Request for Proposal

Research Administration and Compliance Platform

April 5, 2007

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Procurement Services
Charlottesville, Virginia
Research Administration and Compliance Platform  
Request for Proposal #SH040507  
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Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Overview of the RFP Process</td>
<td>1</td>
</tr>
<tr>
<td>II. Background Discussion and Goals of the University</td>
<td>2</td>
</tr>
<tr>
<td>III. Scope of Goods and Services</td>
<td>7</td>
</tr>
<tr>
<td>IV. Basis of Selection</td>
<td>27</td>
</tr>
<tr>
<td>V. Contents of the Proposal</td>
<td>28</td>
</tr>
<tr>
<td>VI. Information about this RFP</td>
<td>33</td>
</tr>
<tr>
<td>A. Procurement Schedule</td>
<td>33</td>
</tr>
<tr>
<td>B. Issuance of RFP and Questions</td>
<td>33</td>
</tr>
<tr>
<td>C. Preproposal Conference</td>
<td>34</td>
</tr>
<tr>
<td>D. Proposal Deadline</td>
<td>35</td>
</tr>
<tr>
<td>E. Oral Presentations and Negotiations</td>
<td>35</td>
</tr>
<tr>
<td>F. Communications</td>
<td>35</td>
</tr>
<tr>
<td>G. Formation of the Agreement with the Selected Firm</td>
<td>36</td>
</tr>
<tr>
<td>H. Provisions Deemed Included in the Proposal</td>
<td>37</td>
</tr>
<tr>
<td>I. Rejection of Proposals</td>
<td>39</td>
</tr>
<tr>
<td>J. Virginia Freedom of Information Act</td>
<td>39</td>
</tr>
<tr>
<td>Attachment 1 - Mandatory Contractual Provisions</td>
<td>40</td>
</tr>
<tr>
<td>Attachment 2 - Preferred Contractual Provisions</td>
<td>46</td>
</tr>
<tr>
<td>Attachment 3 - Procedure for Resolution of Contractual Claims</td>
<td>56</td>
</tr>
<tr>
<td>Attachment 4 - Executive VP and COO’s Request for Commitment</td>
<td>58</td>
</tr>
<tr>
<td>Attachment 5 – Existing University-Produced Systems and Processes</td>
<td>59</td>
</tr>
<tr>
<td>Attachment 6 – Associated Offices and Other Terms</td>
<td>65</td>
</tr>
</tbody>
</table>
This Request for Proposal (RFP) has been posted on Procurement Services web site for your convenience. Addenda and attachments are posted if issued. It is the firm’s responsibility to ensure that the entire RFP and related links, in its latest version, is reviewed prior to submittal of a proposal. We encourage you to check the web site frequently for any changes prior to the due date. To receive a hard copy of the RFP or addenda, please contact Becky Sims, Contracts Administrator, at (434) 924.1346 or email pur-rfp@virginia.edu. For questions about the content of the RFP, contact the buyer listed in Section VI, Information about this RFP. Additional information can be found on Procurement Services web site: http://www.procurement.virginia.edu/main/

I. Overview of the RFP Process

The Rector and Visitors of the University of Virginia (University), a Virginia public corporation, seeks an experienced firm to provide a research administration and compliance platform which will enable the University to efficiently manage and comply with administrative processes related to research. This RFP is part of a competitive procurement process which helps to serve the University's best interests. It also provides firms with a fair opportunity for their services to be considered. The process of competitive negotiation being used in this case should not be confused with the different process of competitive sealed bidding. The latter process is usually used where the goods or services being procured can be described precisely and price is generally the determinative factor. With competitive negotiation, however, price is not required to be the determinative factor, although it may be, and the University has the flexibility it needs to negotiate with firms to arrive at a mutually agreeable relationship.

For ease of reference, each firm receiving this RFP is referred to as a "firm" and the firm selected to provide services for the University is referred to as the "Selected Firm." This RFP states the instructions for submitting proposals, the procedure and criteria by which a firm may be selected, and the contractual terms by which the University proposes to govern the relationship between it and the Selected Firm.
It is the policy of the Commonwealth of Virginia and the University to contribute to the establishment, preservation, and strengthening of small businesses and businesses owned by women and minorities, and to encourage their participation in State procurement activities. The Commonwealth and the University encourage firms to provide for the participation of small businesses and businesses owned by women and minorities through partnerships, joint ventures, subcontracts, or other contractual opportunities.

II. Background Discussion and Goals of the University
When Thomas Jefferson founded the University in 1819, he intended it to be nothing less than a world-class institution of higher learning. Jefferson’s spirit lives on – not only in the Rotunda and Academical Village he designed, and which remain treasures of American architecture, but in the University’s standing as a leader in education, research, and community service.

The over 19,850 students attending the University work within a true meritocracy and live by an Honor Code unique among American universities. Each student is exposed to the widest spectrum of disciplines – from arts and athletics to humanities and technology. Our students also enjoy a unique connection to the world beyond college through the University’s outstanding professional training, exemplified by its nationally ranked schools of Law, Business, and Medicine. The University as a whole has had a consistently high ranking not only among public schools, where it often heads the list, but among all American universities, public and private.

Over 11,600 permanent University faculty and staff are committed to serving both the local and national community. The University makes a real difference in the world, through its invaluable research, a hospital ranked among the nation’s finest, and graduates who have consistently been among the forefront of our
nation’s shapers. At the University, our bright future is the direct result of our great history.

In the last decade, funded research activities at the University have more than doubled, and the complexity of the Federal regulatory environment has expanded resulting in a heavy burden for researchers and increased training and compliance responsibilities for the University. In fiscal year 2006, the University processed approximately 3,000 proposals for funding and received approximately 1,900 new extramural awards. Currently, there are approximately 2,000 open human research protocols and 500 open animal research protocols. The University desires to optimize its research administration practices throughout all of its operations. Such optimization will include, but not be limited to: improvements in customer service; automation of workflow; risk avoidance and mitigation; secure data storage and transfer; enhancement of supervisory control capabilities; and an overall goal to build and maintain a research environment at the University that competes with peer institutions.

The current systems built by University personnel, in their respective areas to meet narrow research administration objectives, are reflected in Attachment 5, Existing University-Produced Systems and Processes. Although there is some data sharing among these applications, the workflow is not automated and the data storage is neither normalized nor centralized.

The University seeks to evolve from this “silo” approach to an integrated research platform. Rather than having individual University investigators submit grant proposals and research protocols to multiple offices using multiple formats, processes and locations, the University desires that investigators be able to access all offices and processes via a centralized web-based portal. The ensuing portal workflow would move the individual grant proposal and/or protocol through the approval process appropriate for the specific research being pursued.
The University’s study personnel could then monitor the status of all of their grant proposals and protocols from this single portal, and all versions of the documents associated with the tailored workflow for their research would be available for tracking and modification as needed.

Investigators and study personnel would be able to maintain profile information, such as bio biographical sketches, office and lab locations, etc…, in this same single portal environment. Their training records for human and animal research subject protection, radiation safety and biosafety should be accessible as should any links needed to register for, or take, any required or expiring training.

Each University office engaged in research would similarly be able to track the status of their relevant grant proposals or protocols awaiting action (i.e., assignment to reviewers, assignment to meetings, outcome letters, etc.). University staff would be able to generate standard reports and create customized reports on demand. As related regulations, office processes, and reporting requirements evolve over time, the University technical team should be able to easily adapt the platform and/or portal to meet these revised requirements through a management console -- with minimal to no code changes.

Attachment 6, Associated Offices and Other Terms, is provided as a reference for some of the research-related definitions and associated University office acronyms used in this RFP.

Success Criteria
The University’s “Success Criteria” for successful deployment and operation of a research administration and compliance platform include:

Short term
- Meeting functional requirements
• Fulfilling needs of administrators, investigators, and study personnel for reporting
• Mitigating research related risk for the University

Intermediate
• Favorable impact on processing time of grant proposals and protocols
• Increased compliance
• Less downtime in comparison to current systems and processes
• Increased investigator and study personnel satisfaction

Long term
• Increased numbers of grant proposals and protocols processed
• Decreased instances of multiple data entry

The objectives listed above are not meant to constitute an all-inclusive list for achievement of the desired Success Criteria. Because the University has never utilized or implemented a research platform and, therefore, does not profess to be expert in this endeavor, firms are expected to suggest additions or changes to the objectives of the desired Success Criteria in order that the resulting research platform is implemented and operated in a manner consistent with prevailing best practices.

Relationship Vision
The University seeks to create a working relationship with the Selected Firm that will propel the University toward attainment of its goals to successfully implement the procedural, organizational, and systems changes described in this RFP.

Elements of the envisioned relationship between the University and the Selected Firm(s) include, but are not limited to:
1. Development of beneficial goals based upon the strengths and capabilities of each party;

2. Capacity and commitment to deliver the right resources and technologies to support the University in maintaining leading-edge capabilities to the satisfaction of all key stakeholders;

3. Experience in managing multi-year relationships;

4. Ability and commitment of the parties to be flexible in addressing issues and concerns and in anticipating a changing environment;

5. Ability to work with multiple parties internal and external to the University to ensure the provision of an industry best-practice research platform;

6. Ability to provide appropriate post-implementation support and services;

7. A willingness to develop an organizational and administrative framework to manage the relationships and to address issues and opportunities that may arise; and

8. Ability to create an environment of trust, information sharing, and the expectation of success, as described in the RFP.

In support of its mission and in an effort to maintain the highest quality services for its customers, the University seeks one or more firms experienced in providing research platforms to similar high-profile research institutions to provide such a research platform to meet the University’s goals and enhance the administrative efficiency of its research operations.

The University reserves the right to award to different Selected Firms to respectively provide any part of the research platform for the University.
III. Scope of Goods and Services

It is the University's intent to enter into an Agreement with the Selected Firm for a flexible, fully functional and robust web-based software platform ("Platform") to include those goods and services necessary to install, integrate, operate and maintain the Platform in a manner that will help the University achieve its goals outlined in this RFP (the "Goods and Services"). In order to achieve this goal the Selected Firm may be requested to provide those goods and services outlined in this section.

The research Platform will include a single web-based point of entry ("Portal") for University end users to the modules that support these and other University “Offices” and areas of interest:

**Administrative Services**
- Office of Sponsored Programs (OSP) including grants management offices within the School of Medicine (SoM), School of Engineering and Applied Sciences (SEAS), College and Graduate School of Arts and Sciences (A&S);
- Conflicts of Interest Committee (COI)

**Human Research Subject Protection**
- Institutional Review Boards (IRB);
- Post Approval Monitoring (PAM);
- Clinical Trials Office (CTO)

**Animal Research Subject Protection**
- Institutional Animal Care and Use Committee (IACUC)

**Safety Committees**
- Radiation Safety Committee;
- Institutional Biosafety Committee (IBC).
The specific requirements for these University offices are described in greater detail within this Section III.

A. **Platform Overview**

   The configured Platform will support a Portal, which will incorporate integrated services for the investigator, study personnel and administrative staff. The Portal will enable faculty investigators and their study personnel to seek funding opportunities, prepare budgets and grant proposals for research projects, route these grant proposals to University central offices and to funding agencies, disclose their financial interests related to research, prepare and submit human research protocols to the IRB and required safety committees, prepare and submit animal research protocols to the IACUC and required safety committees, track the status of grant proposals and protocols, manage their own profiles in regards to subject protection training, occupational health and biographical sketches, and interact with the CTO as necessary for those conducting human subject **clinical trials**\(^5\).

   Additionally, the Platform will support the individuals and offices that certify, review, approve, submit and manage grant proposals, awards, disclosures, and human and animal research protocols including, but not limited to: internal tracking of documents, events, and study personnel; scheduling protocols for review; managing protocol and **consent form**\(^6\) templates; and reporting.

   Each process requiring approval of, and/or collaboration with, more than one office will follow a workflow built on the Platform. The Platform will be configured in such a way as to ease Investigator and administrative burden in seeking appropriate approvals for funded research projects. Additionally, the Platform must be integrated with other University systems outside the scope of this project, such as Oracle Financials and
Oracle Human Resources as well as other locally produced small systems. See Attachment 5, Existing University-Produced Systems and Processes, for a high-level diagram of the new desired Platform.

The functional requirements for the Platform, the Portal and each functional area are outlined below.

B. Platform Core Requirements
The Selected Firm will provide a Platform which will include a core component that will satisfy overall requirements, including, but not be limited to:

1. fully Macintosh and Windows compatible;
2. MS-SQL Server or Oracle database;
3. data must be reportable both from within the Platform application and outside the application;
4. configurable in data structure and workflow to the University environment;
5. user manual templates for each module and each broad category of users: principal investigators, research administrators, staff and board members;
6. technical training on administration, configuration, support and maintenance of the Platform for three technical staff at a mutually agreeable location;
7. legally binding electronic signature solution;
8. the Platform must be capable of storing research training completion records for each associated University Office, or for each user, with the user's individual profile. (These records should be tied with the user profile in the Platform database and linked to the individual user’s research protocols and other applicable records.)
9. research proposals, protocols and other forms must be able to follow decision tree models and routing procedures based on profile data (e.g., if user x or any other person named on the protocol has not completed training, user x may not submit this protocol to the IRB or other review committee);

10. an applications architecture that is designed to integrate with campus Web Single Sign-on environments for authentication decisions and an LDAP directory for authorization decisions. Indicate willingness to work with the University to integrate the product into the central University authentication and authorization infrastructure as needed. Preferably, the Selected Firm will have implemented authentication integration with PubCookie for Web Single Sign-on (http://www.pubcookie.org) or have reviewed the Platform and confirmed that the Selected Firm can complete the integration work;

11. provide or assist in developing a security model based on component configuration, including authentication and authorization schemes.

C. **Portal Overview**

The Portal will be a single point of entry for the investigators, study personnel, research administrators, compliance staff, and clinical trials staff as well as the appropriate workflow to move a project from grant proposal to protocol. Specific functional requirements include but are not limited to:

1. personalized view of affiliated research activities for end-users including, but not limited to: versioned protocol documents; consent documents; training deadlines and submission deadlines;

2. automated email notification to study personnel upon pending protocol or training expiration; and
3. centrally located biographical sketches to be included in grant proposals.

D. Platform/Portal Requirements for Individual Modules

The Selected Firm will provide the Goods and Services in a manner that will support the Offices and areas of interest discussed in this Section III D. Accordingly the Selected Firm will provide the modules below when requested by the University.

1. Administrative Services
   a. Office of Sponsored Programs (OSP) Module

OSP signs grant applications and negotiates contracts and grants with a wide variety of sponsors. Once an award has been made, OSP provides comprehensive service in award administration, accounting, and regulatory compliance to include effort reporting.

The Selected Firm will provide a software solution to support the pre-award activities of OSP which include grant proposal preparation and submission, tracking and reporting of faculty effort on funded research, and notifying faculty of funded awards (internal notices of award). OSP envisions that the software solution’s reporting functions will render obsolete the current pre-award data system (Grants Awards System) used by the University. The Selected Firm will provide a Platform module which will include, but not be limited to these features:

- a user-friendly and robust grant proposal development module centered on submission to federal agencies including, but not limited to, the National Institutes of Health (NIH) and the National Science Foundation (NSF);
• a comprehensive electronic routing and approval system that captures necessary certifications and electronic signoffs prior to submission to a sponsor;

• utilities for budget preparation based on federal and local budget formulae and HR data including the ability to create line item budgets for each grant proposal for use by OSP, research faculty and staff;

• a system-to-system solution for submission to grants.gov using the data created in the budget and grant proposal phase;

• a mechanism for loading budgets prepared in the module into the post-award Oracle Financials system;

• a mechanism for extracting effort and cost share information from the module and exporting that data as required;

• communication tools to enable OSP to announce funding opportunities (i.e., grant and contract opportunities) and internal notices of award to the research community;

• research study expenditure reports to award budgets;

• reporting mechanism for
  ➢ tracking faculty and research staff current effort (committed time) and pending effort (proposed time commitments) based on proposed studies;
  ➢ committed cost share reports;
  ➢ closeout reports, including patent and property reports;
  ➢ Material Transfer Agreements; and
- customized on-demand reporting of pre-award data
- integration with the Conflicts of Interest module for reporting research-related potential conflicts of interest;
- functionality for export control flagging and tracking;
- functionality for routing and tracking of no-cost award extensions and re-budgeting requests upon expiration of an award period; and
- mechanism for tracking clinical trial agreements for industry and privately sponsored projects.

b. Conflict of Interest Committee (COI) Module

This University's dedication to high quality research requires an unwavering commitment to research objectivity. Fulfilling this commitment requires that appropriate safeguards be in place to prevent researchers from using their positions for purposes that are, or appear to be, influenced by private gain for themselves or their families.

To support the newly formed COI committee, the module must include but not be limited to:

- web form-based mechanism for electronic annual and event-driven (grant, contract, gift, etc.) disclosures of financial interests related to research with electronic signature;
- annual disclosures which must provide a mechanism for update by the faculty when their financial interests change;
• meeting agenda generation by the COI staff to include disclosure cases that must be discussed by the COI committee;
• record of potential conflicts and COI committee rulings;
• track managed outcomes to ensure that research personnel comply with committee rulings with escalating notifications to University administration based on defined time periods when necessary;
• in conjunction with the IRB and OSP modules, flag grants or protocols where potential conflicts exist.

2. Human Research Subject Protection

a. The Institutional Review Boards (IRB) Module

The protection of the rights and safety of human subjects participating in research is managed through two separate committees known as the IRBs, both of which operate under the Federal Wide Assurance the University has filed with the Department of Health and Human Services (DHHS) as required by law.

The IRB for Health Sciences Research (HSR) reviews all biomedical studies or medically invasive research conducted on human subjects.

The IRB for Social and Behavioral Sciences (SBS) reviews all non-medical behavioral human research (studies which are considered medically non-invasive).

Based on the nature of the research protocol, an investigator submits protocols for approval to one of the two IRBs which meet on different schedules, maintain
separate boards and operate separate offices; therefore, two implementations of the IRB module may be necessary.

The Selected Firm will provide the IRB module as required by the University. The IRB module(s) will include but not be limited to the following features which apply to both boards unless otherwise noted:

- online protocol and consent form creation based on answers to required questions about the research;
- question branching (e.g., if one answers "yes" to question 12, go to question 13; if one answers "no" to question 12, skip to question 19);
- online protocol and consent submission to the IRB with proper electronic signatures;
- versioning of protocol and associated documents within a document management mechanism;
- all user groups to view (administration, staff, study coordinators and investigators) the status of protocol and consent forms including but not limited to submission dates, signatures received or required, board meeting assignment, approval status, etc.;
- if a study will use radiation or biohazardous materials, the portal must alert the appropriate safety committees, based on the user's answers to the questions mentioned above, and provide a method for their approval (HSR only);
- from the list of protocols submitted online, the Platform must assign protocols for both pre-review and review (or allow a staff member to do so), add protocols to scheduled board meeting dates,
distribute electronic protocol packets to board members and generate agendas for board meetings to include these protocols;

- board meeting minutes recording within the Platform;
- outcome of board decision letter generation to principal investigators regarding the status of the study based on committee vote; letters must be routable to the appropriate parties for editing before sending to the principal investigator;
- electronic assurance forms must be generated in the platform and be printable when necessary;
- online adverse event (AE)12 reporting by the study team and data reporting on these events by the IRB staff; AEs also must be added to the above mentioned agenda for board review (HSR only);
- electronic submissions of study continuations upon expiration of board approved protocols;
- electronic submissions of modifications to protocols;
- grant submissions and tracking of grant reviews; will be linked to the OSP module;
- method for sending targeted (based on protocol, investigator or other pre-defined limits) or mass email to the research community;
- automated email reminders for training renewals, continuations and other deadlines;

b. Post Approval Monitoring (PAM) Module

The purpose of the PAM program is to assess the research activities conducted in accordance with IRB-approved protocols. This program assures human subject safety in
research, provides education to research professionals, and identifies strengths and areas for improvement in research practice at the University.

The PAM office requirements include but are not limited to:

- the ability to generate random lists of IRB-approved and active studies to monitor;
- the module must provide a mechanism for the PAM office to track outcomes from lab inspections and produce reports to the study team based on the inspection and review of research documents and labs;
- based on the outcome of the inspection, the PAM office must be able to refer a study to the clinical trials educator or the IRB, when necessary. These actions must be logged in the database.

c. Clinical Trials Office (CTO) Module

The CTO provides support and resources to School of Medicine (SoM) research personnel in order to ensure the efficient and compliant conduct of human subject research.

The CTO offers a variety of services including Clinical Research Coordinator mentoring, protocol development and preparation, continuing education, monitoring, and quality assurance. These consulting services are made available to SoM investigators and coordinators to promote the smooth and efficient conduct of their research studies.

The CTO module will include, but not be limited to, these features:
• pre-award support for investigators and/or study personnel including budget preparation (as part of OSP module or in addition to);
• post-award support to the CTO, including data and safety monitoring;
• support for collection and aggregation of AE reports for reporting to the IRB, Federal Drug Administration (FDA) or Data Safety Monitoring Committee as necessary;
• a mechanism for clinical trial participant tracking (e.g., track the number of participants enrolled in the study versus the number of participants approved for the study by the IRB);
• ensure appropriate billing of research related activities; for example, the grant account must be billed for research related care and not Medicare or private insurance or vice versa;
• a web-based recruitment site that advertises available trials, including titles, descriptions and contact information, based on approved and active protocols;
• interface with the investigational pharmacy for proper accounting of study-related drugs;
• store demographics of enrolled subjects;
• a user-defined reporting mechanism that mines data relating to clinical trial participation including but not limited to reports about study participation based on demographics, type of study, AE, etc.;
• mechanism to populate standard forms (or forms required by clinical trial sponsors), for example,
FDA Form 1572, FDA Form 1571, Financial Disclosure

- support for investigator-initiated Investigational New Drugs (IND) including access to appropriate forms, reminders for deadlines, and inventory of documents and correspondence by IND and by research study;
- IND tracking information;
- multisite trial tracking information;
- internal monitoring tracking information; and
- AE recording using a recognized AE thesaurus.

3. Animal Research Subject Protection
   a. Institutional Animal Care and Use Committee (IACUC) Module

The University requires that, before any investigator purchases/obtains and begins research involving animal vertebrate species, an animal research protocol be submitted for review and approval by the IACUC. The IACUC office:

- assists investigators in completing the appropriate animal research grant proposal forms;
- sends out annual review of animal research protocol notices;
- assures participation in the occupational health and safety program for personnel interacting with laboratory animals;
- schedules meetings and compiles the minutes of the IACUC meetings;
- schedules the semi-annual inspection of animal facilities and the animal care and use program; and,
provides training on the proper handling of animals used in research.

The Selected Firm will provide IACUC module as requested by the University. To support the IACUC mission as defined by the University and federal regulations surrounding the use of animals in research, the IACUC module requirements include but are not limited to:

- track annual renewal dates for protocols and email notices to alert research staff regarding protocol renewal requirements;
- track Occupational Health status of animal handlers;
- track census of all species utilized;
- track special procedures performed on animals;
- user view of protocols at various levels of approval: Office/Administration, IACUC, Comparative Medicine, principal investigators/contact persons, Vivarium staff, Radiation Safety, IBC, etc.;
- cross reference data with Comparative Medicine, Radiation Safety, IBC, and Occupational Health in real time to determine the status of a protocol;
- track principal investigator approvals for biohazards and radioisotopes and specifics of each approval in order to determine the viability of a protocol;
- provide protocol history (origination date, revisions, renewals, etc…);
- embed links from internal pages to other resources both within and outside the portal;
- report non-compliance or adverse events per faculty/investigator and/or per research facility;
• store and track data from semi-annual facility inspections;
• use administration-defined logic to identify protocols requiring increased scrutiny including but not limited to those protocols involving survival surgery, biohazards, and satellite facilities; and
• track animal protocol post-approval monitoring records.

4. Safety Committees (can apply to both animal and human subject research)
   a. Institutional Biosafety Committee (IBC) Module
      The IBC is a standing committee and is responsible for reviewing all University research and teaching activities conducted by faculty, staff, students and/or visiting scientists on University property that involve the use of biological agents. Biological agents are defined as microorganisms, recombinant DNA\textsuperscript{18} experiments as defined by NIH guidelines, materials derived from human and non-human primates, or biological agents or toxins.

      The mission of the IBC committee is to ensure that all activities involving biological agents and the facilities used to conduct such work are in compliance with all external regulations, and applicable University policies. The IBC committee will function to ensure that investigators handle biological agents in a safe and responsible manner, and meet criteria as described by the NIH Guidelines for recombinant DNA research (specifically those defined in section IV-B-2); the CDC/NIH publication Biosafety in the Microbiological and Biomedical Laboratories; applicable
regulations defined by the Virginia Department of Environmental Quality; the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard; Health and Human Services (HHS) and United States Department of Agriculture (USDA) final rules for the possession, use, and transfer of select agents and toxins; and other applicable requirements. Foremost, the IBC's objective is to ensure that such activities meet the standards of good biological safety practice emphasizing protection of personnel, the public and the environment. The IBC assists principal investigators and protocol directors in meeting their responsibilities; imposes requirements; and reviews and approves policies, grant proposals, procedures, programs, and facilities pursuant to the safe and legally compliant use of biological agents.

The Selected Firm will provide the IBC module as requested by the University. To support the mission of the IBC, the Selected Firm will provide a Platform which will provide functionality including, but not limited to:

- tool for tracking the location and use of regulated bioagents;
- mechanism for Inventory and Activity Registration (IAR) of regulated material and research;
- electronic forms for inspection data storage and retrieval;
- location tracking of Biosafety Level 2 (BSL2) and Biosafety Level 3 (BSL3) microorganisms and reporting by building, study and investigator; and,
- location tracking of human derived material (blood, blood components, fluids, unfixed organs, tissues
and cell lines), primate derived material (blood, blood components, fluids, unfixed organs, tissues and cell lines), select agents, recombinant DNA, and biotoxins and reporting by building, study and investigator.

b. Radiation Safety Module

The Radiation Safety Program’s primary objectives are to protect personnel and the general public from unwarranted radiation exposure, protect the environment by minimizing release of radioactive material in effluents, ensure compliance with all applicable state and federal regulations, and to monitor and advise in the safe use of radioactive materials and radiation producing equipment at the University.

The Radiation Safety Program is responsible for virtually all operational aspects of radiation safety at the University. These responsibilities include:

- training personnel in the safe use of radioactive material;
- administering the personnel and environmental dosimetry21 program;
- procurement of all radioactive material;
- shipment and receipt of all radioactive material for the University;
- collecting, packaging, and disposing of all radioactive waste;
- performing routine laboratory inspections;
- commissioning and decommissioning of all radioactive material use areas;
- emergency response;
provides information and advice to individuals who have questions about radiation; and

- calibration of radiation survey instruments.

The Selected Firm will provide a radiation safety module as requested by the University. The module will include, but not be limited to, this functionality:

- track all receipt, possession, use, storage, decay and/or disposal of radioactive material (RAM);
- track health records of users;
- provide interface for the radiation safety staff to:
  - manage inspection data where RAM is used or stored (all areas are inspected either quarterly or semi-annually);
  - manage the possession quantities and limits of isotopes delivered to the investigators;
  - track the locations of RAM use/storage;
  - manage short and long term storage, decay and disposal of RAM.

E. Project Management

The University will manage the Platform as a coordinated project to include both: the Goods and Services to be provided by the Selected Firm(s); and internal University staffing and support. The project will follow a lifecycle similar to the outline below with several modules in various phases of the cycle based on the strategy jointly developed the University and the Selected Firm(s). The items marked with an asterisk represent areas where Goods and Services are anticipated to be required of the Selected Firm(s).

1. Plan
   a. Initiate project
b. Develop functional requirements  
c. Procure/provide Platform*  
d. Gather requirements* (collaboratively)  
e. Map processes* (collaboratively)  
f. Develop build and rollout strategy*

2. Develop  
a. Design data structure based on Platform and existing systems*  
b. Configure Platform to University environment*  
c. Build forms and other objects*  
d. Build workflow*

3. Test  
a. Internal alpha test*  
b. User acceptance test*  
c. Beta test*  
d. Document Platform both technically and for end users*  
e. Load test

4. Deploy  
a. End user training for each defined role/user type  
b. Rollout modules based on plan

5. Maintain  
a. Provide end user support  
b. Provide technical support*  
c. Fix bugs*  
d. Respond to requests for continuous improvement*

The University plans to staff this project according to the matrix below. In conjunction with the Selected Firm, the University will make adjustments to this plan according to the implementation strategy and the flow of the project. Additionally, the University has assembled a program management committee and a working group of business owners,
technical owners and investigators to guide the project as described in Attachment 5, Existing University-Produced Systems and Processes.

<table>
<thead>
<tr>
<th>Role</th>
<th>Implementation</th>
<th>Maintenance</th>
<th>Number</th>
<th>% of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall PM</td>
<td>x</td>
<td>x</td>
<td>1</td>
<td>75</td>
</tr>
<tr>
<td>Project Assistant</td>
<td>x</td>
<td></td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Business analyst</td>
<td>x</td>
<td>x</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>Technical liaison</td>
<td>x</td>
<td>x</td>
<td>1 per module</td>
<td>75</td>
</tr>
<tr>
<td>(existing tech staff)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Database expert</td>
<td>x</td>
<td>x</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Administrator</td>
<td>x</td>
<td>x</td>
<td>1</td>
<td>25</td>
</tr>
<tr>
<td>Lead developer</td>
<td>x</td>
<td>x</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Module administrator</td>
<td>x</td>
<td></td>
<td>1</td>
<td>25</td>
</tr>
<tr>
<td>Module developer</td>
<td></td>
<td></td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Trainer</td>
<td>x</td>
<td></td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>Support technician</td>
<td></td>
<td>x</td>
<td>2</td>
<td>50</td>
</tr>
</tbody>
</table>

The University anticipates requiring the Goods and Services from the Selected Firm in several stages of the project lifecycle. Specifically, these Goods and Services include, but are not limited to:

1. prepare an implementation strategy and timeline as coordinated with the University;
2. on-site software installation;
3. Project Manager for implementation period to represent the University's needs to the Selected Firm;
4. in collaboration with local technologists, examine differences and gaps between the Selected Firm’s solution and existing, in-house modules and prepare plan for integration and migration;
5. provide a best-practice strategy for deployment of all modules;
6. evaluate and recommend the best hardware configuration based on the University’s specific needs;
7. provide integration services for Oracle Financials and Oracle Human Resources via Web Services or other means of data exchange between the databases as coordinated with the University;
8. assist in development of initial user forms for purchased modules;
9. assist in appropriate data conversion from existing, in-house modules to modules provided by the Selected Firm;
10. recommend number, timing and content of pilot events;
11. provide standard test scripts;
12. propose a best-practice end-user training plan;
13. provide user, administrative and training documentation;
14. provide post implementation support through a stabilization period; provide documentation on upgrade paths in a customized environment. This should include caveats regarding practices and development policies that should be avoided to ensure smooth upgrade transitions; and
15. provide ongoing software maintenance and technical support during local business hours with emergency backup support as needed.

IV. Basis of Selection
The University will evaluate proposals and, if a firm is to be selected, select the firm on the basis of:
1. The firm's plan to assist the University to meet its goals for a Research Platform as discussed in Section II, Background Discussion and Goals of the University, and Section III, Scope of Goods and Services;
2. The firm's relevant experience, qualifications and success in providing the Goods and Services outlined in this RFP;
3. The firm's references from institutions of higher education, teaching hospitals, and clients which are comparable to the University;
4. The firm's financial proposal including but not limited to discounts, service charges and other charges;
5. The quality of the proposal, specifically, responsiveness to requirements and adequacy of information provided;
6. The contractual terms which would govern the relationship between the University and the Selected Firm;
7. The firm’s plan for the utilization of Small, Women-owned and Minority-owned (“SWAM”) businesses. (In evaluating the firm’s proposal, the University will assign a minimum of 10 percent of the total selection weight to this individual selection criterion.); and 
8. Any other factors relevant to the firm's capacity and willingness to satisfy the University.

Note: The University reserves the right to award to different Selected Firms to respectively provide any part of the Research Platform for the University.

V. Contents of the Proposal

Proposals should include information outlined in this section. Copies of proposals must be sent to the Issuing Office, Procurement Services, Carruthers Hall, and not to any other office or department whatsoever at the University.

A. Goods and Services

1. Describe how the firm plans to provide a fully functional research platform and all related Goods and Services. Include a description on how the firm will work with the University to foster a productive, interactive relationship while providing the Goods and Services.

2. Provide a plan of operation to achieve the objectives set forth in Section II, Background Discussion and Goals of the University and Section III, Scope of Goods and Services specifically and clearly responding to each paragraph and subparagraph in the order addressed. Proposals should specifically address, but not be limited to, a discussion of how the firm’s proposed Goods and Services will: be consistent with the University’s RFP; help to achieve the stated Success Criteria; and satisfy the requirements of each individual Platform module as appropriate.
3. Describe the firm's plan for customer service to including how the firm intends to be responsive to the University’s routine and emergency requirements.

B. Firm Information, Personnel, References

1. Provide a brief history of the firm and its experience in providing research platform-related goods and services similar to those described in this RFP.

2. Provide information on those individuals assigned to work with the University including a description of their experience in providing research platform-related goods and services similar to those described in this RFP.

3. Provide a list of all of the firm's clients comparable to the University indicating the length of service of each account. The University may contact and/or visit any of these accounts.

4. Provide a list of all clients lost within the last three years which includes:
   a. A contact name and telephone number
   b. Length of service at the account
   c. Reason for the loss

5. Provide a copy of the firm's most recent audited financial statements.

6. Provide the name of the individual responsible for the firm’s supplier diversity program. This individual is responsible for implementing and reporting on the firm’s Small, Women-owned and Minority-owned (SWAM) program as it will relate to this procurement should the firm be selected.

C. Financial Proposal

1. Describe any and all fees and expenses the firm proposes to charge the University for the Goods and Services. Ensure that all fees and
expenses associated with provision of the Goods and Services are delineated.

2. Describe how the University will be charged. Include any additional discounts available for early payment of invoices.

3. Describe how the firm would propose to allow the University to withhold a portion of its total fees for the Goods and Services in order to guarantee that the University’s goals and Success Criteria have been achieved.

4. Describe how the University will benefit from cost savings by accepting the firm's proposal.

5. State the firm's capability for accepting electronic payments through Electronic Data Interchange (EDI) or Automated Clearing House (ACH) and any additional discounts that may result from paying electronically. Information about the Commonwealth of Virginia’s Financial Electronic Data Interchange (FEDI) program is available on this web site:

   http://www.doa.state.va.us/procedures/GeneralAccounting/EDI/edinew.htm

D. Contractual Arrangements

1. Provide the University with any form or contract the University may be requested to sign.

2. State the firm's acceptance of Attachment 1, Mandatory Contractual Provisions.

3. State the firm's acceptance, with any proposed modifications, of Attachment 2, Preferred Contractual Provisions.

4. Provide a written statement with the firm’s proposal that its principals or legal counsel has reviewed Attachment 1, Mandatory Contractual Provisions, and Attachment 2, Preferred Contractual Provisions, and agrees that these provisions will become a part of any final agreement.
E. Site Visits
It may be necessary or desirable for the University's evaluation team of less than ten people to travel to a site chosen jointly by the firm and the University to view its operation. Each firm will indicate whether it will reimburse the University for the reasonable and actual expenses (travel, lodging, meals, etc.) incurred by the University for its travel.

F. Small, Women-owned and Minority-owned (SWAM) Business
Specify whether the firm is a SWAM. Firms can only be considered a Small, Women-owned or a Minority-owned Business Enterprise if certified by the Commonwealth of Virginia’s Department of Minority Business Enterprise (DMBE). All certified SWAM firms will be assigned a specific identification number. No SWAM firm is required to certify under this program and no SWAM firm will be excluded from doing business with the Commonwealth because of their failure to certify as a SWAM firm.

The Commonwealth’s definitions are:

- **Minority-owned Business Enterprise** means a business concern which is at least 51 percent owned by one or more minorities or in the case of a corporation, partnership or limited liability company or other entity, at least 51 percent of the equity ownership interest in which is owned by one or more minorities and whose management and daily business operations are controlled by one or more of such individuals.

- **Minority Individual** means a person who is a citizen of the United States or a legal resident alien and who satisfies one or more of the following definitions:
  - "Asian Americans" means all persons having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands, including but
not limited to Japan, China, Vietnam, Samoa, Laos, Cambodia, Taiwan, Northern Marinas, the Philippines, U. S. territory of the Pacific, India, Pakistan, Bangladesh and Sri Lanka and who are regarded as such by the community of which these persons claim to be a part.

- "African Americans" means all persons having origins in any of the original peoples of Africa and who are regarded as such by the community of which these persons claim to be a part.

- "Hispanic Americans" means all persons having origins in any of the Spanish speaking peoples of Mexico, South or Central America, or the Caribbean Islands or other Spanish or Portuguese cultures and who are regarded as such by the community of which these persons claim to be a part.

- "Native Americans" means all persons having origins in any of the original peoples of North America and who are regarded as such by the community of which these persons claim to be a part or who are recognized by a tribal organization.

- "Eskimos and Aleuts" means all persons having origins in any of the peoples of Northern Canada, Greenland, Alaska, and Eastern Siberia and who are regarded as such in the community of which these persons claim to be a part.

- **Small Business Enterprise** means an independently owned and operated business which, together with affiliates, has 250 or fewer employees, or average annual gross receipts of $10 million or less averaged over the previous three years. Nothing in this provision prevents a program, agency, institution or subdivision from complying with the qualification criteria of a specific state program or a federal guideline to be in compliance with a federal grant or program.
• **Woman-owned Business Enterprise** means a business concern which is at least 51 percent owned by one or more women who are U.S. citizens or legal resident aliens, or in the case of a corporation, partnership or limited liability company or other entity, at least 51 percent of the equity ownership interest in which is owned by one or more women, and whose management and daily business operations are controlled by one or more of such individuals.

If the firm is not a SWAM firm, describe the firm’s partnering relationships with SWAM firms and how it plans to support the University’s goal to increase business annually by 5% with these firms in accordance with Attachment 4, Executive VP and COO’s Request for Commitment letter.

G. Other Information

Provide any other information which the University should consider in evaluating the firm's proposal.

VI. Information about this RFP

A. Procurement Schedule

Here is a brief schedule for this procurement, specifying the important dates and milestones:

- **Issue Date of RFP:** 04/05/07
- **Preproposal Conference:** 04/19/07
- **Deadline for Receipt of Proposals:** 05/08/07
- **Oral Presentations:** 06/04/07 and 06/05/07
- **Negotiations:** 06/19/07 and 06/20/07
- **Contract Award:** 09/28/07

B. Issuance of RFP and Questions

The Issuing Office for this RFP is:

Procurement Services

University of Virginia
Any questions concerning this RFP will be directed to Steve Heldreth as listed above and not to any other person at the University, with the exception of issues directly related to SWAM business and SWAM subcontracting opportunities. Such SWAM issues may be alternately directed to Bill Cooper, the University’s Director of Supplier Diversity, at (434) 924-7174 or wsc6ja@virginia.edu. The University will determine whether any addenda should be issued as a result of any question or other matters raised.

C. Preproposal Conference
A conference for firms receiving this RFP will be held on Thursday, April 19, 2007 at 1:00 p.m. EDT in the Darden School of Business Room #290, Charlottesville, Virginia (map viewed at this web site: http://www.virginia.edu/Map/). Attendance at this conference is advised if your firm wishes to raise any questions in connection with this RFP. Please print a copy of the RFP and bring it with you as no additional copies will be provided at the conference. The University intends to present general information which may be helpful in the preparation of proposals and to offer firms the opportunity to ask questions concerning this RFP. No firm may have more than two representatives present at the conference.

Firms planning to attend the Preproposal Conference should notify Becky Sims either by email (pur-rfp@virginia.edu) or telephone (434-924-1346), no later than 12:00 noon, EDT on Tuesday,
April 17, 2007 of the names, titles, and phone numbers of the individuals who will attend.

D. Proposal Deadline
All proposals must be received at the Issuing Office by 3:00 p.m., EDT Tuesday, May 8, 2007. Eight copies of each proposal must be provided in individual, bound volumes. Firms must also include an electronic copy of the proposal on a CD-ROM, excluding any pre-printed materials such as financial statements. The electronic copy should be formatted as a Microsoft Word document.

E. Oral Presentations and Negotiations
An oral presentation by two or more firms may be required after written proposals are received by the University. If the University requires such a presentation, the Issuing Office will schedule a time and place. Each firm should be prepared to discuss and substantiate any of the areas of the proposal it submitted, its own qualifications for the services required and any other area of interest relative to its proposal. Oral presentations are tentatively scheduled for June 14, 2007 and June 15, 2007. Negotiations with two or more firms will be conducted by the University on the firms' financial proposals and proposed terms and conditions. Negotiations are scheduled for June 19, 2007 and June 20, 2007.

F. Communications Between the University and the firms Regarding This RFP
Informal Communications
From the date of receipt of this Request for Proposal by each firm until a binding contractual agreement exists with the Selected Firm and all other firms have been notified, or when the University rejects all proposals, informal communications regarding this procurement will cease. Informal communications will include but not be limited to:
1. Requests from the firms to any department at the University, with the exception of Procurement Services for information, comments, speculation, etc.;

2. Requests from any department at the University, or any employee of the University, with the exception of Procurement Services for information, comments, speculation, etc.

Formal Communications

From the date of receipt of this Request for Proposal by each firm until a binding contractual agreement exists with the Selected Firm and all other firms have been notified, or when the University rejects all proposals, all communications between the University and the firms will be formal, or as provided for in this Request for Proposal, or as requested by Procurement Services. Formal communications will include but not be limited to:

1. Preproposal Conference
2. Oral presentations
3. Site visits, Interviews, etc.

Any failure to adhere to the provisions set forth in Informal Communications and the Formal Communications sections above may result in the rejection of any firm's proposal or cancellation of this RFP.

G. Formation of the Agreement with the Selected Firm

All proposals received will be carefully evaluated by the University. The University will then select two or more firms deemed to be fully qualified and best suited among those submitting proposals, on the basis of evaluation criteria described in this RFP. The University will then conduct negotiations with each of these firms. After negotiations have been conducted, the University will select the firm which, in its opinion,
has made the best proposal. The University will award the agreement to
the Selected Firm by either of these methods:

1. Accept the proposal as written by issuing a written notice to the
   Selected Firm which refers to this RFP and accepts all or part of
   the proposal submitted in response to it and/or any addenda
   submitted during the negotiation process; or

2. Execute a mutually satisfactory written agreement based on this
   RFP, the proposal submitted, and the negotiations concerning
   these.

3. If the University determines in writing and in its sole discretion
   that only one firm is fully qualified, or that one firm is clearly
   more highly qualified than the others under consideration, it may
   decide to negotiate and award an agreement to that firm.

Because the University may use alternative (1) above, each firm must
include in its written proposal all requirements, terms or conditions it
may have, and should not assume that an opportunity will exist to add
such matters after the proposal is submitted.

Firms should also note that, as described in Section H, Provisions Deemed
Included in the Proposal, certain matters will automatically be deemed
part of the proposal.

H. Provisions Deemed Included in the Proposal
The University will consider each proposal to include not only the matters
expressly stated in the proposal as requested in Section V, Contents of the
Proposal, but also other provisions which consist of two different types:
those which are "mandatory" and cannot be changed by a firm in its
proposal; and those which are "preferred" by the University, but which a
firm may wish to alter by expressly and specifically so stating in its
proposal.
The University includes mandatory provisions so that all proposals will be governed by the same basic contractual terms. The University encourages any firm which feels that a mandatory provision is unreasonable to contact the University before proposals are due so the University can consider amending the provision. The University includes preferred provisions so that any difference between the firm and the University's preferred contractual provisions can be considered during the University's evaluation of proposals.

1. Mandatory Provisions

   Each proposal received by the University in response to this RFP will automatically be deemed to include the firm's agreement to the provisions of (a) and (b) below. Although such provisions will govern the firm's proposals as submitted, the University and one or more firms may later mutually agree to amend such provisions, such as when additional time is needed to consider proposals, or when contractual negotiations or performance indicate that such amendments are appropriate.

   a. The proposal constitutes an offer by the firm which will remain open and irrevocable for a period of 120 days from the deadline for submitting proposals as stated in Section C, Proposal Deadline.

   b. If selected by the University, the provisions governing the firm's performance will include all the provisions of Attachment 1, Mandatory Contractual Provisions.


   Unless a firm expressly and specifically provides otherwise in its written proposal, the proposal received by the University in response to this RFP will automatically be deemed to include the firm's agreement to these provisions:

   a. The firm consents to the University contacting and obtaining any information relevant to this RFP from the
references and others identified by the firm in its proposal, as well as from any other persons, firms, or organizations which the University wishes to contact; and

b. If selected by the University, the provisions governing the firm's performance will include all the provisions of Attachment 2, Preferred Contractual Provisions.

I. Rejection of Proposals

The University reserves the right to reject any or all proposals received. Nonacceptance of a firm's proposal will mean that one or more proposals were deemed more advantageous to the University or that all proposals were rejected. Firms whose proposals are not accepted will be notified after a binding contractual agreement between the University and the Selected Firm exists, or when the University rejects all proposals.

J. Virginia Freedom of Information Act

Except as provided below, once an award is announced, all proposals submitted in response to this RFP will be open to the inspection of any interested person, firm or corporation, in accordance with the Virginia Freedom of Information Act. Trade secrets or proprietary information submitted by firms as part of its proposal will not be subject to public disclosure under the Virginia Freedom of Information Act; however, the firm must invoke the protections of this section prior to or upon submission of its proposal, and must identify the specific data or other materials to be protected and state the reasons why protection is necessary. Firms may not request that its entire proposal be treated as proprietary information.
Attachment 1

Mandatory Contractual Provisions

A. Nondiscrimination
   During the performance of this Agreement, the Selected Firm will comply with
   the contract provisions contained in Section 2.2-4311 (1) & (2) of the Code of
   Virginia or any successor provisions which may be applicable to this Agreement.
   Also, in accordance with Section 2.2-4343.1, the University does not
   discriminate against faith-based organizations.

B. Conflict of Interests
   The Selected Firm represents to the University that its entering into this
   Agreement with the University and its performance through its agents, officers
   and employees does not and will not involve, contribute to nor create a conflict of
   interest prohibited by the Virginia State and Local Government Conflict of
   Interests Act (Va. Code 2.2-3100 et seq), the Virginia Ethics In Public
   Contracting Act (Va. Code 2.2-4367 et seq), the Virginia Governmental Frauds
   Act (Va. Code 18.2-498.1 et seq) or any other applicable law or regulation.

C. Assignment
   Neither party to this Agreement will have the right to assign this Agreement in
   whole or in part without the prior written consent of the other.

D. Amendments
   No amendment of this Agreement will be effective unless it is reduced to writing
   and executed by the University's Director of Procurement Services and by the
   individual signing the Selected Firm's proposal or by other individuals named by
   either party as specified in Section E, Notices below. If the Selected Firm
   deviates from the terms of this Agreement without a written amendment, it does
   so at its own risk.
E. Notices
Any notice required or permitted to be given under this Agreement will be in writing and will be deemed duly given: (1) if delivered personally, when received; (2) if sent by recognized overnight courier service, on the date of the receipt provided by such courier service; (3) if sent by registered mail, postage prepaid, return receipt requested, on the date shown on the signed receipt: or (4) if sent by facsimile, when received (as verified by sender’s machine) if delivered no later than 4:00 p.m. (receiver’s time) on a business day or on the next business day if delivered (as verified by sender’s machine) after 4:00 p.m. (receiver’s time) on a business day or on a non-business day. All such notices will be addressed to a party at such party’s address or facsimile number as shown below.

If to the University:
Eric N. Denby
Director of Procurement Services
Carruthers Hall
University of Virginia
1001 North Emmet Street
P.O. Box 400202
Charlottesville, Virginia 22904-4202
Fax: (434) 924-6154

If to the Selected Firm:
The person signing the Selected Firm's proposal in response to the University's RFP, at the Selected Firm's address indicated in such proposal; or to such other person or address as either may designate for itself in writing and provide to the other.

F. Independent Contractor
Selected Firm is not an employee of the University, but is engaged as an independent contractor. The Selected Firm will indemnify and hold harmless the Commonwealth of Virginia, the University, and its employees and agents, with respect to all withholding, Social Security, unemployment compensation and all other taxes or amounts of any kind relating to the Selected Firm's performance of this Agreement. Nothing in this Agreement will be construed as authority for the Selected Firm to make commitments which will bind the University, or to
otherwise act on behalf of the University, except as the University may expressly authorize in writing.

G. Workers' Compensation and Employers' Liability
The Selected Firm will (i) maintain Employers Liability coverage of at least $100,000 and (ii) comply with all federal or state laws and regulations pertaining to Workers' Compensation Requirements for insured or self-insured programs.

H. Drug-Free Workplace
The Selected Firm, its agents and employees are prohibited, under the terms of this Agreement, Code of Virginia Section 2.2-4312, and the Commonwealth of Virginia, Department of Human Relations Management Policy Number 1.05, from manufacturing, distributing, dispensing, possessing, or using any unlawful or unauthorized drugs or alcohol while on University property.

During the performance of this Agreement, the Selected Firm agrees to 1) provide a drug-free workplace for the Selected Firm's employees; 2) post in conspicuous places, available to employees and applicants for employment, a statement notifying employees that the unlawful manufacture, sale, distribution, dispensation, possession, or use of a controlled substance or marijuana is prohibited in the Selected Firm's workplace and specifying the actions that will be taken against employees for violations of such prohibition; 3) state in all solicitations or advertisements for employees placed by or on behalf of the Selected Firm that it maintains a drug-free workplace; and 4) include the provisions of the foregoing clauses in every subcontract or purchase order of over $10,000, so that the provisions will be binding upon each subcontractor or vendor.

For the purposes of this section, "drug-free workplace" means a site for the performance of work done in connection with a specific agreement awarded to a Selected Firm, the employees of whom are prohibited from engaging in the
unlawful manufacturing, sale, distribution, dispensation, possession or use of any controlled substance or marijuana during the performance of the agreement.

I. Information Technology Access Act
In accordance with § 2.2-3504 of the Code of Virginia, the following will apply to all information technology Agreements:

NON-VISUAL ACCESS TO TECHNOLOGY: All information technology (the "Technology") which is purchased or upgraded by the University will comply with the following non-visual access standards from the date of purchase or upgrade until the expiration of the Agreement:

- Effective, interactive control and use of the Technology will be readily achievable by non-visual means;
- Technology equipped for non-visual access will be compatible with information technology used by other individuals with whom any blind or visually impaired user of the Technology interacts;
- Non-visual access technology will be integrated into any networks used to share communications among employees, program participants or the public; and
- Technology for non-visual access will have the capability of providing equivalent access by non-visual means to telecommunications or other interconnected network services used by persons who are not blind or visually impaired.

Compliance with the foregoing non-visual access standards will not be required if the Director of Procurement Services, University of Virginia determines that 1) the Technology is not available with non-visual access because the essential elements of the Technology are visual and 2) non-visual equivalence is not available.

Installation of hardware, software, or peripheral devices used for non-visual access is not required when the Technology is being used exclusively by
individuals who are not blind or visually impaired, but applications programs and underlying operating systems (including the format of the data) used for the manipulation and presentation of information will permit the installation and effective use of non-visual access software and peripheral devices.

If requested, the Agreement must provide a detailed explanation of how compliance with the foregoing non-visual access standards is achieved and a validation of concept demonstration.

J. eVA Business To Government Registration
The eVA Internet electronic procurement solution, web site portal www.eva.state.va.us, is the Commonwealth of Virginia's comprehensive electronic procurement system. The portal is the gateway for firms to conduct business with state agencies and public bodies. All agencies and public bodies are expected to utilize eVA. All firms desiring to provide goods and/or services in the Commonwealth are encouraged to participate in the eVA Internet e-procurement solution. The Selected Firm is required to register in the eVA Internet e-procurement solution prior to an award being made.

K. eVA Transaction Fee
The Selected Firm agrees, by accepting an award as a result of this RFP, that it is a registered eVA vendor and will be subject to an eVA transaction fee, for which the Selected Firm will be invoiced by Commonwealth of Virginia, Department of General Services. Additional information is available at www.eva.state.va.us.

L. Contractor License Requirements
State statutes and regulatory agencies require that some firms be properly registered and licensed, or hold a permit, prior to performing specific types of services. If firms provide removal, repair, improvement, renovation or construction-type services they, or a qualified individual employed by the firm, must possess and maintain an appropriate State of Virginia Class A, B, or C
Contractor License (as required by applicable regulations and value of services to be performed) for the duration of the Agreement. It is the firm’s responsibility to comply with the rules and regulations issued by the appropriate State regulatory agencies.

License #______________ Type___________________

A copy of the license must be furnished upon request to the University or VASCUPP member institution.
Attachment 2
Preferred Contractual Provisions

A. Goods and Services
During the term of this Agreement, the Selected Firm will provide for the
University the goods and services offered to the University by the firm in its
proposal and/or any addenda to its proposal which has been approved in writing
by the University and as may be further specified by the University in writing
when it selected the firm.

B. Term of Agreement
The term of this Agreement will be for five years, with the ability to renew on the
same terms and conditions, for additional periods totaling five years, if mutually
agreeable to the University and the Selected Firm. The Selected Firm and the
University will mutually agree at least 180 days prior to each renewal period
whether to renew the terms of the Agreement.

C. Contract Administrator
The University will identify a Contract Administrator for any Agreement which
results from this RFP. The individual will be the point of contact at the
University for day-to-day operations, but cannot approve amendments to the
Agreement or price changes.

D. Waiver
No waiver of any right will be deemed a continuing waiver, and no failure on the
part of either party to exercise wholly or in part any right will prevent a later
exercise of such or any other right.

E. Indemnification
The Selected Firm will indemnify and hold harmless The Commonwealth of
Virginia, The Rector and Visitors of the University of Virginia, and their agents,
employees and officials from any and all costs, damage or loss, claims, liability, damages, expenses (including, without limitation, attorneys' fees and expenses) caused by or arising out of the performance or non-performance of the Agreement by the Selected Firm or its agents or subcontractors, including the provision of any services or products. The Selected Firm warrants that the products, goods and services provided the University may be used by the University without being in violation of any copyright, patent or similar property right or claim by others and will defend, indemnify and save the University (its employees and agents) from and against any such claim.

F. Governing Law
This Agreement will be governed in all respects by the laws of the Commonwealth of Virginia.

G. Termination
If the Selected Firm fails to provide quality goods or services in a professional manner, solely as determined by the University, and, upon receipt of notice from the University, does not correct the deficiency, to the University's satisfaction within a reasonable period of time, not to exceed five calendar days unless otherwise agreed to by both parties in writing, the University reserves the right to terminate this Agreement upon written notice to the Selected Firm.

H. Non-Appropriation
Funding for any Agreement between the University and a Selected Firm is dependent at all times upon the appropriation of funds by the Virginia General Assembly and/or any other organization of the Commonwealth authorized to appropriate such funds. In the event that funding to support this Agreement is not appropriated, whether in whole or in part, then the Agreement may be terminated by the University effective the last day for which appropriated funding is available.
I. Right of Audit

The University reserves the right to audit or cause to be audited the Selected Firm's books and accounts regarding the University's account at any time during the term of this Agreement and for five years thereafter. The Selected Firm will make available to the University all books and records relating to performance of this Agreement as may be requested during said period.

J. Contractual Claims

This Agreement is subject to the University's policy on Contractual Claims which is provided as Attachment 3, Procedure for Resolution of Contractual Claims.

K. Insurance

Listed below is the insurance the Selected Firm must maintain under any Agreement resulting from this RFP. In no event should the Selected Firm construe these minimum required limits to be their limit of liability to the University. The Selected Firm will maintain insurance which meets or exceeds the requirements of the University with insurance companies that hold at least an A- financial rating with A.M. Best Company. No Agreement will be executed by the University until the Selected Firm satisfies the insurance requirements of the University. The Selected Firm may be required to provide the University with a valid Certificate of Insurance before providing any goods or services to the University. The University reserves the right to approve any insurance proposed by the Selected Firm.

Comprehensive Commercial General Liability:

The Selected Firm and any Subcontractor will provide a minimum combined single Limit of Liability for bodily injury and property damage of $1,000,000 per occurrence with coverage for the following coverage:

- [X] Premises/Operations
- [X] Products/Completed Operations
- [X] Contractual
- [X] Personal Injury
Automobile Insurance:
The Selected Firm and any Subcontractor will provide a minimum combined single Limit of Liability for bodily injury and property damage of $1,000,000 per occurrence with the following coverages for vehicles operated by their employees.

{X} Any Automobile {X} Owned and Non-Owned Automobiles

Errors and Omissions Insurance:
The Selected Firm and any Subcontractor will provide a minimum combined single Limit of Liability of $1,000,000 for professional errors and omissions in the performance of services outlined in this RFP.

*Additional Insured:
The University will be named as an Additional Insured, and the proper name is: "The Commonwealth of Virginia, and the Rector and Visitors of the University of Virginia, its officers, employees, and agents."

L. Use of Agreement by Third Parties
In accordance with Section 2.2-4304 of the Code of Virginia, these organizations may have access to any Agreement resulting from this RFP to allow for cooperative purchasing by only the Virginia Association of State College and University Purchasing Professionals (VASCUPP) and all other Commonwealth of Virginia public institutions of higher education (to include four-year, two-year and community colleges). Current VASCUPP member institutions include: College of William and Mary, George Mason University, James Madison University, Old Dominion University, Radford University, University of Virginia, Virginia Commonwealth University, Virginia Military Institute, and Virginia Polytechnic Institute and State University. A list of all other Virginia Public Colleges and Universities is available at 

In addition, access to the Agreement may also be extended to 1) Any University related foundation, and 2) City of Charlottesville and County of Albemarle. Potentially, other member schools of the Atlantic Coast Conference (ACC) may also have access to any Agreement resulting from this RFP if such access is confirmed by the University. The other ACC member schools which may potentially participate are: Boston College; Clemson University; Duke University; Florida State University; Georgia Institute of Technology; University of Maryland; University of Miami; University of North Carolina; North Carolina State University; Wake Forest University, and Wake Forest University Health Sciences. Other institutions which may participate include Emory University.

Participation in this cooperative procurement is strictly voluntary. If authorized by the Selected Firm, the Agreement will be extended to the public bodies indicated above to purchase at the fees in accordance with the terms of the Agreement. The Selected Firm will notify the University in writing of any such institutions accessing the Agreement. No modification of the Agreement or execution of a separate agreement is required to participate. The Selected Firm will provide semi-annual usage reports for all VASCUPP member institutions and public institutions accessing the Agreement. Participating public bodies will place their own orders directly with the Selected Firm and will fully and independently administer use of the Agreement to include contractual disputes, invoicing and payments without direct administration from the University. The University will not be held liable for any costs or damages incurred by any other participating public body as a result of any authorization by the Selected Firm to extend the Agreement. It is understood and agreed that the University is not responsible for the acts or omissions of any VASCUPP member institution, or any other entity accessing the Agreement under this section, and will not be considered in default of the Agreement no matter the circumstances. Use of this Agreement does not preclude any participating public body from using other agreements or competitive procurement processes as required by law.
M. Favored Nations
The Selected Firm represents that the prices, terms, warranties, and benefits specified in its proposal are comparable to or better than the equivalent terms being offered by the firm to any present customer.

N. The University's Authorized Representatives
The only persons who are or will be authorized to speak or act for the University in any way with respect to this Agreement are those whose positions or names have been specifically designated in writing to Selected Firm by the University's Director of Procurement Services.

O. Purchasing Manual
This Agreement is subject to the provisions of the Commonwealth of Virginia "Purchasing Manual for Institutions of Higher Education and Their Vendors" and any subsequent revisions, which is available on Procurement Services web site at: http://www.virginia.edu/procurement/about/PurchasingManual.html

P. Small, Women-owned and Minority-owned (SWAM) Business Reporting
The Selected Firm will identify and fairly consider SWAM firms for subcontracting opportunities when qualified SWAM firms are available to perform a given task in performing for the University under the resulting Agreement. The Selected Firm will submit a quarterly SWAM business report to the University by the 8th of the month following each calendar quarter, specifically the months of April, July, October, and January. The Selected Firm will submit the quarterly SWAM business reports to:

Nancy Noblette
Administrative Assistant to the Director of Procurement Services
E-mail: nrm9g@virginia.edu

The quarterly SWAM business reports will contain this information:

- SWAM firm’s name, address and phone number with which the Selected Firm has contracted over the specified quarterly period.
• Contact person at the SWAM firm who has knowledge of the specified information.
• Type of goods and/or services provided over the specified period of time.
• Total amount paid to the SWAM firm as it relates to the University’s account.

The Selected Firm’s failure to provide SWAM reports on a quarterly basis which contain the information required by this section and/or the Selected Firm’s failure to comply with the plan for utilizing SWAM businesses submitted by the Selected Firm as part of its proposal and/or negotiation response may be grounds for debarment pursuant to Section 4.M. of the “Purchasing Manual for Institutions of Higher Education and their Vendors.”

Q. Intellectual Property Rights/Disclosure
Unless expressly agreed to the contrary in writing, all goods, products, materials, documents reports, writings, video images, photographs or papers of any nature including software or computer images prepared or provided by the Selected Firm (or its subcontractors) for the University will not be disclosed to any other person or entity without the written permission of the University. The Selected Firm warrants to the University that the University will own all rights, title and interest in any and all intellectual property rights created in the performance or otherwise arising from any Agreement resulting from this RFP and will have full ownership and beneficial use thereof free and clear of claims of any nature by any third party including without limitation copyright or patent infringement claims. The Selected Firm will execute any assignments or other documents needed for the University to perfect such rights. Notwithstanding the foregoing, for research collaboration pursuant to subcontracts under sponsored research agreements administered by the University's Office of Sponsored Programs, intellectual property rights will be governed by the terms of the grant or contract to the University to the extent such grant or contract requires intellectual property terms to apply to subcontractors.
R. Confidentiality

Both parties acknowledge that in the negotiation and performance of this Agreement, confidential and proprietary information of each has been and will be made available to the other. The parties agree to use reasonable efforts to maintain the confidentiality of such material, but in no event lesser than was used with like material of the receiving party, and not to make any internal use of such material not required under this Agreement. Neither party will disclose the information to any third party without prior written authorization from the disclosing party, and will not use the information received by it, except to those of its employees, agents, and consultants whose duties justify the need for access to the information provided that such individuals are subject to obligations of secrecy and limited use commensurate in scope with this Agreement. These obligations will apply to verbal information as well as specific portions of the information that are disclosed in writing or other tangible form and marked to indicate its confidential nature.

These obligations will not apply to any of the information which:

1. Was known to the receiving party prior to receipt under this Agreement, as demonstrated by the receiving party’s records; or

2. Was publicly known or available prior to receipt under this Agreement, or later becomes publicly known or available through no fault of the receiving party; or

3. Is disclosed to the receiving party without restrictions on disclosure by a third party having the legal right to disclose the same; or

4. Is independently developed by an employee, consultant, or agent of the receiving party without access to the information as received under this Agreement; or

5. The receiving party is obligated to produce as required by law, lawfully issued subpoena, or a court order, provided that the disclosing party has been given notice thereof and an opportunity to waive its rights or to seek a protective order or other appropriate remedy.
Upon written request of a disclosing party, the receiving party will return all information disclosed in written or tangible form, and the receiving party will destroy all of its copies, excerpts or notes made by it which contain any portions of the information unless otherwise provided for by the parties. Notwithstanding anything to the contrary, disclosure as required by law or by the University to comply with an opinion of its Special Assistant Attorney General that disclosure is necessitated by Virginia's Freedom of Information Act shall not be considered a breach of the Agreement.

S. Training Material
The Selected Firm, at no charge, will supply the University for the University’s own use, with all material used by the Selected Firm when providing training services, including the training database.

T. Future Goods and Services
The University reserves the right to have the Selected Firm provide additional Goods and Services under the same pricing, terms, and conditions to purchase additional services, including upgrades and related software, products and services. Such additional goods and services may include Goods and Services that are newly introduced during the term of this Agreement. Such newly introduced additional Goods and Services will be provided to the University at most favored nations pricing, terms, and conditions.

U. Project Manager
The Selected Firm agrees to provide a named individual (“Project Manager”) to implement, perform, and manage provision of the Goods and Services. The University must approve the appointment of the Project Manager prior to execution of any Agreement with the Selected Firm resulting from this RFP. The Project Manager will be the University’s primary contact, although the Project Manager will be assisted by other members of the Selected Firm’s staff in completing key activities.
In the event that the Project Manager or any other individual responsible for the University’s account, is no longer employed by the Selected Firm, is unavailable for any reason, or is performing in an unsatisfactory manner as determined by the University’s Contract Administrator, Selected Firm will propose a replacement for that individual within a reasonable time frame, so as not to significantly delay the provision of the Services to the University. The University reserves the right to approve the replacement, or to cancel the Agreement. If a proposed replacement is accepted by the University, the replacement will provide the Services at rates no higher than the rates of the original individual and in accordance with all terms and conditions specified.
Attachment 3

Procedure for Resolution of Contractual Claims

The Virginia Acts of Assembly of 2006, Chapter 943, Chapter 3, Exhibit P and its attachments requires contractors with the University to submit any claims, whether for money or other relief, in writing no later than 60 days after final payment; however, written notice of the contractors intention to file such a claim must be given at the time of the occurrence or beginning of the work upon which the claim is based.

The University's procedure for deciding such contractual claims is:

A. The Selected Firm must provide the written claim to:
   Assistant Director of Procurement Services
   University of Virginia
   1001 North Emmet Street
   P. O. Box 400202
   Charlottesville, Virginia  22904-4202

B. Although the Selected Firm may, if it chooses, attempt to resolve its claim by dealing with a University department other than the one stated in Section A above, the Selected Firm must submit any unresolved claim in writing no later than 60 days after final payment to the Assistant Director of Procurement Services if it wishes to pursue its claim.

C. Upon receiving the written claim, the Assistant Director of Procurement Services will review the written materials relating to the claim and decide whether to discuss the merits of the claim with the Selected Firm. If such discussion is to be held, the Assistant Director of Procurement Services will contact the Selected Firm and arrange such discussion. The manner of conducting such discussion will be as the Assistant Director and the Selected Firm mutually agree.
D. The Assistant Director of Procurement Services will mail his or her decision to
the Selected Firm within 60 days after receipt of the claim. The decision will
state the reason for granting or denying the claim.

E. The Selected Firm may appeal the decision to:

Director of Procurement Services
University of Virginia
Carruthers Hall
1001 North Emmet Street
P.O. Box 400202
Charlottesville, Virginia 22904-4202

by providing a written statement explaining the basis of the appeal, within 15
days after the Selected Firm's receipt of the decision.

F. Upon receiving the written appeal, the Director of Procurement Services will
review the written materials relating to the claim and decide whether to discuss
the merits of the claim with the Selected Firm. If such discussion is to be held,
the Director of Procurement Services will contact the Selected Firm and arrange
such discussion. The manner of conducting such discussion will be as the
Director of Procurement Services and the Selected Firm mutually agree.

G. The Director of Procurement Services will mail his or her decision to the Selected
Firm within 60 days after the Director of Procurement Services receipt of the
appeal. The decision will state the reasons for granting or denying the appeal.
Greetings:

The quality of service the University of Virginia is able to deliver to its customers is directly related to the excellent support we receive from you and many other outstanding suppliers of goods and services. Without you, we would not be able to fulfill our educational, health care and research missions. An important part of our procurement program involves our commitment to doing business with small, women- and minority-owned (SWAM) businesses. As one of our most important vendors, we look to you to help us achieve this objective.

We conduct substantial business with small firms. We have been less effective in securing long-term business relationships with minority- and women-owned businesses. We are determined to improve our record.

I seek your assistance in two areas. First, to the extent practical, I ask that you involve small, women- and minority-owned businesses in the delivery of services you provide to UVa. Second, I seek your help in reporting your results through our quarterly subcontracting reports. The terms and conditions previously provided to your organization outlined this process.

This effort is important to us. We depend on you in so many ways – this is another way that we can partner with your company to make things better.

Sincerely,

Leonard W. Sandridge
Executive Vice President and Chief Operating Officer
LWS:dr
Madison Hall · Post Office Box 400228 · Charlottesville, Virginia 22904-4228
Existing University Produced Systems & Processes

Pre- and Post-Award Systems
University, school, and departmental research administration offices use primarily paper-based processes for submitting grant proposals for institutional routing, approval and submission. The Grants Awards System is an Access/SQL system maintained by OSP and ITC to provide University-wide information on grant proposal and award data. In addition, individual University schools and departments have their own local systems to augment such data. The individual University schools and departments also use various local systems to track and monitor workflow, including utilization of web-based Excel spreadsheets that provide grant proposal and award information to the University community.

OSP, the School of Medicine Office of Grants and Contracts, and other offices utilize ImageNow software for file management. OSP maintains cost-share information in an Excel spreadsheet. OSP maintains an Excel spreadsheet of University personnel trained by OSP in areas of research administration and compliance.

Oracle Financials are utilized for research accounting, financial reporting and billing. The University’s effort reporting system is a customized process built upon Oracle’s labor distribution module. OSP provides data file feeds into the effort reporting process for cost share and Health Services Foundation payroll data.

IRB Online
The current system supporting the two IRBs, IRB Online, is a web-based Cold Fusion application with an MS SQL Server backend. It serves faculty investigators, study coordinators, the IRB offices and the IRB members. Several other affiliated offices use data from this system in their own systems. Existing features include:

1. tracks all research protocols involving human subjects;
2. tracks all events associated with protocols;
3. on HSR side, interviews PI regarding research and assembles protocols and consent forms with appropriate language based on PI answers;
4. tracks training data;
5. IRB administrative staff use application to:
   a. create meeting agenda;
   b. communicate with research personnel (via form-driven email);
   c. track status of protocol;
   d. report on protocols and research personnel.

PAM Database
Currently, the PAM office uses a Visual Basic application based on both an Access 2003 database and linked tables from the MS SQL Server based IRB Online system.
IACUC Online
The IACUC application is written in Cold Fusion 5, and the data resides in MS SQL Server 2000 and a Verisign SSL128-bit (minimum 56-bit required) certificate is used with IIS v6. The existing system performs the following high-level tasks:

1. tracks all vertebrate animal research and use at U.Va. both on-Grounds and off-Grounds;
2. PIs use an online web application to create, modify, copy, and submit research protocols to the IACUC;
3. animal handlers use a personalized online web application to access protocol data, online training, training records, health assessment forms, health and safety data, and health assessment data;
4. IACUC administrative and compliance staff use applications to:
   a. manage the submission, review, and approval of protocols;
   b. track locations of: research animal housing, "special" procedures, Drug Enforcement Administration controlled substances, Patient Care Area use, and Hazardous Materials used in live animals (chemical, radioactive, and biological);
   c. manage inspection data/deficiencies (all PIs and locations are inspected at least twice/year);
   d. manage Animal Handler Health Assessment data and training records;
   e. manage user access lists; and
   f. generate reports for accreditation agencies;
5. IACUC committee members have online "read-only" access to all protocols;
6. WorkMed staff and Student Health staff (Occupational Health RNs and Student Health RNs, respectively) use an online application to view potential hazard exposures for every animal handler, to create/update animal handler health status and to update animal handler respiratory fit testing data; and
7. Vivarium staff (both U.Va. employees and non-U.Va. employees have access) use protocol information, via an online application, to properly manage the environment of care for research animals housed in the various vivaria.

IBC Online
The IBC Online application is written in Cold Fusion 5, and the data reside in MS SQL Server 2000. A Verisign SSL 128-bit (minimum 56-bit required) certificate is used with IIS v6. The application:

1. tracks all creation, possession and/or use of: microorganisms, human derived material, primate derived material, biotoxins, recombinant DNA, and select agents as defined by CDC (42 CFR 73) or USDA (9 CFR 121);
2. PIs use an online application to create, modify, copy, and submit their inventories and activities (currently called "Inventory and Activity Registration" or IAR) to the IBC;

3. Handlers of hazardous biological agents use online applications to access online training, training records, and health and safety information;

4. IBC administrative staff and biosafety compliance staff use online applications to:
   a. manage the submittal, review, and approval of IARs;
   b. track locations and handlers of each of the following categories: BSL2 microorganisms, BSL3 microorganisms, human herived material, primate derived material, select agents, recombinant DNA, and biotoxins (tracking of certain biotoxins requires both qualitative and quantitative data);
   c. manage inspection data/deficiencies (all PIs and locations are inspected initially and at least once every 3 years); and
   d. manage handlers of hazardous biological agents training records;

5. IBC members have online "read-only" access to all IARs.

**Radiation Safety Online**
The Radiation Safety Online applications use the following: a non-ODBC compliant database (dBase, 16-bit)/VB application, MS Access, MS Excel, Cold Fusion 5, MS SQL Server 2000, and a Verisign SSL128-bit (minimum 56-bit required) certificate is used with IIS v6. This application:

1. tracks all receipt, possession, use, storage, decay and/or disposal of Radioactive material (RAM);

2. RAM users use online applications to access online training, training records, and health and safety information;

3. Radiation Safety staff use applications to:
   a. manage survey (inspection) data where RAM is used or stored (all areas are inspected either quarterly or semi-annually);
   b. manage the possession quantities and limits of isotopes delivered to the PIs;
   c. track the locations of RAM use/storage;
   d. manage users of RAM training records; and
   e. manage short and long term storage, decay, and disposal of RAM.
High Level View of Existing Research Information Systems

Current Research Information Systems

Grants.gov

Annual Reporting to Sponsors

Adverse Events Updates to Sponsors

Integrated System

OSIR

Compliance

Clinical

Goldenrod

IRB Online

Clinical Trial Online Ads

SoM Grants Tracking

Post Approval Monitoring CIB

Cancer Center

Grants Award System

IBR Online Radiation Safety

GCRC

Effort Reporting System (spreadsheet)

ACUC Online

Tracking Database (spreadsheet)

CCM

Cost Share Database (spreadsheet)


TrackFile (spreadsheet)

CareCost:

Cancer Center CITO
Clinical Data Repository
HSF Billing
Billing to Grantees
Project Organization Chart

Research Administration & Compliance Initiative – Organizational Chart

Executive Sponsors

Program Management Committee

Working Group

Lauren Moriarty
Project Lead

Investigational Pharmacy
IRB-SSG
Clinical Trials Office
Comparative Medicine
IRB-HSR
Animal Care & Use
Sponsored Programs
Inst. Bio-safety
Patient Financial Services
Cancer Center
Patient Financial Services
General Clinical Research Center
Radiation Safety Committee
Conflict of Interest Committee
Grants & Contracts (SOM)

Faculty/Admin Advisory Group

Barbara Baldwin
Peter Brunjes
Barbara Deely
Virginia Evans
Barry Johnson
Jay Scott
Ralph Traylor
Houston Wood

Communication Group

Steve Borowitz
Eugene Barrett
Roseanne Ford
Nathan Fountain
Neal Grandy
Liz Hupf
Luke Kelly
Joel Linden
Jason Lyman
Barbara Mann
Sue Montgomery
Mitch Rosen
Peggy Shupnick

Tom Breeden
Vaughn Kowahl
Chuck Morris
Marty Phillips
Ken Scully
Heather Paris
[Law Burris]

Technical Owners

Amy Adams
Bronwyn Blackwood
Lori Elder
Sandy Feldman
Susie Hoffman
Sarah Hudson
Gerry Kane
Tom Leonard
Brent Mcghee
Geoff Weiss
Rowley Sewell
Pam Sorouse
Debby Steva
Patti Tereskerz
Sarah White

Business Owners
Integrated Research Administration and Compliance Platform

Research Portal

OSP
- Locate potential funding opportunities
- Assist with grant proposal creation
- Prepare budgets for research projects
- Approve grant proposals
- Submit grant proposals to funding agencies
- Measure effort reporting

IRB
- Human subject grant & protocol review & approval process
- Post-approval monitoring
- Human research protection training

IACUC
- Animal protocol review & approval process
- Post-approval monitoring
- Animal subject protection training
- Occupational health status of animal handlers
- Colony management
- Animal ordering

Radiation Safety
- Track location and use of RSU
- Radiation safety training

CTO
- Track clinical trial participants
- Assist in budget development

Biosafety
- Track location and use of biologic agents
- Train in biosafety

Integrated System HR & Financials

Research administration database
Attachment 6
Associated Offices and Other Terms

Associated Offices

- CCM – Center for Comparative Medicine
- A&S – College and Graduate School of Arts & Sciences
- CTO – Clinical Trials Office
- COI – Conflicts of Interest Committee
- IRB-HSR – Institutional Review Board for Health Sciences Research
- IRB-SBS – Institutional Review Board for Social and Behavioral Sciences
- IACUC – Institutional Animal Care and Use Committee
- IBC – Institutional Biosafety Committee
- OEHS – Office of Environmental Health and Safety
- OSP – Office of Sponsored Programs
- PAM – Postaward Monitoring Office
- SEAS – School of Engineering and Applied Science
- SoM – School of Medicine
- VPRGS – Office of the Vice President for Research and Graduate Studies

Other Terms

1 protocol – method and process for performing a research study

2 investigator – an individual, typically faculty, who conducts an investigation or research study

3 grant proposal – document designed and proposed by the principal investigator for financial support for research study.

4 study personnel – the individuals who are essential to the conduct of the research, who are not easily replaced, and who are responsible for or participate in the design, conduct, or reporting of research or proposed research. These may include a study coordinator, sub- or co-investigators, research assistants, etc.

5 clinical trial – a controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

6 consent form – form research subjects sign to indicate that they have been informed of the risks and benefits of participation in a research study

7 electronic signature – an electronic version of a signature which is authenticated by a digital certificate
8 **LDAP** - Lightweight Directory Access Protocol - an industry standard protocol used for accessing and managing information directories

9 **grants.gov** – a mechanism by which investigators seek and submit grant proposals and applications online

10 **export control** – see http://www.virginia.edu/sponsoredprograms/exportcontrols.html

11 **assurance forms** – a formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

12 **adverse event (AE)** - any undesirable sign, symptom or medical or psychological condition even if the event is not considered to be related to the investigational drug/device/intervention of a patient enrolled in a clinical trial

13 **data and safety monitoring** – usually a board that includes a committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

14 **multisite trial** – a clinical trial conducted at multiple locations

15 **Occupational Health** – a program to monitor the health of individuals who have animal contact in the course of their employment or studies at the University. See http://www.healthsystem.virginia.edu/internet/ccm/page5.cfm.

16 **animal handler** – lab personnel that work with or handle animals

17 **Vivarium** – a facility for housing animals

18 **recombinant DNA** – Recombinant DNA is DNA that has been created artificially. DNA from two or more sources is incorporated into a single recombinant molecule. DNA (deoxyribonucleic acid) is a nucleic acid that contains the genetic instructions for the development and function of living organisms.

19 **select agent** – a group of biotoxins and microorganisms as defined by the CDC Select Agent Program (http://www.cdc.gov/od/sap/)

20 **Biosafety Levels** – The CDC specifies four levels (BSL1 – BSL4) of containment precautions for biological agents based on their relative danger. Higher numbers indicate greater risk.

21 **dosimetry** – measurement of absorbed dose in matter and tissue resulting from the exposure to ionizing radiations.