

A Thriving Partnership: The University and High Tech Industry

University of Utah
Salt Lake City

Foreword

These are stories of innovative Utah companies. Some are multimillion dollar giants, others have yet to make a profit. However, they all have two things in common: they deal in high technology, and they trace their origins, directly or indirectly, to the University of Utah.

High technology refers to machines and processes using the very latest scientific knowledge. And the rate at which such knowledge moves from the laboratory into commercial application is increasing all the time.

During the 1980s, an increasingly global marketplace will develop in which the remaining labor-intensive manufacturing activities will shift to what are now the developing countries. This nation's prime product in such a new economic order will be ideas and inventions—in other words, high technology.

As Gov. Scott Matheson noted in his State of the State Address, if Utah wants to participate in this economic future, "we must make a dramatic commitment to new technology." Since, as the governor puts it, "the raw material of the information age is intelligence," education as an "investment in our human capital" is the key to the state's growth.

In fact, a study by the Joint Economic Committee of Congress found that the number one factor high technology

industry considers in locational decisions is the availability of educated, technically skilled workers.

Utah already has considerable assets for attracting high technology industry. Primarily because of companies growing out of artificial organs and biomaterials research at the University of Utah, Science Digest reported that "Salt Lake City is becoming Bionic Valley—the epicenter of a bioengineering effort that promises to shake up the entire health care system."

Further, because of its location in the growing southwest quadrant of the nation and its good quality of life, Salt Lake City is one of 10 "cities of great opportunity" for the 1980s, according to social forecaster John Naisbitt, author of the best seller, "Megatrends," and a University of Utah alumnus. And high technology businesses locating on the Wasatch Front may be expected to eventually establish some satellite operations in Utah's rural communities.

The University of Utah is committed to helping attract and create high technology industry. Its policy is to get research inventions to the marketplace as quickly as is feasible.

While the University owns any technology developed by employees using its facilities, it actively seeks to license the technology to the inventor or to private companies. In return, the University usually receives royalties on sales and sometimes stock in the companies involved. Returns from such license agreements flow back into University education and research programs.


Faculty are free to form or participate in private companies as long as the activity does not conflict with University

interests or the faculty members' academic commitments. Some professors involved with companies have shifted to part-time status or eventually left the University. Some have built up companies, sold them and then been reappointed to the faculty.

The University offers a range of services to high technology industry, including a 300-acre Research Park adjacent to campus, the University of Utah Research Institute which conducts applied research and testing not suitable for academic study, and a patent office and a patent attorney.

Private companies find the University's libraries, computer center and scientific equipment major resources. Top scientists and engineers for private firms, many of whom hold Ph.D.s, attend campus cultural events, take classes and hold adjunct positions on the faculty. Employees of firms in Research Park have privileges at University recreation facilities.

The companies described in this booklet are featured because they developed from, or required association with, a major research university. These stories give an insight to the kind of remarkable technology and innovative firm that is becoming a key element of the Utah economy.



James J. Brophy
Vice President for Research

**Terra Tek Inc.
420 Wakara Way
Salt Lake City, Utah 84108
Sidney J. Green, President**

enough to begin producing a product," says Frank P. McNeil, UICI general manager. The remaining space has been leased to other high technology businesses.

In its headquarters, UICI will provide a technical library, offices, conference rooms and pooled secretarial, legal, computing and other services. Each client will be billed for the services used.

Technology-based companies often need scientific equipment, such as chemical analysis instruments and electron microscopes. Beginning companies seldom can afford such items. But since they are based in Research Park, UICI clients will be able to arrange for use of such equipment on campus.

Besides licensing or selling technology it owns and receiving revenue from its stock in high technology firms, Utah Innovation Center Inc. will do business consulting for existing firms and government agencies on problems related to commercializing new technology.

UICI illustrates the University's role in helping develop the business as well as the scientific expertise essential for launching high technology companies. It shows how successful teamwork among government, academic and private enterprise can help future University researchers in various fields commercialize their products as well as attract non-University-related businesses to the state.

The formation of a company to carry on work begun at the University may be only a beginning. The spin off firm may itself produce spin offs. And talented scientists, engineers and managers who come to Utah to work for those companies may end up founding still other companies.

Terra Tek Inc., which concentrates on geoscience research activities, is an example of a small, single-purpose firm mushrooming into a web of companies. The central corporation now has seven divisions, subsidiaries and affiliates, not counting independent firms launched by former employees.

In fact, the parent firm's chief activity now is simply launching or acquiring an interest in, and then nurturing, other high technology companies. "Terra Tek is really an incubator," says Sidney J. Green, president and chief executive officer. "We help create or develop companies. As they mature, we push them out of the nest, and they gradually proceed on their own."

A philosophy of promoting new ideas and new companies to implement them has led to the group's total annual revenues growing from \$4.7 million to \$12.8 million over the last six years. Terra Tek companies now have more than 350 employees.

The firm originally grew out of federally funded research in the Mechanical Engineering Department studying the characteristics of various types of rock structures under extremely high pressures. The principal investigator was Dr. Wayne S. Brown, professor and former dean of engineering.

In 1969, Brown incorporated Terra Tek, and in 1970, the company opened a four-person office in downtown Salt Lake City. Initially, the company continued work on the federal research contracts started earlier at the University. Most of the firm's research during this period focused on the potential effects of an atomic blast on Minuteman missile silos. The studies also developed data engineers could use to design safe underground bomb tests in Nevada.

Since then, Terra Tek has expanded into a variety of engineering research activities for government and industry clients. It has acquired an interest in or launched seven other enterprises. These include Drilling Research Laboratory Inc., Terra Tek Systems, Terra Tek International, Native Plants Inc., Resource Enterprises Inc., Terra Tek Core Services and GEOTECH Ltd. Terra Tek also was one of the original occupants of University Research Park.

In its early years, Terra Tek financed growth with bank loans, stock sales to employees and its own profits. In 1980, it began seeking investments from national venture capital companies to finance more rapid growth.

Generally, as a Terra Tek operation becomes attractive to investors, stock is

Motor Co.-University of Utah research. DOE is still funding the studies, which are now being conducted by Ceramatec privately. While affiliated with the University, the research attracted \$2.3 million in federal research and development money.

Gordon, who continues to hold his appointment as professor of materials science and engineering and who still teaches part time at the University, became the principal investigator on the Ford-DOE subcontracts.

Initially, research was centered in the Materials Science and Engineering Department. Graduate students assisted faculty, and several theses and dissertations resulted. But gradually, aspects of the research became less academic and thus less appropriate for student training. In 1976, those portions of the work were moved to the University of Utah Research Institute, a University-affiliated but self-supporting entity established to carry on research that has become commercially, rather than academically, oriented.

As work progressed further, however, both Ford and the government wanted a profit-making organization to carry out the technology on a larger scale. So it was up to Gordon to decide whether or not to form a company.

By 1979, ten investors—primarily Gordon and Gordon's collaborators from the University—had raised \$120,000 in working capital. Last year, the firm's income was \$1.3 million, including \$600,000 in commercial sales. Ceramatec now has about 40 employees.

When the University was sponsoring the research of Gordon and his associates, the institution took patents

on various processes and products the team invented. The University has since licensed many of the patents to Ceramatec. In turn, as Ceramatec markets the patented items, the company will pay royalties to the University.

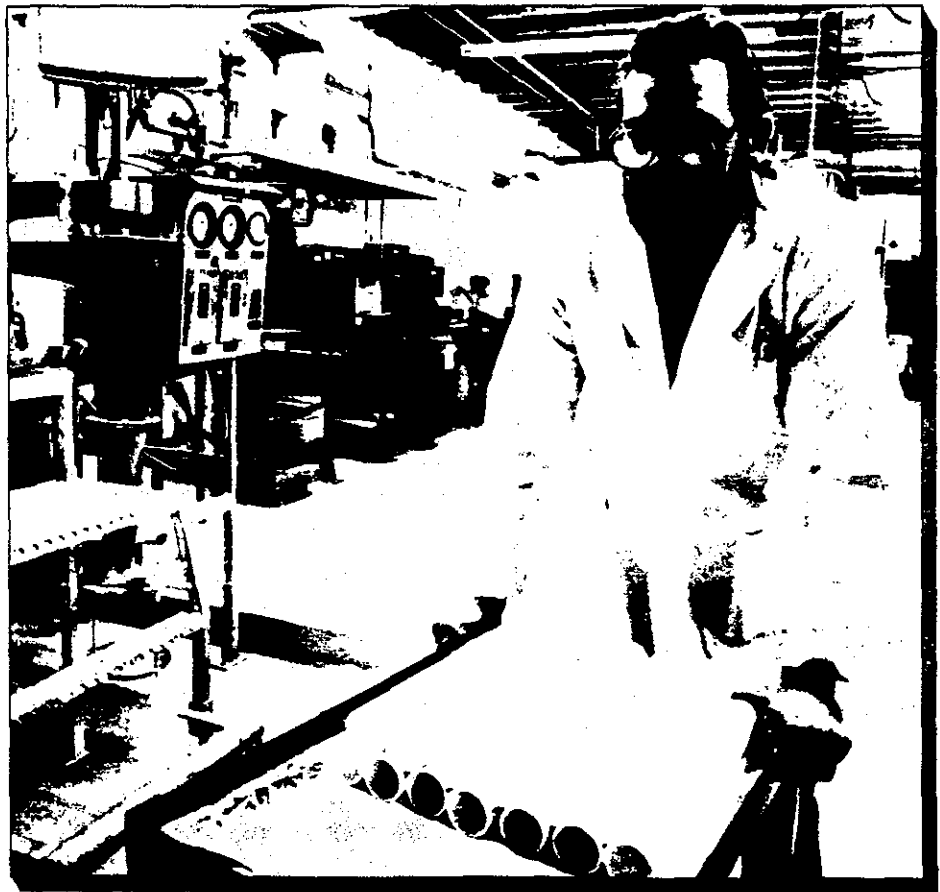
The company seeks to find diverse uses for its specialized ceramics and generally to "operate at the forefront of advanced materials technology," says Gordon.

Ceramatec is now gravitating toward commercial sales. Its specialized products are already being sold in Europe, Japan and throughout the United States, and potential markets are vast.

The company also expects to continue

conducting basic research. And just as Ford Motor contracted with Gordon and his team, Ceramatec has subcontracted with present University faculty for some of this research. "Research contracts are very important," explains Gordon, "because out of them come ideas for our future products."

The company's development illustrates the various roles the University of Utah plays in bringing high technology industry to Utah. Those roles include enabling a new process to be developed, helping the process to be applied commercially and then continuing to feed a stream of ideas for further applications of the process.



Ceramic materials manufactured by Ceramatec Inc., a spin off from the University Materials Science and Engineering Department, could be used to power nongasoline cars and extract metals from sea water

**Bunnell Biomedical Inc.
391 Chipeta Way, Suite G
Salt Lake City, Utah 84108
Dr. J. Bert Bunnell, President**

about 15 employees and is receiving about one order a week for the Utah Arm. In 1982, Wiita, who received his MBA from Harvard, came to Utah because he was "blown away by the technology" of biomedical devices being developed at the University.

Revenues for 1982 totaled about \$500,000, and the present annual sales rate is about \$1 million.

The Utah Arm is another example of a research idea developing into a beneficial product. That has been possible, explains one Motion Control official, "because University of Utah policies encourage the transfer and commercialization of technology to industry when a product becomes viable."

Bunnell Biomedical Inc. recently marketed an air pressure monitor that signals the nurse if a patient's respirator is not working properly. The company is working on a "high frequency ventilator" that could replace respirators now used for critically ill infants and children.

But, says Dr. J. Bert Bunnell, BBI founder and president, if the Utah Innovation Center at the University of Utah had not helped launch the company, development of the life-saving devices would have halted abruptly.

All that would have remained of a decade of research at Harvard University, Massachusetts General Hospital and two private firms, says Bunnell, would have been some disassembled equipment and an untested clinical prototype.

A native of Price, Utah, Bunnell received his doctorate in engineering at the Massachusetts Institute of Technology.

In the course of his research, he became concerned about damage infants were suffering from respiratory therapy. The standard method of treating respiratory distress was forcing air into a baby's lungs at about the same rate as normal breathing, explains Bunnell. If the pulmonary passages contained any leaks, bigger doses of air were forced into the lungs in order to meet the child's metabolic requirements.

However, the continual pressure of air bursts can rupture a weak child's lungs or inhibit the child's cardiovascular activity.

In response, Bunnell began exploring "high frequency" ventilation—a concept

that had been discussed for some years in scientific literature. Eventually he built a new type of respirator that operated much faster than normal lungs—at more than 900 breaths per minute—but released far smaller bursts of air.

After building two more prototypes, the company Bunnell was employed by announced it was closing. That's when the Innovation Center suggested that he start his own company. Within a few months, the center helped Bunnell buy the rights to his research and prototypes.

In 1980, BBI incorporated. The Innovation Center provided space and advice, and initially paid some of Bunnell's technicians. More important, the staff lent moral support. "They kept believing in me," Bunnell says.

In return, the Innovation Center received common stock in BBI. The stock has since been divided between the University of Utah and UICI, giving each of the two entities just over 10 percent ownership of an increasingly valuable biomedical firm.

By the end of 1982, BBI was selling 50 air pressure monitors a month. Revenue was coming in at the rate of about \$1 million annually, and the

fade and otherwise modify recorded sounds.

In 1977, Soundstream Inc. made its first important digital record—a recording of Arthur Fiedler and the Boston Pops. Record companies recognized the superiority of the digital method, but generally they weren't willing to purchase Soundstream's recorder outright. So the firm began offering recording services to Columbia, RCA, Telarc and other music companies, and has now recorded about 300 albums.

One of Soundstream's achievements has been using digital processing to remove distortions and resonance from master recordings of Enrico Caruso. RCA has issued a multi-album collection containing the restored versions of the complete Caruso heritage.

Recently, a number of companies

have begun using digital recording technology to produce inexpensive record cards (similar to computer cards) that can be inserted into special home players to reproduce high quality sound.

In 1980, Stockham decided to merge Soundstream with Digital Recording Corp., a publicly held firm. Soundstream is now a wholly owned subsidiary of Digital Recording Corp., which has moved its headquarters to Salt Lake City.

Digital Recording Corp. was organized to develop a related technology—optical recording of digital data using lasers. The company is working to commercialize a process invented by James T. Russell at the Battelle Laboratories in Richland, Washington.

DRC has focused on digital recording of a variety of information materials,

including words, photographs, color television pictures and business data. The company's current emphasis is on archiving medical diagnostic data, particularly X-rays. A laser beam would be used to put data onto the cards and to retrieve it.

Officials say the method enables storage of a far greater volume of material than can be contained on present magnetic computer tapes. For instance, 1,500 X-rays can be stored on a 3- by 5-inch card.

The merger with Digital Recording Corp. and the fact that companies throughout the world have moved into digital recording have signaled a change in business emphasis for DRC and Soundstream. The developments have influenced Stockham's decision to resume his academic career.

However, Stockham is returning to the University with the satisfaction of knowing that Soundstream's digital albums have provided a key stepping stone for the recording industry. One reason digital recording is coming to the home, he notes, is because of the pioneering efforts of Soundstream.



Dr. Thomas G. Stockham, founder of Soundstream Inc. and pioneer in digital recording of music, has returned to the University faculty to share his business and scientific knowledge with students

Realization of potential is only a
matter of time.

Kolff Medical Inc.
374 West 600 North
Salt Lake City, Utah 84103
Robert K. Jarvik, President

venture capital. The Rockefellers recruited other investors, including the Newmarket Co., a London investment house which now owns about 13 percent of the company.

A year after its incorporation, the company shipped a "Line Drawing System I" computer to the first customer, Bolt, Buranek and Newman, one of the nation's top computer consulting and research firms.

But it wasn't until 1974 that the company turned its first profit and moved from the barracks to a new building in Research Park.

The same year, Evans left the University and began working for the company full time. He is now president and chairman. Sutherland is presently with Carnegie-Mellon University but continues to be a member of the board and a consultant to the company.

By 1978, with sales nearing \$10 million, the company went public with a \$3 million stock offering. It raised another \$10 million in a 1980 offering. The firm now has nine-million shares outstanding, a majority of which are owned by private and institutional investors.

For several years, Evans and Sutherland's chief products have been computerized simulators used in jet pilot training and computers and terminals for engineering design stations.

The design stations, which enable engineers to actually see the results of changes in shapes and dimensions, are used in designing items ranging from soap

bottles to airplanes to the molecular structures of drugs.

Most of the company's research and development is directed toward improving its two key products.

The company's Research Park location and its continued informal ties with the University are keys to attracting its biggest asset—talent. Employees have tuition waivers and staff privileges at University recreation facilities. Company officials find it convenient to consult government contract reports in Marriott Library and to find answers to business and patent questions in the Law Library.

Still, the net benefit probably falls to the University. Besides making substantial voluntary contributions to computer science activities, the company often purchases time on the University computer. Several Evans and Sutherland computer scientists and engineers, including Evans himself, are adjunct faculty members who periodically teach classes and serve on graduate students' committees.

"We just like our relationship with the University a whole lot. That feeling," says Vice President Gary Meredith, "seems to go both ways."

The implant of an artificial heart in Seattle dentist Barney Clark culminated 15 years of research at the University of Utah. It also marked the beginning of a private project aimed at eventually manufacturing and marketing artificial hearts.

"We're right at the juncture where research is transferred to the commercial world," explains William C. Moeller, executive vice president of Kolff Medical Inc., a firm set up to commercialize the total artificial heart and other medical technology.

Although it was established in 1976, Kolff Associates started expanding its activities about one year prior to the implant. Food and Drug Administration regulations require a request to use an experimental medical device to be jointly submitted by the company that may eventually manufacture the device and a chief investigator.

During the past year, Kolff Medical also negotiated two important license agreements with the University. The first gives the company commercial rights to the artificial heart, its drive system and related cardiovascular research.

A second agreement covers an artificial hearing system—essentially an artificial ear for the deaf—which, like the heart, was developed in the University's Artificial Organs Division. It converts acoustic waves to electric signals. These electronic impulses are processed through a tiny computer and applied to appropriate nerve fibers in the inner ear. The artificially stimulated nerves send messages which the brain is able to interpret as distinguishable sounds.

The principal founders of Kolff Medical included Dr. Willem Kolff, artificial organs pioneer and founder of both the Artificial Organs Division and the University's Institute for Biomedical

There's a basic reason why it's blossoming

Native Plants Inc.
360 Wakara Way
Salt Lake City, Utah 84108
Peter D. Meldrum
Chief Executive Officer

Like any good company, Native Plants Inc. looks for common sense, economical solutions to its customers' problems. But Native Plants—to a degree matched by few companies—is finding those solutions on the frontier where technology and basic science meet.

That approach to the biotechnology business reflects Native Plants' history. The company was launched by basic scientists. Later, a business consulting and venture capital company in University Research Park took a strong interest in the firm.

This association helped Native Plants to diversify, to build sales to more than \$4 million in 1982 and to become one of the leading companies of its type internationally.

Among the founders were Dr. Clyde Hill, professor of biology at the University of Utah; G. Michael Alder, who had received a master's degree from the University; and two Brigham Young University biology faculty. Alder is now president of Native Plants.

The firm was established to find ways of producing commercial quantities of western American native plants, such as the familiar Utah juniper tree. The plants were to be used for reclamation, landscaping or erosion control at arid sites, including mines, pipelines, dams and along highways.

Founders believed native plants would be far easier to establish and cheaper to maintain in such locations than traditional, irrigated foliage. In fact, test results show that the cost per plant for establishing traditional plants at arid sites has been as high as \$80, compared to \$5 for native plants.

In 1977, Resource Enterprises Inc., one of the family of Terra Tek companies, made a major investment that helped Native Plants to expand its administrative, laboratory and cultivation facilities and to begin applying diverse technologies.

Native Plants currently addresses three market areas: agriculture, reclamation and natural products. Now, how-

ever, the firm conducts extensive laboratory pretests to determine germination rates and other results of a given reclamation strategy. A computer model calculates per-plant costs of various design alternatives.

Another principal company emphasis is agriculture—the development of more stress tolerant, thus higher yielding, crops.

For instance, the company is studying use of protoplast fusion—removal of the cell walls enabling two cells to merge. Researchers want to join the Idaho russet potato with a strain of wild potatoes that is naturally resistant to a pest called the "leaf hopper."

If the fusion is successful, the resulting plant will have both the edible qualities of the russet potato and the leaf hopper resistance of the wild potato, explains Dr. William Hugh Bollinger, Native Plants' vice president and coordinator of

much of the company's cellular and molecular biology work.

Once a single superior plant is produced, it can be cloned and thus reproduced in exponential quantities. Native Plants has used cloning from tissue cultures to produce large quantities of potato, asparagus and strawberry plants and grapes for wine and edible varieties. Native Plants' microbiologists are presently advancing toward the commercial production of beneficial fungi and bacteria that could diminish the world's chemical fertilizer requirements.

Probably the company's most advanced research project at present involves identifying the traits carried in specific, individual genes in corn plants. The eventual goal is genetic engineering—the capability of infusing a plant with one gene carrying a given, desired characteristic.

A third emphasis is in plant chemistry.



Native Plants Inc. is involved in cloning, cell fusion and genetic engineering of plants. The firm produces a variety of agricultural and plant chemical products.

site plans. Final leases, which run for 40 years with an option for a 10-year renewal, must be approved by the University Institutional Council.

**Research Institute
420 Chipeta Way
Salt Lake City, Utah 84108**

Dr. William S. Partridge, President

The University of Utah Research Institute is a University-controlled, but financially separate, nonprofit corporation set up to conduct applied research.

It presently occupies more than 90,000 square feet of space in University Research Park. The institute has more than 100 research contracts with government agencies and private firms. Revenues for 1982 totaled \$7.5 million.

The institute was established in 1972 under state legislation that allows the University to form nonprofit corporations and foundations. It has a self-perpetuating, nine-member board of directors. Board members presently include the University president, three University vice presidents, the president of the institute and four citizens.

The institute employs about 150 persons, including about 30 Ph.D.s. It has two divisions: the Utah Biomedical Testing Laboratory and the Earth Sciences Laboratory. It is also conducting a number of special projects that are not assigned to a division.

The UBTL contracts mainly relate to medicine, chemistry and engineering. It



Work of the Utah Biomedical Test Laboratory's industrial hygiene group includes analysis for free silica using an X-ray diffractometer. UURI and its divisions have a total of over 100 research contracts.

tests medical devices, conducts small animal research and has facilities for mutagenesis and genetic studies. It also makes chemical analyses and does work in circuit design, fluid dynamics and materials science. Another specialty is industrial hygiene.

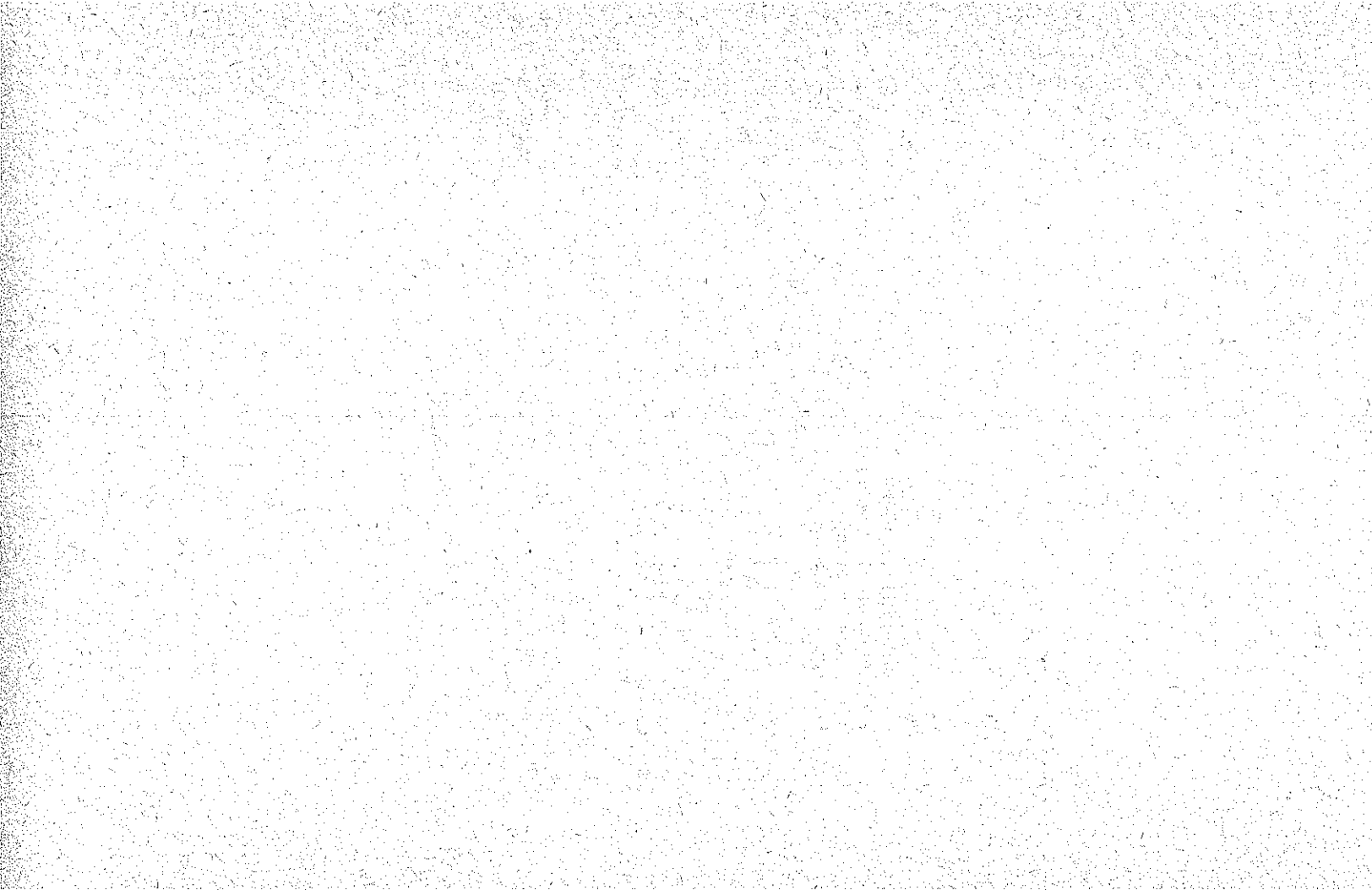
The Earth Sciences Laboratory does field exploration for minerals and energy sources. It also has contracts for geothermal research and for testing of geophysical instruments.

Present special projects include weather studies, remote sensing and cartography work, employment surveys, and laser and optical fiber research.

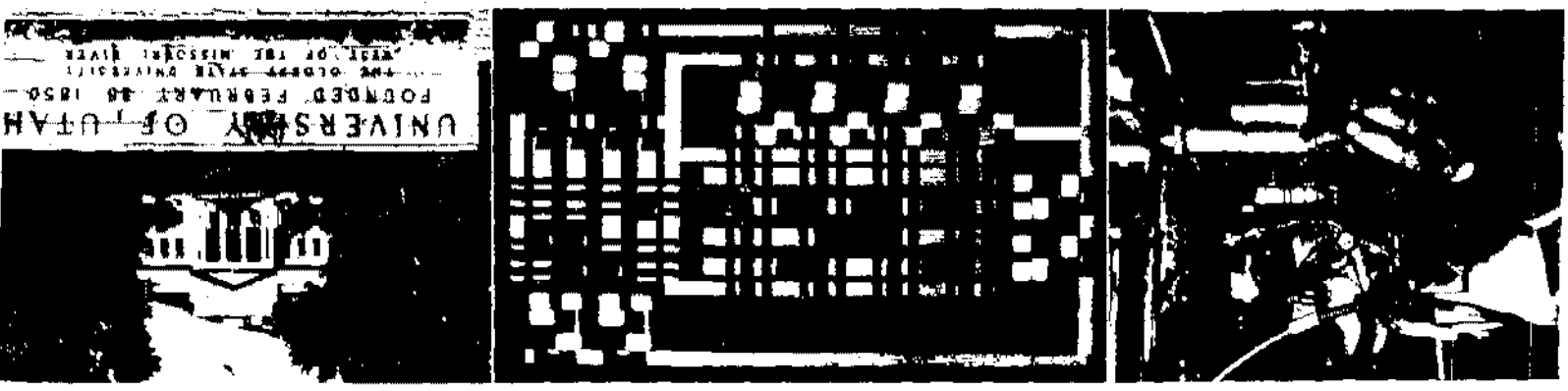
**Patent and Product Development
420 Chipeta Way, Suite 170
Salt Lake City, Utah 84108**

J. Winslow Young, Director

The Office of Patent and Product Development directs University efforts to transfer research developments into the private marketplace. It assures that the University is compensated for innovations developed by University.

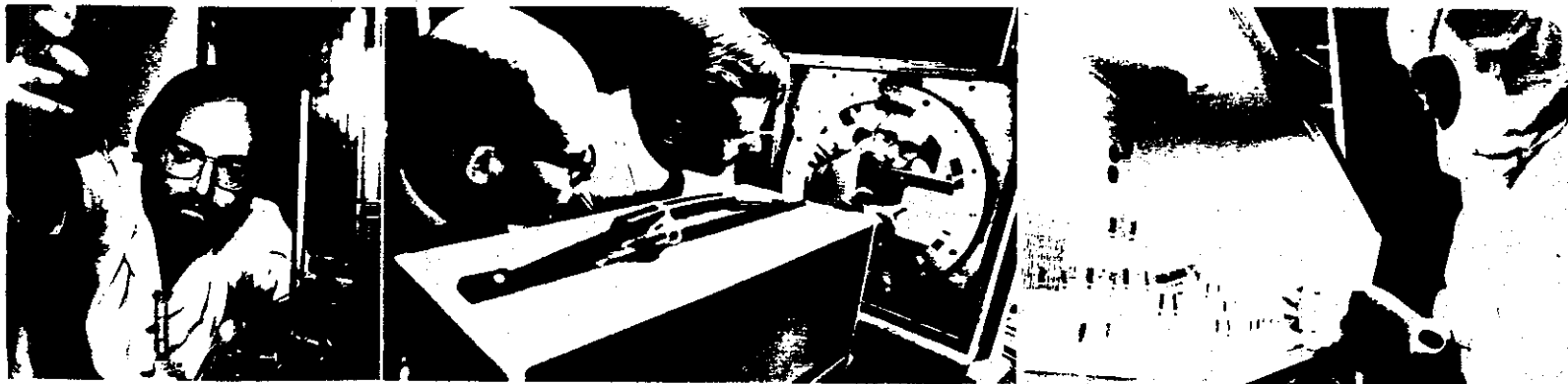


Research for Industry
at the
University of Utah



UNIVERSITY OF UTAH
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Contents



Foreword	3
Industrial Support Arrangements	4
Faculty Research Contracts	4
Jointly Sponsored Programs	4
University of Utah Research Institute	5
Utah Engineering Experiment Station	5
Research Development Grants	5
Representative Industrial Research Projects	6
Data-Driven Computers	6
Optical Properties of Materials	6
Integrated Circuits Laboratory	6
Chemical Structure of Coals	7
Wood Combustion in Spreader Stokers	7
Orthopedic Implant Development	7
Clinical Pharmacology	7
Computer-Controlled Tumbling Mill	8
Solution Mining	8
Tar Sands Pilot Plant	8
Nuclear Magnetic Resonance Facility	8
Testing Services	8
Synthetic Fuels	9
Minerals Beneficiation	9
The Research Agreement	9
Proposal Preparation	9
Budget Proposal	9
Publication Rights	10
Patents	10
Research Performance	10
Appendix - Standard Research Agreement	11

Foreword



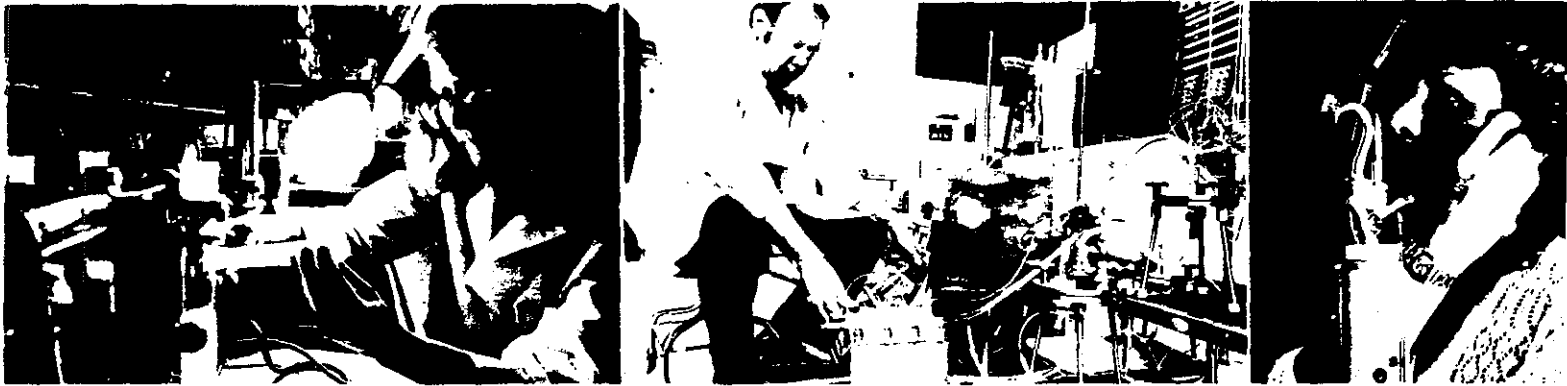
Industrial support of faculty research and education programs is an important aspect of the academic program at the University of Utah. Private funding currently represents approximately 15 percent of the University's annual \$60 million contract and grant total. Industrially supported research and training programs complement and supplement faculty efforts funded by state and federal agencies and introduce an important flavor into the academic program. These efforts prove particularly significant for educational purposes, as it is in the private sector that most graduate students spend the rest of their careers.

Several aspects of industrial funding are refreshingly different from the familiar federal grants program. There is, for example, usually no formal peer review of proposals, and many fewer regulations, and restrictions are placed upon principal investigators in the pursuit of their research. Also, flexible arrangements between the principal investigator and the sponsor are available to better match their mutual interests. On the other hand, it is often true that the timing of awards and research performance must be adjusted to match the sponsor's requirements rather than the academic calendar. Publication of research

results and patent rights become important considerations.

In general, the formal research policies for support by the private sector at the University of Utah are the same as for grant and contract funding by federal agencies. These policies and procedures are described in detail in the Principal Investigator's Handbook. Some special concerns of faculty members and potential industrial sponsors with regard to industrial research programs are covered in Research for Industry. Also included are specific examples of effective university/industry interactions. Inquiries regarding this material should be addressed to the Vice President for Research, 304 Park Building, 801/581-7236.

James J. Brophy
Vice President for Research



University of Utah Research Institute

The combined strengths of the University of Utah Research Institute (UURI) and academic departments are very attractive to industrial sponsors. Since UURI is an independent contract research organization, it has an administrative structure familiar to industrial executives and is capable of organizing team research efforts which can produce important directed research results. This complements the typical academic research effort with its more free-ranging scope and educational function involving graduate students. Often, UURI can act as an organizational buffer between university and industry, particularly for multi-faceted, continuing research efforts.

The administrative machinery at UURI provides for promotion of the project proposal and project operation under the guidance of a joint University-UURI technical committee combined with the research expertise of both institutions and the educational/training capabilities of the University. In selected technical areas, significant support levels can be developed through participation of a number of individual corporations. Although this approach is primarily

designed to attract industrial support, federal participation in cooperative industrial/university activities is not excluded. For additional information, contact William S. Partridge, president, University of Utah Research Institute, 801/581-3000.

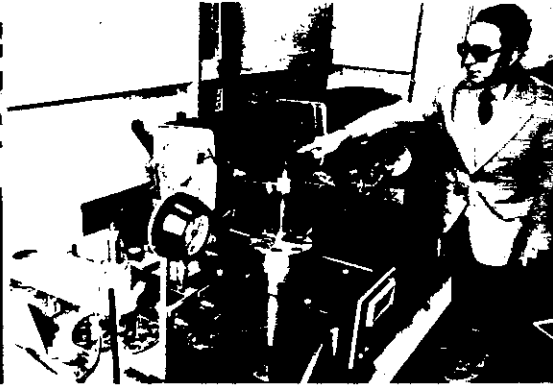
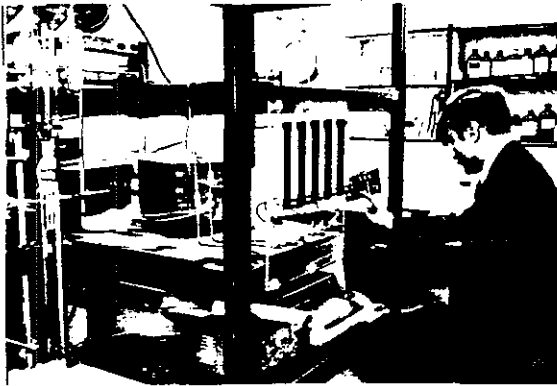
Utah Engineering Experiment Station

The Utah Engineering Experiment Station (UEES) was established in 1909 by the Utah State Legislature to serve as an interface between campus technical resources and industries in Utah. The UEES furnishes services such as materials testing and evaluation of products, processes, equipment, and materials through the technical service laboratories established in several academic departments and divisions. For further information, contact Gordon F. Jensen, director, Utah Engineering Experiment Station, 801/581-6348.

Research Development Grants

Most industrial research efforts involve specific commitments by the principal investigator and the University. That is, in return for support funds, the principal investigator and the University agree to undertake the program described in the technical proposal and deliver at least a final summary of results. In some instances, it may

prove more appropriate for a company to provide general support in a research area through an uncommitted development grant. In such cases, the corporation may consider the grant a charitable deduction for tax purposes, and the grant funds may be expended by the Principal Investigator without regard to technical or budgetary considerations. Although there can be no contractual commitment to report the research results achieved through a development grant, generally the principal investigator will report informally what has been accomplished with the grant funds. Questions about whether any specific activity should be considered a sponsored research effort or a development grant should be referred to Richard H. Timpson, director, Office of Research Administration, 801/581-3003, or J. Michael Mattsson, director of development, 801/581-6823.



Chemical Structure of Coals

Standard Oil Company of Indiana has funded a University study concerned with the chemical structure of coals. Solvents and catalysts are used to depolymerize the coals under mild temperature and pressure conditions, and the products are separated and analyzed by a combination of chemical and spectral methods. This provides information on the structure of original or only slightly modified components of coals. As part of the initial \$211,000 contract, which was extended for 18 months at a level of \$228,753, the principal investigators have agreed not to undertake any other research project on the same subject during the course of the agreement. The project is headed by Professor Joseph S. Shabtai. Professors L. L. Anderson, D. M. Bodily and R. J. Pugmire are co-principal investigators.

Wood Combustion in Spreader Stokers

Researchers in the Chemical Engineering Department are trying to develop a better understanding of wood combustion and the associated pollutant formation in a wood-fired, spreader-stoker combustion system. Weyerhaeuser Company, which is funding the study, receives monthly, quarterly and yearly reports of progress. The project includes an examination of both the rate of volatile evolution and combustion and the formation of gaseous pollutants and

particulates, mostly unburned wood particles. Two graduate and two undergraduate students are assisting. Existing furnace facilities in the department are being used for the \$49,000 study.

Orthopedic Implant Development

Orthopedic implant manufacturers are an important source of funding for the Orthopedic Bioengineering Laboratory, co-directed by H. K. Dunn, M.D., and A. U. Daniels, Ph.D., within the School of Medicine. Industrially supported projects currently include evaluation of the effect of new bone plate designs on fracture healing, development of implants for the correction of spinal deformities and investigation of orthopedic applications for degradable polymers. Recently obtained industrial awards have ranged in size from \$700 for supplies for a medical student's summer project to \$86,000 for a study involving long-term animal implant experiments.

The laboratory has found small industrial grants or contracts extremely valuable. A current example is a six-month project funded at \$14,000, a pilot study that may lead to a larger project if the results show promise. On the academic side, such short-term projects are easily tailored to the schedules of master's degree candidates or surgical residents interested in a research experience. The students assigned to projects of this kind are involved in writing final reports, which can usually be turned into graduate theses.

Clinical Pharmacology

A major pharmaceutical firm has recently underwritten the development of the Abbott Research Center for the development of new drugs. The center is under the direction of Dr. Keith G. Tolman and his colleagues and consists of a 32-bed clinical research unit at the University Medical Center. The center provides an environment in which the company can sponsor confidential research on new drugs, and academic freedom is not compromised because the company recognizes the need for investigators to work in an unrestricted intellectual environment. Toward this end the company provides an unrestricted research grant to the investigators to carry out their own research and also gives the University publishing rights to all of the data generated at the center. In return, the company benefits from high-quality clinical trials conducted on its drugs and retains patent and invention rights. An important benefit of this relationship has been the awarding of new contracts to numerous other faculty members to study drug metabolism and mechanisms of drug toxicity. The unit is available for other University research about 70 percent of the time. Furthermore, the company sponsors an educational program in drug development for pharmacy students and funds two post-doctoral fellowships in clinical pharmacology.

The Research Agreement



of ores and carried out test grinding of cupric oxide. The UEES provides easy access to the full scope of the University's analytical and test services.

Synthetic Fuels

Mobil Research and Development Corporation annually presents a financial gift to the College of Mines and Mineral Industries for the general support of research and educational activities. The grant is presented through the University Development Office to Dr. Alex G. Oblad, distinguished professor of metallurgy and fuels engineering. The funds are invested in the college's diverse research effort in the recovery and upgrading of synthetic fuels from coal, oil shale and tar sands. The University, in turn, keeps the sponsor informed of progress in the research effort.

Minerals Beneficiation

Three prominent researchers in the College of Mines and Mineral Industries share a \$10,000 grant from the Exxon Education Foundation. Professors Milton E. Wadsworth, Jan D. Miller and John J. Herbst are conducting work in minerals beneficiation. The grant was made through the University Development Office on the recommendation of Exxon Research and Engineering Company. The researchers submit an annual progress report and inform the foundation of any problems or obstacles that may arise. The foundation also is advised of any needed changes in the actual conduct of the project.

Funds are accepted by the University on behalf of a principal investigator to pursue a research program in accordance with a formal agreement between the University and the industrial sponsor. This agreement incorporates the technical proposal prepared by the principal investigator, a cost budget and commitments of the University in return for research support.

The Standard Research Agreement is shown in the appendix. The Office of Research Administration can negotiate modifications to this agreement suggested by the sponsor and pertinent to a specific research effort. Questions should be directed to Richard H. Timpson, director, Office of Research Administration, 801/581-3003.

Proposal Preparation

Usually the proposal is prepared following communication with the potential sponsor. The technical proposal may consist of only a few-page description of the general scope of the research, estimated duration of the program and level of personnel anticipated. Brevity is usually desirable, since the proposal will probably not be subjected to a peer review process. However, evidence of past research accomplishments as contained in curriculum vita or pertinent reprints is very important. Most industrial sponsors also are very interested in graduate student participation.

It is appropriate to share a draft of the technical proposal with the potential sponsor on an informal basis in order to adjust the program to the sponsor's requirements. Subsequently, the final draft is submitted formally by the Office of Research Administration together with the budget and Research Agreement. No proposal can be submitted without the approval of the principal investigator, department chairperson and dean indicated on the Official Document Summary Sheet forwarded to the Office of Research Administration.

Budget Proposal

It is usually unnecessary to include a detailed cost breakdown in the budget proposal. Often the following categories suffice:

- Personnel
- Equipment and Supplies
- Capital Equipment
- Miscellaneous

In developing the total budget, however, it is important to prepare a detailed estimate with the advice and approval of the Office of Research Administration. This assures that all direct and indirect costs are included and obviates the possibility of an

Appendix

Standard Research Agreement

This contract is entered into between the _____, hereinafter referred to as the Sponsor, and the University of Utah, an institution of higher education of the state of Utah, located at Salt Lake City, Utah 84112, hereinafter referred to as the University.

Whereas the Sponsor desires research services in accordance with the scope of work outlined within this agreement, and

Whereas the performance of such research is consistent, compatible and beneficial to the academic role and mission of the University as an institution of higher education and, in consideration of the mutual premises and covenants contained herein, the parties hereto agree as follows:

Article I - Scope of Work

University agrees to perform for the Sponsor the research activities described in Attachment A hereto, under the direction and supervision of _____, principal investigator(s).

Article II - Contract Period

This contract shall become effective on _____ and shall be completed on _____ unless subsequent time extension, supplement, addition, continuation or renewal is mutually agreed upon in writing between the parties.

Article III - Compensation

Sponsor agrees to reimburse the University for services performed under this agreement in the amount of \$ _____ in accordance with the budget itemized in Attachment B and to provide payment in accordance with the following schedule:

Monthly billings or other schedule.

Article IV - Reporting Requirements

University will provide reports on the progress of the research as outlined or required in the Scope of Work or as designated as follows:

A final report will be furnished at the completion of the contract period.

Article V - Publication and Confidentiality

University, as a state institution of higher education, engages only in research that is compatible, consistent and beneficial to its academic role and mission and therefore significant results of research activities must be reasonably available for publication. The University agrees, however, for a period not to exceed six (6) months following completion of the project, that it will obtain Sponsor approval prior to publication, which approval will not be unreasonably withheld by Sponsor. University agrees to keep confidential any Sponsor proprietary information supplied to it by Sponsor during the course of research performed by the University, and such information will not be included in any published material without prior approval by Sponsor.

Article VI - Equipment

Special equipment purchases under the terms of this agreement become the property of the University unless otherwise specified herein.

Article VII - Indemnification

Each party hereto agrees to be responsible and assume liability for its own wrongful or negligent acts or omissions, or those of its officers, agents or employees to the full extent required by law, and agrees to hold the other party harmless from any such liability. University is an institution of higher education of the state of Utah and is bound by the



■ **Dr. James E. Pugh**, a professor of mechanical engineering, is shown in his laboratory. He is surrounded by various pieces of equipment, including a large cylindrical tank and several computer monitors. He is looking at one of the monitors, which displays a technical drawing or data.


Research for Industry Photographs

The photographic subjects provide a view of the breadth of research conducted in science, engineering and medicine at the University of Utah. Funding of these investigations from government, industry and private sources totals more than \$60 million annually. These photographs portray the remarkable results that can be achieved in the climate of innovation present at the University. They provide a sampling of the many dynamic research efforts of the University's faculty and affiliate research organizations.

On The Back Cover ■ **Dr. James E. Pugh**, a professor of mechanical engineering, is shown in his laboratory. He is surrounded by various pieces of equipment, including a large cylindrical tank and several computer monitors. He is looking at one of the monitors, which displays a technical drawing or data.

February 1, 1983

TO: Deans, Department Chairmen, Departmental Administrators, Faculty

FROM: Thomas H. Moss 
Director of Research Administration

RE: Guidelines for Research Agreements with
Commercial or Industrial Sponsors

As we are all aware, the University is constantly seeking to broaden and diversify its research support. The Objectives for the University, 1980-1985 specifically acknowledges our position as a research-oriented institution, and cites enhancement of that position as a key objective. Research support is crucial to allowing our teaching staff to reach the Faculty Handbook standards of scholarship and to contribute to the body of knowledge in their chosen fields. It is also vital to broadening the educational horizons and insight of our students.

As part of efforts to maintain and enhance the vitality of our research, we have been seeking industrial support for research activities in those areas where a natural match of interests is evident. Because we have been anxious to avoid compromise of the University's basic goals of education and open scholarship, and because arrangements with commercial sponsors are less familiar than those involved in ordinary federal grant support, some of the details of such research agreements have seemed to present formidable negotiating barriers. The unfamiliarity and complexity have tended to delay decisions and have inhibited formation of these relationships even when many factors point to benefits for both the University and commercial partner. The attached Guidelines are designed to help remove that inhibition and to indicate clearly what arrangements are normally acceptable and simple to implement in our environment.

The Guidelines are based on experience on the CWRU campus and at many other universities where there have now been enough cases of this sort to see a reasonable range of consensus on the key issues. They incorporate concerns of the University legal office, administrative staff, Faculty Senate Research Committee, and many individual Deans and Faculty members. We have found approaches within this consensus to be generally acceptable to all, even though some might have originally entered the discussions with a quite different set of expectations.

The key issues commonly arising are listed on the attachment, with a brief outline of typical considerations determining the University's position in specific cases. This is intended to show examples of how we can handle these issues in an acceptable and prompt fashion. It is important to recognize, though, that there is no single or automatic "model agreement" that can cover even a majority of cases. We have found that there are inevitably a number of specific points unique to the technology, sponsor, or researchers which must be negotiated individually in each case. The Office of Research Administration will provide consultation on these, and participate in negotiations, to aid in reaching agreement efficiently.

The general guidelines listed below are best used in defining the tone of initial contacts between commercial sponsors and university researchers, with commitments being avoided until all parties can discuss and review specific terms. The last page, "Outline of Agreement Essentials", is designed to hand out to prospective sponsors for their information on our practice. The other pages are to assist in forming our negotiating position and are not intended for distribution to potential sponsors.

In certain cases specific arrangements differing widely from these guidelines may turn out to be appropriate. However, these will probably require special discussion with Department Chairmen, Deans, or University Administration. In contrast, agreements within the guidelines are well within existing precedent, and should be acceptable with minimal justification or delay. The Guidelines are designed for arrangements in which the University itself is a party. They thus do not affect individual consulting agreements which are governed by existing departmental and school policies.

I hope you will call these guidelines to the attention of faculty in your schools and departments as you see appropriate. We will also mention their availability in Research News, and copies will be available at the Office of Research Administration. New kinds of issues and opportunities will constantly arise as we gain more experience with these research agreements, and I will welcome at any time your advice on refining our practices.

GUIDELINES FOR KEY ISSUES IN INDUSTRY-UNIVERSITY
RESEARCH AGREEMENTS

- A) Patent Rights: Rights to patents and copyrights stemming from faculty or staff research sponsored by an outside organization are negotiated as appropriate for the specific case. The inventor, outside sponsor, and a representative of the University should be parties to reaching an agreement on this issue before formal joint projects are begun. In accordance with Faculty Handbook policy, the inventor is in any case entitled to 50% of the net income received by the University in the form of royalties or other earnings on inventions.

Generally the University will give up its right to ownership of such patents only with reluctance, but there are cases where it may be reasonable to convey ownership of patents to outside sponsors or the inventor. In many other cases exclusive or non-exclusive licensing arrangements may be a better course. Examples of circumstances where the University might convey patent ownership include:

- 1) The research has a narrowly focused application, and a single commercial partner is able to commit to develop actively, and to pay royalties for the technology, in all potential areas of use.
- 2) The patents arising from the research are likely to be contested, and legal resources beyond the University's are going to be needed to combat infringement.
- 3) The chance of obtaining royalty-generating patents from the research is remote, so that the University could not justify investing its limited funds to obtain the patents.
- 4) The commercial partner is willing to enter into a compensation commitment or other agreement that is fully competitive with what the University might realize by any other approach. A commitment by the industrial partner to pay royalties on any commercial application of patents conveyed allows the University to share in any unforeseen benefits of the patent, and this makes transfer of patent ownership a less serious gamble.

Examples of where the University would want to retain ownership of patents include:

- 1) The possible applications are broader than the areas of interest or expertise of the commercial partners; exclusive or non-exclusive license in a specified field of use would be a preferred approach.
- 2) The University holds or expects to develop related patents, and must be careful not to encumber or limit their potential by losing ownership of one component.
- 3) Proposed royalties are not competitive with reasonably foreseeable alternatives.

- B) Confidentiality of Research Results: As an open institution dedicated to building and disseminating knowledge, the University seeks to minimize its obligations to maintain confidentiality of research results. However, we recognize the need to allow commercial partners to benefit from their research investments including ownership of patents or proprietary information and research results. Examples of reasonable approach are:

- 1) 90 day to 12 month delays on publications to allow a sponsor to identify patent opportunities or inadvertent disclosure of proprietary information. The need for graduate students to submit theses for degree requirements should be particularly protected, however. Graduate students should be made aware of any confidentiality agreements in a project before associating their thesis work with it, and arrangements for rapid or preliminary screening of thesis material must be made with the outside sponsor so that no delays are encountered in award of degrees.
- 2) "Best Efforts" to avoid inadvertent disclosure of proprietary information to outside parties.

Examples of commitments the University will seek to avoid are:

- 1) Lengthy delays of publication or indefinite confidentiality obligations, or granting to outside sponsors unspecified absolute approval rights for publication.
- 2) Any publication restrictions which would delay graduate students degrees or limit future career opportunities for graduate students.
- 3) Requirements that graduate students or employees enter into separate individual agreements with outside sponsors to maintain confidentiality. A better approach, which is usually acceptable to sponsors, is for students and employees to sign a statement for the record that they have read and understand the terms of the University-Outside Sponsor Agreement, and agree to comply with its terms.
- 4) Formal or physical security arrangements which are incompatible with the maintenance of an open and fertile intellectual atmosphere on campus.

- C) Indirect Costs: The University regards the federally audited indirect cost rate as a minimum realistic estimate of true indirect costs. The federal rate is designed to reflect required cost sharing by the University in actual indirect costs, and it explicitly excludes amortization of capital or infrastructure costs or investment in development for the future. Indirect cost rates must then be carefully negotiated; rates should rarely fall below the normal campus rate, and then only when it is recognized that the true cost will have to be absorbed in another fashion.
- D) Third Party Involvement: It has normally worked best for the University to deal directly with developers proposing to manufacture and market our technology, as opposed to those interested in seeking future sublicensing agreements to which the University would not be a party. Control of use of the University's name and reputation is much more clearly guaranteed in this manner.
- E) Use of the University's Name: Many commercial patent developers are very eager to associate the University's name with marketing efforts for a product or technology. This needs to be negotiated with care, insuring especially prior University approval of any advertising material.
- F) Duration of the Agreement: Because of the changing nature of faculty interests and student participation, we should avoid open-ended or very long-term commitments which might be difficult for the University to fulfill.

BASIC CLAUSES FOR UNIVERSITY - INDUSTRY CONTRACTS

1) "Hold harmless" from liability clause:

The UNIVERSITY agrees to idemnify and hold (name of corporation) harmless from any liability for damages, or claims for damages, including legal expenses, of whatsoever nature arising from the performance of this AGREEMENT. (Name of corporation) agrees to idemnify and hold the UNIVERSITY harmless from any liability for damages or claims for damages, including legal expenses, of whatsoever nature arising from the performance of this agreement or (name of corporation's) use of technology resulting from it.

2) "Ohio Laws" clause:

This AGREEMENT shall be construed, interpreted and applied in accordance with the laws of the State of Ohio.

3) "Entire Understanding" clause:

This AGREEMENT sets forth the entire understanding between the parties as to the subject matter of the AGREEMENT. Any Amendment to this AGREEMENT shall be in writing signed by the parties.

4) "University royalty-free use" clause: (name of corporation) agrees to allow the University royalty-free use for on-campus research and development of any technology to which it has acquired in this agreement.

5) "Notices" clause:

All notices to the UNIVERSITY under this AGREEMENT shall be in writing and sent to:

Director
Office of Research Administration
Case Western Reserve University
2040 Adelbert Road
Cleveland, Ohio 44106

All notices to (name of corporation) under this AGREEMENT shall be in writing and sent to:

INDUSTRY-UNIVERSITY JOINT RESEARCH PROJECTS

OUTLINE OF AGREEMENT ESSENTIALS

- 1) The University agrees to a research program described as an attachment
 - a) Starting and ending dates are designated.
 - b) The commercial partner agrees to a funding level and schedule.
- 2) The ownership and/or licensing rights to patents arising directly from the research are designated.
 - a) The duration of licensing or other commitments are specified.
 - b) Royalties and commercial partner commitment to active developing and marketing are specified.
 - c) The terms of third party licensing are specified.
 - d) Options for first refusal of patent and/or licensing rights to unplanned technological developments are specified.
 - e) The University is given royalty-free use of the technology for further on-campus research and development.
- 3) Obligations are specified concerning the exchange or confidentiality of information shared as part of the project.
- 4) Use of the University's name is protected.
- 5) Rights to terminate the project are specified for both parties.
- 6) Parties agree to hold each other harmless from any liability arising from the research project or the developed technology.
- 7) The agreement is specified to reflect the full understanding of the parties, and to be interpreted under the laws of the State of Ohio.

CASE WESTERN RESERVE UNIVERSITY
INDUSTRIAL RESEARCH AGREEMENT

MODEL ONLY

This Agreement made on date is between Case Western Reserve University, a corporation having a principal place of business in Cleveland Ohio (hereinafter CWRU) and XYZ Corporation, a corporation of the State of and having a principal place of business at (hereinafter XYZ).

BACKGROUND:

CWRU proposes to conduct on behalf of XYZ a program of research in field of research

described in the attached proposal incorporated as Appendix I. CWRU has facilities, staff, and graduate students available for the conduct of such a program.

XYZ desires to have CWRU conduct such a program on its behalf.

TERMS AND CONDITIONS OF THE AGREEMENT

ARTICLE I: THE RESEARCH AGREEMENT

1.1 CWRU agrees to conduct and supervise during the term of this Agreement the program of research which is described in Appendix I, including such modifications in the project as may be mutually agreed upon during the course of the program. XYZ will wish to consult with CWRU periodically concerning the course of the research and the results obtained, and to this end CWRU shall keep XYZ fully informed of the progress of the research through direct discussion and with periodic written reports.

1.2 In support of the research program *XYZ* will pay CWRU the sum of \$ *~~~~~*. Payment shall be made either monthly or as otherwise agreed on by the parties.

ARTICLE II: LICENSE OF PATENTS AND TECHNICAL INFORMATION

2.1 CWRU grants to *XYZ*, in the field of *field* *of use* *~~~~~*, exclusive world-wide license, with the right to sublicense, of all patents and appropriate information arising from the research program of paragraph 1.1. The term of the license shall be for the lifetime of the patent or, for proprietary information, seventeen years from the effective date of this agreement unless terminated by the provisions of paragraph 2.3.

2.2 As to all licenses granted to *XYZ*, CWRU retains a royalty-free right to practice the licensed patents and to use the licensed information for research, testing and educational purposes of CWRU.

ARTICLE III: PATENTS RIGHTS AND PUBLICATION

3.1 Title to all inventions, discoveries, information, data and know-how (patentable or unpatentable) arising from the research program of paragraph 1.1 shall be retained by CWRU. CWRU shall, upon prior notice to *XYZ*, have the right to file patent applications in its own name on all inventions arising out of research and testing provided for in paragraph 1.1.

3.2 In the event that CWRU elects not to support a patent application with its own resources for any invention arising out of the research and testing, CWRU shall promptly notify *XYZ* as to the nature of the invention and its need for support in pursuing a patent. Thereupon, if requested by *XYZ*, the University will file a patent application at the expense of *XYZ*. CWRU will cooperate fully with *XYZ* in the preparation and prosecution of all such applications and shall execute all documents as are necessary to the filing.

3.3 CWRU will notify XYZ, in writing, of its desire to publish results or conclusions from the research and testing conducted and reported in accordance with paragraph 1.1 of this Agreement.

XYZ will have thirty (30) days from such notice to review all materials proposed for publication and designate any material that is proprietary information needing patent protection. Further, upon XYZ's request during the thirty (30) day notice period, all publication shall be delayed for up to ninety (90) days from the date of the request to provide adequate time for preparation and filing of a patent application related to information that is proposed for publication.

3.4 CWRU will use a best efforts approach to keep information generated under the research program from being disseminated beyond CWRU except by the vehicle of publication or patents.

ARTICLE IV: ROYALTIES, PAYMENTS AND REPORTS

4.1 In consideration for the right of exclusive license for patents and proprietary information developed from the research program of this agreement, XYZ agrees to pay CWRU as follows:

- a. A royalty on all devices sold by or under the authority of XYZ that are covered by a valid claim of the patents licensed hereunder or are based on unpatented proprietary information developed as part of the research program.

The royalty shall be ~ percent (~) of the net sales price of all such devices including any associated devices or hardware sold in conjunction with them. Royalties under this paragraph shall be due and payable semi-annually.

b. For any sublicenses granted by XYZ under the provisions of Article III, XYZ will pay CWRU 50% of the royalty income from those sublicenses.

4.2 XYZ shall submit to CWRU semi-annual reports on all sales of devices upon which the royalty of paragraph 4.1 is based. Such reports shall be subject to audit and, upon thirty (30) days written notice, XYZ shall make available such records as are reasonably necessary to such audit at the place where such records are regularly kept.

4.3 If, for any period of two consecutive years beginning ~~~ years from the effective date of this agreement, royalties paid to the University shall fall below ~~~ per year, the license granted in Article II shall be terminated unless XYZ chooses to make up the difference between actual annual royalties and ~~~.

ARTICLE V: PATENT INFRINGEMENT

5.1 Each party shall promptly notify the other party of any infringement of patents developed and licensed as part of this agreement. XYZ shall have the unqualified right to fully participate in any legal action to protect its interests, and CWRU and its attorneys shall fully cooperate with XYZ to this end.

5.2 If XYZ requests that CWRU bring an action for patent infringement and, within sixty (60) days, CWRU fails or refuses to do so, XYZ shall have the right to institute suit in CWRU's name against any such third party. If, after said sixty (60) days, XYZ elects to institute suit against any third party, all such costs and attorneys' fees shall be fully credited against any amount due as royalties and against any further royalties accrued pursuant to this Agreement and all damages awarded plaintiff in such suit shall belong exclusively to XYZ.

ARTICLE VI: MISCELLANEOUS

6.1 *XYZ* agrees that CWRU shall be held harmless in any legal actions resulting from *XYZ's* application or marketing of technology arising from this agreement. CWRU agrees to hold *XYZ* harmless from any liability for damages of whatsoever nature arising from research performed under this agreement.

6.2 *XYZ* agrees not to use the name of CWRU or related schools and departments in any publications or marketing materials without the written consent of CWRU.

6.3 All notices to the UNIVERSITY under this Agreement shall be in writing and sent to:

Director
Office of Research Administration
Case Western Reserve University
2040 Adelbert Road
Cleveland, Ohio 44106

6.4 All notices to *XYZ* under this Agreement shall be in writing and sent to:

6.5 This Agreement shall be construed, interpreted and applied in accordance with the laws of the State of Ohio.

6.6 This Agreement sets forth the entire understanding between the parties as to the subject matter hereof and merges all prior discussions between them. Any amendment to this Agreement shall be in writing signed by the parties.

IN WITNESS WHEREOF, the _____ have executed this Agreement on the
day and year first above written:

FOR CASE WESTERN RESERVE UNIVERSITY

FOR _____ INC.

Name _____

Name _____

Title _____

Title _____

Date _____

Date _____

CASE WESTERN RESERVE UNIVERSITY

GUIDELINES FOR KEY ISSUES IN INDUSTRY-UNIVERSITY RESEARCH AGREEMENTS

- A) Patent Rights: Rights to patents and copyrights stemming from faculty or staff research sponsored by an outside organization are negotiated as appropriate for the specific case. The inventor, outside sponsor, and a representative of the University should be parties to reaching an agreement on this issue before formal joint projects are begun. In accordance with Faculty Handbook policy, the inventor is in any case entitled to 50% of the net income received by the University in the form of royalties or other earnings on inventions.

Generally the University will give up its right to ownership of such patents only with reluctance, but there are cases where it may be reasonable to convey ownership of patents to outside sponsors or the inventor. In many other cases exclusive or non-exclusive licensing arrangements may be a better course. Examples of circumstances where the University might convey patent ownership include:

- 1) The research has a narrowly focused application, and a single commercial partner is able to commit to develop actively, and to pay royalties for the technology, in all potential areas of use.
- 2) The patents arising from the research are likely to be contested, and legal resources beyond the University's are going to be needed to combat infringement.
- 3) The chance of obtaining royalty-generating patents from the research is remote, so that the University could not justify investing its limited funds to obtain the patents.
- 4) The commercial partner is willing to enter into a compensation commitment or other agreement that is fully competitive with what the University might realize by any other approach. A commitment by the industrial partner to pay royalties on any commercial application of patents conveyed allows the University to share in any unforeseen benefits of the patent, and this makes transfer of patent ownership a less serious gamble.

Examples of where the University would want to retain ownership of patents include:

- 1) The possible applications are broader than the areas of interest or expertise of the commercial partners; exclusive or non-exclusive license in a specified field of use would be a preferred approach.
- 2) The University holds or expects to develop related patents, and must be careful not to encumber or limit their potential by losing ownership of one component.
- 3) Proposed royalties are not competitive with reasonably foreseeable alternatives.

- B) Confidentiality of Research Results: As an open institution dedicated to building and disseminating knowledge, the University seeks to minimize its obligations to maintain confidentiality of research results. However, we recognize the need to allow commercial partners to benefit from their research investments including ownership of patents or proprietary information and examples of reasonable approach are:

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Director
Office of Research Administration
Case Western Reserve University
2040 Adelbert Road
Cleveland, Ohio 44106

All notices to (name of corporation) under this AGREEMENT shall be in writing and sent to:

DRAFT

PRINCIPLES GOVERNING CMRU PARTICIPATION IN BUSINESS VENTURES

BASED ON UNIVERSITY TECHNOLOGY

In addition to licensing research results for commercial development, there is considerable interest in technology transfer mechanisms in which the University and involved faculty members would participate in start-up business ventures. There are clearly cases where such mechanisms have real benefits relative to simple technology licensing. These include:

- 1) Allowing students and faculty to be more closely and continually associated with the advanced development and application of technologies arising from their research. This can satisfy the creative urge to see ideas through to reality, as well as serve as a stimulus for new research directions.
- 2) Increasing the probability that the technology will be developed locally to the benefit of the regional economy.
- 3) Increasing the magnitude of possible financial rewards to both faculty and the University. This can occur if the University accepts equity participation and thus a share in the full increase in value of the growing venture, as opposed to only a royalty percentage of its sales.
- 4) Increasing the probability that the technology will be intensively developed to full application and full benefit to the public.

However, since the University remains committed to teaching and scholarship as its highest priority goals, there are clearly some risks arising from involvement in start-up commercial ventures. These include:

- 1) Possible conflict of interest in University or faculty actions, in which measures to insure success of the venture could come in conflict with the best interests of the teaching and over-all research goals of faculty or University.
- 2) Risks to the integrity of the University's name through association with the commercial goals of the venture.
- 3) Distraction of administrative or faculty time and energy from attention to the primary goals of the University.

To insure that such risks are minimized, while allowing full realization of possible benefits, the following principles will be followed in negotiations for University participation in such start-up ventures:

- 1) The University's equity participation will be held by DICAR or its successor for-profit technology development corporation. The management and responsibilities of that participation will be carried out by the management of the development corporation, under the supervision of a Board appointed by the University in its role as controlling stock owner.

2) The University and faculty members will not accept a board membership or participate in any way in business decisions of the start-up venture. The role of faculty members will be governed by the guidelines drawn up by the Faculty Senate for faculty equity participation in start-up ventures. Time commitments will be governed by the one day/week consultant rule.

3) The University will not risk its own capital or allow financial needs of the start-up to interfere with channels for financial support of other university activities.

4) The University will make its facilities available to the start-up only for research and development purposes under the same general terms used for all industry supported research (see Guidelines for Industry-University Research Agreements attached). Access to university space or facilities will be fully compensated by equity or royalty participation as in standard industry/university agreements. Development activities on a scale which would disrupt normal campus research or educational programs will be transferred to suitable off-campus locations such as University Circle Research Center.

5) The University's name will be used by the Venture only if the case is reviewed and found acceptable by the Office of Research Administration.

6) The rights to technology granted to the start-up will be recoverable by the University in the event of non-performance as defined in a written agreement.

Under these guidelines, a typical start-up venture might then take the following form:

1) University grants rights to facility-developed technology to a start-up venture, which supports advanced research and development on campus under normal industry-university research agreement guidelines.

2) The venture will be organized, managed, and seek financing by an entrepreneurial team not including university officials or faculty.

3) The faculty member may be involved in the start-up as "chief scientist" or a similar position, but not in a business or financial management role. The faculty member may invest in the venture at his discretion. The University will not accept a financial or business management role, nor will it invest in the venture.

4) University receives equity participation in ownership of the venture instead of normal royalty returns. University splits this benefit with the faculty researcher(s) as it would with royalty income.

5) When commercially-oriented development activities supported by the start-up reach a scale where they are disruptive to normal educational and research programs, they will move to an off-campus location.

January 17, 1984

TO: Faculty Senate Committee on Research

FROM: Thomas H. Moss
Director of Research Administration

RE: Proposed Guidelines for Faculty Equity Participation in Ventures
Utilizing University Technology

With the help of this Committee and the Faculty Senate, we developed guidelines last year for university/industry interactions (attached). These have greatly assisted in negotiating issues such as confidentiality limitations and patent licensing in contracts with industrial sponsors of research.

However, another class of issues is beginning to emerge. This is the case where a small business venture is to be created, built principally around technology derived from faculty University research. In this situation, the faculty member may want a continuing role in the technology development, and both the faculty member and University may be offered substantial equity participation in return for proprietary rights. In a typical case, the small corporation may want to support the faculty member's research on campus to bring the technology to full development, while at the same time it begins business activities such as seeking financing, establishing markets and building production capability.

This scenario has been extremely successful in transferring new ideas to commercial application on some campuses. It provides a special channel of intellectual satisfaction for the faculty member in seeing research results converted to practical fruition, and can provide much greater financial benefits to both faculty member and university than can simple licensing agreements. However, it presents a special conflict of interest problem: there is a potential that a faculty member could be in a position of influencing both sides of a company-university negotiation on technology transfer and conditions of research support. That is, a faculty member in his faculty role would potentially be able to affect university decisions or practices which would benefit himself in his other role as major stakeholder in the company.

The attached guidelines represent an attempt to face this issue. They are aimed at establishing a set of practices which maintain the integrity of the University's primary role of education and scholarship, and yet offer the faculty both the intellectual challenge of participating in technology-based start-up business ventures, and a share of financial rewards through equity participation in the business. It is derived from the general CWRU technology transfer practices expressed in its Guidelines for Industry-University Research Agreements, coupled with a review of ideas from other major universities, the Parajo Dunes Conference, a recent American Civil Liberties Union statement, and other material.

Faculty Senate Committee Research
January 17, 1984
Page 2

With the assistance of Research Committee ideas and advice, I believe the concept can be made fully defensible to outside scrutiny. The technology transfer for which it provides incentive and workable groundrules can provide great benefit to the public as a whole and will be recognized as an important contribution to regional economic well-being.

Proposed Guidelines

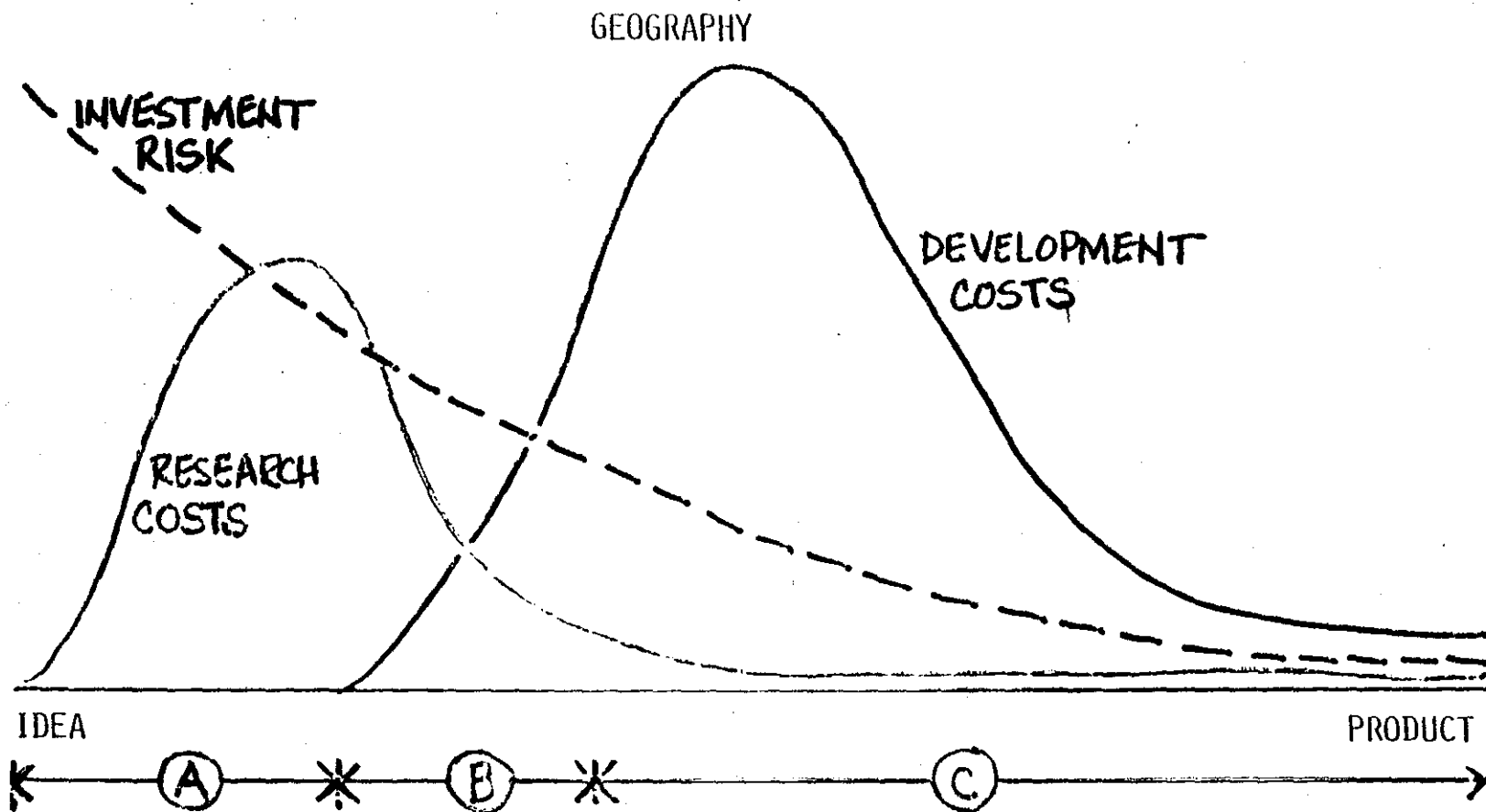
1) Avoiding Conflict of Interest:

To provide an incentive for transfer of university technology to useful applications through new venture start-ups, and to provide an additional channel for creative faculty activity, faculty members are not prohibited from having substantial equity in companies developing University technology. However, the following conditions will apply:

- a) All University agreements with such companies must be on a basis which provides no more favorable treatment to them than is normally given to any other company in similar circumstances. Faculty members should not attempt to influence the University to provide favorable terms or to allow the use of University resources to the special advantage of companies in which they have a role and a substantial financial interest.
- b) All such agreements will be reviewed on a case-by-case basis by the normal sequence of Department Chairman, Dean, and Office of Research Administration for conformity with the standard University Guidelines for Industry-University Research Agreements and other practices. Special attention will be paid to any provisions which might cause the appearance or reality of preferential treatment to the company based on conflict of interest or the prospect of faculty financial gain from the arrangement.
- c) If a faculty member is involved in university research or development which is supported by or for the benefit of a company in which he has substantial equity or leadership position, the conditions and full details of that association must be fully disclosed to Department Chairman, Dean, and Director of Research Administration.
- d) A faculty member with a substantial equity role in a company supporting his research must not be an officer or board member of such a company, or be authorized to make binding decisions for it. He may be a technical advisor, or consultant in determining its technical strategy. His time commitment must conform to normal university practices on outside activities, and his role must not affect his primary allegiance to his position as university faculty member, or distort his judgment in directing his research or teaching activities, or relationships to colleagues or students.
- e) Department Chairmen, Division heads, Deans, or other faculty in leadership and supervisory positions may be required to accept additional limitations on a case-by-case basis on their roles in companies supporting or having rights to university research. These limitations will be designed to insure that such faculty are not in a position to influence students, staff, or other faculty members to channel efforts to the special benefit of the company in which the influential faculty member has a substantial equity or leadership position.

2) University-Faculty Sharing of Equity Benefits Based on University Research:

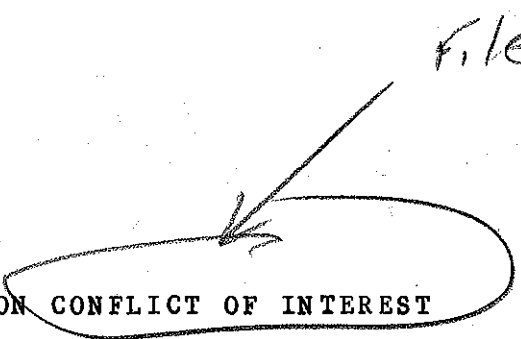
a) University policy as stated in the Faculty Handbook provides that faculty should share equally in net University income from "royalty payments or other earnings on inventions". This equal sharing principle will also be adhered to when the financial benefits from giving rights to technology are in the form of equity participation in a company. However, it should be noted, because of the complexity of business start-up arrangements, that the precise division of benefits will have to be negotiated on a case-by-case basis. Faculty members or the University might invest their own funds or commit other resources to such a venture which could affect their appropriate equity share over and above that determined by their grant of proprietary rights to the venture.



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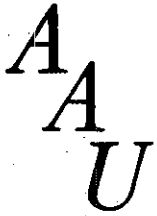


UNIVERSITY POLICIES ON CONFLICT OF INTEREST
AND DELAY OF PUBLICATION

REPORT OF THE CLEARINGHOUSE ON UNIVERSITY-INDUSTRY RELATIONS

ASSOCIATION OF AMERICAN UNIVERSITIES

FEBRUARY, 1985



Association of American Universities

February 19, 1985

President

FROM: Robert M. Rosenzweig

This report, "University Policies on Conflict of Interest and Delay of Publication", is the first written report of the Association of American Universities' Clearinghouse on University-Industry Relations.

The Clearinghouse was established in 1983 with the help of a grant from the Pew Memorial Trust, to provide all interested parties with information about the policies and practices governing the growing connections between universities and industry. The simple assumption underlying the project is that the availability of knowledge about how others have handled problems will help those who are confronting those same problems to avoid mistakes. The large number of requests to the Clearinghouse for information about the experience of others supports that assumption.

The present report answers the two most commonly expressed concerns about the growth of these new relationships: Are universities alert to the potential for conflict of interest and diversion of faculty effort that is inherent in working with business; and have universities addressed the potential threat to the openness of scientific communication that attaches to proprietary interests?

Without attempting to assess the adequacy or effectiveness of institutional policies in these areas, it is clear that neither has lacked for attention. The existence of policy is virtually universal, and most of it is recent enough to have been formulated in the light of experience with industry. Those two facts, alone, are reassuring.

Reports on other topics will be forthcoming in the months ahead. In the meantime, the Clearinghouse exists as a resource for all who may be interested in the subject.

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TABLE OF CONTENTS

Part I - Introduction

A. Purpose of the Report

B. Background: The Growth of University-Industry Collaborative Research

C. Congressional Response to the Emerging Collaborative Relationships and the Establishment of the Clearinghouse on University-Industry Relations

D. The Clearinghouse's Initial Project : Establish an Information Source and Conduct a Study of Conflict of Interest and Delay of Publication Policies

Part II - Conflict of Interest Policies

A. Background

B. Results of the Survey

C. Summary

Part III - Delay of Publication Policies

A. Background

B. Results of the Survey

C. Summary

Part IV - Conclusion

* * * * *

Appendix A - Text of the Survey Request

Appendix B - Dates of the Most Recent Revision of Conflict Policies at Respondent Universities

Appendix C - Principal Terms of Conflict of Interest Policies at Respondent Universities

Appendix D - Respondents Having Equity Interest Provisions In Conflict of Interest Policies

Appendix E - Delay of Publication - Reasons Given by Respondent Universities for Permissible Delay

Appendix F - Length of Time Permitted by Respondent Universities for Delay of Publication

PART I-INTRODUCTION

A. Purpose of the Report

The purpose of this report is to discuss the results of the first university survey conducted by the Clearinghouse on University-Industry Relations. The subject matter of the request was conflict of interest and delay of publication policies of universities engaging in collaborative research efforts with business. The principal focus of the report is not the form of the collaboration but rather how the institutions have prepared for and managed the constraints of entering into such ventures.

The Clearinghouse appreciates the willingness of all respondents to participate in the survey, particularly those who provided copies of policies and supplemental materials.

B. Background: The Growth of University-Industry Collaborative Research

The federal government provides most of the support for basic research at universities. Only a small percentage of university research is sponsored by corporations. There continues to be a great deal of reliance upon corporate philanthropy, but increasingly, universities and industry are establishing collaborative research relationships, more like partnerships. These relationships are based on a *quid pro quo*: the corporate sponsor provides financial support of specific research in

exchange for certain rights to use the results or to maintain an exclusive relationship with the research activity.

Collaborative arrangements have flourished because competition has increased in recent years, increasing the pressure on industry to develop new technologies and be at the forefront of innovation. Concurrently, university and industry scientists find their work more closely linked as the boundaries between "basic" and "applied" research become blurred, especially in areas of new technologies. In general, universities find that research collaboration with industry meets their research needs without compromising fundamental academic principles. The university has the benefit of research support, valuable research experience for students, and broader research opportunities for faculty who might otherwise be lured from the academic environment to industry.

Further, there is growing support for the involvement of universities in the technological and scientific growth of the business community. As the fourteenth annual report of the National Science Board states, "...the interdependencies between good science and good development have been long recognized, but because of the changing character of the problems, more direct research interactions between science and industry are now occurring." /1

Federal, state and local governments encourage university-industry relations. State economic development programs and

legislative initiatives promote collaboration among government, industry, and universities. On the federal level, the National Science Foundation funds start-up research centers in which federal support is phased-out as industry sponsorship is established. Other federal agencies, such as the Department of Commerce, encourage universities to develop research relationships with industry. The National Academy of Sciences is sponsoring the Government-University-Industry Research Roundtable to "foster strong American science through effective working relationships among government, universities, and industry." /2

Generally, universities have been responsive to establishing collaborative research arrangements with industry. The form of the collaboration varies, even within a single university. The most highly publicized arrangements are multi-year, multi-million dollar projects between one university and one company. However, there are many more programs in which several universities and several corporations join to establish a research center or project in which the universities jointly undertake numerous research tasks. Some industries have formed non-profit corporations or foundations to provide support for basic research at universities.

Despite the growth of corporate support for university research, such support is not expected to provide more than a small supplement to federal assistance. Even so, many universities welcome the additional commitment to research. Although the

federal government's support for basic research is strong, it is not always reliable. Most glaring is the long absence of federal funding to remodel and replace inadequate research facilities and instrumentation.

C. Congressional Response to the Emerging Collaborative Relationships and the Establishment of the Clearinghouse on University-Industry Relations

In light of these new collaborative relationships, it was not overlooked that universities and industry have missions that are different, and in some cases, divergent. Policy-makers and university administrators are concerned that university-industry research relationships could damage the research enterprise. Interested observers, including members of Congress and the press, have also expressed concern. Their fear is that universities engaged in these arrangements may compromise their goals of free inquiry and open dissemination of ideas. The Report of the University-Industry Relations Project at the University of California (1982) summarizes the concern of universities: to provide diversity of research activities while preserving the university's independence from undue influence from a single source. /3

In 1981, the Oversight Subcommittee of the House Committee on Science and Technology asked the Association of American Universities (AAU) to develop ethical guidelines to govern university-industry collaboration. That request stated, "...the

ethical dilemmas posed by the metamorphosis of our scientific research force from educators to entrepreneurs have not been resolved. Changes in research priorities, allocation of resources, faculty-student and faculty-university relationships, as well as diminishing scientific openness may soon be evolving from a shifting value system." /4

A Committee on University-Industry Relations was formed by AAU to respond to the Congressional request. The Committee determined that uniform guidelines appeared unnecessary. However, it did conclude that universities, industry, Congress, and the public would benefit greatly from the sharing of information regarding research collaboration. The responsibility for establishing a clearinghouse for such information was undertaken by the AAU. Thus, the Clearinghouse on University-Industry Relations was established by AAU in September, 1983.

D. The Clearinghouse's Initial Project: Establish an Information Source and Conduct a Study of Conflict of Interest and Delay of Publication Policies

Since the establishment of the Clearinghouse, university administrators and industry managers have expressed a great deal of interest in information sharing. The Advisory Committee to the Clearinghouse recommended how best to address that interest. As a result, the Clearinghouse now actively collects and disseminates information relating to university-industry relations.

The Clearinghouse also has established a program of gathering information on a systematic basis from universities concerning activities with industrial sponsors of research. The first request, made during the spring of 1984, focused on two specific problem areas: conflict of interest and delay of publication. The request was made in writing to fifty-six universities. A detailed description of the requested information was provided to each respondent (see Appendix A). The universities were asked to provide copies of relevant documents and examples of cases that arose at their campuses. The information was reviewed and analyzed in detail. In all, fifty-one universities responded.

Conflict of interest and delay of publication are policy issues that arise in almost every type of research arrangement with industry. Each focuses on a different aspect of the university's policies with regard to the university and the faculty. Knowledge about the content of the policies and practices and when and how they are implemented are important tools for other institutions to use in evaluating their own activities. In addition, the patterns of establishing policies and procedures provides insight into the extent to which universities have developed their own structures and procedures for research collaboration, and the extent to which universities accommodate the interests of business entities.

PART II-CONFLICT OF INTEREST POLICIES

A. Background

Universities rely on faculty to make decisions concerning the appropriateness of research, both substantively and procedurally, and to carry out the purposes and goals of the institution. Overwhelmingly, this arrangement is a success for faculty and the institution. Nevertheless, there is not always a single view of the appropriate balance between outside activities that enhance the knowledge and experience of the faculty member, and his or her commitment to the university.

The university itself must recognize its goals and objectives for faculty. At most universities, consulting and sponsored research activities are encouraged. They provide intellectual stimulation and financial support. The line is drawn, however, when that support becomes an improper influence over the faculty member and as a result, university responsibilities are neglected or the faculty member becomes biased in favor of industry's proprietary goals.

Conflict of interest within a university can have two meanings. First, conflict of interest arises when the faculty member's commitment to his or her responsibilities in the university are not met as a result of outside activities. The conventional solution to this conflict is to provide a policy which describes

the faculty member's teaching, research, and administrative duties, and limits outside research and consulting activities to one day per week. Within the past twenty years, the issue of faculty consulting prompted many universities to develop such a policy.

Second, conflict of interest arises where a faculty member uses influence within the university to advance his or her own personal gain. For example a faculty member could promote a research relationship with an outside sponsor in which he or she has an equity interest, managerial role, or consulting relationship. The university would be adversely affected if the faculty member subordinated his or her university teaching and research to the activities of the outside company or used university facilities, equipment, and instrumentation, or graduate students for that purpose.

Of course, conflict of interest is not a new problem. In 1964, the American Association of University Professors (AAUP) and the American Council on Education (ACE) jointly issued a statement entitled On Preventing Conflict of Interest in Government-Sponsored Research at Universities, which has been endorsed by most research universities. The joint statement provides a detailed discussion of conflict of interest and encourages individual universities to establish procedures to address it.

According to the AAUP/ACE statement, conflicts may arise when a faculty member undertakes or orients his or her university

research to serve the needs of a private firm, purchases equipment from a firm in which the faculty member has an interest, transmits to a private firm otherwise unavailable information, influences negotiation between the university and a private firm with which the faculty member has a relationship, or accepts gratuities or special favors from a private firm which might be interpreted as an attempt to influence the recipient's conduct of his or her duties.

The joint statement also addresses a faculty member's conflict of commitment. It states that a researcher has a responsibility not to mislead the sponsor of research or the university about the amount of time and effort to be devoted to the research project. Precise time accounting is recommended.

With respect to the university's responsibilities, the AAUP/ACE statement recommends that each university develop and disclose its accounting procedures, procedures to inform the university about the outside professional work of faculty members, procedures to inform faculty members about the standards relating to conflict of interest, and the availability of advice and guidance to faculty members regarding potential conflicts.

The joint statement concludes:

The above process of disclosure and consultation is the obligation assumed by the university when it accepts Government funds for research. The process must, of course, be carried out in a manner that does not infringe on the legitimate freedoms and flexibility of action of the university and its staff members that have traditionally characterized a university. It is

desirable that standards and procedures of the kind discussed be formulated and administered by members of the university community themselves, through their joint initiative and responsibility, for it is they who are the best judges of the conditions which can most effectively stimulate the search for knowledge and preserve the requirements of academic freedom. Experience indicates that such standards and procedures should be developed and specified by joint administrative-faculty action. /5

B. Results of the Survey

As one might expect from the attention drawn to the problem by the AAUP/ACE statement issued over twenty years ago, most universities in the sample have procedures within the university to direct the initiation and management of sponsored research. Since the university must approve sponsored research projects, the approval process includes a review of the activity for potential conflicts of interest.

It is not surprising that 46 of the respondents have established written conflict of interest policies which are applicable to business-sponsored research as well. Most have been revised in the last five years (See Appendix B).

Twelve conflict policies (out of 22 public institutions responding) are based upon existing state law applicable to public university employees. For example:

1. A university officer or employee is forbidden to participate in his/her official capacity with respect to any transaction between the university and a business entity in which the officer or employee has a substantial interest.
2. A university officer or employee is forbidden to receive compensation (in addition to regular budgeted salary or wages for service to the university) as a result of, or in connection with, any transaction between the university

and a business entity in which the officer or employee has a substantial interest.

3. A university officer or employee is forbidden to accept employment or engage in any business or professional activity which he/she might reasonably expect would require or induce him or her to disclose confidential information acquired by reason of the officer or employee's university position.

4. A university officer or employee is forbidden to disclose confidential information acquired by reason of his/her university position, or to use such information for his/her or another's gain or benefit.

5. A university officer or employee is forbidden to accept other employment which he/she might reasonably expect would impair his/her independence of judgment in the performance of university duties and responsibilities.

* * * *

7. A university officer or employee is forbidden to have personal investments in any business entity which will create a substantial conflict between his/her private interests and university duties. /6

The distinctions among the various policies on conflict of interest were less dramatic than one might expect. Appendix C categorizes the principal focus of the various conflict policies.

The most significant difference among the policies was the mechanism within the university for disclosure of outside activities. One distinction lies in which party, university or faculty member, initiates the disclosure. Nineteen institutions provide for a faculty-initiated disclosure when the faculty member determines that a sponsored research arrangement to which he or she is a party may present a conflict. Many of these policies require a disclosure by the faculty member only if he or she intends to take an equity interest or management position with the sponsor entity.

For example, a typical policy statement in this category reads,
in part:

Responsibility for establishing that activities in business ventures do not conflict with Institute commitments rests first with the Faculty member. Further, on request from cognizant Division Chairmen, the Provost, or the President, the Faculty member shall make a full disclosure of all such ventures including the names of companies, the nature of agreements, the responsibilities assumed by the Faculty member, and the time involved. /7

Twenty-six universities have conflict of interest policies that provide a university-initiated disclosure or annual report from each faculty member engaged in sponsored research or require approval to be granted before the faculty member may undertake a consulting or sponsored research project. Many annual reporting requirements were similar to the following:

D. Reporting.

All faculty members must report through their chairman to both the Dean and the Office of Science and Technology Development all outside professional activities at their inception and shall amend these reports as circumstances change...Such reports shall include consulting arrangements as well as equity holdings, board memberships, managerial positions, etc. in relevant organizations. /8

A summary of a sample financial disclosure procedure at a state university further illustrates:

A. Principal Investigators disclose whether or not they have a financial interest in the sponsor of a proposed research project when funding in whole or in part is through a contract or grant from a non-governmental entity;

B. Principal Investigators disclose whether or not they have a financial interest in the donor of a gift when the gift is from a non-governmental entity and is earmarked by the donor for a specific principal investigator or for a specific research project;

C. Disclosure statements be filed (1) before final acceptance of such a contract, grant, or gift; (2) when funding for such a contract or grant is renewed; and (3) within 90 days after expiration in the case of a contract or grant, or after funds have been completely expended in the case of a gift;

D. When disclosure indicates that a financial interest exists, an independent substantive review of the disclosure statement and research project take place before the contract, grant, or gift is accepted; and

E. Department chairs disqualify themselves from approving a research proposal for a project to be funded in whole or in part by a non-governmental entity in which they have a financial interest.

Failure by a principal investigator to make the required disclosure or by a department chair to disqualify himself or herself may result in state enforcement proceedings against him or her as an individual, as well as University sanctions. /9

With regard to equity interests and faculty managerial involvement in businesses providing research or development, twenty-one institutions have developed specific policies to address this issue. None of the policies prohibited such activities. Rather, the involvement of a faculty member in an outside business is recognized as a potential conflict of interest and commitment for the faculty member which should be disclosed to and approved by the dean. Several state institutions have ceilings beyond which no faculty member may have an ownership interest in a company which does business with the university. For example:

(e) No member of the faculty or academic staff or members of their immediate families and no business in which they own or control at least 5% interest of the outstanding stock, or at least 5% interest in such business, or in which they are an officer or director may enter into any commercial contract with the university unless the contract has been awarded through a process of public notice and competitive bidding under section 16.75(1), Wis. Stats., or unless the

member of the faculty [or] academic staff is not in a position to approve or influence the university's decision to grant the contract. /10

Appendix D lists the respondents that have equity interest provisions in their conflict policies.

Many institutions responded to the survey by providing supplemental materials illustrating recent guidelines or memoranda addressing conflict of interest issues directly related to industry-sponsored research. The following excerpt is an example of one institution's treatment of conflicts arising from equity ownership and management participation in a commercial entity:

1. Participation of the University and its faculty in commercial organizations.

The University, or a faculty member, may of course invest, own stock or other equity in a commercial enterprise. However, if the University and its faculty holds a controlling interest, participates in the management or the conduct of affairs of the commercial organization, or if the work of the University and its faculty is being funded by the organization, conflicts of interest are likely to exist, and the matter should be referred to the Policy Committee.

Faculty members may own a controlling interest in a commercial enterprise, and may participate in its management or conduct of affairs, as long as such participation does not interfere with their ability to fulfill their University commitments, and as long as the activity of the commercial organization is not closely related to the area of the faculty member's University research. If there is a close relationship between the two, the question should be referred to the Policy Committee. The University does not participate in the management or conduct of affairs of a commercial organization.

A faculty member may own significant stock or equity in a commercial enterprise, but a conflict of interest may exist if the faculty member's University research is closely related to the activity of the enterprise, especially when

the faculty member participates in management, in which case the question should be referred to the Policy Committee.

* * * *

2. Funding of research or conduct of research at the University by commercial organizations.

* * * *

If a faculty member has significant stock or other equity interest in a commercial corporation and/or participates in the management or the conduct of its affairs, it is not normally permissible for the University and the faculty member to receive funding from that organization for the faculty member's research at [this] University. These rules apply with particular force when faculty members in question hold administrative positions which permit them significant control of space and other resources at the University. /11

A few institutions have policies relating to the protection of graduate students. For example:

(4) STUDENT RESEARCH PROTECTION. A member of the unclassified staff shall inform students engaged in research under his or her supervision of any financial interest which the unclassified staff member has in the research activity, including, but not limited to, financial arrangements involved in the direct support of the activity, agreements made by the unclassified staff member to obtain data for the research, or agreements concerning copyright or patent rights arising from the research. /12

Finally, several universities responded to the survey with examples of possible conflicts that were reviewed and resolved. One state university with a mandatory disclosure procedure required by state law provided an interesting example:

It was the unanimous opinion of the ISRC [Independent substantive review committee] that Professor A's project be recommended for disapproval. The Committee's decision was made on the basis of an extensive and thorough discussion of the issues raised in Professor A's Disclosure of Financial Interest and in his personal appearance before the Committee. The principal reason for recommending disapproval of the project is the absence of an arms-length relationship

In determining the amount of monies to be paid the university as between Professor A, the Principal Investigator (and thus the individual who determines the amount of such monies on behalf of the University) and Dr. A, the President and 100 percent owner of The Company, who must pay such monies.

A second serious concern of the Committee was that the employees who actually do the work funded by the contract are performing 'secret' work. That is, they are conducting analyses of chemical compounds which have been provided to the Company by outside sponsors who have insisted that the results of the analyses not be disclosed. While the agreement between the University and the Company did not contain a restriction on the publication of research findings, Professor A indicated that all decisions concerning publication will be made by him. He stated that he would honor the commitments made by the Company to its sponsors not to disclose their findings. Thus, a conflict of interest exists between Dr. A's role as a University Professor, with the obligation to disclose the findings of his work, and Dr. A's role as the President of a private corporation which has agreed to treat his findings as confidential. It is Dr. A who will determine whether or not the findings of these projects will be published and therein lies the conflict of interest. /13

In some cases, detailed conditions have been imposed on faculty members. For example, a letter from a university official to a faculty member sets forth conditions under which the faculty member would be allowed to proceed with a project:

The purpose of this letter is to respond to your inquiry concerning your participation in the commercial development of certain prior research efforts It is my further understanding that your participation would take the form of an investment or some receipt of an equity interest in the corporation.

* * * *

It is further understood that you agree to the following specific provisions regarding your participation in the above described corporation:

1. Your equity interest shall not exceed 26 percent and the cumulative equity interest of all members of your department shall not exceed 40 percent of total equity in the new corporation.

2. You do not, and will not in the future, have any involvement in or responsibility for the operation of the new corporation.

3. ... you are under no obligation to make present or future research results available to the corporation, nor will you undertake such an obligation.

4. You will not allow the interests of the corporation to have any influence whatsoever on the current or future directions of your College research.

5. You will not allow the interests of the corporation to have any influence whatsoever on the current or future directions of the College research of members of the Department.

6. You agree to disclose immediately to the Dean any real or apparent conflict of interest that may arise in relation to your interest in the corporation and your position on the [University] faculty.

7. The terms of any consulting agreement or other form of business agreement or relationship between you and the corporation shall be disclosed to the University and be subject to prior University approval.

8. Any use of funds of the new corporation to support your College research will require the prior approval of the Dean.

9. No resources of the University will be committed to the furtherance of the purposes of the corporation without the prior review and approval of the Dean and the negotiation of a written University contract.

10. You will initially provide to the Dean a report of all aspects of your participation in the corporation and you will disclose any proposed changes or modification in the relationships between you and the corporation and your ongoing University research. /14

C. Summary

In general, it can be concluded that universities responding to the survey have developed conflict of interest policies that address the faculty problems arising out of university-industry relationships. A key feature of most of the policies is reliance

on disclosure as a mechanism to deal with conflicts. Perhaps this reflects a conclusion that disclosure will inhibit the formation of inappropriate relationships at the outset. Or, it could be based on the theory that so long as the business relationship between a faculty member and an industrial sponsor has the informed consent of the university, the faculty member may proceed with confidence. In the final analysis, however, should policies based on disclosure actually reveal serious conflicts, the test of the effectiveness of such policies will be in the ability of institutions to use the information that is in their possession.

PART III-DELAY OF PUBLICATION POLICIES

A. Background

Delay of publication relates to the issue of openness. Exchange of ideas, including research results, is an integral part of increasing knowledge. Free communication also allows scholars and scientists to verify and critique research of others and lessen duplication of effort. Further, each faculty member relies on the freedom to select a research path regardless of whether it is likely to produce commercial success.

The federal government has often asserted the sensitivity of research results for national security reasons and requested or required that it be embargoed. In the case of industry-sponsored research, the sponsor is interested in protecting the proprietary

nature of the research and may not want competitors to have access to the information resulting from the sponsored research. Within this context, sponsors of research sometimes request restriction of openness.

The opposing views about information are often a subject of negotiation in university-industry relations. Most frequently, the resolution is a contract provision which allows a specified delay of the publication of the research results in order to permit the sponsor to protect its interests by filing a patent application with the U.S. Patent Office. Patent rights are based on the premise that the owner of the rights should disclose the invention in exchange for the right to exclude others from using or manufacturing it. Thus, the end result of a patent is openness.

In addition to patent rights, some universities allow a specified delay of publication to permit the sponsor to review the publication for proprietary data. Most frequently, proprietary data means information the sponsor supplied to the research enterprise which was not otherwise public. If the sponsor supplied that information to the researcher, it may be determined by the parties, in advance, that such information is not intended to be made available when the results of the research are published.

B. Results of the Survey

Forty-nine universities responding to the survey provided materials on delay of publication. Thirty-two universities have written policies stating the institution's position on freedom to publish. Most of these statements were general admonitions that the university is committed to free publication and open dissemination of ideas. Some provide that delay in publication is permissible under specific circumstances, but that such delay may not be unreasonable. The length of time permitted for delay is rarely stated, but is determined on a case-by-case basis. For example:

3. Publication. In order to fulfill our educational objectives, and with our status as a tax-exempt educational institution, research at [University] aims to serve a public rather than a private purpose. Results are disseminated broadly and on a non-discriminatory basis. Thus [University] will not undertake studies whose results cannot be freely published. We will, however, recognize legitimate proprietary concerns of sponsors where appropriate. Publications may be deferred for an agreed upon limited period of time to protect patent rights, and sponsors may review our publications before release so that they are aware of the contents. On occasions where [University] may have accepted a sponsor's proprietary information as necessary background data for a research project, we will allow a publication review in order to identify any inadvertent disclosure of data that, on a reasonable-efforts basis, we agreed to keep confidential. /15

All of the institutions responding to the Clearinghouse request permit publication to be delayed. Appendix E summarizes the reasons for which the respondents will agree to delay publication. Overwhelmingly, the most common reasons given for permitting delay of publication were to permit the sponsor to review the proposed publication for patentable subject matter or confidential information and to permit the university or the

sponsor to file a patent application in the United States (and sometimes abroad) to protect the sponsor's interest in such subject matter. Nineteen universities specified patent review and filing as the only reason for delay. Twenty-one institutions specified both patent review and filing and review for confidential information supplied by the sponsor.

Delay of publication provisions tend to fall into three categories. Some merely state that the university will permit a delay. Others specify the total length of time that the university will delay. Others specify a two-tiered delay procedure involving a specified review period and a subsequent delay for patent application preparation and filing. This last category may be subdivided based on when the delay may commence. Some calculate the delay from the time that the proposed publication is submitted to the sponsor regardless of when it would have been published. Others calculate the delay from the time that the proposed publication would have been published. Publication includes any presentation of the research results to the public.

The following is an example of a publication provision in a contract between a respondent and an industrial sponsor:

a. The University reserves the right, subject to the provisions of this Agreement, to use the results of all work provided by the University under this Agreement, including but not limited to, the results of tests and any raw data and statistical data generated therefrom, for its own teaching, research and publication purposes only. The University agrees, on behalf of itself and its employees,

students, assistants or associates, not to cause said results to be knowingly used for any commercial purpose whatsoever except as authorized by Sponsor in writing.

b. Any proposed publication by or on behalf of the University, its employees, students, assistants, or associates, involving work hereunder shall be submitted to Sponsor for review and comments at least ninety (90) days prior to submission for publication or presentation. At the end of ninety (90) days after said submission to Sponsor, the University shall be free to proceed with publication. However, if Sponsor believes patentable subject matter is inadvertently disclosed in any publication submitted for review, Sponsor shall immediately identify such subject matter to University. University shall use its best efforts to promptly file or assist Sponsor to file a patent application covering such subject matter with the United States Patent and Trademark Office or through the Patent Cooperation Treaty prior to publication. /16

The length of time that universities will delay publication varies among institutions and among arrangements within institutions. Among the respondents, the shortest delay was thirty days, the longest more than one year. Appendix F summarizes the time periods during which the respondents would delay publication.

C. Summary

In general, all respondents allow some form of delay of publication. Clearly, then, a reasonable delay is considered by institutions generally to be within the scope of free and open publication. Publication delay is confined to patent protection and pre-disclosed proprietary data, issues that are easily defined. Other types of intellectual property protection, such as trade secrets, do not appear in institutional policies as legitimate reasons for interfering with open dissemination of research results.

PART IV-CONCLUSION

All of the universities sampled in the Clearinghouse request have developed policies and practices relating to industry sponsored research. Whether particular policies are too narrow or too broad is a matter for each institution, and each interested person, to evaluate. The sample shows clearly that the issues relating to industry-sponsored research are being addressed by university administrations and faculties, and that generally, procedures are in place to provide adequate disclosure of the arrangements between universities and industry.

The natural extension of the issues addressed in this report concerns the entrepreneurial activities of the university itself. Increasingly, universities are establishing business entities to provide technology transfer and development services for the university. The Clearinghouse's next survey, which is scheduled to commence in May, 1985, will focus on university entrepreneurial activities, as well as intellectual property policies.

For further information or materials, contact:

April Burke, Esq.
The Clearinghouse on University-Industry Relations
Association of American Universities
Suite 730
One Dupont Circle, N.W.
Washington, D.C. 20036

FOOTNOTES

- /1 University-Industry Research Relationships: Myths, Realities, and Potentials, Fourteenth Annual Report of the National Science Board, October 1, 1982, p. 1.
- /2 Government-University-Industry Research Roundtable letterhead, National Academy of Sciences.
- /3 Report of the University-Industry Relations Project, The University of California, October, 1, 1982.
- /4 Letter to Dr. Thomas A. Bartlett, President of the Association of American Universities from Representatives Gore and Fuqua, House Committee on Science and Technology, United States House of Representatives, November 18, 1981, p. 1.
- /5 "On Preventing Conflict of Interest In Government-Sponsored Research at Universities", joint statement of the American Association of University Professors and the American Council on Education, December, 1964, p. 3.
- /6 University of Utah Policy and Procedures Manual, January 22, 1981, based on Utah Public Officers' and Employees' Ethics Act, 1953 Utah Code Annotated, Sec. 67-16-1, et. seq.
- /7 "Conflict of Interest and Conflict of Commitment", California Institute of Technology Faculty Handbook, chapter 7, p. 12.
- /8 "Guidelines for Situations Involving Potential Conflicts of Interest Between Scholarly and Commercial Activities", Columbia University, Draft- May 21, 1984, p. 6.
- /9 "Guidelines for Disclosure and Review of Principal Investigators' Financial Interests In Private Sponsors of Research", University of California, April 9, 1982, p. 2.
- /10 Wisconsin Administrative Code, University of Wisconsin System, UWS 8.03(e).
- /11 "Guidelines for Situations Involving Potential Conflicts of Interest Between Scholarly and Commercial Activities", Columbia University, Draft- May 21, 1984, p. 3-5.
- /12 University of Wisconsin System Board of Regents Policies, UWS 8.03(4).
- /13 Letter from the Vice Chancellor to Professor A, re: Positive Disclosure of Financial Interest from Professor, University of California, Los Angeles, March 4, 1983, p. 1.
- /14 Cornell University, letter to a professor, March 1, 1984.

/15 "Research Relationships with Industry", Princeton University, p. 2.

/16 Sample publication contract clause, University of California at Los Angeles.

APPENDICES

Association of American Universities

March 20, 1984

CLEARINGHOUSE ON UNIVERSITY-INDUSTRY RELATIONS

This is a request for information about some specific university policies and practices in the area of university-industry relations. We would like to receive a response regarding your institution. The thoroughness of each response is crucial to the success of our effort. The purpose, simply stated, is to gather information about policies and practices affecting these relationships and to make it available in ways that will improve the quality of decisions university officers make.

Potential problems associated with university-industry research collaborations have become a subject of concern among interested observers, including members of Congress and the press. The fear is that the universities engaged in these arrangements may compromise the goals of free inquiry and open dissemination of ideas.

In 1981, the AAU was asked by the Oversight Subcommittee of the House Committee on Science and Technology to develop ethical guidelines to govern university-industry collaborations. That request stated, "...the ethical dilemmas posed by the metamorphosis of our scientific research force from educators to entrepreneurs have not been resolved. Changes in research priorities, allocation of resources, faculty-student and faculty-university relationships, as well as diminishing scientific openness may soon be evolving from a shifting value system."

A Committee on University-Industry Relations was formed by AAU to respond. That Committee determined that guidelines appeared unnecessary; however, it did conclude that universities, industry, Congress, and the public would benefit greatly from the sharing of information regarding research collaborations. The responsibility for establishing a clearinghouse for such information has been undertaken by the AAU.

Since the Clearinghouse was established in September, 1983, university administrators and industry managers have expressed a great deal of interest in information sharing. On November 28, 1983, the Advisory Committee to the Clearinghouse met in Washington to recommend how best to address that interest. The Committee recommended that the Clearinghouse request information from universities concerning activities with industrial sponsors of research, beginning with two specific problem areas: conflict of interest and delay of publication.

This is the first request for information and it is confined to those two topics. We are interested in receiving written information concerning university policies and practices, including documentation of policy, such as statements, guidelines, and memoranda, and discussions and documentation of practices, including contracts and other agreements. We are not requesting confidential information. If it is necessary to delete names, dates, dollar amounts, or other specific details from documents, we would be pleased to receive them in such form. We hope to receive information covering the breadth and variety of university activities in this area while including the details of specific arrangements.

The following hypothetical examples may make clearer the kind of information we would like to get and the value that such information might have to university officers confronted with real cases.

University A has a conflict of interest policy which states, in part, that faculty should avoid situations involving conflicts of interest such as financial dealings that are contrary to the University's best interest or which may obligate the faculty member to take actions adverse to the University's interest. Faculty member X, following extensive consulting arrangements with a small biotechnology company, is asked to join the company as a stock holding partner in order to head a new division in his area. X would only dedicate one day a week to the new company and would have the new division contract with him at the University to continue to do research. He notifies his department chairman of his desire to accept the offer, assuring him that the University's interests, including the selection of research topics and the learning experience of graduate students, would not be compromised.

What information about other universities' experiences in similar situations would you like to know to help you resolve University A's situation?

For example:

1. Conflict of interest policies.
2. Faculty contracts with industrial sponsors.
3. How similar matters were resolved, including procedures followed by other universities.

Corporation A and University Y are negotiating a contract under which the university would receive \$10 million over 5 years to conduct basic research in the area of X. The Corporation will be entitled to an exclusive license to develop patents owned by the university for products or

processes developed under the project, but it has asked for very restrictive access and publication measures to be imposed by the university in order to protect possible proprietary rights. As part of those restrictive measures, no faculty member or graduate student involved in research on the project may publish the results of the research without first submitting the proposed publication to the Company for review. The Company is requesting 120 days to determine whether the publication would reveal any patentable product or process, and a subsequent 120 days to file a patent application. The University has no stated policy concerning delay of publication; however, it has never agreed to delay publication for more than 90 days in the past.

What information about other universities' experiences in similar situations would you like to know to help you resolve University Y's situation?

For example:

1. Contracts with delay provisions.
2. Restrictive measures requested by companies.
3. How similar matters were resolved, and whether their resolution treated faculty members differently than graduate students.

We know we are asking your institution to undertake a significant task in responding to this request. We are convinced that it will be in the university community's best interest to share this information. It is important to demonstrate to those who are concerned about university interaction with industry that universities are addressing the legal and ethical problems of entering into business relationships to perform research. We hope your institution can assist in this effort.

All responses should be received at AAU by June 1, 1984. Please direct any inquiries and responses to:

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036
202-466-5030

Please let us know the name, address, and phone number of any member of the university's staff who will be assisting with this request.

Thank you.

APPENDIX B

DATES OF MOST RECENT REVISION OF CONFLICT POLICIES AT RESPONDENT UNIVERSITIES

No date provided

University of Maryland
Northwestern University
University of Pittsburgh
University of Rochester
University of Southern California
Yale University

1982-84

California Institute of Technology
University of California, Berkeley
University of California, Los Angeles
University of Chicago
University of Colorado
Columbia University
Duke University
Georgia Tech University
Harvard University
The Johns Hopkins University
University of Michigan
University of Missouri
University of Nebraska
University of North Carolina
University of Pennsylvania
Purdue University
Rensselaer Polytechnic Institute
Rockefeller University
Stanford University
University of Texas
University of Virginia
University of Wisconsin

1979-81

Brown University
Case Western Reserve University
The Catholic University of America
Indiana University
Iowa State University
University of Kansas
Massachusetts Institute of Technology
Ohio State University
The State University of New Jersey, Rutgers
University of Utah
Washington University

1970-79

Cornell University
Pennsylvania State University
Princeton University
Tulane University
University of Washington

1960-69

New York University
Vanderbilt University

APPENDIX C

PRINCIPAL TERMS OF CONFLICT OF INTEREST POLICIES AT RESPONDENT
UNIVERSITIES

No written conflict of interest policy provided

Carnegie-Mellon University
University of Minnesota
University of Massachusetts
University of Oregon
Syracuse University

General statement

University of Maryland

Faculty-initiated disclosure of outside professional activities
or disclosure required only of equity interest involved

California Institute of Technology
University of Colorado
Cornell University
Indiana University
The Johns Hopkins University
University of Missouri
University of Nebraska
New York University
Ohio State University
Rensselaer Polytechnic Institute
Pennsylvania State University
Purdue University
Rockefeller University
Stanford University
University of Texas
Tulane University
University of Utah
Washington University
Yale University

University-initiated disclosure or annual disclosure or approval
required to undertake sponsored research activity

Brown University
University of California, Berkeley
University of California, Los Angeles
Case Western Reserve University
The Catholic University of America
University of Chicago
Columbia University
Duke University

Georgia Institute of Technology
Harvard University
Iowa State University
University of Kansas
Massachusetts Institute of Technology
University of Michigan
University of North Carolina
Northwestern University
University of Pennsylvania
University of Pittsburgh
Princeton University
University of Rochester
The State University of New Jersey, Rutgers
University of Southern California
Vanderbilt University
University of Virginia
University of Washington
University of Wisconsin

APPENDIX D

RESPONDENTS HAVING EQUITY INTEREST PROVISIONS IN CONFLICT OF
INTEREST POLICIES

The State University of New Jersey, Rutgers
Syracuse University
University of Texas
Tulane University
University of Utah
University of Washington
Yale University
University of Wisconsin
Columbia University
Cornell University (letter to faculty)
Purdue University
Rockefeller University
Duke University
Harvard University
The Johns Hopkins University
University of Michigan
University of Nebraska
New York University
University of North Carolina
University of Pennsylvania
University of Virginia

APPENDIX E

REASONS GIVEN BY RESPONDENT UNIVERSITIES FOR PERMISSIBLE DELAY OF PUBLICATION

Review for disclosure of patentable subject matter and filing of patent application

Brown University
California Institute of Technology
University of Colorado
Georgia Institute of Technology
Harvard University
Indiana University
Iowa State University
University of Maryland
University of Minnesota
University of Nebraska
University of North Carolina
Ohio State University
University of Pittsburgh
University of Rochester
Syracuse University
University of Texas
Tulane University
University of Virginia
Yale University

Review for disclosure of confidential information

University of Utah
University of Wisconsin

Review for disclosure of confidential information or patentable subject matter and filing of patent application

Case Western Reserve University
The Catholic University of America
Columbia University
Cornell University
Duke University
Massachusetts Institute of Technology
University of Michigan
New York University
Northwestern University
University of Oregon
University of Pennsylvania
Pennsylvania State University
Princeton University
Purdue University
Rensselaer Polytechnic Institute

University of Rochester
The State University of New Jersey, Rutgers
University of Southern California
Stanford University
University of Washington
Washington University

Review for confidential information and sponsor approval

Carnegie-Mellon University

Review for comment, patentable subject matter, and confidential information

University of California, Los Angeles

Comment and patent filing

University of California, Berkeley

Review and deletion of sensitive information

Vanderbilt University

Reason not stated

University of Chicago
University of Maryland
University of Missouri

APPENDIX F

LENGTH OF TIME PERMITTED BY RESPONDENT UNIVERSITIES FOR DELAY OF
PUBLICATION*

30-45 Days

Rockefeller University
Yale University

60-90 Days

California Institute of Technology
University of Chicago
Columbia University
Duke University
Georgia Institute of Technology
Massachusetts Institute of Technology
New York University
Princeton University
University of Rochester
University of Southern California
Stanford University
University of Texas
Vanderbilt University
University of Wisconsin

91-120 Days

University of California, Los Angeles
Cornell University
University of Michigan
Northwestern University
University of Oregon
University of Washington
Washington University

121-365 Days

Brown University
Case Western Reserve University
University of Colorado
Indiana University
University of Kansas
University of Maryland
University of Minnesota
University of Nebraska
University of North Carolina
Ohio State University
University of Pennsylvania
University of Pittsburgh

Purdue University
Rensselaer Polytechnic Institute
The State University of New Jersey, Rutgers
Syracuse University
Tulane University
University of Utah
University of Virginia

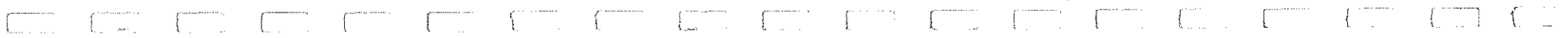
More Than 365 Days

Carnegie-Mellon University

Other

1. "short period"
 - California Institute of Technology
 - University of California, Berkeley
2. "long enough for sponsor to protect their patent application"
 - The Catholic University of America
3. "will not delay publication significantly"
 - Harvard University
4. "limited time"
 - Iowa State University

* Each institution is placed in the category reflecting the longest delay possible, as described in their response. If an institution stated that it typically delays publication for "x days, or longer", such institution was placed in the next longest delay category following x.





GENERAL COUNSEL OF THE
UNITED STATES DEPARTMENT OF COMMERCE
Washington, D. C. 20230

FEB 11 1987

see 86-121

MEMORANDUM FOR: Robert Ortner
Under Secretary for Economic Affairs

FROM: Douglas A. Riggs ~~Douglas A. Riggs~~

SUBJECT: Review of Employee Standards of Conduct Under
P. L. 99-502

Under the provisions of subsection 11(c)(3)(A) of the Stevenson-Wydler Technology Innovation Act of 1980 (Pub. L. 96-480), as amended by section 2 of the Federal Technology Transfer Act of 1986 (Pub. L. 99-502), and at your request, my office has reviewed the Department's employee standards of conduct (15 CFR Part 0). The statutory purpose of the review was to ensure that the standards of conduct contain adequate guidelines to deal with situations likely to arise using the authority of section 11(a) of this legislation. Briefly, section 11(a) authorizes Federal agencies to enter into cooperative research and development agreements with other parties, including licensees of inventions owned by the agencies. As a result of our review, I am satisfied that our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time.

In undertaking our review, we were mindful that a major purpose of the legislation is to establish a framework for permitting employees or former employees or their partners to participate in efforts to commercialize inventions the employees made while in the service of the United States. This would include the authority for those individuals to negotiate licenses or assignments of title to inventions or to negotiate cooperative research and development agreements with their present or former employing agency. These negotiations may, depending upon the facts of the particular situation, present issues under applicable conflict of interest statutes or standards of conduct regulations. The legislation recognizes this, in noting, in section 11(b)(4), that employees or former employees are permitted to participate in commercialization efforts "to the extent consistent with any applicable agency requirements and standards of conduct." The legislative history confirms this intent. The report of the Senate Committee on Commerce, Science, and Transportation (No. 99-283) notes, at page 10, that the legislation

make[s] no changes in the conflict of interest laws affecting Federal employees or former Federal employees. The Committee does not

believe that this section releases former employees from conflict of interest restraints in current law, and does not intend this result. Agencies have the flexibility under this section to establish standards for cooperative research arrangements which prevent former employees from benefitting unjustly from their former employment. Conversely, laboratories may need the assistance of former employees to develop the commercial potential of inventions, and this provision is intended to allow their participation according to agency standards.

We have conducted the required review of our regulations with these principles in mind and, as noted above, we have concluded that the regulations are adequate. We have been faced, from time to time, with inquiries from employees about their ability to commercialize inventions developed by them as part of their official activities. Such matters are decided on a case-by-case basis, in which our overall concern is whether the employee is in a better position, due to his employment, to obtain a license or commercially exploit a device than would be members of the general public. In a major study of this issue last year, my office identified four factors to consider in deciding such questions: (1) whether the license applicant/Government employee had any role in development of the device in question, (2) whether he has a role, as a Government employee, in any decision on whether to continue or discontinue Government development, (3) whether he had any role, as a Government employee, in the decision to seek a Government patent or issue a license or to whom to issue the license, and (4) whether he has access to confidential Government information concerning the device. These factors, all derived from existing conflicts-of-interest provisions, allow an employee to obtain a license and exploit an invention while, at the same time, prevent an abuse of the system by prohibiting an employee from using his position or inside information for private gain. * license

As noted above, these factors will continue to apply. To them, however, we would add a factor that reflects the public policy found in the new legislation. Specifically, we would now take into consideration the expressed Government policy in favor of licensing inventions to Federal employees. I am satisfied this can be done within the framework of our existing regulations, so long as care is taken to ensure that employees receive no unfair advantage due to undisclosed information.

Finally, I note that the full range of Federal conflict-of-interest statutes in title 18 of the U.S. Code would continue to apply. These will, for example, preclude an employee from acting in an official capacity on a matter that will affect his financial interests in a license (18 U.S.C. § 208) and may serve to limit his ability to represent the interests of an outside corporation

regarding its license in the invention before the Government (18 U.S.C. §§ 203 and 205). These restrictions are consistent with the legislation and, in any event, are not addressed by the requirement to review the Department's standards of conduct.

PREPARED BY:GFields:jwm:2/10/87

cc: DRiggs(2)

MWagner

GFields(2)

DMaggi

OG/Chron

Document Title:MEMO FOR ORTNER

LBA

VW
2-11-87

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o The request letter from AAU to universities asking for conflict of interest and delay of publication statements. All responses are not in. April Lewis Burke indicated that I was welcome to return later in the summer and review any additional materials she receives.

o Her files presently include the following university responses:

- Our Files
1. University of California -- Xerox of the letter discussing conflict of interest developments since 1982. I am sending for copies of three reports noted in their letter.
 2. California Institute of Technology -- Copied the cover letter which identified individuals for future contact. Copied a paper on conflict of interest and pages from the faculty handbook covering conflict of interest and conflict of commitment.
 3. Pennsylvania State University -- Copied case examples of industry/university agreements and discussion of research negotiations. Did not copy attachments of actual statements because dated 1977.
 4. Duke University -- Copied cover letter which outlines Duke's conflict of interest position and the appropriate pages from a faculty handbook.
 5. University of Virginia -- A very interesting response because the problem of state employee status of university staff was noted. Along with the university's statement and pages from the financial policy manual, I copied recently enacted Virginia legislation covering exceptions to the Virginia Comprehensive Conflict of Interests Act.

6. Purdue -- Copied the general statement for conflict of interest disclosure requirements and an example format. These were developed after the General Assembly of Indiana passed amendments to the Indiana "conflict of interests" law.
7. Rutgers -- Copied the brief conflict of interest statement. Again, Rutgers notes that faculty are governed by the statutes of the state.
8. New York University -- Copied a sheet of the letter noting that a faculty committee is in the process of developing a new policy statement and that current practice is governed by a 1964 AAUP/ACE Joint Statement.
9. Yale -- A report recently released by a faculty committee on Cooperative Research, Patents and Licensing is copied. Yale promised to send to AAU finalized policies and revisions to the faculty handbook when they are completed.
10. University of Maryland -- Only the cover letter noting that the university is developing a conflict of interest and commitment statement, but is unwilling to share it until it is more final.
11. Washington University -- Copied cover letter and conflict of interest policy paper. Did not copy the handbook and one page blurb because dated 1974. Copied Monsanto-Washington University Agreement.
12. University of Utah -- Copied a great deal of material. April noted the University of Utah was one of the most informative and clearly active responses.

Materials include a broad statement on commercialization of scientific discoveries; the Utah Technology and Innovation Act, 1983; By-Laws of Utah Technology Finance Corporation; "A Thriving Partnership: The University and High Tech Industry"; and, "Research for Industry at the University of Utah."

13. Case Western -- Again, a good example. Materials include general statement; Guidelines for key issues in industry-university research agreements; model research agreement; and, principles governing CWRU participation in business ventures based on university technology.
14. Harvard University -- Copied general statement.

Materials available at AAU, not copied.

1. Colorado University -- 1980 Handbook pages.
2. John Hopkins -- Brochure blurb - time commitment constraints.
3. University of Kansas -- Handbook sheets, 1971.
4. Massachusetts Institute of Technology (MIT) -- 1977
5. Michigan -- Only a blurb on Technology Transfer entity, Michigan Research Corp.
6. Northwestern -- No conflict of interest formally stated.
7. Ohio State -- Newspaper article in 1981 Harvard Gazette.
8. University of Pennsylvania -- Nothing on conflict, just comments on general relations with industry.

9. Princeton -- Agreement format but no conflict of interest mention.
10. Rockefeller University -- No conflict statement.
11. University of Southern California -- No conflict of interest information.
12. Rensselaer -- No real conflict statement merely "flexibility" in relations discussed in letter.
13. Missouri -- 1969
14. University of Michigan -- No conflict statement, just a contract example.
15. Stanford -- Blurb on sponsored research, no conflict statement.
16. Cornell -- 1964
17. Nebraska -- 1982 general paragraph, not copied.
18. University of Rochester -- General encouragement of work with industry, no statement on conflict of interest.
19. University of Oregon -- Conflict of interest new to the university, they are "wrestling" with the problem.
20. University of North Carolina -- 1979

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- | | | | |
|-----|-----------------------------------|----|--|
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Association of American Universities

March 20, 1984

CLEARINGHOUSE ON UNIVERSITY-INDUSTRY RELATIONS

This is a request for information about some specific university policies and practices in the area of university-industry relations. We would like to receive a response regarding your institution. The thoroughness of each response is crucial to the success of our effort. The purpose, simply stated, is to gather information about policies and practices affecting these relationships and to make it available in ways that will improve the quality of decisions university officers make.

Potential problems associated with university-industry research collaborations have become a subject of concern among interested observers, including members of Congress and the press. The fear is that the universities engaged in these arrangements may compromise the goals of free inquiry and open dissemination of ideas.

In 1981, the AAU was asked by the Oversight Subcommittee of the House Committee on Science and Technology to develop ethical guidelines to govern university-industry collaborations. That request stated, "...the ethical dilemmas posed by the metamorphosis of our scientific research force from educators to entrepreneurs have not been resolved. Changes in research priorities, allocation of resources, faculty-student and faculty-university relationships, as well as diminishing scientific openness may soon be evolving from a shifting value system."

A Committee on University-Industry Relations was formed by AAU to respond. That Committee determined that guidelines appeared unnecessary; however, it did conclude that universities, industry, Congress, and the public would benefit greatly from the sharing of information regarding research collaborations. The responsibility for establishing a clearinghouse for such information has been undertaken by the AAU.

Since the Clearinghouse was established in September, 1983, university administrators and industry managers have expressed a great deal of interest in information sharing. On November 28, 1983, the Advisory Committee to the Clearinghouse met in Washington to recommend how best to address that interest. The Committee recommended that the Clearinghouse request information from universities concerning activities with industrial sponsors of research, beginning with two specific problem areas: conflict of interest and delay of publication.

This is the first request for information and it is confined to those two topics. We are interested in receiving written information concerning university policies and practices, including documentation of policy, such as statements, guidelines, and memoranda, and discussions and documentation of practices, including contracts and other agreements. We are not requesting confidential information. If it is necessary to delete names, dates, dollar amounts, or other specific details from documents, we would be pleased to receive them in such form. We hope to receive information covering the breadth and variety of university activities in this area while including the details of specific arrangements.

The following hypothetical examples may make clearer the kind of information we would like to get and the value that such information might have to university officers confronted with real cases.

University A has a conflict of interest policy which states, in part, that faculty should avoid situations involving conflicts of interest such as financial dealings that are contrary to the University's best interest or which may obligate the faculty member to take actions adverse to the University's interest. Faculty member X, following extensive consulting arrangements with a small biotechnology company, is asked to join the company as a stock holding partner in order to head a new division in his area. X would only dedicate one day a week to the new company and would have the new division contract with him at the University to continue to do research. He notifies his department chairman of his desire to accept the offer, assuring him that the University's interests, including the selection of research topics and the learning experience of graduate students, would not be compromised.

What information about other universities' experiences in similar situations would you like to know to help you resolve University A's situation?

For example:

1. Conflict of interest policies.
2. Faculty contracts with industrial sponsors.
3. How similar matters were resolved, including procedures followed by other universities.

Corporation A and University Y are negotiating a contract under which the university would receive \$10 million over 5 years to conduct basic research in the area of X. The Corporation will be entitled to an exclusive license to develop patents owned by the university for products or

processes developed under the project, but it has asked for very restrictive access and publication measures to be imposed by the university in order to protect possible proprietary rights. As part of those restrictive measures, no faculty member or graduate student involved in research on the project may publish the results of the research without first submitting the proposed publication to the Company for review. The Company is requesting 120 days to determine whether the publication would reveal any patentable product or process, and a subsequent 120 days to file a patent application. The University has no stated policy concerning delay of publication; however, it has never agreed to delay publication for more than 90 days in the past.

What information about other universities' experiences in similar situations would you like to know to help you resolve University Y's situation?

For example:

1. Contracts with delay provisions.
2. Restrictive measures requested by companies.
3. How similar matters were resolved, and whether their resolution treated faculty members differently than graduate students.

We know we are asking your institution to undertake a significant task in responding to this request. We are convinced that it will be in the university community's best interest to share this information. It is important to demonstrate to those who are concerned about university interaction with industry that universities are addressing the legal and ethical problems of entering into business relationships to perform research. We hope your institution can assist in this effort.

All responses should be received at AAU by June 1, 1984. Please direct any inquiries and responses to:

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036
202-466-5030

Please let us know the name, address, and phone number of any member of the university's staff who will be assisting with this request.

Thank you.

UNIVERSITY OF CALIFORNIA SYSTEMWIDE ADMINISTRATION

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SANTA BARBARA • SANTA CRUZ

Office of the President

BERKELEY, CALIFORNIA 94720

January 4, 1983

Dear Colleague:

The Association of American Universities, other higher education associations, the government, including Congress, and other institutions have been reviewing the issues arising from university-industry cooperation. Most recently an AAU committee chaired by Bob Rosenzweig, which was established to respond to legislative interest in ethical considerations arising from such relationships, concluded that decisions about these issues are best made at the level of the individual institution. The committee's report also points out that many universities are engaged in serious study of these relationships.

I am pleased to send you under separate cover these documents prepared over the past two years by the University of California concerning this matter: 1) Report of the University-Industry Relations Project; 2) Report of the Committee on Rights to Intellectual Property; and 3) Interim Guidelines on University-Industry Relations.

The Guidelines were developed in response to issues raised in the other two reports and constitute current University policy. The guidelines will be reassessed at the end of this year.

If you have any questions about these reports, may I suggest you get in touch with Belle Cole, Director of Legislation and Public Policy here in Systemwide Administration. She can be reached by phone at (415) 642-4301.

Sincerely,

David S. Saxon
President

cc: Executive Assistant David Wilson
Director Belle Cole

bcc: Robert Rosenzweig, President, AAU ✓ (Note: This letter was sent to each member of the AAU. The enclosures were sent separately on January 17, 1983)

DEC 9 1982

UNIVERSITY OF CALIFORNIA SYSTEMWIDE ADMINISTRATION

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SANTA BARBARA • SANTA CRUZ

Office of Academic Affairs

BERKELEY, CALIFORNIA 94720

November 29, 1982

GORE Group

Dear Friends:

Attached are copies of three reports prepared by the University of California concerning university-industry relations. The Report of the University-Industry Relations Project you saw in draft. The Interim Guidelines on University-Industry Relations has been issued recently as policy.

I hope these will be useful to you.

Sincerely,

Belle Cole

Attachments

cc: Executive Assistant Wilson

INTERNAL CORRESPONDENCE

MAR 12 1984

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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SANTA BARBARA • SANTA CRUZ

OFFICE OF THE CHANCELLOR
LOS ANGELES, CALIFORNIA 90024

March 7, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, D.C. 20036

Dear April:

This material responds to AAU's request for information dated January 10, 1984. We are pleased to provide AAU with information on UCLA's policies and practices with industry. In an effort to expedite Clearinghouse analysis of our response, we have screened policy documents and other materials to provide excerpts relevant to the initial two areas under study. However, if any of the documents referenced are desired in their entirety, we will gladly provide them.

The enclosed materials constitute the majority of our written policy information in each area. Since these enclosures do not specifically discuss practices or experiences illustrated by the hypothetical situations described, some additional information related to the two areas under study may be useful.

Conflict of Interest

In May of 1982, new policies were implemented by the University in compliance with regulations of the California Fair Political Practices Commission. The full nature of the policy and its implementation should be evident from material enclosed.

An Independent Substantive Review Committee ("ISRC") formed in accordance with FPPC regulations has functioned for nearly two years to review the propriety of the University's acceptance of grants, contracts, or gifts, from non-governmental entities in which the principal investigator has a financial interest. We have had a few situations similar to the hypothetical situation described and information on the resolution of two of them may be helpful to other Universities.

Over the past two years, approximately 3% of disclosures of financial interests were "positive" and were therefore reviewed by the ISRC. Only in one case, did the ISRC recommend that an ongoing project be ended because the agreement and the conduct of the work was inconsistent with the University's policies dealing with conflict of interest. The letters enclosed dated March 4, 1983 and March 31, 1983 convey in detail, the reasons for the Committee's recommendations and the final determination in the matter. The correspondence has, however, been modified to eliminate identification of the faculty member and the company.

I will summarize a second situation which may also be of interest. A faculty member had disclosed a consulting agreement with the company under which he was to receive a consulting fee of \$10,000 per year, \$12,000 per year for any renewal periods, and under which he had also received an option to acquire 5,000 shares of company stock at a specified price per share. A research agreement was proposed between the company and the University for support of a project in the faculty member's University laboratory.

In this case, the ISRC found that the research agreement did not pose a conflict of interest and that the faculty member's acceptance of a consulting fee also did not constitute a conflict of interest. The fee was determined to be consideration for services provided by the faculty member and such service was distinct from the work proposed under the research agreement. The ISRC further found that the stock option did not constitute a conflict of interest, but was consideration for the consulting services provided by the faculty and therefore no different in principle from a cash payment. The ISRC found no evidence that the faculty's financial interest in the company would cause him to use University resources to further his own financial interests rather than to engage in impartial research for expanding scientific knowledge.

In the course of ISRC review of this case, however, the consulting agreement between the company and the faculty member was examined and found to contain some provisions which were contrary to University policy (particularly in regard to intellectual property) and were also in conflict with the research agreement. Accordingly, the University requested, and the company and the faculty member agreed, to revise their agreement to bring it into conformance with University policy and to make it consistent with the research agreement. University officers participated in redrafting a new consulting agreement to assure consistency with University policy.

One last matter should be noted regarding requested information in this area. Our policies do not require University review, approval, or retention of individual faculty contracts for consulting with outside entities. The one situation described above was atypical. Accordingly, no individual consulting agreements with industry are provided.

Publication Delay

In our experience, the freedom to publish has never been an issue which, by itself, has prevented any agreement with industry. Most firms we have worked with can, and do, accept the basic tenet of openness and the right of publication by the University.

CALIFORNIA INSTITUTE OF TECHNOLOGY

OFFICE OF THE PRESIDENT

May 23, 1984

April Lewis Burke, Esq.
Director of the Clearinghouse on
University-Industry Relations
Association of American Universities
One Dupont Circle, N.W., Suite 730
Washington, DC 20036

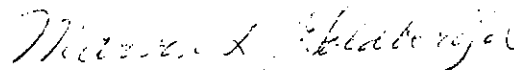
Dear Ms. Burke:

Dr. Rosenzweig's letter of March 20, 1984, enclosed the first request from the AAU Clearinghouse on University-Industry Relations for information regarding our policies and practices in certain areas. The two areas covered in that first request were (a) conflict of interest and (b) delay of publication.

We are delighted to be able to respond to Dr. Rosenzweig's request and to assist in this study of university-industry relationships. It involves a set of subjects of great importance to the future of research-oriented universities in the United States which deserves further study.

Enclosed is a Caltech response to each of the two subjects discussed in Dr. Rosenzweig's letter. If you should desire, or need, a clarification or any further information, please do not hesitate to contact Dr. Robbie Vogt (our Vice President and Provost), Dr. Don Fowler (our General Counsel), or me. We all participated in the preparation of this response.

Sincerely,



Marvin L. Goldberg

cc: D. N. Fullerton
D. R. Fowler
R. E. Vogt

May 23, 1984

CONFLICT OF INTEREST

Policy and Practices

Caltech's policy on Faculty conflict of interest was extensively revised and restated in March 1983. The revised policy reflects the rather considerable amount of discussion and reevaluation of this subject which had taken place at Caltech during the two year period following the 1980-81 academic year, at which time this issue first began to receive prominent national attention, particularly among the academic community. A copy of the restated Caltech policy, now entitled "Conflict of Interest and Conflict of Commitment" so as to reflect that a conflict of commitment or dedication can be as much of a problem as a financial conflict of interest, is enclosed. The 1983 policy is being applied as written by the Caltech Administration and, in general, the policy appears to have the continuing support of the Faculty.

A key to the Caltech policy is that the primary responsibility for seeing that outside consulting or business activities do not result in conflicts of interest or commitment remains with the Faculty member involved. Across-the-board reporting is not required for all outside consulting or business activity, as is the case at some other institutions.

Nevertheless, the Faculty member is obligated to make a full disclosure at any time upon request by the cognizant Division Chairman, the Provost, or the President. Furthermore, no agreements for research support or licenses granting exclusive rights to Caltech patents, copyrights or "know-how" may be entered into with outside organizations in which a Faculty member has an equity interest or with which the Faculty member has a continuing consulting arrangement, if the proposed arrangement would be detrimental to Caltech's interests or pose a real or apparent conflict of interest. The Provost is charged with the responsibility of determining whether such arrangements would involve a conflict of interest. In making these determinations, the Provost does consult with an appropriate advisory group of Faculty members to ensure uniformity and continuity of policy.

In applying the 1983 policy, no arrangements or licenses have been approved to date by the Provost where the Faculty member has an equity interest in or a continuing consulting agreement with, the outside organization and where that organization would receive an exclusive right (or option for such right) to Caltech patents, copyrights or "know-how." On occasion, where the Faculty member has such a relationship with the outside organization, an arrangement or license involving nonexclusive rights has been approved, with the appropriate safeguards.

In general, conflict of interest and conflict of commitment are regarded as matters to be resolved between Caltech and the Faculty member prior to completion of the Caltech arrangement with the outside organization. Therefore, contractual language with the other organization is usually not needed nor appropriate. However, Caltech is prepared to include, and has included, a provision in agreements with outside organizations where special concerns are present. Such a provision would read as follows (modified as necessary to fit the specific facts of the case):

CALTECH PERSONNEL

As part consideration for this exclusive licensing agreement _____ covenants and agrees that neither it nor any related corporation or organization will, during the term of this agreement, directly or indirectly employ or retain in any capacity any CALTECH faculty member, student, officer, or employee without the written consent of CALTECH. _____ further covenants and agrees that, while _____ is a privately-held corporation, it will not knowingly permit any such person, or any members of his or her immediate family, to own any stock or interest in _____ or in any related corporation or organization. If and when _____ becomes a publicly-held corporation or, becomes a part of a publicly-held corporation, then _____ covenants and agrees that it will not knowingly permit any such person, or any members of his or her immediate family, to own any stock or interest in

_____ or in any related corporation or organization, unless such stock is purchased in the open market at not less than the then existing market prices. In the latter event, _____ agrees that it will promptly notify CALTECH of any such purchases that come to the actual attention of _____'s officers or directors.

CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT

The acceptance of a full-time appointment to the Faculty of the Institute involves a commitment which is full-time in the most inclusive sense, with the appointee expected to accord the Institute his or her professional loyalty, and to arrange outside obligations, financial interests, and activities so as not to conflict or interfere with this primary, overriding commitment to the Institute.

Conflict of interest can arise particularly in situations where Faculty members are consultants for, or have an interest in the ownership of, business ventures that are more or less directly related to their fields of research at the Institute. In such situations, there is the danger that academic principles and educational priorities may become distorted because of the possibility for economic gain by the Faculty member, by the Division in which the research is done, or indeed the Institute itself. Furthermore, if proprietary information is introduced into research activities on the campus, its protection will surely foster secrecy or hinder open discussion about research among colleagues within the Institute and at other academic institutions, as well as with personnel at institutions or agencies that contribute substantial support to the Institute. Whenever organizations having Faculty members as consultants, substantial shareholders, or part owners wish to make arrangements with the Institute for support of research, patent licensing and related matters, both real and apparent conflicts of interest with respect to the obligations of the Faculty member to the Institute and of the Institute to its educational goals must be avoided.

Responsibility for establishing that activities in business ventures do not conflict with Institute commitments rests first with the Faculty member. Further, on request from cognizant Division Chairmen, the Provost, or the President, the Faculty member shall make a full disclosure of all such ventures including the names of companies, the nature of agreements, the responsibilities assumed by the Faculty member, and the time involved. It is the policy of the Institute (see also Chapter 7 "Consulting Activities") that acceptance of a full-time Institute appointment precludes a Faculty member's assuming a position of line responsibility in outside organizations for pay or profit.

Irrespective of what agreements have been made in the past, it is the Institute's policy that no agreements for research support, or for the granting of exclusive rights to the use of Institute patents, copyrights or "know-how" will be made with any company or institution where a current Faculty member consults (or is totally or partially owned by the Faculty member) if the proposed arrangements would be detrimental to the Institute's interest or pose a real, or an apparent, conflict of interest with respect to the obligations of the Faculty member to the Institute.

It is not practical to write specific rules covering all possible situations that might constitute potential or real conflicts of interest. The Provost is charged with the responsibility of determining whether proposed agreements for support of research or for the licensing of patents, applicable copyrights (see Chapter 7 "Patent Policy and Royalties and Copyrights") or "know-how" would involve conflict of interest.

Faculty members should notify the Provost of their participation (as consultants, shareholders, owners, and so on) in business ventures in which the Institute might become involved in any way, including preferential transfer of research results obtained at the Institute in advance of publication. It is especially important that such notification be given before any commitment is made that could bind the Institute, either ethically or legally.

The Provost will consult with an appropriate advisory committee of Faculty members to ensure uniformity and continuity of policy in making decisions with respect to conflicts of interest and conflicts of commitment. A Faculty member wishing to appeal a decision of the Provost has recourse to the grievance procedure described in the Faculty Bylaws.

With respect to obligations assumed under grants and contracts awarded by governmental agencies, the Institute subscribes in principle to the 1965 statement on conflict of interest issued jointly by the American Association of University Professors and the American Council on Education.

Examples of Conflicts of Interest and Publication Rights Problems
in Sponsored Research at The Pennsylvania State University

A Report Prepared for the AAU Advisory Committee to Clearinghouse
for Information on University-Industry Relations

R. G. Cunningham

February 10, 1984

Introduction

As a research university, Penn State ranks about 20th in terms of dollar volume of sponsored research. Policies and procedures in research are well established and published in booklet form, see Attachment I. This publication will be updated in regard to conflicts of interest situations within the next year. This need stems from our industry-university cooperative research which has increased from 8% to a current level of 15% of total research. Negotiations of industrial research agreements require more time--and legal services--in comparison with federal agency grants or contracts. I attribute this to the applied nature of most industry sponsored research; the closer the subject to the marketplace, the stickier the negotiations become. Patents, publication rights, conflict of interest (COI) situations, lead the list of problems.

In 1981, we restated our patent policy to emphasize our flexibility in dealing with industrial sponsors. As stated in Attachment Ia, it is University policy to take ownership of patents. But three exceptions to University ownership are listed for use when justified. These are negotiated on a case-by-case basis. The three exceptions (right-of-first-refusal, shared royalty, and assignment of patent rights to the sponsor in exchange for a premium overhead) have successfully accommodated virtually all industrial research agreements during the past three years.

As indicated by pages 24-25 of Attachment I, our policy on private consulting is liberal. Faculty are expected to inform their dean of the general nature and extent of their consulting activity. Details are not required. This policy may be revised in the near future. Among the changes which may be made would be a limit on private consulting stated in days per semester or days per year or per academic year. Reporting of consulting income--and possibly the reporting of all income from outside sources in excess of, say, \$1,000 per year--may be considered.

The following cases are from our files in the Office of Sponsored Programs. Problems and the resolutions are described, albeit, briefly. More details can be provided. It is important to note that the contract-language excerpts represent the final--accepted--language. The original clauses proposed by the sponsor--which are not included here--were often totally unacceptable. For example, sponsor claims to all patent ownership rights, or, the requiring of sponsor permission to publish any results of the work.

Conflicts of Interest (COI) Situations

COI Case 1

Professor A agreed to enter into a consulting agreement with the Z Company, a west coast producer of medical diagnostic equipment. Attachment IIa is a copy of Company Z's consulting agreement. It came to our attention because the Company formally asked the University to "sign-off" on the consulting agreement to provide assurance that the faculty member's consulting duties were approved and would not be in conflict with his responsibilities to the University. Our arguments to the effect that consulting was an agreement between the Company and the faculty member--and not a contractual agreement involving the University--were to no avail. Rather than destroy the consulting opportunity for the faculty member, the University agreed to sign a statement that the faculty member was carrying out this private consulting with the knowledge and approval of the University. Attachment IIb is a memo from our University Patent Counsel who reviewed the consulting agreement and advised the faculty member to seek changes in certain paragraphs. (The agreement proposed by Company Z could have had the effect of limiting the faculty member's research in subsequent years.) If many companies hiring faculty consultants propose similar restrictive clauses--normally unknown to the university--then one suspects that private consulting agreements may comprise a significant source of conflicts of interest.

COI Case 2

Professor B received research support from a for-profit company in a foreign country over a period of several years. Eventually this led to his receiving payments for private consulting duties, in parallel with his research work at the University. (He was unaware that this was a violation of University policy.) Subsequently, the company agreed to provide additional support for a postdoctoral researcher in Professor B's laboratory. The sponsor also wanted to continue Professor B's retainer for private consulting in his area of expertise. Attachment IIIa provides further details. Attachment IIIb is Professor B's statement that the technical areas involved in his private consulting and the employment of the postdoctoral fellow on the research project in his (Professor B's) laboratory are in related, but different, fields. Attachment IIIc is the statement from the dean of Professor B's college confirming that the subject areas are sufficiently different to warrant approval of simultaneous research sponsorship, and private consulting. Based on IIIb and c, I approved the request. (See Discussion 5, below.)

COI Case 3

Professors C and D conducted sponsored research (biomedical) for a number of years, much of the work being sponsored by NIH. Several inventions and patents resulted, but licensing efforts were unsuccessful. Eventually one invention (University support--no NIH money) was turned down by Research Corporation. Under University policy it was released to the inventors at their request and they proceeded to obtain a patent at

their own expense. Company X decided to enter this field of medical technology. They were interested in (a) a license to the inventors' patent, (b) supporting research in the same field at the University, (c) obtaining rights to future research-related inventions, and (d) retaining the faculty members on a private consulting basis. As in Case 1, the Company wanted a sign-off by the University to the effect that the faculty members were functioning within University policy in undertaking the consulting work. The University eventually agreed to this unusual situation, motivated by desires to effect technology transfer and to secure research support for the faculty members involved. As in Case 2 above, the Vice President for Research and Graduate Studies obtained statements from the faculty members and from their academic administrators to the effect that their private consulting and the research work were adequately different to warrant an exception to University policy.

COI Case 4

On two occasions in recent years faculty inventors have violated University policy by hiring patent attorneys to apply for patents on invention of theirs which stemmed from University research. In both cases after protracted discussions, the inventors recognized their obligation to assign inventions to the University. With Research Corporation's help the damage was undone. (Research Corporation in assuming the cases reimbursed the inventors for their out-of-pocket patenting expenses.)

COI Case 5

In contrast to Case 4 above, a different--and frequent--problem is faculty indifference to inventions and the patenting process. Professor G (biochemist) was approached by a government-owned laboratory abroad, to continue his research for them. Before the University entered the negotiations, Professor G had advised the foreign government contract representatives that they would be given all rights to inventions, a condition which they subsequently insisted upon in negotiations. Professor G supported the give-away of patent rights to the sponsor. He felt that patents were of little or no importance in comparison with securing the research funding--a frequently encountered situation. In a sense, a conflict exists between faculty indifference to patents, and the University's obligation to follow published policy. (See Discussion 4, below.)

COI Case 6

The University actively encourages faculty interested in starting up spin-off companies to exploit technology or inventions stemming from University research.

Two faculty members recently started their own company, bought land and constructed a building. The new company will perform research services in the pharmaceutical field. Some of the work requires access to University facilities. A research agreement was executed with the new company at the request of the firm's VP (who is still a faculty member).

Conflicts of interest are clearly a potential problem. The principal investigator for the research in University laboratories is also an officer of the new company. He participated in both ends of the negotiation. The situation was further complicated by the sponsor company's request for the premium overhead exception to patent policy, i.e., payment of a 20% premium in return for which the University grants patent rights to the Company (with the approval of the faculty members involved which was, of course, forthcoming). The Vice President for Research approved the research contract. Justifications were (a) to encourage start-up companies and the creation of jobs and (b) to secure research support for faculty and graduate students.

Policy to safeguard faculty and the University must be developed.

Publications Clauses in Research Contracts

Publications Case 1

Attachment IV is an excerpt from a recently negotiated agreement. The technology under development will be close to the marketing stage; consequently inventions and patents are viewed as important. The faculty investigators and college administrators had no objection to being required to send publications to the sponsor for review at least sixty days prior to submission for publication. If patentable subject matter is found in the publication, the University then agrees to withhold publication for nine months to permit filing a U.S. patent application. Alternatively, the authors could delete the patentable subject matter and proceed without delay.

Publications Case 2

In this instance, the sponsoring company had a prior patent and/or trade secrets position in the field of the research agreement. Patents are expected to be important. The negotiation encountered a problem with publications. We resolved the issue as indicated in Attachment V. The sponsor was willing to recognize that the University had the right to publish results of the investigation in scientific journals, textbooks, or theses. But the sponsor stipulated that the subject matter of such publications

"shall not contain information about the process,
methods or materials of Sponsor or other information

considered by sponsor to be proprietary to the Sponsor, but shall be confined to statements of new discoveries and interpretations of scientific fact. The Sponsor shall be provided with an advance copy ... to prevent premature disclosure of an invention and/or information considered proprietary by the Sponsor."

Consultation with the inventors and their academic administrators established that publication delay would only occur if the author used proprietary information, e.g., trade secrets. Since this would not occur, there was no objection to giving the sponsor the right to review papers prior to publication. As indicated on page 2 of Attachment V, the sponsor is required to notify the University in writing within thirty days of receipt of the advance copy of the publication. In the absence of a written response from the sponsor within thirty days, the University is free to proceed with publication. Additional statements cover the patent statutory-bar situation.

These two cases cover the most frequently encountered problems regarding publications, namely, delays or reviews (a) for patent purposes and (b) providing the sponsor an opportunity to protect against disclosure of proprietary information. The negotiation results above are typical.

Discussion of Research Negotiations

The following observations may be helpful in understanding the major and minor sources of problems--which often involve conflicts of interest and publication issues--in negotiating industrial contracts.

1. While publication clauses are always present, they are rarely a sticking point in completing an agreement with a sponsor company. Publication delays are, of course, approved for patent purposes. Furthermore, the University will agree to a sponsor's prior review of publications, if the work involves information proprietary to the sponsor. Contract-language in these cases requires the sponsor to label information they view as proprietary so that faculty and graduate students understand the situation. Also, "best effort" to protect language is used. [The University in comparison with industrial concerns cannot guarantee protection of proprietary information and trade secrets.]
2. Some faculty take an interest in inventions and patent law. But many faculty researchers regard patent policy and procedure as a nuisance and are less cooperative than they should be. The statutory bars which arise are symptomatic. Publications--the coin of the realm--are

far more important to faculty than invention disclosures and the possibility of patents.

3. In the Office of Sponsored Programs, a large amount of staff and legal counsel time is consumed in negotiating contracts with sponsor representatives who are unfamiliar with research in academia. The typical problem: an attorney who has never before dealt with a university and who approaches the negotiation on a company-to-company hard-line traditional basis. Research agreements with pharmaceutical companies have led the list in stubbornness or rapaciousness in their negotiating stances. We rarely, if ever, fail to complete a negotiation, but the consumption of time and effort in reviewing endless drafts and redrafts has been costly.
4. The attitude of the faculty principal investigator (PI) is all important in negotiating industry-university research agreements. When the faculty members' attitude is one of cooperation, conflicts of interest situations either do not arise or they can be easily handled. At the other extreme, lack of cooperation and/or a single-minded drive on the part of the faculty member to obtain the research money can seriously impair negotiations.

5. With reference to COI Cases 1, 2, and 3 above, we are not comfortable with our policy controlling private consulting by faculty which is coincident with his or her research at PSU sponsored by the same company. Exceptions are approved, based on evidence that the fields involved in the consulting and the research are "sufficiently different." We hope to develop clearer policy and procedure in this area.