



Molly Stoufer

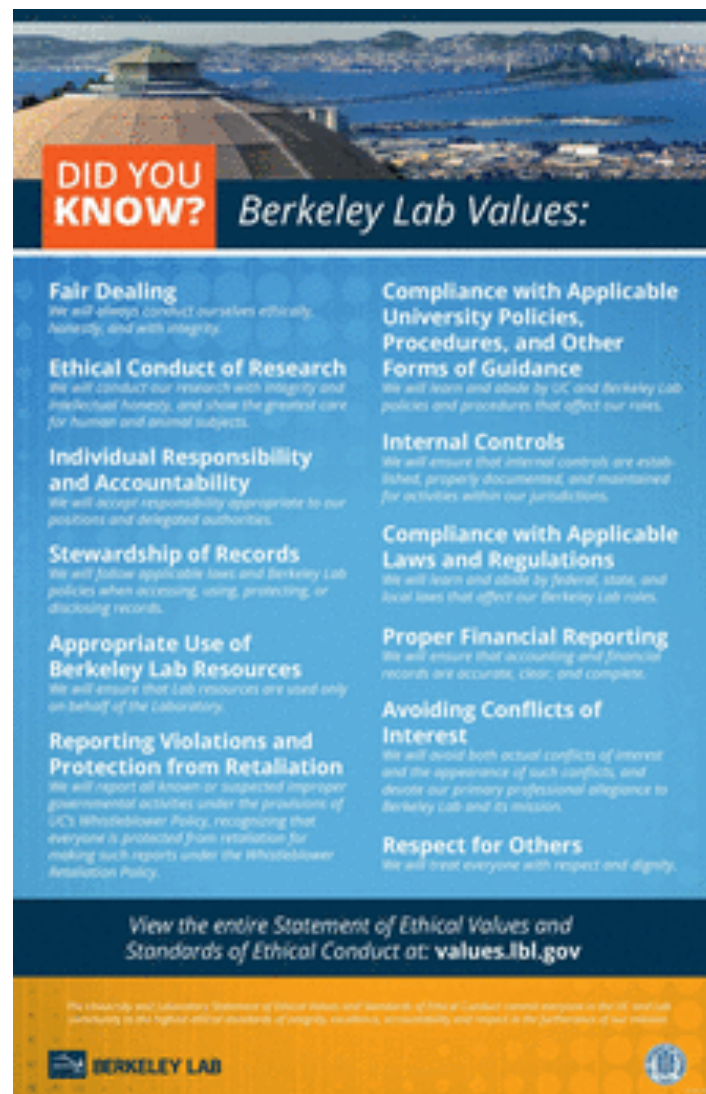
Office of Institutional Assurance and Integrity

April 12, 2016

Regulatory Environment



Ethics and Conduct




DID YOU KNOW? *Berkeley Lab Values:*

Fair Dealing <i>We will always conduct ourselves ethically, honestly, and with integrity.</i>	Compliance with Applicable University Policies, Procedures, and Other Forms of Guidance <i>We will learn and abide by UC and Berkeley Lab policies and procedures that affect our roles.</i>
Ethical Conduct of Research <i>We will conduct our research with integrity and intellectual honesty, and show the greatest care for human and animal subjects.</i>	Internal Controls <i>We will ensure that internal controls are established, properly documented, and maintained for activities within our jurisdictions.</i>
Individual Responsibility and Accountability <i>We will accept responsibility appropriate to our positions and delegated authorities.</i>	Compliance with Applicable Laws and Regulations <i>We will learn and abide by federal, state, and local laws that affect our Berkeley Lab roles.</i>
Stewardship of Records <i>We will follow applicable laws and Berkeley Lab policies when accessing, using, protecting, or disclosing records.</i>	Proper Financial Reporting <i>We will ensure that accounting and financial records are accurate, clear, and complete.</i>
Appropriate Use of Berkeley Lab Resources <i>We will ensure that Lab resources are used only on behalf of the Laboratory.</i>	Avoiding Conflicts of Interest <i>We will avoid both actual conflicts of interest and the appearance of such conflicts, and devote our primary professional allegiance to Berkeley Lab and its mission.</i>
Reporting Violations and Protection from Retaliation <i>We will report all known or suspected improper governmental activities under the provisions of UC's Whistleblower Policy, recognizing that everyone is protected from retaliation for making such reports under the Whistleblower Retaliation Policy.</i>	Respect for Others <i>We will treat everyone with respect and dignity.</i>

View the entire Statement of Ethical Values and Standards of Ethical Conduct at: values.lbl.gov

The University and Laboratory Statement of Ethical Values and Standards of Ethical Conduct commit everyone in the UC and Lab community to the highest ethical standards of integrity, excellence, accountability and respect in the furtherance of our mission.

 BERKELEY LAB 

Organizational Conflicts of Interest Unfair Advantage in Seeking Funding

Government contemplates program/
funding opportunity

LBNL develops specifications
or statement of work

LBNL receives information
from funding agency not
released or available to the
public

Restrictions on LBNL ability to
propose or compete for
subject funding

Fairness of Opportunity in Procurement

LBNL contemplates an acquisition that
will result in a Request for Proposal
(RFP)

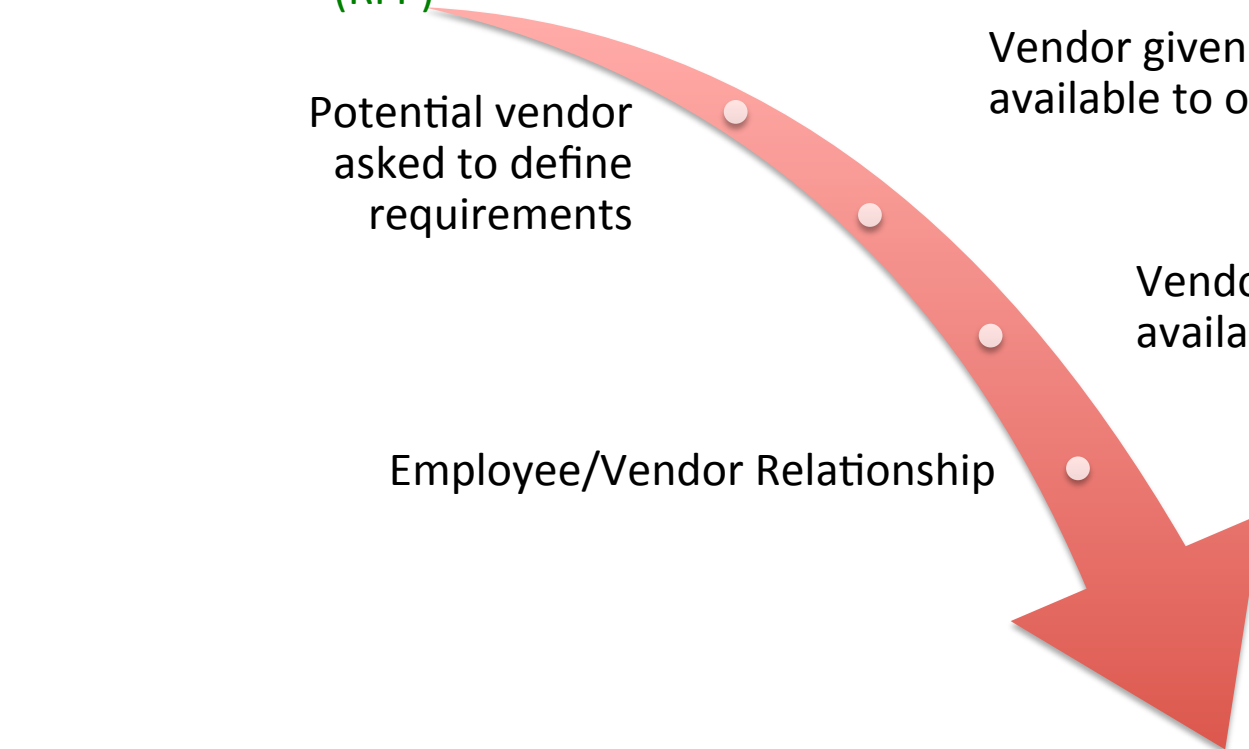
Potential vendor
asked to define
requirements

Vendor given advantage not
available to other competitors

Vendor receives information not
available to other competitors

Employee/Vendor Relationship

Integrity of procurement
compromised; subject to
prohibitions and/or challenge



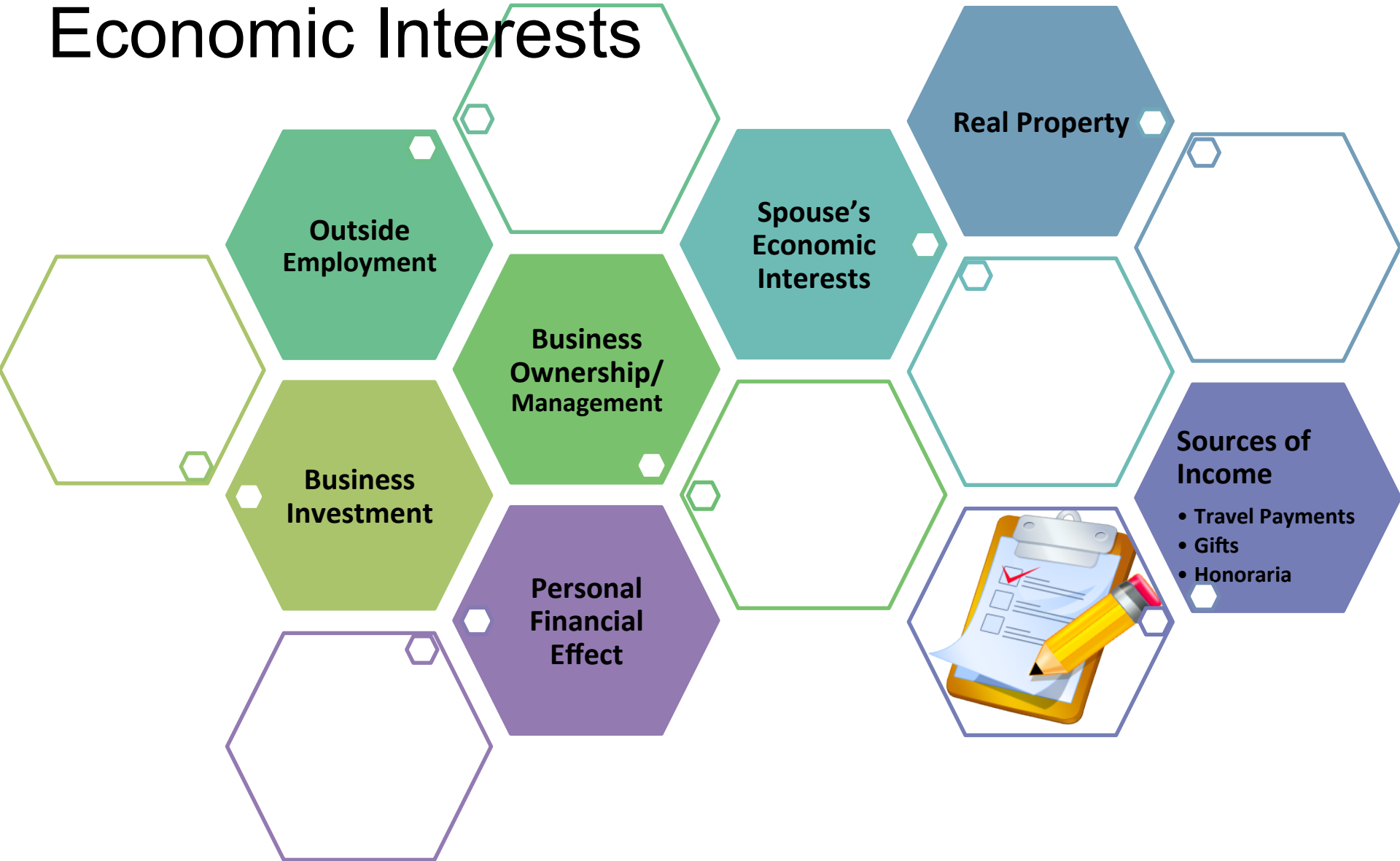
INDIVIDUAL CONFLICT OF INTEREST

What is a Conflict of Interest?

A COI a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

Fully and transparently identifying and managing conflicts of interest helps maintain the integrity of the research and fosters public trust in the research enterprise.

Economic Interests



The Case of the Shiny Mirrors

- Read the case
- Please understand that it is a hypothetical only, and does not represent what may be allowable or manageable within our environment
- Identify required processes
- Think about potential conflicts of interest

Required processes

- Adams
 - COPA/Outside Work must be reviewed and approved by Berkeley Lab prior to her engaging in work for the company
 - Disclose ownership interest in MirrorsPlus
 - Inventor Statement of Economic Interest
 - Employee-vendor list
 - Disclose equity and management position in potential sponsored work (SBIR/SPP)
 - Disclose equity in NIH, probably other federally funded proposal submissions
- Lucas
 - COPA must be reviewed and approved

Policies and Procedures

Requirement to disclose/disqualify

Prior approval for compensated outside professional activities

Employee – vendor relationships

Organizational conflict of interest

Sponsored Research

Human Subjects

Limits on gifts/gratuities

COI in Licensing

Post employment restrictions

Policy on employment of near relatives

Required Disclosures

Employees seeking compensated outside professional activities

Employees with vendor relationships

PI on privately sponsored research and gifts

Those responsible for the design, conduct or reporting of research funded by PHS/NSF and other entities

Human Subjects Researchers

Inventors

Designated officials

Peer reviewers (proposal, program, publications)

Potential conflicts

- Time committed to MirrorsPlus could interfere with LBNL responsibilities
- Economic interest could bias design, conduct or reporting of research or award of license
- Potential misuse of LBNL resources (time, facilities, phone/computer, etc.) for personal gain
- Lucas reporting to her in both organizations – potential misdirection of subordinate work
- Appearance of conflict creates personal/LBNL reputational risks
- Subcontract to employee-owned company

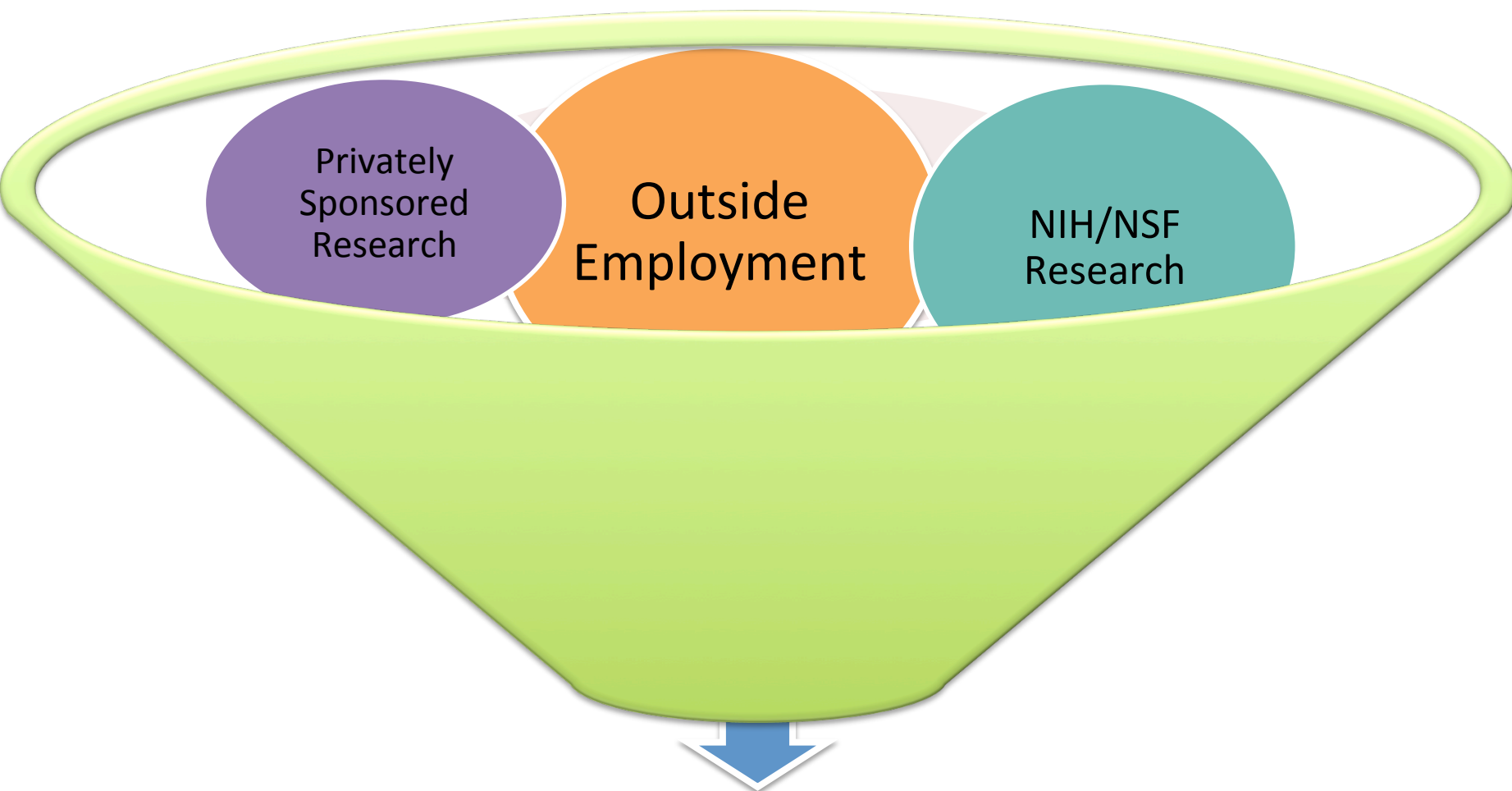
Managing the conflicts

- Both researchers disclose financial interests
 - Research group
 - Publications/presentations
 - Program managers
- Division reduces Adams' time commitment at LBNL or Adams reduces time commitment at MirrorsPlus, or both
- Division provides additional oversight and changes supervisory structure
- OIAI notifies DOE Berkeley Site Office, possibly NIH of the conflict and resulting management plan

Unmanageable conflict of interest

- Though MirrorsPlus may engage in SPP with Berkeley Lab, Adams may not be Berkeley Lab PI (no separation of personal and public interests, potential bias of research, misuse of Lab resources for personal gain)
- Lucas cannot report to Adams for both organizations (potential misdirection of work)
- Adams may not subcontract work to MirrorsPlus
- LBNL must find another way to accomplish the production of the prototype coatings, or not accept this part of the research project

Single COI Review Process



Conflict of Interest Advisory Committee

COIAC Review Triggers

Income

- Any \$ amount for COPA

Equity

- Varies by process

Relationship to Lab

- Technology license
- Research Sponsor
- Supplier/Vendor/Subcontractor

Other employee involvement

- Reporting relationships

COI Review Principles

Employees may participate in outside professional interests, including employment relationships and equity holdings, as long as those financial interests do not interfere with employees' Laboratory obligations, involve use of Laboratory resources, embarrass DOE or the University, create an unmanageable conflict of interest.


Each regulatory entity has similar principles and frameworks for reviewing outside interests and addressing conflicts that arise therein.

Managing Research Conflicts



Disclosure

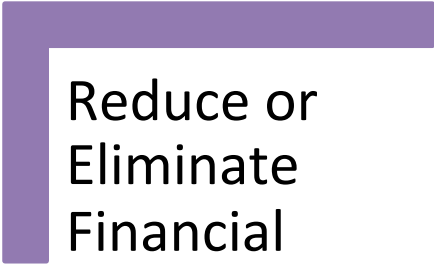
- Research Group
- Funding Source
- Publications



Independent Oversight/ Supervisory Change

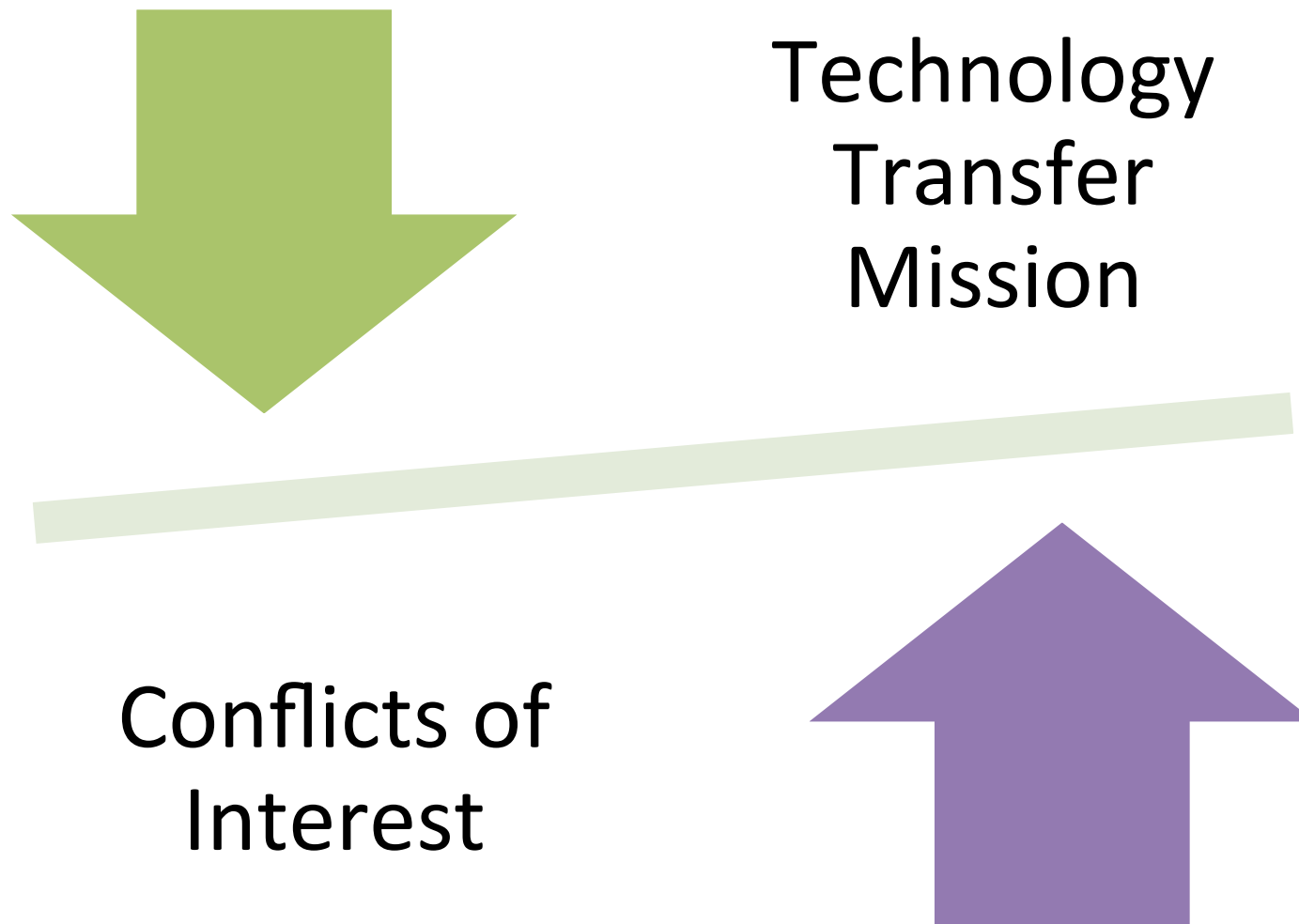


Limit Researcher Role



Reduce or Eliminate Financial Interest

Competing Interests





Potentially Significant Consequences Personal/Institutional



Personal
criminal/civil
prosecution/
fines



Personal
disciplinary
action



Delay in ability
to compete for
funds



Disqualification/
debarment



Loss of UC
Contract

Remember

Be Alert to Potential COI Situations

- Activities in which you have an economic interest
- Interactions with funding agency personnel
- Interactions with subcontractors/bidders
- Interactions with previous/prospective employers

Know Your Economic Interests

- Sources include employee, spouse, registered domestic partner, dependent children, etc.
- Types include income, real property, investments

Ask Experts

- Office of Institutional Assurance and Integrity
- Procurement
- Intellectual Property Office
- Lab Counsel

Disclose/Self-Disqualify

Questions?
coi@lbl.gov

Molly Stoufer

BLIC COI Training

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