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

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

Grant Processes
- Electronic Application Process
- Grant Application Forms NCI
- Extramural Glossary NCI Grant
- Activity Codes/Mechanisms NCI
- Grant Process NCI Research and Funding
- FAQ’s NCI Grant Review Process Preparing Grant Applications

NCI Sponsored Initiatives
- NIH Guide for Grants and Contracts
- NCI Contract Program
- Notice of Award
- Request for Application
- Request for Proposal (RFP) Solicitations
- Small Business Coordination (SBIR/STTR)
- Trans-NIH Initiatives
- Trans-NIH Small Grants

Policies and Guidelines
- Clinical Research
- Human Subjects
- Clinical Research
- NIH Grant Submission and Review Policies
- NIH Grants

Grant Processes
- NIH Guide for Grants and Contracts
- NIH Guide for Grants and Contracts Other Funding
- NIH Contract Program
- Notice of Award
- Request for Application
- Request for Proposal (RFP) Solicitations
- Small Business Coordination (SBIR/STTR)
- Trans-NIH Initiatives
- Trans-NIH Small Grants

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

The following groupings represent the main types of grant funding we provide:

- 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

...more

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...more
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

NIH Clinical Trial Planning Grant (R34)
- Designed to permit early peer review of the rationale for the proposed clinical trial and support development of essential elements of a clinical trial
- Usually 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
THREE-PHASE PROGRAM

FAST-TRACK (PH I & II)

- Proof-of-Concept
- Up to $500,000 over 6 to 12 months

PHASE II

- Technology validation & clinical translation
- Follow-on funding for SBIR Phase I awardees from any federal agency
- Expectation that applicants will secure substantial 3rd party investor funds
- Up to $2M over 2 years

PHASE III

- Commercialization stage
- Use of non-SBIR/STTR funds

CONTRACT TOPICS

Contracts in NCI SBIR Portfolio

Topics are in NCI priority areas with strong potential for commercial success.

GRANT vs. CONTRACT

<table>
<thead>
<tr>
<th>GRANT</th>
<th>CONTRACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope of the proposal</td>
<td>Investigator-defined within the mission of NIH</td>
</tr>
<tr>
<td>Peer Review Venue</td>
<td>NIH Center for Scientific Review (CSR)</td>
</tr>
<tr>
<td>Questions during solicitation period?</td>
<td>May speak with any Program Officer</td>
</tr>
<tr>
<td>Receipt Dates</td>
<td>3 times/year for Omnibus</td>
</tr>
<tr>
<td>Set-aside of funds for particular areas?</td>
<td>NO</td>
</tr>
<tr>
<td>Basis for Award</td>
<td>Based on score during peer review</td>
</tr>
<tr>
<td>Reporting</td>
<td>One final report (Phase I); Annual reports (Phase II)</td>
</tr>
</tbody>
</table>
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:

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

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

<table>
<thead>
<tr>
<th>Fast Track</th>
<th># of anticipated awards</th>
<th>Budget (max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT accepted</td>
<td>2 - 3</td>
<td>Phase I: $300K for 9 months</td>
</tr>
</tbody>
</table>

**Goal:**
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 group.
- Describe plan on harmonizing imaging for tumor and normal tissue identification.
### NIH/NCI 390 - Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators

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<tbody>
<tr>
<td>Accepted</td>
<td>3 - 4</td>
<td>Phase I: $300K for 9 months</td>
</tr>
</tbody>
</table>

**Goal:**
The purpose of this contract solicitation is to: (i) promote stronger academic industry partnerships in radiobiology to develop clonogenic survival-based HTS systems (ii) to exploit recent advances in the technical maturity of HTS technologies and combine them with advances in clonogenic assays, (iii) encourage small businesses to specifically develop HTS systems for screening potential anti-cancer agents based on a clonogenic 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 Response Generated by Radiation Therapy

<table>
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<tr>
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<td>2 - 3</td>
<td>Phase I: $300K for 9 months</td>
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</table>

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

**Phase 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 (mouse 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 (mouse 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

<table>
<thead>
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<tr>
<td>FT ONLY</td>
<td>2 - 4</td>
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**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 radionuclide
  - 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**

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**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.

**Phase I Activities and Deliverables include:**
- Development of the sensor to measure biologic response to radiation.
- Demonstrate sensor stability in vitro.
- Perform in vivo efficacy studies in the relevant cancer cell line(s) and in normal tissue(s): measurement of the target gene/enzyme/other signal.
- Establish specificity of the construct and conduct validation studies.
- Perform a small in vivo efficacy study in animal model systems to evaluate appropriate correlative endpoints.

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

**Fast Track**

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**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 tissues. 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:**
- Demonstrate that the expected release/activation action with a proper amplitude can be induced in vitro and in vivo by safe doses of radiation.
- Demonstrate (if appropriate) tumor-specific targeting and localization of the TA and activation of the 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

**Fast Track**

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**Goal:**
The goals of the solicitation are to develop a cancer imaging technology to identify patients who are likely to respond to cancer immunotherapies, evaluate the efficacy and potential toxicities of the treatment, and/or monitor cancer patients’ progress. 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 to: cell surface receptors, immune or associated non-immune cells, cellular infiltrates, enzymes, metabolites 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.