Executive summary

Keynote address: The Current Context for Science, Society and Public Policy

Alan Leshner, CEO of AAAS and Executive Publisher of Science

• The main factors of the broader societal context within which science is imbedded: issues arising within science; government regulations, priorities and funding; relationship between science and the public.

• Major trends within science: ever-accelerating pace of scientific advances; blurring or even demise of traditional disciplinary structure and increasing necessity for research that crosses multiple disciplines; rapid technological advances driving the science that is done, rather than science driving the technology, as in the past.

• The events of September 11, 2001, brought major changes to the context and priorities of American science: restrictions on international travel decreased the number of international graduate applications in the U.S.; national research priorities shifted to national security; and new areas of research received generous funding while traditional areas did not.

• Though a vibrant science and technology (S&T) enterprise is central to the success of a developed country, the traditionally good relationship between science and American society shows signs of deteriorating. Science and its findings are increasing politicized and the public's overall confidence in science appears to be eroding. Historically, S&T have been evaluated primarily on their relative costs and benefits, but are increasingly judged by their relationship to core human values; examples: embryonic stem cell research, the attempt to teach creationism alongside evolution.

• The increased tension between science and segments of society results in increasing attempts by the public and policymakers to shape or modify the research agenda. While in the past science and technology influenced the course of civilization and society, the reverse is now occurring, even to the level of determining what can and cannot be studied. The result is a widening divide between science and society.

• Scientific illiteracy or lack of understanding is not the only cause of the rift. The public often understands the science but does not like what it shows or what it means.

• We must continue to defend the integrity of science, but that is not enough to bridge the divide in the science-society relationship. An open and genuine dialogue with the public can move us from a public understanding model to a true public engagement model and a lessening of the tensions. The best ways to do this are still being explored.

• AAAS is developing a new programmatic center focused on a combination of approaches to improve public engagement with science and technology.

Classified Research and the Open University

Jim Roberts, Vice Provost for Research, The University of Kansas

- Classified research presents several thorny issues for universities: philosophical opinions, publication restrictions, practicality, costs, academic freedom concerns, possible harm to students' educational progress.
- Developing an institutional research policy is hindered by the common practice of collapsing a complex set of questions into a single question to be answered "yes" or "no." Classified research embraces multiple questions, but a policy is often seen to be either for or against it. What is needed is to deal with classified research as a single question, in the true sense of the word, and then tease out the other questions that are contained in the term.

Philosophically, we have the following questions:

- Should an institution engage in research when some or all of the research material/ results cannot be released to the general public?
- Should a university directly support the military/industrial complex, conduct embryonic stem cell research, etc.?
- Should some faculty and students have access to information that others cannot know?

Some people are concerned about having research material that cannot be released to the public, others about supporting the military/industrial complex. Some object to embryonic stem cell research, others to research using laboratory animals. There may be opposition to almost any area of research that one can think of.

Publication restrictions: most institutions accept in principle the Association of American Universities position that member institutions should not accept unlimited scope or time publication restrictions, but allow exceptions.

The requirements of doing classified research: Does it mean we have to have a security force? A building with barbed wire and guards? What costs are there? Who pays? What set of rules are imposed by the federal government?

Can academic freedom and segregating students and faculty into "cleared" and "un-cleared" categories coexist? Are we doing anything that harms a student's progress toward a degree?

In the sense of what "classified" means, we deal with "classified research" every day at our institutions, and there is much information that we do not publish. For example, we conduct human subject research where we release general study results, but not details about the participants. We keep company material private. We release survey data but not data about specific students. National security classified information is really no different. It simply represents data that cannot be released. A particular person's answer to a survey question, or the wingspan of an advanced military airplane are both restricted, meaning classified per se; the data cannot be released to the public without someone else's approval.

Should the university accept a contract or grant with an unlimited delay of publication? At KU, we can accept delays up to a certain period of time, but we simply do not accept a grant or contract that has an unlimited delay. But that is a different question than whether or not we do research that involves national security.

Comparison of 15 institutional research policies found different levels of banning or compliance; a chart on page 12 gives the full results.

I propose a Conduct of Research Policy to replace a Classified Research Policy. In a return to the Jeffersonian ideal, I propose that institutions have a simple statement about academic freedom and research:

Principle I: Free and open inquiry Principle II: Ability to publish Principle III: Specified Process for Granting an Exception to Principle II Principle IV: Protect the students and the campus

Prohibition IVa: Top secret facilities on campus Prohibition IVb: Classified theses and dissertations Prohibition IVc: Accepting sponsored agreements with ambiguous language Prohibition IVd: Sponsored agreements wherein the agreement itself is classified Prohibition IVe: Disrupting the educational program of a student.

Researchers who abuse the system should be dealt with as are any faculty member who violates the rules. Don't create policies to prevent things a few bad apples might do and thus restrict the rights of everyone else who plays by the rules; deal with the bad apples.

Be careful. Take care that the exceptions do not become the rule. We do not need a Department of Classified Research. Exceptions really do have to be exceptions. Institutional policy should be clear on publication expectations. This is one place *not* to make an exception. Arguing that a faculty member did not publish as much as expected because of conducting research involving classified material should fall on deaf ears. In fact, the opposite should be true.

Summary

- Don't ban classified research just because it is classified; don't ban any type of lawful research.
- Don't even use the term "classified research."
- Promote an environment that expects quantity and quality of publications from faculty. Carefully define a process for considering exceptions; use existing policies to deal with bad behavior.
- Have a "conduct of research" policy that adheres to the principles of free and open inquiry of research, expectation of publication of results, clear process for dealing with publication restrictions in sponsored agreements, and protection of the campus and the students.

Meeting the Science Workforce Challenges in the Post 9/11 Environment

Prem Paul, Vice Chancellor for Research / Dean of Graduate Studies,

University of Nebraska, Lincoln

Public policy can either benefit or hamper scientific progress. Our nation has benefited
tremendously from the National Defense Education Act of 1958, which resulted in the
creation of NASA. The agency has provided funding for the training of thousands of
scientists. Conversely, the increased scrutiny of graduate students post 9/11 has fostered a
perception of the United States as an unwelcoming place to pursue graduate studies. Recent
changes to the regulations governing the ability of international students to come to the U.
S. to pursue graduate training in science and engineering disciplines have resulted in
notable declines: from 2003 to 2004, the overall number of applications decreased 28%,

admissions fell 18%, and enrollment dropped 6%. These reductions are attributed primarily to problems international students encounter obtaining visas.

- The availability of science and engineering (S&E) talent has implications for our global economic competitiveness. The primary factors in the longstanding U.S. global leadership have been the creation of innovation through research and development (R&D) investments in science and technology and the availability of scientific talent. There is a concern our leadership position may be in jeopardy. A number of Asian and European countries are increasing their R&D investments, thus increasing the overall competition for talent. We as a nation have been depending more and more on the international workforce as the number of American-educated students in science and engineering has been on the decline. Restrictive post-9/11 policies have made it increasingly difficult for interna-tional graduate students and scientists to come to this country, whether it be to pursue graduate study, work as a visiting scientist, or participate in international meetings.
- *Current State of the S&E Workforce*: The percentage of American S&E doctoral degrees awarded to U.S. citizens/permanent residents has been on the decline since the early 1980s. In 1966, 78% of all S&E doctorate holders were born in the U.S.; by 2000, that number had decreased to 61%. In addition, the number of S&E doctoral degrees collectively awarded by European countries has exceeded the number of those awarded in the U.S; the number of Ph.D.s awarded by Asian countries also is on the increase.
- Since 1966, the number of scientific papers published by authors from western Europe has surpassed the number published by authors from the U.S. Unless these trends can be reversed, more and more R&D will go offshore and high paying jobs move to other countries.
- *Talent is Key to Innovation*: The Council on Competitiveness asserted in its workforce study that talent is the nation's key innovation asset and recommended building a strong base for scientists and engineers. The study also concluded the demand for scientists and engineering talent far outstrips supply. The number of jobs requiring technical training is growing five times the rate of other occupations, and the average age of the members of the science and engineering workforce is rising. New entrants into S&E fields are not replacing retirees in sufficient numbers. A quarter of the current S&E workforce members are 50 years of age or older; many will retire by the end of this decade.
- Where will the talent come from? Some of the major recommendations of the report from the National Academies COSPUP committee on Policy Implications of International Graduate Students and Postdocs in the United States:
 - The United States must maintain its current quality and effectiveness in science and engineering; attract the best graduate students and postdocs regardless of national origin; make every effort to encourage domestic student interest in S&E programs and careers.
 - The overarching goal for universities and other research institutions should be to provide the highest quality training and career development to both domestic and international graduate students and postdoctoral scholars of truly outstanding potential.
- Positively, a significant percentage of foreign-born students earning doctorates from U.S. institutions end up staying here, contributing to the nation's S&E innovation and, subsequently, the economy. This number increased to 71% for 2001 Ph.D. recipients.

However, recent trends indicate some countries are aggressively recruiting talent back home by increasing their R&D investments.

- To stabilize and increase our S&E workforce, we must intensify our efforts to prepare and encourage K-16 students to pursue undergraduate and graduate studies in S&E related fields. Special emphasis may need to be placed at the middle school level to keep students engaged. American high school students routinely perform below their peers on international mathematics and science tests. Special incentives similar to the National Defense Education Act initiative of 1958 must be launched to provide incentives to students to pursue S&E education and careers. Incentives also are critical in reaching out to underserved and underrepresented students as they constitute an increasing percentage of our population. The college-age population will be as much as 40% racially or ethnically diverse by the year 2020.
- The United States must attract and train the best domestic and international talent in science and engineering in order to maintain its global leadership position. Without sufficient talent, our ability to provide global S&E leadership is jeopardized.

Public Policy and Research at KUMC

Joan Hunt, Senior Associate Dean for Research, The University of Kansas Medical Center

- Public policy has a major impact on research direction at The University of Kansas Medical Center (KUMC). KUMC research leadership has focused on developing programs that are in accord with the aims and goals of (1) world leaders, (2) agencies in the United States that support biomedical research, (3) the State of Kansas, (4) the Kansas City region, and (5) The University of Kansas Medical Center.
- At KUMC, remaining competitive means staying in accord with funding goals of the NIH; this is critical because the institution receives an additional 47% for facilities and administration in addition to direct research awards, and these funds cover many KUMC needs. Commercialization has additional potential for supporting the costs of running the institution.
- The traditional investigator-initiated approach where researchers designed the goals and worked to learn more about how organisms function so as to improve human health is quickly being replaced with the top-down goal of finding uses for research discoveries that will benefit economic growth. Researchers are falling agreeably into the new pattern because (1) biomedical researchers are strongly committed to improvements in human health and would like to see their work bring better health care, and (2) because of top-down direction, researchers must now focus on translational aspects of their work in order to win research funding to support their ventures into discovery biomedical research.
- As sources of funding for research change, the influence of funding agencies increases. The major point of the first graph (page 22) is that states supply little funding support for research (2%); most (63%) is contributed by government grants and contracts. Because translational research is favored for funding by governments, this drives the aims and goals of research submitted by public agencies. Research not authorized by the government is frequently supported by private foundations (8%) or industry (5%). This is the situation for

KUMC research; the university and state contribute little to research while strong emphasis is placed on acquisition of extramural funding. [Statistics credit: Characteristics of Research Centers and Institutes at U.S. Medical Schools and Universities, 2005, American Association of Medical Colleges (AAMC); full report at <u>www.aamc.org/publications</u>]

- KUMC has competed effectively for extramural research awards. Figure 2 (p. 23) shows that awards and consequent expenditures 1997-2005 have nearly doubled.
- NIH awards comprise half of all extramural research awards to KUMC, and KUMC has received equivalent increases to NIH awards over the same time period across the U.S. (figure 3, p. 23).
- KUMC basic science departments in the School of Medicine have competed more effectively for the NIH-mandated initiatives than have the clinical departments (Figures 4 and 5, p. 24).
- Translational research is well supported in the other two schools at KUMC: the Schools of Nursing (SoN) and Allied Health (SoAH).
- Though the IDeA program supported by NCRR is responsible for the growth in KUMC NIH awards, it is not the only factor. As shown in Figure 6 (p. 25), IDeA funds have contributed substantially to growth of NIH awards to IDeA states, while overall awards to IDeA states are on a significantly steeper trajectory. In Kansas, approximately \$75 million has been awarded through the IDeA program to teams at K-State , KU-Lawrence, and KUMC. The magnitude of the IDeA awards influences the drive and direction of research at KUMC, as all program awards are reviewed under the same criteria as other NIH awards.
- KUMC leads the State of Kansas institutions in acquisition of NIH funding (Figure 7, p. 26). Because of the inter-institutional IDeA programs, Kansas researchers across institutions are more likely to be cooperative rather than competitive, as they are in many states.
- KUMC does not have a large contingent of researchers when compared to peer medical centers. As a consequence, the university has chosen to focus on areas where strength has already emerged (Figure 8, p. 27). One major focus is development of an NIH-supported Comprehensive Cancer Center. This program partners with the KU-Lawrence campus through its Experimental Therapeutics Program; drug development for cancer treatments is facilitated by the high throughput screening facility in medicinal chemistry supported by an NIH IDeA grant. Drug development takes place on both campuses: KU-Lawrence is in charge of the chemistry and initial testing, while KUMC handles the clinical aspects (Figure 9, page 27).
- KUMC continues to compete effectively for the funds to facilitate translational research and commercialization, in the new direction for health-related research in the U.S. The university is building a 205,000 sq. ft. biomedical research center to be opened in late 2006, has been actively recruiting 177 replacement and new faculty in the past three years, and has developed more active outreach, community-oriented efforts to acquire additional extramural support.

State and Local Plans to Leverage University Research into Economic Development: You Can't Always Get What You Want and You Don't Always Get What You Need

Lisa Freeman, Associate Professor, Kansas State University

- The Federal Government is the largest supporter of academic-based research in the life and health sciences. In return for this investment of tax revenue, Americans expect steady progress in development of safe and effective diagnostic tests, surgical procedures, vaccines, drugs, and devices. Americans today benefit from both the advances in health-related technology and the economic expansion that result from technology transfer.
- Passage in 1980 of the Bayh-Dole Act served as a major stimulus for expansion of technology transfer by universities and academic medical centers. This legislation gave universities the right to own and license their inventions that result from federally-funded research. Estimates are that university research contributed significantly to the development of 27% of the new products and 29% of the new processes commercialized by pharmaceutical companies in the 1980s.
- In 2003, universities received 3179 new patents and spun off 348 companies, yet there is significant concern that translational research and technology transfer occur too slowly. Intellectual property developed in academic laboratories, but not disclosed nor developed represents a loss to society. At the federal level, recent attempts to remedy this have focused on facilitating basic research breakthroughs and accelerating the speed of translation of those discoveries into clinical practice. One initiative is the NIH Roadmap, with its three major themes: new pathways to discovery; research teams of the future; re-engineering the clinical research enterprise.
- The emphasis of regional and state governments is decidedly more focused on economic health than preventing or curing disease. Numerous regions look towards local research universities to help them become national centers for life sciences research and industry; more than 40 states are pursuing a bioscience agenda as a statewide goal. State strategies for support of the biosciences include tax credits and incentives, direct investments in research, technology and education infrastructure, and improving the business climate for biotechnology start-ups. Though the biomedical research enterprise is widespread and there is growing interest by the states in leveraging university research into economic development, however, only a handful of the largest metropolitan areas in the U.S. have demonstrated success. Of the 51 largest metropolitan areas, nine regions account for the bulk of economic growth in biotechnology. Even these successful biotechnology clusters have produced only modest returns to local economy.
- What determines success and returns on research? The significant challenges facing aspiring regional biotechnology centers include: fostering a climate conducive to university spin-offs on campus and in the community, attracting adequate amounts of venture capital to move an idea from "mind to market", and developing a local workforce suitable to the lifesciences industry. When local officials assess their potential for success, they may overestimate the adequacy of existing resources and infrastructure, underestimate the time required for return on investment, and thereby foster or fuel unreasonable expectations.

- Realistic consideration of the infrastructure available to support a biosciences cluster must take into account the available research base, capital flow, and labor force. In 2002, the nine established U.S. biotechnology corridors accounted for of 59% of NIH funding, 68% of biotechnology patents, 92% of active biotechnology venture capital firms, and 75% of biotechnology start-up firms. Whereas biomedical research activity became more dispersed during the fifteen years between 1985 and 2000, patents, capital flow and the growth of biotechnology firms became more concentrated over the same time period. Productivity in research and life sciences education is necessary but not sufficient for success in economic impact. See text and Table 1: Research Infrastructure Comparison, p. 32, for more information on the specific communities.
- The pathway to prosperity was not identical for the upstart regions. In each case there was a long term plan built around existing strength and based upon support of sensible strategic partnerships, promotion of private capital investment, and encouragement of local entrepreneurship. These are key components of effective programs.
- In metro areas, including Kansas City, where traditional industries are outside of science and technology, attracting private capital investment may represent the most significant challenge. Biotechnology is both expensive and risky. Funding for early stage technology is difficult to obtain, and this investment gap is worse when market uncertainty is heightened by lack of investor proximity and lack of regional experience with commercialization of academic inventions. In regions like these, it will be important for state and local initiatives to provide support for mid-to-late stage funding for development of products with commercial potential, to offer business development assistance, and to invest in workforce development. Academic institutions and established corporations also have the potential to contribute in these areas. Increasingly, universities are making venture funding and campus-based business expertise available to new life science companies. Innovative corporate partnerships are allowing for enhanced educational opportunities in entrepreneurship and professionalism.
- Managing Expectations: Entrepreneurs and executives are susceptible to cognitive biases that lead to inflated self-confidence and an exaggerated view of their own power to influence complex series of events. Organizational and political pressures to emphasize the positive and downplay the negative contribute to overoptimistic forecasts. The net result is too often a shared unrealistic view of future outcomes for major initiatives. Many strategies to leverage university innovation into regional economic development suffer from this type of "delusional optimism"; the results are flawed decision making and unreasonable community expectations.
- See the full text for a case study of the 2001 formation of the University of Buffalo (NY) Bioinformatics Center of Excellence. The exuberant expectations for the UB Center reflect over-optimism and result directly from the planners reliance on an "inside view." It is likely that more realistic expectations would have been generated by taking an "outside view" and adopting "reference class forecasting."The latter approach ignores the details of the project at hand, and instead uses the experiences and outcomes of a class of similar projects to gauge the current position and forecast the future course. The advantage of an outside view is most pronounced for large scale initiatives where the planners lack experience.

- Precedents that can be used for reference class forecasting exist and are accessible. Comparison data similar to Table 1 can be excerpted from the surveys and reports generated by the Association of University Technology Managers (http://www.autm.net/ index.cfm), the US Bureau of Census, the federal agencies that provide research funding to universities (NIH and NSF), TheCenter (http://thecenter.ufl.edu/), and the numerous forprofit and not-for-profit organizations that review the bioscience industry.
- *Implications*: Optimism generates more enthusiasm and commitment than realism. Significant instability and lack of trust, however, may be induced or exacerbated by promoting unrealistic expectations in the context of a state bioscience initiative. In these projects, it is typical for the alliances to be uneasy; the agendas to be in conflict; and the resources to be inadequate. Impatience is common where persistence is needed. Establishing a new biosciences corridor is a challenging, long term proposition. Regardless of where the journey ends, one can expect to encounter a long hard road with many obstacles, detours and potholes. Success will be driven by significant investment in research infrastructure, realistic long-term planning, and management of expectations. Reference List, p. 34-35.

Science and Public Policy: Historically Speaking

James Guikema, Associate Vice Provost for Research, Kansas State University

- This paper examines historical examples where public policy decisions collided with the science research enterprise. I use the perspective of history to focus on two obvious questions both of which lead to a third item: research compliance concern.
- Can policy decisions shape the future of science?
- Yes. Government largely provides the funding for our work, and, despite the concept of peer review, Washington feels free to set our research agendas
- The Kansas Cosmosphere and Space Center (KCSC) tells a remarkable story of the U.S. commitment to the space program. Much of this commitment grew during the Eisenhower presidency and led the way to today's robust science programs. The Eisenhower presidency made a major decision which set the stage for initial losses in the space 'race' but set led to the larger victory.
- The decision had its roots in events during WWII when, in February 1945, Stalin, Churchill, and Roosevelt met to divide Germany. Stalin was ecstatic, since the Russian zone would contain the major weapons and missile development region—Peenemünde. In June 1945, however, Dr. Warner von Braun surrendered to US troops, and Secretary of State Cordell Hull approved moving von Braun, 126 members of his staff, and 300 train cars of V2 rockets and missile parts to the U.S. Stalin was furious and, immediately following the war, launched an aggressive missile development program.
- When Eisenhower assumed the presidency, the Army (von Braun et al.) and the Navy were active in U.S. missile development. Eisenhower added a civilian effort that later became NASA. Von Braun's team was shut out, despite overwhelming superiority, because it was a military, not civilian, operation.

- Then the Soviets launched Sputnik I (October 4, 1957) and Sputnik II (November 3, 1957), and the U.S. lost the space war part 1. In a complete reversal, on November 7, 1957, Eisenhower announced that the Jupiter program (von Braun's) had solved all of the U.S. problems, and that orbital flight was near. In January 1958, Explorer I was launched, putting into orbit a radiation sensing payload developed by a University of Iowa colleague, Professor James van Allen.
- The U.S. lost phase 1 of the space race because of Eisenhower's pro-civilian policies. Kennedy, however, needed to reclaim international leadership. He asked his staff to recommend strategies, and Lyndon Johnson provided the answer – put a man on the moon. The Apollo program had begun. Would we have gone to the moon if Eisenhower had won the race to orbital spaceflight – I think not.
- Can (bad) science shape the future of public policy?
- An historical example of science shaping public policy was suggested by K-State Vice Provost for Research, Dr. R.W. Trewyn: the activities occurring during the Viet Nam war, when the U.S. extensively used defoliants like Agent Orange to deny terrain to the enemy. Little personal protective equipment was used, and adverse conditions such as prop-wash from helicopters did not deter spraying.
- Dr. Trewyn was asked to be a consultant on a study of the health effects on soldiers involved in herbicide application. He was asked to testify to the National Affairs, Veterans Affairs, and International Affairs Subcommittee of the House Committee on Governmental Reform. The focus was on the Air Force Ranch Hands Study on the Health Effects of Agent Orange (March 2000). And his message was this: the study was flawed, because the control group was inappropriate.
- The U.S. government based its treatment of veteran soldiers on a flawed study. Even though the flaws were unearthed, the science team refused to change the parameters during the two decades of the study. Bad science helped to create bad policy.
- Are there implications for the research administrator?
- Export Administration Regulations (EAR) are administered by the Department of Commerce to regulate items that could be mutually used for business or for defense (such as global positioning systems). International Traffic in Arms Regulations (ITAR), administered by the Department of State, regulate weapons and related items. EAR violations could result in faculty members being fined up to \$1 million and 10 years imprisonment. ITAR violations could result in \$100,000 and two years imprisonment. The faculty member, not the university, is personally liable.
- Since 1994, the concept of 'deemed export' has come into play. Simply put, in order to convey restricted information or protected software code to a foreign coworker (undergraduate student, graduate student, postdoctoral, or faculty colleague), one must first obtain an export license. The restrictions come into play when faculty members accept research contracts/agreements which (a) contain limitations on publishing the findings of research, (b) are based on the sponsor providing sensitive or confidential information which will not be published, or (c) is classified by the government.

• EAR, ITAR, and the concept of deemed export mean that universities must add a layer onto their research compliance activities. At Kansas State University, we have begun that process.

Research Compliance Challenges

Robert Hall, Associate Vice Provost for Research, University of Missouri

- Compliance with an increasing number of federal and, to a lesser extent, state laws and regulations consumes resources of all major research institutions at an increasing rate. This also burdens investigators with administrative requirements that compete with their academic pursuits.
- Most institutions seeking federal funding have augmented their human research protection programs, often at the expense of other priorities.
- Animal use in research presents another fiscal challenge.
- Conflicts-of-interest have raised compliance antennae nationwide.
- A recent report suggests that the amount of research misconduct actually occurring at U.S. universities may be underestimated, supporting the ongoing educational efforts focused on a Responsible Conduct of Research (RCR) initiative.
- Related compliance areas currently taking considerable MU time and resources: biological safety and the Institutional Biosafety Committee (IBC).
- Recent federal guidance indicates that all recombinant-DNA research proposals should be reviewed at a convened IBC meeting, and further that such meetings should be open to the public when practicable. Similar compliance committee meetings have not traditionally been open to the public, nor have their minutes been accessible via state open-records law.
- The USA Patriot Act appears to have sufficient congressional support to continue generally un-amended; thus, rules applying to Select Agents will remain a part of research compliance into the foreseeable future.
- Export controls loom as the single regulatory issue in university research compliance with the potential for significant resource allocation in the immediate future. Although current export control regulations have been in place for many years, universities have traditionally relied on what is known as the "fundamental research exclusion" to exempt the majority of research projects from Department of Commerce licensing requirements. In fact, a quick review of existing export control regulations reveals that these are complicated rules administered by three major federal departments: Commerce, State and Treasury.
- Following recent compliance challenges in human subjects oversight, research animal welfare, and biologicals under the Patriot and Bioterrorism acts, the potential for additional staff in any administrative compliance function will be hard to justify to hard-pressed senior administrators.
- A frequently unappreciated portion of compliance costs is faculty and staff time.
- Fielding an effective compliance effort is one of the major costs associated with running an ambitious institutional research program.

Introducing the Center for Economic Development, Innovation, and Commercialization: A pathway for economic sustainability from research and application to enterprise, by Ron Kessler and Pike Powers

Robert Barnhill, Vice Chancellor for Research and Technology Transfer, The University of Texas System

From the beginning, the Merrill Center conferences have brought together the university leadership from Kansas, Missouri, Iowa, and Nebraska. Many research and research policy collaborations have begun, both directly and indirectly, as a result of these meetings. Now we are ready to consider a next geographical step for research and its societal utility to encompass the Big 12 conference; the key architects of this plan are Pike Powers and Ron Kessler. Their description of this project follows:

Center for Economic Development, Innovation, and Commercialization

- The purpose of the Big 12 Center for Economic Development, Innovation, and Commercialization (CEDIC) is to develop, foster, and nurture more collaborative and mutually beneficial activities within and among the 12 universities, and to facilitate the flow of innovation, commercialization, entrepreneurship, and "know-how" from the universities to the private sector, thereby creating new jobs and enhancing the well-being of the citizens of each university's state and region.
- Intending to *accelerate economic growth and intellectual excellence through collaboration,* the Big 12 CEDIC has already created momentum and support. The 12 universities individually and their seven home states have benefited significantly from collaborating in the Big 12 Conference. This athletic success will be extended and enhanced by addressing the significant issues facing each state and university through the Big 12 CEDIC.
- Our approach involves five areas: collaboration, competition, celebration, communication, and capital. Initiatives in each of these five areas will be launched over the six months beginning on October 1, 2005.
- After meeting and developing relationships with KTEC, the Kauffman Foundation, the Kansas City Federal Reserve Bank, Department of Commerce (EDA), RUPRI, LCRA, SBC, SAIC, IBM and various Chambers of Commerce, we are ready to launch the Big 12 CEDIC.
- We have found significant interest among the private, foundation, and government sectors and from economic development entities for this innovative approach. Equally important, we have also received enthusiastic responses from Big 12 Vice Provosts for Research (VPR), Deans, and faculty members.
- We have asked the school presidents/chancellors to sign a Big 12 CEDIC Charter to acknowledge their commitment to our seven-state region and to commit the universities to addressing the regions' economic needs and collaborating on increasing research funding.
- We will collaborate outside the universities to leverage the various economic development, workforce training, and capital providers for a focused seven-state regional economic development network.

• The universities of the Big 12 have a tremendous opportunity to move beyond their past successes and to fulfill the significant role that the university plays in today's economy. By the Big 12 being the first to attempt such a collaboration and doing it well, we will set the "gold standard" for athletic conferences, economic development, innovation, and commercialization.

Research and Engagement Opportunities for Applying Science to Public Policy: The University of Nebraska Public Policy Center

Alan Tomkins, Director, University of Nebraska Public Policy Center

- In 1997, a University of Nebraska task force recommended the creation of a university-wide policy center to assist Nebraska's policymakers; in January 1998, the University's Board of Regents formally established the Public Policy Center to assist policymakers on a wide range of public policy issues.
- The University of Nebraska Public Policy Center (http://ppc.nebraska.edu/) serves the state and communities in Nebraska, as well as the nation, by providing information to policymakers that allows them to make better strategic decisions. The Center also serves a brokering function, linking policymakers with the vast expertise that exists at a large, public (and land-grant) university.

The University of Nebraska Public Policy Center in Action

- The Center has worked on a diverse issue array: Business/Economics/Taxes, Persons with Disabilities, Education, Food and Society, Governmental Administration, Natural Resources, and Rural Community and Economic Development (see http://ppc.unl.edu/ program_areas/by_category.html). We currently are actively engaged in 15-20 projects; the Center employees about 40 people (about half students); and has a budget of approximately \$3.0 million (approximately \$175,000 from University appropriation). We are a unique policy center in that we purposively serve all three branches of government. The Governor, the Chair of the Legislature's Executive Board, and the State Court Administrator serve along with the provosts from each of the five NU campuses on the advisory board.
- Over the years, the Public Policy Center has created a bridge between the university community and policymakers.
- Simply because one scientist (or Center) advocates a position does not mean that a policymaker will necessarily follow the advice, nor should they. As the saying goes, "One scientist's gold is another's junk." A recent analysis by Dr. Ioannidis of biomedical clinical studies originally published in highly regarded medical journals between 1990-2003 and cited by others more than 1,000 times, found that nearly one third of the studies were either contradicted or modified by subsequent studies (John P. A. Ioannidis, "Contradicted and Initially Stronger Effects in Highly Cited Clinical Research," Journal of the American Medical Association, 294:218-228 [2005]). It is important to be prepared to help a policymaker deal with the fact of changing scientific evidence. Scientific information is nonetheless a highly valuable tool to shape policy. Academia has a special role to play in ensuring that quality scientific information is presented understandably and effectively to policymakers.

• There have been several instances in which the Public Policy Center has had an impact on policy decisions in the state of Nebraska. The full text details the PPC making a difference in: child support payments & disbursements; inequities in the justice system for minorities; behavioral health; and water resources.

Public Policy and the Scientific Agenda: Is there a place for Social Science?

Mary Lee Hummert, Associate Vice Provost for Research, The University of Kansas

- Federal funding for basic research in the behavioral and social sciences (BSS) lags significantly behind funding for research in the natural, physical, and medical sciences. The 2004 Report of the Working Group of the NIH Advisory Committee to the Director on Research Opportunities in the Basic Behavioral and Social Sciences (http://obssr.od.nih.gov/activities/Basic%20Beh%20Report_complete.pdf) reports that total federal research spending 1993-2003 has been consistently lower in behavioral and social science fields than in life sciences, physical sciences, mathematics and computer sciences, and engineering fields.
 - Administrative restructuring and a change in policy at the National Institute of Mental Health also promise to have negative effects on basic BSS research. NIMH was one of the institutes that provided a home for basic BSS research, with 8.1% of its funding awarded to basic BSS research in 2003. However, in October 2004, NIMH Director Thomas Insel announced an increased emphasis on translational research and a decreased emphasis on basic research, especially in the social sciences (*Science*, 22 October 2004).
 - Clearly, public policy as set by those within the National Institutes of Health in particular, and the federal government in general, has an influence on future progress in basic BSS research.
 - Why should we care about the challenges to funding basic BSS research? Because the insights gained from such research are essential to a full understanding of the scientific challenges we face today.
 - Basic BSS research is a necessary precursor to translational research and an important partner in many investigations of interest to the medical, natural, and physical sciences. Similar arguments, however, were advanced in the Report of the Working Group of the NIH Advisory Committee to the Director on Research Opportunities in the Basic Behavioral and Social Sciences (http://obssr.od.nih.gov/activities/Basic%20Beh%20 Report_complete.pdf).
 - As research administrators, we are concerned with promoting funding opportunities for basic researchers in all disciplines, including the behavioral and social sciences. Therefore we must consider ways that we can help our basic BSS researchers to be successful in this funding climate.
 - Lending our support to recommendations such as those from the NIH Advisory Committee is helpful, but we can offer more immediate, direct benefits to behavioral and social science researchers on our campuses by: building interdisciplinary research

programs; developing faculty mentoring programs targeted at BSS researchers; and ensuring that basic BSS research is included in materials featuring campus research.

- Ensuring that reports of university research successes include examples of funded basic BSS research will communicate to students and faculty that basic research in the behavioral and social sciences is valuable and valued. Communicating this message is critical to maintaining the morale of basic BSS researchers and providing an incentive for adding to BSS successes in the future. Second, it will help to broaden external audiences' conceptions of "research" and "science" beyond the natural, physical, and medical sciences.
- The data show that basic BSS research faces funding challenges, even though evidence of its importance to a full understanding of the scientific challenges of the 21st century is abundant. Advocating for policy change within funding agencies and adopting the three strategies outlined above would improve the research climate for those in all disciplines. References list, p. 67.

When Science and Politics Collide

Barbara Atkinson, Executive Vice Chancellor, The University of Kansas Medical Center

- As a physician, an educator, a researcher and a leader in the health care community, I believe it is the responsibility of all scientists and educators to be a resource, both to the public and to lawmakers who have a responsibility to decide crucial issues such as stem cell research and therapeutic cloning. For that reason, I have testified before the Kansas House Federal and State Affairs Committee against House Bill 2355, conducted a series of Stem Cell Research 101 seminars with Kansas legislators, and given 50 talks on the science of stem cell research to citizens throughout the state of Kansas.
- The critical problem that I see with HB 2355 is that, while it aims to outlaw human cloning, the specific language of the bill does so at the expense of criminalizing the exploration of an entire category of research that holds the potential to profoundly ease human suffering—research that will allow us to study the molecular basis of diseases as they develop from conception to death. This research holds the promise of discovering treatments and cures for such chronic diseases as Parkinson's, juvenile diabetes, ALS, heart disease, cancer, spinal cord injuries and Alzheimer's disease.
- Much of the controversy and misunderstanding about stem cell research centers on use of the emotional and highly-charged word "cloning." When most of us hear this word out of context, we tend to think of the process of creating genetically identical human beings--human reproductive cloning—a terrifying prospect to be sure. In fact, there is another type of cloning; "therapeutic cloning" seeks to create a line of stem cells genetically identical to the originating cell for use in research and treatment.
- One of the most promising forms of therapeutic cloning is "somatic cell nuclear transfer" or SCNT. This is the transplanting of a patient's DNA into an unfertilized egg in order to grow stem cells that could replace organs or tissue in order to cure diseases. They could also be used to discover new drugs for the treatment of patients.

- SCNT is not meant to create new life; it literally extends life. SCNT works with the cells of an already-living person to create an environment where these cells can multiply to produce stem cells. These stem cells can then replace damaged cells in the body. SCNT is also essential to help scientists understand how stem cells and other cells develop. This includes understanding how cancer cells grown and develop, which is essential for ultimately finding a cure for cancer.
- The goal of therapeutic cloning or SCNT is not to produce babies, but to produce cells. There is no fertilization of the egg by sperm, no implantation in the uterus and no pregnancy.
- SCNT's aim is to treat or cure patients by creating tailor-made, genetically identical stem cells that the patient's body will not reject after transplantation. SCNT could allow patients to be cured using their own DNA and could result in significant breakthroughs just as the use of stem cells in bone marrow transplants is saving lives today. Unfortunately, SCNT could be criminalized under the provisions of HB 2355.
- At The University of Kansas Medical Center, we are supportive of efforts to utilize adult stem cells--stem cells drawn from fetal cord blood or from other adult issue sources – for biomedical research. However, adult stem cells and early stem cells are not replacements for one another. Because early stem cells are pluripotent – meaning they can become any cell in the body – they can be applied to a far greater variety of contexts than adult stem cells and can also be grown in a lab indefinitely. Consequently, we believe that pursuing both avenues provides the best hope for achieving dramatic progress in discovering new cures.
- Another unintended consequence to criminalizing SCNT could be that patients and physicians may leave our medical centers and hospital to pursue the possibility of more innovative care provided in other states. If that occurs, there will be a direct economic impact and an indirect loss of additional business growth.
- WSJ/Harris Interactive Poll, June 2005:
 - o 74% of Americans think that stem cell research should be allowed
 - o 14% believe it should not be allowed
 - 12% are not sure

According to similar polls conducted in Kansas and Missouri, 61% of Kansans and 56% of Missourians approve stem cell research; 21% and 24%, respectively, disapprove. When asked if they approve or disapprove of SCNT research, 71% of Kansans and Missourian said they approved.

- Anti-stem cell or human cloning bills introduced this year in the legislatures of Missouri and Kansas but that were not passed into law are likely to be reintroduced in 2006.
- In response to restrictions on stem cell research, many Americans have become involved in advocating *for* research. We have a group of committed individuals in the Greater Kansas City Chamber of Commerce who has made this its top legislative agenda item. A campaign by the Kansas Coalition for Life Saving Cures will encourage many Kansans to advocate for research to improve the quality of life for those suffering from debilitating disease. It is our

opportunity to teach new audiences, to build new coalitions and to advance our mission of improving human health through research.

• I applaud efforts to outlaw human reproductive cloning, as do all reputable researchers, but I urge our lawmakers to advance the cause of research, education and healthcare by opposing legislation that limits the life-saving cures and treatments central to our shared mission and the overall quality of life of Kansans.

Scales of Engagement, Challenges, and Opportunities in Linking Public Policy and Research

Duane Nellis, Provost, Kansas State University

• Global and national level policies and agendas at times drive priority research thrusts; yet state and local policy decision-makers and incentives, as well as the public at large, can strongly influence university research agendas and strategies and must not be minimized. Often, strategies that are sensitive to maximizing research potentials between global, national, state, and local policies and attitudes have the greatest potential to advance university research success and create sustainable development opportunities.

The Global and National Scale

- As Alan Leshner has pointed out (2003), science is an integral part of everyone's lives: "every major issue facing our global society today has science and technology components at its core." The international and national levels of policy response to these core issues have created research challenges and opportunities as scientists attempt to address these substantial research questions.
- The resulting challenges and opportunities for the research university can be influenced by public perception and attitudes toward a particular science issue, as well as by international or national policies that restrict research agendas. At various times, scientist efforts to "enlighten" the public have only further divided the public on certain sensitive issues. International and federal policies in response to long-term global change create other challenges for the research university.
- Global climate change, post-9/11 federal policies related to immigration, debates around renewal of the Higher Education Act, and strategic priorities related to major federal agencies will continue to have ongoing impact on university graduate programs and research. The reauthorization of the Higher Education Policy Act now being debated could further increase federal performance expectations of universities receiving federal funding. Federal agency funding priorities are also changing as new strategic security research thrusts gain higher levels of congressional support.

National Policy Debates, State and Local Level Adjustments, and Kansas State University

• At the federal level, only limited forms of stem cell research have access to federal research funds, and Kansas and other states have threatened to further regulate stem cell research and any link to cloning. A team of K-State scientists in partnership with a University of Kansas researcher has done research on umbilical cord matrix stem cells, which are readily available and less controversial than stem cells linked to somatic cell nuclear transplantation. Efforts are underway at K-State to establish a center for such stem cell research. Uni-

versity researchers are also working in issues surrounding genetically modified crops and BSE—bovine spongiform encephalopathy.

Kansas Senate Bill 345, Performance Agreements, and Kansas State University Research

- Coupled with passage of Kansas Senate Bill 345 in 1999 and some restructuring of Kansas Higher Education was a movement toward block grants for Kansas regents universities, tuition retention, evolving performance agreements from the Kansas Board of Regents, and incentives for looking anew at revenue sources and creative approaches to sustain and, where possible, enhance university success. At Kansas State University, state level funding as a proportion of our total appropriation has dropped from over 40 percent ten years ago to approximately 27 percent in the most recently completed fiscal year. In response to this trend and Senate Bill 345 K-State has been working to identify alternative financial resource areas, including creative ways to advance K-State's position as a premier land grant institution while enhancing our success in competitive extramural funding.
- The institution's recently created Targeted Excellence program has a strong focus on interdisciplinary, integrative collaborations geared to exploiting and developing institutional strengths, with overarching national and global concerns for security and resource sustainability as factors of influence, collaborations, and emphases. Details of the program and examples of successfully funded projects are found in the full text.
- We are exploring ways to extend our Targeted Excellence and related research initiatives through: (1) enhanced community-state partnerships, (2) enhanced links to the National Institute for Strategic Technology Acquisition and Commercialization (NISTAC), and (3) capitalizing on opportunities presented through the Kansas Bioscience Authority and related partnering with The University of Kansas and K.U. Medical Center

Conclusion: This is a period of significant transition as universities respond to changing public policy at various scales of influence that extend from local to state to national levels and beyond. Our future success will be determined by how well we engage the public at all scales of operation as well as how effectively we create new approaches to enhance revenue streams to our university research enterprise within new public policy environments. In the public policy arena we need to:

- use citizen groups to engage local communities and the public on the value of science;
- train more journalists who can communicate the scientific basis of and opportunities resulting from scientific discovery;
- have a more coordinated effort at all levels to popularize science;
- better articulate the impact of science on the quality of our lives, and
- better understand the impact of scale and relationships in modes of operation from local to state to national.
- Simultaneously, we need to explore creative alternative revenue sources through new partnerships and ideas that allow research universities to continue to thrive as beacons of research discovery and engines for economic development. References list, p. 77.

The Science and Public Policy Interface: Subset of a Larger Problem

David Shulenburger, Provost, The University of Kansas

- A major source of the current stress on higher education in the United States, particularly public higher education, is the decision made implicitly in the legislative halls of every state that higher education is primarily a private good, not a public one. At least since the passage of the Morrill Act in 1862, the notion that higher education serves public ends has been widely accepted; but during the last thirty years, legislative opinion, as evidenced by legislative appropriations, has changed. We now appear to believe that higher education has such a private goods nature that it should be paid for primarily by those who receive it, the students, and to a smaller degree, by the public, which apparently is deemed to be only a minor beneficiary.
- Since the cost of providing higher education has increased while the public support has decreased, students, private donors, corporate donors, research foundations, etc., have become the new financers of higher education. As additional monies have come from these sources, so have additional demands and influences. Many of these demands have come from the U.S. government in the form of restrictions on the foci of research, but the U.S. government is hardly the only donor making demands on the academy.
- State legislatures have not appropriated funds to higher education proportional to the growth in personal income. In 1977, 8.5% of personal income was appropriated to support higher education. By 2003, this amount had fallen to under 7%. The decline in expenditure relative to total state expenditure shows the same trend.
- Public universities have responded by increasing tuition. Tuition as a proportion of funding grew from just over 13% of budgets in 1977 to over 18% in 1997. The state-funded portions of university budgets comprise less than 25% of the total.
- Private universities had no state support to lose. To compensate, they instituted tuition levels several times higher than their public counterparts and vigorously sought private endowments. Except for the occasional reversal in endowment levels caused by market fluctuations, this combination of endowment earnings and high tuition has given private universities a funding edge.
- The biggest portion of any educational institution's budget is for faculty salaries. Due to the lower level of tuition and relatively smaller state appropriation, salaries at public institutions have declined relative to salaries at private ones. In 1977, full professor salaries at public institutions were close to parity with those at privates; salaries of assistant professors were slightly greater and associate professors were paid exactly on par. By 1997, professors' pay at public institutions was at 82% of private peers, associate professors were at 88% and assistant professors were at 84%. Those differences are enough to cause those who are mobile to relocate and to lower morale for those who are not able to move. Unfortunately, the reduction in relative salaries was accompanied by increases in teaching loads.
- Over 20 years this differentiation in resources was accompanied by increased differentiation in the quality of entering students at public and private universities. On both verbal and math SAT scores, the private institutions widened their advantage over their public

brethren. Student quality statistics are complemented by the perceptions of tenured faculty: Substantially more public than private faculty felt undergraduate education had declined in quality at their institutions.

- The tuition increases that have been so much in the headlines are a defensive measure designed to keep the relative decline in the quality of public universities from growing worse. The stakes are high. The competitiveness of our country in science and industry may well rest in the balance.
- When public institutions' historic patrons--state governments--withdraw support, those institutions either must reduce their budgets or find other funding. The former choice has severe, negative quality implications that are illustrated clearly by the previous data. The competition to public universities comes from private institutions. The decline in available funding per student already has had the apparent effect of relative quality reduction. In my judgment, the nation will be poorly served if we permit public higher education to fall further behind in quality relative to the private sector.

Sources from which additional funding is being sought:

- \circ Tuition
- Federal grants
- Athletics
- Sale of intellectual property
- Private giving
- o Exclusive commercial rights and sponsorships
- Donors, sponsors, vendors, etc., generally want something for the money they contribute. Examples are given in the full text of what various subsets of fundors want in return for their financial support, including the constraints to research that result from a growing dependence on federal sources for funding. Similar demands made by students, athletics, and other funding sources are discussed, as is the increasing intrusion of the commercial world into the academy.
- The clever university bureaucrat can dance to the various donors' tunes without being unfaithful to the university's mission. But does this process have unwanted consequences? At a minimum, valuable administrative time is spent doing all the permutations needed to satisfy donor demands. More menacing is that this process of accommodation corrodes trust.
- Rather than using our brains to outwit those whose resources and power might enable them to restrict university activities, it would be far better to persuade them of the long-term good done by letting free inquiry characterize the academy. The larger society has been well served by academic freedom and this truth is evident all around us.
- We must integrate the academic mission into society and be accountable to the broader community or risk losing the support necessary to succeed. The pressure to bend the long-term mission of the academy to the short-term desires of individuals is pernicious and will serve no one well in the long-term. Let us work for understanding to redirect these pressures to the long-term good of the academy and society.