ITEM	DETAILS	PAGE LIMIT
ABSTRACT	**Overview of product, technical approach for development, and commercialization potential**	**0.5**
SPECIFIC AIMS	**List of development and testing goals which would be necessary to demonstrate that the device is commercially viable. Generally includes list of engineering goals that the device should meet, bench-top tests, and human-subject testing goals**	**1**
RESEARCH STRATEGY	**(a) Significance** • Explain the importance of the problem • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, or services that drive this field will be changed if the proposed aims are achieved. • Explain the project's potential to lead to a marketable product, process or service. • For Phase II, Fast-Track, and Phase IIB Competing Renewals, explain how the commercialization plan demonstrates a high probability of commercialization.	**6**
	(b) Innovation • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.	
	(c) Approach to achieving Aims • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Provide a tentative sequence or timetable for the project. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • Describe the strategy to establish feasibility. • Address the management of any high risk aspects of the proposed work. • Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.	
COMMERCIAL-IZATION PLAN	**a.** Describe, in layperson's terms, the proposed project and its key technology objectives. State the final product, process, or service to be developed. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project.	**12**
	b. Market, Customer, and Competition. Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation. Describe any strategic alliances, partnerships, or licensing agreements you would propose to get FDA approval (if required) and to market and sell your product. Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. (It is very important that you understand and know the competition.)	
	d. Intellectual Property (IP) Protection. Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar	

	to yours.	
	e. Finance Plan. Describe the necessary financing you will require to commercialize the product, process, or service, and when it will be required. Describe your plans to raise the requisite financing to launch your innovation and begin the revenue stream. Plans for this financing stage may be demonstrated by outlining the specific steps you are going to take to secure Phase III funding.	
	f. Production and Marketing Plan. Describe how the production of your product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/process/service. For example, explain plans for licensing, Internet sales, etc.	
	g. Revenue Stream. Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.	