

## Flash Grant Proposal Guidelines & Instructions

### Deadline for Application

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#### FY2023 Cycle 2 Deadline:

Wednesday, December 7, 2022 (noon)

This solicitation is open to proposals in all areas of the life sciences, *except Class I medical devices or consumer products*.

Proposals associated with technical innovations in the following topic areas are particularly encouraged:

- *Global health*
- *Pandemic preparedness*

See pages 3 – 4 for definitions of the topics.

Award announcements: February 2023

### Pre-Submission Information

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Application materials can be found on the Flash Grant webpage at: [www.ncbiotech.org/Flash](http://www.ncbiotech.org/Flash)

Flash Grant FAQs are located at: [www.ncbiotech.org/FlashFAQ](http://www.ncbiotech.org/FlashFAQ)

Read these Flash Program Guidelines & Instructions thoroughly prior to preparing an application. If you have any questions about the program, use the contact information at the end of this document.

### Online Submission Portal

Flash Grant proposals are submitted using an online application system.

**Important:** *Pls applying for the first time must register for an account at least 5 business days before submission of the proposal. See Step 7, page 12 for details.*

If you have applied for any North Carolina Biotechnology Center (NCBiotech) grant using the online funding portal previously, you do not need to register again.

## Eligibility

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### Eligible Institutions

Any North Carolina university or non-profit research organization may apply.

- ⊗ *Companies and individuals are not eligible to apply for Flash Grants.*

### Principal Investigator Eligibility

At the time of submission, the Principal Investigator (PI) must hold a full-time, tenure-track, or tenured faculty appointment, or an appointment as permanent, full-time, clinical or research faculty at the applicant institution or hold an equivalent position.

- ⊗ *Postdoctoral research fellows, adjunct faculty, and non-permanent research personnel are not eligible.*
- ⊗ *The PI may not have more than two active awards from the North Carolina Biotechnology Center at the same time.*

### Intellectual Property Eligibility

No prior invention disclosure, patent application, patent award, or other intellectual property filing is required in order to submit a Flash Grant proposal.

For any project with an associated intellectual property filing or award [e.g, invention disclosure to a university technology transfer office or patent committee/counsel, trademark, copyright, provisional patent application, full patent application, PCT filing, or awarded patent], the technology transfer office of the applicant institution must provide a letter of support attesting that the IP rights are assigned to the institution and have not been committed through license or exclusive option to license to any third party at the time of application.

## Purpose

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NCBiotech's Flash Grant program was created to identify and energize the most creative ideas that exhibit early indications of exceptional commercial potential. Like a flash of inspiration, Flash Grants infuse a quick jolt of funding at a critical early point when a small, targeted influx of funds can be crucial to shaping innovative research ideas into high potential life sciences technologies.

Flash Grants support short, tightly-focused research projects in these two categories:

1. To obtain initial exploratory, proof-of-concept, or feasibility data necessary to suggest the disruptive potential of a life sciences technology
- and/or**
2. To conduct the final experiment(s) needed to advance a basic life sciences research program into the translational research phase of development

Disruptive life sciences technologies are those that may significantly alter the way a market or industry functions, how a product is developed or sold, or how a disease is treated. Disruptive technologies may also displace or render previous products, methods, and business models obsolete.

Translational research represents the shift in the research from the basic or foundational phase establishing the underlying biological mechanisms (the “how does it work” phase of research) into the earliest stages of product development (the “what is the product/market/route towards commercialization” phase). A “pre-translational” Flash Grant proposal might describe a laboratory project that will generate data necessary to advance to subsequent *in vivo* studies, pre-clinical or clinical trials, or *in situ* field trials.

These micro-grants are intended to provide funding for projects that may ultimately generate follow-on funding, intellectual property filings, licenses, and startup company formation, but are too early for traditional grant funding mechanisms.

⊗ *Proposals that simply extend, supplement, or defray the costs of existing research programs will not be considered for Flash funding.*

## Project Requirements

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The FY23 Cycle 2 Flash Grant solicitation is open to projects in **any** life sciences sector **except Class I medical devices and consumer products**. **While projects representing any eligible life sciences sector will be considered for funding, proposals in the following topic areas are especially encouraged:**

### Global Health Technologies

Eligible global health technology projects will focus on research and development of health technologies that are affordable for low-and middle-income countries; adaptable for use in low resource environments that lack infrastructure, electricity and equipment; and easy to administer or use in areas where trained health workers are scarce. Eligible projects include those that relate to development of devices, diagnostics, drugs, microbicides or vaccines for use in low resource settings. Agricultural innovations that address challenges predominantly experienced in Third World countries are also eligible.

Examples include:

- *Injection tools that make vaccine delivery safer and easier*
- *Vector control innovations that prevent mosquito-borne diseases\**
- *Affordable, portable, easy-to-use, and quick diagnostics*
- *Therapeutics that overcome drug resistance in diseases such as tuberculosis and malaria*
- *Biomedical products that block the transmission of HIV and other sexually transmitted infections\**
- *Vaccines for diseases of poverty for which existing vaccines are poorly effective or unavailable, such as HIV, tuberculosis, Chagas disease, and chikungunya*

- *Development of drought-resistant crops that can be grown in sub-Saharan Africa*
- *Improvements in the nutritional value of foods to overcome malnutrition*

*\*Note that innovations rely solely on establishing a physical barrier for effectiveness without an accompanying life sciences component will not be considered.*

## **Pandemic Preparedness**

Eligible life sciences-based pandemic preparedness projects include those that involve research and development of vaccines, therapeutics and diagnostics to stop, treat and detect pandemic threats.

Examples include:

- *New approaches and systems to detect emerging threats by genome sequencing, wastewater sampling or other methods*
- *Medical countermeasures (e.g. vaccines, therapeutics and monoclonal antibodies) for prototype pathogens, representative pathogens from viral families known to infect humans or livestock, and high-priority pathogens most likely to threaten human or livestock health.*

## **Required Elements of the Project**

All projects must meet the following requirements:

- Project outcome(s) clearly advances a line of research or application that has the potential to lead to the creation of a disruptive technology or actionable body of knowledge and/or will advance the research into the translational research phase of development
- Directly addresses a recognized unmet need
- Describes a well-defined scientific or technical project that definitively:
  - Addresses a specific question
  - Has well-defined, measurable success/completion metrics
  - Has a clear endpoint
- Describes a well-defined scientific or technical project with aims that are achievable within the requested budget and timeline

## **Compelling Proposals**

A compelling and competitive Flash Grant proposal will, additionally, demonstrate several of the following features:

- Has strong potential for creating, expanding, or advancing protectable intellectual property
- Has strong potential to lead to follow-on funding from public or private sources
- Involves high-risk and/or high-impact research
- Leverages investments and research funding from NC-based sources

## Program Details

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### Amount and Period of Funding

A maximum of \$20,000 may be requested for projects of up to 12 months in duration.

An additional supplement may be requested by applicants from non-R1 universities for undergraduate interns required to execute the project. See the Flash Grant [FAQs](#) webpage to determine whether your institution qualifies for the intern supplement.

For Budget details, see Step 3, page 10, or the [Flash Grant FAQs](#).

There is no match requirement for the Flash Grant program.

### Funding Decisions and Payments

Funding decisions will typically be announced within 120 business days of submission. The awards selection process is competitive. Award funding is subject to availability of funds and partial funding may be awarded.

If awarded, grant funds will be disbursed in a two-part payment structure with 90% of funds released at the start of the funding period and 10% held back until approval of required final reporting.

## Resubmissions

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Only one resubmission of a previously considered Flash Grant proposal is allowed. Any resubmitted proposal must be identified as a resubmission on the online submission form and on the coversheet.

- *A resubmitted proposal must align to the RFP topic and guidelines of the cycle in which it is submitted.*

## Review Process

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- Examination by NCBiotech staff and/or outside subject matter experts to ensure the proposed project meets program requirements and goals and to evaluate the potential for success.
- Final approval by the Biotechnology Center's senior management.

## Evaluation Criteria

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Each proposal will be evaluated to determine its compliance with the proposal requirements, and it's fit for the program cycle topic areas. Proposals will be evaluated based on the following criteria:

1. Degree of fit with one or both of the Flash Grant categories [disruptive and/or step to translational (see page 2)]:
  - The degree of disruption anticipated in the commercial markets

**and/or**

- Likelihood of success in transitioning to the translational research phase of development.

**Important:** *Special attention is given to this statement in evaluating the proposal.*

2. Degree of fit with the Flash Grant “Required Elements” and with the “Compelling Proposals” elements listed on pages 3 – 4.
3. Clarity and specificity of the rationale/statement of need, study design, deliverable(s) and a realistic budget and timeline.

## Post-award Reporting

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A post-award final report that describes the outcomes and impact of funded activities is required. A final financial statement indicating how the funds were spent is also required. More information on reporting requirements will be provided on request or if a grant is awarded.

After a grant is closed, the PI is required to participate in periodic surveys designed to track information on subsequent funding, patents, publications, jobs, companies created, licenses executed, *etc.*, resulting from the awarded project. This information will be used to demonstrate the impact of our programs and may be collected for up to 10 years.

Grantees will notify NCBiotech if subsequent grants are received as a result of Flash Grant funding.

Grantees will acknowledge NCBiotech in publications resulting from Flash Grant support.

## Information Release

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NCBiotech announces its awards through press releases and other publications. These communications typically include the Project Title and Public Information Summary.

The Public Information Summary is provided by the applicant with the online application and should be written for a lay audience.

No information is released on declined proposals.

## Confidentiality

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As part of the grants review process, NCBiotech routinely shares the contents of grant applications with both internal and/or external experts to assess the merits of each application.

The Biotechnology Center will endeavor to maintain the confidentiality of all information provided by the applicant. While measures are in place to assure the appropriate handling of all information provided, the applicant is responsible for limiting the disclosure of any sensitive information that should not be shared outside of the Biotechnology Center.

We encourage applicants to consult with their institution's technology transfer office or intellectual property professional for more specific counsel, as necessary.

## Application Instructions

Application materials are located on the Flash Grant webpage at [www.ncbiotech.org/Flash](http://www.ncbiotech.org/Flash).

A complete Flash proposal is comprised of a completed application form and four documents:

1. Coversheet signed by the PI and a representative of the institution's sponsored research office
2. Flash proposal
3. Budget form
4. Supporting documentation

A proposal checklist is provided on the Flash Grant webpage.

### Step 1: Read the Guidelines & Instructions

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Read these Flash Grant Program Guidelines & Instructions thoroughly prior to preparing an application. If you have any questions about the program, use the contact information at the end of this document.

- *Applications that do not include the signature of a representative of your institution's Sponsored Research Office (or an authorized official) on the coversheet will be administratively declined without review.*
- *Applications that do not follow all requirements and instructions may be administratively declined without review.*

### General Proposal Formatting Guidelines

- Use standard font (such as Times New Roman, Calibri, or Cambria) no smaller than 11 point.
- Page set-up should be for single-spacing on 8½"x11" paper.
- Number each page.
- Margins should be ¾" to 1".
- Do not use logos or letterhead on any pages of the proposal except for support letters.

### Step 2: Prepare the Flash Proposal

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The proposal should be no more than **3 pages** in length and must include the sections listed below. Use the **headings** provided to identify the sections of the proposal.

**Problem** (suggested 2 sentences)

Define the problem or unmet need that this project will address.

**Identification and justification of project type** (see page 2-3 for definitions, suggested 1 – 2 paragraphs)

Identify and justify your choice of which category of Flash Grant project is being submitted:

- Disruptive technology proof-of-concept
- Transition to translational research
- Both

Please explain why your technology/line of research/discovery applies to either the disruptive category and/or the bridge to translational research category.

**Rationale and Statement of Need** (suggested ½ page)

- Briefly describe how this line of research will contribute to the development of a commercially available solution to a recognized problem and how your product/discovery/technology/scientific finding will be used.
- Briefly describe how your solution will be superior to available alternative solutions for this problem.
- Explain the financial requirements necessary to accomplish the task(s) proposed. Demonstrate how the funds will impact this project and what will be enabled with funding. Please be specific.
- Describe any qualitative and/or quantitative measures of sustainability related to the experimental design and expected outcomes of the project.

**Current Status of Research** (suggested 1 paragraph)

- Describe the work that has been done to date on this project. Indicate the source of preliminary funding for this project.
- Describe any intellectual property (invention disclosure, patent application, issued patent, trademark, copyright, *etc.*) that has been established to protect the invention(s) relating to this project and line of research. If intellectual property covers this project, the university’s technology transfer office is required to write a Letter of Attestation to be included with the supporting documents (See Step 4, page 11 for details).

**Experimental Design/Tasks/Timeline** (suggested 2-4 paragraphs with 1 graphic)

- Describe the specific task(s) or experiment(s) to be accomplished. Detail the possible outcomes for each task.
- Provide a graphic that demonstrates a timeline for completing the project tasks.

**Deliverables** (suggested 1 paragraph)

Projects should have at least one defined, measurable success/completion metric and should be milestone-oriented with a clear end-point or deliverable identified.

**Next Steps** (suggested 1 paragraph)

Discuss the immediate and long-term next step(s) after completion of the project. Include information pertaining to future intellectual property protections and/or regulatory approvals to be sought based on the results of this project.

**Roles and Responsibilities** (suggested one sentence per person)

Describe the specific roles and responsibilities for any key personnel conducting the work on this project.

Use first initial, last name (e.g., J. Smith) format for all personnel identified in this section.

- ⊗ *Inclusion of a to-be-determined postdoctoral fellow, research technician, or other staff member is strongly discouraged. Significant delays can be anticipated for the hiring and training of TBD personnel. This does not apply to undergraduate student interns, who may be hired after receipt of an award.*

**References** (optional; does not count toward page limit; one page maximum)

References may be included but are limited to a maximum of one page; hyperlinks are allowed.

### **Step 3: Prepare the Budget**

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Prepare your budget using the Flash Budget Form provided on the Flash webpage. ***Use of the Flash Budget Form is required.***

Please include the PI and title at the top of the form.

Each line item must include a **justification**. The Justification should be no more than one sentence long.

The Budget Form is provided in Excel but must be converted to PDF for submission.

**Ensure that all lines of the Budget Form are legible after conversion to PDF format prior to submission.**

### **Budget Guidelines**

- **A maximum of \$20,000** for project periods ranging up to **12 months** may be requested.
- There is no match required for a Flash Grant.
- A \$7,500 supplement is available exclusively to applicants at non-R1 universities to engage an undergraduate intern for a 12-month project. For semester-long interns, the maximum that can be requested is \$3,750.

These supplemental funds are in addition to the \$20,000 maximum for the base grant.

Supplemental funds may not be requested for expenses other than an undergraduate intern.

See the Flash Grant [FAQs](#) webpage to determine whether your institution qualifies for the intern supplement.

- NCBiotech grants do not pay for any type of overhead or indirect costs.

***Allowable items as requested funds include, but are not limited to:***

- For non-R1 universities requesting an undergraduate intern supplement, a maximum of \$7,500 for the year (or \$3,750 for a semester) can be requested. To request the intern supplement, a separate individual line item labeled “Intern supplement” should be entered under the “Non-R1 intern supplement, CRO, Contractual, and Consultant Costs” section of the budget form.
- Laboratory and experimental supplies

- Equipment purchases less than \$5,000 (total)
  - Contracted research services
  - Contractual and consultant fees
  - Commissioning an independent professional assessment of the business case for technology development
- ⊗ *Technical project activities cannot be subcontracted to any commercial firm or individual with financial ties to the PI. These arrangements carry the risk that the project may appear as subsidized R&D for a company, which is not consistent with program objectives.*

***Unallowable items as requested funds include:***

- Indirect costs/overhead/facilities and administrative (F&A) costs
  - Travel expenses
  - Legal fees including licensing or litigation fees
  - Patenting and publication costs
  - Equipment purchases over \$5,000
- ⊗ *Salary for any personnel is **NOT** allowable, except for an undergraduate intern at non-R1 universities. (See above for details). All supplemental undergraduate intern funds requested must be used for undergraduate intern salary only.*
- ⊗ *Undergraduate, graduate, or professional student stipends, tuition, housing support, and fees are **NOT** allowable*

## **Step 4: Prepare the Supporting Documentation**

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Combine the following Supporting Documents into a single PDF file.

*Proposals where individual documents are uploaded separately may be administratively declined.*

**A. Biosketches** (Required, 1 page each)

Biosketches are required for all personnel named in the Roles and Responsibilities section (see above). Use of the form provided on the Flash Grant webpage is required.

Please include an undergraduate intern biosketch if available at the time of submission. If the undergraduate intern is hired after receipt of an award, please provide this information to NCBiotech staff once hired.

**B. If applicable: Letter of Attestation from the Technology Transfer Officer** (or appropriate authorized institutional official)

If there is any intellectual property related to the line of research/project (invention disclosure, provisional patent application, full patent application, issued patent, trademark, copyright, *etc.*), this letter should:

- a. Confirm the current status of intellectual property (IP) protection relating to the core

technology, including filing numbers, titles, and dates where appropriate

- b. Attest that the IP rights are assigned to the applicant's institution and have not been committed through license or option to license to any third party at the time of application.
- c. Confirm the university's commitment to continued IP development
- d. Provide a non-confidential summary of any licensing discussions to date relating to the technology
- e. Indicate how the proposed project will support continued IP development and licensing efforts

**C. Letters of support from university representatives, partners, or other stakeholders** (Optional, but encouraged)

A maximum of three letters may be submitted. Include letters of support that demonstrate enthusiasm for the proposed project.

**D. Price quotes (Required, if applicable)**

Quotes must be provided for all contracted research services, core facility fees, library licensing fees, business case development materials, consultant services, or equipment over \$500.

A Letter of Commitment or Statement of Work from consultants may be provided in lieu of a quote, provided that the letter/ SOW is dated, is on letterhead, and directly references the total cost, tasks, and deliverables to be provided.

Limit quotes to a **maximum of 3 pages each**.

**E. Documentation for projects involving animal or human studies**

(Required if applicable)

- Document that notification of the research has been made to the Institution's IRB or IACUC
- Provide a power analysis indicating that the studies proposed have the correct number of human or animal subjects required to achieve an *a priori* confidence level of at least 80%,

**Or**

- For proof-of-concept studies, provide the rationale for why a power analysis is not warranted

## **Step 5: Complete the Coversheet**

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Use the Cover Sheet form provided on the Flash webpage.

***The Cover Sheet must be signed by the PI and an authorized official of the Sponsored Research Office at the time of submission.***

## **Step 6: Convert all of your proposal documents into PDF format**

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Convert your four proposal documents directly into four PDF files.

- ⊗ *Do not print and scan the proposal into a PDF document as this increases the size of the file and can distort the images.*

## **Step 7: Complete the Online Application Form**

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**Note:** *The Flash Grant application form will be available online by **August 15, 2022**.*

### **IMPORTANT FIRST STEP:**

The PI for the Flash proposal must register for an account on the NCBiotech Funding Portal (<https://ncbiotech.fluxx.io>) at least five days prior to the deadline in order to submit a proposal. Click [here](#) for more information on the registration and application process.

**If you have applied for a grant using the Funding Portal previously** (for any NCBiotech funding program), you do not need to register again.

The PI must submit the proposal through their NCBiotech Funding Portal account. Proposals cannot be submitted through accounts belonging to OSR representatives.

After the registration is completed, log into your Funding Portal account. The Flash application form will be located under the “Apply for Funding” folder at the left of the screen. Follow the instructions provided.

- ⊗ *Proposals sent by e-mail or hard copy will not be accepted.*

### **Principal Investigator and Organization information**

The contact information for the submitting PI and organization will be pre-populated on the application form.

### **Proposal Information**

Complete all other fields on the form regarding the project.

### **Additional information for the following fields:**

#### **Public Information Summary**

A Public Information Summary is required and is entered directly into the application form. If your proposal is funded, this concise, easy-to-read summary may be used in Biotechnology Center press releases and other publications. This summary is intended for a general audience. This summary should not include complex scientific terminology.

The summary should convey to the citizens of North Carolina why the project is important. The maximum allowable length for this summary is 50 words.

#### **Upload your four PDF documents**

Follow the instructions for attaching the required documents to the online application (Coversheet, Proposal, Budget Form, and Supporting Documentation).

**Important:** Only one of each of the proposal files may be attached to the application for a total of four attachments.

- ⊗ Applications which have multiple individual files uploaded instead of the four files noted above are subject to administrative declination.

## **Step 8: Review and Submit**

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Carefully review your application package then submit your Flash application prior to the Program Deadline.

Submission of your grant application indicates that:

1. You have read and understand the information and directions in this Application Package and agree to be bound by the conditions stated herein.
2. You release the North Carolina Biotechnology Center from any claim for damages caused by:
  - a. Disclosures required under the provisions of any North Carolina or United States law, statute, or regulation,
  - b. Disclosures made in connection with the North Carolina Biotechnology Center’s funding review and approval process,
  - c. Disclosures required by rule or order of any court of competent jurisdiction,
  - d. Any other non-negligent, inadvertent, unintentional, unknowing, or immaterial disclosure.
3. All research conducted during the proposed project is performed in accordance with established university policies and procedures, including—but not limited to—policies and procedures applicable to research involving human subjects, laboratory animals, or hazardous agents and materials.
4. If the project proposed involves vertebrate animals, the project complies with federal guidelines for vertebrate animal care and experimentation

## **Submission Notification**

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You will receive a confirmation email notifying you that the Biotechnology Center has received your application.

## **Contact Information**

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