

Biotechnology Innovation Grant (BIG) Proposal Guidelines & Instructions

Deadline for Application

The Biotechnology Innovation Grant (BIG) will have two proposal cycles for fiscal year 2015-2016.

Cycle 2 Deadline:

NOON, Wednesday, February 17, 2016

Application materials and the link to the online application form can be found on the BIG webpage via www.ncbiotech.org/grants. The North Carolina Biotechnology Center's policy on deadlines in the event of inclement weather can also be found at that link.

Program Requirements

Purpose

This program supports studies that enable commercialization of early-stage university life science inventions that have significant commercial potential. Typically, funding will support studies that yield a "go/no-go decision" for the university regarding the pursuit of intellectual property protection and/or commercialization of the invention.

- Eligible projects should have demonstrated successful results in basic research (ideally funded through a federal or other peer-reviewed process) and be poised for patenting and/or commercialization pending additional development.
- Funds are awarded for technology development and commercialization activities including proof-of-concept studies, prototype development, scale-up pilot studies, and studies designed to assess commercial feasibility. Projects should be designed to reveal potential weaknesses, provide go/no-go

decision points, enhance IP value, and position the invention for subsequent commercialization funding.

- This program is intended to be upstream of the Center's other commercialization program for universities, the *Technology Enhancement Grant*, which is for later stage technologies managed by technology transfer officials. The BIG program is also intended to coordinate with and leverage other programs that support technology commercialization.

As a secondary goal, this program is also intended to support an entrepreneurial culture within the university by focusing attention and resources on commercialization statewide.

Applicants are encouraged to review the Evaluation Criteria section for more details. There are also *FAQs online* that offer additional clarification.

Who May Apply

Proposals must be submitted by a North Carolina university or non-profit research organization.

Principal Investigator Requirements:

- The Principal Investigator must hold a full time tenure-track or tenured faculty appointment, or an equivalent appointment as a full time research faculty with a dedicated independent lab at the applicant university.
- The PI must have an invention disclosure on the project technology.
- The PI must be supported by at least one commercialization advisor or team that is based in North Carolina.

- ⊗ The PI may have no more than two active awards from the North Carolina Biotechnology Center at the same time.

Commercialization Advisor Requirements:

- The Commercialization Advisor conducts essential activities that will set the stage for the technology to move forward beyond the project period of this grant.
- The Commercialization Advisor should be based in North Carolina.
- The Commercialization Advisor role allows for a wide variety of experiences and backgrounds, including but not limited to: business expert(s) outside of the lab but within the university (such as an MBA team with a faculty advisor or an entrepreneur in residence); or business experts outside the university (such as serial entrepreneurs experienced in start-up management or investors with experience serving on the boards of startup companies or venture capital funds.)
- A company should not serve in the role of Commercialization Advisor.

See the [FAQs online](#) for more information on the role of the Commercialization Advisor.

Funding & Matching Requirements

See 'Budget Guidelines' for budget details and allowable/unallowable costs.

- A maximum of \$100,000 for project periods ranging from 6 to 18 months may be requested.
 - There is a minimum 10% match requirement.
 - In addition to the minimum 10% match, any equipment items costing over \$40,000 require a direct 25% cash match.
 - Funds should be allocated toward both the technical and commercialization aspects of the project. A minimum of 20% of the requested funds should be directed toward commercialization activities.
- ⊗ *Biotechnology Center grants do not support any type of overhead or indirect costs.*

Preliminary Consultation

Although not required, a consultation may be helpful to the applicant. Please contact us at least **three weeks prior** to the deadline if you would like to schedule a consultation or have a draft proposal reviewed. Use the contact information at the end of this document.

Resubmissions

If this is a resubmission of a previously submitted BIG proposal, you must contact Deborah De at 919-549-8845 or Deborah_De@ncbiotech.org to indicate your intent and schedule a consultation. You will also receive instructions for including a response to the previous reviews in this proposal.

Resources for Applicants

If commercialization expertise is needed: There are a number of organizations throughout the state that provide assistance to entrepreneurs and could potentially serve as Commercialization Advisors. These organizations include but are not limited to NC SBTDC, the UNC Kenan Institute of Private Enterprise, Carolina KickStart, the NCSU TEC program, Duke Innovation and Entrepreneurship, the Blackstone Entrepreneurs Network, and others. A number of these operate statewide.

Review Process

The external review process will include evaluation by a Commercialization Advisory Panel. Members of this panel have significant experience in and knowledge of technical assessments of commercializing life science technologies.

Evaluation Criteria

Each proposal will be judged on its plan to move the invention toward intellectual property protection and/or commercialization. The technology must have the potential for significant contribution to the development of commercial products in the biotechnology sector. *A project plan that leads to a clear decision whether a*

technology should move forward toward intellectual property protection and commercialization or not (i.e. go/no-go) is considered a successful outcome.

BIG proposals are evaluated on a 100 point scale based on the following questions:

A: Solid Foundation of Basic Research: Has the PI completed the foundational work to move toward a solution and move the technology towards commercialization? Have foundational questions been addressed? Is the work ready to move out of the basic phase? Is the status of IP at the right stage with a good understanding of the state-of-the-art and freedom to operate? (25 points)

B. Problem-Solution Intersection: Is there a well-defined technology that solves a clearly stated problem? Is the solution unique and better than existing solutions? Does the proposed project advance the invention to a go/no-go decision point? (20 points)

C. Realistic Approach to Market Potential: Does the proposal demonstrate a realistic approach to understanding the market potential for the technology? Are the commercialization goals well-defined, realistic, and appropriate for this stage of the project? (15 points)

D. Appropriate Activities and Budget: Are the proposed technical and commercialization activities an appropriate use of the budget? (15 points)

E. Effective PI/Commercialization Advisor Team: Is the team appropriate for moving the technology forward on the commercialization continuum? Do they have the necessary expertise and knowledge? (10 points)

F. Potential Impact of Funds: To what extent would a BIG award enhance the invention or generate value in development of a product with commercial potential? Will the project position the invention for a strong, defensible patent? Will all activities move the technology forward on the Commercialization pathway? (15 points)

Post-award Reporting

Post-award technical and financial reports are 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 biennial surveys to track information on subsequent funding, patents, publications, jobs, etc. that are a direct result of an award. This information will be used in support of justifying state funds for Center programs and may be collected for up to 10 years.

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 that are provided by the applicant with the online application. No information is released on declined proposals.

Confidentiality

The Biotechnology Center will endeavor to maintain the confidentiality of all applicants' information. However, the applicant is responsible for not disclosing any information that should not be reviewed outside of the Biotechnology Center.

Application Instructions

Application materials are located on the BIG webpage at www.ncbiotech.org/research-grants/research-funding/biotech-innovation-grant.

The BIG proposal is comprised of three documents: the Proposal, Budget Form, and Supporting Documentation. Please use the checklist provided to make sure all components of the proposal application are included.

Step 1: Read the Guidelines & Instructions

Read these BIG Program Guidelines & Instructions thoroughly prior to submitting 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 will be declined without external review.*

Step 2: Prepare the Proposal

General Proposal Formatting Guidelines

- Use standard font (such as Times New Roman, Calibri, or Cambria) no smaller than 12 point.
- Page set-up should be for single-spacing on 8½"x11" paper.
- Number each page.
- Margins should be ¾" to 1".
- Each section should be titled using the header sections listed below and should match the Table of Contents.
- Do **not** use logos or letterhead on any pages of the Proposal *except* for support letters.
- Judicious use of headings and white space for ease of reading is appreciated.

Proposal Requirements

The Proposal must include the sections listed below. Use the **headings** provided to identify the sections of the proposal.

Table of Contents (*does not count toward page limit; should be on a separate page*)

Include title, PI name, institution and page numbers.

Abstract (no more than one page): Provide an overview of the project, including a brief description of the technology, the name of the Commercialization Advisor, and a summary of the technical and commercialization goals.

Technical Proposal Narrative: The technical narrative should be no more than **4** pages long and include all sections below. Use the **headings** provided.

-Problem

Define the problem that this invention could address.

-Current Status of Research

Describe the work that has been done to date, both in the lab of the scientist and in the field.

-Technical Goals

Explain the goals for the development of the technology to be achieved in this project.

-Project Plan

Describe the studies that will be performed to meet the stated technological goals, including key technical milestones and a timeline narrative.

-Evaluation

- 1) Define the criteria for a go/no-go decision within the technical phase. Include defined metrics that will indicate or demonstrate a successful outcome.
- 2) Discuss the anticipated challenges within the technical aspects of the project.

Commercial Proposal Narrative: The commercial narrative should be no more than **2** pages long and include all sections below. Use the **headings** provided.

The Commercialization Advisor should participate in the preparation of this section of the proposal.

-Problem

Define the market problem that this invention could address.

-Commercial Goals

Explain the commercialization goals for this project.

See the [*FAQs online*](#) for examples of commercialization goals.

-Market

Assess the potential for a solution to the market problem, the size of the market, and the relevant market drivers. Identify specific companies or industries with potential for commercialization of the technology.

-Intellectual Property

Discuss the current state of the art and probable freedom to operate with regard to IP.

-Project Plan

Describe the plan for meeting the commercialization goals, including key milestones and a timeline narrative.

-Evaluation

- 1) Explain how the results of the commercialization activities of the project will be evaluated and the criteria for a go/no-go decision within the commercial phase.
- 2) Discuss the anticipated challenges within the commercial aspects of the project.

Roles and Responsibilities *(does not count toward page limit)*

- 1) Describe the roles and responsibilities for the Principal Investigator and Commercialization Advisor.
- 2) Describe the management plan for coordination of the technical and commercialization goals and activities of the project.

Project Timeline *(does not count toward page limit)* Provide a graphic or table that demonstrates the integrated timeline for completing the Project Plan, including both technical and commercialization steps. Indicate in the graphic or table who will perform each step.

Budget Justification *(does not count toward page limit)*

Describe each budget line item and provide justification for each cost. Explain the source(s) and use of the matching funds.

Bibliography *(does not count toward page limit)*

Give full citation including title and complete author list. If complete author list is extensive, include the first three (3) authors listed.

Previous, Current, and Pending Grants *(does not count toward page limit)*

- 1) Include a list of previous grants that directly provided the foundation for the technology that is being developing in this project.
- 2) In addition, list current or pending grants related to this project.

Provide the following information for each grant:

- Funding agency
- Project title
- Award amount
- Date and duration of award

Biographical Sketches *(does not count toward page limit)*

Provide bio sketches for the Principal Investigator, Commercialization Advisor, and any other key personnel. Limit each biographical sketch to no

more than one (1) page using the Biographical Sketch form provided on the BIG webpage. Include position title and department. Insert the biographical sketches at the end of your proposal document.

Convert Your Proposal into a PDF

Document

Convert your proposal document directly into a PDF file.

- ⊗ Do not print and scan the proposal to PDF – this causes the PDF to be significantly larger.

Step 3: Complete the Budget

Prepare your Budget using the BIG Budget Form provided on the BIG webpage. The Budget is provided in Excel format and may be submitted as an Excel or PDF file.

The title and length of the project must be included in the spaces at the top of the Budget Form.

All funds requested on the Budget Form must be justified under the Budget Justification section of your proposal (described above).

- *Failure to use the Budget Form provided will result in rejection of the proposal.*

Budget Guidelines

A maximum of \$100,000 for project periods ranging from 6 to 18 months may be requested.

Funds should be allocated toward both the technical and commercialization aspects of the project.

- A minimum of 20% of the requested funds should be directed toward commercialization activities.

Allowable requested items include:

- Salary costs for research scientist
- Salary costs for technical or commercial personnel directly conducting work on the project
- Commercialization Advisor fees
- Professional development for Commercialization Advisor
- Market reports
- Minor lab equipment and equipment fees
- Lab supplies

- Travel costs only if directly related to achieving technical or commercial goals
- Contractual and consultant fees, including CRO costs
- Graduate Student salary – up to 25% of the student’s salary may be requested

Unallowable items as requested or matching funds include:

- Legal fees
- Patent costs
- Publication costs
- Tuition (other than for professional development for the Commercialization Advisor). This program is not intended to be a support mechanism for graduate students
- Indirect costs/overhead/facilities and administrative costs
- Travel to scientific meetings
- Graduate student salary may not be used as match.

Matching Contributions:

- The applying institution must provide a minimum 10% direct cost match. This match represents the commitment of the institution to develop the technology.
- The 10% match is calculated as a percentage of the requested amount.
- In addition to the minimum 10% match, any equipment items costing over \$40,000 require a direct 25% cash match.

Step 4: Gather Supporting Documentation

Combine the following Supporting Documents into a **single** PDF file. You can accomplish this by scanning related files together and then converting to PDF.

- **Cover Sheet (required)**
Use the Cover Sheet provided on the BIG webpage. This sheet must be the first page of the Supporting Documentation PDF file.
- **Letter(s) of Commitment for Matching Contribution (required)**
The specific dollar value of the matching funds must be included in the letter(s). This letter(s) must be on letterhead and signed by an authorized individual of the applicant institution.

• Program-Specific Supporting Documents

- Letter of Commitment from Commercialization Advisor (required)
- Letter of support including evidence of invention disclosure from the Tech Transfer Office or appropriate authorized institutional official (required)
- Letters of interest from companies and other entities interested in seeing the technology move forward (encouraged)
- Documentation of IACUC Approval with Animal Welfare Assurance # (for projects involving any animal studies) or documentation of IRB Approval (for projects involving human subjects)

Step 5: Complete the Online Application Form

Use the link to the online application provided on the BIG webpage. Complete all pages of the form. You can stop and save at any time and return to finish later.

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

The online application form includes a field for the **Public Information Summary**. 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, allowing the Biotechnology Center to share granting information with the general public and other interested parties.

- 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**.

Step 6: Attach the Required Documents

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

Important note: Only **ONE** of each of the proposal files may be attached to the application for a **total of three attachments**.

Step 7: Review and Submit

Carefully review your application package using the checklist provided on the website then submit your BIG application prior to the Grant 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, or
 - 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.

You will receive a confirmation email notifying you that the Biotechnology Center has received your application. Any Center request for additional proposal information must be addressed within 24 hours.

Contact Information

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North Carolina Biotechnology Center

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919-541-9366 • See our grant application Web page at www.ncbiotech.org/grants