Annual Report on Research and Scholarship

FY2004

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Vice President for Research
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INTRODUCTION

OVPR’s concrete impact on the campus occurs through its facilitation of major interdisciplinary research initiatives and seed funds in the support of faculty research and scholarship, the development of policies to guide the conduct of research on campus, facilitation and promotion of technology transfer and economic development, and a service-oriented administrative infrastructure to serve the faculty and staff involved in research. To promote faculty collaboration and the development of new avenues of research, OVPR annually spends several million dollars in seed funding of faculty projects, cost-sharing with the schools and colleges, and for special initiatives aimed at promoting new areas of expertise on campus. In all of these activities, OVPR works in coordination with the Provost and the Deans to support the overall academic mission of the University, as well as with other offices, especially the Office of the General Counsel.

At any given time, more than 5,000 externally sponsored research projects are underway at the University, all of which receive administrative care from OVPR and other units that report to it. OVPR is deeply involved in issues related to the proper conduct of research and compliance with University and government regulations. The University has about 7,000 research protocols involving human subjects that are active on campus, all of which must receive annual scrutiny from a number of campus boards and committees. Likewise, the use of over 400,000 animals in research each year is also carefully reviewed to ensure compliance with the highest standards of care.
FY 2004 RESEARCH EXPENDITURES

Research expenditures for FY2004 topped $752 million, an increase of 0.42% over FY2003 (Figure 1). This is the smallest year-to-year increase since the negligible growth from FY1998 to FY1999. This slowdown follows a period of quite rapid growth of about 10% per year for the previous five years. The slowdown reflects a combination of factors that include: (a) much slower growth (3.3%) in last year’s federal appropriation for basic and applied research to all universities, (b) sharp decline in research support from industry, and (c) acute reduction in research expenditures for social-science survey research by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). These factors are in addition to the reduced rate of growth of 1.6% from FY2003 to FY2004 in UM’s expenditure of internal funds in support of research compared to the 9.3% increase from FY2002 to FY2003. This drop-off is a direct consequence of the severe cuts in State appropriations over the past two years. Figure 3 on the next page details FY2004 research expenditures by source.

The Federal government is the largest source of sponsored project funding, currently providing about 71% of the total research expenditures at the UM (Figure 2). The second largest source is internal funds, at about 15%. Industry funds just under 5% of the total, with Foundations, State and Local Governments, gifts, and other non-profit institutions providing the remainder.

The breakdown by School or College shows that nearly two-fifths of UM sponsored research expenditures occur in the Medical School. The College of Engineering spends about 18% of the total, the Institute for Social Research (ISR) is responsible for 12%, and the College of Literature, Science
and the Arts (LSA) accounts for just under 9% of UM research spending. A complete breakdown of research expenditures by School and College is provided in Appendix I.

A closer look at research expenditures specifically from external sources by these largest UM units sheds some additional light on the impact of FY2004’s slow spending growth to the campus. As Figure 4 indicates, the slow growth in research expenditures experienced by the University as a whole in FY2004 can be attributed to slower growth in research expenditures in the Medical School, in comparison to prior years, and a decline in the College of Engineering. In addition, the Survey Research Center in ISR (Figure 5) experienced a significant drop-off in expenditures in FY2004 compared to FY2003. As the graph shows, the Survey research center experienced a significant “bubble” in expenditures during the FY2001 to FY2004 period. This expenditure growth was due to several major projects funded by the federal government that collected large quantities of data and, consequently, were very expensive to conduct. The data collection phase of these projects has ended, and now ISR and others across the country will begin work studying these datasets -- valuable research activity, but...
not nearly as costly as the original data collection. Fortunately, this decline in Survey Research Center spending had minimal impact on the Institute’s ability to conduct research in the traditional, academic sense. In fact, if you remove the “bubble” from ISR expenditure data, the general trend (dashed line) continues to show reasonable growth.

Several other factors suggest that FY2004 may be more of an interruption of the growth the UM has experienced over the last several years rather than a major trend reversal. For instance, expenditure growth for projects funded by the three federal agencies that support most campus research -- the National Institutes of Health, National Science Foundation, and Department of Defense -- shows that UM support grew at about the same rate or better than those agency’s overall growth (Figure 6). The federal agency with the largest year-to-year decline in support was the Centers for Disease Control and Prevention, mentioned above in connection with the Survey Research Center, and most of this drop can be attributed to withdrawal of support for certain ISR survey projects.

In most areas of “basic” and “applied” research, research expenditures were up in 2004 compared to 2003:

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<tr>
<th>Agency</th>
<th>Change $</th>
<th>Change %</th>
<th>Agency Total Change %</th>
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<tr>
<td>NSF</td>
<td>+$7 M</td>
<td>+11.3%</td>
<td>4.8%</td>
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<td>NIH</td>
<td>+$9 M</td>
<td>+2.6%</td>
<td>3.0%</td>
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<tr>
<td>DOD</td>
<td>+$3 M</td>
<td>+5.7%</td>
<td>2.6%</td>
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<td>The significant decreases were primarily in:</td>
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<td>CDC</td>
<td>-$6.1 M</td>
<td>-52%</td>
<td>(not avail.)</td>
</tr>
<tr>
<td>Education</td>
<td>-$3 M</td>
<td>-30%</td>
<td>-11%</td>
</tr>
<tr>
<td>Commerce</td>
<td>-$1.5 M</td>
<td>-14%</td>
<td>+4.6%</td>
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**Conclusion:**
No negative impact on academic research and scholarship.
**FY2005 PROJECTION**

Preliminary data on research expenditures for the current fiscal year (FY2005) shows that research spending is up 5.9% for the first half of the year, and indirect cost recovery has risen 7.1% over last year. Furthermore, our projection of expenditures for the whole of FY2005 based on performance through six months of the fiscal year suggests that total research expenditures will likely surpass $800 million for a gain of about 7% overall, with indirect cost recovery projected to increase by just over 7% (Figure 7). Total U.S. spending in support of science and technology research will grow about 2% this year.

![Figure 7](image)

The most recent comparison to our peer institutions is found among data assembled by the National Science Foundation on R&D spending by universities, currently only available through FY2002. By this measure, the UM has ranked in the top five institutions in the nation from FY1990 to FY2002, when it ranked second only behind UCLA. However, these data are too far removed from the present to give us a sense as to whether other universities may have experienced a similar flattening in FY2004.

The trend comparing awards to support research activity with expenditures from external sources (Figure 8) shows a slight rise in FY2004 relative to the previous fiscal year, from $697.0 million to $707.3 million (+1.5%).

![Figure 8](image)
OUTLOOK FOR FY2006

Three federal agencies -- National Institutes of Health, National Science Foundation, and Department of Defense -- are the source of the majority of federal support for UM research, accounting for 85% of the University’s total federal expenditures in FY2004 (Figure 9). The President’s FY2006 budget request to Congress includes very modest increase for NSF and NIH, and a 13.5% reduction for basic and applied research for DOD (Figure 10). The overall R&D budget request reflects an increase of only 0.6%. When these figures are compared with a likely adjusted inflation rate of 2%, they translate into significant reductions of federal funding to universities. The reaction to these cuts will manifest itself in the form of greater competition by universities for research dollars, as well as more intense lobbying by academic institutions for Congressional “earmarks.” Even though the outlook for FY2006 and beyond may look somewhat bleak, it is important to remember that the UM has always competed exceedingly well against other institutions, and will continue to do so in the future, so long as we do not compromise our long-held tradition of placing academic quality above all other considerations when hiring new faculty and in promotion and tenure decisions concerning current faculty.
MAJOR RESEARCH INITIATIVES

OVPR considers the development or enhancement of research activities on campus as one of its important roles. In many instances, this has involved providing leadership so that a promising area can grow to the point that it becomes a nationally important, self-sustaining research direction. Several approaches are used, depending on the level of current activity in a particular area, the need for infrastructure development, the interdisciplinary or inter-unit collaboration that may need to be fostered, and the potential for future external funding. Two recent initiatives are described below.

Nanoscale Science and Engineering Initiative

Over the past decade, several research groups at the UM have been involved in the emerging field of nanoscale science and technology. About two years ago, OVPR initiated an analysis of the status and potential for this area of research on our campus. In addition, OVPR co-sponsored an international symposium in October 2003, which brought many leading researchers in the field to campus to present papers on their research and to meet with senior officials to discuss the potential UM niche in the field. In the early part of 2004, a general plan was developed that calls for a modest investment of up to $10 million ($5 million from OVPR with equal matching from participating schools and colleges) over the next four years. This plan was presented to the Executive Officers and several deans of key schools, which gave OVPR the go-ahead to assemble a faculty group to further develop a more detailed plan for enhancing nanoscale science and technology research on campus. The committee has submitted this plan, which OVPR has accepted and is now administering its implementation.
**Great Lakes Initiative**

Ann Arbor is home to several international, federal, state, and academic organizations dedicated to the study and protection of the Great Lakes. These include the Great Lakes Environmental Research Laboratory (NOAA), the Great Lakes Science Center (USGS), the Institute for Fisheries Research (MDNR), the Great Lakes Fishery Commission, the Great Lakes Commission, and other federally and state funded research efforts, such as the Michigan Sea Grant Program and the Cooperative Institute for Limnology and Ecosystems Research (both NOAA funded). In 2002, OVPR helped launch an effort to revitalize and expand Great Lakes research activities. OVPR joined with Michigan Sea Grant to fund several new multidisciplinary projects and to sponsor a major symposium on the Great Lakes in November 2002. Since 2002, OVPR has committed about $500,000 with about $250,000 in cost sharing from the schools and colleges.

Another effort to enhance Great Lakes research in the region is an effort to build a new Great Lakes Research Facility in Ann Arbor that would bring together into a single office and research complex the activities of the many Great Lakes-related labs, agencies, and other activities. A feasibility study commissioned by NOAA was completed in 2003. OVPR is exploring options with its state and federal partners for financing the joint facility.

**RESEARCH-RELATED POLICY DEVELOPMENT**

Periodically, the University finds that a need exists to develop a new policy on some specific research-related topic, or to revise an old policy. Policy development on research-related activities and issues is supervised by OVPR, with input from faculty, other central administration offices, and other stakeholders. During the past year, OVPR has been involved in revising or developing policies and procedures related to stem cell research, conflict of interest and conflict of commitment, royalty distribution, and biosafety.

**University of Michigan Policy on Stem Cell Research**

In 2001, OVPR charged a faculty committee with the goal of developing University of Michigan guidelines that govern the use of human embryonic stem cells. Based upon the recommendations of this committee, on January 28, 2002, OVPR approved a policy in which UM oversight of federally-funded research with human embryonic stem (ES) cells will conform to the updated NIH policy of August 9, 2001, which limits federally-funded research to ES cell lines found in the NIH Human Embryonic Stem Cell Registry. As of January 2002, the Registry had 72 eligible cell lines in various stages of development. With respect to the oversight of non-federally-funded research, the University will apply the objectives of the earlier NIH guidelines of August 24, 2000, which vest the Institutional Review Board with responsibilities for reviewing the ES cell derivation protocol and proposed use of the ES cells to assure conformity with the principles set forth in the guideline.

UM policy prohibits the use of federal funds in support of personnel, equipment, or other research involving ES cell lines not listed in the NIH registry. The policy conforms to all federal and state policies and statutes including the State of Michigan statute, which prohibits “human cloning” (but does not prohibit other scientific or cell-based therapies with human ES cells or other cells).

In 2004, OVPR formed a new faculty committee and charged it with reviewing the current ES cell policy and recommending revisions, if appropriate. The committee report reaffirmed the
appropriateness of the current policy and made only minor modifications to it to keep it in conformance with federal regulation.

**Conflict of Interest/Conflict of Commitment**

The University discovers, transmits, and secures new knowledge through the research, teaching, and service of its faculty. The concept of service traditionally includes both activities within the University in support of its operations, but also professionally related activities outside the institution. Given that the involvement of faculty in entrepreneurial activities can help the state and nation’s economy by promoting commercialization of cutting-edge technologies, the University has traditionally supported the outside activities of its faculty members, including technology transfer, so long as these are done within the University’s conflict of interest and conflict of commitment policies and philosophy.

In 2003, the Vice President for Research, in partnership with the Provost, named a faculty/staff committee to review existing conflict of interest and conflict of commitment policies and to recommend any changes deemed necessary to update those policies. In particular, the committee was asked to consider an institution-wide conflict of commitment policy more specific than the number of allowable consulting days.

The committee prepared a draft conflict of interest/conflict of commitment policy containing definitions of both concepts, articulating the principles underlying them, and proposing a succinct policy statement. With the assistance of OVPR, the committee consulted widely with OVPR staff, with the Research Policies Committee, with the Schools and Colleges, and with the Deans.

A revised document was submitted to the Vice President for Research and the Provost. Given that the institutional principles anticipate development of school/college implementation policies, a joint effort by OVPR, the Provost’s Office and the Office of General Counsel is currently developing a strategy for engaging the schools and colleges in such an effort, including the development of model features that should be incorporated into local implementing policy. Upon completion, a formal policy statement will be submitted to the Board of Regents for its approval.

**Royalty Distribution Policy**

In 1996, the University adopted a royalty distribution policy that defined how royalties from licensed inventions and income from University’s equity shares in start-up companies were to be shared among the inventor(s), the central administration, the schools and colleges, and the academic departments of the inventors. A recent review of the distribution policy revealed that the policy is flawed because it expects the central administration to support the continued growth of technology transfer activities, but returns the royalty revenue to stakeholders -- except for the central administration. OVPR proposed a new, more realistic model, consistent with the common practice at other academic institutions. The new policy was approved by the Board of Regents on May 20, 2004.

Under the new formula, (Figure 11), applicable to new agreements starting July 1, 2004, the central administration would receive 15% of the first $200,000 in royalty revenue, with the remainder distributed as follows: 50% to the inventor(s), 18% to the inventor’s school(s) or college(s), and 17% to the inventor’s academic department(s). Above $200,000 in revenue, the formula shifts to provide somewhat larger shares to the unit, school/college, and central administration.
This new distribution formula directs a portion of the funds derived from intellectual property to the central administration for purposes of reinvestment in research and technology transfer. This more accurately reflects the relative investment in technology transfer and allows the central administration to recover funds, especially when there are highly successful discoveries. Central administration proceeds will be divided equally between the Office of the Provost and the Office of the Vice President for Research; at least 25% of the OVPR portion will be dedicated to supporting technology transfer and economic development and 50% to support fellowships for graduate students. The Research Policies Committee assisted in formulating the current policy, which we believe will serve equally well all of the parties to IP agreements and will foster optimal conditions for promoting technology transfer.

Select Agent Restrictions/Institutional Biosafety

Select agents are those biological agents and toxins specifically identified by the Department of Health and Human Services Center for Disease Control (CDC) and the United States Department of Agriculture (USDA) as posing a severe threat to public health and safety. There is a long history of federal guidance and regulatory restrictions on the possession, use, and transport of these agents.

The attacks of September 11, 2001 and the anthrax contamination episodes in the fall of 2001 elevated national concerns about the potential for use of dangerous biological agents and toxins by bioterrorists. Two statutes in particular, the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness Act of 2002, impose new restrictions on the use, possession, and oversight of select agents at Universities and other research facilities. The requirement for personal background checks on researchers, the prohibition on access by foreign nationals, and the physical safety requirements challenge the University’s traditional value of openness.

The University has an oversight structure for safety review and management of research involving agents created using recombinant DNA techniques (rDNA). This structure – the Institutional Biosafety Committee (IBC) – is appointed and administratively supported by OVPR. The University’s Biosafety Officer is a member of the committee and provides the inspection services for the IBC.

Passage of the USA PATRIOT Act, the Bioterrorism Preparedness Act, and the subsequent codification of regulation required establishment of a response team across Vice Presidential areas. OVPR initiated coordinated actions by the Institutional Biosafety Committee, the Biosafety Officer, the UM Office of Safety and Environmental Health, the General Counsel’s Office, and the Department of Public Safety.

A multistage process was developed for receipt, review, and, ultimately, management of faculty requests to receive, use, or transmit select agents. This process has been used in a small number of times since establishment and appears to successfully gather, sequence, and route information to the appropriate institutional decision-makers.
OVPR joined with the Medical School, Life Sciences Institute and others to organize the 2005 Jerome B. Wiesner science policy symposium on biosafety issues and their impact on university research. The symposium - “Academic Freedom and National Security: Biological Research in the Post-9/11 Era” - was held on the morning of February 14, 2005, in the Great Lakes Room, Palmer Commons. Biological research has unquestionably benefited society and has great potential to continue to do so. However, in the hands of terrorists, research findings can be misused to cause great public harm. This symposium examined how such research can continue to thrive even as procedures are developed to prevent potential public health disasters. The keynote speaker was Ronald M. Atlas, Professor of Biology and Graduate Dean at the University of Louisville, past President of American Society for Microbiology, and a member of the Institute of Medicine Committee, which authored the 2004 National Research Council report “Biotechnology Research in an Age of Terrorism.” Following the keynote address, panelists from the NIH, CDC, FBI, and the UM faculty presented their thoughts on this topic, followed by discussion and audience questions.

TECHNOLOGY TRANSFER

UM Tech Transfer is the University organization responsible for facilitating the transfer of UM technology to the marketplace so as to generate benefits for the University community and the general public.

The organization consists of a central Office of Technology Transfer (OTT) and a satellite office in the College of Engineering. The offices work closely to provide responsive, professional service to UM inventors and our industry partners.
In FY2004 OTT, including its satellite operations, had an overall budget of $3 million, employed 24 staff that managed over 281 invention disclosures, executed just over 70 licenses and facilitated 13 new start-up companies.

Technology transfer activity (Figure 12) at the UM has grown significantly over recent years. New invention disclosures by faculty have grown from about 150 in FY1999 to more than 285 in FY2004. Revenues from royalties and equity sales grew from $3.5 million in FY1999 to $11.7 million in FY2004 (Figure 13), with about $15 million expected for FY2005. Over the same time period, 36 start-ups have been launched based on UM discoveries. (Figure 14.)

Major OTT activities include:

- **Disclosure Facilitation** - Advice about potential tech transfer issues during research activities; assist in the invention disclosure.
- **Patenting and Other Protections** - Plan patent copyright or trademark strategy.
- **Start-up Assistance** - Analysis of potential opportunities to form a start-up.
- **Licensing** - Technical and market assessments; secrecy, evaluation, material transfer, option and license agreements.
- **Legal Support** - Legal assistance for UM Tech transfer activities.
- **Decision Support** - Business support and advise on UM policies & procedures including conflict of interest issues.

### New Business Start-ups (all based on UM technology)

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<td>KeraCure *</td>
<td>Originus *</td>
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*indicates Michigan headquarters

*Figure 13*

*Figure 14*
RESEARCH ADMINISTRATION AND COMPLIANCE

Development of the MPRIME System (E-Research)

MPRIME, the Michigan Program for Research Information Management and Education, (a component of eResearch) aims to improve the management of research information at the University. The first focus is the continuing proper attention to human subjects in research through improvements in the efficiency of the approval and administrative processes for research projects and protocols. The goal is to develop systems that ensure the safety and privacy of persons who volunteer to participate in research studies. (Figure 15)

Under the leadership of the Office of the Vice President for Research and the Michigan Administrative Information Services (MAIS), the MPRIME team is implementing an electronic administration system to support the review and oversight of human research. (Figure 16)

System testing of the web-based system for the preparation, submission, and management of human subjects approvals was largely completed last fall. Modules for submitting adverse events, modifications, and other parts of study management have been created. Training sessions for IRB staff, reviewers, PIs and other users are being planned. At the beginning of 2005, the system went into use by a limited number of faculty so that any possible system needs can be determined and added before full implementation of the system takes place this spring. (Figure 17)
The overall costs of establishing a human subject system under MPRIME are approximately $2 million, with an annual operating budget for the program estimated at $700,000.

Figure 17

- Strongly endorsed and fully financed by the Provost's Office
  ($2M for start-up; $700K annual operating costs)
- Jointly managed by OVPR and Provost's Office (MAIS)
- Schedule
  - 2001 Formulation of Initial Plan
  - 2002-03 Definition of business processes, vendor selection
  - 2004-05 Design by vendor, jointly with UM team
  - Jan-Apr 2005 Prototype testing
  - May 2005 Fully operational
FUTURE CHALLENGES

Increased restrictions by Federal Agencies

In reaction to the September 11, 2001 tragedy and the enactment of the USA PATRIOT Act, some federal agencies, such as DOD and DOE, have expanded the use of Export Control regulations in funded projects (Figures 18-20). Export controls carry restrictions on publication of research findings and on the participation of foreign nationals in research projects. A task force composed of several deans and co-chaired by the Provost and Vice President for Research developed a “Research Restrictions Policy” which reaffirms the position that the University will not accept projects that exclude the participation by researchers on the basis of their ethnicity or national origin. Exceptions are allowable under special circumstances, but they require approval by the Vice President for Research.

This issue continues to plague major research universities and has been the subject of many discussions among senior research officers, as well as at many meetings with government officials, including with the President’s Science Advisor Jack Marburger.

Figure 18

Federal Research Restrictions

- Export Controls
  - ITAR: International Traffic in Arms Regulations (DOD, Dept. of State)
  - EAR: Export Administration Regulations (Dept. of Commerce)
- “Export”: transfer (to a foreign person) of information, physical item, or computer program pertaining to the design, development, manufacture, testing or modification of a defense article on the U.S. Munitions List (54 pages) or Commerce Control List (272 pages)
- Even through these regulations have been in place since 1994, imposing restrictions in university research contracts really started after 9/11.

Figure 19

Federal Research Restrictions

- Possible severe civil and criminal penalties, including fines and imprisonment, for violation of export control laws.
- Types of restrictions:
  - Pre-approval of publications
  - Segregating students into 4 categories:
    - US (citizens and permanent residents) - no license required
    - NATO countries - License required, but process is straightforward
    - Non-NATO countries (but specifically excluding Specially Designated Countries) - application may take a year or more
    - Specially Designated Countries (selected countries in Eastern Europe, Asia, Middle East and Africa) - unlikely that a license will be issued

Figure 20

Academia’s Response to the Rise in the Number of Export Control Projects

- AAU, AAAS and NAS meetings involving University research officers and officials from the White House (Science Advisor Jack Marburger), Pentagon, State Department, Department of Homeland Security, etc.
- Letters from University Presidents
  - Vest letter (9/9/2004): “…Under various reinterpretations and recommendations suggested by the DoD IG, we estimate that large research universities would need to apply for thousands of such export licenses annually.”
  - Rice response (10/13/2004): “…The current rules governing deemed exports, and the government’s interpretation of those rules, remain the same today as when they were first adopted in 1994.”
  - Hasselmo AAU report (10/14/2004): “…of most serious concern is the assertion in the Commerce IG’s report that the use of export-controlled equipment or technology necessarily conveys information about that equipment or technology and hence may be a deemed export, even if the research being conducted with that equipment is fundamental.”
Economic Development

Over the last several years, the University has helped promote success in technology-based economic development (TBED) through its focus on licensing research discoveries to industry and its active facilitation and investment in new business start-ups. The economic development benefits that stem from the UM technology transfer process (including the business and venture funding relationships that must be nurtured) have benefited the University in attracting and retaining the research, faculty and student talent it needs, while at the same time benefiting the region’s economy. To a great extent, continued University success in some ways is intertwined with the ongoing economic success of our region. Plans are underway to expand the efforts by the University and greater Ann Arbor community by launching a more focused and aggressive approach to innovation and technology-based economic development through a public-private partnership. President Coleman has convened a meeting of local business leaders to discuss the plan specifics (Figure 21).

In addition, there are many other activities that OVPR supports that enhance regional economic development, including the leadership roles many OVPR and other UM staff provide to the Ann Arbor Chamber of Commerce, the IT Zone, and in formulating State strategies for improving the relationships between universities and industry.

CLOSING REMARKS

While FY2004 ended a stretch of several years of exceptional growth in research expenditures, it does not necessarily signal the beginning of a downward trend (Figure 22). In spite of the challenges facing the institution, UM faculty have an excellent foundation and long-term track record that suggests we will be highly competitive for the dollars that are available. Our efforts to streamline the review of human subjects protocol should improve the efficiency of many research projects, as well. Potential problems do loom in connection with export controls, but the UM and its peers continue to press Federal agencies to stop inserting export-control restrictions in research agreements.