CALL TO ACTION:
Managing Financial Relationships Between Academia & Industry in Biomedical Research

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Role of Investigators

- Academic-industry relationships are beneficial, but challenges exist
- Financial Interests ≠ Improprieties
- The vast majority of biomedical researchers are guided by the highest ethical and professional motives
- Scientists want to do the right thing
- Investigators, as a group, determine the effectiveness of policies and practices
- The perspective of investigators had not been well-articulated in the policy debate
Phase I (’05-’06)

• December 2006 - FASEB guidelines for investigators published*

• Identified challenges for investigators
  – Ensuring compliance with requirements
  – Protecting against bias
  – Addressing issues about data and material access, analysis, and dissemination of results
  – Overlap of roles
  – Protecting trainees

• Proposed principles to help guide individual decision-making

Two underlying factors contributing to challenges for investigators

- Current lack of clarity and consistency in some areas may cause confusion and noncompliance
- Sufficient awareness of these issues on the part of investigators may be lacking
Phase II (’06–’07)

- Objective 1: Promote national guidelines for the disclosure and management of financial relationships between academia and industry in biomedical research
- Objective 2: Increase awareness and promote investigator education
Major Activities

- October 2006, convened coalition of stakeholders and experts to develop/refine principles, recommendations, and an action plan to implement them – built on work of FASEB, AAMC, AAU and others
  - Identified three guiding principles *(FASEB had 19)*
  - Recommended development of Toolkit to include practices and tools that may be used to achieve the principles
  - Urged a communications plan - outreach to broader community
- July 17, 2007 - Call to Action Meeting to discuss and seek feedback from broader community
- Beyond July 17 – seek endorsement, modify and release Toolkit
Coalition Advisors

• Coalition of advisors
  – Leo T. Furcht – Chair, FASEB
  – Carol Blum, COGR
  – Eric G. Campbell, Institute for Health Policy, Harvard/MGH
  – Gail Cassell, ASM and Eli Lilly Corp
  – Tony DeCrappeo, COGR
  – Susan Ehringhaus, AAMC
  – Ezekiel Emanuel, NIH
  – Mark S. Frankel, AAAS
  – Joan Goldberg, ASCB
  – Todd Margolis, ARVO
  – Barbara Perry, U of Washington and NASULGC
  – Lawrence Rhoades, ORI
  – Norka Ruiz Bravo, NIH
  – Janet Shoemaker, ASM
  – Nicholas Steneck, ORI
  – James Severson, U of Washington

• FASEB Staff
  – Laura Brockway
  – Howard Garrison
  – Kimberly McGuire

• Acknowledgements
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  – Kevin Wilson, ASCB
Guiding Principles

• Framework for a national policy guideline

• Three principles
  – Investigators must conduct research activities objectively
  – Investigators must operate with transparency
  – Investigators must be accountable to all stakeholders
Recommended Practices

- Investigators
  - Responsible for compliance with requirements and ensuring research objectivity
  - Obligation to and for trainees and patients
  - In sponsored research, responsible for data collection, analysis, and publication with no undue delays
  - Consulting and entrepreneurial activities should have a defined scope and compensation with scrutiny tailored to degree of risk each type poses (e.g. equity)
  - Adherence to patent law and disclosure to institution of inventions and co-inventors
  - Disclose as required but transparency enhanced by voluntary disclosure
• Institutions and publishers
  – Harmonization of policies and practices to avoid confusion and ensure compliance
  – Specifically, work towards more consistent disclosure requirements and replace the term “conflicts of interest” with “financial interests” when appropriate
• Professional societies and organizations should embrace their role in promoting research ethics for members
• Industry has a role insuring that collaborating investigators are in compliance
COI Toolkit

- Highlights recommended practices, tools, and resources developed by FASEB and others that may be used by the community to better navigate financial relationships between academia and industry
- A freely available, on-line resource hosted and maintained by FASEB
- A start - to be improved upon over time based on use and feedback from community
Call to Action

• Endorse the concept of a national guideline for the disclosure and management of financial relationships between academia and industry based on the principles of objectivity, transparency, and accountability

• Implement practices that can be used to accomplish these principles

• Link to the Toolkit from your website, submit materials for inclusion in the Toolkit, and provide ideas on how it might help develop your own activities
Conclusions

• The scientific community has a shared responsibility to ensure public trust in research. Those responsible for the review and oversight of academic-industry relationships should work together to develop more clear and consistent policies and practices across institutions.

• Investigators are individually accountable for making choices, to comply with policies, and to take responsibility to protect against the risks.
Summary

• Guidelines for policies and procedures
• Education
• “Toolkit”
• Investigators “own” this issue
End Game

- Enhanced trust in the biomedical research enterprise
Funding

• Association of American Medical Colleges – Office of Research Integrity Responsible Conduct of Research Program for Academic Societies
Questions?