Dr. Reitzes called the meeting to order at 3:05 pm.

Approval of Minutes

The first order of business was review and approval of the minutes from the February 16, 2004 meeting. No member present at the meeting asked that changes be made to the minutes. Dr. Reitzes made a motion for approval of the minutes; the motion was seconded by Dr. Bartness and unanimously approved by those members present.

Update on Office of Research FY05 Budget

Dr. Tai, a member of the FACP Committee, reported on the outcome of meetings concerning the FY05 budget request by Dr. Louis for the Office of Research. The FACP Committee decided not to cut the unit’s budget, but to instead consider an increase in funding for FY05. The decision about increasing the Office of Research budget for FY05 will be made in April.

Report from the Vice President for Research

Dr. Louis stated he and Ms. Barrett would make a presentation to the Committee on two important issues:

- Roles and Responsibilities of Employees Engaged in Sponsored Project Management/Oversight at Georgia State University
- NIH Site Visit scheduled for May 11, 2004

Dr. Louis handed out copies of the Roles and Responsibilities document to all Committee members. He reminded members that the document is also available on the Office of Research website at http://www.gsu.edu/~wwwosp/resources/RAARolesResponsibilities.doc.

Ms. Barrett began the presentation about the Roles and Responsibilities topic. Highlights from the presentation are included below:

In response to requirements of federal agencies funding sponsored awards, the Office of Research in consultation with a number of GSU offices, including the Comptroller’s Office, Internal Audit Office, and Offices of Deans, has developed a document that is similar to that now used by most research universities which defines the roles and responsibilities of all individuals within the university that play any role in the management and/or oversight of sponsored awards. It is the first document that the NIH Proactive Site Visit team will want to examine so it was very fortunate that our office has been working on this for the past half year. The Roles and Responsibilities document has been arranged to order the functions by either Transaction or Individuals.
Transactions: Proposal preparation, proposal submission, project closure, etc.

Individuals: Principal Investigator, Department Administrator, Senior Executives of the University, etc.

Sponsored Projects are externally funded activities in which a formal written agreement, i.e. a grant, contract or cooperative agreement, is entered into by Georgia State University and a sponsor. A sponsored project may be thought of as a transaction in which there is a specified statement of work with a related reciprocal transfer of something of value.

Like other universities, Georgia State University utilizes an Institutional Oversight Model for sponsored projects. This oversight model gives departments and colleges the local accountability for many functions.

Responsibility is defined as having the authority to make a decision.

Accountability is defined as being liable for the results of a decision by a responsible person.

The Principal Investigator is the person charged with the accountability and responsibility for decision making on sponsored projects at Georgia State University.

Responsibility for decision making on sponsored projects can be delegated from the Principal Investigator to another person, but accountability for sponsored projects cannot be delegated.

Responsibility must be maintained locally to the extent possible so that decisions are made by individuals with the best information.

Oversight must always be separated from the operating Unit where the responsible person makes the decisions.

ALL proposals for sponsored projects MUST be submitted to the Georgia State University Office of Sponsored Programs PRIOR to submission to funding agencies.

Role of Principal Investigators

The Principal Investigator is the primary individual in charge of a sponsored project. While most funding agencies refer to “Principal Investigator”, others may use terms such as “Project Director”, “Program Director”, to describe this individual.

Technical Proposal

The PI documents all equipment items costing more than $5,000.

The PI requests an F&A cost waiver, if required by sponsor.

The PI requests matching funds, if required by sponsor.

The PI proposes cost sharing through contributed effort, if a sponsor requirement.

The PI identifies and specifies all effort of those participating in the project.

The PI identifies all available financial resources in direct support of this or other sponsored endeavors (other support).

The PI identifies all subcontractors.

The PI identifies separately any extra compensation to be paid.

The PI identifies anticipated program income.

The PI identifies anticipated intellectual property.

Regulatory Requirements

The PI prepares the appropriate forms from the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee or the Department of Safety & Risk Management if the proposal involves:

- human subjects;
- live animals as subjects;
- recombinant DNA, infectious agents, biohazardous agents or biological toxins;
- human blood or body fluids;
radioactive materials and/or ionizing or nonionizing radiation-producing equipment; or hazardous materials in an off-campus space.

The PI ensures approval of all compliance forms is secured prior to the award date, depending on requirements of agency sponsor.

The PI must obtain IRB, IACUC and/or IBC approval prior to project start date.

The PI is responsible for adhering to all federal compliance regulations when conducting research.

If a potentially significant conflict of interest situation exists, the PI prepares a Disclosure Form and submits to their Unit Head.

The PI is responsible for any research conducted by one of their students.

The PI is responsible for renewing yearly protocols and notifying the IRB, IACUC and/or IBC of amendments, modifications or adverse events during the conduct of the project.

**Proposal Routing Form**

The PI prepares, or directly supervises the preparation of, the Proposal Routing Form.

The PI reads and understands relevant policies and certifications identified on this form.

The PI has responsibility for ensuring that answers are provided to ALL questions on this form.

If other departments and colleges are involved, the PI provides this information, and ensures they are included in the approval routing chain.

The PI signs the Proposal Routing Form. This responsibility cannot be delegated and the signature certifies that each item on the form is filled-out completely and accurately.

**Preaward**

As appropriate, the PI reviews and approves the Notice of Grant Award (NOGA), which contains the terms and conditions of the award.

If the NOGA is sent directly from the funding agency to the PI, she or he must submit it to the Office of Sponsored Programs within 7 calendar days in order to establish an account.

If approved budget differs from proposed budget, the PI is obligated to provide the Office of Sponsored Programs a revised budget within 7 calendar days to establish an account.

The PI obtains approvals if cost sharing becomes necessary.

The PI obtains compliance approvals as required.

The PI obtains Advance Account or Preaward Account, if needed.

**Negotiations with Sponsor**

The PI negotiates and approves the project scope.

The PI in collaboration with the Office of Sponsored Programs modifies the project budget in line with the award budget provided by the sponsor.

The PI notifies the Unit Head and the Office of Sponsored Programs about the changes in project scope and budget.

The PI notifies the appropriate regulatory office if changes to project scope will affect approved protocols.

**Conduct of the Research**

The PI ensures his/her students and other research personnel maintain the highest ethical standards in the use of project resources and the overall conduct of research.

The PI is responsible for all actions required to manage and complete the programmatic aspects of the sponsored project.

The PI initiates programmatic changes to the project.

The PI initiates the hiring or assignment process and approves the selection or appointment of individuals to the project.
The PI ensures the integrity and safeguarding of notebooks and data.
The PI ensures the completion, accuracy and timeliness of interim programmatic (technical) reports.
The PI initiates and approves subcontract agreements prepared by Office of Sponsored Programs.
The PI ensures the quality, timeliness, and programmatic performance of subcontracts.
The PI is responsible for attending required and appropriate project-related training.
The PI is responsible for obtaining appropriate compliance training certification.
The PI is responsible for reporting adverse events and research misconduct.
If using materials from another source, the PI initiates a materials transfer agreement.

**Budget Management**

At the time expenditures are initiated, the PI determines their allowability and reasonableness.
The PI initiates the process of documenting required cost sharing.
The PI initiates requests for rebudgeting as the sponsor requires.
The PI initiates cost transfer requests.
The PI identifies and proposes a resolution of any overdraft.
The PI approves payments of subcontractor invoices.
The PI utilizes financial system reports for monitoring expenditures and identifies and resolves errors on the account in a timely manner.
The PI is responsible for providing interim financial reports as requested.
The PI reviews the financial system reports each month for appropriateness, correctness, and completeness.
If appropriate at budget period end, the PI requests that remaining balances be carried forward or no-cost extensions.

**Effort Reporting**

The PI complies with effort reporting policy by assuring the accurate completion and timely return of effort reports to the Office of Grants and Contracts.

**Inventions**

The PI adheres to the principles and policies outlined in the Intellectual Property Policy and the Conflict of Interest Policy.
The PI initiates the disclosure process and completes the Invention Disclosure Form in order to notify Technology Commercialization and the Unit Head.
The PI assists in preparing patent applications.
The PI initiates the processing of copyrights.
The PI assists in processing licensing agreements.

**Project Closure**

The PI prepares the final technical narrative report and provides a paper or electronic copy to the Office of Sponsored Programs.
The PI provides information such as cost share and matching documentation for preparation of final financial report.
The PI provides information on other closing reports, such as for patents and on equipment.
The PI retains the project data on behalf of Georgia State University.

Dr. Louis then continued the presentation by announcing the upcoming NIH Site visit; highlights of his presentation are as follows:
NIH Proactive Site Visit – May 11th & 13th 2004

NIH Attendees
Diane Dean, Director
Cheryl Chick, Assistant Grants Compliance Officer
Division of Grants Compliance and Oversight,
Office of Policy for Extramural Research Administration, OER National Institutes of Health, DHHS

Not an audit or investigation.
No report.
Mutual information exchange – emphasis on partnership.
Collaborative relationship between NIH and grantee.
Mutual need to assure compliance and implement proactive compliance measures.
GSU must be in compliance with institutional as well as Federal requirements. Recipients of NIH grant funds must comply with all applicable Federal statutes, regulations, and policies.

May 11th
Interviews at GSU with staff managing sponsored awards, Principal Investigators, and many of the individuals identified in the Roles & Responsibilities document that manage or oversee sponsored awards.

May 13th
Half day work-shop at the Emory Center for Continuing Education that all these same individuals from Georgia State University are required to attend.

Attendance by all GSU administrators will demonstrate our commitment to compliance.

Common contributors to compliance problems identified in these NIH site visits:
- Lack of understanding of roles and responsibilities of institutional staff.
- Inadequate resources.
- Inadequate staff training and education.
- Outdated or nonexistent policies and procedures.
- Inadequate management systems (e.g., effort reporting, financial management).
- Perception that internal control systems are not necessary.

Roles and Responsibilities should be clearly defined, communicated, and accessible.
- Provide a detailed listing of responsibilities, including oversight responsibilities, by role.
- Communication is essential. Foster working groups or discussion groups for staff involved with grant and contract administration at the sponsored research and departmental levels.
- Ensure there is a connection between these groups, so key information, policy changes, and new developments are consistently communicated.

Education Programs: A culture of compliance begins with a culture of understanding.
- Training and continuing education is critical!
- Develop formalized education programs and consider mandatory training requirements.
- Offer certificate programs.
- Involve respected faculty members to promote faculty buy-in.
- Develop an education program to accommodate new and existing staff.
Provide orientation for new employees.
Provide continuing education programs for staff involved with sponsored research.
Include all personnel with a role in sponsored research, including PIs, departmental administrators, and sponsored programs staff.
An effective culture of compliance must be established from the TOP and must be an institutional expectation.
Establish a mechanism for concerns to be heard.
Personnel need to understand their responsibilities.

**Proactive actions by Research Office in preparation for this site visit:**
- Roles & responsibilities document completed.
- Implemented year-long series of training programs.
- Integrated Sponsored Programs and Financial systems.
- Enhanced human subjects protection program.
- New Director of Technology Commercialization appointed.
- New Biosafety Officer achieved Select Agent compliance.

**PROBLEMS:** Voluntary participation in training programs has been poor; policies not well understood.

**Q & A from Presentation**

Dr. Reitzes asked if the Committee was the first faculty group to see this presentation. Dr. Louis responded the Deans and Department Chairs had been the first group to see it. Dr. Reitzes suggested a group of four or five faculty researchers be given the opportunity to review the Roles and Responsibilities document on an informal basis and provide feedback to Dr. Louis. Dr. Louis agreed this would be very helpful and looks forward to their input.

Dr. Bartness asked how long to keep original notebooks/data from sponsored projects. Ms. Barrett responded the PI should keep data for three years after completion of the project. Dr. Louis advised the University needs to develop and adopt a data retention policy. A member of the Committee noted the Board of Regents has such a policy which should apply to GSU.

Dr. Bartness asked about the usability of financial management reports for PIs. He stated the reports are very difficult to interpret and are almost useless for understanding the financial standing of a sponsored project. Dr. Louis responded that the Office of Research offers training classes on this topic for PIs. Dr. Bartness countered that the reports should not be so difficult to understand that a training course is required. Dr. Louis stated the reports are the best he has been able to obtain from the Spectrum system. Other Committee members suggested creating a “cheat sheet” for PIs to help interpret the information. Ms. Byrum noted she is involved with a team working on a training program for expense management review and have been trying to simplify financial reporting of expenses. She will provide an update on this initiative at the next meeting.

**Standing Subcommittee Reports**

- **Center for Risk Management and Insurance Research (Dr. Benardot)**
  Dr. Benardot stated his group had completed their review and it was favorable. Dr. Reitzes added that the Research Center Review Subcommittee is caught up on its projects, there are no new APACE reviews needed at this time.

- **Internal Grants (Dr. Romski)**
  Dr. Romski stated the group has not met, but is scheduled to meet in April.
Research Infrastructure (Ms. Byrum)
Ms. Byrum asked about the status of the Openness in Research Policy. Dr. Reitzes stated it is waiting to be reviewed by the Executive Committee of the University Senate. It is likely to be voted on by the full Senate at its next meeting in April.

Next Meeting

Dr. Reitzes stated the next meeting will be held on Monday, April 19, 2004 at 3:00pm in Room 718 of the General Classroom building. He then adjourned the meeting at 3:55pm.

Respectfully submitted,
Gary Brennaman