

Flash Grant Proposal Guidelines & Instructions

Deadline for Application

FY2022 Cycle 2 Deadline:

Wednesday, December 8, 2021 (noon)

This solicitation is open to proposals in the following areas:

Clinician Innovators developing:

- *Medical devices*
- *Pharmaceuticals and biologics*
- *Precision health solutions*
- *Clinical software and workflow solutions*

See page 2 for definitions of the topics.

Pre-Submission Information

Application materials can be found on the Flash Grant webpage at:

www.ncbiotech.org/Flash

Flash Grant FAQs are located at:

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: *PIs applying for the first time must register for an account at least 5 business days before submission of the proposal. See Step 7, page 8 for details.*

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

Eligibility

Eligible Institutions

Any North Carolina university, non-profit research organization, or non-profit medical system located within North Carolina may apply.

- ⊗ *Companies, for-profit health systems, employees of for-profit health systems, and individuals are not eligible to apply for Flash Grants.*

Principal Investigator Eligibility

For this cycle of the Flash Grant program, the Principal Investigator (PI) must be a clinician innovator. Clinician innovators are clinical health care providers including physicians, nurses, nurse practitioners, physician assistants, allied health professionals (*e.g.*, physical therapy, respiratory therapy), EMTs, and paramedics.

At the time of submission, the PI must hold a full-time, tenure-track, or tenured faculty appointment, or an appointment as a permanent, full-time, clinical employee performing direct patient care, or clinical faculty at the applicant institution or hold an equivalent position.

A letter of support from the applicant's institution attesting that the PI is eligible to receive grants and act as a PI on an awarded grant must be included in the supporting documents submitted with the proposal.

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

Purpose

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 crucial proof-of-concept or feasibility testing 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 model obsolete.

The translational research phase of development for life sciences technologies 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 bench 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 ongoing research programs will not be considered for funding.*

Project Requirements

The technology/product/idea being researched or in development must fall within one of the following areas:

Medical devices

Medical devices are defined as “An instrument, tool, machine, test kit, or implant that is used to prevent, diagnose, or treat disease or other conditions.”¹ Only Class II and Class III medical devices are eligible.

- ⊗ *Class I medical devices, unregulated products (e.g., nutritional/health/wellness/fitness apps, etc.), supplements, or consumer products are not eligible for grant funding.*

Please see the FAQs for a more comprehensive definition of a medical device.

Pharmaceutical/biological therapeutics

Pharmaceuticals/biological therapeutics are defined as “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”²

Precision health solutions

Precision health combines data about an individual's genes, environment, and lifestyle with innovation to predict and diagnose disease, target therapies, and personalize health and wellness plans more precisely.

Clinical software and workflow solutions

Clinical software and workflow solutions are digital and data-driven life science technologies intended as a patient engagement, assessment, or management solution where the primary objective will be met through computational, digital, or data-driven means.

These technologies include but are not limited to:

- Computational Biology
- Bioinformatics
- Biostatistics
- Cloud computing
- Machine learning (ML) and artificial intelligence (AI)
- Lab automation

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

Amount and Period of Funding

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

There is no match requirement for the Flash Grant Program.

See Budget details beginning on page 6.

Funding Decisions and Payments

Funding decisions will typically be announced within 90 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 as 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

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

- Examination by Biotechnology Center staff and 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

Each proposal will be evaluated to determine its compliance with the proposal requirements, and alignment with 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.
- 2) Degree of fit with the Flash Grant "Required Elements" and with the "Compelling Proposals" elements listed on pages 2-3.

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

- 3) Clarity and specificity of the rationale/statement of need, study design, deliverable(s) and a realistic budget and timeline.

Post-award Reporting

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, participation is expected in periodic surveys to track information on subsequent funding, patents, publications, jobs, companies created, licenses executed, *etc.* that are a direct result of the award. This information will be used to demonstrate the impact of our programs and may be collected for up to 10 years.

Grantees will notify the NC Biotechnology Center if subsequent grants are received as a result of Flash Grant funding.

Grantees will acknowledge the NC Biotechnology Center in publications resulting from Flash Grant support.

Information Release

The North Carolina Biotechnology Center 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

As part of the grants review process, the Biotechnology Center 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.

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

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 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

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.

Current Status of Research

(suggested 1 paragraph)

- Describe the work that has been done to date on this particular project. Indicate the source of preliminary funding for this project.
- Describe any intellectual property (invention disclosure/patent application/issued patent/trademark/copyright, etc.) that is held surrounding this project and line of research.

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 endpoint 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.*
- ⊗ *A Flash Grant is a project-based grant and is not intended to support postdoctoral fellows, clinical or research trainees, students, or other newly hired individuals.*

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

Prepare your budget using the Flash Budget Form provided on the Flash webpage. 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.

!Important: *Use of the Flash Budget Form is required.*

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

!Important: *Ensure that all lines of the Budget Form are legible after conversion to PDF.*

Budget Guidelines

A maximum of \$20,000 for project periods ranging up to 12 months may be requested. 90% of requested funds will be available upon award; the remaining 10% will be dispersed following receipt and approval of final financial and technical reports.

There is no match required for a Flash Grant. Funds may only be used for direct costs.

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

- 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:

- ⊗ *Salary for any personnel is **NOT** allowable*
- ⊗ *Undergraduate, graduate, or professional student stipends, tuition, or fees are **NOT** allowable*
- 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

Step 4: Prepare the Supporting Documentation

Combine the following Supporting Documents into a single PDF file.

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

A. Bio Sketches (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.

B. Letters of support from university representatives, partners, or other stakeholders

1. A letter of support from the PI's institution, either from the PI's direct supervisor or from the institution's sponsored research office, attesting that the PI is eligible to receive grants and act as a PI is required. This letter must be on university/institutional letterhead, signed and dated. (Required)
2. A maximum of three letters may be submitted. Include letters of support that demonstrate enthusiasm for the proposed project. (Optional but encouraged)

C. 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**.

D. 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

Use the Cover Sheet form provided on the Flash webpage.

- *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.*

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

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

Note: *The Flash Grant application form will be available online by **November 8, 2021**.*

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 her/his 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

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

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

Contact Information

Director of Grant Process Operations
Science and Technology Development
North Carolina Biotechnology Center
SciTechGrants@ncbiotech.org

References

¹ Section 201(h) Federal Food, Drug and Cosmetic Act (FD&C Act)

² Section 201(g) Federal Food Drug and Cosmetic Act (FD&C Act).