

Essential Elements of a Sustainable University IP and Technology Transfer Function

Regional High-Level Summit for University Presidents and Senior Policy Makers on EIE

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Dr. Richard Cahoon
President, BioProperty Strategy Group, Inc.

Dr. Ashley J. Stevens
President, Focus IP Group, LLC



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Agenda

- ❑ Why do we do what we do?
- ❑ Conflict of Interest and Conflict of Commitment Policies;
- ❑ Relationships with industry

The Many Missions of Universities

- ❑ To teach existing knowledge to the next generation
 - ❑ While helping them to transition from adolescents to adults
- ❑ To discover new knowledge and disseminate it broadly
 - ❑ While training the next generation of researchers
- ❑ To care for patients
 - ❑ While advancing medical care
- ❑ To be a source of economic development
 - ❑ While not conflicting with the previous three elements of their Mission!
 - ❑ The newest of the missions

What Are the Benefits of Technology Transfer?

- ❑ Economic development
 - ❑ Being seen to benefit the regional and national economies
 - ❑ → Increased government support
- ❑ Reputational
 - ❑ Enhancing entrepreneurship regionally and nationally
 - ❑ → Increased government support
- ❑ Student recruitment
 - ❑ This generation of students is highly entrepreneurial
- ❑ Financial
 - ❑ Corporate support
 - ❑ Faint possibility of financial return from licenses and spin-outs



We've decided to rebrand the Technology Transfer Office. You're now the Office of Technology Licensing and Commercialization, Venture Creation, Industry Liaison, Economic Development and Societal Impact

What Drives Technology Transfer In Your Institution?

- ❑ Why are you doing technology transfer?
 - ❑ To make money?
 - ❑ To indulge faculty?
 - ❑ To disseminate the results of your research?
 - ❑ To benefit society?
 - ❑ To develop the local economy?
- ❑ Management's response is often "Yes"
 - ❑ Do them all
 - ❑ *You're now the Office of Technology Licensing and Commercialization, Venture Creation, Industry Liaison, Economic Development and Societal Impact*
- ❑ Can you do them all?
 - ❑ Or are there trade-offs?

Operating Models for Technology Transfer

- ❑ Faculty Service
 - ❑ Support the creative and entrepreneurial aspirations of faculty and graduate students
- ❑ Revenue Maximization
 - ❑ Generate the maximum amount of license income
- ❑ Knowledge Transfer
 - ❑ Licensing, Sponsored Research, Faculty Consulting
- ❑ Economic Development
 - ❑ Maximize job creation / retention
 - ❑ Regionally
 - ❑ Nationally
- ❑ Societal Benefit
 - ❑ Meet the needs of society that market forces will not meet

Organizational Implications

- ❑ Where should OTT report within the university?
- ❑ Depends on Model/Mission chosen
 - ❑ Faculty Service VP for Research
 - ❑ Revenue Maximization VP for Finance
 - ❑ Knowledge Transfer VP for Research
 - ❑ Economic Development VP for Economic Development
 - ❑ Societal Impact VP for Development

What Drives Technology Transfer in the U.S.?

<u>Driving Factor</u>	<u>Number of Institutions Ranking Factor First</u>	<u>%</u>
Faculty service	51	39.2%
Translating research results	45	34.6%
Revenue maximization	15	11.5%
Other	15	11.5%
Research Support	4	3.1%
<u>Risk Management</u>	<u>0</u>	0.0%
Total	130	

Source: How US Academic Licensing Offices are Tasked and Motivated – Is it all about the money?”, Irene Abrams, Grace Leung and Ashley Stevens, *Research Management Review*, 17.1, Fall/Winter 2009;

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Conflict of Interest Policy



Conflict of Interest

- ❑ A conflict of interest doesn't mean you've done anything wrong
 - ❑ Probably means you're doing things right
- ❑ The Yang to the Ying of technology transfer:
 - ❑ We encourage faculty to commercialize their research and create relationships with companies
 - ❑ Then we bury them in paperwork
 - ❑ Will impact their ability to participate in the clinical development of their work
 - ❑ May impact their ability to receive corporate support of your work
- ❑ Some parts of the institution may resent the commercialization activities

“No conflict

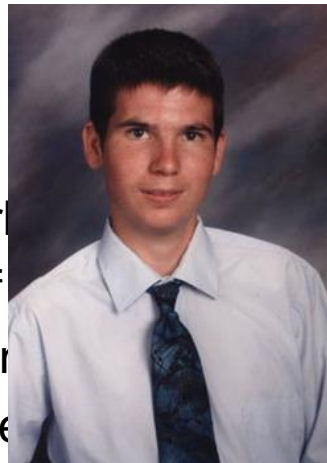
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no interest”

David Blake, JHU, 1992

Conflict of Interest

- ❑ Tech transfer introduces personal profit into the non-profit world
- ❑ Some really ugly incidents occurred in the late 1980's / early 1990's
- ❑ One example:
 - ❑ The successful development of gene therapy was set back 10 years by a Col driven event
 - ❑ Jesse Gelsinger
 - ❑ Seventeen years old
 - ❑ Had ornithine transcarbamoylase deficiency syndrome
 - ❑ Enrolled in a clinical trial of gene therapy at U. of Pennsylvania
 - ❑ Adenovirus + OCD gene
 - ❑ 18th patient to receive gene therapy
 - ❑ Severe reaction
 - ❑ Intense inflammatory response
 - ❑ Dangerous blood-clotting disorder
 - ❑ Kidney, liver, and lung failure



Conflict of Interest

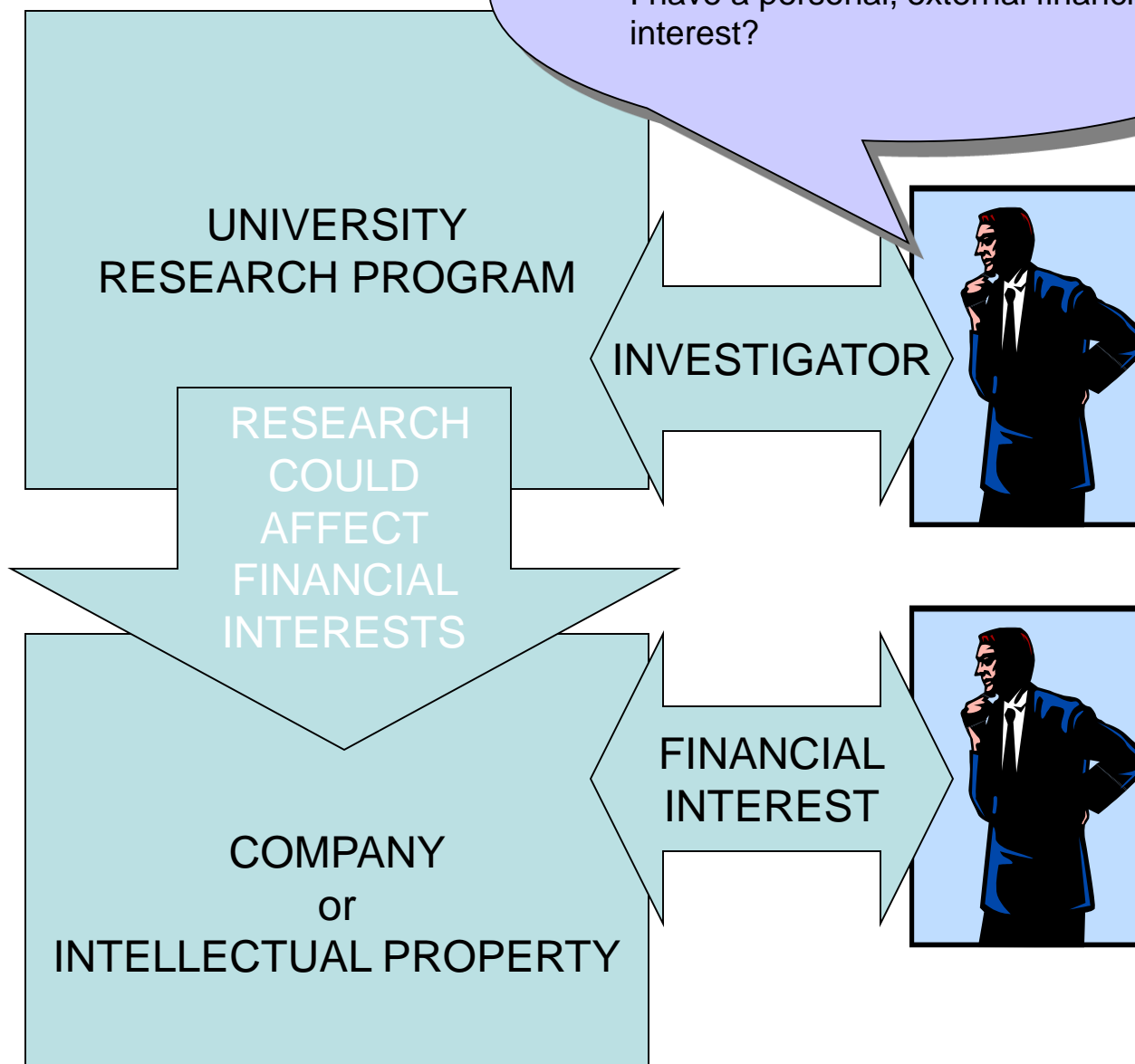
- ❑ PI James Wilson MD
 - ❑ Founded Genovo
 - ❑ 1992
 - ❑ Had rights to the t
 - ❑ Didn't disclose his financial interest in the informed consent
 - ❑ FDA banned clinical research in Institute for Human Gene Therapy at Penn
 - ❑ University shut program down
 - ❑ FDA charged Wilson with several violations
 - ❑ Restrictions on human research for five years
 - ❑ University paid a \$540,000 fine
 - ❑ Has since come back as a leader in AAV gene therapy vectors



genovo



How bad could a journalist make this look?



Universities Now Have Robust Col Infrastructures

- ❑ Col policies
- ❑ Col Committees
- ❑ Compliance officers

Policies on Investigators' COI

- ❑ It's all about the PSD
 - ❑ Project Specific Disclosure
 - ❑ Identifies potential conflicts affecting institutional research projects
- ❑ All “Investigators” must file Project Specific Disclosures.
- ❑ Filed when:
 - ❑ Funding application submitted to Research Administration
 - ❑ IRB application, only if unfunded
 - ❑ Any unfunded research project affected by significant financial interest
 - ❑ Material change not previously disclosed

Key Issues for the Policy to Address

- ❑ Who are Investigators?
 - ❑ Family members
- ❑ What is a Significant Financial Interest (SFI)?
- ❑ How can an SFI affect the research?
- ❑ How will Col be managed?
 - ❑ Responsible staff member
 - ❑ Col Committee
- ❑ Must conflicts be eliminated?
 - ❑ Or can they be managed?
- ❑ What compelling circumstances might impact the decision?
- ❑ What will a management plan cover?

Conditions or Restrictions: Management?

- ❑ Management Plans are developed by the Committee with investigator input and reviewed with Investigators before being recommended to the Provost or President

Conflict of Commitment – Consulting Policy



Consulting

- ❑ Faculty consulting is critical to the technology transfer process
 - ❑ Academic inventions are embryonic
 - ❑ Continued faculty involvement is essential
 - ❑ They have the know-how in their heads
- ❑ US academic contracts allow one day per week for consulting
 - ❑ Offsite
 - ❑ Can't use the institution's facilities
 - ❑ That needs an SRA
 - ❑ Can't use students
 - ❑ Can't give away IP owned by the institution
 - ❑ Can invent new things at the company's facilities and assign IP to the company

Consulting

- ❑ Critical to company spin-out process
 - ❑ Professor commits his one day per week exclusively to the company
 - ❑ Gets substantial equity stake in company
 - ❑ In return for the “know-how” in his head
 - ❑ Chairs the Scientific Advisory Board
 - ❑ Helps guide the company’s technology development programs
 - ❑ Grad student/Postdoc joins the company fulltime

Moving Forward

- ❑ Get ahead of the game
 - ❑ Do it now rather than in response to a problem
- ❑ Plenty of U.S. models
 - ❑ Everyone posts their policies on-line
 - ❑ Look at some
 - ❑ Pick one and adapt to your situation
 - ❑ Pick a reasonable one
 - ❑ **DON'T PICK HARVARD'S**
 - ❑ Harvard feels no conflict can be managed
 - ❑ Must be eliminated
 - ❑ No sponsored research from a company a faculty member owns shares in
 - ❑ Can't even get biological materials from such a company!

Relations with Industry

Relations with Industry

- ❑ Must be open to working with industry
- ❑ Relationships can take many forms
 - ❑ Consulting
 - ❑ Evaluation
 - ❑ Collaborations
 - ❑ Sponsored research
 - ❑ Licensing
- ❑ Relationships can take time to develop
 - ❑ E.g., BU / Schlumberger

Relations with Industry

- ❑ Relationships can take time to develop
 - ❑ E.g., BU / Schlumberger
 - ❑ Schlumberger closed its Connecticut research center
 - ❑ Opened Doll Research Center
 - ❑ Cambridge, MA
 - ❑ 2007
 - ❑ We decided to attempt to form a strategic relationship
 - ❑ Had relevant sensor expertise
 - ❑ First step – student internships
 - ❑ They talked to co-workers about their PI's
 - ❑ Second step – PI consulting relationship
 - ❑ Third step – collaborative research
 - ❑ i.e., no funding!
 - ❑ Fourth step – sponsored research
 - ❑ Five years from decision to pursue till first funding received



An Important Need

- ❑ The TTO Director must have the authority to commit the university
 - ❑ U.S. and European Directors generally have signatory authority
 - ❑ Nobody in the institution has a better idea of the value of a technology than the TTO

Some Issues

- ❑ “We don’t pay overhead”
 - ❑ Don’t call it overhead – they’re Indirect Costs (IDC)
- ❑ “We shouldn’t have to pay you anything – we paid for the research through our taxes”
 - ❑ The government paid for the research
 - ❑ They want us to be fairly compensated for the value we’ve created
- ❑ “Universities are too slow”
 - ❑ Frequently true
 - ❑ Turn agreement drafts around quickly
 - ❑ Getting a business deal tends to be fairly straightforward
 - ❑ Turning that into a legal agreement can be very slow
 - ❑ Particularly if TTO uses OGC for legal help.
 - ❑ No layers of internal review
 - ❑ The TTO Director has the authority to bind the university

Thank you for listening

Questions?

astevens@bu.edu

