Title: Development of cytostatic/cytotoxic combination therapy for TSC tumors

DOD Tuberous Sclerosis Complex Research Program 2016

Research

Exploration - Hypothesis Development Award

Funding Opportunity Number: W81XWH-16-TSCRP-EHDA

PI:

$200,000 directs over two years; no subcontracts in this grant application

Budget Nov 1, 2017 – Oct 31, 2019

Preadmission through eBRAP—application submission through grants.gov

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| Full Application 11:59 p.m. ET, July 18, 2016 |
| Attachment 1: Project Narrative (4-page limit): Upload as “ProjectNarrative.pdf.” | ○ Rationale: Clearly articulate the rationale for the proposed research project, including a clear mechanistic underpinning. Include relevant literature citations. The presentation of preliminary and/or published data is not required.○ Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.○ Specific Aims: Concisely explain the proposed research project’s specific aims to be funded by this award.○ Research Strategy:– Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific peer review. Address potential problem areas and present alternative methods and approaches.– Describe the statistical plan appropriate for the proposed research project. |  ‘final’ to KM 07/14Need figures replaced for crispness |  |
| Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named “Support.pdf.” | * References Cited:
* List of Abbreviations, Acronyms, and Symbols:
* Facilities, Existing Equipment, and Other Resources:
* Publications and/or Patents:
* Letters of Organizational Support—dept chair confirming lab space, equipment, and other resources
* Letters of Collaboration --Yu
* Intellectual Property
* Intellectual and Material Property Plan
 | FXM letter doneJY letter doneFacilities? |  |
| Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.” | ○ Background: Present the ideas and rationale behind the proposed research project. ○ Hypothesis/Objective: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis. ○ Specific Aims: State the specific aims of the proposed research project. ○ Study Design: Briefly describe the study design including appropriate controls. ○ Innovation: Briefly describe how the proposed research project is innovative in the field of TSC. ○ Impact: Briefly describe how the proposed research project will have a short- and long-term impact on TSC research and/or patient care. . |  | To TB 07/1 |
| Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.” | ○ Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***. ○ Describe the ultimate applicability of the research. − What types of patients will it help, and how will it help them? − What are the potential clinical applications, benefits, and risks? − What is the projected time it may take to achieve a patient-related outcome? − If the proposed research is too basic for clinical applicability, describe the interim outcomes. ○ What are the likely contributions of this proposed research project to advancing the field of TSC research and/or patient care?  | Draft to Kope 07/14 |  |
| Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.” | “SOW for Generic Format.” The SOW must be in PDF format prior to attaching. | Need to add animal numbers |  |
| Attachment 6: Innovation 1 pageUpload as “Innovation.pdf” | ○ Explore a novel idea and/or research question in TSC.○ Use or develop novel methods or technologies to address a question in TSC research and/or patient care.○ Apply or adapt existing methods or technologies for novel TSC research or clinical purposes that differ fundamentally from those originally intended. |  |  |
| Attachment 7: Impact Statement (one-page limit). Upload as “Impact.pdf.” | State explicitly how the proposed research project addresses one or more of the FY16 Focus Areas |  |  |
| Attachment 8Data and Resource Sharing Plan“ResourceSharing.pdf.”describing how data and resources generated during the performance of the proposed research project will be made available to the scientific community should be included in the applicationUpload as “ResourceSharing.pdf” | TSCRP Research Resources Initiative: Resources developed through TSCRP funding are available to the scientific community and can be found at http://cdmrp.army.mil/tscrp/resources/ tscresources.shtml; investigators are urged to leverage these resources. Investigators are expected to share data and resources developed through TSCRP funding via the Research Resources.. | draft to KM 07/14 | To TB 07/14 |
| Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.” | N/A | N/A | N/A |
| 3. Research & Related Senior/Key Person ProfileKoheiJane Yu | “Biosketch\_LastName.pdf.”Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.” |  |  |
| 4 Budget Justification 1 page limit | “BudgetJustification.pdf.” | Kope to KM 07/14 | To TB 07/14 |
| 5. Project/Performance Site Location(s) Form: | TB | TB | TB |
| 6. R & R Subaward Budget Attachment(s) Form (if applicable): | N/A | N/A | N/A |