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# Examining Core Elements of International Research Collaboration: Summary of a Workshop

ISBN
978-0-309-21640-1

128 pages
6 x 9
PAPERBACK (2011)

Susan Sauer Sloan and Tom Arrison, Rapporteurs; Planning Committee for the Workshop on Examining Core Elements of International Collaboration; Government-University-Industry Research Roundtable; Policy and Global Affairs; National Academy of Sciences, National Academy of Engineering, and Institute of Medicine of the National Academies

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# EXAMINING CORE ELEMENTS OF **INTERNATIONAL RESEARCH COLLABORATION**

## SUMMARY OF A WORKSHOP

Susan Sauer Sloan and Tom Arrison, *Rapporteurs*

Planning Committee for the Workshop on
Examining Core Elements of International Collaboration

Government-University-Industry Research Roundtable
Policy and Global Affairs

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This study was supported by Contract/Grant No. FA9550-10-1-0041 between the National Academy of Sciences and the Air Force Office of Scientific Research, the Office of Naval Research, and the U.S. Army International Technology Center–Atlantic. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the organizations or agencies that provided support for the project.

International Standard Book Number-13: 978-0-309-21640-1
International Standard Book Number-10: 0-309-21640-0

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu

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# Preface and Acknowledgments

Serving as co-chairs of the Planning Committee for the Workshop on Examining Core Elements of International Collaboration, we enjoyed an extraordinary opportunity to work with some of the world's leading scholars, practitioners and global thinkers. Indeed, every workshop participant played an integral role in making this GUIRR workshop a success.

The Planning Committee worked collaboratively over several intense months to identify and secure internationally recognized experts who could come to Washington, D.C. to speak and share insights and experiences from their respective areas of expertise.

An active GUIRR working group known as the "I-Group" supported the efforts of the Planning Committee and must be commended. Members of the I-Group include: Norka Ruiz Bravo (National Institutes of Health/ Pan American Health Organization), Susan Butts (The Dow Chemical Company), Brian Fitzgerald (Queensland University of Technology, School of Law – Australia), Wayne Johnson (Independent; formerly Hewlett-Packard Company), Maria Koszalka (Consultant; Northrop Grumman Corporation), Mark Maurice (Air Force Office of Scientific Research), Walter Schaffer (National Institutes of Health), Patrick Schlesinger (University of California, Berkeley), Robin Staffin (U.S. Department of Defense), Sandra Titus (Department of Health and Human Services-Office of Research Integrity), and Larry Weber (National Science Foundation). Planning Committee members were also part of I-Group.



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Throughout this demanding planning process, we also drew energy from the leadership of Dr. C. D. (Dan) Mote, Jr., President of the University of Maryland at College Park, and co-chair of the Government–University–Industry Research Roundtable (GUIRR). Similarly, the workshop could never have been realized without the skills and able assistance of Susan Sauer Sloan, Director of GUIRR, Denise Greene, Administrative Coordinator (GUIRR), Laurena Mostella, Administrative Assistant (GUIRR), Claudette K. Baylor-Fleming (FDP) and Chris Verhoff, Financial Associate, Policy and Global Affairs. Similarly, Tom Arrison, a Senior Staff Officer, Policy and Global Affairs, along with Bob Killoren, an I-Group member who had to withdraw for medical reasons, were also terrific resources throughout.

We would also like to thank the workshop sponsors: the Air Force Office of Scientific Research, the Office of Naval Research, the U.S. Army International Technology Center–Atlantic, and the National Institutes of Health.

This summary has been prepared by the rapporteurs as a factual summary of what occurred at the workshop. The planning committee's role was limited to planning and convening the workshop. The statements made in this volume do not necessarily represent positions of the planning committee, the workshop participants as a whole, GUIRR, or the National Academies.

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Academies' Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for quality and objectivity. The review comments and draft manuscript remain confidential to protect the integrity of the process.

We wish to thank the following individuals for their review of this report: Norman Hebert, Brown University; Ralph Kuncl, University of Rochester; Tembeka Mpako-Ntusi, Cape Peninsula University of Technology, South Africa; Neela Patel, Abbott Laboratories; and Anne Petersen, University of Michigan.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the content of the report, nor did they see the final draft before its release. Responsibility

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for the final content of this report rests entirely with the rapporteur(s) and the institution.

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# 1

# Introduction

The globalization of science, engineering, and medical research is proceeding rapidly. As the National Science Board (2010) points out, "S&E (science and engineering) activities are occurring and intensifying in more regions and economies, largely in response to recognition by governments that S&E research and development (R&D) leads to economic growth, employment, and overall social well-being of their citizens." For example, researchers working outside the United States, Europe, and Japan account for a growing share of the peer reviewed literature. The share of scientific publications and patents that is internationally co-authored has increased from eight percent to 22 percent over the past several decades (NSB, 2010). And international collaborative research projects such as the Large Hadron Collider at CERN are critically important to the advance of knowledge.

The globalization of research has important implications for the U.S. research enterprise, for the U.S. government agencies, academic institutions, and companies that support and perform research, and for the world at large. As science and technology capabilities grow around the world, U.S.-based organizations are finding that international collaborations and partnerships provide unique opportunities to enhance research and training. At the same time, significant obstacles exist to smooth collaboration across national borders. Enhancing international collaboration requires recognition of differences in culture, legitimate national security needs, and critical needs in education and training.



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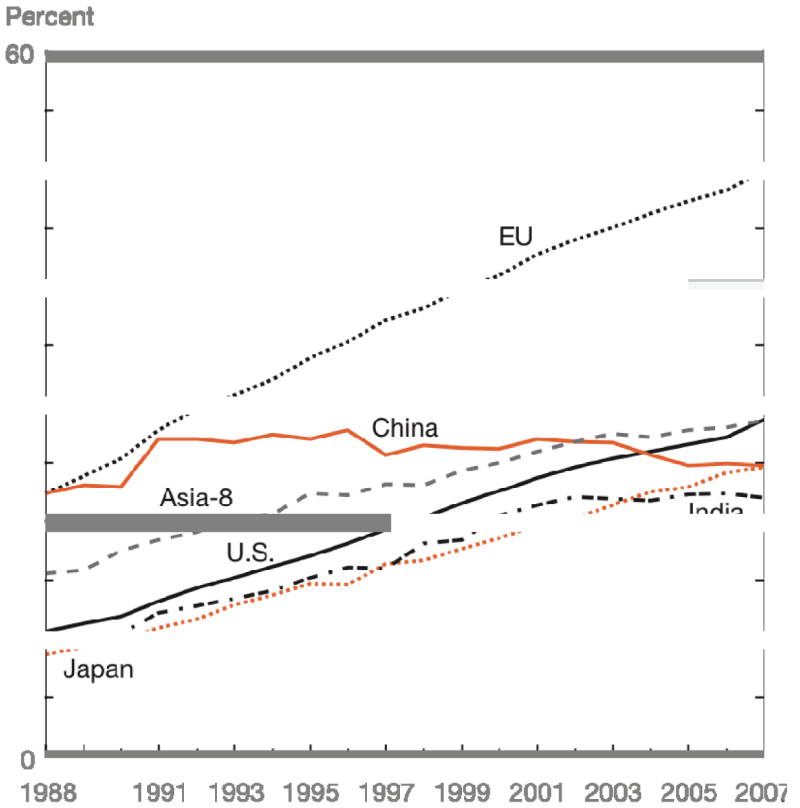


**FIGURE 1-1** International coauthorship of S&E articles, by region/country: 1988–2007.

EU = European Union

NOTES: Asia-8 includes India, Indonesia, Malaysia, Philippines, Singapore, South Korea, Taiwan, and Thailand. EU includes all 27 member states. Articles classified by year that they entered the database and assigned to region/country on basis of authors' institutional address(es). For internationally coauthored articles, each collaborating country or sector credited one count.

SOURCES: Thomson Reuters, Science Citation Index and Social Sciences Citation Index, http://thomsonreuters.com/products_services/science/; The Patent BoardTM; and National Science Foundation, Division of Science Resources Statistics, special tabulations. This figure originally appeared in National Science Board. 2010. *Science and Engineering Indicators 2010.* Arlington, VA: National Science Foundation.

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## 1.1 BACKGROUND AND CONTEXT FOR THE ACTIVITY

In response to these trends, the Government-University-Industry Research Roundtable (GUIRR) launched a Working Group on International Research Collaborations (I-Group) in 2008, following its meeting on New Partnerships on a Global Platform that June. Sponsored by the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, GUIRR serves as a forum for dialogue among the top leaders of government and non-government research organizations. GUIRR and two organizational affiliates, the Federal Demonstration Partnership (FDP) and the University-Industry Demonstration Partnership (UIDP), facilitate research collaborations in the U.S. context. Past GUIRR discussions have also covered important aspects of the international environment for research activities (see Thursby and Thursby, 2006, which was commissioned by GUIRR).

l-Group was formed to examine international research collaborations in a systematic, practical way. The goal is to work with stakeholders to develop a more structured approach to collaborations and help companies and universities deal with various cultural, administrative, and legal complexities in undertaking them. According to its Statement of Purpose, I-Group "engages in dialogue and discussion to facilitate international collaborations among academic, government, and industrial partners by: (1) identifying policies and operations that enhance our ability to collaborate; (2) identifying barriers to collaboration—policies and operations that could be improved; (3) developing a web-based resource or other compendium of successful strategies and methodologies; and (4) suggesting how barriers might be addressed."

As part of I-Group's continuing effort, a workshop on *Examining Core Elements of International Research Collaboration* was held July 26-27, 2010 in Washington, DC. The National Research Council formed a Planning Committee to organize the activity. The charge to the Planning Committee was as follows:

> An ad hoc committee will plan and conduct a two-day public workshop on international research collaborations. The agenda of the workshop will be developed with topics to enhance international understanding and diminish barriers to research collaborations, providing an important forum for the expected participants from scientific and engineering research communities in the U.S. and other countries. Issues to be addressed in the workshop include the following: (1) Cultural Differences and Nuances; (2) Legal Issues and Agreements; (3) Differences in Ethical Standards; (4) Research Integrity

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and the Responsible Conduct of Research; (5) Intellectual Property; (6) Risk Management; (7) Export Controls; and (8) Strategies for Developing Meaningful International Collaborations. An individually-authored workshop summary will be published. In addition, a password-protected website will be created to permit workshop participants and others to post questions and share information on specific tools for research collaboration that have been useful to practitioners.

The Planning Committee was assisted by GUIRR staff and volunteers from numerous GUIRR member organizations in organizing the meeting. The workshop brought together subject matter experts from universities, government, and companies/corporations in the United States and other nations to share perspectives on the opportunities and challenges presented by international research collaborations, and examples of successful approaches. The agenda included plenary sessions that provided expert overviews of various issues, and breakout discussions to allow for a deeper sharing of perspectives. Following the workshop, the rapporteurs prepared this summary, which reports the main themes that emerged from workshop presentations and discussions. The organization of the summary follows that of the workshop by focusing on the "core elements" of international research collaborations identified in the Planning Committee charge. The goal for the workshop and the summary is to serve as an information resource for participants and others interested in international research collaborations. It will also aid I-Group in setting its future goals and priorities.

Financial support for the activity was provided by the Air Force Office of Scientific Research, the U.S. Army, the Office of Naval Research, and the National Institutes of Health.

## 1.2 FRAMING THE ISSUES[1]

In his opening remarks at the workshop **University of Maryland President Emeritus C. D. (Dan) Mote, Jr.** noted that the overall environment for international collaborative research is very positive, with significant freedom of action for institutions. However, the context is also characterized by risks that may not be well understood by participants new to cross-border partnerships. The formation and pursuit of international research collaborations is largely a decentralized process. As the president of a major public

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research university, Dr. Mote faced few constraints in concluding research collaboration agreements with foreign governments, academic institutions, and companies. He estimated that the University of Maryland at College Park has over 50 agreements with entities in China alone.

Agreements are not only concluded at the University of Maryland's central administration level—schools, departments and even individual faculty and student groups can conclude agreements with non-U.S. counterparts to pursue collaborative research. Particularly in the case of broad memoranda of understanding, special permissions are not generally required.

The types of governmental organizations participating are also proliferating. They can include multilateral organizations (such as the World Bank) and governments at all levels (including municipalities and tribal governments). Industry partners may be large, established multinational enterprises or small start-ups.

Partnerships become more vulnerable to pitfalls at the point where collaborative research is made operational through the allocation or transfer of funds, the specification of deliverables, and the development of concrete research plans. One primary goal of the workshop, Dr. Mote said, is to better understand the risks involved in international research collaboration for organizations and individual participants, and the mechanisms that can be used to manage those risks.

**Kathie L. Olsen, Vice President for International Programs at the Association of Public and Land-Grant Universities (APLU), now Founder and Managing Director of ScienceWorks, LLC**, was a keynote speaker at the workshop. She pointed out that the advantages of international research collaborations are being more widely recognized. At the same time, globalization poses some challenges to the United States. These challenges also represent opportunities to renew U.S. strengths.

For example, students may represent a competitive strength for the United States. Many campuses have multiple international research efforts. U.S. industry needs employees who are comfortable working in international settings. How can research be integrated with year-abroad and other educational programs to provide expanded opportunities for U.S. students? What should academic research programs look like in five or ten years? Can U.S. universities plan strategically so that students are prepared, research is enhanced, and U.S. global competitiveness is strengthened?

Dr. Olsen explained that part of the context is that the number of foreign students in the United States far exceeds the number of American

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students abroad, although the latter has been growing consistently (IIE, 2010). Beyond the raw numbers, the characteristics of U.S. study abroad do not reflect overall U.S. international engagement and the overall U.S. population in significant ways. For example, Europe is the predominant study abroad destination, accounting for about half of the opportunities in recent years. In terms of subjects studied, social sciences, business management, humanities, fine and applied arts, and foreign languages combined make up about two-thirds of the total, with science, engineering, and related fields making up less than 20 percent. Over eighty percent of the students are white, and almost two-thirds are female.

Dr. Olsen encouraged GUIRR and its membership to stay engaged with the issue of international research collaborations, and to lead strategic thinking on how to maximize the benefit of these collaborations to the U.S. research enterprise.

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# 2

# Creating an Environment for Productive International Collaboration

*"The role of international collaborations in advancing knowledge and offering economic opportunities worldwide is growing, thanks to factors such as access to the Internet; globalization; and greater mobility of information, ideas, and people. Though international research collaborations also are growing (as measured, for example, by multinational co-authorship on publications and shared funding for international research projects), there are bottlenecks and frictions that can pose impediments to meaningful and successful international collaborations. This track will look broadly at trends and issues that pertain to fostering productive international collaboration from the point of view of governments, universities, and industry."* (Workshop Agenda)

## 2.1 RESEARCH COLLABORATION, U.S. FOREIGN POLICY, AND THE GLOBAL CONTEXT[1]

The opening panel of the workshop on *Examining Core Elements of International Research Collaboration* featured several different perspectives on the overall environment for collaboration. **Lawrence Gumbiner, Deputy Assistant Secretary of State for Science, Space and Health**, dis-

[1]In this section and other sections summarizing presentations, views and opinions are attributed to the presenter unless stated otherwise.



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cussed how effective collaboration in science and technology can advance broader U.S. foreign policy objectives.

Although science and technology have long played a role in U.S. foreign relations, they are receiving renewed emphasis from the current administration. One indicator of the overall importance of science is the recruitment of several Nobel laureates to fill key executive branch positions, including Secretary of Energy Steven Chu, National Cancer Institute Director Harold Varmus, and Office of Science and Technology Policy Associate Director of Science Carl Wieman.

President Obama (2009) laid out the broad philosophical context for international research cooperation in a speech at the National Academy of Sciences: "So many of the challenges that science and technology will help us meet are global in character. . . . That is why my administration is ramping up participation in and our commitment to international science and technology cooperation across the many areas where it is clearly in our interest to do so." U.S. Secretary of State Hillary Clinton has reinforced this commitment. For example, she has stated (2009) that "science diplomacy and science and technology cooperation between the U.S. and other countries is one of our most effective ways of influencing and assisting other nations and creating real bridges between the United States and counterparts."

Mr. Gumbiner explained that international cooperation in science and technology delivers several concrete benefits to the United States. The first benefit is that it opens doors. In many countries where political and economic relations with the United States are difficult or complex, scientists can and do work together to find answers and promote human advancements. This was true in the case of science and technology collaboration during the Cold War with countries behind the Iron Curtain, and the same is true today in relations with countries such as Cuba, Syria, and Iran.

The second benefit is problem solving. Many pressing global challenges have a scientific or technological component. Researchers gain greater access to information, ideas, and facilities through international collaboration. This can facilitate a more rapid advancement of knowledge and discoveries.

A third benefit of international science and technology collaboration is that it builds lasting relationships. While science has always transcended borders, the current level of global interaction among scientists is unprecedented. The communications revolution and today's open innovation model allow scientists to partner with colleagues worldwide. Even in the heavily networked world of today, face-to-face meetings still play a critical

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role. American scientists and engineers who have benefited from opportunities to work abroad testify to the value of their lifelong connections. Lasting relationships also deliver benefits at the national level, allowing the United States to share the costs of science, particularly for large, expensive facilities where the cost of going it alone would be prohibitive. One such example is ITER (the International Thermonuclear Experimental Reactor).

Finally, Mr. Gumbiner pointed out that science and technology cooperation is a powerful tool for promoting democratic values. Scientific discovery is based on open and fluid discussion, and conclusions are based on fact, not on issues of national origin, age, ethnicity, gender, or political views. These values and the approach to international relations are close to the core of what the United States seeks to do internationally.

The U.S. Department of State promotes science in several ways, serving to coordinate and support over 20 technical agencies that actually implement collaborative programs. The State Department's Bureau of Oceans and International Environmental and Scientific Affairs (OES) plays a key institutional role, including the negotiation and management of bilateral science and technology agreements, of which there are currently 47. These agreements create a framework for bilateral cooperation by facilitating the exchange of scientific results; increasing access to data, ideas, and facilities for researchers; addressing taxation issues; and responding to the complex set of issues associated with economic development, security, and stability. Intellectual property is often a key element of these agreements. For the most part, bilateral S&T agreements are funded through the annual budgets of research agencies.

The Science and Technology Adviser to the Secretary of State is a position created about a decade ago in response to a National Academies report (NRC, 1999). Key tasks for the S&T Adviser are to build partnerships with international scientific communities; provide accurate advice; enhance science and technology literacy and capacity within the Department of State; and shape a global perspective on scientific and technological developments. The Department of State and individual bureaus also make use of less formal mechanisms for incorporating science into policymaking, such as fellows programs.

According to Mr. Gumbiner, another important policy area related to international cooperation is visa processing for foreign researchers. The Department of State has made significant progress in easing the difficulties some foreign researchers have experienced due to post 9/11 visa processing changes.

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The Department of State also participates in several relevant activities of the Organization for Economic Cooperation and Development (OECD), including the Global Science Forum, which recently completed work on dealing with allegations of research misconduct in international projects, and is developing a compendium on issues and options for establishing large-scale facilities.

**Eduardo López Moreno, Director of the Urban Monitoring Division of the United Nations Human Settlements Division (UN-HABITAT),** identified tasks in developing urban areas that can be addressed through international research collaboration. The Urban Monitoring Division is based in Nairobi, Kenya, and is charged with research on urban trends and urban policy analysis. It is responsible for producing UN-HABITAT's bi-annual *State of the Cities* report, which identifies urban trends around the world. One of its main thrusts is the global sample of cities—about 500 cities around the world that are monitored constantly in order to discern trends that can be extrapolated to the rest of the world's urban areas.

A second thrust is a project called "local urban observatories," of which there are currently about 350. These are local groups of stakeholders that often include universities and non-governmental organizations (NGOs), sometimes with the involvement of government. The local urban observatories produce urban indicators and policy analysis, performing studies for UN-HABITAT.

These programs provide opportunities for international research collaboration, with the ultimate goal of effecting positive change in cities, as opposed to advancing science or knowledge *per se*. One important issue is developing definitions that can be accepted broadly. For example, what is meant by "adequate housing"? There may be agreement that housing is a fundamental problem, but each stakeholder will use their own context to develop solutions. NGOs may tend to see adequate housing through the prism of advancing human rights, government through the prism of improving its technical approaches, and owners of land or real estate through the prism of their own interests. It is important to develop operational definitions that are nonthreatening to local actors. This can be helpful in creating conditions that are conducive to collaboration and to building local consensus.

Dr. López-Moreno cited Target 11 of the Millennium Development Goals, adopted in 2000, which is "to have achieved (by 2020) a significant improvement in the lives of at least 100 million slum dwellers." At that time there was not an agreed definition of what constitutes a slum in Mexico, in

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China, or in Africa. Ultimately, a definition was developed that is based on five key indicators: (1) lack of access to water, (2) extent of public sanitation, (3) percent of durable structures, (4) overcrowding, and (5) security of tenure. This allows the United Nations to conduct analysis and track developments over time in a sustainable way, even in countries that may prefer to avoid the issue.

Another project undertaken by UN-HABITAT examined 250 cities in the developing world to find out what drives prosperity and positive change in these particular communities. The Latin American research concluded that cities prosper because of civil society and cultural and political rights; the Asian research concluded that national government efforts are critical; and African research focused on the importance of private sector activity. This illustrates that even research that is scientifically conceived and defined has fundamental limits in the cultural and ideological position of development in these regions. In UN-HABITAT's own analysis, the ability of local, central, and provincial governments to articulate a vision of change and work together was very important to driving prosperity and positive change. Analysis of best practices is also important, but has limitations.

Finally, organizational partners in developing countries may have been created decades ago with very specific missions that may be outmoded. For example, although 60 percent of cities and regions are shrinking in populations, institutions aimed at controlling urban growth may still be developing policies. Rather than "smart growth," it is necessary to think about "smart shrinking."

## 2.2 INTERNATIONAL COLLABORATION TO ADVANCE NATIONAL GOALS

**Rafic Makki, Executive Director of the Office of Planning and Strategic Affairs, Abu Dhabi Education Council**, spoke about how international partnerships fit into Abu Dhabi's overall strategy for upgrading higher education. Abu Dhabi, home of the capital and largest Emirate in the United Arab Emirates (UAE), has developed its higher education strategy in order to meet changing human capital requirements that are resulting from major diversification of the economy. Dr. Makki estimated that the Emirate needed to add 232,000 workers over the next five years, with about 50,000 being Emirati citizens and the rest international.

Abu Dhabi has outlined ambitious plans to transition over the next several decades from an oil-based economy (oil currently accounts for over

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60 percent of output) to one based on leadership in international exchange, culture, and media. These knowledge-based activities will require higher education institutions to become more research-focused, to produce graduates with the skills needed by employers, to raise the quality of instruction, and to expand access. The economic sectors of particular focus are semiconductor, aerospace, renewable energy, and health. Steady progress is being made. Starting from scratch a few years ago, Abu Dhabi has already moved into third place in the world in contract semiconductor manufacturing.

Dr. Makki explained that Abu Dhabi's higher education strategy is centered around four priorities (Figure 2-1: Abu Dhabi Higher Education Strategy). The Emirate is poised to devote significant resources to research and education, with public investments in research projected to increase to 0.75 percent of GDP by 2019.

International collaboration has been central to developing Abu Dhabi's higher education strategy, and strategic international partnerships will play an important role in pursuing it. For example, higher education institutions will be encouraged to seek accreditation from internationally recognized bodies, and to create the research environment needed to attract and retain world-class researchers. International higher education partners include INSEAD[2] in business education, University of Paris-Sorbonne in science and law, Mohammed V University (Morocco) in Islamic Studies, and New York University, which has established a campus in Abu Dhabi.

International collaboration is not without challenges. For example, two foreign universities that established campuses in another Emirate have closed. Abu Dhabi is pursuing a partnership strategy that ensures long-term stability through carefully developed strategic and business plans.

Another perspective on how international research collaboration can advance national goals was provided by **Professor Low Teck Seng, Deputy Managing Director of A*STAR (Agency for Science, Technology, and Research) and Executive Director of A*STAR's Science and Engineering Research Council (SERC)** in Singapore. For some time science and technology have been recognized as the driving force behind the rapid economic growth of this island nation in Southeast Asia. Singapore's economy is 254 times as large as it was when it gained independence in 1965. Gross domestic expenditure on R&D (GERD) is three percent of GDP, one of

[2]INSEAD (Institut européen d'administration des affaires) is a graduate business school based in France, with campuses and research centers in several other locations around the world.

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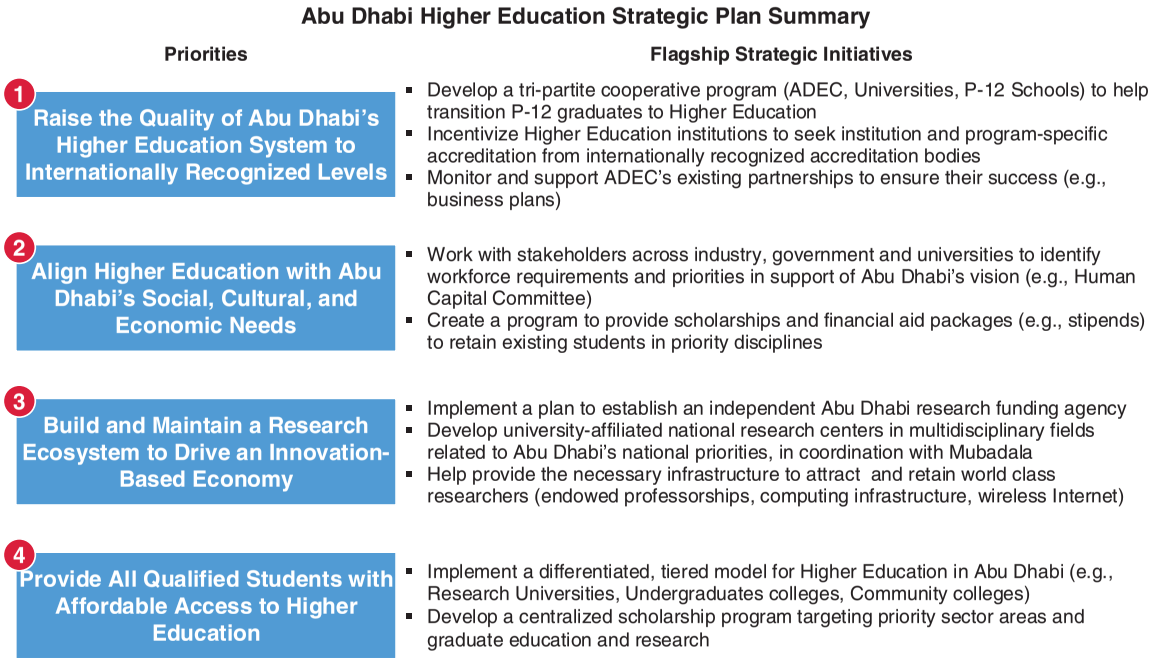


**FIGURE 2-1** Abu Dhabi Higher Education Strategy. Abu Dhabi has identified four priorities and associated flagship initiatives
NOTES: ADEC=Abu Dhabi Education Council; Mubadala=Mubadala Development Company, an investment vehicle of the Government of Abu Dhabi, which has a mission of helping diversify the Emirate's economy through long-term, capital-intensive investments.
SOURCE: Rafic Makki.



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the highest levels in the world. Singapore often benchmarks itself against Norway, because the populations are similar, at about 5 million, and GDP is similar. Singapore is much smaller in land area, however, at 700 square kilometers (a bit larger than Howard County, Maryland).

Singapore's approach to S&T strategy has always been collaborative and outward-looking. It started with the movement of disk drive manufacturing from the United States to Singapore in the 1980s, starting with Seagate (a global leader in the manufacturer of hard drives and storage solutions). In a few years just about all the major disk drive companies were manufacturing in Singapore. By the late 1990s it was recognized that in order to keep the disk drive industry it would be necessary to build a stronger infrastructure in the areas of R&D and education.

Professor Low pointed out that Singapore's explicit S&T strategy was launched in the early 1990s. Building on successful initiatives such as the Data Storage Institute—today the leading center for storage technology development as measured by papers and patents—the country has seen rapid growth in R&D spending. This period has also seen several periods of retrenchment, notably during the Asian economic crisis of 1997-1998. The 2008-2009 global recession has also brought challenges. In response to each setback, Singapore has reexamined its strategies and redoubled its commitment to fostering R&D activities.

A*STAR represents Singapore in the development of international collaborative activities with government agencies in the United States, Europe, and Asia. For example, A*STAR co-funds joint grants with the United Kingdom (UK) Medical Research Council for research collaboration between researchers in Singapore and the UK. Similar agency-to-agency joint funding programs are in place with Japan and China. When new initiatives of this type are launched, joint workshops are held involving researchers from each country to explore interest in working together.

A*STAR also helps to facilitate relationships with international universities, including the Massachusetts Institute of Technology (MIT). The new CREATE campus at the National University of Singapore will support cutting edge research efforts by several foreign universities. A*STAR also continues to work directly with international companies in storage, microelectronics, and aerospace.

Research funding and collaboration are complemented by efforts to support education and to attract talented foreigners to Singapore, both students and senior scientists and engineers. The goal is to sustain Singapore as a global S&T node.

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## 2.3 CLARIFYING COMMONALITIES AND DIFFERENCES

**Dr. John Kirkland, Deputy Secretary-General of the Association of Commonwealth Universities (ACU)**, discussed some of the broad trends in international research collaboration that he sees, and implications for institutions entering partnerships. Founded in 1913, the ACU is the oldest international association of universities, with over 500 members located in 54 countries. Two-thirds of member institutions are located in the "developing Commonwealth."

Research management is one of several priority focus areas for ACU. The Global Research Management Network was launched in 2005 and brings together research practitioners around the world. Activities include benchmarking, strengthening research management systems in the developing world, and professional development.

Dr. Kirkland suggested that developed and developing country institutions be clear about commonalities and differences when they develop collaborative agreements. The commonalities include curiosity regarding the core research questions, the process being led by individuals and research teams rather than institutions, and a trend toward competitively-awarded projects. The differences may include resources, institutional infrastructure, time, and incentives. In the developing world, for example, academic salaries may not cover all of a faculty member's salary, and they may operate more like a small business. Institutions may not have a research office. Expectations for how problems are handled during the project should be adjusted accordingly.

At the broad, conceptual level, sides need to be clear on how they and their prospective partner answer some simple questions: What are you trying to achieve? Why this partner? Who are you really dealing with? What is their motivation? What outcome would make both parties happy? The issues that arise in practice include the allocation of tasks, finances, contracts, intellectual property, continuation of the partnership, and public presentation. The partnership will benefit from clarity and directness upfront.

## 2.4 EXAMPLES OF U.S. INTERNATIONAL ENGAGEMENT IN SCIENCE AND TECHNOLOGY

**Nina Fedoroff, Science and Technology Advisor to the Secretary of State and to the Administrator of the U.S. Agency for International Development (USAID)**, gave the keynote talk at the workshop. Dr. Fe-

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doroff was in the last week of her government service at the time of the workshop, and reflected on successful examples of international research collaborations.

One successful example from the 1990s is the Nunn-Lugar program to redirect weapons scientists from the former Soviet Union with U.S. funding motivated by a desire to prevent nuclear proliferation. In parallel, the International Science Foundation, funded by George Soros, supported research and the provision of scientific literature to former Soviet scientists. Both of these programs changed over time to adapt to new conditions.

Today, the United States may be embarking on a new era of using science in an international setting, with recognition that science is one of America's best diplomatic tools. One initiative that is a successor to those in the former Soviet Union is the Iraqi Virtual Science Library, a web portal for Iraqi scientists that the U.S. government developed with participation from Sun Microsystems. Today, the advent of digital technology has made the dissemination of scientific literature much easier.

Online access to scientific information is still a problem, but even underserved areas such as Africa are adding significant network infrastructure. There is still a lack of people-to-people connections to a large extent. Many of the university-to-university agreements between U.S. and developing country institutions are not on the radar of the average researcher. This may constitute a "last mile" problem in human terms, analogous to the problem of providing broadband access over the "last mile" to individual homes and organizations.

Dr. Federoff stated that many higher income developing countries now have mechanisms to fund their own investigators, but may face independent applications processes. Are there ways of reviewing collaborators at the same time in both countries? The United States does have some agreements with individual agencies abroad, but this is not done across the board.

Even longstanding international research programs such as the Human Frontier Science Program are difficult to sustain because of the need for annual appropriations from governments. The Israel-U.S. Binational Industrial Research and Development Foundation was endowed some time ago, but this is an exception.

One very successful bilateral collaborative effort is the Pakistani-U.S. Science and Technology Agreement, where USAID and the Higher Education Commission of Pakistan each contributed funding to implement. The National Academy of Sciences independently reviews the applications for funding, and then there is a joint meeting. The program has accomplished

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remarkable things, such as bringing telemedicine to Pakistan, retrofitting buildings following the 2005 earthquake, and creating electronic health records.

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# 3

# Cultural Differences and Nuances

*"Quite often cross-cultural nuances and culture-centric perspectives—grounded in one's experience or merely assumed—often cloud conversations between faculty researchers and research administrators when they are negotiating the shared development of meaningful international research agreements. In this session we will hear from a number of experts on cross-cultural communications, understanding, and collaborations."* (Workshop agenda)

## 3.1 THE IMPACT OF CULTURE ON RESEARCH COLLABORATIONS[1]

**Dr. Riall Nolan, previously Associate Provost and Dean for International Programs and currently Professor of Anthropology at Purdue University**, provided perspectives on how cultural differences can influence international research collaborations. Researchers are increasingly focused on addressing important social, political or economic issues in their research, and on application as well as discovery. This work is increasingly cross-national and cross-cultural in nature, and a central challenge is ensuring that people from different backgrounds work together effectively.

[1]In this section and other sections summarizing presentations, views and opinions are attributed to the presenter unless stated otherwise.



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Dr. Nolan predicted that in the near future the best universities will be those that have established strong structural relationships with other top universities around the world. Success or failure in these relationships will be determined by how cultural differences are managed. Globalization does not mean the end of difference, but that we now have to deal with difference directly instead of at a distance.

Culture can be thought of as a management system; a shared understanding of how the world works. Culture has three components: (1) the things we make (artifacts), (2) the things we do (behavior), and (3) what we carry around in our heads (cultural knowledge). An individual may belong to a number of "cultures," for example institutional (e.g., Harvard, Purdue), disciplinary (e.g., law, engineering), and national. Furthermore, individuals may have a professional culture based on their main area of work (e.g., "she's a quant," or "he's a soybean guy"). Finally, there are the national and international aspects of culture, including the emerging body of laws, regulations, and customs that inform or constrain research activities. These include export controls and intellectual property.

Dr. Nolan trains many engineers for international internships, and finds that they return with a greater appreciation for how common sense can be defined differently in different countries. Culture does matter to what people see, how they interpret what they see, and what they do. One problem is culture's inflexibility and low tolerance for ambiguity in messaging, which leads to miscommunication. For example, in one negotiation between American and Chinese university deans, the American dean would give responses such as "we'll think about that," or "we'll look into that." In Chinese culture those sorts of phrases are almost always interpreted as "No." After the issue was explained to both deans, they quickly came to agreement.

Research collaborations can take many forms (Figure 3-1: Forms of Collaboration, Riall Nolan). They range from lab-centered collaborations between individuals with a defined scope and limited duration to long-term, developmental partnerships between institutions that involve many participants doing external applied work. As collaborations become larger and more complex, they are more influenced by cultural rules, norms, and expectations.

Dr. Nolan has drawn several lessons from his 20 years of experience in helping several large research universities forge structural relationships. It is always important that the institution itself understands both its own cultural identity and the nature of the partnership that it is seeking. University partnerships can take one of three basic forms: (1) Predominant capability,

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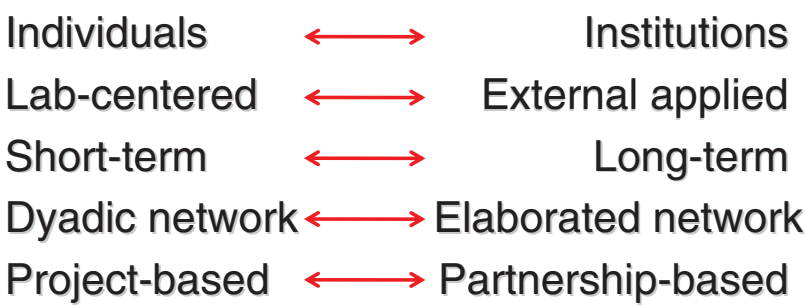


**FIGURE 3-1** Forms of collaboration.
SOURCE: Riall Nolan

where an institution is the strongest in a particular field, and partners with the strongest counterpart in a given country, (2) Complementary partnerships, where the institution is strong in one area, perhaps less strong in another, and the partner institution brings what is lacking, or (3) Technical assistance, which is a helping relationship. Each type has different cultural norms and expectations. There are also great differences between a project (short-term), program (longer term), and a partnership. The partnership is the most cross-cultural and it is also the hardest to develop and sustain.

Multiple intersecting and often internally contradictory cultures make it difficult to create and sustain good partnerships. They render true collaborative work difficult even within a single institution, to say nothing of collaborative work with institutions 10,000 miles away. In the end, collaboration occurs between people and not between institutions.

It is important to understand how individuals operate in cultural terms and how well they know how to operate across cultures. Faculty development becomes very important in this context. A few of the cultural factors that tend to shape success or failure include attitudes toward protocol, politeness, approaches to information sharing, how relationships of trust and confidence are developed, and notions of what constitutes good leadership. Some of this can be handled with interpreters and translators, but not all.

According to Dr. Nolan, the good news is that research indicates that many of the individual characteristics that favor cross-cultural aptitude are found in most researchers. These include openness to others and to new information, tolerance for ambiguity, flexibility, curiosity, the ability to ask good questions, and the ability to quickly discern pattern.

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In today's world, everybody knows something, and nobody knows everything. Cross-cultural collaboration, when it works, is synergistic, bringing into existence arrangements and understandings between partners that no one partner is likely to be able to develop working on their own.

## 3.2 RESEARCH COLLABORATIONS IN A GLOBAL ORGANIZATION

**Christopher Williams, Washington Representative of the United Nations Human Settlements Program** (UN-HABITAT, discussed in Chapter 2 above), gave examples and perspective on cultural issues that can arise when doing research in the developing world. UN-HABITAT, one of the few UN agencies not based in Geneva or New York, is headquartered in Nairobi, Kenya, with operations in over 87 countries.

The context for UN-HABITAT's work is that the world is rapidly becoming more urban. A majority of the world's population now lives in areas with 20,000 people or more, and the world is expected to be 75 percent urban by 2035 to 2040. Sub-Saharan Africa and South and Southeast Asia are urbanizing fastest. This represents a massive change. Unlike the urbanization of Europe and North America that occurred in the 19th and early 20th centuries, the current urbanizing trend is not being accompanied by widely distributed economic growth.

Mr. Williams gave three examples of research undertaken by UN-HABITAT that indicate what the agency is trying to accomplish and that illustrate the issues. The three research activities were very different, but all were applied research within the context of informal settlements and slum improvement. Each faced significant cross-cultural, linguistic, and ideological challenges.

The first project was an evaluation of the UN-HABITAT Community Development Program, which had been undertaken over ten years in seven countries in Latin America, Asia, and Africa. The project assessed the impacts of the program on living and working conditions in informal settlements and slums. It involved development and measurement of a set of indicators and the use of a survey of households to allow for comparison across countries.

The second project was an examination of Slum and Shack Dwellers International, a group that represents 12-14 million urban poor in 15 countries who are associated in savings groups. In particular, the research looked at the methodology the group uses to stop violent forced evictions and create

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policy alternatives for resettlement in South Africa, India, and the Philippines. The research was turned over to Slum and Shack Dwellers International itself, in order to document its own experience and develop case studies.

The third project was a situation analysis of 110 informal settlements and slums in UN-HABITAT's home city, Nairobi. This was done on a very short timescale (four months), and was sensitive because Kenya's President Moi was a patron for the exercise. It was based on focus group analysis. Urban social movements, the central government, international and local NGOs, the donor community, and private industry all gave perspectives on trends and what could be done to improve conditions.

Mr. Williams reviewed several important lessons generated by these research projects, including: (1) the need for coordination among multiple stakeholders; (2) the necessity of establishing agency (whose project is it?); (3) how to address problems arising from the differing pay scales of international and local researchers; (4) how to determine appropriate contracting mechanisms (with institutions or individuals?); (5) a greater appreciation for cultural nuances and ethnicity (need to hire beyond groups that might be overrepresented in a given country's university system); and (6) how to address challenges that arise when the research agenda is politicized.

Finally, these projects raise the broader issue of how findings can ultimately be acted upon. How do researchers and scientists hold themselves accountable for addressing the implications of their work?

## 3.3 PERSPECTIVE OF A SOUTH AFRICAN INSTITUTION

**Tembeka Mpako-Ntusi, Director of Research at the Cape Peninsula University of Technology (CPUT) in Cape Town, South Africa,** focused her remarks on cross-cultural nuances and culture-centric perspectives in international research collaborations, particularly how the personal experiences of individual researchers influence research.

As collaborations move from those undertaken between investigators to more complex partnerships at the departmental, school, and institutional levels, layers of cultural nuance are added. In the case of South Africa, the historical issues of race, past intimidation, and power imbalances play a role. Researchers collaborating across racial barriers may be carrying baggage from those experiences. Care needs to be taken to ensure that imbalances of power based on history do not affect the research.

Gender can also unexpectedly raise issues. Dr. Mpako-Ntusi related her experience in setting up a women-in-research program. At the outset, one of

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the senior female members of the faculty was reluctant to become involved, expressing the belief that women should not get preferential treatment. This faculty member later reconsidered her stance and become one of the most active participants in the project.

Other barriers to international collaboration include "cultural noise" (misunderstandings that can occur even when collaborators speak the same language), material differences in working environments, and government policies. Making sure that any formal ethical codes (national or institutional) are compatible is also important.

Objectives and mechanisms to address problems encountered in the collaboration need to be honestly stated in the beginning. Is the partner's primary motivation to attain a better status for collaborating within a given country, or to obtain funding? Is the opportunity to work with a particular researcher driving the collaboration? Recognizing the possible impacts of personal backgrounds and cultural orientations is also important.

For Dr. Mpako-Ntusi, concluding a memorandum of understanding (MOU) is a valuable first step. This is a document that is drawn between two institutions, and the signatories are members of executive management. When that process is over, the next stage is to conclude a memorandum of agreement (MOA). This second document is between the actual individual researchers from the different institutions who are going to be involved in the research project. It is a contract about roles, intellectual property rights, timeframes, other partners and the disposition of data. At Cape Peninsula University of Technology, MOAs are processed by the Legal Office and managed by the Research Office in order to protect the integrity of the institution, as well as that of the country. The Research Office sees its role as one of providing support in addition to ensuring compliance with institutional and national policies.

## 3.4 PERSPECTIVE OF A PUBLISHER

**Elias Wondimu, Publisher and Editorial Director of Tsahai Publishers**, is also associated with Marymount Institute Press and the African Academic Press. He discussed the role of diaspora communities in fostering international research collaboration, reflecting on his own personal and professional experience. He is an exiled journalist from Ethiopia.

Looking at international statistics for global knowledge production, Africa is underrepresented, and a large part of Africa's scholarship comes

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from South Africa. African scholars working in Africa as well as diaspora scholars working in other parts of the world often experience difficulties in publishing. What are the causes for this, and what can be done about it?

Dr. Wondimu previously worked for the journal *Aztlán,* an interdisciplinary journal of Chicano studies founded in 1970. *Aztlán* was launched as a response to the difficulties that Mexican-American scholars were facing in getting published at that time. Over the decades since, many of the young academics who had an opportunity to publish in *Aztlán* later became department heads and leaders in their fields.

In founding the *International Journal of Ethiopian Studies* some years ago, Dr. Wondimu was inspired by the *Aztlán* experience. The journal did succeed in fostering a community of Ethiopian diaspora scholars, and connecting the younger and older generations. But Dr. Wondimu also realized that the challenges facing Ethiopian scholars were also facing the broader community of African scholars working both inside and outside of Africa. This realization led him to launch the African Academic Press and Tsahai Publishers to publish African scholarship within and outside of Africa. These are now fulltime enterprises for him.

This work has to be done on a shoestring, but there are many significant rewards. One major focus is on human resources, developing the next generation of African publishing professionals. In addition, Dr. Wondimu has seen his publishing ventures build bridges between African intellectuals working within and outside Africa.

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# 4

# Ethics

*"The ethics panel stands between the culture panel and the research integrity panel in the sense that ethics are informed by culture and govern behavioral choices in the conduct of research. This panel will explore issues related to the ethics of safeguarding privacy, security, and confidentiality; bioethical issues related to human subjects research as well as other activities with bioethical implications, all from both a domestic U.S. and a global perspective."* (Workshop Agenda)

## 4.1 ETHICAL ISSUES IN INTERNATIONAL INDUSTRY-UNIVERSITY RESEARCH COLLABORATION[1]

**Dr. Susan Butts, Senior R&D Director (retired) at Dow Chemical Company**, provided perspectives from her extensive industry experience with international and cross-sectoral collaborations. Her roles included negotiating research agreements and coaching Dow researchers in their interactions with external collaborators. Her group was responsible for overseeing collaborations with over 150 universities located around the world, including intervention and problem resolution. If ethics and integrity are not addressed when the collaboration is formed, problems—real or perceived—can arise down the road. Sometimes perceived ethical lapses can cause significant problems.

[1]In this section and other sections summarizing presentations, views and opinions are attributed to the presenter unless stated otherwise.



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Rather than focus on researchers that are not behaving ethically, Dr. Butts focused on those who are behaving ethically but run into problems because of differences in cultural expectations or context issues such as the source of funding. For example, expectations about the ultimate goals of the research, sharing of results, and other issues can differ depending on whether a project is supported by a profit-making company or a government agency.

Companies often seek out collaborations with universities because university researchers are perceived to be neutral and so the results will have more credibility. This premise only holds if the public believes that they can trust university researchers. Some people question whether industry funding taints university research. Both companies and universities have a significant stake in ensuring that this is not the case. Two specific issues that arise in this context are the right to publish and the integrity of results.

Misunderstandings and problems sometimes arise from differences in how government, industry, and universities relate to each other in the United States compared to other countries. In some countries, government takes a much more active role than the United States does in promoting their industries. Universities in some countries may be more willing than those in the United States to enter "work for hire" agreements with industry, where the sponsoring company exercises significant control over the project. Companies also need to be attentive to faculty expectations about continued funding beyond the original research program, being clear that research without commercial potential will not receive continued funding even if the science is interesting.

Dr. Butts stated that it is important to avoid value judgments in international collaborations. Some common practices overseas might not be typical in the United States, which does not mean they are wrong. It is also important to ask questions, clarify the goals and expectations of all the partners, and establish how the project will be managed during the initial negotiations. Sometimes the parties will find that research collaboration will not work because of divergent goals or for other reasons.

## 4.2 ETHICAL CONSIDERATIONS AFFECTING CLINICAL RESEARCH INVOLVING CHILDREN IN THE DEVELOPING WORLD

**Lisa Bero, Professor of Clinical Pharmacy at the University of California, San Francisco**, discussed her work over the past several decades with

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the Better Medicines for Children Project, which is undertaken by the World Health Organization (WHO) Department of Pharmaceutical Policy and Essential Medicines. WHO has had an Essential Medicines List (EML) since 1977, but in 2002 the list became much more rigorously evidenced-based. Medicines get on the list based on health care need and data on their efficacy and safety. The list is used by many countries to help them procure medicines at favorable prices and then launch an essential medicines program.

The Better Medicines for Children Program was launched in 2007. The program raises many of the issues discussed at the workshop thus far. There is a persistent need for more research on medicines for children, since many of the top causes of death among children under five can be cured or ameliorated by medicine. Wider availability of essential medicines would help make a big dent in childhood mortality. The WHO launched the first Essential Medicines List for Children in 2007. Even with the existence of the list, there can still be problems with regard to the supply chain and misuse. In addition, many medicines actually prescribed to children are not effective at all.

According to Dr. Bero, zinc sulfate, which is used to treat diarrhea, illustrates some of the barriers to getting medicines to children in developing countries. In addition to having an EML that includes zinc sulfate, the appropriate dosage form must be available. For low income settings, this would need to be a dissolvable tablet. At this time there is only one manufacturer of this form of the medicine. The medicine has to be registered in the country, which may involve local research (not necessarily local clinical trials). It must be procurable at a reasonable cost. There must be clinical guidelines and an implementation strategy. Parents must be willing to use the medicine and children must be willing to take it. Zinc does not taste good, and taste formulation can be culture specific.

From the above, it is clear that there is a real need for research in developing countries related to medicines for children. The EML for Children Committee's recommendations put a high priority on pharmacokinetics studies (research on what the body does to the drug), particularly in neonates (newborn infants). Examples include research on the effects of malnutrition on pharmacokinetics, dosage, and the timing of drug administration in relation to food intake. According to Dr Bero, there is not a good research base in these areas today.

One of the projects within the WHO Better Medicines for Children Program is to develop reporting standards for clinical trials in children and regulatory standards for new drugs and formulations. Part of this involved

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a review of ethical guidelines to identify gaps and inconsistencies in the ethical guidelines of different countries related to conducting research in children. Regulatory authorities from 82 countries are involved.

The focus of the effort is on Africa and India, where implementation is being supported by the Bill & Melinda Gates Foundation. Some existing ethical guidelines do not mention children, while a few state that children should be included in research studies. The defined age for a child differs, with some defining the upper age limit as 12 years old and some as high as 21. The EML uses a cutoff of 12. Neonates are hardly mentioned. All the guidelines that mention children recommend special safeguards for consent and assent, specify that research should be relevant to the health needs of the child, and that appropriate care be provided.

Dr. Bero explained that existing ethical guidelines diverge in significant ways. For example, should less risk be tolerated in children, or should more benefit be demanded to make a trial in children acceptable? Some of the guidelines state that no risk can ever be tolerated even if the benefit is potentially great. Even a child with a fatal condition might not be allowed to get an experimental treatment in some cases. Other guidelines that allow variations are often unclear. There are also differences on the issue of whether healthy children may be included in research. Participation by healthy children is very useful for pharmacokinetic studies and dosage studies. Some ethical guidelines state that studies in children should only be carried out after phase III clinical trials have been carried out on adults, which does not make sense from a pharmacological standpoint because children are not just little adults.

Payment for participants in clinical research is another important issue. As a practical matter, payment for participants is necessary in low resource settings, but some of the guidelines are not clear on this point. Note that participants are often compensated in developed country clinical research.

Efforts are ongoing to review existing evidence and work on developing appropriate standards and the capacity to conduct clinical trials involving children, with the ultimate goal being to increase the availability of essential medicines.

## 4.3 ETHICAL CONSIDERATIONS IN SCIENCE AND ENGINEERING PRACTICE

**Stephanie Bird, Co-Editor-in-Chief, *Science and Engineering Ethics***, provided perspectives from engineering ethics that can be general-

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ized to address science, technology, and engineering research more broadly. She drew on the work of several engineering ethicists.

One of Eugene Schlossberger's (1997) points is that beyond being competent, engineers are responsible for considering the foreseeable impacts of technology, including the long-term effects of social change that are associated with their particular projects. These include economic change, safety considerations, environmental impacts and cultural disruption. As an example, Schlossberger considers engineers working with the government as part of a team to build a dam in a lesser developed nation. When choosing the site, a given location may be appropriate for building the dam, but might have broader, problematic implications for the local population. The purpose of the dam is to facilitate movement of the region from subsistence farming to cash crops in order to improve the economy of the whole country. Yet the dam might involve displacement of villages and peoples. It might lead to safety concerns due to the use of pesticides, including products that are banned in the United States. Environmental damage might result from runoff. Finally, cultural disruption might result from displacing traditional ways of life.

While negotiations are clearly a matter for the engineering firm and the government of the country that has asked the engineering firm to design and build a dam, Schlossberger says that the participating engineers themselves need to consider the larger impacts and ethical implications of what they are doing. This is consistent with an elaboration of the Paramountcy Requirement that is essentially universal among engineering codes of ethics, which says that "engineers should hold paramount, the safety, health and welfare of the public in the performance of professional duties." This extends to the public no matter where the work is carried out.

Michael Davis (1991) and Ed Harris (1998) have identified the public relevant to the Paramountcy Principle as "any person or group vulnerable to the effects of the tasks through lack of political or financial power, information, technical training or time for deliberation." This includes anyone who is not able to understand what is involved. One can ask whether those who bear the risks actually receive the benefits, whether those who bear the risks do so voluntarily, and whether those who bear the risks are aware of the full extent of the risks that they are bearing. Clearly, individuals in some settings, in a particular region, in a particular economy, may not be in a position to speak up for their own concerns.

Dr. Bird stated that for international collaborations, the primary ethical concern is to explicitly address and avoid exploitation. The potential trap

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is paternalism, which may arise when collaborations involve groups with different economic conditions and different cultural values, and where the power differential is substantial. The challenge is to achieve a partnership between and among different collaborators.

In order to get deeper perspectives on international differences in values, foreign post-doctoral trainees and graduate students are potentially a valuable resource because they are confronted with the differences in values and style between the United States and their native national homelands. Dr. Bird discussed work done at Children's Hospital of Philadelphia, which surveyed its many foreign national post-doctoral trainees (Alexander and Williams, 2004). The trainees commented on the corporate feel of at least some U.S. laboratories compared with the less formal, sharing atmosphere in research settings abroad. Alexander and Williams found that trainees experienced "some difficulty reconciling their interest in science and the advancement of humankind with the need for restrictions in sharing (tech transfer), limitations on collaborations, the politics of funding (especially in hot fields), and the hassles of negotiating system hierarchies." Of course, these issues would likely be raised by U.S. citizens as well.

They further found that "intellectual property and data ownership stimulated lively discussion about the tension between science and commerce, and about the potential for infringement of academic freedoms." The foreign trainees also raised concerns about "the export of Western values to international collaborators."

Dr. Bird also talked about her own work at the Massachusetts Institute of Technology teaching the responsible conduct of research and heading up the ethics domain in health science technology, teaching many graduate students from other countries. These students are often sensitive to the circumstance that their top-flight education would help to develop products (e.g., auditory and optical implants) to serve a relatively small, privileged population. They may have originally been motivated by the desire to improve the mobility of, say, individuals who had lost their limbs to landmines.

Clearly, the students themselves notice some disconnect between what they were experiencing in their education and what it was that they saw as a focus of their education. In this sense, science and technology collaboration can be a double edged sword. Foreign students and collaborators with social concerns may be put off by the competitiveness of the research environment at many U.S. institutions. Dr. Bird urged that care be taken in addressing the ethical issues that arise in collaboration and to not get too caught up on

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compliance. Checking the appropriate boxes on forms may involve settling for the minimum. What is the bigger picture? Why is the policy there in the first place? To borrow from Greg Koski, formerly with the U.S. Department of Health and Human Services (DHHS) heading the Office of Human Research Protections, how can we foster a culture of conscience rather than a culture of compliance?

## 4.4 SAMPLE PERSPECTIVES FROM THE BREAKOUT SESSION ON ETHICS

The Ethics breakout session organized its discussion around what one might put in a primer on how to undertake international research collaborations.

Individual participants made a number of points during the discussion. This is a non-exhaustive list, and is not intended to represent consensus views of the workshop or the breakout session:

- Ethics is relevant to all aspects of international agreements from conceptualizing the idea, to working the idea into a concrete plan, to developing a set of agreements, and all the way through the implementation. It is important to consider that the collaboration is a process, not a one-time event. Conversations about the ethical implications of provisions or actions are going to happen at every step of the process. Perspectives may change over time, but the earlier the ethics discussion begins, the better.
- Ethical issues can be difficult to talk about and cultural implications may be an impediment to straightforward discussion. This makes it all the more important to develop a context and setting in which that conversation can be held. This is a function of several factors, such as the availability of support for workshops and the development of networks. It is easier to have these conversations with those one knows and with whom one has developed some trust.
- There is value in articulating the general ethical principles in the agreement. The group discussed a possible list of principles (e.g., transparency, fairness), and collaborators might similarly agree to the important parameters and how to apply them in a systematic way.
- This is not just an abstract discussion. It is important that ethical principles are reflected in the details of business practices and how the partnership will function.

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- International partnerships may encounter some issues that are quite distinct from domestic partnerships. On the other hand, there are issues that are going to be relevant across the board. Cultural differences may be clearer when accompanied by ethnic, national, or linguistic differences. Cultural differences between organizations and sectors in the same country may be less apparent but perhaps no less real.
- As these principles are operationalized, some clearly bad practices or actions might be forbidden. In addition, there could be actions that are okay, actions that are recommended, and actions that are required. Doing a systematic analysis within the setting of the partnership and taking into account the legal and regulatory frameworks may help in coming up with a clear approach.
- There are several tools that might be developed for a primer on international research collaborations. For example, it might be useful to have a list of frequently asked questions, covering issues that may be confusing. Also, case studies and vignettes could be very valuable.

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# 5

# Research Integrity and the Responsible Conduct of Research

*"The research integrity panel continues the ethics discussion by focusing on standards and practices that promote responsible data collection and appropriate authorship byline decisions. The panel will explore issues related to current RCR training for data integrity and authorship as well as consider the impact that different international PhD educational standards can have on data integrity. The panel will conclude with a discussion by an international team who will describe their experiences in negotiating authorship agreements and in building capacity to assure data integrity."* (Workshop Agenda)

## 5.1 THE VALUE OF WRITTEN AGREEMENTS[1]

**David Resnick, Bioethicist and Chair of the National Institute of Environmental Health Sciences (NIEHS) Institutional Review Board at the Department of Health and Human Services**, began his talk with perspectives on collaboration and disputes. As the staff bioethicist, Dr. Resnick is often called in to provide advice when ethical issues arise in research. Most of the issues that he sees involve authorship, with some disputes arising about data management or intellectual property. Many of the authorship

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disputes occur because the researchers had different understandings when they began the collaboration.

One way to minimize these disputes is to work out an agreement beforehand with some of the specific details of the collaboration and what is going to happen. These agreements are important for several reasons. Researchers may have different ideas about what an "author" is, different understandings of human research, and so forth. Educational background can play a role. An MD in one country may have very different training than a U.S. MD. Researchers also vary with respect to their knowledge and training on the responsible conduct of research and specific issues such as data management, authorship, publication, and research integrity.

Collaboration agreements should discuss authorship and how it will be determined. For example, the International Conference Medical Journal Editors Guidelines can be helpful. It should cover publications—where and when they are to be submitted. Data management is an especially important issue in large, international collaborations where research records may be kept in different countries, and in different languages. How will the data be stored, analyzed, and shared? Will any data be confidential, and how can this be protected? Management and sharing of research materials (cell lines, tissue samples, and reagents) should be covered as well. Intellectual property and funding expectations should be addressed at the beginning whenever possible.

Dr. Resnick pointed out that conflict of interest is a very serious issue. There are real conflicts of interest and perceived conflicts of interest—both should be dealt with because something one researcher might consider a perceived conflict could ethically tarnish the whole project. Also, concrete expectations regarding roles and responsibilities in the research and timelines should be covered. Finally, regulation is a very important issue, particularly in meeting requirements of different national jurisdictions and addressing any conflicts that do not harmonize.

Entering into a formal agreement implies that some level of trust already exists. So prior to concluding an agreement it is necessary to learn about one's potential collaborator. Does he or she actually have the qualifications that they claim to have? How do you know that they will fulfill their commitments?

In practice, these sorts of agreements are not utilized very often. One reason is that researchers are not aware that they can develop these sorts of agreements. Another reason is inconvenience. Researchers may not want to take the time to develop an agreement, or want to avoid being legalistic

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and work things out informally. As a result, misunderstandings can develop when the project is undertaken.

A written collaboration agreement does not supersede other sorts of agreements that exist in research, such as material transfer agreements, data use agreements, confidentiality agreements, cooperative research and development agreements, and memoranda of understanding. These are all important but none of them addresses some of the key issues discussed above.

## 5.2 THE IMPORTANCE OF UNDERSTANDING YOUR COLLABORATOR'S CONTEXT

**Philip Altbach, Director of the Center for International Higher Education at Boston College**, emphasized one key takeaway: researchers should know about the universities and academic systems in which their potential overseas partners work.

World higher education has been expanding dramatically in the latter half of the 20th century and will continue to expand. In the rich countries, the rate of expansion has by and large stopped. In fact most of the growth in global higher education in the coming years will come from China and India.

In the United States, most research is performed in doctoral-granting institutions. In much of the world doctoral education is not well-developed. The majority of those individuals teaching in colleges and universities around the world (excluding the top institutions) do not have doctorates. There are essentially two approaches to doctoral education around the world. It is important to understand what they are and how that is developing. One is the American style PhD, or course doctorate, which involves heavy coursework, a dissertation and examinations. In contrast, most doctorates in most of the rest of the world are research doctorates, where students register for a PhD, write a dissertation under a supervisor, and get the degree when it is complete. There is a move globally, in the direction of the American style PhD or a modified American style PhD.

Dr. Altbach explained that the academic culture of a potential collaborator may be an important influence on their priorities and behavior. For example, countries may lack full academic freedom, which may raise issues connected with access to data and controls over the Internet, even in science and engineering. Some research topics may be restricted. University corruption in admissions, examinations, and promotions is also a problem in some countries. Even if one's collaborator is not corrupt and wants to do the right thing, their context may make it difficult for them.

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Other aspects of the academic culture have to do with the incentives and reward structures, such as the degree to which academic promotion is meritocratic or the degree to which faculty members at the institution received all their degrees at the same institution. Are faculty rewarded and recognized for superior research, or are they rewarded for just having been at the school for a long time? The culture of the academic profession and of the university is of central importance in understanding how people approach collaboration and their careers.

Dr. Altbach concluded by pointing to the importance of working conditions. Faculty members in most of the world have very heavy teaching loads, and are still expected to produce research.

More importantly, in most of the developing world, professors are not paid enough to work full time at their academic jobs. The collaborative agreement with an international partner may allow them to spend more time on their academic work. This is a positive aspect of collaboration. Other aspects of pay (compensation) are important to keep in mind as well. Faculty members may receive significant payments for publishing in a prestigious domestic journal or an internationally recognized journal, so receiving authorship credit is very important.

## 5.3 RESEARCH INTEGRITY ISSUES IN A COLLABORATIVE PROJECT

**William Blattner, Director and Principal Investigator for the Institute of Human Virology (IHV) HIV Vaccine Trials Unit, University of Maryland; and Aliyu Gambo Gumel, Fogarty International Research Fellow**, discussed their research project on Recruiting Acute Cases of HIV in Nigeria, the REACH Study. The sponsor was the Centers for Disease Control, and the research was undertaken collaboratively by the University of Maryland and the Nigerian Federal Ministry of Health.

**Dr. Blattner** gave an overview of the project. There was a large project team, with a variety of roles. The specific deliverable was the generation of samples in serial follow up from patients with acute infection, meaning that they were viral positive before they were antibody positive, very early in infection. CDC wanted these in order to develop and improve tests. The project had additional goals, such as to explore the magnitude and the correlates of infection, to address the operational issues of getting patients into treatment and care through the PEPFAR (U.S. President's Emergency Plan for AIDS Relief) Program, and to

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understand more about the genetic diversity of the virus and the performance of blood test screening assays.

The project worked with several populations. Some women came into the project through health facilities because they were pregnant and were being screened for prevention of mother-to-child transmission. There were also groups of brothel-based sex workers, street-based sex workers, and the so-called Okada motorcycle taxi drivers who sometimes collect their fee in non-cash payment, meaning sex.

The two-phase study involved consent for testing and then consent for enrollment in prospective follow up. The project team was looking for people who had not been previously tested, and outreach included efforts to promote safer sex among the target populations. About half of the sex workers are HIV positive. There are real challenges in getting services to this population. Although prevalence may be falling for Nigeria as a whole, certain populations are experiencing an increase. Those in most need generally have the least knowledge of what services are available.

Dr. Blattner reviewed the several different types of intellectual work product that resulted from the project. The Nigerian collaborators are co-authors of some papers. Others addressed the Center for Disease Control's (CDC) need for laboratory test development. One goal was to ensure the Nigerian researchers were integrated at all levels of the program, not just the clinical and epidemiological aspects, but also into the more sophisticated laboratory pieces, and to meet the criteria for authorship credit. Ultimately, the Fogarty Program administered by the National Institutes of Health (NIH) aims to provide international partners with the skills to successfully compete on their own for independent research funding.

**Dr. Aliyu** discussed the ways in which the project increased the capacity for the Nigerian partners to ensure data integrity, by developing effective methods for data collection, storage, transfer and validation. There were three teams working together: counselors, lab technicians, and data managers. Through training, the team was able to essentially double its capacity for data integrity in the year prior to the launch of the project in May 2005. This capacity continued to increase in the areas of data collection, data capture, and data storage. Data analysis and interpretation was the only area that did not see a consistent, significant increase in capacity.

Several factors contributed to the increase in data integrity capacity. Training was mostly led by IHV (University of Maryland) faculty with some help from local resource people. Training covered issues in data collection, data capturing and storage, and analysis and interpretation. Also, clearly-

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written standard operating procedures (SOPs) were very helpful. Having the right equipment and office facilities was also essential.

There were challenges as well. Most of the analysis and interpretation continued to be done in the United States, which is why there were not any papers with Nigerian lead authors. At the start of the project there were sometimes mistakes in data collection, such as multiple screenings of the same person, the same ID number being assigned to different participants, missing forms, and unsigned consent forms. At the beginning, some data had to be discarded, but performance improved over time. Some problems with faulty data entry, missing data, multiple entries, and database design continued to occur.

In the area of data storage and transfer, weak backups like flash drives and CDs sometimes caused problems. The instability of the electricity supply was a continuing issue, and required the project to buy backup generators. Multiple log books (lab, data capture, and counselor) were utilized to facilitate validation. This made it easier to discover cases of missing or incorrect data for participants. Weekly meetings allowed the teams to troubleshoot problems. Weekly conference calls with the IHV team and regular visits provided additional monitoring.

A future task will be to build capacity in data analysis and interpretation. Dr. Aliyu also reflected on his own experience, and on the value of long-term training he had in the United States. At the time of the workshop, he was designing a study to look at the possible relationship between bovine TB in Nigeria and HIV, responding to a surge in the prevalence of bovine TB. He has developed the protocols, the forms, the SOPs, and the database, and also secured ethical approvals.

The goal of building capacity among the participating Nigerian researchers and the broader research enterprise in Nigeria continues to be pursued by the Institute of Human Virology in Nigeria. It is a free standing academic center of excellence affiliated with a number of universities. The West African Bioethics Center in Nigeria has also established a national legal framework for research ethics. Although research funded by U.S. government agencies undertaken abroad will generally follow U.S. ethical conduct procedures, such as the Common Rule for human subjects protection, research collaboration is much easier when partner countries develop their own frameworks for institutional review boards, animal subjects protection, and so forth.

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## 5.4 SAMPLE PERSPECTIVES FROM THE BREAKOUT SESSION ON RESEARCH INTEGRITY AND THE RESPONSIBLE CONDUCT OF RESEARCH

Participants in this breakout session discussed key points from several of the presentations given in the plenary session. Much of the conversation focused on data integrity and authorship issues as important areas that would benefit from additional discussion and understanding of international approaches. The group was especially interested in problems facing the three sectors—government, universities, and industry—and ways they could be addressed.

Individual participants made a number of points during the discussion. This is a non-exhaustive list, and is not intended to represent consensus views of the workshop or the breakout session:

- **Possible Issues for Industry.** Industry-supported research is moving offshore, particularly clinical trials in the pharmaceutical industry. Cost is an important factor driving this. Also, the incidence of some diseases is overwhelmingly in developing countries. Industry may need to takes steps to avoid the perception of being self-serving in the host country. When there is documentation of biased reporting, who is responsible? Do the researchers in developing countries know what they are supposed to do? There are complexities in managing the roles of contract research organizations (CROs), site management organizations (SMOs), study coordinators and investigators.
- **Possible Actions by Industry.** Good communication with the public by companies in the host country is helpful. Steps have been taken to increase transparency, such as establishing the clinical trial portal, but industry could better clarify responsibility and accountability in clinical trial roles. Industry could also get more involved in education and training in areas where companies have expertise, such as data integrity.
- **Possible Issues for the U.S. Government.** U.S. government agencies have regulations related to responsible conduct of research (RCR) training by grantees. Some government regulations related to research may not be applicable to modern research operations. Institutions may not take responsible conduct or research (RCR) seriously and only require some online courses.

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- **Possible U.S. Government Actions.** The government might clarify clinical trial responsibilities and accountability. The RCR training plan and mandates could be put on the front page of the grant along with human subjects, etc. Government might require institutions to ensure that every researcher has had RCR training, specifically on data retention policies. Greater resources could be devoted to monitoring and enforcing existing RCR regulations. Institutions could be required to provide mentorship training. Agencies could support the development of better systems to ensure data stewardship and transparency.
- **Possible University Actions.** The quality of RCR training could be made part of regional accreditation. Universities could improve training programs for their own investigators. Universities could perform due diligence on collaborating institutions and investigators. They could specify research misconduct investigation procedure in all agreements.
- **Societies and Journals.** Journals could establish and strengthen requirements that data supporting published work be made public.

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# 6

# Risk Management

*"Risk Management is a continuous process designed to proactively identify and mitigate risks to help promote the achievement of the organization's objectives, strategy, and mission. Risk management also drives accountability and integrity of the organization's work and helps ensure individuals within the organization see it as their responsibility to reduce risk as part of their daily jobs. The panel will explore specific issues relating to risk management in the international setting."* (Workshop Agenda)

## 6.1 INTERNATIONAL COOPERATION ON RISK MANAGEMENT[1]

**Manning Muntzing, A Founder and Director of the International Risk Governance Council (IRGC)**, described the goals and activities of this relatively new organization. Based in Geneva, Switzerland, IRGC aims to support governments, businesses and other organizations in many countries and to foster public confidence in risk governance and in related decision-making. It reflects different views and practices on risk governance, provides independent authoritative information, contributes to understanding and assessment of important risk issues, and designs innovative, efficient and balanced governing strategies (IRGC, 2010).

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IRGC has issued a number of publications exploring how its risk governance framework can be applied in various contexts and making recommendations for appropriate strategies. IRGC's report on risk governance in nanotechnology is a good example (IRGC, 2007). The organization's reports are prepared by experts from around the world, and are intended to incorporate conflicting opinions in order to reach an objective result.

## 6.2 U.S. FEDERAL AGENCY APPROACHES TO RISK MANAGEMENT IN RESEARCH

**Suzanne Servis, Director of the Risk Management Program at the National Institutes of Health (NIH)**, explained how NIH understands and manages risk. NIH's general experience has been that outstanding management practices are essential to sustainable scientific innovation. Scientific merit is addressed through many internal and external processes at NIH, so the focus of risk management is on operational areas that support science such as finance, grants, information technology, radiation safety, and animal welfare.

A basic concept is that risk is the uncertainty around a future outcome. Framed in this way, risks are all around, and risk management is a continuous process. If risks are not managed effectively at research organizations the result can be a loss of public trust. Possible dangers include not allocating resources to address the higher priority risks, and complacency that might come from the mere existence of systems and processes in a given area. Looking at NIH's structure, risks can come from intramural or extramural projects, ethics, facilities, and human resources.

Ms. Servis reviewed several areas of possible risk. Examples include inadequate human subjects protection due to faulty protocols or informed consent procedures. Problems might arise in extramural research if information is not disseminated within the grantee institution. Samples and other assets might be lost if the proper temperature and humidity conditions are not maintained in storage facilities. Policies and structures may not be in place to address risks, such as Institutional Review Boards (IRBs). Information technology security policies put in place to protect private information and maximize data integrity may not be adequate. Are these evaluated proactively in order to see how they are working, or only reactively in response to a breach?

NIH's risk management approach has a number of goals: (1) Support the NIH research mission and vision, (2) Provide a consistent and cross-

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cutting look at risks across NIH, (3) Identify risks and proactively manage those that present the highest risk to NIH, (4) Develop data and information about NIH risks, and (5) Improve strategic planning with data and information about risks. Figure 6-1 illustrates NIH's risk management methodology.

Several issues are apparent in implementing this methodology. To begin with, the key subject matter experts need to be involved, particularly in identifying risks. Risks are scored based on the impact that it could have on the organization and the likelihood of that risk occurring. They are then plotted. Those risks that are of high likelihood and high impact are where effort should be focused.

Ms. Servis gave a hypothetical example to illustrate. Suppose an inexperienced researcher removes tissue samples from an organization without patient authorization. Then the researcher's interest in personal gain could undermine the rights of human subjects, creating a conflict of interest. In the "assess phase" it might be determined whether researchers had received the required training in human subject protection. If the result is a finding that fifteen percent of researchers had not received the training, the business owner would be tasked with formally tracking the completion of training, and to develop a corrective action plan to fix the problem. Developing policies to communicate the importance of training to the research community, or to restrict researchers who have not completed training from participating in protocols, represent other options.

Risks and corrective action plans need to be inventoried and monitored over time, because they change. If significant progress is made, the risk might be rescored. Management should be provided with regular information on what risk assessments are being done, the results, and corrective action plans.

## 6.3 UNDERSTANDING RISK IN INTERNATIONAL PARTNERSHIPS

**Maria Velez de Berliner, Managing Partner at Intelligent Decision Partners, LLC,** discussed the less obvious risks that sometimes can do significant damage to organizations. These risks may arise from external political, economic, or social conditions. Decision-makers need to recognize the global nature of risk, and understand that information will usually find its way to the public arena.

One element is the nature of governments. Democratic governments have a proclivity to interfere in collaborations. Some research—on atomic

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**FIGURE 6-1** NIH risk management program, methodology
The NIH Risk Management methodology is a customized six-step approach that provides a standard means of addressing risks and assessing internal controls.
SOURCE: National Institutes of Health.

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weapons, human subjects, and so forth—is heavily regulated in the United States and elsewhere. In some countries, provincial or state regulations have more weight than national level rules. And changes in national or provincial governments that result from elections may affect the regulatory environment or the funding for research. Even if these changes cannot be predicted, it is important to consider the possibilities.

Dr. Velez de Berliner pointed out another emerging reality. U.S. institutions are not the only ones launching collaborative research efforts in countries such as Brazil and Columbia. Chinese researchers and institutions are also pursuing collaborative research agreements.

As has been mentioned by other speakers, it is important to understand the cultural and institutional context of potential partners when agreements are negotiated. Even with a detailed written agreement, enforcement may vary in different countries. It is always important to ask "what can go wrong here," and "what is the worst that can happen"? The BP oil spill of 2010 showed how difficult it is to cope with low likelihood-high consequence risks.

## 6.4 SAMPLE PERSPECTIVES FROM THE BREAKOUT SESSION ON RISK MANAGEMENT

The context for the Risk Management breakout session was set by a paraphrase of the Sufi sage Mulla Nasrudin: "Good judgment comes from experience. Experience comes from bad judgment." The context for managing risk in international research collaborations includes the global challenges addressed by collaboration, the greater ease of communications, and the possible impact of negative consequences.

Individual participants made a number of points during the discussion. This is a non-exhaustive list, and is not intended to represent consensus views of the workshop or the breakout session:

- **Organizations and researchers cannot eliminate risk, they can only minimize and mitigate it.** Participants in collaborations are challenged to prepared to deal with risks that were not anticipated, while trying to imagine all the eventualities that they can.
- **It is helpful for participants in international collaborations to understand their international counterparts as fully as possible.** A shared vision among collaborators can be important**.** Establishing relationships can be vital to establishing successful collaboration, and is preferably done prior to a formal contract.

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- **Involving university deans and others who can help ensure implementation can be critical.** Overseas visits can be very helpful.
- **Encouragement and support for student visits abroad and exchanges could be helpful.** Some universities are doing a lot, but overall only a small percentage of U.S. students have a study abroad experience.
- **Cultural issues in U.S. academia can be an important factor.** It is important for U.S. academics to understand some ways in which they might be different from academics elsewhere. For example, American faculty can be fiercely independent, and they might take the view that their actions do not reflect on their institution. They may lack awareness of centers of excellence outside the United States. Students can drive internationalization and encourage reluctant faculty to modify the curriculum or to give credit for courses taken elsewhere.
- **Sample suggestions for successful collaborations:** (1) Seek mutual interests at the outset, (2) Identify benefits for each participant, (3) Ensure that collective resources are sufficient to achieve objectives, (4) Ensure that agreements are made at the right level to commit necessary resources.
- **Potential partners outside the department:** (1) The business school, which may have international programs, (2) Federal labs which have international activities, (3) States with international consortia (e.g., Washington, Oregon), (4) International universities, INSEAD being an example.

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# 7

# Intellectual Property

*"Intellectual Property (IP) is a central issue in international research collaborations. What is the balance between the facilitation of research and the protection of IP? The members of the IP track will discuss and outline the major issues, challenges, and successes of IP on the international level. This will include such topics as background intellectual property (BIP), the connection between IP and export control, the management of IP at the university, industry, and governmental levels, and emerging issues in the coming years (such as managing IP given the increasing transportation of large data sets and research across national borders). The IP team will pay particular attention to practices and models of IP used in individual countries, for inclusion in project deliverables."* (Workshop Agenda)

## 7.1 IP TRENDS FROM A U.S. UNIVERSITY PERSPECTIVE[1]

**Brian Warshawsky, Senior Contracting Officer at Northwestern University**, began his talk by outlining several trends that he has seen. On the one hand, international collaborations are more frequent. On the other hand, agreement negotiations are increasingly bogged down due to a lack of understanding on the part of industry about what collaborations

[1]In this section and other sections summarizing presentations, views and opinions are attributed to the presenter unless stated otherwise.



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universities can and cannot engage in. This is the case for U.S.-focused collaborations as well as for international agreements, and comes after years of sustained effort to raise awareness.

Mr. Warshawsky attributes some of these problems to the downturn in the economy, combined with a trend for industry managers with experience in working with universities to retire and be replaced with managers who are more comfortable in a commercial procurement context. This is happening in negotiations with companies that have master agreements or set contract templates in place with Northwestern.

It is important to remember that the university's core mission is to educate, both through classroom teaching and through the publication of research. Working with industry and with international partners is worthwhile if it advances this mission. Potential partners, and even faculty and departments heads eager to secure funding, may lose sight of this.

One issue that has caused difficulties lately is background intellectual property (BIP). BIP is a term used to define IP that exists before the development of an invention. In one recent negotiation, an international collaborator wanted assurances regarding BIP. The university has no capacity to check BIP at the time of an agreement or to provide such assurances. The most that happens is the faculty member provides a list of publications. The larger issue is that the university is performing research, not selling IP. The research does not come with any warranty that the result can be commercialized. Of course, the university wants to provide sponsors with opportunities to license the outputs, but cannot guarantee that there will be no bumps in the road due to background IP.

The role of the central administration is to balance the various interests at stake, to protect the integrity of the institution and the faculty, and to ensure that the university can comply with the agreements that it signs. In a recent case, an international collaborator from the Middle East was interested in supporting the development of course software. Mr. Warshawsky had to point out to a faculty member that if the sponsor was given the broad rights that it asked for, future research in that area might infringe on the copyright, raising the danger that the faculty member could be shut out of working in this area again.

In another case, a U.S. corporation refused to sign a letter of support for a faculty member seeking an NSF early career award until the university agreed to IP terms. As part of a much larger project, the faculty member and a student would be going into the company to study workflow issues, without receiving any IP or confidential disclosures from the company, with

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just a small amount of funding in return. The company wanted a piece of any IP that might be generated by the much larger project. The longstanding master agreement with the company covered IP from work funded exclusively by the company. The faculty member was caught in the middle. The issue was ultimately resolved, but with some acrimony along the way.

In yet another case, a major corporation with an international focus was seeking to support research by a young faculty member, with most of the support funding a student. The research was very early stage, but the company retained outside patent counsel to aggressively pursue rights to BIP. This made no sense. Northwestern looked at its own portfolio, and suspects that the company might have been seeking to snag non-exclusive rights to an obscure patent going back ten years arising from the work of a faculty member no longer at the institution. The company could have simply licensed the technology.

In the current difficult environment, are there best practices to keep in mind? Mr. Warshawsky suggests that universities avoid artificial deadlines when dealing with companies. Universities should also be wary of master terms that could go beyond the contract that is being negotiated. Universities should understand the possible impact of agreements on unrelated research and unrelated researchers. In a perfect world, every contract will reflect the statement of work behind it.

## 7.2 INTERNATIONAL COOPERATION IN IP ISSUES

**Brian Fitzgerald, Professor in the Faculty of Law at Queensland University of Technology in Brisbane, Australia,** discussed several issues related to international collaboration in IP. He began by covering several trends in collaboration between national patent offices.

He reminded the audience that it is important to remember that patents are granted by national patent offices. There is no such thing as an "international patent." Over time several major agreements have established a framework aimed at facilitating the ability of inventors to apply for patents in multiple jurisdictions while reducing the amount of redundant work on the part of applicants and patent offices. For example, the Paris Convention of 1883 grants an inventor the priority date established in their original application for applications made within a year in other convention-member jurisdictions. The Patent Cooperation Treaty of 1970 established an international application, allowing an inventor to do an international search to discover the jurisdictions in which it would be advantageous to file while

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keeping the priority date from the original application for 30 months. Most jurisdictions publish applications 18 months after filing. The European Patent Office was established in 1973, and allows inventors to file in one place for patents in all EU countries. When granted, the patents would take effect as national patents.

Despite this progress, there are still barriers to international patenting. For example, there are millions of applications in a backlog awaiting assessment. There is still considerable duplication of effort across national offices in the application, examination, and grant processes. And patent laws are not harmonized.

Professor Fitzgerald reviewed several initiatives ongoing to address these barriers. One that has become prominent recently is the patent prosecution highway (PPH) concept. A PPH is a bilateral agreement between two national offices that allows an applicant to request accelerated consideration of an application from one office if at least one of its claims has been found to be patentable by the other. The "big three" largest patent offices (United States, Europe and Japan) are involved in this process, with Japan providing much of the impetus.

Another initiative is the Vancouver Group Mutual Exploitation Principles. This is a recent agreement between Canada, Australia, and the United Kingdom aimed at eliminating duplication of effort. This is achieved by the Vancouver Group countries agreeing to rely on each others' examination reports where possible.

Another area of effort is substantive and procedural reform. The Director General of the World Intellectual Property Organization (WIPO) has identified several priority areas, including adoption of a uniform patent classification model, particularly among the "big three" (Quinn, 2010). This sort of harmonization would facilitate the work-sharing arrangements discussed above.

In addition to efforts at expanding collaboration between national patent offices, there is the potential for expanded engagement between patent offices and the community. One obvious trend is the emergence of patent informatics and the ability to source technological information from patent databases. This is not especially relevant to this discussion but is important in the broad IP scene.

A second trend is Peer-to-Patent, which is basically crowd sourcing prior art (information relevant to the patent's claim of novelty and inventiveness). The idea is that the knowledge of citizen experts could be harnessed through technology to help examiners determine whether a patent

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should be granted over an invention. Several pilot projects to test the concept have been run in the United States, and others have been launched in Australia, Japan, and Korea as well. In the U.S. pilots, there were over one thousand registered peer reviewers and 197 patent applications. The applicant could voluntarily make their application available for peer review. About 10 percent of the claims were affected by the prior art forwarded by the peer reviewers.

According to Professor Fitzgerald, potential benefits to the public of peer-to-patent include improved patent quality and a clearer patent landscape. Applicants would benefit from the resulting patent being more robust and less likely to be disputed or litigated. The identification of weak claims early in the process also allows the inventor to save resources that might have been used to pursue an application that would ultimately be rejected.

## 7.3 SAMPLE PERSPECTIVES FROM THE BREAKOUT SESSION ON INTELLECTUAL PROPERTY[2]

The group began by reviewing the plenary session presentations and identifying those that were particularly relevant to intellectual property issues. Important aspects of the current context for research include stresses on the global and U.S. economies, and impacts on universities and industry.

Individual participants made a number of points during the discussion. This is a non-exhaustive list, and is not intended to represent consensus views of the workshop or the breakout session:

- **Intellectual Property (IP) Metrics.** IP metrics were not a part of the American Reinvestment and Recovery Act (ARRA). They are part of the STAR Metrics program (Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science), a U.S. multi-agency effort launched in 2010.
- **IP-Related Barriers to Collaboration, Tensions and Pressure Points.** The continued slowdown in the global and U.S. economies can create friction. Cross-cultural misunderstandings can raise barriers. Understanding of patent models in various countries is

[2]While unable to attend the workshop, Dr. Ma Jun, Director, Overseas R&D Management Office, Tsinghua University, Beijing, China, provided written responses to the breakout session questions.

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often limited. There are differences of efficiency between national patent offices. University administrative structures are under stress. Differences in technology (all technologies have unique quirks to them that impact IP) and asymmetries in IP negotiating strength (one party generally has more power than the other) can also cause problems.

- **Possible Solutions and Workarounds.** Trust and personal relationships appear to be keys to success. Partnership strategies are developed over time, although one-time, ad hoc relationships are still common. Agreeing on a common language or terminology can help ensure success. The Patent Protection Highway discussed by Brian Fitzgerald and other non-U.S. strategies appears to be worth exploring. Professional development is critical to building international collaboration—this can be accomplished through more intensive faculty/staff communication, exchanges, conferences, and workshops.
- **Opportunities for IP to Facilitate International Collaborations.** International exploration of methods of managing IP, such as the iBridge Network developed by the Kaufmann Foundation, could be helpful. Understanding the nuances in IP negotiations, such as differences in perspective between public universities and private, large and small entities, and so forth, can help ensure success. There might be a role for technology specialists, that is, consultants to serve as intermediaries between inventors and companies.
- **Key Short- and Long-Term Issues for IP and International Research Collaborations.** Short-term issues include improving the compatibility, efficiency, and quality of output (patents) in various national systems. Harmonization is a highly desired long term goal. The status of the global economy is an uncertainty that has short-term and long-term impacts. Issues related to students and export controls, and the implications for IP are issues for the future.
- **Possible U.S. Government Actions.** Ideas include building a U.S. Innovation Strategic Policy, convening an IP forum similar to the Federal Demonstration Partnership (FDP), and steps to facilitate commercialization of government-created IP.
- **Possible Actions by U.S. Educational Institutions.** Improving primary and secondary schools and providing role models, such as professionals in the science, technology, engineering, and mathematics (STEM) disciplines, could be helpful. Expanding undergraduate

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study abroad opportunities for U.S. students as suggested by Kathie Olsen in her keynote talk might also be worthwhile. Establishing some level of "innovation literacy," and understanding that innovation literacy includes technical and non-technical elements, are other goals to consider.

- **Possible Industry Actions.** Companies could benefit by becoming more "university literate," i.e., understanding better the operating context of universities. Companies also could better define what is "precompetitive" for IP purposes; this will allow for better opportunities to collaborate early in the research process.
- **Possible Actions by Government, Universities, and Industry Together.** Better understanding among the three sectors could be helpful. This includes a shared understanding that IP is part of the commercialization pipeline and is a means, not an end.

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# 8

# Export Controls

*"Export control regulation presents special challenges when working with international collaborators and when conducting research overseas. Researchers who are used to open academic environments are often surprised to learn that certain areas of collaboration, especially in science and engineering, may be more difficult with certain international partners. In addition, trade embargoes and sanctions, reflecting foreign policy concerns of different nations, can affect a researcher's ability to travel to certain countries and transport certain research equipment. The Export Control panel will discuss the various issues raised by these regulations, their effect on international research collaborations, and compliance strategies used by various institutions to meet these challenges."* (Workshop Agenda)

## 8.1 THE U.S. POLICY CONTEXT FOR EXPORT CONTROLS[1]

**Steven Pelak, Deputy Chief of the Counterespionage Section of the U.S. Department of Justice**, gave perspectives on the broad context for export controls, as well as current initiatives at the Department of Justice. U.S. export controls can be confusing, because there are several sets of rules for different types of products that are enforced by different agencies. The

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Department of Treasury Office of Foreign Asset Controls issues and enforces sanctions against particular countries. The Department of Commerce oversees the regulations for dual-use items. The Munitions List is under the jurisdiction of the Department of State.

Mr. Pelak gave an overview of why the United States is concerned with export controls, using several specific cases as examples. United States vs. Mayrow is a prosecution involving illegal export from the United States to Iran, through various other countries, of electronic components that could be used in building improvised explosive devices (IEDs). Another case involves the export of triggered spark gaps, which are used in medical devices that crush kidney stones, but can also be used to detonate nuclear devices. Ultimately, the goal of maintaining export controls and prosecuting violations is to protect the U.S. military and the broader public.

The Justice Department only deals with willful violations, not with negligent, accidental, or mistaken violations. The vast majority of export control violations that occur in an academic or research context fall into the latter category.

## 8.2 UNIVERSITY PERSPECTIVE ON EXPORT CONTROLS

**Steven Eisner, Export Control Officer at Stanford University**, described how a university that performs fundamental basic and applied research ensures compliance with export control laws and regulations. Export controls address the transfer of technologies, hardware or software code, that have the potential to adversely affect U.S. national security. Such exports can take the form of physical shipments or the transfer of technical information through oral or visual disclosure, including specification sheets or blueprints. Hardware or information carried by hand is also considered an export.

The primary focus of compliance at Stanford is ensuring that the university only engages in research considered fundamental (basic and applied) and thereby stays within the safe harbor known as the "fundamental research exclusion." The results of research intended for broad dissemination and sharing should be free from regulation. Fundamental research is increasingly international, at federal laboratories as well as at universities. For example, there is a great deal of information exchange between the Large Hadron Collider at CERN in Switzerland and Stanford University.

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Certain countries are subject to U.S. embargos. For example, Stanford students cannot travel to Cuba to conduct research for a term paper. Also, hardware that goes along with some of the exempted activities might require export licenses.

Regulated information is information not intended to be broadly shared with the scientific community. But in the conduct of research, the university may need access to proprietary or disclosure-restricted information to generate results. This is true domestically and internationally. The third parties could be overseas corporations or non-profits. So information and related hardware covered in non-disclosure agreements, commercial licensing agreements, procurement agreements, and material transfer agreements are subject to restriction if they deal with regulated technologies or technical information. The vast majority of these come from the commercial sector, not the military.

Examples include acoustic dopplers that Stanford faculty might use for mapping sea beds and ocean tides around the world. Stanford will not make its own, but will buy them from a company, which will provide a technical manual and train university personnel in how to use them. That activity may be regulated.

Mr. Eisner went on to explain that in addition, transfers of some types of technological knowledge to foreign nationals within the United States may be regulated, and are known as "deemed exports." These can occur on campus. Increasingly, universities have to deal with issues related to deemed exports, since the number of foreign nationals in U.S. science and engineering graduate programs and post-doctoral positions has grown significantly over the years.

The extraterritorial reach of U.S. law can offend foreign research partners overseas and foreign students in the United States, retarding short-term and long-term relationships. Stanford does quite a bit of fundamental space science research, which is regulated as a munitions activity, and this constitutes a significant barrier to international collaboration. Sharing such information at conferences outside the United States, particularly in non-NATO countries, can be problematic.

The question arises whether our export control regime should be reformed, particularly for technologies that are widely available outside the United States. The National Academies report *Beyond Fortress America* (2009) covered many of these issues.

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## 8.3 EUROPEAN PERSPECTIVE ON EXPORT CONTROLS

**Emmanuael de Lipkowski, Space Attaché and CNES (Centre National d'Etudes Spatiales, the French space agency) representative at the Embassy of France**, provided his perspective on export controls.

CNES has very significant cooperation with the United States, even outside that of the European Space Agency, of which France is a member. Europe and the United States are very interdependent in space research.

Export controls are very important because they protect what is being developed. Every technology development has a cost, an influence, and an outcome. The export control regime is important because it is protecting what is being developed. France is very careful about protecting U.S. technology that it receives, and strict about re-exporting it.

Sometimes export controls raise economic issues. For example, a few years ago a U.S. company bought an advanced piece of equipment from a European company, which ended up not operating properly. Because of U.S. export controls, the company was not able to send it back for exchange or repair.

Dr. Lipkowski advocated a rethinking of export controls for this new era of international collaboration. Particularly in space-related areas, co-development of technologies is increasing. International dialogue on adapting export controls for this new reality makes sense.

## 8.4 INDUSTRY PERSPECTIVE ON EXPORT CONTROLS

**Michael Gold, Director of Washington D.C. Operations and Business Growth for Bigelow Aerospace**, discussed his experience in working through the export control regime to advance international collaboration. He sees the experience of his company as something of a breakthrough.

Bigelow Aerospace is developing a private sector space station. The basic technology, termed "expandable space habitats," is like a tent in space versus hard traditional aluminum structures. It has a number of advantages, including a lower weight to put into orbit. Bigelow is working with ISC Kosmotras, a joint Ukrainian-Russian entity that takes the Russian SS-18 missile, removes the nuclear warhead, puts on a commercial fairing, and uses it for commercial space launch. In addition, it would be launched from an active Russian nuclear missile base, saving money.

During the negotiations with the Russians, two monitors from the State Department were present at all times, paid for by Bigelow. They

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submitted a commodity jurisdiction (CJ) request, in which the Directorate of Defense Trade Controls (DDTC) determines whether the item to be transferred is on the munitions list. Ultimately, in this case, DDTC determined that the items were essentially cargo, and not on the munitions list, although the process took some time.

Mr. Gold also chairs the export controls working group of COMSTAC (Commercial Space Transportation Advisory Committee), an advisory committee to the Federal Aviation Administration. The Obama Administration put forward a concept for reform known as "the four singles": a single control list, a single licensing agency, a single enforcement agency, and a single IT system. Getting to that point would be accomplished in several phases. Mr. Gold sees considerable progress already, in areas that can be addressed without congressional action, such as the processing Technical Assistance Agreements (TAAs). Making additional changes requiring congressional approval or notification will be more difficult.

## 8.5 SAMPLE PERSPECTIVES FROM THE BREAKOUT SESSION ON EXPORT CONTROLS

The Export Controls breakout group focused on technical issues that might be of most interest to practitioners.

Individual participants made a number of points during the discussion. This is a non-exhaustive list, and is not intended to represent consensus views of the workshop or the breakout session:

- **Export controls can be an impediment to international research.** There is a distinction between the onshore collaboration that occurs with international sponsors of research and international research collaborators. In the latter case, items are actually being shipped.
- **Deemed exports, where a technology will be "deemed" to be an export when it is shared with a foreign national, is a distinctive feature of U.S. regulations.** Other countries either do not have such a regulation or manage it differently.
- **The Obama Administration has already made some proposals for reform.** There is a multi-agency group doing important work on export control reform and inter-agency coherence. Possible future steps could include additional non-agency participants, and exploration of impediments to research.

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- **A more comprehensive review of export controls could be beneficial.** Issues include possibly cutting back the U.S. Munitions List and the Commerce Control List to those items that are of unique U.S. content and that represent significant military value. Examination of the broad value of the deemed export rule is another possible topic. Other issues include the export of experimental navigational research satellites and the export of commercial satellites, where oversight could be moved back to the Department of Commerce. The possibility of sunsetting technologies, or automatically removing them from the Commerce Control List after a certain time, was also raised.
- **Embargoes and sanctions, which were not covered in the plenary talks, were also discussed in the breakout session.** In these cases it is difficult to predict what is going to be regulated or not, because decisions may be based on current foreign policy and political concerns. It might make sense to harmonize export control laws with the sanctions regime and review existing sanctions.

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# 9

# Legal Issues and Agreements

*"Conducting research with foreign partners can take a wide variety of forms. Sometimes this involves conducting research in the United States with foreign partners; other times it may involve field research, setting up limited business operations, or even establishment of a new campus overseas. This panel will discuss the legal issues related to these various scenarios. The speakers will discuss registration and memoranda of understanding with foreign governments and governmental approvals. It will also cover legal agreements and documents used to facilitate particular business activities, such as payment of taxes, real estate issues, and employment requirements. The panel will cover methods used by institutions to incorporate legal review into ongoing operations. In addition, the panel will discuss the research funding opportunities and challenges presented by the European Union's 7th Framework Program."* (Workshop Agenda)

## 9.1 COLLABORATIVE MECHANISMS: PROS AND CONS OF VARIOUS APPROACHES FOR U.S. UNIVERSITIES[1]

**Jamie Lewis Keith, Vice President and General Counsel at the University of Florida**, discussed legal and contract issues that arise in inter-

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national research, mainly from the viewpoint of U.S. universities. Clearly, these are not the drivers of the research endeavor, but they can undermine the primary objectives if they are not effectively addressed.

Several issues affecting the reputational, financial, operational and legal risks of the endeavor and how best to structure the administrative and legal vehicle for the intellectual program should be decided at the outset of the collaboration. To begin with, it is critical to determine whether the parties' objectives and expectations are realistic, understood, and aligned, or at least compatible. It is also important to have a clear sense of the activities that will be undertaken in the foreign locale, since this will drive tax and regulatory compliance requirements and liabilities that apply to the endeavor. In addition, the U.S. entity needs to understand the jurisdictions, laws, and processes of the overseas locale and whether they are predictable or whether local officials enjoy wide discretion. Finally, there is a need to ensure that negotiations are conducted with somebody who actually has the legal and political authority to close the transaction and who will be there for the duration of the relationship, or at least until the endeavor is well-established.

Ms. Keith explained some options for structuring the administrative and legal mechanisms to carry forward the research endeavor. Although the term "partner" may be used in casual parlance to indicate a close relationship, in most cases it is best to avoid creating a formal, legal partnership. A legal partnership carries with it 100 percent joint and several liability of each partner to the other for torts, debts, contracts and other liabilities of the endeavor. The foreign government might create a new, single-purpose corporation to contract with the U.S. university, particularly if it is investing a considerable amount of money. It is often easier politically and practically for a foreign government to fund a corporation organized locally and allow that entity to fund the U.S. university. Alternatively, the U.S. university and foreign university might be the co-creators and members of the new corporation if there is a joint commitment to a long-term relationship with adequate funding. This can be helpful since the corporation provides limited liability to the members. On the other hand, corporate formalities can add a level of bureaucracy that faculty find burdensome and unnatural. For example, the faculty working on the research endeavor of the new entity may have to attend board meetings, pay attention to using the correct title, stationery and business cards, and so forth. Typically, it is not worth creating a formal legal entity unless there is a large amount of money involved, a long-term commitment, and a high level of certainty that the relationship

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will be successful. For example, MIT and Cambridge University set up a separate entity to undertake a collaborative program that totaled $100 million over several years.

Another option is something called a "service blocker corporation." In this case, the U.S. university would create a corporation on its own in the foreign country or the United States, without a foreign partner, in order to limit legal or tax liability. This mechanism can be useful in jurisdictions where enforcement of the laws is unpredictable or subject to considerable discretion, or where the political situation is unstable, presenting heightened risks. The service blocker corporation may be willing to take on greater risks than the university, and the corporation, if properly formed, operated and governed, insulates the university's assets from tax, regulatory and other legal and financial exposures. Of course, the university will be closely identified with the corporation and will continue to be exposed to reputational risk.

One of the familiar models is a research collaboration agreement. This is an attractive option when there is some foreign government funding, and when the U.S. university is collaborating with an existing university or group of universities. Many times the foreign government prefers to fund an entity in its own jurisdiction because it is difficult to send money directly to the United States in any significant amount. Sensitivities may arise when the foreign university is to receive significant funding from its government and is then expected to flow a majority of the funding to the U.S. university. The U.S. university needs to ensure that the funding it receives will be available and adequate, which requires a clear understanding of the relationship between the foreign entity and its government. It is also important to ensure that the collaboration does not become a *de facto* partnership, by being clear about the nature of the relationship both in the express provisions of the agreement and in describing the relationship to third parties and to the public.

Ms. Keith pointed out that some universities have actually established foreign campuses or research institutes to provide a long-term, robust multicultural opportunity for students and faculty, while they maintain a close association with the primary institution. There are a variety of mechanisms to do this. One is for the U.S. university to actually own or lease facilities and employ the personnel. This may not be possible under the laws or customs of some jurisdictions. Also, this structure involves some special risks and burdens. There is a need to ensure that the entity follows foreign laws in areas such as human resources, environmental protection, and real estate, for example. Considerable local expertise is essential. In addition, if the

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endeavor ends, whether in an orderly, planned manner or under emergency circumstances, it is critical to factor in the need to abandon valuable assets and to address long-term contractual commitments in the foreign locale. It is important to pre-arrange contingency plans, security, and protections for assets and personnel to the greatest extent possible.

Another approach, which presents fewer financial, operational and compliance risks, is for the foreign entity to own or lease facilities and employ the people, while the U.S. university enjoys approval or veto rights on key personnel, administrative systems that affect the research endeavor, and the design and specifications for the facilities. The U.S. university would have the responsibility under the agreement to operate and have appropriate control of the research program. The foreign entity would participate in, and could also have appropriate control of, the research endeavor, and would have responsibility for performing administrative duties, employing staff, and ensuring compliance with the jurisdiction's regulatory and other legal requirements.

Establishing a foreign campus may involve long-term and very substantial financial obligations. If the U.S. university is dependent on a foreign government or entity to fund those obligations, it may be necessary to require the funding entity to secure a demand letter of credit issued by a bank in a neutral country to secure its funding commitments.

Although joint degree-granting programs are not a focus of this discussion, Ms. Keith reviewed several aspects of these. The degree program may be an add-on to the research endeavor or free-standing. These initiatives work best when there is some commonality in the quality of institutions, faculty and students. The curricula should also have some commonality or complementary elements. Each institution will need to ensure that its admission and appointment standards are met and that it has discretion for admission and appointment decisions. It may be difficult to commit faculty to be present in another country for an extended period of time, so it is important not to over-commit. In addition to traditional methods, the institution may want to consider distance learning and other options.

## 9.2 RISK AREAS AND KEY CONTRACT PROVISIONS IN INTERNATIONAL COLLABORATIONS

**Ms. Keith** then reviewed risk areas that should not dissuade undertaking a research initiative but need to be managed appropriately for the endeavor to be a success, as well as key contract provisions. Obviously, the

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university's reputation is its most valuable asset. Therefore, it is critically important to protect that reputation in the endeavor. One of the biggest reputational risks is misunderstanding the objectives of one's collaborator. Does the U.S. university share the same objectives as the foreign government and university? Are the objectives and expectations feasible and realistic? Is there wider support in the country outside the current government, or is the project dependent on a particular champion and more broadly viewed as controversial? It is very important to be clear about expectations and not to over promise. For example, the U.S. university cannot change the foreign jurisdiction's economy and probably cannot adapt some approaches to fit foreign norms. The university can share what it has done successfully, can undertake joint research and education, and provide advice, but the foreign jurisdiction must have the responsibility for adapting the information provided to its own context.

As a practical matter, it is important to recognize that most foreign governments require their laws to govern the contract. A public institution in the United States might have similar restrictions. Silence as to the governing law of the contract may be the only practical solution. In such event, the common law of "choice of law" will determine the governing law if there is a contract dispute. When another jurisdiction's law governs the contract, it is important to have counsel who is expert in those laws. There are some foreign and U.S. laws that have to govern, even if the governing law of the contract is that of a particular jurisdiction. So, for instance, in the general governing law provision, there will always be a carve-out for export controls and trade sanctions because these apply to U.S. institutions wherever they operate. Also, the laws of the jurisdiction in which activities are undertaken will govern those activities; an institution's home laws may also govern the activities, making it necessary to satisfy both sets of laws.

Tax liability can be a hidden cost that should be considered in advance. It is not only a question of whether or not the collaboration involves activities that could be taxable in a foreign jurisdiction, but also whether tax accounting and filings are required in the foreign country. This can be a significant administrative undertaking and involve substantial costs for record-keeping, accounting and legal advice and procedures. Where foreign taxation can be avoided without undermining core objectives of the endeavor, it is worth the planning time and effort to avoid the cost. Sometimes taxation in another country is triggered by the contract being signed in the foreign jurisdiction. This is one reason why it is always better to sign the legal document at home, even if there is also a ceremonial signing in the

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foreign country. Maintaining a foreign bank account, possessing a foreign office or residence, or undertaking research that generates intellectual property interests can all lead to tax liability. Many times tax treaties will have an exemption for educational activities. Tax, accounting and filing costs must be allocated to the foreign collaborator or the funding for the endeavor must be adequate to cover the core program activity costs as well as the costs associated with tax compliance. And, of course, individuals from the U.S. university who actually go abroad and spend enough time there may be subject to individual personal taxation. A citizen of a foreign country may be subject to automatic taxation there upon undertaking activities for his or her U.S. employer there. The U.S. university may need to supplement the salary of faculty and staff who are working in the foreign jurisdiction to address added tax liability.

Ms. Keith went on to identify payment provisions as a potential risk. Currency fluctuations, or restrictions on the amount of dollars that can be sent out of the country or brought into the country, can affect available funding for the research collaboration. Reporting and accounting required by U.S. government agencies is embedded in U.S. university practices but may differ considerably from what is required by a foreign government. It may be possible to specify in the contract that the university will provide the same level of reporting and accounting to the foreign government as is provided to the U.S. government.

The U.S. university also needs to allow for an adjustment in the scope of work if it turns out that funding is not adequate to the task, since obtaining additional funding might be difficult. In the European Union, there is a prohibition against governments providing what is called "state aid" to entities that would distort their market advantage. If foreign support violates the state aid rules, a clawback provision of EU law may require repayment. Sometimes it is necessary to get an opinion on state aid from an expert, to establish a contingency fund and to include a footnote about the claw back provision and opinion in the financial statements.

Termination and dispute resolution provisions are also important. The goals are to protect the institution's reputation and to provide the least controversial way to get out of the agreement if the relationship is not working well. It is usually a good idea to provide for no-cause terminations that have a fairly long lead time, as well as carve-outs for terminations that have to be undertaken quickly (such as when that is necessary to comply with law).

Ms. Keith stated that sometimes it is a good idea to create a one-year pilot project to explore the mutual interest, expectations, and objectives of

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the parties and to initially express the common program objectives at a high level. That relationship can end automatically without penalty at the end of the year unless the entities actually take the affirmative step to extend it. It is easier politically to take an affirmative act to extend a successful relationship than to take an affirmative act to terminate a relationship that is not working well.

In the dispute resolution provisions, it is usually a good idea for each party's president or other senior officer to lead informal dispute resolution before more formal processes are pursued. There might be an obligation under the contract to spend 30, 60, or 90 days at that level trying to resolve a dispute before going to the next level. If an informal resolution is not reached, providing for arbitration may be preferable to lawsuits in a foreign court. It is important to pick a neutral jurisdiction such as Singapore, London or Switzerland, and specify the rules governing arbitration. Arbitrators with extensive experience in arbitrating university research disputes should be engaged. The contract should also provide for enforcement of the arbitral decision in any court of competent jurisdiction and the agreement of both parties to venue in such courts.

The contract for a foreign or other substantial collaboration is important to the success of the endeavor, and considerable planning and analysis is necessary to structure a relationship in a practical manner. The effort is worthwhile because the approach must be both implementable and effective in the real world, as well as reasonably managing the reputational, financial, operational and legal risks of the endeavor to the parties.

**William Ferreira, Attorney at Law, Hogan Lovells LLP**, continued the discussion of contract provisions and managing international risks.

Mr. Ferreira identified international employment as an important area. International programs often require university staff to live and work overseas. These universities should have a fundamental understanding of how foreign employment law applies to them. Employment-related disputes are among the most common type of lawsuit against U.S. universities abroad. As a general rule, host country employment law applies to the employment of foreign nationals and U.S. expatriates assigned to positions overseas. Unless an exception applies, the core employment relationship—compensation, minimum wages, benefits, work hours, income tax withholding, vacation, workplace health/safety, dismissal, severance pay—is subject to foreign law. Foreign law may be substantially more protective of employee rights than U.S. law.

It may seem convenient to engage overseas staff, especially foreign nationals, as "independent contractors" or "consultants" as opposed to

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employees, in order to avoid involvement with host country employment laws, overseas payroll, and withholding foreign income taxes. However, most countries will look to substance rather than form and disregard the independent contractor or consultant designation if the arrangement between the parties suggests that an employment relationship exists. Generally, the analysis used to distinguish between employees and independent contractors is similar to the well-known U.S. analysis. Independent contractor arrangements under which the contractor receives employee-like benefits, such as paid vacation, or under which the contractor must adhere to a personnel manual or similar policies are suspect. To misclassify employees as contractors exposes an institution to host country liabilities such as payment of back taxes and social security withholdings, retroactive local benefits, vacation and holidays, and penalties. The U.S. institution should take this issue very seriously and retain adequate foreign law expertise.

With respect to immigration, in many jurisdictions, U.S. expatriates may lawfully enter a country and stay for up to ninety days before a special visa is required. However, the fact that a person's entry is lawful does not necessarily mean that the person may work in the country. Proper work authorization, such as a work permit or other nonimmigrant visa, often is required, and both developed and developing countries now take assertive approaches to immigration-related requirements. Mr. Ferreira related the experience of a U.S.-based NGO operating in Africa that was given a heavy fine because its local employees did not have valid work permits.

Mr. Ferreira observed that U.S. government funding for research and development work overseas continues to be available. Federal grantor agencies have begun scrutinizing these and other federal projects with greater frequency. Institutions have poured significant resources into federal research compliance programs in the United States, but compliance obligations are no less important when the project occurs overseas. The university's operating structure overseas is very important for federally-funded programs. The nature of the relationship between the university and, for example, its separate wholly owned entity operating overseas, can have a profound effect on cost recovery and particularly on F&A (facilities and administrative) cost recovery.

Other issues to consider involve foreign subawards. Some agencies limit F&A recovery for foreign entities. Others do not. Also, some countries might have strict rules governing the disposition of assets such as equipment and vehicles when the project is completed. If these assets are federally-funded and carry their own disposition requirements under the award, the situation can become complex.

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Conflicts of commitment for faculty can also arise in overseas work. In addition, difficult cost allowability questions often arise on overseas federal projects. For example, some federal sponsors do not consider foreign value-added tax ("VAT") payments to be reimbursable under their awards. This forces grantee universities to pursue time-consuming and uncertain applications for foreign VAT exemption. And even those sponsors that do not explicitly prohibit VAT charges might not allow all of them if, say, a VAT exemption was available but the university did not pursue it.

Federal officials consider foreign subawardees to be high-risk organizations, for many reasons. Foreign entities are typically unfamiliar with the normal U.S. federal research compliance obligations. Taking a federal award and flowing down all of the provisions to a foreign subawardee may not work, and relying on some of the popular templates for foreign subawards may not be in the university's interest. Subrecipient monitoring overseas requires time and resources, trips overseas, and plain language explanations of what the subrecipient should do to comply with the terms of the award.

Mr. Ferreira then went through a federal audit report of a university's grant program overseas, and some of the audit findings. The audit found weaknesses in procurement processes (e.g., not checking foreign vendors against the U.S. government's debarred, suspended, and specially designated nationals list). The audit also found that subrecipient monitoring was not occurring. Another finding was that the institution could not provide detailed documentation to support salary and equipment charges at the foreign site. Foreign entities may have rudimentary time-keeping systems.

One issue raised during the discussion following the panel talks was the combination of limitations on F&A cost recovery and the time and expense required to adequately monitor foreign subawards. Is it possible for U.S. institutions to adequately monitor foreign subawards given the amount of cost recovery that is allowed? Is this issue a significant barrier to collaboration that U.S. agencies should attempt to ameliorate? Another participant pointed out the potential additional problem for U.S. institutions of program officials and contract officials in U.S. agencies having different expectations regarding foreign subaward monitoring. Also, while the discussion focused on U.S. universities, U.S. agencies may also be challenged by monitoring requirements for programs in which they make direct grants to foreign entities.

It is very important, even outside the U.S. federal context, to understand the types of audits that the foreign counterpart is subject to under U.S. or foreign regulations. If these audits are not sufficient to secure the integrity

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of the relationship with a foreign institution, then the U.S. university could consider implementing its own audit requirements.

Human and animal research overseas is also a tricky area. Mr. Ferreira noted that the pharmaceutical industry often collaborates with U.S. institutions on foreign clinical research. This is a very complex topic, but a few general points are important to remember.

First, both the U.S. and foreign regulations apply in this area. In the United States we are familiar with the "Common Rule" and 45 CFR Part 46 (DHHS, 2011) for DHHS-sponsored research. In places like Bangladesh, a Bangladeshi governmental body technically must approve human subjects research by any foreign entity operating such research in Bangladesh. For legal, practical, and other reasons, it is usually a good idea to have a foreign IRB (institutional review board) take a look at the research even if a U.S. IRB has granted approval. DHHS has stated that any federally-funded research at a foreign site has to comply with the U.S. Common Rule. This creates a number of obligations with respect to IRB membership, expertise, informed consent, and tissue banking. Foreign entities may be unaware of these requirements.

A second point is that cultural sensitivities are critical, especially with regard to clinical research in developing countries. It is essential to have personnel involved who understand the cultural sensitivities.

Regarding patient care issues, it can take considerable time and effort to ascertain the rules and regulations in a foreign country that apply in areas such as credentialing health professionals entering the country. Often, local lawyers are not familiar with these rules, and may not know where to look to find the answers to questions. Therefore, significant lead time is required to actually understand what is required for your institutional clinical personnel to be able to begin treating people or conducting other medical activity.

Animal research can also raise complicated issues overseas. Any foreign entity that is conducting DHHS-sponsored animal research will have an Office of Laboratory Animal Welfare Statement of Compliance on file. Foreign collaborators may promise to comply without being able to fulfill their commitments.

Mr. Ferreira explained that the shipment of tissues, samples and biological materials is also very complicated. These are heavily regulated in the United States by multiple agencies as well as abroad. Specialized expertise is required when shipping anything that is alive (e.g., an insect or a plant), anything that is toxic, anything that is alcohol-related, or anything that is a "select agent" as defined by Centers for Disease Control.

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The U.S. government maintains a complex set of "antiboycott" laws designed to discourage, and in some circumstances prohibit, U.S. organizations from supporting or participating in boycotts of friendly countries, or furthering or supporting the boycott of Israel as sponsored by the Arab League and certain other countries. Under these laws, the receipt of a request, whether verbal or written, to further a boycott may need to be reported. These laws are very easy to break. For example, agreements to refuse or actual refusal to do business with or in Israel or with a blacklisted company could constitute a violation.

The Foreign Corrupt Practices Act (FCPA) is also relevant, but might not be on the radar of some institutions. There has recently been a significant uptick in Department of Justice enforcement actions in this area. The anti-bribery provisions of the FCPA broadly prohibit giving, offering, or promising anything of value to any foreign official for the purpose of obtaining or retaining business or any other advantage. Universities may have the perception that they cannot run afoul of FCPA because they are a nonprofit and do not deal with elected government officials, but this is actually not the case. There are a number of plausible scenarios under which universities can encounter the FCPA.

## 9.3 INTERNATIONAL COLLABORATION AND THE EUROPEAN COMMISSION'S 7TH FRAMEWORK PROGRAM

**Astrid-Christina Koch, Science Counselor for the Science, Technology and Education Section at the Delegation of the European Commission (EC)** in Washington, DC, works on strengthening trans-Atlantic research cooperation and promoting networking and mobility of researchers. She discussed collaboration in the context of the EC's 7th Framework Program (FP7), a 53 billion € program that began in 2007 and runs through 2013. The Lisbon Treaty of 2009 explicitly mentions science and technology advancement as an objective of the European Union.

There are several rationales for the EC to support trans-Atlantic research collaboration, including the imperative of solving global problems and the need to build better networks of researchers and institutions. The EC has a science and technology agreement with the United States originally signed in 1998 and renewed several times since. There is an annual meeting of the Joint Consultative Group associated with the agreement. Most collaboration under the agreement is within the context of FP7. FP7

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is open to international partners, with U.S. partners mainly supported by their own funding sources.

Dr. Koch discussed mechanics of collaboration, focusing on the Grant Agreement (GA). Signing the GA is necessary for contracting with the EC. The GA includes the Technical Description of Work (Annex I), General Conditions (Annex II), and Specific Provisions for funding schemes. There are other annexes, mainly forms. The Consortium Agreement spells out the relationship among the partners, and most of the legal issues are covered there.

Some of the terminology used by the EC differs from what is common in the United States. A "beneficiary" is an entity that is part of the GA, whether or not it is receiving funding. The "coordinator" could be the person who did all the paperwork, but most of the time corresponds to a principal investigator in the United States.

Several important principles are embodied in the GA. The EC generally does not become an owner of intellectual property generated by collaborative research. Intellectual property ownership is covered in the Consortium Agreement. The GA is aimed at "providing (a) minimum self-sustainable framework while allowing participants flexibility to determine additional rules specific for their cooperation." "Special clauses" that have been developed by the EC can be inserted into the grant agreement. Some of these address issues in U.S. law that would prevent U.S. entities from legally signing the standard GA. There are also provisions for subcontracting, sanctions, and arbitration. There are special simplifying provisions for participants not receiving funding from the EC.

The annual call for the FP7 is published in July and closes in November or December. There are currently about 200 projects with U.S. partners. The EC is working to make the program even more accessible to U.S. participants. Having three EU partners is required for funding, so the easiest way to participate is to connect with an existing partnership.

## REFERENCE

DHHS (U.S. Department of Health and Human Services). F*ederal Policy for the Protection of Human Subjects ('Common Rule')*. See http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html (accessed February 2011).

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# 10

# Summary Discussion

At the end of the workshop, participants discussed possible activities for I-Group and for others interested in helping to facilitate international research collaborations. One possibility would be to put together a primer or guide to international collaborations aimed at U.S. and foreign researchers, administrators, and sponsors. The primer would outline the necessary steps in forming and undertaking various types of collaboration, explore possible pitfalls, and point the reader toward helpful tools and information. I-Group might identify groups to sponsor the preparation of such a primer. It could be an online resource that would be updated over time.



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# Appendix A

# Workshop Agenda

Government-University-Industry Research Roundtable (GUIRR)
Working Group on International Research Collaborations ("I-Group")

**Examining Core Elements of International Research Collaboration: A Workshop**

**July 26-27, 2010**

The National Academies
500 Fifth Street, N.W.
Washington, DC 20001

**AGENDA**

***Monday, July 26***

LOCATION: The National Academies Keck 100

| | |
|---|---|
| 7:30-8:00 a.m. | Continental Breakfast |
| 8:00-8:30 a.m. | Welcome from Organizers, Workshop Goals<br>**C. D. (Dan) Mote, Jr**., President, University of Maryland at College Park |



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8:30-10:00 a.m. **Creating an Environment for Productive International Collaboration**

*The role of international collaborations in advancing knowledge and offering economic opportunities worldwide is growing, thanks to factors such as access to the Internet; globalization; and greater mobility of information, ideas, and people. Though international research collaborations also are growing (as measured, for example, by multinational co-authorship on publications and shared funding for international research projects), there are bottlenecks and frictions that can pose impediments to meaningful and successful international collaborations. This track will look broadly at trends and issues that pertain to fostering productive international collaboration from the point of view of governments, universities, and industry.*

- Moderators—**Celia Merzbacher**, Vice President, Innovative Partnerships, Semiconductor Research Corporation *and* **John Carfora**, Associate Vice President for Research Advancement and Compliance, Loyola Marymount University-Los Angeles
- Five speakers (15 minutes each)
  - —**Lawrence Gumbiner**, Deputy Assistant Secretary of State for Science, Space & Health, U.S. Department of State
  - —**Rafic Makki**, Executive Director and interim Executive Director of Higher Education, Abu Dhabi Education Council
  - —**John Kirkland,** Deputy Secretary General, Association of Commonwealth Universities, London
  - —**Low Teck Seng**, Executive Director, A*STAR's Science and Engineering Research Council (Singapore)
  - —**Eduardo Lopez Moreno**, Director, Urban Monitoring Division, United Nations Human Settlements Division
- Q&A (15 minutes)

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10:00-10:10 a.m. Break

10:10-11:40 a.m. **Cultural Differences and Nuances**

*Quite often cross-cultural nuances and culture-centric perspectives—grounded in one's experience or merely assumed—often cloud conversations between faculty researchers and research administrators when they are negotiating the shared development of meaningful international research agreements. In this session we will hear from a number of experts on cross-cultural communications, understanding, and collaborations.*

- Moderator—**John Carfora**, Associate Vice President for Research Advancement and Compliance, Loyola Marymount University-Los Angeles
- Four speakers (20 minutes each)
  - —**Riall Nolan**, Vice Provost for International Programs, Purdue University
  - —**Christopher Williams**, Representative, UN-HABITAT Washington Office
  - —**Tembeka Mpako-Ntusi**, South African Research and Innovation Managers' Association; Director of Research, Cape Peninsula University of Technology, Cape Town, S.A.
  - —**Elias Wondimu**, Publisher and Editorial Director, Tsahai Publishers, Marymount Institute Press, African Academic Press
- Q&A (10 minutes)

11:40 a.m.-12:30 p.m. **Ethics**

*The ethics panel stands between the culture panel and the research integrity panel in the sense that ethics are informed by culture and govern behavioral choices in the conduct of research. This panel will explore issues related to the ethics of safeguarding privacy/ security/ and confidentiality; bioethical issues related to human subjects research as well as other activities with bioethical implications, all from both a domestic U.S. and a global perspective.*

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- Moderator – **Barbara Mittleman**, Director, Public-Private Partnership Program, Office of Science Policy, Office of the Director, National Institutes of Health (NIH)
- Three speakers (15 minutes each)
  —**Susan Butts**, Senior R&D Director [retired], Dow Chemical Company
  —**Lisa Bero**, Professor, University of California-San Francisco
  —**Stephanie Bird**, co-Editor-in-Chief, *Science and Engineering Ethics*
- Q&A (5 minutes)

12:30-1:30 p.m. Lunch

Introduction: **John Carfora**, Associate Vice President for Research Advancement and Compliance, Loyola Marymount University-Los Angeles

KEYNOTE SPEAKER: **Nina Fedoroff**, Science and Technology Adviser to the Secretary of State and to the Administrator of USAID

***"International Research Collaborations: The Promise and the Practice"***

1:30-2:20 p.m. **Research Integrity and the Responsible Conduct of Research**

*The research integrity panel continues the ethics discussion by focusing on standards and practices that promote responsible data collection and appropriate authorship byline decisions. The panel will explore issues related to current RCR training for data integrity and authorship as well as consider the impact that different international PhD educational standards can have on data integrity. The panel will conclude with a discussion by an international team who will describe their experiences in negotiating authorship agreements and in building capacity to assure data integrity.*

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- Moderator – **Sandra Titus**, Director, Intramural Research, Office of Research Integrity, Department of Health and Human Services (DHHS)
- Three presentations (15 minutes each)
  - —**David Resnik**, Bioethicist, Chair of National Institute of Environmental Health Sciences (NIEHS) Institutional Review Board, National Institutes of Health (NIH)
  - —**Philip Altbach,** Director of the Center for International Higher Education, Boston College
  - —**William Blattner**, Director and Principal Investigator for the Institute of Human Virology HIV Vaccine Trials Unit, University of Maryland *and* **Aliyu Gambo Gumel**, Fogarty International Research Fellow
- Q&A (5 minutes)

2:20-3:10 p.m. **Risk Management**

*Risk Management is a continuous process designed to proactively identify and mitigate risks to help promote the achievement of the organization's objectives, strategy, and mission. Risk management also drives accountability and integrity of the organization's work and helps ensure individuals within the organization see it as their responsibility to reduce risk as part of their daily jobs. The panel will explore specific issues relating to risk management in the international setting.*

- Moderator – **John J. McGowan**, Deputy Director, National Institute of Allergy and Infectious Disease (NIAID)
- Three speakers (15 minutes each)
  - —**Manning Muntzing**, A Founder and Director of the International Risk Governance Council
  - —**Suzanne Servis**, Director, Risk Management Program, National Institutes of Health
  - —**Maria Velez de Berliner**, Managing Partner, Intelligent Decision Partners, LLC
- Q&A (5 minutes)

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3:10-3:20 p.m. Break

3:20-4:10 p.m. **Intellectual Property**

*Intellectual Property (IP) is a central issue in international research collaborations. What is the balance between the facilitation of research and the protection of IP? The members of the IP track will discuss and outline the major issues, challenges, and successes of IP on the international level. This will include such topics as background intellectual property (BIP), the connection between IP and export control, the management of IP at the university, industry, and governmental levels, and emerging issues in the coming years (such as managing IP given the increasing transportation of large data sets and research across national borders). The IP team will pay particular attention to practices and models of IP used in individual countries, for inclusion in project deliverables.*

- Moderator – **James Casey**, Director of Contracts and Industrial Agreements, University of Texas at San Antonio
- Two speakers (20 minutes each)
  —**Brian Warshawsky**, Senior Contracting Officer, Northwestern University
  —**Brian Fitzgerald**, Professor, Queensland University of Technology Faculty of Law, Australia
- Q&A (10 minutes)

4:10-5:10 p.m. **Export Controls**

*Export control regulation presents special challenges when working with international collaborators and when conducting research overseas. Researchers who are used to open academic environments are often surprised to learn that certain areas of collaboration, especially in science and engineering, may be more difficult with certain international partners. In addition, trade embargoes and sanctions, reflecting foreign policy concerns of different nations, can*

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*affect a researcher's ability to travel to certain countries and transport certain research equipment. The Export Control panel will discuss the various issues raised by these regulations, their effect on international research collaborations, and compliance strategies used by various institutions to meet these challenges.*

- Moderator, **Giulia Del Brenna**, Head of Unit, Competitiveness in the Pharmaceuticals Industry and Biotechnology, European Commission, DG Enterprise and Industry
- Five speakers (10 minutes each)
  —**Steven Pelak**, Deputy Chief, Counterespionage Section, U.S. Department of Justice
  —**Richard Johnson**, Senior Counsel and Senior Partner (Ret.), Arnold & Porter LLP
  —**Steven Eisner**, Export Control Officer, Stanford University
  —**Michael Gold**, Director, Washington DC Operations and Business Growth, Bigelow Aerospace
  —**Emmanuel de Lipkowski**, Space Attaché and CNES Representative, Embassy of France
- Q&A (10 minutes)

5:10-5:30 p.m. Recap; Review Break-out Plans for Meeting Day Two

6:30 p.m. Dinner—National Academies Keck Center, 3rd Floor Atrium

Introduction: **James Casey**, Director of Contracts and Industrial Agreements, University of Texas at San Antonio

KEYNOTE SPEAKER: **Kathie L. Olsen**, Vice President, International Programs, Association of Public and Land-Grant Universities (APLU)

***"Internationalization/Globalization of Higher Education"***

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***Tuesday, July 27***

LOCATION: The National Academies Keck 100

8:00-8:30 a.m. Continental Breakfast

8:30-10:00 a.m. Plenary Session: **Legal Issues and Agreements**

*Conducting research with foreign partners can take a wide variety of forms. Sometimes this involves conducting research in the U.S. with foreign partners; other times it may involve field research, setting up limited business operations, or even establishment of a new campus overseas. This panel will discuss the legal issues related to these various scenarios. The speakers will discuss registration and memoranda of understanding with foreign governments and governmental approvals. It will also cover legal agreements and documents used to facilitate particular business activities, such as payment of taxes, real estate issues, and employment requirements. The panel will cover methods used by institutions to incorporate legal review into ongoing operations. In addition, the panel will discuss the research funding opportunities and challenges presented by the European Union's 7th Framework Programme.*

- Moderator: **Patrick Schlesinger**, Assistant Vice Chancellor, Research Administration and Compliance, University of California, Berkeley
- Three speakers (25 minutes each)
  - —**William Ferreira**, Attorney at Law, Hogan Lovells LLP
  - —**Jamie Lewis Keith**, Vice President and General Counsel, University of Florida
  - —**Astrid-Christina Koch**, Science, Technology and Education, Delegation of the European Union
- Q&A (15 minutes)

10:00-10:10 a.m. Break

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10:10 a.m.-12:30 p.m. Track-Specific Break-out Groups

— Ethics (Keck 202)
  - **Norka Ruiz Bravo**, Advisor, Research Policy Development, Pan American Health Organization (PAHO)*
  - **Barbara Mittleman**, Director, Public-Private Partnership Program, Office of Science Policy, Office of the Director, National Institutes of Health (NIH)
  - **Lisa Bero**, Professor, University of California, San Francisco
  - **Susan Butts**, Senior R&D Director [retired], Dow Chemical Company
  - **Rachelle Hollander**, Director, Center on Engineering Ethics, National Academy of Engineering
  - **Kelly Joyce**, Program Director , Science, Technology, and Society Program, NSF

— Research Integrity and the Responsible Conduct of Research (Keck 100)
  - **Sandra Titus**, Director, Intramural Research, Office of Research Integrity, Department of Health and Human Services (DHHS)*
  - **William Blattner**, Institute for Human Virology, University of Maryland
  - **Miriam Kelty**, Consultant, Bioethics and Research Strategy and Chair, Inter-Institute Bioethics Interest Group, National Institutes of Health
  - **Sheila Garrity**, Director, Division of Research Integrity, Johns Hopkins University School of Medicine
  - **Sharon E. Moss**, Health Science Specialist, Research Integrity & Assurance, Office of Research Oversight, U.S. Department of Veterans Affairs

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- **Adil Shamoo**, Editor-in-Chief, *Accountability in Research*, University of Maryland School of Medicine
- **Stephanie Bird**, Editor, Science and Engineering Ethics
- **Cynthia Kleppinger**, Medical Officer, U.S. Food and Drug Administration (FDA)
- **Susan M. Russell**, Business Development, Oncology, GlaxoSmithKline
- **John Krueger**, Division of Investigative Oversight, Office of Research Integrity, Department of Health and Human Services
- **Aliyu Gambo Gumel**, Fogarty International Research Fellow

— Intellectual Property (Keck 205)

- **James Casey**, Director of Contracts and Industrial Agreements, University of Texas at San Antonio*
- **Louis Rodriquez**, Deputy General Counsel, Southwest Research Institute (SwRI)
- **Brian Fitzgerald**, Professor, Queensland University of Technology, Australia
- **Ma Jun**, Director, Tsinghau University (Beijing, China)
- **Steve Merrill**, Director, Board on Science, Technology and Economic Policy, The National Academies
- **Bernard Trombley**, Director, Huron Consulting Group
- **Ann Hammersla**, Esq., Director, Division of Policy, Office of Technology Transfer, National Institutes of Health
- **Brian M. Warshawsky**, Senior Contracting Officer Northwestern University
- **Eskil Ullberg**, ICES-George Mason University [Sweden]

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— Risk Management (Keck 208)
- **Celia Merzbacher**, Vice President, Innovative Partnerships Semiconductor Research Corporation*
- **Manning Muntzing**, International Risk Governance Council
- **Maria Velez de Berliner**, Managing Partner, Intelligent Decision Partners, LLC
- **Suzanne Servis**, Director, Risk Management Program, National Institutes of Health
- **Ron Kaese**, The Maryland Technology and Development Corporation

— Export Controls (Keck 213)
- **Patrick Schlesinger**, Assistant Vice Chancellor, Research Administration and Compliance, University of California, Berkeley*
- **Giulia Del Brenna,** Head of Unit, Competitiveness in the Pharmaceuticals Industry and Biotechnology, European Commission, DG Enterprise and Industry*
- **John Carfora**, Associate Vice President for Research Advancement and Compliance, Loyola Marymount University-Los Angeles*
- **Steven Eisner**, Export Control Officer, Stanford University
- **Susan Wyatt Sedwick**, Associate Vice President for Research and Director of Sponsored Projects, University of Texas at Austin
- **Bernie Kritzer**, Director of Outreach, Bureau of Industry and Security, U.S. Department of Commerce
- **Emmanuel de Lipkowski**, Space Attaché and CNES Representative, Embassy of France

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- **Michael Gold**, Director, Washington DC Operations and Business Growth, Bigelow Aerospace
- **Steven Pelak**, Deputy Chief, Counterespionage Section, U.S. Department of Justice
- **David Brady**, Director, Office of Export and Secure Research Compliance, Virginia Polytechnic Institute and State University

12:30-1:30 p.m. Lunch (Keck 100)

1:30-2:00 p.m. Track-Specific Break-out Groups – *continued*

— Ethics (Keck 202)
— Research Integrity and the Responsible Conduct of Research (Keck 100)
— Intellectual Property (Keck 205)
— Risk Management (Keck 208)
— Export Controls (Keck 213)

2:00-3:00 p.m. Reports from Break-out Groups (~10 minutes per group)

3:00-3:30 p.m. Summary Discussion and Next Steps (Keck 100)

3:30 p.m. Adjourn

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# Appendix B

# Workshop Participants

**Philip Altbach**
Professor
Boston College

**Sam Armstrong**
General
USAF (Retired)

**Tom Arrison**
Senior Staff Officer
National Research Council

**Claudette Baylor-Fleming**
Administrative Coordinator
Federal Demonstration Partnership

**William Behn**
Senior Science Advisor
U.S. Department of State

**Lisa Bero**
Professor
University of California, San Francisco



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*Science and Engineering Ethics*

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Executive Director
Policy and Global Affairs
National Research Council

**William Blattner**
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University of Maryland Medical School

**Anthony Boccanfuso**
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University-Industry Demonstration Partnership

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**Gila Budescu**
Director, Sponsored Research & Program Development
The Rockefeller University

**Susan Butts**
Senior R&D Director (retired)
The Dow Chemical Company

**John Carfora**
Associate Vice President for Research Advancement and Compliance
Loyola Marymount University

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Director of Division of Policy
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The National Academies

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University of Illinois, ISTEM

**Rachelle Hollander**
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NIAID Designated Presidential Management Fellow (PMF)
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National Science Foundation

**Ma Jun**
Director
Tsinghua University

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**Karumuna Kaijage**
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Vice President and General Counsel
University of Florida

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Associate Director for Extramural Affairs (retired)
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National Institutes of Health

**John Kirkland**
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**Manning Muntzing**
Co-founder and Director
International Risk Governance Council

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# Appendix C

# Bio Sketches of Planning Committee Members, Workshop Agenda Speakers and Staff

## PLANNING COMMITTEE MEMBERS

**John Carfora** (*Co-Chair*) is currently Associate Vice President for Research Advancement and Compliance at Loyola Marymount University in Los Angeles. He was a Research Scholar at Radio Free Europe-Radio Liberty in Munich, Germany, in the 1970s, where he authored studies on social, economic and political themes for radio broadcasts in Russian and other languages. He has been a professor of economics and an international consultant with clients such as American Airlines, Disney, and *U.S. News and World Report*. Dr. Carfora also served as Director of International Education at the Russian Academy of Management in Moscow, and was founding Curator of the Sir Leonard Bertram Schapiro Collection at the British Library of Political and Economic Sciences. He holds graduate degrees from a number of colleges and universities, including The London School of Economics, Harvard University, and a doctorate from Teachers College, Columbia University.

**James Casey** (*Co-Chair*) is Director of the Office of Contracts and Industrial Agreements (OCIA) at The University of Texas at San Antonio (UTSA). Building upon 17 years experience in research and grant administration, in his current role he established and manages the OCIA, negotiates research and sponsored project agreements, and expands industrial partnerships. Prior to joining UTSA in June 2008, Jim held the position of Visiting Professor



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of Leadership at the Upper Iowa University campus in Hong Kong, China. His research administration career includes tenures at large and medium size universities, most notably Northwestern University and the University of Wisconsin-Madison. He holds a BA *cum laude* in political science from the University of Wisconsin-Whitewater; MA, international political economy, from Marquette University; MPA, urban administration, from the University of Dayton; and JD from the University of Dayton School of Law.

**Dr. KunMo Chung** is an internationally recognized energy engineer and science and technology educator. He served twice as Minister of Science and Technology in South Korea, is former chairman and CEO of the Korea Science and Engineering Foundation, and is former President of the Korean Academy of Science and Technology. As an educator, Dr. Chung has been Professor of Energy Engineering at MIT, Polytechnic Institute of New York (PINY), Korea Advanced Institute of Science and Technology (KAIST), Ajou University, and Ecole Polytechnique Federale de Lausanne (EPFL). Dr. Chung was founding provost of KAIST, which has become a preeminent science and engineering university. He is a Foreign Member of the U.S. National Academy of Engineering, and helped found the International Risk Governance Council (IRGC) in Geneva.

**Giulia Del Brenna** has worked as an Administrator in the European Commission since April 1996 in a number of positions. She has followed developments in European Pharmaceutical Policy since being appointed Assistant to the Director-General in May 2005. She has been appointed Head of the Unit "Competitiveness in the Pharmaceuticals industry and Biotechnology" in October 2008. Since then, she has been in charge of the dialogue with the Pharmaceuticals and Biotech industry as well as the cooperation among Pricing and Reimbursement authorities in the European Union.

**Celia Merzbacher** is Vice President for Innovative Partnerships at the Semiconductor Research Corporation (SRC). She is primarily responsible for developing partnerships with stakeholders in government and the private sector in support of SRC's research and education goals. Prior to joining SRC, Dr. Merzbacher was Assistant Director for Technology R&D in the White House Office of Science and Technology Policy (OSTP), where she coordinated and advised on a range of issues, including nanotechnology, technology transfer, technical standards, and intellectual property. Previously, she was on the staff of the Naval Research Laboratory in Washington, DC.

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**Barbara B. Mittleman** is the Director of the NIH Public-Private Partnership Program of the U.S. National Institutes of Health (NIH). In this capacity she works to develop a wide range of partnerships between the NIH and industry, foundations, academic institutions, and other entities both in the United States and abroad. Dr. Mittleman is an internist and rheumatologist and trained at the University of Pittsburgh for medical school, residency and fellowship. She came to the NIH in 1991 to pursue post-doctoral laboratory research training in cellular immunology and autoimmunity. Her current research interests include biomarkers, particularly for systemic lupus erythematosus (SLE), health disparities, and bioethics.

## AGENDA SPEAKERS

**Philip G. Altbach** is J. Donald Monan, S.J. University Professor and Director of the Center for International Higher Education in the Lynch School of Education at Boston College. He has taught at Harvard University, the University of Wisconsin-Madison, and the States University of New York at Buffalo, and been a visiting scholar at the SciencesPo, Paris, France, the University of Bombay, India, and is a guest professor at Peking University, China. He is author of *Turmoil and Transition: The International Imperative in Higher Education, Comparative Higher Education, Student Politics in America,* and other books. His most recent book is *World Class Worldwide: Transforming Research Universities in Asia and Latin America.* Philip Altbach holds a BA, MA, and PhD from the University of Chicago.

**Lisa A. Bero** is a Professor in the Department of Clinical Pharmacy, School of Pharmacy and Institute for Health Policy Studies, School of Medicine, University of California, San Francisco. She is a pharmacologist with primary interests in how clinical and basic sciences are translated into clinical practice and health policy. She is Vice Chair in the Department of Clinical Pharmacy and Chair of the UCSF Chancellor's Advisory Committee on Conflicts of Interest. Dr. Bero is an advisor to the World Health Organization Department of Essential Medicines and Pharmaceutical Policies and serves on several national and international committees related to conflicts of interest and research, such as the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education and Practice.

**Stephanie J. Bird** is an independent consultant and co-Editor-in-Chief of *Science and Engineering Ethics*, an international publication that explores

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ethical issues of concern to scientists and engineers. Now in its 16th year, the journal is widely abstracted and indexed and has been cited by the National Academies as a leading resource for scholarly articles on research integrity. Dr. Bird was formerly Special Assistant to the Provost and Vice President for Research of the Massachusetts Institute of Technology (MIT). She is a laboratory-trained neuroscientist whose current research interests emphasize the ethical, legal and social policy implications of scientific research, especially in the area of neuroscience.

**William J. Blattner** has pioneered studies of the epidemiology and prevention of the human retroviruses, HIV and HTLV since 1980. Focusing on Nigeria in collaboration with the Centers for Disease Control, he is playing a key role in developing capacity for implementing the President's Emergency Plan for AIDS Relief by supporting laboratory capacity building, training of providers and developing implementation structures. Dr. Blattner graduated from Washington University School of Medicine, interned at Strong Memorial Hospital, completed residencies at the New York Cornell Medical Center and Memorial Sloan Kettering Cancer Institute and did his oncology training at the National Cancer Institute (NCI) in Bethesda. He joined the Environmental Epidemiology Branch of NCI in 1976 and served for over two decades, retiring in 1995 as founding Chief of the Viral Epidemiology Branch.

**Susan Butts** recently retired as Senior Director of External Science and Technology Programs at The Dow Chemical Company. In this capacity she was responsible for Dow's contract research activities with U.S. and European government agencies and sponsored research programs at over 150 universities, institutes, and national laboratories worldwide. Before joining the External Technology group she held several other positions at Dow including Senior Resource Leader for Atomic Spectroscopy and Inorganic Analysis within the Analytical Sciences Laboratory, Manager of PhD Hiring and Placement, Safety and Regulatory Affairs Manager for Central Research, and Principal Investigator on various catalysis research projects in Central Research. Dr. Butts holds a BS in Chemistry degree from the University of Michigan and a PhD degree in organometallic chemistry from Northwestern University.

**Steve Eisner** has served as Stanford University's Export Control Officer since January 2006, overseeing institutional compliance with export con-

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trols (EAR, ITAR) and trade sanctions regulations (OFAC) for both Stanford and the SLAC National Accelerator Laboratory. Steve began his career in Washington, D.C. as a budget officer for international trade programs at the Office of Management and Budget (OMB) and as an export control specialist at the law firm of Arnold & Porter. Mr. Eisner holds a BA from Stanford University and a Master of International Affairs from Columbia University's School of International and Public Affairs (SIPA), where he was Associate Editor of Columbia's Journal of International Affairs.

**Nina V. Fedoroff** is the Willaman Professor of the Life Sciences and an Evan Pugh Professor at Pennsylvania State University, as well as a member of the External Faculty of the Santa Fe Institute. She has also served on the faculties of the Carnegie Institution of Washington and the Johns Hopkins University. She has served as the Science and Technology Adviser to the Secretary of State and is President of the American Association for the Advancement of Science (AAAS). Dr. Fedoroff received the National Medal of Science in 2006, and is a member of the National Academy of Sciences and the American Academy of Arts and Sciences. She received her PhD in Molecular Biology from the Rockefeller University.

**William Ferreira** is Attorney at Law, Hogan Lovells LLP. His practice covers a broad range of government grants and contracts compliance and regulatory issues. A significant portion of his practice involves representation of colleges, universities, and other institutions engaged in federally sponsored activity. In addition, Bill has done significant work for institutions on the operational aspects of conducting federally sponsored and other activity overseas. Mr. Ferreira's experience involves the operational and business aspects of setting up programs abroad (including in developing countries), and addressing the unique challenges of global operations and foreign collaborations. He received his BA, *summa cum laude,* from the University of Notre Dame and his JD, *magna cum laude*, Order of the Coif, from Georgetown University Law Center.

**Brian Fitzgerald** is a Professor at Queensland University of Technology (QUT), Faculty of Law, in Australia. He is well known in the areas of Intellectual Property and Internet Law and has worked closely with Australian governments on facilitating access to public sector information. From 1998-2002 he was Head of the School of Law and Justice at Southern Cross University in New South Wales, Australia and from January 2002

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to January 2007 was appointed as Head of the School of Law at QUT in Brisbane, Australia. Mr. Fitzgerald is currently a specialist Research Professor in Intellectual Property and Innovation at QUT, Honorary Professor at City University of London and Chief Investigator in the ARC Centre of Excellence for Creative Industries and Innovation. He studied law at the Queensland University of Technology graduating as University Medallist in Law and holds postgraduate degrees in law from Oxford University and Harvard University.

**Michael Gold** currently serves as Bigelow Aerospace's Director of D.C. Operations & Business Growth. He is responsible for a broad array of activities at Bigelow Aerospace including international business development; export control; media, corporate, and federal relations; as well as NASA Space Act Agreement implementation, patent report maintenance, and general strategic planning. Prior to joining Bigelow Aerospace in a full-time capacity, Mr. Gold previously assisted the company as an attorney in the Washington office of Patton Boggs, LLP. In September of 2008 Mr. Gold was appointed by the Secretary of the U.S. Department of Transportation to serve on the Commercial Space Transportation Advisory Committee ("COMSTAC"). Mr. Gold is a member of the District of Columbia and New York State Bar Associations, and graduated from the University of Pennsylvania Law School.

**Lawrence J. Gumbiner** is Deputy Assistant Secretary of State for Science, Space & Health. In this position, he is in charge of managing a team of more than 50 foreign affairs professionals and programs in the areas of Science & Technology Cooperation, Space & Advanced Technologies, and International Health and Biosafety. His previous State Department positions include Director of Environmental Policy for the Bureau of Oceans, Environment & Science and Counselor for Economic Affairs at the U.S. Embassy in Bogota, Colombia. Mr. Gumbiner joined the U.S. Department of State in 1988. He holds a BA from the University of California at Davis, and a JD from Hastings College of the Law. He is licensed to practice law in the State of California.

**Richard Johnson** retired as senior partner after 30 years in Arnold & Porter LLP's Washington, DC office, but continues an active practice as senior counsel. He focuses his practice on: legal and regulatory issues related to research and innovation—especially in biotechnology and the life sciences,

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nanotechnology, energy technology, and next-generation information technology; and international trade, intellectual property, national security, export controls, and global regulatory matters related to fundamental research, entrepreneurship, and innovation. He formerly served as General Counsel for International Trade at the U.S. Commerce Department. He received his Juris Doctor degree from the Yale Law School where he was Editor of the Yale Law Journal, his Master's degree from the Massachusetts Institute of Technology (MIT), and his undergraduate degree with Highest Honors from Brown University.

**Jamie Lewis Keith** is Vice President and General Counsel of the University of Florida, a position she assumed in October 2006. She is responsible for all of the legal affairs of this large public research university and leads the university's General Counsel's Office. She was previously the Senior Counsel of the Massachusetts Institute of Technology. Prior to joining MIT, Ms. Keith was a junior partner at the Boston law firm of Hale and Dorr LLP (now Wilmer Cutler Pickering Hale and Dorr LLP), and served in former Governor William Weld's Administration. Ms. Keith graduated from Cornell University, College of Arts and Sciences, and *magna cum laude* from Boston University School of Law, where she was an outside Article Editor on the Law Review.

**Astrid-Christina Koch** is Science Counselor of the "Science,Technology and Education" section at the Delegation of the European Commission (EC) in Washington, DC. She works towards better awareness of funding opportunities, bringing teams together to strengthen transatlantic research cooperation and promotes networking and mobility of researchers. Prior to this assignment she was employed as Program Officer for Advanced Materials in the Research Directorate of the European Commission. Before joining the Commission she worked as senior managing scientific officer in the German Ministry of Finance and as lecturer and chemist at the German Customs Science & Training Center. Astrid holds a Ph.D. in Natural Sciences from Kiel University.

**Emmanuel de Lipkowski** is Space Attaché and Representative for the French space agency, the Centre National d'Etudes Spatiales (CNES) in the French Embassy in the United States. Before his appointment in June 2007, he served as Counsellor for bilateral relations with the American Continent. From 2003 to 2006 he served as General Secretary of the French

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Parliamentary Space Committee (Staffer of the French Assemblée Nationale and Senate). Mr. de Lipkowski has also held positions with the European Commission. He holds a Master of International Relations degree from the Free University of Brussels (ULB), and a Master of International Trade from the CESI.

**John J. McGowan** is Deputy Director for Science Management and Operations at the National Institute of Allergy and Infectious Diseases (NIAID). He joined NIAID in 1986 as a Program Officer in the AIDS Program, which later became the Division of AIDS (DAIDS), and also served as Associate Director of the Basic Research and Development Program, and Director of the NIAID Division of Extramural Activities. Prior to joining NIAID, Dr. McGowan was on the faculty of the Uniformed Services University of the Health Sciences. He is widely recognized in the extramural community for networking skills, the ability to bring disparate groups together, and the capacity to work out viable solutions to issues confronting an organization.

**Rafic Makki** is currently serving as Executive Director, Office of Planning and Strategic Affairs and interim Executive Director of Higher Education, Abu Dhabi Education Council. From 1984-2003, Rafic served on the faculty of the University of North Carolina at Charlotte, where he was promoted to the rank of Professor of Electrical Engineering in 1995 and directed the computer engineering program from 2000-2003. In the UAE, Dr. Makki held the position of Dean of the College of Information Technology at UAE University, where he led the building of seven degree programs and the recruitment of over 40 faculty members. He also served as VP of Research at the Masdar Institute of Science and Technology. He received a PhD in Electrical Engineering in 1983 from Tennessee Tech University.

**Eduardo López Moreno** is the Director of City Monitoring within the Monitoring and Research Division, UN-HABITAT, the United Nations Human Settlements Programme headquartered in Nairobi, Kenya. He has over 20 years of academic and professional experience in housing and urban development policies, institutional analysis and urban poverty alleviation issues. Dr. López Moreno is the Task Manager and principal author of the *State of the World's Cities Report 2006/7,* 2008/9 and 2010/11, one of the UN-HABITAT flagship reports. He received a PhD in urban geography and a master's in urban sociology from the University of Paris III-Sorbonne in France. He also

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received a BA in Architecture from the University of Guadalajara, Mexico.

**C. D. (Dan) Mote, Jr.** is Glenn L. Martin Institute Professor of Engineering and former President of the University of Maryland. Prior to assuming the Presidency at Maryland, Dr. Mote served as Vice Chancellor at the University of California at Berkeley, held an endowed chair in Mechanical Systems and was President of the UC Berkeley Foundation. He has served as vice chair of the Department of Defense Basic Research Committee, and is a member of the Council of the National Academy of Engineering. His science policy work includes serving on the committee that authored the National Academies' *Rising Above the Gathering Storm* report and participating in the Leadership Council of the National Innovation Initiative, an activity of the Council on Competitiveness. In 2005 he received the Founders Award from the National Academy of Engineering in recognition of his comprehensive body of work on the dynamics of moving flexible structures and his leadership in academia.

**Tembeka Mpako-Ntusi** is Director of Research at the Cape Peninsula University of Technology in Cape Town, South Africa. She started her career as a social worker in the Transkei Government, followed by an academic career at the University Fort Hare and the University of Transkei. In 1991 Dr. Tembeka Mpako-Ntusi was Visiting Professor at the School of Advanced International Studies at Johns Hopkins University. She holds BA (Social Work) and BA (Hons) Social Sciences degrees from the University of Fort Hare. She completed a Diploma in Tertiary Education at the University of South Africa, followed by an MSc in Social Work at the University of Wales in Cardiff. In 1996 she obtained a PhD at Bryn Mawr College, supported by a Fulbright Scholarship.

**L. Manning Muntzing** is a Founder and Director of the International Risk Governance Council, based in Geneva, Switzerland. As the former director of regulation for the U.S. Atomic Energy Commission (whose functions now are overseen by the Nuclear Regulatory Commission) from 1971 to 1975, Mr. Muntzing was responsible for considering any possible threats to human health and safety posed by nuclear power plants, including accidents, natural disasters or intentional acts of sabotage. After leaving the AEC in 1975, he went into the private practice of law, specializing in energy law with clients in the United States and abroad. He is a graduate of the University of North Carolina at Chapel Hill and Harvard Law School. He

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also attended Princeton University's Woodrow Wilson School for Public and International Affairs.

**Riall Nolan** is Professor of Anthropology at Purdue University, where he was Associate Provost and Dean of International Programs from 2003-2009. He received his doctorate in Social Anthropology from Sussex University, and lived overseas for nearly twenty years, in North and West Africa, Asia, and the Southwest Pacific, working in higher education and international development. Prior to coming to Purdue, Dr. Nolan managed international programs at the University of Pittsburgh, Golden Gate University, and the University of Cincinnati. He has also held administrative and teaching positions at the School for International Training, Georgia State University, and the University of Papua New Guinea.

**Kathie L. Olsen**, PhD, is Founder and Managing Director of ScienceWorks Consulting. She was previously Vice President, International Programs at the Association of Public and Land-grant Universities (APLU). She has served in a number of science policy leadership positions in the federal government, including Deputy Director and Chief Operating Officer of the National Science Foundation (NSF); Associate Director and Deputy Director for Science at the Office of Science and Technology Policy in the Executive Office of the President; and Chief Scientist for the National Aeronautics and Space Administration (NASA). Dr. Olsen earned a BS in Biology and Psychology with honors from Chatham College and PhD in Neuroscience from the University of California, Irvine.

**Steven W. Pelak** currently serves as the Deputy Chief of the Counterespionage Section of the Department of Justice and as the Justice Department's National Coordinator for Export Enforcement. In these positions, he supervises investigations and prosecutions of export control and embargo violations across the country along with espionage and other national security investigations and prosecutions. Mr. Pelak previously served as an Assistant United States Attorney in the District of Columbia, and practiced law with Washington, DC, firms Arnold & Porter and Hughes Hubbard & Reed. He graduated *cum laude* from Kalamazoo College and the University of Michigan Law School.

**David B. Resnik**, Bioethicist, is Chair of the National Institute of Environmental Health Sciences (NIEHS) Institutional Review Board, National

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Institutes of Health. Dr. Resnik was an Associate and Full Professor of Medical Humanities at the Brody School of Medicine at East Carolina University (ECU) from 1998-2004, and an Associate Director of the Bioethics Center at ECU and University Health Systems from 1998-2004. He previously held faculty positions at the University of Wyoming. He holds an MA and PhD in philosophy from the University of North Carolina at Chapel Hill and a JD from Concord University School of Law. He received his BA in philosophy from Davidson College.

**Patrick Schlesinger** leads the Office of Research Administration and Compliance at the University of California at Berkeley. That office includes Berkeley's Office for the Protection of Human Subjects, Office of Animal Care and Use, the Conflict of Interest Committee, and the Sponsored Projects Office. The office also provides support to the campus on export control issues. Prior to joining UC Berkeley in December 2008, Mr. Schlesinger served as the systemwide Director of Research Compliance at the UC Office of the President. Prior to joining UC, Mr. Schlesinger was a partner in the San Francisco law firm of Landels, Ripley and Diamond and worked as a staff attorney at the U.S. Environmental Protection Agency.

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**Suzanne J. Servis** is the Director of the Office of Management Assessment in the Office of the Director, National Institutes of Health. She heads an office that is at the center of NIH integrity issues, investigations, and internal controls, and oversees a number of NIH-wide management support systems, including the NIH privacy program, the NIH Policy Manual, and others. She previously held positions at the Department of Defense, the National Weather Service, the National Oceanic and Atmospheric Administration, and Research Foundation of the State University of New York.

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Ms. Servis received her undergraduate degree from the State University of New York at Albany

**Sandra Titus**, PhD, is Director of Intramural Research at the Office of Research Integrity (ORI), Department of Health and Human Services. She is responsible for establishing and implementing the research agenda for ORI. Recent studies have focused on faculty awareness of research misconduct and their perceptions of institutional integrity, the role and capabilities of research integrity officers who implement the research misconduct regulations and faculty involvement in mentoring or advising their PhD candidates. Prior to joining ORI eight years ago, Dr. Titus worked at the Food and Drug Administration. She currently is on the nursing faculty at the Uniformed Services University. Dr. Titus has a social psychology, public health and nursing background; she did her undergraduate work at Wagner College, Staten Island, NY, and her graduate work at the University of Minnesota.

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**Brian Mitchell Warshawsky** is licensed to practice law in Michigan, Illinois, and Florida, and has over 20 years of experience negotiating complex agreements with the major companies and governments from all over the world. He currently serves as the Senior Contracting Officer for Northwestern University's Office for Sponsored Research. In his current position he focuses on contract negotiations and regulatory compliance including issues of foreign national participation in research and export controls. Prior

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to joining Northwestern University, Mr. Warshawsky served in a similar capacity for the Gas Technology Institute, the energy research think tank, located in Des Plaines, Illinois.

**Christopher W. Williams** is the Washington Representative for the United Nations Human Settlements Programme (UN-Habitat), the Nairobi-based agency of the United Nations responsible for housing and urban development. He is responsible for working with Congress and the Administration to promote sustainable urbanization in foreign policy and development assistance programming of the Government of the United States. He previously held several other positions with the UN. Mr. Williams holds a BA, Economics from Tufts University; an MA, Public Policy Studies from the University of Chicago; and MA, Sociology from the Graduate Faculty of the New School for Social Research.

**Elias Wondimu**, an exiled journalist from Ethiopia, has institutionalized his activism and played pivotal roles in his and the larger community by establishing a publishing house, international journals, academic conferences, a nonviolence institute, a film festival and a summer institute. With an activist zeal, Mr. Wondimu is one of the leading agents who are actively engaged to increase Africa's knowledge production within the African continent and the diaspora academic communities. He is also a strong voice in the effort to reverse Africa's brain drain through institutional engagement and collaborative research and publication. He is a member of African Studies Association.

## STAFF

**Susan Sauer Sloan** is Director of the Government-University-Industry Research Roundtable (GUIRR) at the National Academies. She was previously Executive in Residence at the Center for the Advancement of Scholarship on Engineering Education (CASEE) of the National Academy of Engineering and Chief Executive Officer of the Global Wireless Education Consortium (GWEC), a university-industry membership organization committed to the development and incorporation of current wireless technology curricula in academic institutions worldwide. Earlier in her career, Ms. Sloan worked as Corporate/Foundation Relations Consultant to the National Science Foundation's Division of Undergraduate Education. She received her BS in Biology at the University of Oregon.

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**Tom Arrison** is a senior staff officer in the Policy and Global Affairs division of the National Academies. He joined the National Academies in 1990 and has directed a range of studies and other projects in areas such as international science and technology relations, innovation, information technology, higher education, and strengthening the U.S. research enterprise. He holds MAs in public policy and Asian studies from the University of Michigan.

**Denise Greene** is Administrative Coordinator, Government-University-Industry Research Roundtable (GUIRR)/University-Industry Demonstration Partnership (UIDP) at the National Academies. Ms. Greene has worked with the Office of the Chief Financial Officer (OCFO) in Travel Services and with the Division on Earth and Life Studies (DELS) during her fifteen year tenure with The National Academies. Prior to joining GUIRR, she was an Executive Assistant with the Federal Demonstration Partnership (FDP) and was a Senior Program Assistant with the Ocean Studies Board in DELS. Ms. Greene attended the University of Maryland, College Park, and plans to complete her studies in Sociology.

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**Claudette K. Baylor-Fleming** is Administrative Coordinator, Federal Demonstration Partnership (FDP). She comes to the FDP from the Division on Engineering and Physical Sciences where she was the Administrative Assistant to the Director of the Space Studies Board for nine years. Ms. Baylor-Fleming came to the National Research Council in 1988, working first as senior secretary for the Institute of Medicine's Division of Health Sciences Policy, and then as the administrative/financial assistant for the Board on Global Change for seven years. In 2003, Ms. Baylor-Fleming completed two certificate programs, one at the Catholic University of America in web technologies, and the other at Trinity College Washington in information technology applications. She is currently pursuing a Bachelor of Science in Computer Information Technology from the University of Maryland, University College.

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**Chris Verhoff** joined the National Academies as a Financial Associate in April 2006. Prior to joining the Academies, he worked at Lennox International in Texas as a Treasury Analyst managing the company's day to day cash operations and procurement card program and assisting in short term investments. Mr. Verhoff received his Masters in Business Administration from the University of Texas and his Bachelors of Science in Computer Science from the University of New Mexico.

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