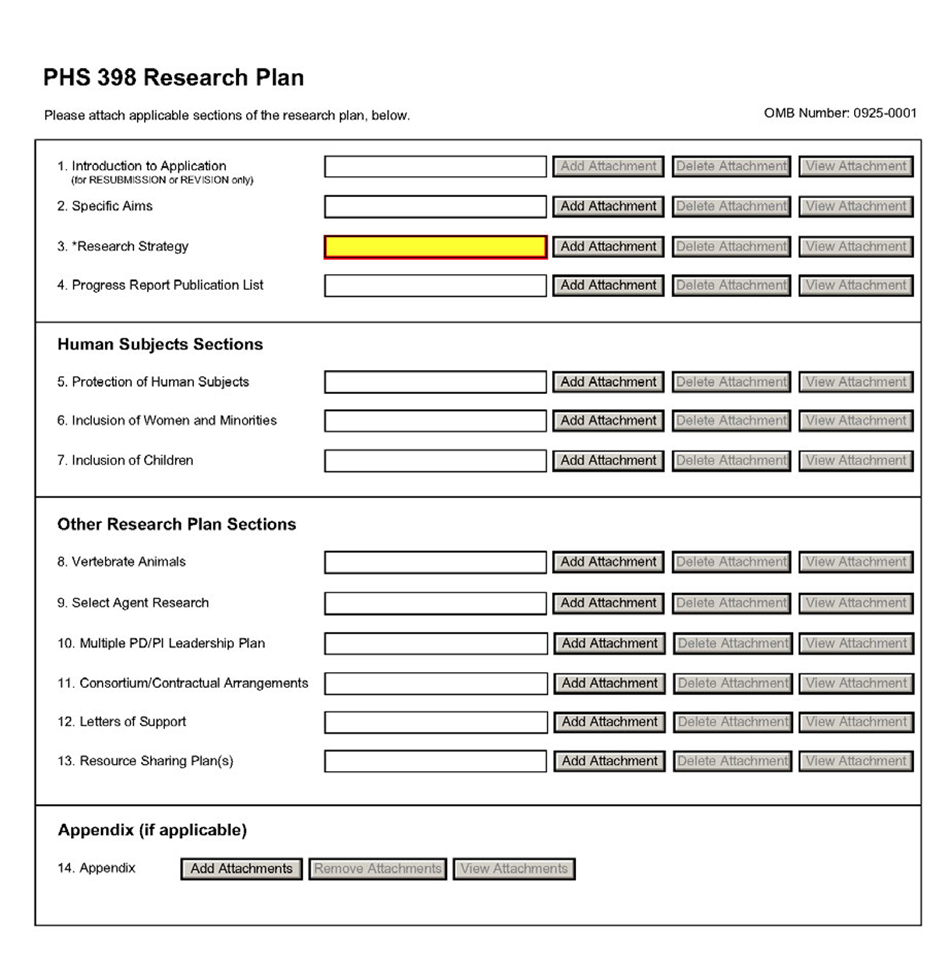
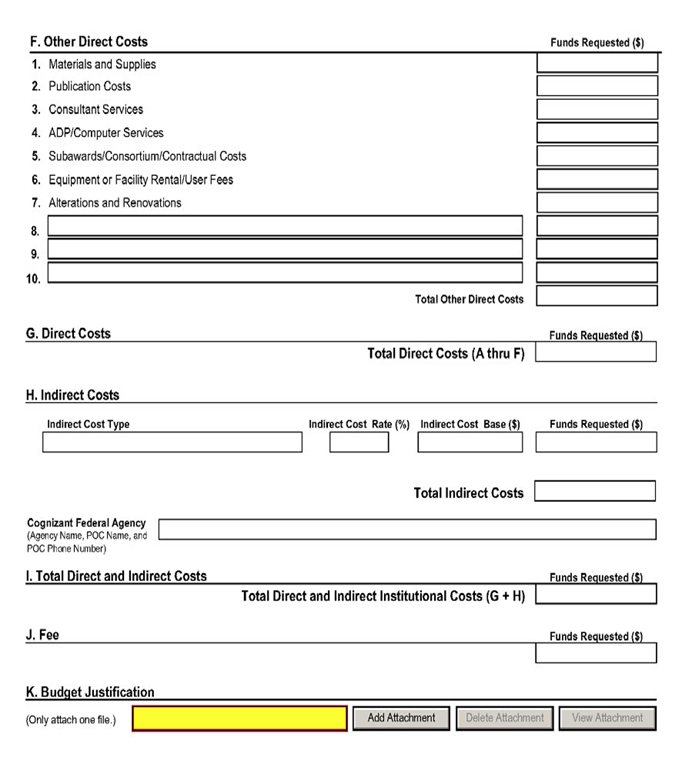
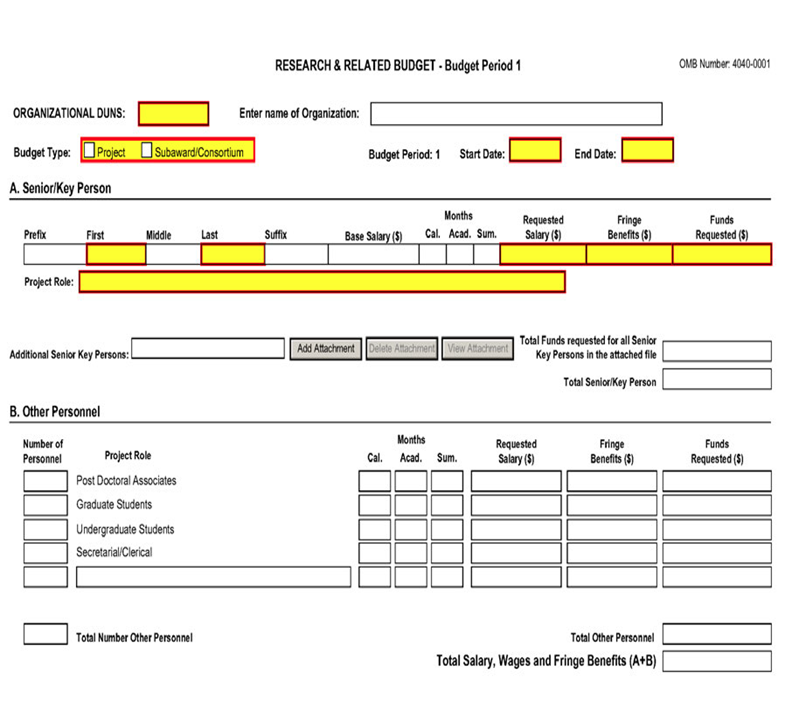
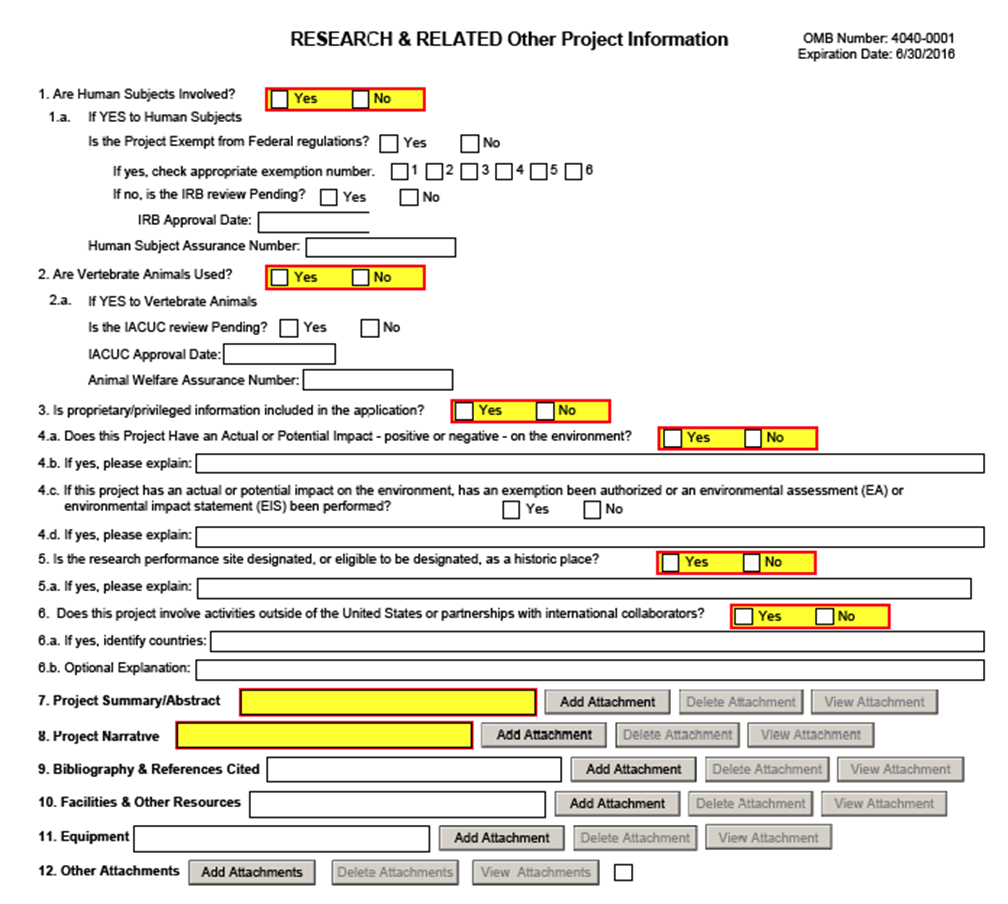
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**HHS NIH STTR/SBIR Grant Application Submission Plan (12-step process)**

1. Find relevant topic and develop the one-page “Specific Aims” (Project Summary) to submit to the NIH Program Manager for his/her review and comment to decide whether or not to proceed
   * Problem Statement (Why is it important?)
   * Proposed Solution (What is the expected impact?)
   * Overall Goal and Specific Aims (state what you intend to do and by when)
   * Assuming you prove feasibility in Phase I close with expected results in Phase II
2. Finish required Registrations – do these early as it takes several weeks to complete
   * DUNS
   * SAM
   * SBA – you will receive a SBA Company Registry as a PDF file (see step 10)
   * eRA Commons
   * Grants.gov
   * ASSIST (submission portal)
3. Solidify your Project Team
   * Need dedicated PI w/ relevant project management and technical experience
   * Need clinical professional
   * Need NIH bio-sketches from all team members (must follow NIH format)
4. Determine available tools/resources needed to be obtained using grant funding and determine how much grant funding you need ($100K to $225K with waiver)
5. Obtain Letters of Support from:
   * Collaborators (i.e. University) and consultants that will contribute to this research
   * Organization(s) that would be an interested customer or test site
   * Organization(s) that would provide matching funds if any awarded (i.e. State agency)
6. Develop materials needed to populate the Research Plan
   * Must have team solidified and research strategy roughed out for what you intend to do and Statements of Work for subawards that are agreed to by all parties.
   * Must have planned budget allocations for research funds including subawards
   * Must provide information on current state of intellectual property
   * Understanding of market position, competition, and barriers to entry
   * Must provide paragraph to summarize the company capabilities. Details regarding previous research and commercialization history is helpful.
7. Solidify detailed Research Plan content
   * Determine a scientific approach to accomplish specific aims
   * Design an experiment to test your hypotheses
   * Determine key project risks and mitigation strategies
   * Determine quantitative success metrics
   * Determine SBIR research timeline and task assignments (Gantt Chart)
   * Determine specific research steps/milestones and elaborate on the resources required to complete (i.e. elaborate on what is defined in Gantt chart)
   * Create diagrams/charts that help illustrate key concepts
   * Develop bibliography and references cited



1. Complete first draft of Research Strategy (6 pages) with the following sections:
   * Significance
   * Innovation
   * Approach (How are specific aims achieved?)
   * Preliminary Data (Describe what you have accomplished to date)
   * Project Team (Define roles and qualifications – bios will contain details)
   * Relevant Experience (What past work has organization done that is relevant?)
   * Anticipated Future Plans (for Phase II and beyond)
2. Develop detailed budget excel spreadsheet to match with resources as stated in research plan
   * Direct labor hours and labor rates of all key participants (salary cap is $187K/year)
   * Determine employee fringe benefits (Social Security and Medicare deductions, health care insurance, vacations, sick leave, retirement plans, etc.)
   * Determine other direct costs (University subcontract, consultants, materials & supplies)
   * Determine indirect cost rate and desired profit or fee
   * Develop budget justification narrative
   * Include contractual agreements with University and others that will be under contract
3. Develop supplemental documents 
   * Develop project abstract (one paragraph non-proprietary)
   * Develop project narrative (one paragraph on how it relates to mission)
   * Develop facilities and other resources description
   * Develop equipment description
   * Develop any additional required documents such as plans for testing human subjects and vertebrae animals
   * Attach proof of registration with the SBA Company Registry in Question 12
   * Cover Letter to request appropriate study section or use PHS Assignment request Form



1. Red Team Review of proposal in its entirety to confirm it meets NIH requirements.
2. Revise, review and submit final grant application. Verify receipt by NIH.

Questions? Contact Dr. Jim Wasson, SC SBDC Technology Commercialization Business Consultant at 843-804-9026 or [wassonjw@mailbox.sc.edu](mailto:wassonjw@mailbox.sc.edu) **Our services are free paid for by a grant from the SBA.**