Cancer Tissue Engineering Collaborative: Enabling Biomimetic Tissue-Engineered Technologies for Cancer Research (U01) Pre-Application Webinar

PAR-16-105

NIH NATIONAL CANCER INSTITUTE

September 13, 2016

Purpose of the Funding Opportunity Announcement (FOA) *Cancer TEC Research Program*

This FOA will support the development and characterization of state-of-the-art biomimetic tissue-engineered technologies for cancer research. Collaborative multidisciplinary projects that engage the fields of regenerative medicine, tissue engineering, biomaterials, and bioengineering with cancer biology will be essential for generating novel experimental models that mimic cancer pathophysiology. The projects supported by this FOA will establish and collectively participate in the Cancer Tissue Engineering Collaborative (TEC) Research Program.

Goals of the Funding Opportunity Announcement (FOA) *Cancer TEC Research Program*

This projects supported by this FOA will utilize tissue-engineered technologies that mimic tumor biology to elucidate specific cancer phenomena that are otherwise difficult to examine *in vivo*. Applicants are encouraged to leverage existing resources, such as *in vivo* models, imaging techniques, or computational models.

The FOA is expected to

(1) catalyze the advancement of innovative, well characterized *in vitro* and *ex vivo* systems available for cancer research,
(2) expand the breadth of these systems to several cancer types, and
(3) promote the exploration of cancer phenomena with biomimetic tissue-engineered systems.

Possible research areas of emphasis that could be considered as examples are included in the FOA, Part 2, Section I, “Research Objectives and Scope”

Mechanism of Support & Funding

Mechanism of support: U01, Research Project – Cooperative Agreement

Supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interest and competencies. Used when substantive programmatic involvement is anticipated by the NIH.

Application Type: All submissions will be Type 1 (new applications). Resubmissions are allowed.

Budget: Not to exceed $400,000 Direct Costs per year. *Cap is exclusive of 3rd party F&A costs.*

Project Period: Not to exceed 5 years.

Note on Eligible Applicants: Foreign (non-U.S.) institutions are eligible to apply and foreign components are allowed.

Funds Available and Anticipated # of Awards: Contingent upon budget and submission of a sufficient number of meritorious applications.

Mechanism of Support & Funding: FAQ

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.

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.

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 for ESI status on NIH applications.

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, these *applications will not be given special consideration* for those with ESI status.

Leadership Expertise

Eligible Individuals (PD/PI): This FOA strongly *encourages the use of the multi-PD/PI option* given the required multidisciplinary expertise for developing and characterizing state-of-the-art biomimetic tissue-engineered technologies for understanding cancer pathophysiology. At least one project team member must have the prior experience and/or necessary qualifications ***in cancer research*** to support the successful execution and implementation of the proposed project.

New NIH Biosketch Required

All research applications are required to utilize the new NIH Biosketch format:

See NOT-OD-15-032 for general information and tools -- including instructions and a sample.

**Further updates have been made to the NIH Biosketch instructions and are required for submission after May 25th, 2016. Please see NOT-OD-16-080 for more information.

Frequently asked questions are addressed at:
http://grants.nih.gov/grants/policy/faq_biosketches.htm

Key Dates

	Pre-Application Webinar	Letter of Intent Due Dates (6 weeks prior to app)	Application Due Dates	Review Dates	Earliest Anticipated Start Dates
~~Round 1~~	~~Apr 26, 2016~~	~~Apr 19, 2016~~	~~May 31, 2016~~	Oct 2016	Apr 2017
Round 2	Sep 13, 2016	Oct 19, 2016	Nov 30, 2016	Mar/Apr 2017	Aug 2017
Round 3	TBD, est Feb 2017	Apr 18, 2017	May 30, 2017	Sep/Oct 2017	Apr 2018
Round 4	TBD, est Aug 2017	Oct 19, 2017	Nov 30, 2017	Mar/Apr 2018	Aug 2018
Round 5	TBD, est Feb 2017	Apr 18, 2018	May 30, 2018	Sep/Oct 2018	Apr 2019
Round 6	TBD, est Aug 2017	Oct 19, 2018	Nov 30, 2018	Mar/Apr 2019	Aug 2019

Letter of Intent (LOI)

Due dates: ~~Apr 19, 2016~~ | **Oct 19, 2016** | Apr 18, 2017 | Oct 19, 2017 | Apr 18, 2018 | Oct 19, 2018

Highly encouraged, but not required. *Not binding and does not enter into the review*.

Standard elements:

- Descriptive title of the project
- Name(s), address(es), telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating Institution(s)
- Number and title of this funding opportunity (PAR-16-105)

Additional recommended information:

- **Provide a brief (3-5 sentence) description of the project**
- **Include relevant expertise and Keywords**

Email LOI to nas.kuhn@nih.gov

NIH Updated Application Forms

See NOT-OD-16-004 for details on new application forms (FORMS-D) that are **required** for applications with due dates of May 25, 2016 and beyond.

Link to FORMS-D annotated form set:

http://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-D.pdf

A list of significant changes can be found at:

http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.120-significant-changes.htm

R&R Budget

Maximum of $400,000 Direct Costs per year (exclusive of 3rd party F&A). Application budgets should reflect the actual needs of the proposed project.

Proposed budgets must include appropriate travel funds to support travel for at least one PD/PI to attend an annual Cancer TEC Research Program meeting in the Washington, DC area.

PHS 398 Research Plan: *Research Strategy*
12 page limit – see FOA Section IV-2

The Research Strategy should clearly describe and consist of the following sub-sections (in addition to the standard sub-sections):
State-of-the-art technology; Research Approach; Characterization

State-of-the-art technology

- The tissue-engineered technology and whether it is an adaptation of an existing technology or a new technology. What the advantage is of the proposed technology/methodology over existing/alternative technologies.
- Additional novel concepts, approaches, tools, or technologies for the proposed studies.

PHS 398 Research Plan: *Research Strategy*
12 page limit – see FOA Section IV-2

The Research Strategy should clearly describe and consist of the following sub-sections.

Research Approach

- The significance of the cancer research problem to be investigated, and the relevance of the technological approach to the cancer research question being asked. How the proposed approach could ultimately bring novel insight to cancer biology and oncology.
- The research design, conceptual procedures, and analyses to be used to accomplish the Specific Aims of the project and the rationale for selecting these approaches.
- The potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

PHS 398 Research Plan: *Research Strategy*
12 page limit – see FOA Section IV-2

The Research Strategy should clearly describe and consist of the following sub-sections

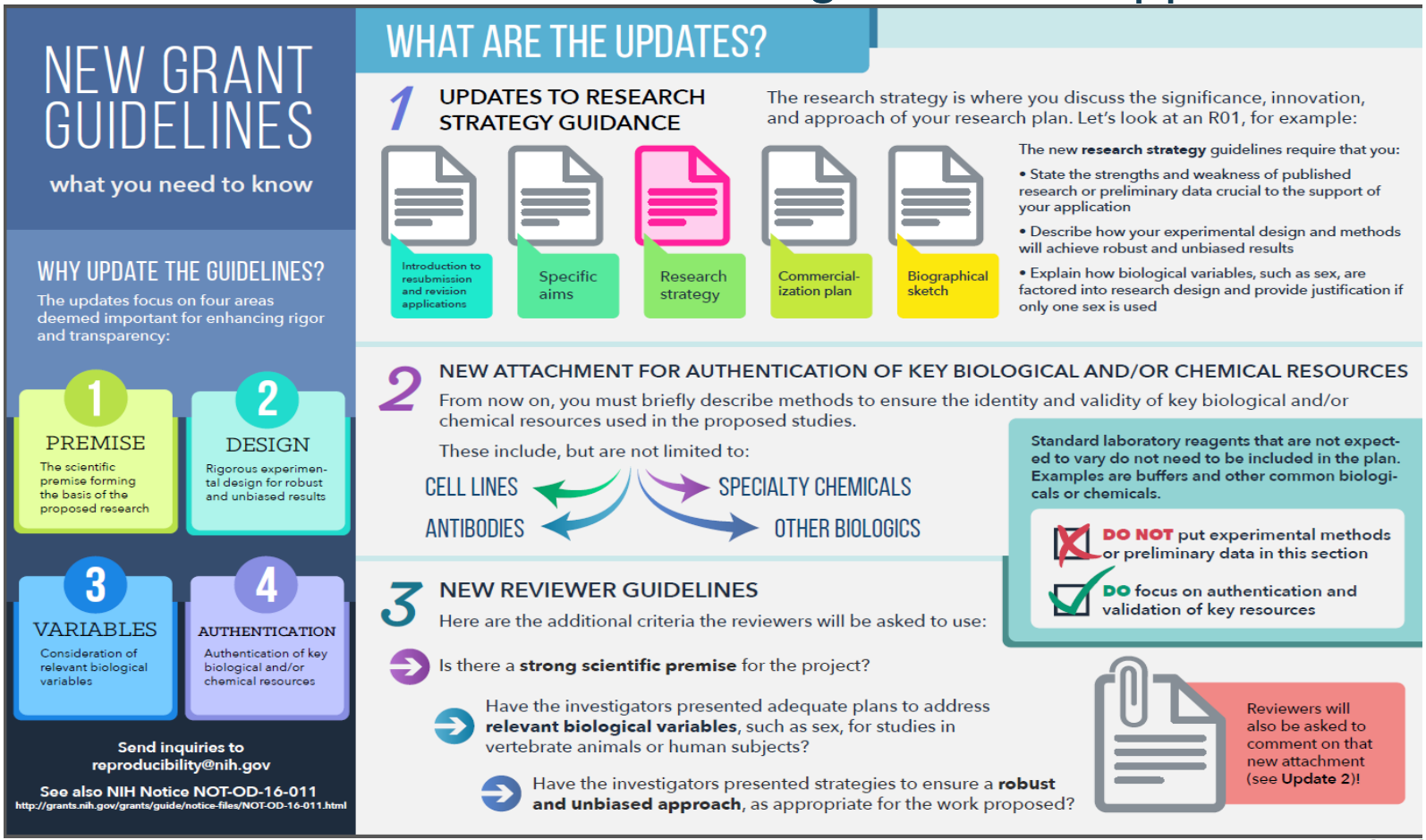
Characterization

- How the technology will be characterized to demonstrate that it replicates the aspect of tumor biology that will be studied in the context of the underlying research hypothesis.
- How the use of the proposed cell types are sufficient to capture the complexity of the tissue(s) being studied and how the cell source(s) used in the project will be characterized to demonstrate that they indeed represent the expected species, tissue and cell type from which they are derived.
- A tentative sequence or timeline for the project.

PHS 398 Research Plan: *New Rigor and Reproducibility Standards*

- All applications submitted after January 25, 2016 must address **Scientific Rigor and Reproducibility**.
  - http://grants.nih.gov/reproducibility/index.htm#guidance
  - http://grants.nih.gov/grants/RigorandReproducibilityChart508.pdf
- *The "Resources" section includes examples and two videos about what to include in your application and how the new criteria will be reviewed.*
- Scientific Premise, Scientific Rigor and Inclusion of Relevant Biological Variables must be addressed **within the 12 page** Research Strategy.
- Use an additional attachment for Authentication of Key Biological and/or Chemical Resources to address plans for authentication in one page or less.

Overview of New Guidelines for Rigor in Your Application



Application Review Information: *Criteria*
See FOA, Section V-1

Carefully consider the FOA-specific questions under each of the standard review criteria shown below

- Significance (**)
- Investigator(s)
- Innovation
- Approach (**)
- Environment

**** Don't forget the new review criteria for **scientific premise, scientific rigor, and inclusion of relevant biological variables** included in these sections.**

Application Review Information: *Review and Selection Process*

See FOA, Section V-2

Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group convened by the NCI, using the stated review criteria.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score.
  - Note the applications will not be percentiled.
- Will receive a written critique.

Application Review Information: *Review and Selection Process*

See FOA, Section V-2

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Cancer Advisory Board.

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Application Review Information

- (NEW) Applicants are encouraged to include a PHS Assignment Request Form with their application that includes information about:
  - Potential conflicts of interest
  - Areas of scientific expertise needed for a fair and knowledgeable review of the application *(not necessary to request a specific review group)*
- 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
- The review panel roster will be available in eRA Commons 30 days prior to review. Applicants may contact the Scientific Review Officer (SRO) directly with concerns prior to review.

NIH Genomic Data Sharing Policy (GDS)
NOT-OD-15-027

NIH GDS Policy

- Applies to applications submitted after January 25, 2015
- Covers wide range of genomic analyses across various experimental platforms and sample types (human and non-human)
- NCI specific guidelines for the number of samples that qualify as ‘large-scale’ data collection. Minimum threshold is met quickly given different combinations of patient samples, cell lines, time points, and chemical/therapeutic perturbations.
- Documentation to satisfy GDS policy is part of the standard Just-in-Time information so now is the correct time to determine if your work will fall under the policy.
- If applicable, generate a Genomic Data Sharing Plan and apply for Institutional Certification.
- **Include a cover letter stating the GDS Policy applies to your application**

NIH Policy on Late Application Submission

NOT-OD-15-039

- 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)
- *Example reasons why late application might be accepted*
  - Temporary or ad hoc service by a PD/PI on an NIH advisory group during the two months preceding or the two months following the application due date.
  - Delays due to weather, natural disasters, or other emergency situations, not to exceed the time the applicant organization is closed.
- *Example reasons why late application will not be accepted*
  - Heavy teaching or administrative responsibilities, busy schedule
  - Review service for participants other than a PD/PI or MPI
- **Cover letter must be included with application that explains reasons for the delay**
- **Permission for late application submission is not granted in advance**
  - Note – NIH program or review staff do not make the decision – direct inquiries to NIH Division of Receipt and Referral csrdrr@mail.nih.gov

NIH Policy on Post-Submission Application Materials NOT-OD-13-030

- See Policy or NIH FAQ for examples of acceptable post-submission application materials
  - e.g., news of an article accepted for publication (do not include a copy of the article)
  - News of professional promotion
- *News must be received by 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.*

Agency Contacts:
See FOA Section VII

Scientific/Research Contacts:

Nastaran Z. Kuhn, PhD
Division of Cancer Biology
240-276-7610
nas.kuhn@nih.gov

Richard Mazurchuk, PhD
Division of Cancer Prevention
240-276-7126
richard.mazurchuk@nih.gov

Peer Review Contact:

NCI Referral Officer
240-276-6390
ncirefof@dea.nci.nih.gov

Financial/Grants Management Contact:

Martinson Owusu
240-276-6297
owusumo@mail.nih.gov

Slides will be posted on http://pson.cancer.gov