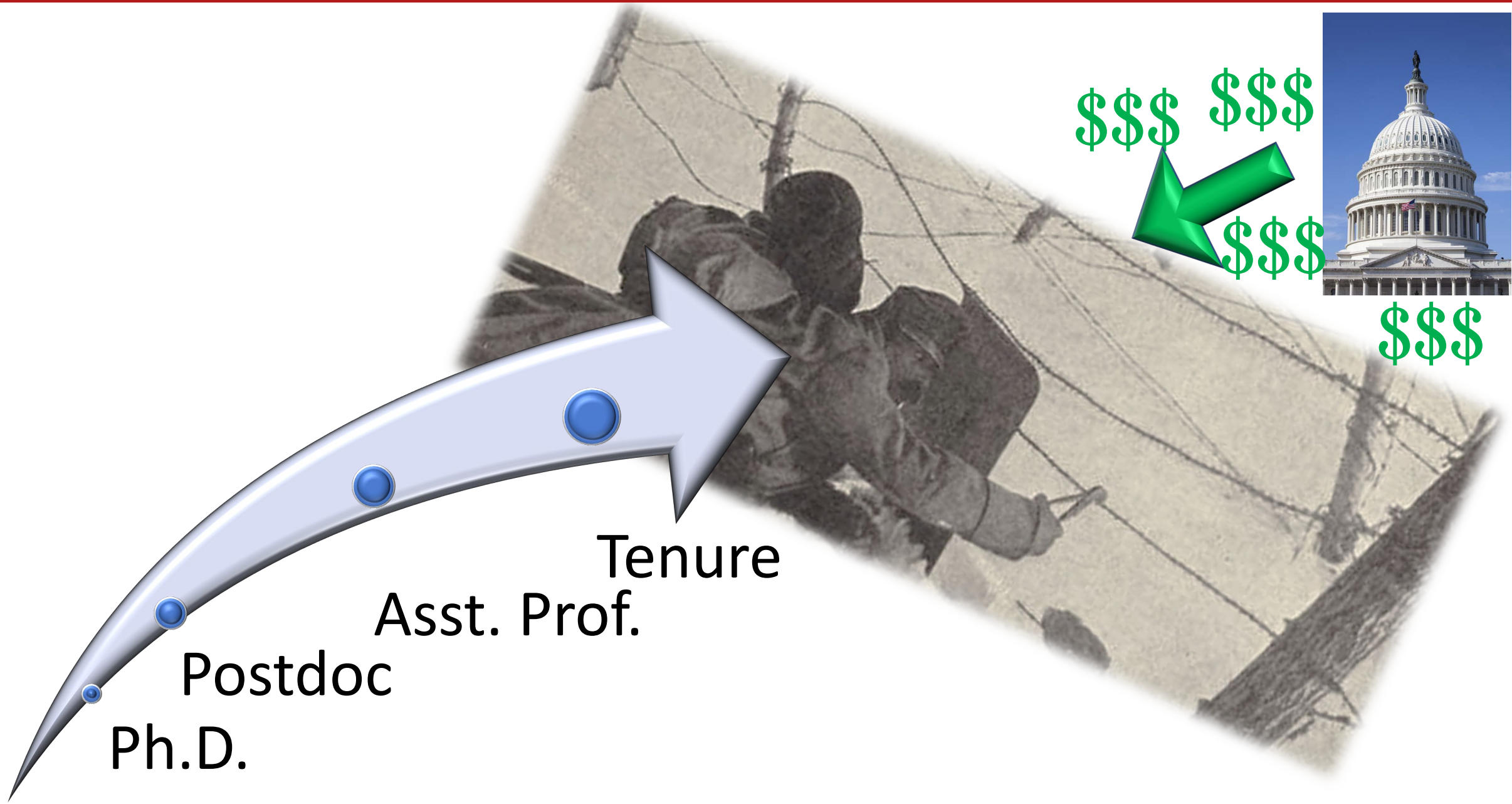
Compliance Affiliation



Office of Research Integrity & Assurance (ORIA)

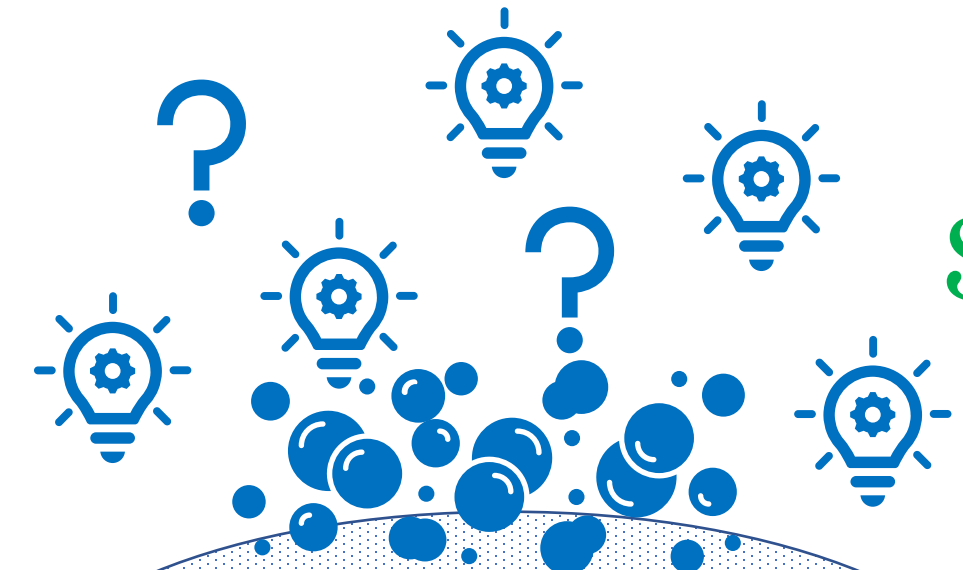
- ORIA educates the Cornell research community about Research Integrity and Responsible Conduct of Research (RCR) requirements.
- ORIA administers research compliance programs for all aspects of RCR:
  - Integrity in reporting research results
  - Conflict of Interest & Commitment
  - Export and Import Control
  - Human participants, Animal, r/sNA, and Biohazardous Materials

To the Researcher, Compliance can Appear as a Barrier…



Photos courtesy of Bridgeman Education.

To Sponsors, Compliance is Keeping Faith with the Public



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National Pool of Research Scientists

Taxpayers

Reliable Information

Patents, Start-ups, Jobs

Evolving Challenges in Innovation

How to enable entrepreneurship while protecting fundamental research?

Cornell University Spinout History

We prefer to avoid headlines like these…

Brian Wansink WIKIMEDIA COMMONS

Cornell nutrition scientist resigns after retractions and research misconduct finding

By Kelly Servick | Sep. 21, 2018 , 11:25 AM (AAAS Science Website)

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 and Research Related Misconduct

- "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.

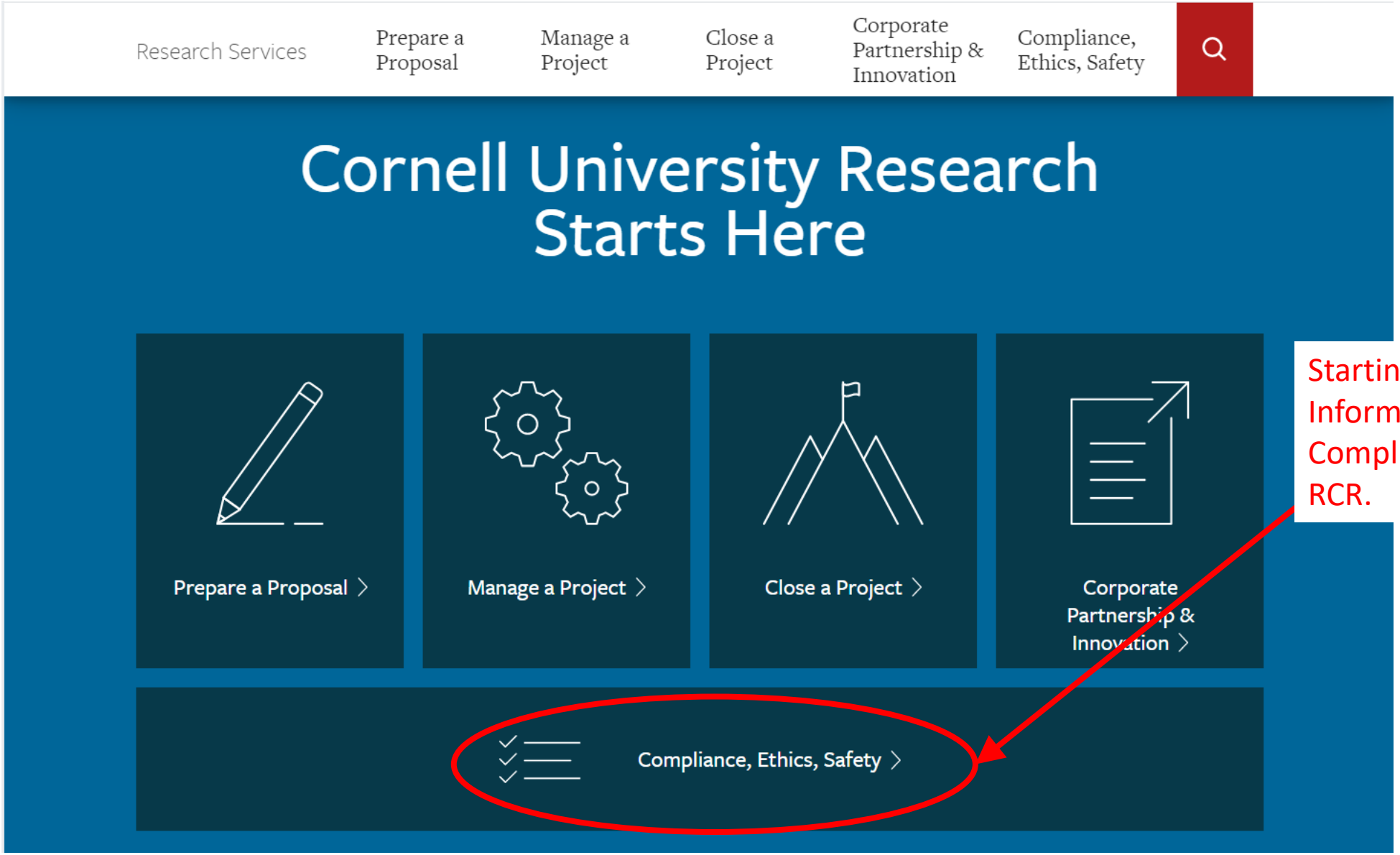
Data Management and Reproducibility are Critical to Integrity

- 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



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..

Foreign Influence

- 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!

External Contract Addendum

- 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.

ADDENDUM TO CONSULTING AGREEMENT ("Addendum")

This Addendum is hereby incorporated into that certain Consulting Agreement between _____ ("Consultant") and _____ (["Company"] or ["Entity"]) dated _____ ("Consulting Agreement").

1. The purpose of this Addendum is to ensure that Consultant's commitments to Company are consistent with Consultant's obligations to Cornell University and, where applicable, its Weill Cornell Medical College (collectively, "Cornell"). The undersigned agree that this Addendum is a part of the Consulting Agreement and further agree that if anything in the Consulting Agreement is inconsistent with this Addendum, this Addendum shall govern with respect to such inconsistency.

2. Company acknowledges that the terms and conditions of the Consulting Agreement are subordinate to obligations which Consultant has to Cornell as a Cornell faculty member, researcher and/or employee. Company understands and agrees that Consultant is an employee of Cornell, and that Consultant's services under the Consulting Agreement may not restrict or limit Consultant's obligations to Cornell or Consultant's activities within the course and scope of their employment with Cornell.

3. The parties further understand and agree that Consultant is required to comply with Cornell policies related to faculty conflicts of interest and commitment, patent and intellectual property, and scientific or research misconduct, and that such compliance takes priority over, and shall supersede, any obligations Consultant may have to Company under the Consulting Agreement. Consultant may not have principal investigator responsibility for research outside of Cornell, and outside activities may not include the extension of Cornell research into the consulting activity.

4. Company understands and agrees that Consultant is obliged to assign and has preemptively assigned to Cornell all of Consultant's rights in intellectual property resulting from activities conducted in the course of Consultant's employment at Cornell or supported by more than incidental use of Cornell resources. Company has no rights by reason of the Consulting Agreement in any intellectual property that is subject to Consultant's employment-related obligations to Cornell. Company further acknowledges that Consultant does not have the authority to assign, license or otherwise transfer rights in any of Cornell's inventions.

5. The undersigned acknowledge (i) that Consultant is entering into the Consulting Agreement, and providing services to Company thereunder, as a private individual and not as an employee or agent of Cornell; (ii) Cornell is not a party to the Consulting Agreement and has no liability or obligation thereunder; (iii) Cornell is intended as a third party beneficiary of this Addendum and certain provisions of this Addendum are for the benefit of Cornell and are enforceable by Cornell in its own name; and (iv) Cornell and Consultant may have current or prospective legal and regulatory obligations to report this consulting activity and disclose the Consulting Agreement to applicable funding agencies, as well as obligations under applicable privacy laws, U.S. Export Control regulations, and/or applicable anti-corruption and anti-bribery laws.

6. The above provisions shall be and hereby are applicable to the entire term of the subject Consulting Agreement between Consultant and Company.

AGREED and ACCEPTED:

Authorized Official of Company	Signature	Date
Consultant	Signature	Date

Research with Humans - Institutional Review Board (IRB)
Myles Gideon, [Chair: Andrew Willford]

- 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.

Institutional Biosafety Committee (IBC)
Michael Betteken, [Chair: Colin Parrish]

- 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).

Real People

- **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
- 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
- Use of r/sNA and Biohazardous Agents: *Michael Betteken (mib46)*
  IBC Institutional Biosafety Committee
  https://researchservices.cornell.edu/compliance/rsna-or-biohazardous-research
- Responsible Conduct of Research: *Bridget MacRae (bm483)*
  RCR 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

Image Credits

- **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.

Lifecycle of a Company: Personnel Involvement

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