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Executive Summary

The purpose of this report is to provide an updated five-year business plan for the Office of Research (OR) units providing essential administrative support for the University’s growing research enterprise. Development of this report originates in the fiscal 2006 budget process from the University Budget Committee and the Office of Business and Finance. This report contains a summary of our strategic missions, goals, initiatives and investments for research administrative infrastructure that will allow the units listed above to fully support the colleges in fulfilling their individual research objectives within the University’s Academic Plan.

Overview of OSU Research Enterprise

The Ohio State University (OSU) ranks 8th among public higher education institutions in the United States in total R&D expenditures and 12th overall among all public and private institutions. Our R&D expenditures increased by over $300 million from 1996 to 2006, surpassing $600 million for FY 2006. In addition to the growth in R&D expenditures, we have realized significant growth in key research metrics like sponsored project expenditures, number of active sponsored projects, number of active human subject protocols, number of animal related research protocols, and number of invention disclosures (see Appendix A for specific growth statistics).

Strategic Mission / Goals

The purpose of OR is to support the University’s Academic Plan by creating a culture that promotes research activities among our faculty, scientists, staff, and students. In this role, we have the responsibility to administer all sponsored research projects, oversee compliance for these activities, manage protocols and infrastructure surrounding animal and human subjects, secure commercialization rights to the results of our investigator’s research, and invest financial resources to seed strategically promising areas of future research.

Our aim over the next five years is to continue to build a service organization that will enable our faculty, staff, and students to reach the university’s goal of becoming a sustained top-ten research institution. In order to fulfill our purpose and role in this objective, we have identified the following strategic goals:

1. Provide faculty, staff, and students the highest level of service by enabling a collaborative research environment through a more efficient organizational structure, focused administrative processes, and seamless and user-friendly information technology tools.
2. Promote a strong culture of ethics and compliance for all research activities.
3. Increase the economic value of our faculty’s research pursuits by assisting them in obtaining grants, contracts, and licensing revenue.
4. Recruit and retain a diverse and highly skilled service team to support the University research community.

Strategic Initiatives

We have identified the following six strategic initiatives that are vital to the Office of Research’s support of the Academic Plan over the next five years. These strategic initiatives are described in more detail throughout this plan.

1. Support the needs of the University’s research community by creating a more efficient and coordinated organizational structure for research administration, one which enhances collaboration among OR operating units, and between the OR units and the colleges/departments which they support. Key elements will be the placement of additional research support specialists locally within the research-intensive colleges/departments and the continued seamless integration of core OR units such as Information systems (ORIS) and Education, Training and Communication (ORTEC).
2. Continue to improve the information technology systems used to support the researchers’ work.
3. Accelerate revenue generation by increasing Technology Licensing and Commercialization’s (TLC’s) focus, activities, and resources applied to revenue generation activities.
4. Continue to establish an Office of Research Compliance to coordinate compliance activities across Office of Research units and assume responsibility for developing and implementing a research compliance program that meets the requirements outlined by the federal government.
5. Establish OSU’s Human Subjects Protection Program to be among the highest quality programs including the successful attainment of accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).
6. Continue to re-establish OSU’s animal care and use program as one of the highest quality programs by successfully resolving issues identified during the institution’s 2005 site visit by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). Resolution of the problems identified will ensure continuation of OSU’s accreditation in good standing with AAALAC.

Strategic Initiatives Details

1. Organizational Structure for Research Administration

   a. Expand partnerships with colleges and departments in grants management support to improve the competitiveness of our faculty through high-quality service by increased emphasis on locating research administrative specialists at the college level.

   One of our primary goals is to provide faculty, staff, and students with the highest level of service by building a more collaborative research environment. Given the growth in size of the research enterprise, the increasingly complex nature of research administration, and the decentralized nature of university administrative structure, it is imperative for our units to be located at the college level and integrated into the daily activities of our faculty.

   Departments and colleges are faced with an increasingly complex administrative and internal control environment, which often leads to stretch support staff resources and increase the administrative burden on faculty and researchers.

   In order to provide the faculty with more specialized research administration support at the local level and keep them competitive among their peers, we will undertake an expansion of the Research Foundation program to locate personnel physically in the department and college units while integrating the Office of Responsible Research Practices (ORRP) personnel into these offices. In order to accomplish this goal we will seek to build partnerships with colleges to share in space and personnel costs to enable their faculty and administrators to accomplish their long-term research program goals.

   b. Restructure the training and information technology support functions within the Research Foundation to enable these units to support all Office of Research units, including ORRP, University Laboratory Animal Resources (ULAR) and TLC.

   In FY2007, OR began the initial steps to establish overarching units in Information Systems (ORIS) and Training, Education and Communications (ORTEC). Directorships, Governance Committees, and internal reallocation of financial resources have taken place in order to promote improved consistency, efficient integration of information, and more seamless service to our researchers.

   ORIS, in coordination with ORRP, is leading a two-prong approach for an E-Protocol initiative approved in the in FY2007 budget process, including coordinating a Request for Proposal (RFP) process from industry leading software companies and the development of a spring 2007 pilot of an initial web-based electronic protocol submission tool for animal-related research.

   ORTEC has begun coordinating a comprehensive review of research administration education curriculum in order to identify additional training delivery tools and methods to better serve our faculty and departmental/college research administrators and develop faculty and staff educational programs and certifications in research administration.

   Several leading institutions, including Stanford University, Harvard University and the University of Minnesota, have established specialized support functions for information systems and education and training that cover the broader spectrum of central and departmental research IS support needs. Transitional projects and resources should be completed by the end of FY2007 to begin an expanded scope of services to ensure that all OR and University-wide needs are effectively prioritized and integrated in a more strategic manner.
2. **Information Technology Systems**

   *Strategic Initiative #2* - Continue to improve the information technology systems used to support the researchers’ work.

   a. **Develop an integrated information technology plan that identifies and prioritizes the research support needs over the next five years.**

   The Research Foundation has done an effective job of integrating technology into research administration processes. Many of the research administration business processes for the Research Foundation have been automated, including the development of the Principal Investigator (PI) Portal. Separately, and with fewer resources, ORRP and ULAR have also developed database tools within their business process, but have no effective way to communicate this across units.

   With the creation of ORIS in FY2007, we will develop an information technology strategic plan for research administration that effectively integrates technology into all OR units research administration processes to allow us to better support our faculty’s research activities. When developing the strategic plan, we will address the following issues:

   - The critical needs of the various research administration offices and academic units.
   - The model for research administration business processes at OSU for the next 10 years.
   - Plans for current databases or systems in ORRP, ULAR and TLC.
   - Plans for an upgrade of the PeopleSoft Financials system.

   b. **Implement a web-based protocol management system to improve the efficiency and effectiveness of human and animal protocol review processes.**

   The number of active human and animal protocols at OSU is increasing at a rapid pace. While ORRP does a good job of managing these protocols, the current databases that support the protocol processes are not meeting the needs of the researchers, Institutional Review Board (IRB) members or ORRP. The protocol management processes are still very paper-based and manually labor-intensive compared to other research administration processes at OSU and compared to benchmark institutions.

   As a result of the FY2007 budget process, ORIS and ORRP initiated an RFP for a protocol management system and began developing a pilot web based data entry tool for faculty protocol submission. Based on a 2005 ORRP survey, researchers at OSU indicated that a web-based system would be beneficial by:

   - Eliminating paper forms/copies;
   - Providing the ability to submit protocols online to reduce IRB review time;
   - Providing the ability to route protocols for approvals online to reduce time spent routing paper documents for signatures;
   - Providing ability to track protocol application status online;
   - Enabling more efficient and timely protocol renewals;
   - Providing the ability to store protocol documents and subsequent modifications and versions in a central system that gives access to the IRB office to improve version control efforts.

   Our current schedule is to complete both the pilot and software selection process by the end of FY2007 and begin the implementation process.

   c. **Evaluate the modification or replacement of independent databases in TLC and ULAR.**

   Both TLC and ULAR face challenges in completing their unit’s mission due to continued growth and complexity of their business process. While ULAR’s animal population used in research has grown 111% over the last 6 years, expectations of their accreditation body (AAALAC) has heightened. TLC continues to focus on revenue generation to more fully realize the value of our faculty’s technology development in their research activities. FY2006 and FY2007 will see revenue increases in excess of 30% while continuing to look for more efficient tools to allow their staff to continue to increase productivity.
ULAR’s Topaz and TLC’s TechTracS were developed earlier in the decade but lack the ability to be integrated into the overall ORIS landscape. They are at best barely meeting the needs of the units and are either being augmented by spreadsheets and financial software or have unusable functions in today’s environment.

As part of strategic initiative 2a (information technology plan), we will determine the plan for meeting the increased needs of these units in order to develop a single data repository and set of tools for each unit that would seamlessly be integrated into all other facets of the OR research administration enterprise.

d. Continue development of the PI Portal to ensure that we are providing faculty and administrators with all of the information they need to effectively manage their research portfolios.

The PI Portal at OSU provides PIs and support staff with an on-line source for sponsored projects information. Through the Portal, PIs and/or administrators can receive information such as:

- A list of pending proposals and active awards.
- Basic information about each of these proposals or awards.
- An up-to-date financial statement showing both detailed and summary financial data for each active award.
- Effort, appointment dates, and salary / benefit costs for all current and future personnel appointments.
- Non-personnel expenditures for a given period.
- Sponsor invoice and payment information.
- Financial Conflict of Interest Clearance Status.
- List of Animal Subject Protocols and Institutional Animal Care and Use Committee (IACUC) deadlines.
- Status of compliance with conflict of interest disclosure and required research training.

We plan to design and build the next generation PI Portal within the next five years. This new design will move us toward a fully integrated application and reporting tool for Principal Investigators, including newly developed E-Protocol, ULAR, and TLC applications.

3. Office of Technology Licensing and Commercialization (TLC) – Accelerate Revenue Generation

Strategic Initiative #3 – Accelerate revenue generation by increasing TLC’s focus, activities, and resources applied to revenue generation activities.

The highest priority initiative for the TLC is developing and sustaining year over year improved revenue generation for inventors and the university. In FY2006 and FY2007, we have already seen realized or projected growth rates in excess of 30% annually. Still lagging our peers in this and other key revenue and performance indicators, TLC must continue to build on this trend by:

- Fostering an entrepreneurial culture at The Ohio State University through educating the university community on all relevant topics in technology commercialization;
- Serving as a catalyst in identifying faculty and staff inventions, maximizing their value, and accelerating their adoption in public use;
- Generating a significant, sustainable revenue stream from university intellectual assets with benefits returned to inventors, OSU, and the public;
- Establishing and growing a network of internal and external partners who will assist our teams in maximizing the value of the university intellectual assets;
- Assisting research teams and support teams in securing university R&D awards.
In FY2007, in addition to increasing revenue, TLC began reestablishing internal relationships with colleges through improved coordination, communication and reporting, and improving external relationships with TechColumbus, the Ohio Investment Network, and the Ohio Department of Development (ODOD). Internally, TLC began rebuilding its business process through new tracking mechanisms of all agreements, completing a comprehensive inventory of all intellectual property matters, and developing a more consistent means of tracking and forecasting existing and projected deal flow.

4. Office of Research Compliance (ORC)

Strategic Initiative 4 - Create an Office of Research Compliance (ORC) to coordinate compliance activities across Office of Research units and assume responsibility for developing and implementing a research compliance program that meets the requirements outlined by the federal government.

As a result of the FY2007 budget process, OR began the initial steps to establish an Office of Research Compliance through assignment of an Associate Vice-President, hiring an additional research compliance specialist, and beginning the internal and university partnering in order to develop a comprehensive policy and process to mitigate risk in our research enterprise.

These actions are the result of increasing scrutiny by federal oversight agencies over a wide range of research compliance issues including effort reporting, cost transfers, direct charging procedures, and clinical trials, as noted above, as well as conflicts of interest, sub-recipient monitoring, export controls, adhering to good laboratory practice requirements, and research misconduct. As a result of these activities, a number of our peer research universities and academic medical centers have faced adverse audit findings resulting in major financial settlements and material damage to their institution's reputation.

ORC’s goal is to achieve a research compliance program that addresses the eight elements identified by the National Institutes for Health Office of the Inspector General listed below:

- **Policies and Procedures**: Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance;
- **Compliance Leadership**: Designating a compliance officer and compliance committee;
- **Training**: Conducting effective training and education;
- **Communication**: Developing effective lines of communication;
- **Monitoring**: Conducting internal monitoring and auditing;
- **Enforcement**: Enforcing standards through well-publicized disciplinary guidelines;
- **Corrective Response**: Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate federal agency;
- **Roles and Responsibilities**: Defining roles and responsibilities across the institution and assigning oversight responsibility for compliance to designated individuals and offices.

The coordination of compliance activities among and across Office of Research units, central University compliance offices, and college research and compliance units has become a critical need. In FY2008, ORC will continue to establish its primary roles in accomplishing this by:

- Identifying and assessing compliance risks across the University’s research enterprise;
- Serving as a central University source for research compliance information and new requirements and best practices - and effectively communicating these to the research community;
- Partnering with University faculty and staff researchers to develop novel and effective ways to minimize and manage compliance risks, while also providing value to the institution and minimizing the administrative burden on researchers;
- Coordinating institution-wide research compliance policy, procedure development and monitoring with the colleges and central administration;
• Performing or coordinating general or targeted compliance reviews in consultation with Office of Research units as well as other University units, such as Internal Audits and the Medical Center’s compliance office.

• Providing necessary compliance reports and trend analysis to the Senior Vice President for Research, the University’s executive leadership, the faculty, and the institution’s Board of Trustees.

5. Human Subjects Protection Program

Strategic Initiative #5 – Establish OSU’s Human Subjects Protection Program to be among the highest quality programs.

a. Pursue AAHRPP accreditation to ensure that OSU establishes and maintains the highest quality Human Research Protection Program – one comparable to its peer institutions.

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) was founded in 2001 by the Association of American Medical Colleges, Association of American Universities, Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, National Association of State Universities and Land-Grant Colleges, National Health Council, and the IRB professional association, Public Responsibility in Medicine and Research. AAHRPP serves as a voluntary, peer-driven, educationally focused program, which bases its accreditation criteria on the recommendations contained in the IOM’s “Preserving Public Trust” report. Currently thirty-two (32) of our peer academic medical centers, research universities or research hospitals are accredited and all of our Big Ten peers are either accredited or working towards accreditation. This was the result of the federal Office of Human Research Protections (OHRP) disciplinary actions against several academic medical centers and Veteran’s Administration hospitals.

We have included AAHRPP accreditation as one of our strategic initiatives over the next five years because it further ensures the safety of subjects enrolled in research activities, improves competitiveness of researcher’s grant proposals, and clarifies and improves roles, responsibilities and procedures through education and communication. AAHRPP accreditation brings the institution more in line with the best compliance practices and makes us more able to adapt and respond to growth of the research enterprise.

In FY2007, OR submitted the university’s pre-application to AAHRPP in order to get a comprehensive evaluation of the current condition of our human subject program. Based on initial feedback, we are reviewing and enhancing our policy and procedures, focusing on opportunities to educate and promote a culture of ethical and compliant research practices, and repositioning our available resources to continue moving the process forward.

6. AAALAC Accreditation

Strategic Initiative #6 - Re-establish OSU’s Animal Care and Use Program as one of the highest quality programs by successfully resolving operational and cultural issues identified during AAALAC’s 2005 site visit. Successful resolution of these issues will insure continuation of full AAALAC accreditation for our institution.

In October 2005, AAALAC International conducted an on-site evaluation of OSU’s animal care and use program. A number of serious deviations from federal guidelines and best practices were identified and AAALAC informed Ohio State that its accreditation could be jeopardized if problems were not expeditiously remedied. OSU responded immediately and continues to implement processes to improve oversight of the animal research activities of the university and to establish a culture of full compliance among our researchers.

Initiatives to address concerns in the IACUC protocol review process and record keeping, inspections and oversight of animal housing, and the Institution’s Occupational Health and Safety Program training were reviewed again by AAALAC in February 2007. The university should receive an update to its accreditation status by fiscal year end.

The Offices of Research, Business and Finance, and the Medical Center will continue to unify and strengthen the institution’s animal care and use program by:

• Continuously evaluating the performance of IACUC processes including facilitation of compliance monitoring, identification of all individuals involved in animal handling, processing of modifications and amendments to protocol documents, proper completion of detailed committee meeting minutes, proper limits of protocol renewal reviews, and appropriate timing of approvals in coordination with proper training for research personnel and committees with related jurisdiction to protocols (ex. University Biosafety Committee);
• Ensuring that all faculty, staff and students handling animals complete the animal usage-training course;

• Continuing combined ORRP, ULAR and IACUC animal facility inspection processes that includes every university laboratory that houses animals for more than 12 hours or is used for animal procedures. These processes will include oversight and monitoring of analgesics and other controlled agents. Labs that meet standards will be re-inspected semi-annually.

• Verifying that the Office of Operations and Environmental Health and Safety conduct risk assessments for all individuals (faculty, staff and students) handling animals and refers animal handlers to Employee Health or to Student Health for occupational medical evaluation, as required.

• Confirming the execution of training programs by the Office of Operations and Environmental Health and Safety for all university personnel (faculty, staff - including ULAR, and students) handling animals, or biological, chemical, and/or radiological agents that will specifically include education on the health affects of such agents and the proper handling of animals, tissues, or excrement of animals exposed to these agents.

• Monitoring Employee Health Services at the Medical Center and Student Health Services that provides medical evaluations for all University faculty, staff and students as determined by the Office of Operations and Environmental Health and Safety as requiring a medical evaluation and follow-up.