Behind the Scenes of NIH’s COVID-19 Research Funding: Relevance to the Radiation Community

Andrea DiCarlo, PhD
Director, Radiation and Nuclear Countermeasures Program (RNCP)
National Institute of Allergy and Infectious Diseases (NIAID)

RRS Webinar
April 29, 2020
NIH is Open for Business

- Extramural staff are working remotely
- We continue to process applications and make awards
- We are conducting peer review meetings virtually
- We are working diligently to provide funding opportunities to support COVID-19 research
A Day in the Life of a Program Officer (PO)

- **Reading/reviewing**
  - Literature
  - Applications
  - Progress reports

- **Writing**
  - RFAs / BAAs
  - Meeting reports and reviews
  - Evaluations

- **Talking**
  - To awardees
  - To interested PIs / Companies
  - Presentations at meetings

- **Planning**
  - Scientific meetings
  - Inter-agency coordination
A Day in the Life of a Program Officer (PO)

- Reading/reviewing
  - Literature
  - Applications
  - Progress reports

- Writing
  - RFAs / BAAs
  - Meeting reports and reviews
  - Evaluations

- Talking
  - To awardees
  - To interested PIs / Companies
  - Presentations at meetings

- Planning
  - Scientific meetings
  - Inter-agency coordination
Webinar Outline

- About the RNCP
- NIH policy changes related to COVID-19
- COVID-19 and radiation injury
- NIH funding for COVID-19
- NIH funding application insights
- NIH COVID-19 resources
About the RNCP
Radiation Emergency Preparedness

- In 2004, NIAID established the Radiation and Nuclear Countermeasures Program (RNCP) and identified priorities for triage and treatment of acute and delayed radiation injuries.

- Scenarios of concern are detonation of a nuclear device, nuclear power plant accident/attack, or dissemination of radionuclides.

- Emergency concept of operations necessitates treatment +24 hours or later post-irradiation.

- RNCP research funding reinvigorated a dormant field:
  - Investments in animal radiation facilities (GLP & non-GLP)
  - Development of animal models
  - Funding for academic programs and training
  - Emphasis on industry engagement and product development.
Scientific Areas

- Hematopoietic (H)
- Lung
- Kidney
- CNS
- Gastrointestinal (GI)
- Cardiovascular
- Cutaneous
- Hematopoietic (H)

- Biodosimetry & biomarkers for triage, treatment and tracking

- Approaches to mitigate/treat acute (ARS) and delayed (DEARE) injuries

- Decorporation of internal radionuclide contamination

- Combined injuries
Research Continuum

Basic Research
- Mechanisms of injury
- Target discovery
- Initial efficacy
- Biomarker consideration
- *In vitro* & *in vivo* models

Early Preclinical Development
- Lead candidate identification
- Optimization of *in vivo* dosing
- Formulation development
- Safety, tox, PK/PD
- Device prototypes

Advanced Development
- Pivotal animal studies
- IND/IDE submissions
- Phase I safety
- FDA Licensure
- SNS procurement

NIH ICs/DoD/Academics   Companies/Contractors   BARDA & FDA
Available Programs

**CMCRC**
- MCMs & Biodosimetry
- Pilot projects
- Online textbook

**Companies**
- Guidance
- Product testing
- SBIR/STTR
- R43, R44

**Contracts**
- Product Development Support
- MCMs & Biodosimetry
- Radionuclide Decorporation

**Grants (R01/U01)**
- MCMs & Biodosimetry
- Cell therapies
- Vascular injury

**International**
- WHO, GHSI, IAEA
- France, Japan, India

**Regulatory**
- DAIT/ORA
- FDA/CDER, CBER, CDRH

**Government**
- Trans-NIAID
- Trans-NIH
- Trans-HHS
- DHS, DoD, DOE
- NASA, NIST, NRC

**Companies**
- Guidance
- Product testing
- SBIR/STTR
- R43, R44
NIH Policy Changes Related to COVID-19
Administrative Flexibilities

OMB has authorized agencies to be flexible with awardees affected by COVID-19

NIH is allowing:

- Pre-award costs to be incurred
- Extensions of post-award reporting
- Prior approval requirement waivers
- Submission of post-application materials if revisions are needed
- Numerous flexibilities regarding expenditures of funds

Learn more (NOT-OD-20-086):
Salaries and Stipends

- If unable to work on grant or training activities, salaries and stipends may be charged to NIH grants
  - Ensure that your organization’s policy allows such charges from federal and non-federal funds

- Prior approval is not required to divert faculty from research to clinical work related to COVID-19 until the end of the public health emergency period
Accommodations for Loss of Research Time

- ESI extensions: describe the nature of the disruption to your research:
  - Submit the request once you know how much research time was lost, unless your upcoming application deadline is imminent and an ESI extension is urgently needed.
  - ESI extension submission instructions may be found here: [https://era.nih.gov/erahelp/ESIE_ext/Default.htm#cshid=4](https://era.nih.gov/erahelp/ESIE_ext/Default.htm#cshid=4)

- NIH will be flexible with extending time constraints for fellowship, career development, and training awards, including phased awards
COVID-19 and Radiation Injury
Rising to the Challenge

- People are dying, hospitals are being stretched to the breaking point, and people are out of work.
- We currently have only limited scientific tools (some testing, masks, handwashing, and social distancing).
- We need better and more rapid large scale testing and treatments.
- This moment in our history is an opportunity for the research community to step up.
- You can be a part of the solution!
COVID-19 Attributes

- Inflammatory hyper-reactions
  - Cytokine storm
  - C-reactive protein
  - Interleukin-6

- Thrombocytopenia/coagulopathies

- Vascular injuries

- Early & late lung complications
  - Acute respiratory distress syndrome (ARDS)
  - Fibrosis

- Multi-organ dysfunction

- Higher mortality in elderly and in those with co-morbidities

- Sex differences
Overlap of Radiation Science With COVID-19

- Biomarkers of injury may be similar
- Common pathways to target
- Diagnostic devices could be re-tooled for virus detection
- Treatment approaches addressing:
  - Lung
  - Vasculature
  - GI (new symptomology)
  - Immunosenescence
- Radiation exposure can cause ARDS
Potential Study Areas

- Radiation treatments to make PPE safer when re-used
- Radiation to inactivate the virus for vaccine use (Durante, M.)
- Testing treatments that target lung fibrosis pathways
  - TGF-beta
  - NF-kB
  - MCP-1
- Drugs that target the vasculature
- Growth factors
- Anti-inflammatories / Anti-oxidants
- Cellular therapies
- Diagnostics – modify biodosimetry devices to diagnose, validate vaccine tests, and identify organ biomarkers of major morbidity
Reach Out Before Formal Submission of a Supplement Request

- Contact your RNCP Program Officer or other IC contact
- Discuss your intended plan of action
  - Consider providing a one-page summary
- Get feedback about your proposed aims
- Discuss logistics of submission and review
NIH Funding for COVID-19
NIH COVID-19 Funding Levels

- Funding provided to Institutes & Centers (ICs) to expand research on COVID-19
  - NIAID - $1.53B
  - NHLBI - $103M
  - NIBIB - $60M
  - NCATS - $36M
  - NIH OD - $30M
  - NIEHS - $10M
  - NLM - $10M

- Other ICs seeking COVID-19 studies using internal funds
Notices of Special Interest (NOSIs) for COVID Research

NIAID NOSI: NOT-AI-20-034

Interest in
- Viral natural history, pathogenicity, transmission
- Medical countermeasures
- Animal models
- Diagnostics
- Vaccine qualification

All activity codes of current NIAID grants are eligible

Applications must be submitted using PA-20-135
- 6 page research plan
- Up to 2 years
- Budgets should not exceed annual amount of parent award (exceptions considered case-by-case)
- Contact your PO or person listed in NOSI to discuss before submission
NCI NOSI: NOT-CA-20-042 (-043 for SBIR/STTR)

- Interests areas may include:
  - Mechanism of viral interaction with cancer cells
  - Co-morbidities of cancer and infection
  - Impacts on treatment and clinical outcomes of virus infected persons in the context of cancer
  - Assessment of COVID-19 disease on the efficacy of anticancer agents, radiation treatments, surgical methods, and other cancer treatments
  - Repurposing cancer treatments for COVID-19 patients

- Must be an active award (not in NCE)
  - 6 page research plan
  - 1 year / budget $100,000 direct costs per year

- Contact PO of the parent award to discuss application
PA-20-135: Emergency Competitive Revision to Existing NIH Awards

- Notifies the community that:
  - “Funds may be available for applications based on a presidentially declared disaster...only applications submitted in response to a NOSI can apply”
  - Intended to provide funds for NIH grantees applying to expand the scope of their active grant


- Follow NOSI instructions for each participating IC
  - Page limits
  - Budget limits
  - Areas of interest
  - Must include NOSI number in Agency Routing Identifier Field (box 4B) of the SF424 form

- Grantees seeking funds for research within the scope of an ongoing grant should instead apply for an administrative supplement under PA-18-59
Identify a NIAID (or other IC) Awardee as a Collaborator

- NIAID has the most available funding of any of the ICs
- Any NIAID awardee in an active grant period can submit a competitive revision request (special rules for NCEs)
- Use the NIH Project Reporter - https://projectreporter.nih.gov to identify PIs at your institute and suggest a partnership
COVID-19 Funding Application Insights
Possible COVID-19 Models

- **In vivo**
  - Jackson Labs has a human ACE2 transgenic mouse line, but not available until June
  - The Mutant Mouse Resource & Research Centers (MMRRC) have human ACE2 transgenic mice (https://www.mmrrrc.org/)
  - Infection with mouse hepatitis virus, a member of Betacoronavirus, like SARS-CoV and SARS-CoV-2

- **In vitro**
  - Mouse coronavirus strain A59 (MHV-A59)
  - hACE2 transfection to a mouse cell line
    - Infect with hACE2-expressing adenovirus, then infect with Coronavirus

- It may not be necessary to work with live virus
How COVID-19 Supplements Are Reviewed at the NIAID

- Submissions are assigned to three NIAID POs for review
- POs have weekly review teleconferences for prior week requests
- Applicants are notified soon thereafter
- Awards can be made rapidly (~1 month from submission date), as COVID-19 supplements are prioritized for award
Applications of Greatest Interest

- Have more immediate potential impact
- Have the appropriate expertise covered
- Have relevant data in other viral models/diseases
  - Influenza
  - ARDS
  - Diabetes
- Have human data, patient access and/or available treatment/diagnostic platform
  - Repurposed from another indication
  - In clinical trials for something else
- If research will generate data with a public health impact, include a comprehensive resource sharing plan
NIH COVID-19 Resources
COVID-19 Literature

- NIH-curated source for publications related to COVID-19
- Articles from PubMed and pre-prints from other sources
- Portfolio updated daily
- https://icite.od.nih.gov/covid19/search/
Valuable NIH Websites on COVID-19

- General news and information
  - https://www.nih.gov/health-information/coronavirus

- Information for NIH applicants and funding recipients

- FAQs about COVID-19 grants policy & program flexibilities
Sign Up to Receive the NIH Guide

- Lists funding announcements from all the NIH ICs released during the previous week – sent every Friday
- Hear about new opportunities & COVID-19 rapid awards
- [https://grants.nih.gov/grants/guide/listserv.htm](https://grants.nih.gov/grants/guide/listserv.htm)
- Sign up for specific COVID-19 updates:
RNCP Team – Reach Out with Questions

- Andrea DiCarlo, PhD – Director, RNCP
  - David Cassatt, PhD
  - Brynn Hollingsworth, PhD
  - Carmen Rios, PhD
  - Merriline Satyamitra, PhD
  - Lanyn Taliaferro, PhD
  - Thomas Winters, PhD

cohena@niaid.nih.gov