Berkeley Campus Shared Services

Checklist for NIH R01 Applications

This document does **NOT** replace the detailed information available within the Funding Opportunity Announcement. Particular funding opportunity announcements may have specific requirements that may not be included in this checklist. **Please refer to the FOA, if needed.**

Principle Investigator: _____
Due to Sponsor (NIH): _____
Due to SPO: _____
(must be submitted to SPO 5 business days before Sponsor due date)

* Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger * Type density, including characters and spaces, must be no more than 15 characters per inch * Type may be no more than six lines per inch *

General Documents	Page Limits/Instructions	Responsible Party
Introduction	1 page maximum; (for resubmissions and renewals)	PI
Project Summary/Abstract	30 lines of text maximum	PI
Project Narrative	2 - 3 sentences maximum	PI
Specific Aims	1 page maximum	PI
Facilities & Other Resources	(see attached guidelines)	PI
Equipment	List major items of equipment already available for this project and, if appropriate, identify location and capabilities	PI
Research Strategy (in the specified order) *Significance *Innovation *Approach	12 page limit (see details on page 2)	PI
Bibliography & References Cited	See additional details	PI

Human Subject Documents	Page Limits/Instructions	Responsible Party
Protection of Human Subjects	see SF-424	PI
Inclusion of Women & Minorities	see SF-424	PI
Targeted/Planned Enrollment	see SF-424	Pi
Inclusion of Children	see SF-424	PI

Other Research Plan Sections	Page Limits/Instructions	Responsible Party
Vertibrate Animals	see SF-424	PI
Select Agent Research	see SF-424	PI
Multiple PI Leadership Plan	see SF-424	PI
Consortium/Contractual Arrangements	See subaward/consortium checklist	PI
Letters of Support	PI to correspond and obtain support letters.	PI
Resource Sharing Plan(s)	See additional details	PI
Cover Letter	Applicants are encouraged to include a cover letter with the application.	PI
Appendix Materials	As needed.	PI
Biosketches	4 pages maximum to include items A, B, C, & D. Required for all Key Personnel.	PI

Budget Documents	Page Limits/Instructions	Responsible Party
Detailed Budget	PI will share needs and budget ideas with RA. RA will prepare a budget for PI review.	RA & PI
Budget Justification	RA will provide template to PI. PI only needs to fill in justification sections that have not been completed by RA	RA & PI
Modular Budget	For budgets less than $250k per year in direct costs. RA will create internal budget for PI to review, but will transfer modular details into proposal.	RA & PI
Personnel Justification	For Modular budgets only. RA will provide PI with template. PI only needs to complete justification sections for applicable personnel duties and responsibilities.	RA & PI

Reference http://grants.nih.gov/grants/forms_page_limits.htm#other for page limits

Document	Additional Details/Instructions	Reference
Project Summary/Abstract	The **Project Summary** is meant to service as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Make every effort to be succinct. This section **CAN NOT** be longer than 30 lines of text. *An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission.*	SF-424
Project Narrative	Using no more than two or three sentences, describe the relevance of this research to **public** health. In this section, be succinct and use plain language that can be understood by a general, lay audience.	SF-424
Biblography & References Cited	Provide a bibliography of any references cited in the Research Plan. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.	SF-424
Facilities & Other Resources	This section is used to describe the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). Describe only those resources that are directly applicable to the proposed work. Provide any information describing Other Resources available to the project and the extent to which they would be available to the project. *No special form is required but this section must be completed. If there are multiple performace sites, each site must describe the resources at each site.*	SF-424
Equipment	List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.	SF-424

Research Strategy	Organize the Research Strategy in the specified order and using the following instructions. Start each section with the appropriate section headling - Signigicance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and Reference Cited section.	SF424
	(a) Significance - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. 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, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.	
	(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 mehodologies, instrumentation or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.	
	(c) Approach - Describe the overall strategy, methodology, and analyses to be used to accomlish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address teh 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.	

Resource Sharing Plan(s)	*Data Sharing Plan:* Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1- paragraph description of how final research data will be shared, or explain why data-sharing is not possible. *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. *Genome Wide Association Studies (GWAS)*: Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition.	SF-424
Modular Budget	*Modular Budget Guidelines.* Modular budgets are applicable to certain research grant applications requesting $250,000 or less per year for direct costs. Note, consortium/contractual F&A costs are not factored into the direct cost limit. Consortium F&A costs may be requested in addition to the $250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application. The modular budget is applicable only to R01, R03, R15, R21, and R34 applications.	SF-424