

## Frequently Asked Questions related to RFA-CA-20-054 Collaborative Approaches to Engineer Biology for Cancer Applications (U01 Clinical Trial Not Allowed)

### RFA-specific questions

1) *How does the RFA define "synthetic biology"?*

Please see the RFA (Part 2, Section I, "Research Objectives"). A synthetic biology technology is defined as an engineered/reengineered biological system with sense, compute, and response capability.

2) *Which section of the application will be screened for responsiveness? Should the four categories be addressed in the specific aims page?*

As long as the four categories are explicitly and clearly addressed within the Specific Aims and/or Research Strategy section, the content will be covered in the responsiveness screen. Please see the RFA for the details on what a project must include and what constitutes a non-responsive project (Part 2, Section I, "Research Objectives" and "Non-Responsive Projects").

3) *Can you elaborate on mammalian tissues and mammalian model systems appropriate for the RFA?*

The RFA is open to a variety of mammalian tissues or model systems and encourages investigators to select the most appropriate testbed that fits the stage of the technology and is biologically relevant for the cancer question being addressed. Guided by the needs of the project, examples include, but are not limited to: tissue-engineered models, mouse models, human cancer biospecimens, or cell lines. Approaches that are conducted exclusively in microbial systems are not appropriate. Engineered microbes are appropriate if they are used in mammalian systems.

4) *Are the additional costs for cooperative agreement activities covered in the direct costs or are those in addition to the direct costs?*

Please see the RFA (Part 2 Section IV, "R&R or Modular Budget" section). The *Trans-Program Collaborative Funds* (\$20,000 per year) and the *Travel Expenses Budget* should be included within the overall budget, which is limited to \$499,999 or less in direct costs per year.

5) *Can you help an individual PI to form a team for this funding opportunity?*

We may be able to guide you to some potential collaborators but are relying on you to form a team with others in the research community that complement your skill set and fulfill the expertise requirements for the RFA. Please see the RFA (Part 2, Section III, "Eligible Individuals (Program Director/Principal Investigator)").

6) *Should proposals extend to the entire five-year mark funding?*

The maximum project period is five years and please select the project period that best aligns with the time needed to complete the proposed research. The collaborative

program activities, including the trans-program synthetic biology technology development projects, will occur over five years.

7) *Do you expect another deadline for this RFA?*

At this time, we are not expecting another deadline. All applications are due on January 15, 2021.

If you cannot meet the deadline, you could consider submitting under the Notice of Special Interest (NOSI): Synthetic Biology for Biomedical Applications which is connected to several funding opportunities across multiple NIH Institutes and Centers. Please see NOT-EB-20-017 for more information: <https://grants.nih.gov/grants/guide/notice-files/NOT-EB-20-017.html>

8) *Does the Letter of Intent (LOI) title need to be the same as the title submitted in the final application?*

The LOI is not binding. You are welcome to use a temporary place holder title for the LOI and change it when you submit the final application.

9) *What are potential research opportunities for projects that are not fully aligned to this RFA?*

a) New technology development:

a. NCI's Innovative Molecular Analysis Technologies (IMAT) program

<https://imat.cancer.gov/>

R21, RFA-CA-21-003 - <https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-21-003.html>

b. NIBIB Bioengineering programs

<https://www.nibib.nih.gov/research-funding/division-discovery-science-technology-ddst>

b) Nanotechnology-driven projects:

a. Innovative Research in Cancer Nanotechnology (IRCN) – R01, PAR-20-284, <https://grants.nih.gov/grants/guide/pa-files/PAR-20-284.html>

b. Toward Translation of Nanotechnology Cancer Interventions (TTNCI) – R01, PAR-20-116, <https://grants.nih.gov/grants/guide/pa-files/par-20-116.html>

c) Tissue-engineered technologies for cancer applications:

Cancer Tissue Engineering Collaborative: Enabling Biomimetic Tissue-Engineered Technologies for Cancer Research – R01, PAR-19-113,

<https://grants.nih.gov/grants/guide/pa-files/PAR-19-113.html>

d) Molecular biology or genetic engineering:

Parent R01 – PA-20-185, <https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html>

10) *Are there other funding opportunities for synthetic biology research?*

Yes, please contact David Rampulla and Michelle Berny-Lang for input on other possibilities tailored to the scope of your research. One example is the Notice of Special

Interest (NOSI): Synthetic Biology for Biomedical Applications. Please see NOT-EB-20-017 for more information: <https://grants.nih.gov/grants/guide/notice-files/NOT-EB-20-017.html>

### Cooperative agreement questions

1) *What is a U01?*

A U01 is like an R01 with a single research project consisting of multiple specific aims to achieve the goals of the project. The “U” designates the cooperative agreement and indicates that there will be substantial programmatic involvement by NIH program officials beyond the normal stewardship role; e.g. NIH staff could provide scientific guidance and help make connections to other awardees or other consortiums for scientific input and collaborations. Please see the RFA (Part 2, Section VI-2, “Cooperative Agreement Terms and Conditions of Award”) and below links for more information: [https://grants.nih.gov/grants/funding/funding\\_program.htm#u01](https://grants.nih.gov/grants/funding/funding_program.htm#u01)  
<https://grants.nih.gov/grants/glossary.htm#CooperativeAgreement>  
<https://www.niaid.nih.gov/grants-contracts/closer-look-cooperative-agreements>

2) *Is there a requirement for having an NIH staff member to be either a PD/PI or a key personnel member on the application?*

No there is not. Please develop your research team as needed to best perform the proposed research and fulfill the expertise requirements for the RFA. Please see the RFA for details on required expertise (Part 2, Section III, “Eligible Individuals (Program Director/Principal Investigator)”). Upon award, a project scientist from NIH will be assigned to your project to provide programmatic and scientific input.

### Early Stage Investigator questions

1) *If I am an NIH Early Stage Investigator (ESI), will I lose my ESI status if designated as PD/PI of an awarded U01?*

Yes, you will lose the ESI designation.

2) *Is special consideration given to applications that have PIs or PDs with eligible ESI status?*

No, unlike R01s submitted to the parent research project grant funding opportunity announcement, ESI applicants will not be given special consideration.

### General questions

1) *How can I recommend expertise needed to review my application or provide information on potential conflict of interest for review?*

Applicants can submit a PHS Assignment Request Form with their application that addresses the possible conflicts of interest and areas of expertise needed for a fair and knowledgeable review of the application. Please see the link for more information on the PHS Assignment Request Form:

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.600-phs-assignment-request-form.htm>

Additionally, the review panel roster will be available in eRA Commons about 30 days prior to review. Applicants may contact the Scientific Review Officer (SRO) directly with concerns prior to the start of the review process.

- 2) *As a standing study section member, do I get an extension of the submission deadline?*  
All applications are due on January 15, 2021. NIH will not consider late applications. Please see the below link to NOT-OD-15-039 with policy details when an RFA indicates, “No late applications will be accepted for this Funding Opportunity Announcement:”  
<https://grants.nih.gov/grants/guide/notice-files/not-od-15-039.html>