Responsible Conduct of Research: Collaborative research including collaborations with industry

Roy S. Weiner, M.D.
Associate Dean for Clinical Research and Training
Most of the work still to be done in science and the useful arts is precisely that which needs knowledge and cooperation of many scientists…that is why it is necessary for scientists and technologists to meet…even those in branches of knowledge which seem to have least relation and connection with one another.

Antoine Lavoisier, 1743-1794
Scientific Integrity: An Introductory Text with Cases, 3rd Ed. F. Macrina, ASM Press, 2005 Page 187
May 27, 2009, New York, NY / Los Angeles, CA

Stand Up To Cancer (SU2C), the Entertainment Industry Foundation's charitable initiative supporting groundbreaking research aimed at getting new cancer treatments to patients in an accelerated timeframe, has reached a significant milestone, awarding the first round of three-year grants -- that total $73.6 million -- to five multi-disciplinary, multi-institutional research Dream Teams.
Figure 4.6. National R & D Funding by Source of Funds: 1953-2002
Power of Collaborative Research

Expertise is Unique
Technology is Specific
Resources are “fixed”

Collaboration permits multidimensional inquiry
Multidimensional inquiry enhances validity
Drivers of Collaboration

Compelling questions beyond the scope of individual Expertise, Technology, Resource
Environmental organization – Centers and Institutes rather than Departments
Funding Incentives – SU2C, NIH Roadmap, CTSA
New Transdisciplinary Training Programs – Enhanced Communication
Challenges to Collaboration

Departmental Structure – Space, Indirect Costs, Measures of Success, Control of Time
Peer Review – Discipline-oriented Study Sections
Industry Sponsorship – IP, Indemnity, and Publication
Politics, Geography, Culture – Informed Consent
Sharing Research Materials – Academic Competition
Fair Play – Collaboration with “Bob”

Spectrum of Formality:

“Bob, what do you make of this consistent fragment I get when I run this gel at 20 degrees?”

“Bob, you may find this mutant cell line I made very interesting.”

“Bob, can you alter this peptide to conform to this molecular pocket?”

“Bob, would you be interested in studying the biodistribution of this nanoparticle?”

“Bob, let’s write a grant together to support this “proof of principle” trial.”
Collaborative “Bobs”

The Physical Chemist
The Bioengineer
The Biostatistician
The Medicinal Chemist
The Clinical Researcher
The Surgeon
The Pathologist
Geographical “Bobs”

Department
School
University
Industry
Government
State
Country
Language
Nuance
Custom
Law
Science Meets Business

- Technology Transfer
- Young Scientists
- Academic Scientists
- Legal Services
- Investment Banking
- Venture Capital
- Private Equity
- Corporate R&D
- Corporate Business Dev
- Corporate Ventures
Collegial Help or Collaboration – Acknowledgement or Authorship

If unpublished, think Authorship
If published, Acknowledgement or Authorship
COMMUNICATE!!
Collaborative Principles

Communicate – *First, Forthright, Full, Frequent*  
“Pre-nuptial agreements” are essential  
Conflicts of Interest and Disclosure  
Goals of the Collaboration  
Roles of each Collaborator
Collaborative Principles, Cont.

Responsibilities of all Parties
Performance Timelines
Milestones and Benchmarks
Monitoring Data, Quality, Progress
Accountability – Regulatory and Fiscal Compliance
Termination
Custody, Ownership, and Data Sharing*
IP and Publication
Mixed Marriages – Collaborations among research ‘sectors’ (Industry, Academia, Not-for-Profits)

Cultural Norms – Confidentiality, Regulatory, Legal, Material Transfer Agreements (MTA) Indemnification, Hold Harmless, IP, Publication rights of review/approval Incentives, Ethics, and COI
The Role of the Academic Home

IRB – Protection of Human Subjects
Grants and Contracts Office – Submits Proposals, Negotiates Funding, IP, Indemnity, Publication, Manages Funds
Technology Transfer Office – Negotiates IP, Licensing
Department – Research Quality and Integrity
Sponsor – Research Progress, Quality, and Integrity