NIH/NCI Funding Opportunity Announcement (FOA) PAR-16-105

"Cancer Tissue Engineering Collaborative: Enabling Biomimetic Tissue-Engineered Technologies for Cancer Research (U01)"

Frequently Asked Questions

Purpose

The purpose of this funding opportunity announcement (FOA) is to encourage investigator-initiated research efforts aimed at the development and characterization of state-of-the-art biomimetic tissue-engineered technologies for cancer research. Tissue-engineered in vitro and ex vivo systems that reflect the pathology and physiology of human disease are needed within the existing continuum of cancer models as new tools for studying cancer biology. Complementary implementation of these tools with existing cancer models is envisioned to ultimately lead to advances in cancer prevention, early detection of aggressive cancer, diagnosis and treatment. To date, only a handful of validated, biologically relevant tissue-engineered technologies exist for addressing specific cancer research questions. Recent technological advances in biomimetic tissue-engineered systems for the purposes of regenerative medicine could allow for new, innovative applications to cancer research. This FOA will support multidisciplinary research projects, and the funded investigators will collectively establish and participate in the Cancer Tissue Engineering Collaborative (TEC) Research Program. Projects will focus on the development and characterization of in vitro systems using tissue-engineered technologies that mimic tumor biology to elucidate specific cancer phenomena that are otherwise difficult to examine in vivo.

This FOA is intended to encourage collaborative, multidisciplinary projects that engage the fields of cancer research with regenerative medicine, tissue engineering, biomaterials, and bioengineering. It is also expected to catalyze the advancement of innovative, well characterized in vitro and ex vivo systems available for cancer research, expand the breadth of these systems to several cancer types, and promote the exploration of cancer phenomena with biomimetic tissue-engineered systems beyond commonly studied areas such as cell migration and angiogenesis. Applicants are encouraged to leverage existing resources, such as in vivo models, imaging techniques, or computational models.

General questions about the funding opportunity:

1. **Will late letters of intent (LOIs) be accepted?** Yes, LOIs can be sent after the deadline stated in the FOA to Nastaran Kuhn at nas.kuhn@nih.gov.

2. **Are resubmission applications permitted?** Yes, resubmissions in response to PAR-16-105 will be permitted beginning the 2nd round (November 30, 2016 receipt date).

3. **What is a U01?** A U01 application is similar to an R01 application in that it is a single project consisting of multiple specific aims that are outlined to achieve the goals of that project. http://grants.nih.gov/grants/funding/funding_program.htm#u01

4. **What does the "U" designate (vs. "R")?** The U designates a cooperative agreement where there is programmatic involvement beyond the normal stewardship role in awards by the NIH program official(s). See the FOA, Section VI-2, "Cooperative Agreement Terms and Conditions of Award" for responsibilities of the PD(s)/PI(s), the NIH staff, and the areas of joint responsibility.

5. **What was the rationale for making this a U01 mechanism vs. an R01 mechanism? Is this U01 encouraging utilizing a "consortium" for the project?** From an NIH perspective, the U01 mechanism was utilized because program staff will support a group of investigators who will be working together on common goals and meet on an annual basis at minimum to discuss these technologies as well as to discuss any ongoing challenges. We would like to leverage other NIH programs that exist to form partnerships for joint meetings, projects, and research resources. There are no specific requirements in the FOA to encourage utilizing a consortium however we do recognize that these are going to be multi-disciplinary projects where there may be multiple PIs.

6. **Are there any new forms to be aware about for the application process?** Applicants are encouraged to include a PHS Assignment Request Form with their application that includes information about potential conflicts of interest and areas of scientific expertise needed for a fair and knowledgeable review of the application. This information was previously collected in the Cover Letter attachment but now, this optional information must be provided on the Assignment Request Form. https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.600-phs-assignment-request-form.htm

7. **What is the NIH Genomic Data Sharing Policy (GDS)?** The NIH GDS policy applies to applications submitted after January 25, 2015 and covers a wide range of genomic analyses across various experimental platforms and sample types (human and non-human). Documentation to satisfy NIH GDS policy is part of the standard Just-in-Time information, so the correct time to determine if your work will fall under the policy is during the preparation of your application. Review the NCI specific guidelines, and if applicable, generate a Genomic Data Sharing Plan and apply for Institutional Certification. Include a cover letter stating the NIH GDS Policy applies to your application.

8. **What is the NIH policy regarding late application submissions?** There is a 2-week window of consideration after the application due date, during which time NIH *might* consider accepting a late application (not applicable for all FOAs – see Policy for details). A cover letter must be included with the application that explains reasons for the delay. Permission for late application submission is not granted in advance. NIH program or review staff do not make the decision – direct inquiries to NIH Division of Receipt and Referral csrdrr@mail.nih.gov.

9. **What are acceptable post-submission application materials?** Please see the Policy or NIH FAQ for examples of acceptable post-submission application materials. News must be sent to the Scientific Review Officer (SRO) 30 calendar days prior to the review meeting, and demonstrate concurrence from the Authorized Organization Representative (AOR) of the applicant organization.

Questions about investigators:

10. **Are there advantages or disadvantages if the PIs are all from the same institution?** This is neither an advantage nor disadvantage for the application. It will be important to thoroughly

describe the expertise of each investigator, what capacity they will contribute to the project and to justify their role, percent effort and any salary that may be requested.

11. **If I am an NIH Early Stage Investigator (ESI), will I lose ESI status if designated as PD/PI of an awarded U01?** Yes, if you are designated as a PD/PI on an awarded U01 you will no longer be eligible for ESI status on NIH applications.

12. **Is special consideration given for applications that have PD(s)/PI(s) with eligible ESI status?** No, unlike R01s submitted to the parent research project grant FOA, the applications received in response to PAR-16-105 will not be given special consideration for those with ESI status.

13. **If a Co-PI on an awarded U01 project has ESI status, will that ESI status be lost for subsequent applications submitted to the NIH?** Yes, if you are listed as a Co-PI on a U01 project that is awarded, you will lose ESI status. However, if you are listed as a co-investigator you will not lose ESI status.

14. **What is the difference between a Co-PI and a Co-investigator?** PD/PI(s) are individual(s) designated to direct the project being supported by the grant. A Co-Investigator is an individual involved with the PD/PI in the scientific development or execution of a project. A Co-Investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The role type "Co-PI" is not used by the NIH, rather MPI designates multiple principal investigators. More information regarding this can be found on the NIH website: http://grants.nih.gov/grants/multi_pi/overview.htm.

Questions about funding:

15. **How many applications will be funded?** The number of applications funded will be dependent on the budget available and the submission of a sufficient number of meritorious applications.

Questions about review:

16. **How will the scientific review panel evaluate applications?** The panel will review applications according to the specific review criteria guidelines outlined in the FOA PAR-16-105.

Questions about scientific scope of PAR-16-105:

17. **For the characterization of tissue-engineered technology, should we use animal or human models?** Any mammalian model could be utilized to characterize the tissue-engineered technology. The choice of model will depend on many factors and will depend on the scope of the cancer research question being addressed in the project. It will be important to clearly describe the rationale for the species used to characterize the technology.

18. **Is the FOA more focused on foundational technologies that would be applicable to numerous cancer types versus specific cancer types?** The tissue-engineered technologies developed and characterized for the projects submitted in response to the FOA do not have a requirement to

be foundational technologies that could be applied to numerous cancer types. It is acknowledged that the technologies may have limited utility for the particular cancer research question being addressed in the project.

19. **Is the FOA more focused on cancer biology versus drug screening?** The scientific scope of the projects that will be supported by this FOA is broad. Projects focused on basic cancer biology will be considered responsive to the funding opportunity as well as projects focused on drug screening.

20. **How much emphasis will be placed on translational potential?** There is no requirement for projects that have immediate translational potential. Projects that are aimed at understanding mechanisms of basic cancer biology will be responsive to this funding opportunity.

21. **Are you anticipating submissions that lean more toward biological questions, or technology development?** We are expecting technology development in the context of answering a cancer biology question. There must be an underlying cancer research question that is being addressed in the project.

22. **In the application, do we need to specifically address a particular cancer cell or can we look at different cancer cell variants within a particular organ?** There is no limit to the different types of cancer cells you can address. It is not a requirement to use multiple cancer types, but you can certainly do so if it is an important component of your project.

Finally, visit this NIH website for information on avoiding common errors when submitting your grant application: https://grants.nih.gov/grants/how-to-apply-application-guide/learn-how-we-check-your-application-for-completeness/avoiding-common-errors.htm.