Ceferino Obcemea

Program Director Radiation Research Program National Cancer Institute

1. Overview of NCI Funding Mechanism 2. New 2018 Med Phys – related funding initiatives at NCI

#1. https://deainfo.nci.nih.gov/



NCI Sponsored Initiatives

 NIEl Sponsored Initiatives
 Policies and Guidelines Clinical

 Contracts Other Funding - NCI
 Research/Human Subjects

 Contracts Other Funding - NCI
 Contracts Other Funding - NCI

 Carnt Application Forms NCI Grant
 Applications (RFA) Request for Applications, RFA) Request for Applications
 NIH Guide Applications

 Activity CodessMechanisms NCI Grant
 Applications (RFA) Request for Applications
 NIH Grant Submission and Applications

 Activity Codesses Proparing Grant Applications
 Small Subiness Coordinations
 NIH Grant Policies NCI Andress Name Subiness Coordination

 Applications
 -more
 Small Subiness Coordinations
 Yolding Network

 Applications
 -more
 Small Subiness Coordinations
 Yolding Network

 Small Subing
 Small Subing Network
 Yolding Network
 Yolding Network

#2. https://grants.nih.gov/grants/funding/funding_program.htm

The following groupings represent the main types of grant funding we provid

Research Grants (R series)
 Career Development Awards (K series)
 Research Training and Fellowships (T & F series)
 Program Project/Center Grants (P series)
 Resource Grants (various series)
 Trans-NIH Programs



NIH Exploratory/Developmental Research Grant Award (R21) •Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. Sometimes used for pilot and feasibility studies. - Limited to up to two years of funding - Combined budget for direct costs for the two year project period usually may not exceed \$275,000. - No preliminary data is generally required

Designed to permit early peer review of the rationale for the proposed clinical trial and support development of essential elements of a clinical trial -Usualy project period of one year, sometimes up to 3 -Usually, allows for a budget of up to \$100,000 direct costs, sometimes up to \$450,000

-Support small research projects by undergraduate and/or graduate students and faculty in institutions that have not been major recipients of NIH research grant funds. - -Elipibility limited (see <u>https://grans.inh.gov/grans.findou/graea.htm</u>) - Direct cost limited to \$300,000 over entire project period R15

 Not rene •Support for high quality conferences/scientific meetings •Foreign institutions are not eligible to apply •Award amounts vary and limits are set by individual ICs •Support for up to 5 years may be possible <u>R13</u>

Project period limited to up to 3 years

R21

<u>R34</u>

 Provides limited funding for a short period of fime to support a variety of types of projects, including plot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, development of new research technology, etc.
 Limited to two years of funding
 Direct costs generally up to \$50,000 per year
 Mort meanwide <u>R03</u>

 Used to support a discrete, specified, circumscribed research project
 No specific dollar limit unless specified in FOA
 Advance permission required for \$500K or more (direct costs) in any year
 Generally awarded for 3 -5 years R01

2



CONTRACT TOPICS



SBIR

SBIR

GRANT vs. CONTRACT

	GRANT	CONTRACT
Scope of the proposal	Investigator-defined within the mission of NIH	Defined by the NIH (focused)
Peer Review Locus	NIH Center for Scientific Review (CSR)	NCI DEA (target 50% business reviewers)
Questions during solicitation period?	May speak with any Program Officer	MUST contact the contracting officer
Receipt Dates	3 times/year for Omnibus	Only ONCE per year
Set-aside of funds for particular areas?	NO	YES
Basis for Award	Based on score during peer review	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH
Reporting	One final report (Phase I); Annual reports (Phase II)	Kick-off presentation, quarterly progress & final reports



R&D Contract Funding Opportunity

- HHS Small Business Innovation Research (SBIR) Program Contract Solicitation
- ONE application receipt date per year: Published July of each year

Receipt Date: October 22, 2018, 5:00 PM Eastern Daylight Time

More info about NCI's topic areas: #3. http://sbir.cancer.gov/funding/contracts/

FY2019 SBIR/STTR Contract Webinar will be held on August 16, 2018

FY19 NCI CONTRACT TOPICS

NIH/NCI382 Integrated Subcellular Microscopy and 'Omics in Cancer Cell	NIH/NCI 390 Clonogenic High-Throughput: Assay for Screening Anti-Cancer Agents and Radation Modulators
NIH/NCI 383 Smart, Multi-Core Biopsy Needle	NIH/NCI 391 Drugs or Devices to Exploit the Immune Response Generated by Radiation Therapy
NIH/NCI 384 Digital Healthcare Platform to Reduce Financial Hardship for Cancer Patients	NIH/NCI 392 Clinical Trials of Systemic Targeted Radionuclide Therapies (FAST TRACK ONLY)
NIH/NCI 385 Leveraging Connected Health Technologies to Address and Improve Health Outcomes of Long- Term Cancer Survivors	NIH/NCI 393 Sensing Tools to Measure Biological Response to Radiotherapy
NIH/NCI 386 Novel Approaches for Local Delivery of Chemopreventive Agents	NIH/NCI 394 Combinatory Treatment Modalities Utilizing Radiation to Locally Activate or Release Systemically Delivered Therapeutics
NIH/NCI 387 Multiplexed Preclinical Tools for Longitudinal Characterization of Immunological Status in Tumor and Its Microenvironment	NIH/NCI 395 Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia
NIH/NCI388 In vitro Diagnostic for the Liver Flukes Opisthorchis viverrini and Clonorchis sinensis	NIH/NCI 396 Imaging for Cancer Immunotherapies
NIH/NCI 389 Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts' Radiation Therapy Planning for Prostate Cancer	11

NIH/NCI 389 - Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts' Radiation Therapy Planning for Prostate Cancer-

Fast Track #	of anticipated awards	Budget (max)	
NOT accepted	2 - 3	Phase I - \$300K for 9 months	Phase II - \$2M for 2 years

Coat: The goal of this contract solicitation is to develop and evaluate AI's capacity to duplicate expert radiation therapy planning. The purpose is to develop radiation therapy treatment plans through AI interpretation of radiomic data from diagnostic images with the intent of fully or at least largely automating treatment planning to eliminate subjective biases, improve treatment quality and reduce cost.

- Phase I Activities and Deliverables include:
 Choose three expert radiation therapy planning teams comprised of a physician and planners (i.e., a person who is knowledgeable in treatment planning with good understanding of the treatment planning system) and evaluate expert cognition process in developing treatment planning for all three strata of patient risk groups (i.e., low, intermediate, and high).
 Teams including experts must be identified prior to submission of the proposal.
 Identify criteria by which an expert planner develops each treatment plan and plan for each risk groups.

- group Describe plan on harmonizing imaging for tumor and normal tissue identification

NIH/NCI 390 - Clonogenic High-Throughput Assay for	SBIR
Screening Anti-Cancer Agents and Radiation Modulators	1.1.1

Fast Track # of anticipa Phase I - \$300K for 9 months Phase II - \$2M for 2 years Accepted 3 - 4

Goal: The purp Use: The purpose of this contract solicitation is to: (i) promote stronger academic industry partnerships in radiobiology to develop clonogenic survival-based HTS systems (ii) be exploit recent advances in the technical maturity of HTS technologies and combine them with advances in choogenic assays) encourage small businesses to specifically develop HTS systems for screening potential anti-cancer agents based on a chonogenic endpoint, and (iv) integrate relevant technologies.

- Phase I Activities and Deliverables include:

 Prototype of integrated/customized robotic or automated platform for cell plating, maintaining the temperature and CO2.

 Develop integrated HTS system that couples plating micro-fluidics, irradiation system, microscopy,
- imaging software and statistical software for estimating cell survival (inactivation radiobiologic estimates) and dose enhancement and modification factors to demonstrate improved efficacy of radiation treatment
- Integration of localized radiation exposure with precise real-time dosimetry into HTS platform.

NIH/NCI 391 - Drugs or Devices to Exploit the Immune SBIR Response Generated by Radiation Therapy

Fast Track

Phase I - \$300K for 9 months Phase II - \$2M for 2 years Accepted 2 - 3

Goal: The goal of this solicitation is to develop agents or devices (engineered cellular therapies, antibodies, small molecules, siRNA/CRISPR-CAS9 or in-two physical/chemical modulating instrumentation-based approaches) that can augment (immune stimulation) or negate (immune subpression) one or more of the immune modulation events induced by radiation therapy.

Phase I Activities and Deliverables include

- ase I Activities and Deliverables include: Selection of cancer type(s), organ site(s), immune modulation agent(s), and radiation dose & fractions, with adequate justification. Proof of concept animal (mice or rat) studies demonstrating augmentation or inhibition of radiation-induced immune activation or suppression respectively with the combination of the agent or device. Proof of concept animal (mice or rat) studies demonstrating tumor regression in a syngeneic contra-lateral tumor model whereby regression is observed in both the irradiated primary tumor as well as distal non-irradiated tumor when the agent is combined with radiation.

NIH/NCI 392 - Clinical Trials of Systemic Targeted Radionuclide Therapies			ed SBIR
Fast Track	# of anticipated awards	Budget (max)	
FT ONLY	2 - 4	Phase I - \$300K for 9 months	Phase II - \$2M for 2 years

Goal:

Goal: To apply for this topic, offerors must have met IND requirements for their product or provide convincing data indicating that an IND will be accepted by the end of the Phase I period of performance. The short-term goal of the project is to perform clinical studies testing the use of new TRT compounds or strategies for the treatment of cancer as described above. The long-term goal of the project is to enable a small business to bring a fully developed TRT compound or novel TRT treatment strategy to the clinic and eventually to the market.

Phase I Activities and Deliverables include: • For offerors who do not expect to have an IND accepted by September 2019, it is expected that specific plans for a pre-IND meeting with FDA will be described in the SBIR proposal. Pre-IND Phase I work may include:

- Scale up and manufacturing of the new tested radiopharmaceutical Completion of any activities required for IND submission Finalized Clinical Trial Protocol for submission to FDA

NIH/NCI 393 - Sensing Tools to Measure Biological Response to Radiotherapy

Fast Track # of anticipated awards

3 - 4 Phase I - \$300K for 9 months Phase II - \$2M for 2 years Accepted

Goal: The purpose of this solicitation is to develop in vivo or in vitro sensor tools to measure biologic response to radiation. These will ultimately be used in optimizing the definition and use of radiation dose; specifically, to help to redefine dose from solely the traditional physical dose to include the additional dimension of biological response.

Budget (m

SBIR

SBIR

- Phase I Activities and Deliverables include:

 • Development of the sensor to measure biologic response to radiation.

 • Demonstrate sensor stability in vitro.

 • Perform in vitro efficacy studies in the relevant cancer cell line(s) and in normal tissue(s): measurement of the target gene/erzyme/other signal.

 • Estabilits peoficity of the construct and conduct validation studies.

 • Perform a small in vivo efficacy study in animal model systems to evaluate appropriate correlative endnoints.
- endpoints.

NIH/NCI 394 - Combinatory Treatment Modalities Utilizing Radiation to R Locally Activate or Release Systemically Delivered Therapeutics

Fast Track

2 - 4 Phase I - \$300K for 9 months Phase II - \$2M for 2 years Accepted

Goal: This contract solicitation seeks to stimulate research, development, and commercialization of innovative techniques that could synergistically improve the effectiveness of RT and TA and reduce toxicity to normal issues. Proposals addressing the following technology areas are encouraged: new treatment strategies, design, synthesis, and evaluation of innovative TA and formulations.

Phase I Activities and Deliverables include:

- Encounter and the expectations include: Demonstrate that the expectations includes and the expectation of the expectation of the expectation of the the expec
- TA only after exposure to radiation. Carry out a pilot animal pharmacokinetic/pharmacodynamic studies utilizing an appropriate animal
- model
- · Significantly characterize the chemistry and purity of the TA and chemistry of the reaction.

NIH/NCI 396 - Imaging for Cancer Immunotherapies			pies SBIR
Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 4	Phase I - \$300K for 9 months	Phase II - \$2M for 2 years

Goal:

Coai: The goals of the solicitation are to develop a cancer imaging technology to identify patients who likely to respond to cancer immunortrapies, evaluate the efficacy and potential toxicities of the treatment, and/or monitor cancer patients' prognosis. The imaging modality could be one of the following, but is not limited to: ultrasound imaging, optical imaging, photoacoustic imaging, PET, SPECT, MRI or combination of multiple modalities. Molecular markers of interest could include but are not limited time of containation or multiple modalities, while can impress to itserest could include out are not inner to cell surface receptors, imme or associated non-immune edits, cellular inflates, enzyme, metabolities or metabolic states, DNAs, RNAs, or epigenetic modifications. The technology development should be platform driven.

Phase I Activities and Deliverables include: Phase I activities should generate scientific data confirming the clinical potential of the proposed imaging for cancer immunotherapies. The Phase I research plan must contain specific, quantifiable, and testable feasibility milestones