



**Request for Proposal**

**Enterprise-wide Research Compliance System**

**RFP NO. B0008483**

**Due: 10:30a.m. CST on February 12, 2020**

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## **Auburn University**

### **Request for Proposal**

#### **Integrated Electronic Research Administration, Research Compliance, and Laboratory Animal Management Solution**

## **I. Introduction and Institutional Background**

### **A. Introduction to Auburn University**

Auburn University is a public land grant University and instrumentality of the State of Alabama. Our research portfolio has grown slowly and steadily over the past decade. Award obligations were \$162.3 million in FY 19 and research expenditures as reported to the HERD survey (2018) were \$212.9 million. A recent initiative to promote research and scholarship created 5 strategic research clusters to align Auburn's efforts with national funding trends. Auburn then strategically hired experienced researchers to work within each cluster to support and enhance interdisciplinary work across the institution. With over 6,000 students, the Samuel Ginn College of Engineering has recently completed one new laboratory building and is well underway on construction of a new research building housing state of the art technologies for structural engineering research. The College of Engineering doubled their awards in fiscal year 19 over fiscal year 18. The College of Science and Mathematics has recently completed construction of a science laboratory building for Physics research. New specialized research facilities offering opportunities for increased human and animal subjects research, location on campus of a new independent College of Osteopathic Medicine, continual growth and expansion of our College of Veterinary Medicine, AAALAC accreditation, and increased oversight of our animal program by regulatory agencies have increased attention on the compliance programs and the associated workload. The University has just launched a campus-wide Conflict of Interest Policy. However, in the current economy where hiring new staff members is unlikely but compliance standards, transparency requirements, system to system proposal transmission, increased cyber security requirements, and the need for immediate access to volume and performance metrics are increasing almost daily, we believe it necessary to begin replacing many of our existing databases and paper based processes with electronic forms creation and workflow, database management, improved proposal development and submission support, on-demand reporting systems to facilitate change management, new methods of research and compliance administration as well as improved compliance oversight and internal control. Improved service to investigators to reduce burden and improve transparency and communication is critical to this effort.

Auburn has undergone three separate reviews conducted by Higher Education consultants regarding our research administration and compliance enterprise. After interviewing Investigators and staff members on campus, each consultant provided recommendations for improved efficiency with the most common being implementation of an enterprise-wide electronic research administration and compliance solution.

### **B. Office of Sponsored Programs (OSP) Background Information**

The Office of Sponsored Programs is responsible for processing and submitting research and other proposals for external sponsorship; pre-award support of grant and contract negotiations, subcontract processing, and collaboration agreements, as well as a variety of other specialized

agreements. Additionally, OSP provides non-financial post-award assistance to investigators and institutional offices related to sponsored programs administration. The Office consists of a Director, Assistant Director and 6 Contract Administrators. In addition to these individuals, 7 of our 13 Colleges and Schools have an individual in their dean's office who is specifically authorized to submit proposals without OSP oversight. These College Level Designees (CLD's) report to the Deans but are involved in staff meetings and regular communication with the OSP staff. In collaboration with OSP, the Office of Proposal Services and Faculty Support (PSFS) provides proposal development support, funding opportunities identification, limited submission processing, and education and awareness resources to the campus. PSFS personnel will engage with OSP and CLD's in the operations of an ERA system. The functions any software solution must provide include, but are not limited to, workflow and automation of proposal development and submission throughout campus; budget development and calculations; system to system transmission of Federally sponsored proposals; ability to account for contributions of Faculty on multi-investigator projects; creation and management of administrative and financial subcontracting; data analytics and performance metrics reporting; and monitoring of project performance reports. It would be desirable for the pre-award data to populate the post award grants information in Banner.

### **C. Office of Research Compliance Background Information**

Auburn University, as a grantee institution receiving federally sponsored awards is responsible to assure due diligence in compliance with U.S. Federal government statutes and regulations that apply to the following heavily regulated areas:

#### **1. Protection of Human Subjects**

In brief, the campus Institutional Review Board (IRB) assures that all sponsored and non-sponsored research involving human subjects, including vulnerable populations (e.g., children), is in compliance with federal government statutes (e.g., The Public Health Service Act) and regulations (e.g., Department of Health and Human Services). The sanctions for noncompliance (e.g., civil and criminal penalties) and potential damage to institutional reputation/integrity are significant and severe.

The functions any software solution must provide include, but are not limited to: Tracking and monitoring the IRB membership; identifying IRB member terms; creation of and routing phases for protocols between or among various campus offices; assisting in the management of compliance committee meetings; identifying different protocol phases (e.g., continuations); identifying different types of protocol review (e.g., exempt, expedited); documenting protocol approval; facilitation of the single IRB of record process; documenting the completion of applicable trainings; providing ability to easily report information from the system; assuring the ability to comply with requirements of the Common Rule; and assuring confidentiality is maintained.

#### **2. Protection of Animal Subjects**

In brief, the campus Institutional Animal Care and Use Committee (IACUC) assures that all sponsored and non-sponsored activities that involves the use of, or intended use of, vertebrate animals in research, teaching, experimentation, testing, training, demonstration or related purposes is in compliance with federal government statutes (e.g., The Animal Welfare Act) and

regulations (e.g., Department of Agriculture). The sanctions (e.g., civil and criminal penalties) and potential damage to institutional reputation/integrity are significant/severe.

The functions that the software solution must provide include, but are not limited to: Tracking and monitoring the IACUC membership; identifying IACUC member terms; creation of and routing phases for protocols between/among various campus offices; identifying different protocol phases (e.g., renewals); identifying different types of protocol review; documenting protocol approval; assisting in the management of compliance committee meetings; providing ability to easily report information from the system; sending impact notifications (e.g., approval to order animal species - purchasing); connecting to other impact areas (e.g., facilities for inspections); documenting the completion of applicable trainings; and assuring confidentiality is maintained.

### 3. Biological Safety Program

In brief, the Biological Safety Program provides guidance and assistance on issues related to the use of biohazardous materials in teaching, research and related activities. The goal of the program is to minimize the risks associated with the use and maintenance of biohazardous materials. Maintain a safe and healthy work environment; and guard against the release of biohazardous material that may harm humans, animals, plants or the environment. Given other software available on Auburn's campus related to laboratory safety, Auburn may choose not to procure an IBC module.

The functions that the software solution must provide include, but are not limited to, tracking and monitoring the IBC membership; identifying IBC member terms; creation of and routing phases for protocols between/among various campus offices; identifying different protocol phases (e.g., renewals); identifying different types of protocol review; documenting protocol approval; assisting in the management of compliance committee meetings; providing ability to easily report information from the system; documenting the completion of applicable trainings; and assuring confidentiality is maintained. The ability to interact with the BIORAFT Laboratory Safety product is desired.

### 4. Research Integrity Program

The Research Integrity program is responsible for management of the financial conflict of interest disclosure and management process as mandated by university policy and sponsor regulations. Additionally, the office oversees responsible conduct of research and scientific misconduct.

### **D. Division of Laboratory Animal Health and University Veterinarian Background Information**

In brief, the University Veterinarian and Director of the Division of Laboratory Animal Health provides daily oversight and management of the Institutional Animal Program and facilities. The office is responsible for coordination of the AAALAC accreditation process as well as submission of the Research Facility Annual Report to USDA-APHIS.

The functions that the software solution must provide include, but are not limited to, tracking and monitoring of animal usage per protocol, species, and individual animal including large animals and exotics; monitoring and managing animal ordering and protocol approved animal numbers; cost accounting and management of per diems; facilities inspections and census; medical records; and ability to easily report information from the system; and assuring confidentiality is maintained.

## II. Instructions to Respondents

Auburn University invites interested parties that meet the qualifications listed in this document to submit proposals regarding their products and related service offerings, to include all-in service packages if any. All information shall be submitted in the format stipulated in this RFP. Additionally, Auburn reserves the right to procure only partial solutions from any given vendor such as a sponsored programs module but not the Human Subjects Protection module. All pricing should be module specific, as well as module bundle values, to the extent possible.

The University desires to contract with the successful firm(s) under this solicitation via any electronic methods of ordering offered by the successful firm, and to make payment for these orders using electronic funds transfer. The successful Contractor must complete the registration process through the University's vendor center at <http://www.auburnuniversity.net/vendor/>. Auburn may, at its sole option, choose to make more than one award.

### **Pre-Bid Conference:**

Please note that there will be a mandatory pre-bid conference held at 2:00 PM CST, Thursday January 16, 2020.

The meeting will be available via Zoom at the following link:

Time: Jan 16, 2020 at 02:00 PM Central Standard Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: <https://auburn.zoom.us/j/7188654085>  
Connect using Computer/Device audio if possible.

Or Telephone: Meeting ID: 718 865 4085  
Dial: +1 646 876 9923 (US Toll)  
or +1 669 900 6833 (US Toll)

Or an H.323/SIP room system:  
H.323: 162.255.37.11 (US West) or 162.255.36.11 (US East)  
Meeting ID: 718 865 4085

SIP: 7188654085@zoomcrc.com

<https://auburn.zoom.us/j/6764147091>

### **A. Proposal Overview and Definitions**

Auburn University is requesting sealed proposals from qualified firms to establish a pricing agreement (contract) with a supplier(s) to service the University's needs for a University wide ERA solution with a minimum of administrative effort and offering the highest value for the dollars expended.

Proposals will be received in the AU Procurement and Business Services office at 212 Ingram Hall, Auburn University, AL until 10:30 AM CST on February 12, 2020. Throughout the remainder of this Request for Proposal, all entities involved will be referred to as follows:

1. Auburn University will be referred to as "University" or "AU".
2. ERA providers will be referred to as "Contractor", "Vendor", "Offeror", or "Supplier".
3. This document will be referred to as "RFP".

All inquiries regarding this proposal and its contents should be directed to:

John P. Corgill  
Assistant Director, Procurement Services  
(334) 844-3561  
E-mail: [jpc0004@auburn.edu](mailto:jpc0004@auburn.edu)

## **B. Proposal Response**

1. Proposals should be addressed and delivered to Procurement and Business Services, Auburn University, 212 Ingram Hall, Auburn University, Alabama, 36849-5101, on or before the time and date set for closing. Proposals should be in a sealed envelope marked:
  - a. Company Name
  - b. RFP Number
  - c. Date and Time Proposal is Due
2. Proposers may withdraw proposals at any time prior to the time and date set for opening.
3. The University reserves the sole and exclusive right to reject or accept any or all proposals and to waive any informality in proposal. The best interest of the University and their subsequent facilities shall be considered as the number one determining factor in selecting or not selecting a Proposer.
4. No department, school, or office at the University has the authority to solicit official proposals other than Procurement and Business Services. All solicitation is performed under the direct supervision of the Executive Director of Procurement and Business Services and in complete accordance with the University policies and procedures.
5. The University reserves the right to conduct discussions with proposers, and to accept revisions of proposals, and to negotiate price changes. The University will make reasonable efforts to protect proprietary information but all records are subject to State of Alabama open records laws.
6. Proposers submitting proposals which meet the selection criteria and which are deemed to be the most advantageous to the University may be requested to give an oral presentation to a selection committee. Procurement and Business Services will schedule the presentations.
7. The University is committed to the development of Small Business and Small Disadvantaged business (SB & SDB) suppliers. If subcontracting is necessary, the contractor will make every effort to use SB & SDB in the performance of this contract. Reporting will be required throughout the duration of the contract indicating the extent of SB & SDB participation.
8. The Suppliers shall indemnify, defend, and hold harmless the University, its officers, agents, and employees from any claims, damages, and actions of any kind or nature arising from or caused by the use of any materials, goods, equipment, or services furnished by the Supplier,

provided that such liability does not attribute to the sole negligence of the University.

9. Suppliers must read and comply with all instructions, specifications, General Terms and Conditions, and Bid Conditions.

### III. Form of Proposal

#### A. Proposal Format

1. Submit one (1) original and five (5) copies of the offeror's proposal in hard copy form. Also, one (1) electronic copy on a flash drive of the proposal must be submitted to Auburn. ***Failure to include the original response, the electronic copy, and all signed copies will be grounds for rejection of your initial response without further evaluation.***
2. Original proposal and all copies must be on 8-½ x 11 text weight paper, using binding tabs that will facilitate the distribution and evaluation of the proposals.
3. The original hard copy response should be in a standard size 3 ring binder or binders, tabbed and numbered as described on the following page.
  - a. Copies must be bound but may be bound using alternative binding.
  - b. If there is any information or required submittals which due to size or binding cannot be incorporated following the proper tab, the offeror must provide information following the numbered tab, telling the evaluator where the information can be found in the response.
4. Copies may be submitted in bulk.
5. The outer carton of the response must include the name of Company, RFP number, and due date and time.
6. Questions and requests for information may not be rearranged, regrouped, or divided in any way.
7. No telephone, facsimile or telegraphic proposals will be considered. Proposals received after the time for closing will be returned to the proposer unopened.
8. Ownership of all data, materials, and documentation originated and prepared for Auburn pursuant to this RFP shall belong exclusively to Auburn. Trade secrets or proprietary information submitted by an Offeror shall not be subject to public disclosure; however, a written notice must be provided that specifically identify the data or materials to be protected and state the reasons why protection is necessary.
9. Oral Presentation: Offerors who submit a proposal in response to this RFP may be required to give an oral presentation of their proposal. This provides an opportunity for the Offeror to clarify or elaborate on the proposal but will in no way change the original proposal. This is a fact finding and explanation session only and does not include negotiation. Auburn will schedule the time and location of these presentations.
10. Oral presentations are an option of Auburn and may or may not be conducted; therefore, proposals should be complete
11. Product demonstrations may be requested to facilitate vendor product selection.

#### B. Tabular / Paginated Format

1. **Tab 1:** A one to two page executive summary of the offeror's proposal, including brief descriptions of the company's expertise procuring a contract the size and scope described in the RFP, and how the proposer plans to address the University's requirements.
2. **Tab 2:** Completed and signed cover page, vendor response/quotation page, addendum pages, & State of Alabama Vendor Disclosure Statement.



3. **Tab 3:** Contact name(s), title(s), location(s) and resume(s) of the individual(s) responsible for the company's proposal and negotiation during this RFP process.
4. **Tab 4: Financial Statements** - The financial statements of the company for the past three years. If the company is a division of a larger corporation, the statements must be submitted for the corporation as a whole **and** for that division of the corporation.
5. **Tab 5:** Complete Section VII – **Scope of Work** - Specific plans for providing the proposed services including, but not limited to (a) list of proposed services; (b) proposed approach and methodology (Project implementation methodology and timeline) (c) how the services will be performed and schedules; (d) method of initiating services; (e) any pending features in development and the time line for delivery; and (f) description of any other services not outlined in the solicitation.
6. **Tab 6: Support Services** – Please detail your Customer Support processes, including ongoing training, product support, Service Level Agreements. Assume SAAS is a preference.
7. **Tab 7: References** - A list of at least five (5) references where the Offeror has provided within the past 5 years the services described in the RFP. Include the organization, contact name, title, location, telephone number, and email address. Provide the information on past and current contracts. These should be customers in the Higher Education space.
8. **Tab 8:** Provide a proposed summary and schedule for the key activities required to implement a smooth transition should you be awarded the contract. Include and identify all action, staffing or information required from Auburn.
9. **Tab 9:** Hardware and Software Requirements – Provide details on any specific hardware or software needed to support your solution. Provide a sample license agreement.
10. **Tab 10:** Detailed Price proposal and Cost analysis, including all one time and recurring costs
11. **Tab 11:** Additional comments. Please describe in this section any significant differences or updates between the RFP response and prior responses provided under the MAY 2019 Request for Information response.
12. **Tab 12:** Data Security Questionnaire, Accessibility Questionnaire, & Accessibility Addendum as per Attachment A, B, & C. (describe cloud server security protocols)
13. **Tab 13:** Exceptions to any terms and conditions.

#### **IV. Bid Conditions**

##### **A. Functional Requirements of Contract to be Awarded Term**

The term ("Term") of this contract will be for five (5) years from the date of the last signature on the contract ("effective date"). The contract may be renewed on a yearly basis thereafter for up to three (3) additional years upon mutual signed agreement of both parties. Either party may terminate this agreement effective thirty (30) days after providing written notice to the other party that such party has breached any material provisions of this agreement if such other party fails to cure said breach within the thirty (30) day notice period. A written agreement on termination shall set forth the basis and terms of the termination as well as the timeline for closing down the project and migrating all Auburn University data back to the University. The contract may also be terminated by convenience by Auburn University. The effective date of termination for convenience shall be thirty (30) days after written notice by Auburn University. The vendor will, however, be required to honor all orders placed prior to the date of termination if required to do so by the University.

Any contract resulting from this request will be made available to other eligible entities. This may include but is not limited to; Auburn University at Montgomery, The University of Alabama System, comprised of The University of Alabama; The UAB Enterprise, consisting of The University of Alabama at Birmingham, the UAB Health System and their related foundations and affiliates , and The University of Alabama in Huntsville, Huntsville, AL; and other state entities. Contracts resulting from the award of this request cover licenses by any entity listed above. Each entity will generate its own purchase orders, payments, etc. and delivery must be made according to the instructions on the purchase order.

The thrust of the contract is to obtain greater volume price discounts by combining the volume of purchases from participating entities within the State of Alabama.

## **V. Evaluation Criteria**

The objective of this process is to identify the Best Value suppliers that can serve the University well and provide attractive pricing. The University shall determine the award after evaluating each response on the following points. For the basis of award, each of the points will be considered in the listed order:

1. 10% - After contract support and service, including ongoing user and admin training
2. 45% - Ability to meet Business and Technical requirements.
3. 40 % -Total cost, including all one time and recurring costs
4. 5% - References

Issuance of this RFP and receipt of proposals does not commit Auburn to award a contract. Auburn reserves the right to postpone receipt date, accepting or rejecting any or all proposals received in response to this RFP, or to negotiate with any of the firms submitting an RFP, or to cancel all or part of this RFP.

## VI. Calendar of Events

Task	Date
RFP Bid Issued	December 18, 2019
Questions from Vendors Due	By 4:45 PM CST January 6, 2020
Mandatory Pre-Bid Conference	January 16, 2020
Responses to Questions Received	January 22, 2020
RFP Bid Opening	February 12, 2020
Candidate Presentations	March-April 2020
Final Selection	May 2020

## VII. Scope of Work

### A. Overview

Auburn University is seeking a system that integrates the full life-cycle of compliance for the Protection of Human Subjects, the Protection of Animal Subjects, and the Institutional Biosafety Program. The University is likewise seeking a system that provides pre-award administrative and proposal development support, S2S transmission, award receipt and negotiation, post-award non-financial management support, and research integrity compliance management. The University has defined a set of requirements and desired features for the system(s), which are outlined below. Our intent is to evaluate the proposed system(s) against our requirements and choose the system that can best address our needs.

The university seeks a solution that is configurable without requiring extensive programming or code modification from the University's Office of Information Technology or Information Systems Support. It seeks a comprehensive software and architecture that minimizes the number of vendors involved.

The University is looking for a Respondent to provide a software solution that provides the functionality listed below. The solution must provide "out-of-the-box" application modules or equivalent functionality that supports the following compliance and animal order/census functions and pre/post award research administration volume and functions:

#	Name	Acronym	Function	Relevant Statistics
1	Institutional Review Board	IRB	The Auburn University IRB reviews research projects which involve human subjects to ensure that two broad standards are upheld: first, that subjects are not placed at undue risk; second, that they give un-coerced, informed consent to their participation.	Active protocols = 887/year approx  New protocols = 524/year approx  Three IRB's each meet once per month
2	Institutional Animal Care & Use Committee	IACUC	The Institutional Animal Care & Use Committee (IACUC) reviews all projects involving animals to ensure that they are justified by their benefits and minimize any animal pain or suffering that might occur. This includes research teaching and display of Auburn University-owned animals. The IACUC regularly inspects all projects using animals and all projects housing animals along with the University's Research Animal Resources staff.	Active protocols = 520/year approx.  New protocols = 337/year approx.  Modifications = 258/year approx  One IACUC meets twice per month
3	Institutional Biosafety Committee	IBC	The Institutional Biosafety Committee (IBC) reviews all projects teaching, research, and related activities involving biohazardous materials. Biohazardous materials include materials of biological origin that could potentially cause harm to humans, animals, or plants.	Active BUA's = 178/year approx.  New BUA's = 52/year approx  IBC meets once per month
4	Office of Research Compliance IRB Post Approval Monitoring	ORC IRB	The ORC provides compliance oversight, independently and in conjunction with the IRB, for research activities involving the use of human subjects. The ORC serves as an advisor and informational resource for institutional policy and regulatory requirements; provides educational opportunities, training, and investigator consultations; and serves as the administrator of the IRB. Compliance reviews are performed on any human subjects research and includes post approval monitoring for conducting post IRB approval review of studies, identify/track/report on deficiencies to be resolved.	# Records Managed=887/year Approx.

#	Name	Acronym	Function	Relevant Statistics
5	Office of Research Compliance IACUC Post Approval Monitoring	ORC IACUC	The ORC provides compliance oversight, independently and in conjunction with the IACUC, for the humane care and well-being of live vertebrate animals which are a part of the AU Animal Program. The ORC serves as an advisor and informational resource for institutional policy and regulatory requirements; provides educational opportunities, training, and investigator consultations; and serves as the administrator of the IACUC. The office conduct post IACUC approval monitoring/inspections, identify/track/report on deficiencies to be resolved.	# Records Managed= 520 Approx.
6	Division of Laboratory Animal Health	DLAH	The Division of Laboratory Animal Health is responsible for animal acquisition, housing, welfare, veterinary care, and tracking throughout the lifecycle of the laboratory animals maintained under the institutional animal care and use program. It is responsible for enforcing protocol compliance and reporting to regulatory agencies (e.g., United States Department of Agriculture (USDA), Office of Laboratory Animal Welfare (OLAW)) and accrediting bodies (e.g., Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC))	# Records Managed= 1322 animal records of various species individually and in colonies approx.  67 distinct animal facilities approx.  4 vivaria and 8 dog kennels in addition to several Agricultural Experiment Station locations around the state and along the coast of Alabama.
7	Office of Sponsored Programs	OSP	The Office of Sponsored Programs is responsible for proposal submission and award acceptance as well as non-financial post award administrations.	# proposals submitted in FY 2019 = 1219 for \$525M Award obligations in FY 2019 = \$162.5M HERD survey expenditures for FY 2018 = \$213M
8	Office of Research Integrity	ORI	The Research Integrity manager is responsible for the institutional research integrity program related to scientific misconduct, RCR training and COI	Filed FCOI disclosure questionnaires = 6000 approx  Annual disclosures = 1000 approx.  150 current management plans  RCR records maintained in CITI

For the following list of software solution attributes, please be descriptive in how the product will or will not meet our needs. If something is anticipated in a future release, please explain. If something cannot be provided, please explain. Please be as detailed as possible in the description. Note that additional on-line software demonstrations via ZOOM are probable to show our Investigators the product possibilities.

## GENERAL FUNCTIONALITY

### *USABILITY*

- 1 The solution **must** offer user a Central User Portal that allows the user to access all solution-based modules from one online access point.
- 2 The solution **must** offer a consistent and intuitive look, feel, logic, and navigation throughout all functional modules.
- 3 The solution **must** support all major browsers and portable devices
- 4 The solution **should** offer users “dashboard” views that are customizable to user’s system role.
- 5 The solution **must** offer a smart form starter template for each function that can be easily modified by administrative staff as regulations, compliance requirements, terminology, and criteria change.
- 6 The solution **should** offer a build-from-scratch smart form which can be used to accommodate changed, supplementary or supporting business processes.
- 7 The solution **should** offer functionality that allows different team members to complete different sections of the smart form without having to complete each section fully in a particular order.
- 8 The solution **should** offer context sensitive help functionality on forms that can guide users through processes.
- 9 The solution **should** offer an auto-spell check functionality.
- 10 The solution **must** allow users to easily clone prior submission documents when a new submission is similar to a prior submission.
- 11 The solution **must** offer online “Help” functionality including but not limited to:
  - a. Help link to online documentation for general help questions, e.g., PI, Faculty, Administrator, Committee Member assistance.
  - b. User reference documentation for operational assistance (Mgmt/Admin help).
  - c. Ability to embed hyperlinks to supporting sites.
  - d. Ability to embed help videos.

### *COMMUNICATION*

- 12 The solution **should** provide the ability to create and manage template-based email communications with ability for the system administrator to embed database elements directly into the email template.
- 13 The solution **should** provide email functionality including but not limited to:
  - a. Logic-based triggers for auto-notification (logic = by date, submission type, action type, action overdue, status change, etc.)
  - b. Non-template based manual email functionality
  - c. Reminder emails based on specific reminder frequencies

- 14 The solution **should** notify users via University email account that action has occurred or is required within the Solution—i.e. users receive system notifications whether or not they are operating within the system at the time.
- 15 The solution **should** be able to send auto-notification to other administrative units based on user response to application questions (e.g. notify IBC staff when user responds “Yes” to IACUC smart form question “Will recombinant DNA be used in your study?”).
- 16 The solution **should** allow the administrator to create email lists for group emails. (e.g. the system can send a specific news bulletin to research staff involved in a study or notifications about regulatory or policy changes.)

#### ***WORK FLOW / BUSINESS PROCESS MANAGEMENT***

- 17 The solution **must** provide workflow functionality which allows administrators to override elements of work flows.
- 18 The solution **must** be highly scalable to support increases in users and traffic.
- 19 The solution **must** provide flexible workflow programming including but not limited to:
  - a. Sequential workflows
  - b. Parallel workflows
  - c. Rules-driven workflows
  - d. Trigger dependency-based workflows
- 20 The solution **must** provide electronic review and approval routing
- 21 The solution **should** allow administrators to develop future business processes/work flows which augment primary workflows. This could include but not be limited to:
  - a. Form handling and process initiation.
  - b. Initial data collection and storage
  - c. Additional email communication with customers
- 22 The solution **must** be able to halt workflow if specific requirements are not met (e.g. required attachments to proposal, protocol, training requirement, immunization requirements, COI disclosure, etc.)
- 23 The solution **should** provide “Turn-around-Time” reporting that can identify bottlenecks (e.g. Submissions that are taking a long time to process, a PI that is not responding to stipulations, etc.) in workflows

#### ***DOCUMENT MANAGEMENT***

- 24 The solution **must** allow users to attach files (e.g. Word, PDF, audio, video) to submissions (e.g. documents related to smart form questionnaires, company sponsored communications, investigator brochures, consent forms, budgets, collaboration commitments, other supporting agreements, etc).
- 25 The system **should** allow for S2S submission of proposals to federal agencies in the format required by the sponsor.

#### ***QUERY – ANALYSIS – REPORTING (BUSINESS INTELLIGENCE)***

- 26 The solution **must** provide robust query functionality which will allow the user to create ad-hoc queries and reports based on any data field(s) or combination of fields across different modules as permissions allow.
- 27 The solution **must** allow users to query/report on current and historical records.
- 28 The solution **must** provide the ability to save an ad-hoc query for future use.
- 29 The solution **should** provide the ability to allow third party analysis and reporting tools for developing additional reports beyond the standard (canned) reports associated to the solution (e.g. SSRS, QLIK, Tableau, App dashboard tools, MS Excel etc. ).
- 30 The solution **should** provide the following reporting functionality:
  - a. Parameter-based reports which prompt users to select or input report criteria.
  - b. User selected output format including PDF, Word, Excel, CSV
  - c. Enables 21 CFR Part 11 signatory compliance ("Secure, computer-generated, time-stamped audit trails for (operator entries and actions) to electronic records which shall not obscure previously recorded information")
  - d. Watermark Options
  - e. "Canned" standard accreditation and regulatory reports

#### ***INTERFACING / INTEGRATION***

- 31 The solution **should** be able to interface into existing campus authentication systems.
- 32 The solution **must** support full data integration between modules within the solution.
- 33 Solution **should** provide the ability to integrate with other systems/applications in use at the university through standard API / ETL tools and/or development activities. Please identify delivered interfaces and the tools used to develop them.
- 34 Solution **should** provide an open database that can be accessed by other systems/applications within the University through standard data access calls to connect and utilize table data.
- 35 Solution **should** allow connectivity by third party reporting tools to support information access, analysis, and ad-hoc/custom reporting activities.
- 36 The solution **should** be able to interface with external 3rd party systems including but not limited to:
  - a. Single Sign On, LDAP
  - b. University Financials database
  - c. Grants.gov S2S system
  - d. CITI (Collaborative Institutional Training Initiative) (**highly desirable integration**)
  - e. AALAS (American Association for Laboratory Animal Science) Learning Library

#### ***PERMISSIONS/ROLE MANAGEMENT***

- 37 The solution **must** support role-based permissions.
- 38 The solution **must** support multiple roles per user.
- 39 The solution **should** allow the System Administrator to perform non-code altering updates (e.g. Modify value lists for form controls, etc.)

#### ***DATA QUALITY BEST PRACTICES***

- 40 The solution **must** be able to accommodate different combination of letters & numbers as well as special characters and scientific symbols. Generating unique auto-ID fields for every record & have the ability to add custom pre-fix and suffix



- 41 The solution **must** provide auto-review data/field validation within smart forms and management screens. Validation rules **should** include but **should** not be limited to:
- a. Required field
  - b. Validation of data type (e.g. alpha vs. numeric)
- 42 The solution **must** allow the System Administrator to set auto-review validation criteria.
- 43 The solution **should** manage data in a manner that requires the user to enter unique data a single time and be able to reference and have it auto-populated across all modules.
- 44 The solution reports **should** provide the following functionality around value lists (list boxes, combo boxes, pick lists, etc.):
- a. Values **should** be table driven and reusable (rather than embedded into single form control).
  - b. Values **should** be query-driven (allowing the system Administrator to sort by alpha/numeric, exclude values where “active” = “no”, etc.)
  - c. **Should** allow user to select multiple values where programmed business rule allows multiple values.
- 45 The solution **must** offer functionality that enables HIPAA compliance as needed
- 46 The solution **should** accommodate the use of “flat” signatures generated by “Adobe-Acrobat Self-sign plug in.

#### **SECURITY**

- 47 The solution **should** be prepared to address the CMMC data security framework (<https://www.acq.osd.mil/cmmc/index.html>) directly or through proper segregation and data protection in the cloud.
- 48 Vendor’s CSP **must** be FedRamp authorized at moderate or high level.
- 49 The vendor **must** provide satisfactory answers to the Data Security Questionnaire, included in this RFP
- 50 The solution **must** provide Single Sign On (CAS preferred)
- 51 The solution **should** provide two Factor Authentication (Duo preferred)
- 52 The solution **should** allow control access down to the field level
- 53 The solution **should** provide the ability to manage data through Access and Permission levels, including Read Only, Read/Write access by user or by role.
- 54 System administrators **should** have the capability for auditing/audit logs of tables, and users as well as at the database application level.
- 55 The solution **should** be network Redundant, 100% multi-tenant, cloud based
- 56 The solution **should** provide the ability to segment data according to a data security model.
- 57 The solution **should** provide the ability for files to be attached to records but only viewable by those with appropriate permission levels.
- 58 Please provide business continuity plans and disaster recovery processes.
- 59 All Auburn University data **must** be stored within the CONUS.

#### **TECHNICAL SUPPORT AND TRAINING**

- 60 The vendor **must** provide details about service level agreements and technical support.
- 61 The vendor **must** provide details related to training process, materials, and online help.
- 62 Support **should** be free and on demand with customizable training.
- 63 Support **should** be available 24/7 for systems related concerns and during regular business hours (central time) for user concerns.

## **SYSTEM AND INTEGRATIONS**

- 64 Upgrades **should** be seamless and occur multiple times per year to enhance system functionality and, as necessary, for bug fixes and security patches.
- 65 Solution **should** provide the ability to change all field and tab labels to reflect internal terminology/vocabulary
- 66 The solution **should** provide documented web services based API for completing custom integration with other applications as well as publicly open APIs: The API must be publically accessible and freely available to encourage innovation and partnership
- 67 The solution **must** allow that all configuration changes be protected across all upgrades
- 68 Integrations **should** be provided for access to a variety of third party applications and systems, via web systems or API, including, but not limited to:
  - Banner (ERP)
  - a. Qualtrics (surveys)
  - b. Qlik and other business analytics tools
  - c. Adobe forms
  - d. MS Outlook
  - e. L. MS Excel
  - f. MS Word
  - g. Azure
  - h. AWS gov cloud
  - i. Sophia software from Wellspring (Patent Application Management)
  - j. BIORAFT Laboratory safety management
- 69 Vendor **should** provide a high level architecture diagram of the solution

## **DATA OWNERSHIP AND MANAGEMENT**

- 70 All data entered into the solution is the sole possession of the University. Vendor **must** agree not to use or disclose Auburn data without Auburn's written permission.
- 71 Vendor **must** provide a mechanism for returning all data at the end of the contract. The mechanism must provide for automated load into a relational database system.
- 72 Any breach of vendor system **must** be reported to Auburn's Chief Information Security Officer in accordance with The Alabama Data Breach Notification Act and the European Union General Data Protection Regulation.

## **INSTITUTIONAL REVIEW BOARD (IRB)**

### **SUBMISSION**

- 1 The solution **must** allow user to create an initial IRB protocol online using a smart form or dynamic questionnaire that guides user to answer questions that are specific to their study type and detail.
- 2 The solution **must** allow the user to create an initial protocol over time including but not limited to the following functions:
  - a. Edit saved drafts
  - b. Delete saved drafts
  - c. Clone previously created protocol
- 3 The solution **should** provide user with mandatory submission process "checklists" that guide user and ensure that all necessary information, attachments, etc. have been included.

- 4 The solution **must** allow the addition of attachments such as consent documents/information letters, recruitment materials, site approval letters, and other documentation.

#### ***PRE-APPROVAL***

- 5 The solution **must** allow the user to submit the protocol online.
- 6 The solution **should** allow user to view (read-only) current status for all of their submissions (e.g., initial protocol, change requests).
- 7 The solution **should** allow user to view auditable submission history throughout study lifecycle (both pre- and post-approval).
- 8 The solution **should** allow user to modify information on submitted but pre-approved protocol (e.g., title, staff, funding).
- 9 The solution **should** allow other authorized users listed in the contacts on protocol to view (read-only) or edit based on privileges.
- 10 The solution **should** allow the ORC staff and committee members to view (read-only) comments and stipulations by other committee/staff members (both pre-and post-approval).
- 11 The solution **should** allow user to respond to the ORC staff's comments and/or committee stipulations.
- 12 The solution **must** allow for tracking of other approvals associated with protocols (i.e. IBC, radiation safety, etc.)

#### ***ASSESS SUBMISSION & ASSIGN REVIEW LEVEL, REVIEWER & COMMITTEE***

- 13 The solution **must** allow ORC staff to view (pre-review) and modify submitted protocols.
- 14 The solution **must** allow ORC staff to create review committees.
- 15 The solution **must** allow ORC staff to modify review committees (e.g., alter membership, roles, and permissions).
- 16 The solution **must** allow ORC staff to specify review type for each protocol (e.g., determine if protocol **should** be routed to Full Committee, Designated or Administrative).

#### ***MEETING PREPARATION***

- 17 The solution **must** allow ORC staff to assign review(s) for each protocol.
- 18 The solution **must** allow section-specific reviewer comments to be compiled in a "study-specific reviewer comments" report to be used at committee meetings.
- 19 The solution **must** allow ORC staff to assign multiple roles to a committee member.
- 20 The solution **should** allow ORC staff the option to allow committee members to electronically vote on review decision (full review or designated review)
- 21 The solution **must** allow committee members to view meeting agenda online.
- 22 The solution **must** allow ORC staff to send the protocol and supporting documents/attachments to committee members electronically for review (e.g., MS Word, PDF)
- 23 The solution **must** allow ORC staff/IRB chair(s) to create review meetings, including but not limited to:
  - a. Assign primary reviewers, secondary reviewers and expert reviewers
  - b. Specify meeting date
  - c. Email meeting invite to reviewers/committee
  - d. Create agenda (specify and/or auto-generate
  - e. Assign agenda
  - f. Email agenda to committee
  - g. Print meeting agenda (as PDF, MS Word)

## **COMMITTEE REVIEW**

- 24 The solution **should** allow ORC staff to capture and manage committee meeting minutes in real time during review.
- 25 The solution **should** allow for side-by-side comparisons of original protocol submission and revisions made pursuant to reviewer or committee comments/requirements.

## **POST-APPROVAL STUDY LIFECYCLE MANAGEMENT (HUMAN SUBJECTS)**

- 26 The solution **must** allow user to view/print study approval letter.
- 27 The solution **must** allow user to create and submit online Continuing Review and Amendment request utilizing a smart form.
- 28 The solution **must** allow user to create and submit online events notification using smart form.
- 29 The solution **must** allow user to close approved study (post-approval).

## **POST-APPROVAL MONITORING AND DEFICIENCY TRACKING**

- 30 The solution **must** provide a standard (out-of-the-box) Human Subjects Research Compliance functional module for post-approval review and deficiency tracking functionality.
- 31 The solution **must** allow ORC staff to select approved studies for post-approval compliance review process using queries of any single data field or combination of fields.
- 32 The solution **should** allow user to create a checklist that can be used to create study review report.
- 33 The solution **should** allow reviewer to generate template-based review checklists and pre-populate with study-specific information.
- 34 The solution **should** allow ORC staff to document deficiencies identified in post-approval review and these deficiencies **should** be viewable (with appropriate permissions) across modules.
- 35 The solution **should** allow management to specify required action to resolve deficiency, verify deficiency has been resolved, and close out deficiency.
- 36 The solution **should** track due dates for deficiency required actions and send auto-notifications when due dates are pending/overdue.

## **INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)**

### **SUBMISSION**

- 37 The solution **must** allow user to create an initial IACUC protocol online using a smart form or dynamic questionnaire that guides user to answer questions that are specific to their study type and detail.
- 38 The solution **must** allow the user to create an initial protocol including but not limited to the following functions:
  - a. Edit saved drafts
  - b. Delete saved drafts
  - c. Clone previously created protocol
- 39 The solution **should** provide user with mandatory submission process "checklists" that guide user and ensure that all necessary information, attachments, etc. have been included.

### **PRE-APPROVAL**

- 40 The solution **must** allow the user to submit the initial protocol online.
- 41 The solution **should** allow user to view (read-only) current status for all of their submissions (e.g., initial protocol, change requests).

- 42 The solution **should** allow user to view auditable submission history throughout study lifecycle (both pre- and post-approval).
- 43 The solution **should** allow entering and tracking USDA pain and distress categories.
- 44 The solution **should** allow customizable drop down animal procedures that can be selected and will auto-populate with data from other parts of the protocol that was filled in.
- 45 The solution **should** allow for pre-approved animal procedure.
- 46 The solution **should** allow other authorized users listed in the contacts on protocol to view (read-only) or edit based on privileges.
- 47 The solution **should** allow ORC staff and committee members to view (read-only) comments and stipulations by other committee/staff members (both pre-and post-approval).
- 48 The solution **should** allow user to respond to ORC staff comments and/or committee stipulations.
- 49 The solution **must** allow for tracking of other approvals associated with protocols (i.e. IBC, radiation safety, etc.)

#### ***ASSESS SUBMISSION & ASSIGN REVIEW LEVEL, REVIEWER & COMMITTEE***

- 50 The solution **must** allow ORC staff to view (pre-review) and modify submitted protocols.
- 51 The solution **must** allow ORC staff to create review committees.
- 52 The solution **must** allow ORC staff to modify review committees (e.g., alter membership, roles, and permissions).
- 53 The solution **must** allow ORC staff to specify review type for each protocol (e.g., determine if protocol **should** be routed to Full Committee rather than Designated Member Review).

#### ***MEETING PREPARATION***

- 54 The solution **must** allow ORC staff to assign reviewer(s) for each protocol and/or amendment.
- 55 The solution **must** allow ORC staff to assign multiple roles to a committee member.
- 56 The solution **should** allow ORC staff the option to allow committee members to electronically vote on review decision (full review or designated review)
- 57 The solution **must** allow committee members to view agenda online.
- 58 The solution **must** allow ORC staff to send protocol and supporting documents/attachments to committee members electronically for review (e.g., MS Word, PDF)
- 59 The solution **must** allow ORC staff to create IACUC meetings, including but not limited to:
  - a. Assign reviewers/committee
  - b. Specify meeting date
  - c. Email meeting invite to reviewers/committee
  - d. Create agenda (specify and/or auto-generate)
  - e. Assign agenda
  - f. Email agenda to committee
  - g. Print meeting agenda (as PDF, MS Word)

#### ***COMMITTEE REVIEW***

- 60 The solution **should** allow ORC staff to capture and manage committee review meeting minutes.
- 61 The solution **should** allow for side-by-side comparisons of original protocol submission and revisions made pursuant to reviewer or committee comments/requirements.

#### ***POST-APPROVAL STUDY LIFECYCLE MANAGEMENT***

- 62 The solution **must** allow user to view/print study approval letter.

- 63 The solution **must** allow user to create and submit online Continuing Review and Amendment utilizing a smart form.
- 64 The solution **must** allow user to close approved study (post-approval).
- 65 The solution **should** allow user/ ORC staff to report on animal subjects including but not limited to:
  - a. Number of animals requested
  - b. Number of animals transferred

#### ***POST-APPROVAL & SEMI ANNUAL INSPECTION MONITORING AND DEFICIENCY TRACKING***

- 66 The solution **must** provide a standard (out-of-the-box) Animal Subjects Research Compliance functional module or equivalent post-approval review and deficiency tracking functionality.
- 67 The solution **must** allow ORC staff to select approved studies for post-approval compliance review process using queries of any single data field or combination of fields.
- 68 The solution **should** allow reviewer to generate template-based review checklists and pre-populate with study-specific information.
- 69 The solution **should** allow user to create an inspection report post-review from the review checklist.
- 70 The solution **should** allow ORC staff/auditor to document deficiencies identified in post-approval review and these deficiencies **should** be viewable (with appropriate permissions) across modules.
- 71 The solution **should** allow management to specify required action to resolve deficiency, verify deficiency has been resolved, and close out deficiency.
- 72 The solution **should** track due dates for deficiency required actions and send auto-notifications when due dates are pending/overdue.
- 73 The solution **should** allow the users to manage, change, track, and trend a variety of categories generated from the compliance reviews.

### **DIVISION OF LABORATORY ANIMAL RESOURCE MANAGEMENT (DLAR)**

#### ***ANIMAL REQUISITION AND ORDERING***

- 1. The solution **must** provide a standard (out-of-the-box) Laboratory Animal Resource Management functional module for animal requisition, ordering, animal transfer, census, cage card creation and billing functionality.
- 2. The solution **should** provide integration with the IACUC system automatically pulling all necessary data for animal ordering (e.g. protocol number, protocol title, species approved, number of animals approved, etc.) through direct interaction or through API if third party IACUC.
- 3. The solution **must** provide automatic tracking and display of number of animals approved, animal balance remaining, requested animals that need to be ordered and number of animals to be received.
- 4. The solution **must** provide a process for submission of animal requisition & ordering
- 5. The solution **must** provide a process to assure that animal numbers/species are validated
- 6. The solution **must** provide a visual indicator showing number of animal balance remaining for order
- 7. The solution **should** provide a form for submission or **should** generate a Purchase requisition as needed in the Universities format.
- 8. The solution **should** provide internal clarification request and response workflow between animal staff and PI
- 9. The solution **must** provide a mechanism to record confirmation of receipt of animals

#### ***ANIMAL RECEIVING***

10. The solution **must** provide the following:
- a. Animal Transfer Functionality for PI to PI, Protocol to Protocol and Location to Location
  - b. Print Cage Card functionality before or after receiving order
  - c. Cage Splits (Weaning/Protocol)
  - d. Quarantine Animals
  - e. Unique identification for large animals and farm herd animals

#### ***INVENTORY/CENSUS***

11. The solution **must** provide the following:
- a. Ability to add to Inventory & Receiving
  - b. Census for large animals, exotics, farm herds, and laboratory animals
  - c. Check in / Out & Deactivation with Bar-coding
  - d. Check in / Out & Deactivation with wireless RFID
  - e. Mobile scanning device and app support for iPhone, iPad, iPod
  - f. Animal Transfer Functionality for PI to PI, Protocol to Protocol, Location to Location and Externally

#### ***BILLING***

12. The solution **must** provide the following:
- a. Billing Functionality for animal orders, supplies, service, etc.
  - b. Billing Account Setup & Management
  - c. Setup and use functionality for per diem charges, service charges and supply charges
  - d. Credit & Adjustment Functionality
  - e. Ability to automate transfer of financial data (orders/debits/credits) to outside financial system.
13. The solution **must** have the capability to track costs, and time study data to allow for calculation of service center rates.
14. The solution **should** have the capability to assess and assign workflow for vivaria staff and veterinary technicians.
15. The solution **should** include medical recordkeeping for species maintained in a vivarium setting.

#### ***REPORTS***

16. The solution **should** provide the following:
- a. Annual USDA Reports
  - b. Pending for Order Report
  - c. Fully ordered requisitions Report
  - d. Fully received orders Report
  - e. Delivery schedule for receiving, cage wash, barcodes report
  - f. Room Census Report
  - g. Monthly Census Report
  - h. Cage Card Report
  - i. Unused Barcodes Report
  - j. Quarantine Data Report
  - k. Euthanized Species Report
  - l. Species By Cost Code Report
  - m. Invoices Report
  - n. Monthly Service Report
  - o. Billing Distribution Report

- p. Facilities Inspection reports and checklist
- q. Investigator annual animal usage reports
- r. Semi-annual program review report and checklist

## **INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

### ***SUBMISSION***

- 74 The solution **must** allow user to create an initial IBC protocol online using a smart form or dynamic questionnaire that guides user to answer questions that are specific to their study type and detail.
- 75 The solution **must** allow the user to create an initial protocol over time including but not limited to the following functions:
  - a. Edit saved drafts
  - b. Delete saved drafts
  - c. Clone previously created protocol
  - d. Assign sections to various research team members for completion
- 76 The solution **should** provide user with mandatory submission process "checklists" that guide user and ensure that all necessary information, attachments, etc. have been included.
- 77 The solution **should** allow the user to submit the initial protocol online utilizing smart forms
- 78 The solution **should** allow user to view (read-only) current status for all of their submissions (e.g., initial protocol, change requests).
- 79 The solution **should** allow user to view auditable submission history throughout study lifecycle (both pre- and post-approval).
- 80 The solution **should** allow other authorized users listed in the contacts on protocol to view (read-only) or edit based on privileges.
- 81 The solution **should** allow ORC staff and committee members to view (read-only) comments and stipulations by other committee/staff members (both pre-and post-approval).
- 82 The solution **should** allow user to respond to ORC staff comments and/or committee stipulations.

### ***Assess Submission & Assign Review Level, Reviewer & Committee***

- 83 The solution **must** allow ORC staff to view (pre-review) and modify submitted protocols.
- 84 The solution **should** allow for subsets of full protocol be accessible to roles with appropriate permissions.
- 85 The solution **must** allow ORC staff to create review committees.
- 86 The solution **must** allow ORC staff to modify review committees (e.g., alter membership, roles, and permissions).
- 87 The solution **must** allow ORC staff to specify review type for each protocol (e.g., determine if protocol **should** be routed to Full Committee rather than Biosafety Officer Review).

### ***MEETING PREPARATION***

- 88 The solution **must** allow ORC staff to assign review(s) for each protocol.
- 89 The solution **should** allow users of various roles to enter section-specific comments throughout the process (pre-review through review).
- 90 The solution **should** allow section-specific reviewer comments to be compiled in a "study-specific reviewer comments" report to be used at committee meetings.
- 91 The solution **should** allow ORC staff to assign multiple roles to a committee member.
- 92 The solution **should** allow committee members to view review agenda online.
- 93 The solution **should** allow ORC staff to send protocol and supporting documents/attachments to committee members electronically for review (e.g., MS Word, PDF).



- 94 The solution **should** provide a lock/unlock feature for editing the protocol (and related attachments) during review periods.
- 95 The solution **must** allow ORC staff to create review meetings, including but not limited to:
  - a. Assign reviewers/committee
  - b. Specify meeting date
  - c. Email meeting invite to reviewers/committee
  - d. Create agenda (specify and/or auto-generate
  - e. Assign agenda
  - f. Email agenda to committee
  - g. Print meeting agenda (as PDF, MS Word)

#### ***COMMITTEE REVIEW***

- 96 The solution **should** allow ORC staff to capture and manage committee review meeting minutes.
- 97 The solution **should** allow for side-by-side comparisons of original protocol submission and revisions made pursuant to reviewer or committee comments/requirements.

#### ***POST-APPROVAL STUDY LIFECYCLE MANAGEMENT***

- 98 The solution **must** allow user to view/print study approval letter.
- 99 The solution **must** allow user to modify information on approved study with appropriate management review/validation (e.g., title, staff, protocol).
- 100 The solution **must** allow user to create and submit online Continuing Review and Amendment form via smart form.
- 101 The solution **must** allow user to create and submit online Incident Report via a smart form.
- 102 The solution **should** allow user/ ORC staff to report on biosafety information including but not limited to:
  - a. Recombinant DNA
  - b. Gene Transfer
  - c. Infectious Agents
  - d. Biological Toxins

#### ***RESEARCH INTEGRITY AND FINANCIAL CONFLICT OF INTEREST/COMMITMENT***

##### ***SUBMISSION***

- 103 The solution **must** allow user to complete an initial Financial Interest Disclosure online using a smart form or dynamic questionnaire that guides user to answer questions that are specific to their financial interests.
- 104 The solution **must** allow the user to complete an initial disclosure over time including but not limited to the following functions:
  - a. Edit saved drafts
  - b. Delete saved drafts
  - c. Clone previously created disclosures
- 105 The solution **should** provide user with mandatory submission process "checklists" that guide user and ensure that all necessary information, attachments, etc. have been included.
- 106 The solution **must** allow the user to submit the disclosure online utilizing smart forms
- 107 The solution **must** allow user to view disclosure history
- 108 The solution **should** allow other authorized users to view (read-only) and approve for further workflow routing based on privileges.

- 109 The solution **should** allow ORC/ORI staff to view (read-only) and comment on disclosed information.
- 110 The solution **should** allow user to respond to ORC/ORI staff comments.
- 111 The solution **must** allow ORC/ORI staff to create a review committee and assign permissions to committee members for access to the disclosure as needed.
- 112 The solution **must** allow ORC/ORI staff to modify review committees (e.g., alter membership, roles, and permissions).

#### ***COMMITTEE MEETING PREPARATION***

- 113 The solution **should** allow committee members to enter section-specific comments throughout the review process
- 114 The solution **should** allow section-specific reviewer comments to be compiled in a summary report to be used at committee meetings.
- 115 The solution **should** allow ORC/ORI staff to assign multiple roles to a committee member.
- 116 The solution **must** allow committee members to view review agenda online.
- 117 The solution **must** allow ORC/ORI staff to send the financial interest questionnaire and supporting documents/attachments to committee members electronically for review (e.g., MS Word, PDF).
- 118 The solution **must** allow ORC/ORI staff to create meetings, including but not limited to:
  - a. Assign committee members and permissions
  - b. Specify meeting date
  - c. Email meeting invite to committee members
  - d. Create agenda (specify and/or auto-generate
  - e. Email agenda to committee
  - f. Print meeting agenda (as PDF, MS Word)

#### ***COMMITTEE REVIEW***

- 119 The solution **should** allow ORC/ORI staff to capture and manage committee meeting minutes.

#### ***POST-DISCLOSURE LIFECYCLE MANAGEMENT***

- 120 The solution **must** allow user to create and submit online updates to the financial interest questionnaire
- 121 The solution **must** allow ORC/ORI staff to create a report and summary of actions related to potential COI.
- 122 The solution **should** allow user/ ORC staff to create a COI management plan and route electronically for review and approval by various personnel to be assigned by ORC/ORI staff.
- 123 The solution **should** allow for reporting of all disclosure questionnaires, identified COI, management plans, and status of pending or completed actions related to the COI process from beginning through the lifecycle of the user's disclosed financial interests.
- 124 The solution **should** allow for distribution of disclosure reports via the web
- 125 The solution **must** allow for automation of electronic reminders to users
- 126 The solution **should** allow for escalation in the review process
- 127 The solution **should** provide a reviewer dashboard for tracking compliance
- 128 The solution **should** allow for annual COR report for federal funding agencies
- 129 The solution **should** provide management plan templates.

#### ***CONFIGURATION***

- 130 The solution **should** natively integrate with Sponsored Programs module
- 131 The solution **should** natively integrate with IRB and IACUC modules
- 132 The solution **must** provide COI/COC disclosure templates with branching logic
- 133 The solution **must** allow ORC/ORI staff to create custom disclosures with branching logic.

#### ***RESPONSIBLE CONDUCT OF RESEARCH (RCR)***

- 134 The solution **must** integrate with CITI
- 135 ORC/ORI staff **must** be able to track users training records monitoring and notifying others when training is due or delinquent
- 136 The solution **must** provide reporting capabilities for management of completed and outstanding training
- 137 The solution **must** allow ORC/ORI staff to assign others to review the training records based upon permissions
- 138 The solution **must** provide electronic communications for management of RCR within the system and across the campus.

#### ***SPONSORED PROGRAMS PRE- AND POST-AWARD (OSP)***

##### ***Pre-award proposal development and submission***

- 139. The solution **should** provide a user interface for collection of information related to proposal development consisting of, but not limited to, the following:
  - a. Unique identifier for project or proposal
  - b. Investigator names with identifying characteristics such as home department, college, Banner HR information. There should be no limit to the number of investigators allowed. Ability to assign credit splits is **desired**.
  - c. Performing unit such as a specific center or institute
  - d. Budget detail with provision for automatic calculations and escalations
  - e. Cost sharing and matching budget details and commitments
  - f. Ability to download budgets into excel or csv
  - g. Collection of data related to personnel effort
  - h. Ability to upload documents such as proposal narrative in native format
  - i. Approvals from department heads and deans as well as central administration including electronic signatures as needed
- 140. The solution **should** provide hard and soft stops in workflow related to institutional or sponsor defined proposal requirements such as certification of training or COI disclosure.
- 141. The solution **should** provide for proposal review and modification during the development and routing lifecycle
- 142. The solution **should** allow for collaborators to work on the proposal simultaneously
- 143. Communication related to proposal development, review and approval **should** be maintained within the system or through institutional email
- 144. The solution **should** provide for notifications of proposal deadlines and allow for bypassing the routing by the system administrator if needed.
- 145. The solution **should** provide a visual of where a proposal is within the submission process.
- 146. The solution **should** provide S2S as well as a mechanism for proposal submission where S2S is not an option such as non-federal or private sponsors

147. The solution **must** store proposals and allow for the identification of the status during the proposal lifecycle (e.g. pending, awarded, denied, etc.)
148. The solution **should** allow for the cloning of submitted proposals for modification of a resubmission or for starting a new submission.
149. The system administrator **must** be able to edit or delete saved proposals.
150. The solution **should** provide for standard proposal templates and a checklist for institutional requirements when a particular sponsor does not provide specifications or format guidance to assure all pertinent parts of a quality proposal have been examined and prepared as needed.
151. The solution **should** provide for subcontracting and collaboration from outside parties including the exchange of documents and potential login capability from an outside user assuming institutional security will allow such.
152. The solution **should** provide a logical road map or checklist for preparation and submission of a proposal assisting the investigator in following prescribed steps for proposal development.
153. Approvals from and/or notifications to other offices required during development may be required so those offices **should** have a mechanism for engaging during the proposal development process.
154. Proposal identification **should** include title as well as keywords to describe the general areas of discipline
155. The proposal records **should** capture field of science codes as used in the HERD survey
156. Proposal records **should** identify any particular security concerns such as export control, classified work, or publication restrictions
157. Proposals involving GXP or FDA compliance **should** be specifically identified and appropriate campus offices notified as with IRB, IACUC and IBC.
158. Proposals requiring specialized facilities **should** be identified with specific offices notified during proposal routing.

***Post-award agreement acceptance, negotiation and fund establishment***

159. The solution **must** populate data in the award record from information generated within the proposal record but also allow for creation of an award record where no proposal first existed.
160. Communications related to award negotiation and acceptance internally and with sponsors **should** be maintained within the system
161. The solution **should** capture data related to Investigator effort, credit distribution of the awarded amount amongst investigators, departments and colleges. That is, the solution **should** allow for allocation of credit amongst multiple Investigators, departments and colleges that is separate from an allocation of effort and/or an allocation of F&A return.
162. The solution **should** capture data related to the function of the work being conducted (e.g. research, instruction, outreach/service, cooperative extension)
163. Communication between the sponsored programs office and other campus offices **should** take place within the system to facilitate fund establishment and problem resolution
164. The solution **should** have the ability to generate agreements as needed using standard templates or smart forms created by the institution.
165. The award records **should** capture field of science codes as used in the HERD survey
166. Award records **should** identify any particular security concerns such as export control, classified work, or publication restrictions
167. Awards involving GXP or FDA compliance **should** be specifically identified and appropriate campus offices notified as with IRB, IACUC and IBC.

- 168. Awards requiring specialized facilities **should** be identified with specific offices notified during processing.
- 169. The solution **should** provide the ability to split awards between multiple funds/accounts in the system.
- 170. The solution **should** provide the ability to codify projects by type of function or activity as well as off campus or on campus and any other specialized characteristics such as classified or security risk.
- 171. The solution **should** integrate with Banner for post-award data transfer from pre-award for fund establishment.

#### ***Subcontracting and Subrecipient Monitoring***

- 172. The solution **must** allow for the creation of subcontracts at the same general time as the processing of the award
- 173. The solution **must** allow for use of FDP templates for subagreements
- 174. The solution **must** track information related to and characteristics of the subcontractor including contact information and F&A rate agreements, duns number, small or disadvantages status, type of entity etc.
- 175. The solution **should** provide for the ability to track and manage the financial as well as scientific engagements with the subrecipient. Tracking of amounts due and paid are important as is performance milestones or reports due.
- 176. The solution **should** provide checklists for management of subcontracts including possible records related to subcontractor selection are critical.
- 177. Communication with Investigators related to subrecipient performance and approval of payment is **desired**.

#### ***Reporting***

- 178. The solution **should** provide reports related to proposals and awards must cross over modules for comprehensive data analysis
- 179. The solution **should** assist Investigators in meeting the deadlines, preparation and submission of technical reports.
- 180. The solution **should** provide a dashboard of pending items must be included to assist in transparency to the campus community.
- 181. The solution **should** provide reporting by investigator characteristics, proposals, awards, dollars, agencies, agency types, functional descriptions of the work, related compliance protocols, scientific keywords and other data elements describing the entire sponsored programs portfolio are critical and currently available in our existing home grown system.

#### ***Sponsoring agency records***

- 182. The solution **must** allow for record management of sponsoring entities from contact information to entity type and segregation of records for subsidiaries and subagencies (e.g. subagencies under DOD or PHS and regional offices of corporations or foundations)
- 183. The solution **should** provide the ability to document and report on equipment procurements under sponsored awards by source of funding and ownership.

### ***Archiving and close out of records***

184. The solution **should** provide for date stamped archiving and storage maintenance of closed files
185. The solution **should** provide date stamped notifications of critical dates in the lifecycle of a project from technical and administrative reporting to closeout procedures and long term data storage and retrieval

## **Section VII. AU General Terms and Conditions**

### **1.0 – General Terms and Conditions**

1.1 – These terms and conditions are hereby incorporated into this quote/bid and apply in like force to any subsequent contract order resulting from this bid quote/bid. Some conditions listed herein may not apply due to the nature of the product or service, or the manner in which it is procured.

1.2 – Whenever and wherever items of materials or equipment have been identified by describing a proprietary product, the identification is intended to be descriptive, but not restrictive, and is used to indicate the quality and characteristics of products that will be satisfactory to the University. Bids offering equal or alternate materials and equipment will be considered for award provided such items are clearly identified in the bids, and are determined by Auburn University to be of equal value in all material respects to the proprietary items specified.

Unless the firm submitting the bid has clearly indicated in its bid that it is offering an “equal,” or “alternate” items the bid shall be considered as offering the items as specified in the invitation for bids/ quotations.

If the firm submitting the bid plans to furnish an equal or alternate items , the brand name and identifying numbers and/or letters are to be inserted in the spaces provided or shall be otherwise clearly identified in the bid. The evaluation of the bids and the determination as to quality of the product offered shall be the responsibility of Auburn University. The bid award shall be based on the information furnished by the bidder or identified in the bid, as well as information reasonably available to the Procurement Services.

1.3 – The University will consider acceptable substitutes that meet, or exceed the quality of materials and workmanship of the items specified in

the bid/quotation. Substitutions shall be of the same general design, size and style.

All proposed substitutes submitted must be accompanied by illustrations showing the design and style. Each illustration is to have on it, or attached to it, the item number of the specified piece to which it is an alternate. Sizes shall also be included.

All substitutes shall be listed in the spaces provided. Should additional space be required, the bidder shall use separate sheet of paper to list alternates. Any additional list should be prepared in like form to the bid document.

Auburn University will consider all proposed; however, it is not bound to any which, in the University’s opinion, is not in the University’s best interest.

1.4 – Any deviation from these general terms and conditions or exceptions taken shall be described fully and appended to the bid form on the bidder’s letterhead and over the signature of the person authorized to sign the bid form. Such appendages shall be considered part of the bidder’s bid form. In the absence of any statement of deviation or exception, the bid shall be accepted as being in strict compliance with all terms and conditions.

1.5 – There are no Federal or State laws that prohibit vendors from submitting bids/quotes lower than a price or bid given to the U. S. Government.

1.6 – The successful bidder may be required to furnish a monthly or quarterly summary of purchases made under the provision of the contract. The format and frequency of the report will be determined by the University.

1.7 – Auburn University reserves the right to require a performance bond from the successful bidder at the discretion of the University’s Procurement

Professional. Unless specifically to the contrary in the bid documents, the cost of the bond shall be paid for entirely by the successful bidder.

When required, the proper and timely submission of any performance and payment bonds is a material condition for award/performance of this order. Vendor is not authorized to proceed with work and/or deliveries unless all required bonds have been obtained, are acceptable to and received by the University.

1.8 – Failure of the successful bidder to adhere to delivery schedules as specified or to promptly replace rejected materials shall render the successful bidder liable for the difference between the “open market” and the quoted price where emergency purchases become necessary.

1.9 - Any and all items received under a resulting contract will be subject to inspection and testing to determine the quality and to ascertain that they meet specifications.

1.10 – Samples, when required, must be furnished free of expense after the opening of the bid and if not destroyed, will upon request, be returned at the bidder’s expense. Request for the return of samples must be made within ten days following the opening of bids/quotation, unless otherwise stated. Each individual sample must be labeled with the bidder’s name and item number.

1.11 – Deliveries shall be F.O.B. Auburn University (destination). Delivery by the successful bidder to the common carrier will not constitute delivery to the University.

1.12 - Successful bidder must agree to replace, free of charge, all defective items delivered under contract. All transportation charges covering return and replacement of items is to be done by the successful bidder.

1.13 - Payment for any item delivered may be withheld until all items and conditions have been complied with in full.

1.14 - It is agreed and understood that the bidders may attend the bid opening and may inspect the bid tabulation. However, no information will be given out as to opinion concerning the ultimate outcome while consideration of the award is in progress. Information regarding disposition will be available after an award is made and upon request.

1.15 – The successful bidder shall maintain, or have available for his own use, an inventory sufficient to make delivery within the time specified in this bid/quotation, provided that no default shall occur to deliver in less than the number of days stated in this bid/quotation from the date of receipt of notice to ship/deliver.

1.16 – Auburn University is not necessarily bound to accept the lowest bid if that bid is contrary to the best interest of the University. In making an award, intangible factors such as the service capability, integrity, facilities, equipment, reputation and past performance of the firm submitting the bid may be weighed. When other factors are clearly stated in the bid document, they will also be used in determining an award.

In the case of a tie for low cost, the Procurement Official may use the following: If one of the bidders has an existing contract and performance on an existing contract is satisfactory, this bidder gets the award.

Conversely, if performance on an existing contract is documented as not satisfactory, award goes to the other tie bidder. If one tie bidder is local, preference may be given to that bidder.

1.17 – All additional charges such as shipping, installation, insurance or other cost must be fully itemized with the bid/quote. Charges not specified at the time of the bid/quote will not be honored.

1.18 – It is mutually agreed by and between Auburn University and the bidder that the University’s acceptance of the bidder’s offer by the issuance of a Purchase Order shall create a contract between the two parties. Any exceptions taken by the bidder, which are not included in the Purchase Order, will not be a part of the contract. Therefore, in the event of a conflict between the terms and conditions of this bid/quote and information submitted by a bidder, the terms and conditions of this bid/quotation and resulting Purchase Order will govern.

1.19 – The successful bidder must provide service manuals with full documentation and schematics when applicable and appropriate.

1.20 – The apparent silence of this specification and any supplemental specifications as to any details, or the omission from it of a detailed description concerning any point shall be regarded as meaning

that the best commercial practices are to prevail, and that only materials of first quality and correct type, size, and design are to be used. All workmanship is to be first quality. All interpretations of this specification shall be made on the basis of this statement.

1.21 – Should it become necessary in order to evaluate a bidder's qualifications, the University may require the bidder to furnish information as indicated below:

1. Financial resources
2. Personnel resources
3. Executive or key person resumes
4. Evidence of ability to meet delivery schedule
5. Ability to meet specification quality requirements
6. Availability of production capacity

1.22 – In the event that the successful bidder fails to make delivery of acceptable goods on or before the agreed delivery date and the University expends unreasonable time, effort, telephone calls and correspondence, the University will bill the supplier at a reasonable cost for such and deduct it from the applicable invoice.

1.23 – Any Purchase Order/contract resulting from this bid/quotation can be cancelled without penalty if any of the following conditions exist:

- a. Breach of contract
- b. The vendor fails to furnish a satisfactory performance bond within the time specified when such a bond is required.
- c. Failure of the vendor to make delivery within the time specified.
- d. In the event material, supplies or equipment furnished does not meet specifications.
- e. Where the contract was obtained by fraud, collusion, conspiracy or any other unlawful means.

The Purchase Order/contract may also be cancelled by convenience by any party. The effective date of cancellation shall be thirty days of written notice of intent by one of the parties. The vendor will, however, will be required to honor all orders that were prepared and dated prior to the date of cancellation, if required to do so by the University.

1.24 – The University reserves the right to award as many term contracts for the supply of any class or type of commodity as may be to the best interest of the University.

1.25 – This section will apply when items in the bid/quotation are requested to be on a "furnish and install" basis. The successful bidder will have the complete responsibility for the items or system until it is in place and working. Any special installation preparation and requirement will be submitted to the University after the receipt of a purchase order. All transportation and cooperation arrangements will be responsibility of the successful bidder. The delivery of equipment will be coordinated so that items will be delivered directly to the installation site. This will minimize the risk of damage and avoid double handling by University personnel.

1.26 – Any alleged oral agreement made by a bidder or contractor, with any university department or employee will be disregarded.

1.27 – Prompt payment discounts ("cash discounts") will not be considered in determining the lowest bidder.

1.28 – Successful bidder may be required to furnish policies or certificates of insurance, with Auburn University, its Board of Trustees, Faculty, Staff, and agents named as additional insured, as follows:

1. a. Workman's Compensation – Statutory  
b. Employer's Liability - \$1,000,000.00
2. Comprehensive General Liability
  - a. General Aggregate - \$1,000,000.00
  - b. Products-Complete - \$1,000,000.00
  - Operations Aggregate
  - c. Personal & Advertising - \$1,000,000.00
  - injury
  - d. Each occurrence or single limits of - \$1,000,000.00
3. Automobile Liability
  - a. Bodily injury - \$1,000,000.00 Each Person
  - \$1,000,000.00 Each Occurrence
  - b. Property damage or combined single
  - \$1,000,000.00 each occurrence limit of
  - \$1,000,000

Due to the nature of some projects, Auburn University reserves the right to require additional limits of liability coverage.

1.29 - Successful bidder agrees to comply with the conditions of all applicable Federal Non- Discrimination and Equal Opportunity laws, the Federal Occupational Safety and Health Act of 1970 (OSHA), the Washington Industrial Safety Act of 1973 (WISHA), as amended, and the standards and regulations issued there under, and certifies that all items furnished and purchased will conform to and comply with such applicable standards and regulations. All



applicable contracts will comply with the Davis-Bacon Act.

1.30 – ADVERTISING. No advertising or publicity matter having or containing any reference to Auburn University or any of its faculty/staff shall be made by successful bidder or any one in successful bidder's behalf unless successful bidder has written consent of the University.

No public release of information, news release, announcement, denial or confirmation of this order or the subject matter hereof, shall be made without the University's prior written approval.

1.31 - LAW. The laws of the State of Alabama shall govern any order, and the venue of any action brought hereunder may be laid in or transferred to the County of Lee, State of Alabama.

1.32 – PAYMENT TERMS. Unless otherwise specified in the purchase Order/contract terms of payment are "Net 30 days."

1.33 – INSOLVENCY. If vendor ceases to conduct normal business operations (including inability to

meet its obligations), or if any proceedings under bankruptcy or insolvency laws is brought by or against vendor, or a receiver for vendor is appointed or applied for, or vendor makes an assignment for the benefit or creditors, the University may terminate this order, without liability, except for deliveries previously made and for supplies completed and subsequently in accordance with the terms of the order. In the event of the vendor's insolvency, the University shall have the right to procure the balance of this order from others without liability.

1.34 - CANCELLATION FOR LACK OF FUNDING. This purchase order/contract may be cancelled without further obligation on the part of Auburn University in the event that sufficient, appropriated funding is unavailable to assure full performance of its terms. The Vendor shall be notified in writing of such non- appropriation at the earliest opportunity.

1.35 - Contractor certifies that neither it, nor any of its employees who will provide or perform services under this contract, have been debarred, suspended, or declared ineligible as defined in the Federal Acquisition Regulation (FAR 48 C.F.R Ch 1 Subpart 9.4). Contractor will immediately notify the University if the Contractor or any of its employees who will provide or perform services under this contract is placed on the Consolidated List of Debarred, Suspended, and Ineligible Contractors.