Stanford Cardiovascular Institute

R31:R66 Application Checklist

Application Components:

Done	Section	Description
	Trial management plan	5 pages. How trial will be managed, how ensure management activities are met. Role of project mange, risk assessment, address contingencies if milestones slow, key methodology and SOP, how resolve fiscal and logistical issues, project closure. **Study organization plan references not included.**
	Specific Aims	1 page
	Research Strategy	12 pages. Significance, Innovation, Approach (supporting data and experimental approach), core milestones (do not include information on human subj studies or clinical trial). *** Include section on Rigor and Reproducibility; new**
	Letters of Support	Combined as single PDF for attachment
	Biosketch – NIH compliant	For all senior/key personnel. References need PMCID
	Resource sharing plan	Include data sharing plan – 1 paragraph description of how final data shared (should have been discussed with PO).
	Authentication of Key Biological and/or Chemical Resources	PDF attachment. Briefly describe methods to ensure validity of key resources to be used in proposed studies. Max 1 page.
	Project summary	30 lines of text
	Project Narrative	3 sentences
	References Cited	Include PMCID
	Facilities and Other Resources	Describe how scientific environment contributes to success
	Equipment	
	Budget Justification	To justify personnel, equipment, travel, publications, direct costs
	KP – Budget Justification	To justify personnel – Robert Chang, Coordinator (TBN), Sr. Consulting Data Analyst (TBN)
	KP Budget	
	PHS Human Subjects and Clinical Trials	
	Section 2. Study population Characteristics	2.2. Eligibility criteria (fill-in box) 2.3. Age limits
	2.4. Inclusion of Women, Minorities, and Children	1 attachment with 2 sections: 1. Inclusion of Women and Minorities. Describe planned distribution of subjects by gender/sex, race, ethnicity. Describe rationale. Proposed outreach programs. 2. Inclusion of Children. Discuss if excluding individuals by age, and why. Describe expertise of team working with ages included.
	2.5. Recruitment and Retention Plan	Describe how will recruit and retain participants. Planned recruitment and proposed engagement strategies.
	2.7. Study timeline	Descriptive diagram describing timeline (months)
	Inclusion Enrollment Report	Tables of planned and cumulative enrollment
	3.1. Protection of human subjects	1. Risks – overall study design, population, how assigned to groups. Study procedures, materials, potential risk – describe all planned procedures, all potential risks and risk level and impact, alternative treatment or procedures if possible 2. Protection against risk – informed consent process, protection against risk, incidental findings, medical intervention. 3. Potential Benefits – to participants and others, why risks are reasonable in relation to benefits

		4. Knowledge gained – importance, and how risk is worth gained knowledge 5. Data and Safety monitoring for clinical trials *Include information in 5 headings
	5.4. Data and Safety monitoring plan	Framework for safety monitoring, frequency, what, process of reporting/managing adverse effects, who responsible for trial monitoring and advising. **Clarify DSMB role.**
	5.5. Structure of Study Team	Overview of organizational/admin structure and function of study team. Figure?
	4. Protocol Synopsis	
	4.1. Brief summary	Limited to 5,000 characters, usually 2,000. Lay language
	4.2.a. Narrative study description	Limited to 32,000 characters, usually 5,000. Layperson terms. Can repeat what is in Research Strategy. Describe plans for assignment of participants and interventions
	4.2.c. Interventions	Table – describing metformin. Name and description of interventions
	4.3. Outcome Measures	Table of all primary, secondary, or other outcomes
	4.4. Statistical Design and Power	Number of subjects, effect size, power, methods
	4.6. Pre-IND exemption letter	Pre-IND exemption letter from previous submission
	4.7. Dissemination Plan	Describe plan for dissemination of trial data, including ClinicalTrials.gov, consent form includes that relevant data onto CT.gov
	5.1.a. Clinical Trial Research Experience	Table with 7 columns, not more than 3 pages, total. Listing characteristics of trials that demonstrate experience in trial coordination in the last 5 years. For each Key Personnel (Dalman, Mahaffey, Lu). Column A: clinical study title Column B: applicant's role in the study Column C: a brief description of the study design Column D: planned enrollment Column E: actual enrollment Column F: whether the studies completed on schedule or not Column G: publication reference(s)
	5.1.b. Project Management Plan	
	5.1.c. Single site justification plan	2 pages describe how participants will be enrolled in the allotted timeframe. Save as: single-site justification plan.pdf
	5.1.d. Data Management Plan	
	5.1.e. Clinical Protocol Synopsis	
	Multiple PD/PI	Rational for multi PIs, organizational structure and governance, communication plan, decision making process, conflict resolution. (Figure?) *Include conflict resolution, make less general. Support why multiple PIs needed.
	Consortium/Contractual Arrangement	Explain programmatic, fiscal, admin arrangements made between organizations.
	Appendix	Blank consent form
	Study Record	For each study involving human subjects