

*Pre-application webinar for NCI-NIBIB [RFA-CA-20-054](#),
Collaborative Approaches to Engineer Biology for Cancer Applications*

Presentation will begin at 1:00pm ET.

Using WebEx & Webinar Logistics



Everyone will be muted upon entry.
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Please keep your cameras off.



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(link also in the chat)

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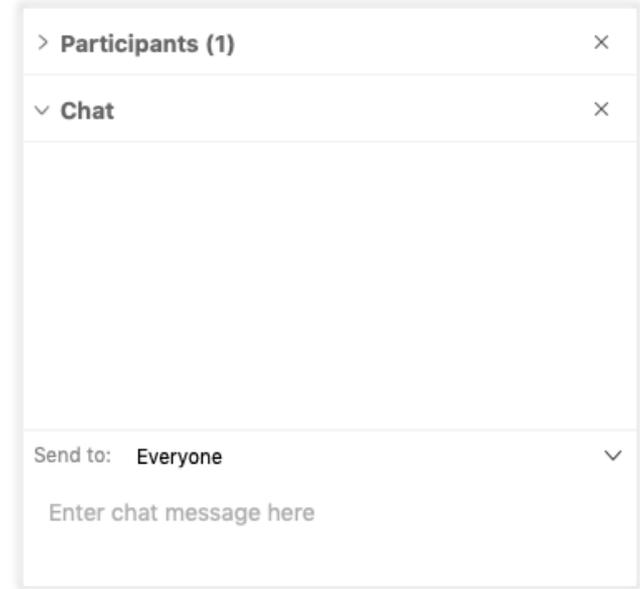
Webinar Logistics—Questions

Submit questions at any time using the Chat. You may chat with “Everyone” or with “Michelle Berny-Lang.”

You may need to activate the appropriate box using the floating navigation panel found on the center of your screen.



A moderator will ask the question on your behalf during the Q & A portion at the end of the webinar.



Collaborative Approaches to Engineer Biology for Cancer Applications (U01)

Pre-application webinar for RFA-CA-20-054

December 10, 2020

Presenters



Michelle Berny-Lang, PhD

Center for Strategic Scientific Initiatives,

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David Rampulla, PhD

Division of Discovery Science and Technology,

*National Institute of Biomedical Imaging and
Bioengineering (NIBIB)*

david.rampulla@nih.gov

Agenda

- Background of Opportunity
- Funding Opportunity Details
- Questions
 - *NOTE: Questions about specific aims or individual projects will not be addressed today*

National Cancer Institute (NCI) & National Institute of Biomedical Imaging and Bioengineering (NIBIB) Collaboration

- Shared NCI and NIBIB goals
 - Stimulate collaborations between engineers and cancer researchers
 - Expand use of synthetic biology to advance understanding and management of cancer



- Jointly developed/supported funding opportunity: *Collaborative Approaches to Engineer Biology for Cancer Applications (U01)*

Purpose of the Funding Opportunity Announcement (FOA)

- This FOA invites applications to develop and apply ***innovative synthetic biology approaches*** to address ***challenges across the spectrum of cancer research***.
- Projects will be required to **apply a technology**, based on an engineered biological system, **to an important and well-defined cancer research question**.
- Collaborative **transdisciplinary teams** are expected with PIs representing **expertise in cancer research, engineering, and other disciplines relevant to synthetic biology**.

Research Objectives of the Funding Opportunity

- The goal is to support **collaborative, transdisciplinary projects** to ***advance synthetic biology approaches to tackle cancer research questions.***
- Applications must balance the **significance of the cancer question** with the **unique potential of the synthetic biology technology** to address that question.
- Key opportunities to be explored span the *continuum of cancer research* including, but not limited to: cancer biology, prevention, early detection, or therapeutics.

Please see FOA Part 2, Section I, “Research Objectives” for sample research areas

Research Project Requirements (*must meet all four*)

- 1) Clearly define and focus on a *significant, challenging cancer research question*
- 2) Apply a synthetic biology technology, as defined by an *engineered/reengineered biological system with sense, compute, and response capability*
- 3) Use a technology/method with *demonstrated early feasibility*
 - The technology or methodology should have overcome early feasibility gaps demonstrated by *supportive preliminary data*.
 - Initial *technology development in a cancer setting is not required*
- 4) Deploy technologies in *mammalian tissue or mammalian model systems*

Responsiveness Criteria

- Non-responsive projects will be administratively withdrawn and will not advance to review
 - Projects without a focus on a *defined cancer research question*
 - Projects that do not apply a *synthetic biology technology, as defined by an engineered/reengineered biological system with sense, compute, and response capability*
 - Projects with an exploratory or early stage technology without a *demonstration of technical feasibility*
 - Projects without components in *mammalian tissue or mammalian model systems*

If you have questions on responsiveness of your project, please contact scientific contacts (Michelle Berny-Lang, michelle.berny-lang@nih.gov and David Rampulla, david.rampulla@nih.gov) before submission

Mechanism of Support and Funding

Mechanism of support: **U01**, Research Project - Cooperative Agreements

*A support mechanism used when there will be **substantial Federal scientific or programmatic involvement**. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities.*

Budget: \$499,999 per year (direct costs)

Project Period: Maximum of 5 years

Foreign Institutions: Foreign (non-U.S.) institutions are eligible to apply and foreign components are allowed.

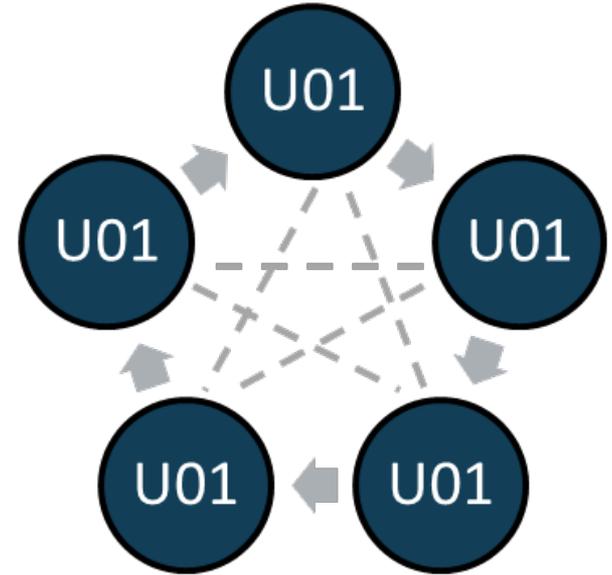
Clinical Trials?: Not allowed

Fund Available & Anticipated # of Awards: \$4.2M in FY 2021 to fund 4-6 awards

Post-award Collaborative Activities

- Requirements include:
 - Annual investigators' meeting
 - Trans-program meetings
 - Data sharing
 - Synthetic biology technology development projects for tools, components, and models that are applicable to multiple funded projects

- Interactions with investigators from other NIH-supported consortia and networks may be appropriate and encouraged.



Leadership Expertise

Eligible Individuals (Program Director/Principal Investigator)

- Strongly encourages the use of the multi-PD/PI option.
- Open to all collaborating teams with formal training and *expertise in both cancer research and engineering or other fields relevant to synthetic biology*.
 - Established through undergraduate or graduate degrees or through a body of work that demonstrates contribution to the field
 - In some instances, a single PD/PI will already have the combined expertise to bring a synthetic biology perspective to study an important problem in cancer research and may not need the multi-PD/PI option

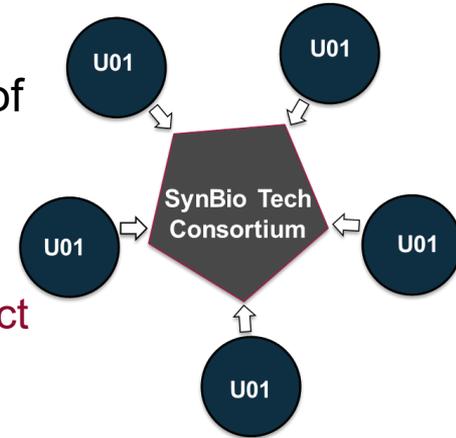
Letter of Intent (LOI)

Due **December 16, 2020** (next week!)

- Highly encouraged, but not required. Not binding and does not enter into the review.
- Email to: Michelle Berny-Lang, michelle.berny-lang@nih.gov
- Details:
 - Descriptive title of proposed activity
 - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
 - Names of other key personnel
 - Participating institution(s)
 - Number and title of this funding opportunity – *Collaborative Approaches to Engineer Biology for Cancer Applications*, [RFA-20-054](#)
- Additional recommended information:
 - Brief, 3-5 sentence description of the project

R&R Budget

- Limited to \$499,999 in direct costs per year and must reflect actual needs of proposed project.
- *Trans-Program Collaborative Funds*: Set aside a minimum of **\$20,000 (direct costs)** from annual budget for collaborative *trans-program synthetic biology technology development projects*.
 - The set-aside amount should be presented in the **Other Direct Costs category** under the heading “**Collaborative Funds.**”
 - The use of the set-aside funds will be restricted for collaborative studies proposed post-award and released upon advice of the Steering Committee and authorization by NCI and NIBIB.
- *Travel Expenses Budget*: Applicants must budget for travel and per diem expenses for at **least one PD/PI to attend annual investigator meetings.**



PHS 398 Research Plan

- All instructions in SF424 (R&R) Application Guide, plus additional criteria:
- **Research Strategy**, clearly describe:
 - The **cancer research question** to be addressed and its *significance* within the broader cancer research landscape
 - The **synthetic biology technology**, including a description of the engineered/reengineered biological system and its ability to sense, compute, and respond
 - The level of *innovation* of the proposed synthetic biology technology, including **why the technology is uniquely suited to address the cancer research question**
- **Resource Sharing Plan**, FOA-specific modifications:
 - All applications should address a Data Sharing Plan.
 - Data, tools, models, and software should be shared in an easily accessible format.
 - Describe the types of data, tools, models, and software that are expected to be generated and shared.
 - Address sharing of data, tools, models, and software across the program.

Application Review Information

- Special Emphasis Panel convened by NCI
- Standard review criteria plus **FOA-specific questions** for starred criteria
 - Significance*
 - Is the selected cancer research question compelling and well-defined? How will making progress towards addressing the question advance cancer research broadly?
 - Investigator(s)*
 - How well does the Project integrate the combined synthetic biology and cancer research expertise to address an important question in cancer research?
 - Innovation*
 - How novel is the proposed application of synthetic biology technologies and how are those technologies uniquely suited to address the cancer research question?
 - Approach*
 - Defined for this FOA as engineered biological systems with sense, compute, and response capability that have overcome early feasibility gaps, how well are the synthetic biology technologies integrated into the approach?
 - How well does the proposed synthetic biology approach address the cancer research question being studied?
 - Environment

Carefully consider the FOA-specific questions

Cooperative Agreement Terms and Conditions

- *Participating in program activities* – investigator meeting, teleconferences with NIH staff, program-sponsored meetings/workshops, collaborative program activities
- *Serving on the Steering Committee* – contact PI and one other key personnel per project to represent synthetic biology and cancer expertise
- *Establishing/conducting collaborative trans-program synthetic biology technology development projects*

More detail in FOA Part 2, Section VI-2, “Cooperative Agreement Terms and Conditions of Award”

Key Dates

Pre-Application Webinar	December 10, 2020
Letter of Intent Due Date	December 16, 2020
Application Due Date	January 15, 2021
Review Dates	April/May 2021
Earliest Anticipated Start Dates	October 2021

Resources

- Read the FOA *very carefully*, RFA-CA-20-054
grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-054.html
- Posting of today's webinar and slides:
cssi.cancer.gov/synbio
- For questions specific to your application:
 - Michelle Berny-Lang michelle.berny-lang@nih.gov
 - David Rampulla david.rampulla@nih.gov

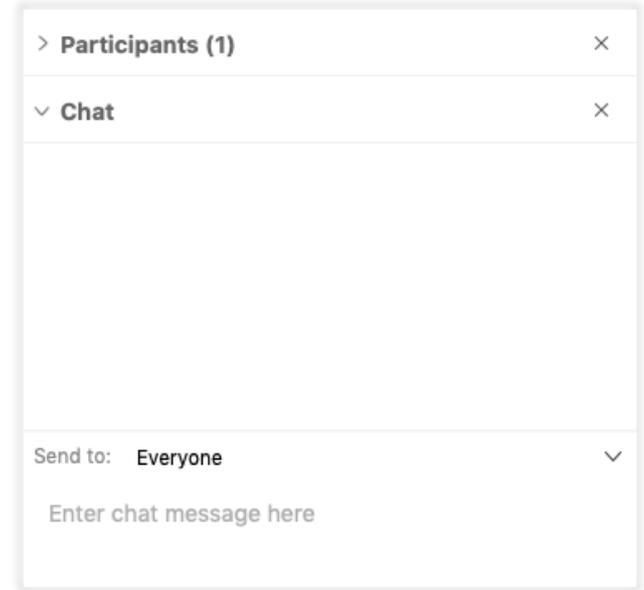
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Research that May Not Fit the FOA, Relevant Opportunities

- New technology development
 - [Innovative Molecular Analysis Technologies](#) (IMAT) – R21, [RFA-CA-21-003](#)
 - [NIBIB bioengineering programs](#)
- Nanotechnology
 - Innovative Research in Cancer Nanotechnology (IRCN) – R01, [PAR-20-284](#)
 - Toward Translation of Nanotechnology Cancer Interventions (TTNCI) – R01, [PAR-20-116](#)
- Tissue engineering
 - [Cancer Tissue Engineering Collaborative](#): Enabling Biomimetic Tissue-Engineered Technologies for Cancer Research – R01, [PAR-19-113](#)
- Molecular biology/genetic engineering
 - Parent R01 – [PA-20-185](#)

Tool for related projects/program officials:

NIH RePORTER, Matchmaker - projectreporter.nih.gov/reporter_matchmaker.cfm



New Synthetic Biology Opportunity

Notice of Special Interest (NOSI): Synthetic Biology for Biomedical Applications

- [NOT-EB-20-017](#)
- Issued by NIBIB, NIA, NIAID, NICHD, NIGMS, NCCIH, NCI, NHGRI

The purpose of this Notice of Special Interest (NOSI) is to announce that [NCCIH](#), [NCI](#), [NIA](#), [NIAID](#), [NIBIB](#), [NICHD](#), [NIGMS](#), and [NHGRI](#) are encouraging new applications to advance research activities relevant to synthetic biology.

- The overarching goal(s) of this Notice are to:
 - develop tools and technologies to control and reprogram biological systems.
 - apply synthetic biology approaches for the development of biomedical technologies.
 - increase the fundamental understanding of synthetic biology concepts as they relate to human health.
 - gain fundamental biological knowledge through the application of synthetic biology approaches.

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Mechanism of Support and Funding: FAQs

What is a U01?: A U01 application is *like an R01 application* with 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* with *programmatic involvement beyond the normal stewardship role* in awards by the NIH program official(s). See 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 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.

Application Review Information: Assignment Request Form

- 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: grants.nih.gov/grants/how-to-apply-application-guide/forms-e/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.

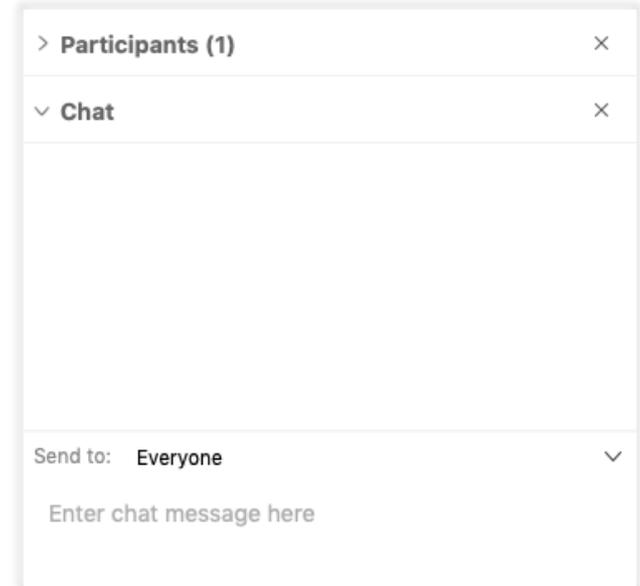
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