Georgia Southern University ORSSP Check List

Proposal questions (pre-award)

1) Acquire and review the application and guidelines from the funding agency/sponsor.
   o Is this proposal a contract or a grant?
   o If this is a grant, is this for a new application, a competitive renewal, a non-competitive (continuation) renewal, a supplemental request, or a budget revision?

2) Review the project concept with appropriate Co-PI, project collaborators, and other institutions.
   o Are any additional faculty or researchers participating in the proposed project? If so, in what capacity (i.e., co-investigator, research associate, consultant, evaluator, etc.)?
   o Have these persons agreed to be involved in the project?
   o Are all persons for whom salaries are being requested employees of GS?

Scope of Work questions

1) Scoping
   o Is this a research, public service, or professional services agreement?
   o Is this a product development/testing project? If so, is the product commercialized?
   o Does the narrative or scope of work is in line with the preliminary budget information?
   o Does the project require outside evaluators?
   o Has the department head reviewed the proposal and approved the levels of effort and commitment of space and resources required for the proposed project?

2) Period of Performance
   o Have the proposed start and end dates been clearly stated, and are they consistently used throughout the proposal?
   o Given the proposal submission date, is the proposed start date realistic?
   o If funded, is it likely that an advance account and/or pre-award costs will be necessary?

3) Place of Performance
   o Will the project effort be conducted on-campus, off-campus, or both?
   o If both, what proportion of the project will be performed off-campus?
   o Are there any indirect cost or subcontracting considerations for off-campus activities?

4) Level of Effort/Personnel
   o What level of effort has each investigator committed to the project? Is the effort reflected in the budget?
   o Is the stated level of effort reasonable in relation to the proposed project and each investigator's current and pending support?
   o Does the proposal promise any institutional commitments to staff beyond the proposed period of performance?
   o Does the project require the hiring of new personnel? If so, have you discussed the issue with the department head and ASU's Human Resources?
   o Does the agreement prohibit the hiring of foreign nationals for the project?
   o Is anyone working on this project an employee with the state or university system of Georgia?
Budget questions

1) Budget
   o Is the proposed budget accurate and complete?
   o Have the correct budget categories been used (i.e. salary, fringe benefits, travel, participant costs, supplies, subcontractors, lab fees, overnight shipping, etc.)?
   o Does the budget include partial fees for participants that decide not to complete the study?
   o Are estimated costs proposed in the manner that they will be expended?
   o Has the budget been justified appropriately?
   o Has the appropriate indirect cost rate been used (i.e. on-campus vs. off-campus)?
   o If less than the full indirect cost rate has been applied, has approval been given to recover costs using a lower rate?
   o Does the project require the purchase of any equipment? Is so, are the equipment costs based upon vendor quotes?
   o Have travel costs been included? If so, are they based on the state/federal per-diem rates or some other known and/or accepted source of information?

2) Cost Sharing or Matching Funds
   o Does the proposed project require the financial support of the University?
   o If so, have the sources of this funding been identified?
   o Is there any “hidden” cost sharing identified in the body of the proposal that could become mandatory cost sharing in the event an award is made?

Other questions

1) Subcontractors or Consultants
   o Is a budget included for each proposed subcontractor? Is this budget accurate and reasonable?
   o Does the proposal contain a subcontractor commitment form or a letter of commitment/intent from each subcontractor organization, indicating their willingness to participate in the project, if funded?
   o Is there a scope of work included for each subcontractor or for each consultant?
   o Are letters of intent included for each consultant on the project, paid or otherwise?
   o Did the subcontractor adopt a Conflict of Interest Policy? If not, will they abide by GS’s policy?
   o Is anyone working on this project an employee of the state or university system of Georgia?

2) Space and Facilities
   o Is adequately equipped space available with which to conduct the project?
   o Will extra space be needed?
   o If so, have the appropriate institutional officials approved these commitments?
   o Will any alterations be required to the facilities being utilized?

3) Patents and Copyrights
   o Does the proposal contain any potentially patentable or copyrightable material?
   o Are there IP restrictions indicated in the sponsor guidelines or requested by the sponsor?
   o If proprietary material is included, has the material been marked appropriately?
   o If proprietary material is included, did you communicate this information to personnel working on the project?
   o Ownership Rights: Who owns rights to a) data, b) inventions, or c) joint inventions/joint ownership? If so, is there licensing language?
   o Does GS maintain the right to use data for internal, educational, and research purposes?
4) Publishing
   o Does the sponsor or agency impose any restrictions on investigators or graduate students that would keep them from freely publishing research results?
   o Are rights of prior review requested?
   o Are limitations placed on publications? Who owns data generated for publication?
   o Is there a publication delay requested? Are there other intellectual property restrictions? If yes, are the restrictions within the limits of university policy?

5) Confidentiality
   o Does the agreement require the disclosing party to mark confidential information as such?
   o If not, is the definition of Confidential Information, so broad as to preclude publication rights?
   o Are there exceptions as to what is considered Confidential Information stated in the agreement?
   o Is there a reference to a Nondisclosure Agreement (NDA)/Confidentiality Agreement (CDA)?
   o Are GS employees required to sign an NDA/CDA?
   o Is there any Private Health Information in the project?

6) Terms and Conditions
   o Warranties: Is there a disclaimer by sponsor? If so, has the mitigating language been inserted?
   o Does the sponsor require GS to warrant the work being performed? If so, has the mitigating language been inserted?
   o Breach of contract/termination: Does GS have the right to prorate payment based on the amount of work performed prior to termination?
   o In the event of termination, will GS be reimbursed for funds irrevocably committed pre-termination?
   o Is the University able to collect payment on current/expired awards from the sponsor to whom this proposal is being submitted?
   o Has the sponsor deemed the work subject to Export Controls?
   o Are there any reporting requirements?

Post Award Questions

1) Terms and Conditions
   o Does the awarded period of performance match the proposed period of performance?
   o Does the awarded funding match the proposed funding?
   o If the award amount is lower than the proposal, has sponsor been provided a reduced scope of work to avoid implied cost sharing?
   o Does the Agreement contain language on deliverables and reporting requirements?
   o What is the frequency of technical reports/financial reports?

2) Billing and Invoicing
   o What is the frequency/format for invoicing?
   o When will the final invoice be due after end date (i.e. 60 days, 90 days, etc.)?
   o If the project has any subcontracts and/or professional services agreements did you build some lag time for the closeout dates?
IRB/IACUC/IBC Approval

Human Subjects
- Does the project involve the use of human subjects? If so, has the proposal been submitted to the Institutional Review Board (IRB) for review and approval of the protocol?
- If approval by the IRB has not been granted, why not and when will the protocol be reviewed?
- Does the project include the use of Protected Health Information from a HIPAA Covered Entity (i.e. health care providers who transmit any health information electronically, health plans, health care clearing houses, etc.)? If so, was the information included in the scope of work and/or IRB?
- Does the project include Practice of Medicine (prescribing, ordering, administering any drug or medicine; offering to prevent/diagnose/treat any disease/illness/pain; and performing any surgical operation)?
- Does the IRB review require additional recommendations (i.e. physician contract, phlebotomist, etc.)?

Does the project involve the use of vertebrate animals?
- If so, has the proposal been submitted to the Institutional Animal Care and Use Committee (IACUC) for review and approval of the protocol?
- If IACUC approval has not been granted, why not and when will the protocol be reviewed?

Research Risks
- Does the project involve the use of any hazardous, toxic, or carcinogenic materials, chemicals, or recombinant DNA?
- If so, has the proposal been submitted for review by ASU Office Environmental Health & Safety and/or Institutional Biosafety Council (IBC)?
- Is the product being tested a “new product?”
- Is the sponsor trying to change the labeling of a product?
- If the sponsor will provide any items/equipment/personnel to conduct the project, was the information included in the scope of work and/or IRB?

Dietary Supplements:
- Does the project involve research with dietary supplements (A product that is intended to supplement the diet, including: (1) vitamins, (2) minerals, (3) herbs or other botanicals, (4) amino acids, (5) substances found in the diet (such as enzymes and edible organ tissues and glandular), and (6) concentrates, metabolites, constituents, extracts, or combinations of the substances identified above)?
- Does the dietary supplement contain a “new dietary ingredient” (a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994)?
- Is the intent of the project to determine the impact of the dietary supplement on the diagnosis, cure, mitigation, treatment, or prevention of a disease?
- Is the label included in the scope of work and/or IRB application?

Medical Devices:
- Does the project involve research with Medical Devices (An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized by the FDA or the US Pharmacopeia; and intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.)?
- If so, was the information included in the scope of work and/or IRB application?