

1. The Environment for Research

Introduction

The Massachusetts Institute of Technology is a \$2 billion non-profit corporation. The Institute's revenue includes tuition and gifts, as well as a significant amount of funding from external research sponsors, including the federal government, industrial sponsors and foundations. The research enterprise can be characterized by a "cradle to grave" process. This process begins with a concept or idea that is turned into a proposal, followed by an award, the performance of the project, and several other steps that ultimately lead to the closeout process. Understanding the entire process will help you to become a more effective research administrator.

The Principal Investigator (PI) has overall responsibility for the technical and fiscal management of a sponsored project, including the management of the project within funding limitations, and assuring that the sponsor will be notified when significant conditions related to the project status change. While responsibility for the day to day management of project finances may be delegated to administrative or other staff, accountability for compliance with MIT policy and sponsor requirements ultimately rests with the PI.

Proposal Preparation and Processing

The Office of Sponsored Programs (OSP) is the central administrative office responsible for submitting proposals

and accepting awards on behalf of MIT. Sponsored project proposals may only be submitted, and awards accepted, by individuals authorized in OSP to sign the necessary documents. Because proposals are submitted, and awards are granted to the Institute and not individual PIs, PIs and administrative staff are not authorized to submit proposals, accept grants, or execute contracts on behalf of the Institute. Questions in this regard may be addressed to the Director of OSP.

Award Acceptance Process

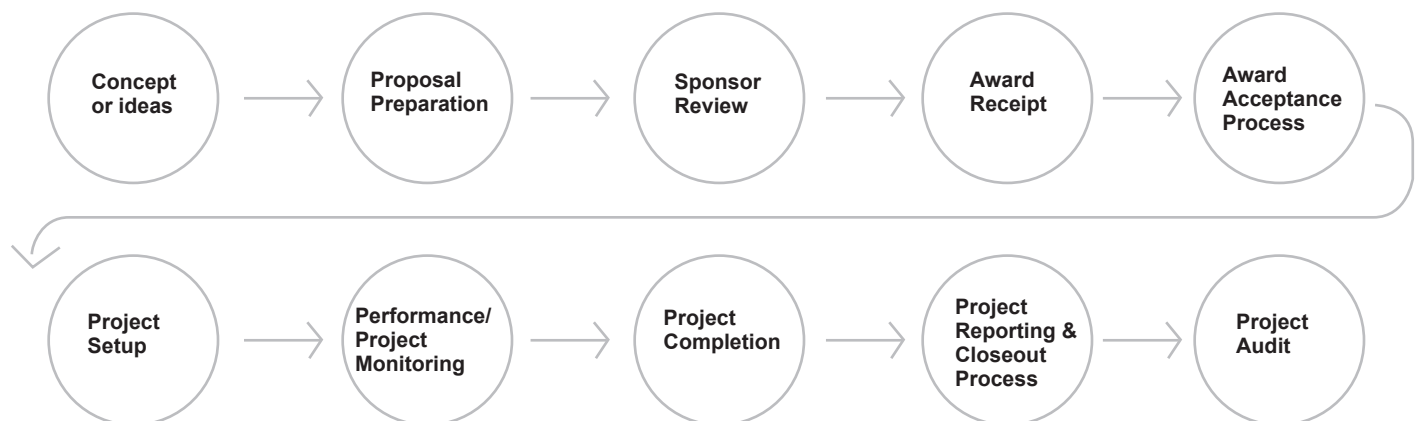
After a proposal has been accepted by OSP and submitted to a sponsor, and the proposal is selected for funding, the negotiation and acceptance processes begin. Awards are reviewed and, if necessary, negotiated by the appropriate Institute official to ensure the terms and conditions are acceptable. As appropriate, OSP will consult with the PI, department/laboratory/center (DLC) administrators, and other administrative offices, such as the Technology and Licensing Office or the Office of Intellectual Property Counsel. The negotiation process can take as little as a few days or a long as several months.

Performance/Project Monitoring

This is the core of research administration. While the research is underway, the project is being administered and monitored. Expenditure statements are reviewed and reconciled. Effort and salaries are distributed and certified.

Figure 1.1: Work Flow – Proposal to Closeout

Each of the elements described in the overview below are described in more detail in subsequent chapters.



Activities such as subaward setup and monitoring and procurement of materials and supplies, need to be performed during the course of the research.

Project Completion

At the end of each project, the Institute must go through the closeout process. It is important to submit all deliverables (including technical reports and patent/intellectual property reports) to sponsors in a timely manner, and to assist OSP and the Controller's Accounting Office (CAO) as requested, as all reports normally must be completed and submitted within 90 days of the end of the project.

Project Audit

Every project's records must be kept a minimum of 3 years from project closeout for audit availability, and longer in certain instances. Audits may be performed during the life of the project or at completion, and any specific project may be selected randomly for a systems audit.

Your Responsibilities

It is the job of those who approve financial transactions for the Institute to uphold the stewardship responsibilities delegated by the MIT Corporation. These responsibilities are fulfilled by assuring that the expenditures are:

- Allocable to the project based on benefit received.
- Reasonable and necessary for the performance of the project.
- Consistent with established Institute policies and practices.
- Consistent with sponsor or donor restrictions.
- Applicable to the work of the Institute, including instruction, research, and public service.

Everyone who authorizes the expenditure of Institute funds for any purpose must understand how MIT's accounting system (SAP) works, as well as the Institute policies and federal regulations which are implemented through the system.

OSP maintains a glossary of terms and conditions related to the research enterprise which is useful to an individual unfamiliar with the terms and new to research administration (this list appears on the OSP website, the link to which is in the Appendix). In addition, OMB Circular A-110 has an extensive list of federal definitions related to research.



Key References - See website links in Appendix and on the OSP home page

- ▶ MIT Policies and Procedures
- ▶ Procurement Department Policies and Procedures
- ▶ Personnel Policy Manual
- ▶ Controller's Accounting Office:
 - Financial Reports
 - On-line Systems
- ▶ Office of Sponsored Programs (OSP) Terms and Definitions
- ▶ OMB Circular A-110
- ▶ In the Public Interest: MIT Report on Access to and Disclosure of Scientific Information

The Research Team

There are a large number of ongoing, externally-sponsored research projects at MIT. These projects are accomplished by dedicated research teams typically composed of a principal investigator (PI), research staff, and students; department/laboratory/center (DLC) administration; and central administration.

The administrative responsibilities and roles of the research team can be described as follows:

Principal Investigator

- Has overall responsibility for all aspects of the research project.

Departmental/Laboratory/Center Administration (DLC)

- Ensures compliance with award terms and conditions, MIT policies, and sponsor requirements.
- Processes transactions to support research initiated by the principal investigator and his/her designee.

School Administration

- Reviews, advises and approves proposals.

Central Administration*

- Provides guidance, training, clarification and interpretation of policies, terms and conditions.
- Reviews, advises and submits proposals and purchases, and approves agreements.
- Represents the Institute on behalf of the MIT Corporation based on transactions initiated by the departments.

* Central and Academic Administration includes the following offices that are involved in the administration of research: the Office of Sponsored Programs (OSP), the Office of the Vice President for Research, the Controller's Office, Procurement, Internal Audit, the Technology Licensing Office, the Intellectual Property Office and the Office of the Vice President and General Counsel.

Awards for research and other sponsored activities are made to MIT, not to individual researchers. However, the principal investigator (PI) is ultimately responsible for the design, conduct, and reporting with respect to the research project. Departmental, school, or central offices provide the infrastructure necessary to support the PI's work, **but ultimate responsibility lies with the PI.**



Key References - See website links in Appendix and on the OSP home page

- ▶ Office of Sponsored Programs
- ▶ Vice President for Research
- ▶ Technology Licensing Office
- ▶ Controller's Office
- ▶ Procurement Department
- ▶ Property Office
- ▶ Audit Division

Role of the Federal Government— The Need for Regulation

In FY05, MIT had expenditures of more than \$550 million in external research and sponsored program funds. A significant majority of these funds came from the federal government. In its role as a steward of the taxpayer's money, the government has a responsibility to provide principles for determining costs allocable to research and administrative regulations to augment the principles.

These principles and regulations are discussed in this manual's chapter on Sponsored Research Basics. The most significant for the research enterprise are the following:

- **OMB Circular A-21:** Cost Principles for Educational Institutions
- **OMB Circular A-110:** Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
- **OMB Circular A-133:** Audits of States, Local Governments, and Non-Profit Organizations
- **Federal Acquisition Regulations:** Contracting Requirements

Why do we have regulations?

Regulations serve to maintain the public trust; that is, trust in research results and outcomes; trust that human subjects and animals are given the best care and treatment; trust that public funds are spent for the benefit of all; and trust that scientific research is done responsibly.


Research administrators are charged with aiding the PI to ensure total compliance with regulations regarding research.

What are the consequences of violations of policy or regulation which occur during the course of a sponsored project?

If a PI or his designate violated a regulation through a voluntary or involuntary act or omission, the individual and the Institute could face severe penalties which affect the entire research enterprise at MIT, not just that particular project.

Consequences would include some or all of the following:

- Increased scrutiny by sponsors and audit agencies,
- Corrective action plans,
- Additional regulations,
- Fines, penalties,
- Potentially disallowed costs,
- Harm to the health and safety of individuals,
- Harm to MIT's reputation.

 **Key References** - See website links in Appendix and on the OSP home page

- ▶ OMB Circular A-21
- ▶ OMB Circular A-110
- ▶ OMB Circular A-133
- ▶ Federal Acquisition Regulations

Types of Sponsored Agreements

When the federal government or other entity decides to fund research or other sponsored activities, there are several different types of awards that can be used. Assistance awards (grants) allow the most flexibility. Procurement awards (contracts) tend to be more restrictive because they normally require specific deliverables. Other Transaction Agreements (OTAs) are used in limited circumstances and are not the ideal vehicle for support of Institute research.

Assistance Awards

- **Grants.** A grant is defined as assistance bestowed without expectation of any tangible deliverables other than a final report. It is the appropriate agreement to use in a relationship between the federal government and a recipient whenever:
 - The principal purpose is the transfer of money, property, services, or anything of value to the recipient in order to accomplish a public purpose of support, and
 - There is **no** substantial involvement anticipated between the government agency and the recipient during performance of the activity.
- **Cooperative Agreements.** A cooperative agreement is defined as assistance that substantially involves the sponsor in the outcome of the research results. It is the appropriate agreement to use in a relationship between the federal government and a recipient whenever:
 - The principal purpose is the transfer of money, property, services, or anything of value to the recipient in order to accomplish a public purpose of support, and
 - There is **is** substantial involvement anticipated between the government agency and the recipient during performance of the activity.

Procurement Awards

- **Contracts.** A contract is generally described as a procurement action. The sponsor is procuring research from the institution and acts as the technical overseer. It is the appropriate agreement to use in a relationship between the federal government and a recipient whenever:
 - The principal purpose of the agreement is for the government to acquire property or services for direct benefit and use of the federal government, and
 - There is **is** substantial involvement between the governmental agency and the recipient during the performance of the activity.

Other Transaction Agreements

- **An Other Transaction Agreement (OTA)** is generally described by what it is not—that is, it is not an assistance or procurement award. It is the appropriate agreement to use in a relationship between the government and a recipient whenever:
 - Commercial technology is more advanced than military, innovative commercial products should be introduced rapidly, and non-traditional partnerships are most effective, and
 - The government determines that the activity requires that standard terms (particularly intellectual property) are inappropriate for the award.

The terms and conditions the Institute is required to follow varies widely among these different award types. COEUS, MIT's award management system, indicates the specific award type as well as a summary of the terms and conditions of that award.

Non-federal agencies are less precise in their classification of awards, but the Institute is still responsible for classifying these projects accurately in its accounting system.

Sponsored Projects

Characteristics of a sponsored project agreement include:

- Specific statement of work (or a set of specific aims);
- Detailed financial accountability and/or reporting;
- Disposition of property;

- Deliverables, including a final technical report, and
- Period of performance.

Sponsored projects are typically awarded to MIT in response to a proposal to accomplish a specific statement of work and commitment to a specified project plan. This statement of work is typically supported by both a period of performance and a budget, both of which are key to financial accountability. The written agreement typically includes detailed and complex financial accountability, including:

- Project budget, including F&A costs;
- Specified period of time in which project funds may be expended, usually defined as “start” and “end” dates;
- Requirement to return any unexpended funds at the end of that period, and
- Regular financial reporting and the possibility of audit.

The Difference Between Gifts and Grants


Grants are made to MIT to accomplish a specific purpose and the funds carry terms and conditions stipulated by the sponsor. Grants are exchange transactions which require MIT to provide something of value to the sponsor, typically a deliverable such as a report.

Gifts are contributions made to MIT for which the donor receives nothing in exchange. Gifts may be restricted to a specific purpose, or they may be unrestricted and used by the Institute for any purpose consistent with MIT’s mission and not-for-profit status. Other than restricting the purpose of the gift, the donor may not impose terms and conditions on the use of the gift funds or require deliverables from MIT.

Proper identification of gifts versus grants and appropriate classification of the purpose of gifts versus grants (i.e., as Instruction, Organized Research, etc.) of gifts and grants are important aspects of MIT’s fiduciary responsibilities and accountability for proper stewardship of Federal funds.

The Office of Sponsored Programs (OSP) is responsible for the administration of grants, contracts and cooperative agreements. The Recording Secretary’s Office, part of Re-

source Development, is responsible for the administration of MIT gifts. In situations where it is not clear whether funds coming to MIT represent a gift or grant, OSP confers with the Recording Secretary’s Office to determine the appropriate classification.

 **Key References** - See website links in Appendix and on the OSP home page

- ▶ Internal Orders and Non-Research WBS Elements
- ▶ Awards: Treatment as Gifts or Sponsored Contracts

Policy and Regulation—The Role of Audit and Research Compliance

Two very important infrastructure and support units to the research enterprise are the Audit Division and the research compliance activities of the Office of Sponsored Programs. The goal of these offices is to work with academic units to help them comply with the myriad of federal compliance regulations and with the requirements for appropriate expenditure of federal (and other) sponsored funds. These offices can provide direct consultation and support to units as they develop departmental level tools to help ensure compliance.

 **Key References** - See website links in Appendix and on the OSP home page

- ▶ Audit Division
- ▶ Office of Sponsored Programs

Institute Policy and Federal Regulations

Sponsored projects are externally funded activities governed by terms and conditions specified in a written agreement between the sponsor and MIT, and they account for the **largest single source of revenue** to the Institute.

Funding for sponsored projects is comprised of both direct and F&A (Facilities and Administrative) costs.

Direct Costs

- Expenses that are specifically associated with a particular sponsored project or activity and/or can be directly

assigned to that project or activity with a high degree of accuracy.

Example: On a sponsored project, examples of **direct costs** are technical staffing and project materials. One can directly associate the salary of a person working on a specific project and equipment and materials purchased and specifically used on the project.

F&A Costs

- Institute expenses that cannot be specifically identified with a particular project or activity. Sometimes called “indirect costs” or “overhead,” these are the costs of administration, buildings, utilities, and the many other expenses necessary for the operation of the Institute.

Example: One example of an F&A cost is utilities because they benefit many activities in a building. Separate utility meters could be installed in every room in the building to track power and water use, but that would be extremely expensive and impractical and would not measure usage for specific projects. Because individual F&A costs cannot be assigned to projects, the Institute calculates a rate to determine the fair share of F&A costs each project should be charged and negotiates this rate with the government. The rate is then applied to all sponsored research projects-including federal and non-federal sponsors.

MIT administrators, regardless of whether they work with sponsored projects, must understand the impact of sponsored programs and the related F&A recovery on MIT operations.

Your Role in Implementing Policy & Regulations

You have an important role in implementing MIT’s policies and federal regulations. Whenever you order supplies, authorize the payment of salaries, reimburse a student, fill out an expense report, receive cash or checks, or perform any of the many tasks involving MIT finances, you process financial data for the Institute. The Institute uses this information to manage its budget, and to be reimbursed for direct project costs and F&A costs from sponsors.

MIT Recovers F&A Costs from Sponsors According to Federal Regulations

In 2005 the Institute **expended \$550 million** for campus activities from external sponsors to support the direct costs of sponsored projects. These funds **included \$149 million** from sponsors to pay for the Facilities and Administration (F&A) costs associated with those projects.

The federal government provides specific regulations regarding what costs are allowable and which are unallowable for reimbursement through direct and F&A cost recovery. Many of the Institute’s fiscal policies mirror federal cost regulations.

All Institute expenses (costs), regardless of fund source, are sorted and categorized according to classifications included in federal regulations, so the calculation of the F&A cost rate can be correctly determined. The Office of Cost Analysis, part of the Office of Sponsored Programs, is responsible for the calculations of the F & A rate and the classification of MIT expenses into the A-21 categories.

Consequently, each expense must be classified and coded properly according to the four cost principles (Allowable, Allocable, Reasonable, Consistent) as outlined in the chapter entitled “Sponsored Programs Basics,” which are incorporated in:

- Institute policy.
- Federal regulations which have been incorporated into Institute policy, such as OMB Circular A-21.
- The specific terms & conditions of each award.

Compliance

Compliance is an area of increased federal government emphasis, both in the areas of financial and programmatic compliance. Financial compliance normally is seen in the context of financial audits, both of systems and individual grants and contracts. Programmatic audits cover a wide range of activities, as described in OMB Circular A-133. The Circular applies to all sponsored activities where funding is derived from federal sources and includes a compliance supplement which specifies the auditors’ areas of focus and the range of regulatory requirements placed on federal awardees.

Regulations affecting sponsored research programs may be imposed as a result of laws passed by Congress or policies set by executive agencies to achieve social or economic goals; they may provide protection and security to individuals and the country; or they may impact how science is performed.

The False Claims Act (31 U.S.C. §§ 3729-33) was enacted originally by the federal government during and after the Civil War to counteract fraud by government contractors. Its application has been greatly broadened and includes penalties for making a fraudulent statement to get a claim paid by the government. The False Claims Act also provides protection for employees who make “Whistleblower” claims against employers who make inappropriate charges to Federal programs. The impact on research in higher education is the potential for a false claims charge brought by an employee in connection with any invoice submitted to the government for payment. Financial compliance programs at universities are one response higher education is making to prevent inappropriate charges. In addition, the U.S. Sentencing Guidelines, 69 Fed. Reg. 28994, 29019 (May 19, 2004), provide that a viable and active training program is a mitigating factor in any settlement amounts imposed by the government.

On the programmatic side, there are a host of regulations which impose compliance requirements on recipients of funds for sponsored programs for research misconduct, including the falsification of research results. The institution that receives the funds is responsible for compliance, but in many instances the requirements for compliance lie with the principal investigator as well as, or in addition to the institution.

The National Council of University Research Administrators (NCURA), a professional development association for research administration professionals, has published [Regulation and Compliance: A Compendium of Regulations and Certifications Applicable to Sponsored Programs](#), available in the OSP office, which provides an overview of the range of compliance regulations applicable to sponsored programs. A few of the topics included are:

- Misconduct in Science
- Financial Conflicts of Interest
- Care and protection of animals used in research
- Care and protection of humans used in research

Misconduct in Science

The federal government has adopted a formal statement on what constitutes misconduct in science (see 65 Fed. Reg. 22286), which the agencies are gradually adopting into their individual regulations. MIT’s implementation of the misconduct in science regulations appears in the Appendix and on the OSP home page.

Financial Conflict of Interest

The National Science Foundation (NSF) and the National Institutes of Health (NIH) have adopted regulations on financial conflicts of interest by principal investigators and other key personnel responsible for proposing, conducting and reporting on the results of research. MIT’s implementation of both agencies’ regulations includes a requirement that the principal investigator and other key personnel provide information PRIOR TO THE SUBMISSION OF PROPOSALS on the extent (if any) of any financial holdings or income which meet the government’s thresholds (NIH and NSF thresholds are identical). Although any potential conflicts do not need to be resolved before submission of the proposal, disclosure in advance is required; resolution needs to be accomplished before any resulting award is available for expenditure. The OSP proposal routing sheet includes a place for the investigators to certify that they have provided such information. Further, and equally important, the Institute requires the submission of financial conflict of interest disclosures electronically. For more information, see page 3 of the OSP Summary Form.

Care and Protection of Animals Used in Research

The Institute’s Animal Care and Use Committee is the entity which approves protocols for the use of animals in research. Information about how the committee operates and the requirements for protocol submission appear online on the CAC home page (see Appendix for link).

Care and Protection of Humans Used in Research

Federal mandate (The Common Rule 45 CFR 46) and longstanding MIT policy requires that the Committee on the Use of Humans as Experimental Subjects (COUHES) review and approve ALL research involving human subjects that is performed under the auspices of MIT.

Types of research that must be reviewed by COUHES include investigation of new drugs and medical, radiological, engineering, physiological, behavioral, sociological, and nutritional studies. This includes projects involving human tissues, blood, or images, and questionnaires, interviews, and other procedures.

Federal guidelines (45 CFR 46) define “human subject” as: “A living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information.”

“Intervention” includes both physical procedures by which data are gathered (for example, drawing blood) and manipulations of the subject or the subject’s environment that are performed for research purposes.

“Interaction” includes communication or interpersonal contact between investigator and subject.

COUHES does not consider research to involve “human subjects” where the research uses only coded private data, specimens or cells, provided the data, specimens or cells were not collected specifically for the proposed research by an intervention with a living individual, and provided the researcher cannot identify the individual(s) from whom the data, specimens or cells were obtained (for example because the key to decipher the code has been destroyed or an agreement exists prohibiting the release of the key to the investigators). COUHES also takes jurisdiction over research involving blood, tissue or other specimens derived from human subjects.

COUHES approval must be obtained BEFORE any human studies are begun. For research involving minimal risk, approval is granted for one year and must be renewed annually. For research involving more than minimal risk, renewal frequency will be determined by the Committee upon approval.

Ethical and legal guidelines for conducting studies involving human subjects are explained in an online training course on human subjects research hosted by the Office of Sponsored Programs.

Federal regulations require that all personnel involved in any NIH sponsored research take and pass a training course on human subjects research before embarking on such research. MIT policy extends this requirement to all MIT personnel involved in any human subjects research.

This requirement extends to all personnel who play a role in research involving human subjects including principal investigators, associate investigators, student investiga-

tors, study coordinators, visiting scientists, consultants, laboratory technicians and assistants. The requirements encompasses all types of interactions with human subjects including direct contact, indirect involvement, analysis of data and analysis of blood/tissue samples.


Principal Investigators are responsible for confirming that all study personnel have taken and passed the training course on Human Subjects Research, and are “certified” to participate in studies involving human subjects.

All personnel involved in studies utilizing humans as research subjects must undergo recertification in human subjects research training every three years from the date of original approval.

If you engage primarily in biomedical research then you must complete a specially designed web-based training course by following the link to Training for Biomedical Researchers on the COUHES website. You may also view a list of current trainees at this link. This course is hosted by the Office of Sponsored Programs at MIT.

If you engage primarily in social and behavioral research then you must complete a specially designed web-based training course by following the link on the COUHES website to Training for Social and Behavioral Researchers. This course is hosted by the CITI program at the University of Miami. (When registering, select only the Social and Behavioral modules and complete only the basic course.)

COUHES policies and procedures, definitions, and resources including an investigator quick guide and criteria for acceptance of studies can be found on the MIT COUHES website.

 **Key References** - See website links in Appendix and on the OSP home page

- ▶ OSP Summary Form
- ▶ Procedures for Dealing with Academic Misconduct in Research and Scholarship
- ▶ Supplement to Academic Misconduct Policy
- ▶ Committee on Animal Care (CAC)
- ▶ Committee on the Use of Humans as Experimental Subjects (COUHES)
- ▶ Human Subjects Training, VP Research Memo

- ▶ Protection of Human Subjects, The Common Rule 45 CFR 46

COEUS—MIT's Management System for Sponsored Programs

MIT has created COEUS, the Institute's sponsored programs management system, to assist the Office of Sponsored Programs and DLCs in proposal development and pre- and post-award management. The purpose of the system is to simplify, and make more efficient, award acquisition and administration for all offices within the Institute. With its comprehensive proposal development module and post award functionality, COEUS is one of the first cradle-to-grave award management tools in the nation.

This software now makes it possible to prepare proposals, route them internally to obtain proper approvals, and submit them to sponsors electronically. The main modules in COEUS are Proposal Development, Proposals, Awards, Subcontracts, Negotiations, Person, Conflict of Interest and Report Tracking.

Individual administrators and units can download COEUS onto their desktop and use it immediately. Because of the modules within COEUS that are needed to prepare electronic research proposals, submit financial conflict of interest forms, manage awards and subawards, and track report requirements, it is important that all personnel supporting the research enterprise download and use COEUS.



Key References - See website links in Appendix and on the OSP home page

- ▶ COEUS web site