North Carolina **Biotechnology Center**

Biotechnology Innovation Grant (BIG)
Proposal Guidelines & Instructions

Deadline for Application

The Biotechnology Innovation Grant (BIG) program has two proposal cycles for fiscal year 2016-2017.

Cycle 2 Deadline:

NOON, Wednesday, February 15, 2017

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

Program Requirements

Purpose

Every day, North Carolina researchers are making life science discoveries that have the potential to impact lives. The Biotechnology Center supports the scientific community in its efforts to transform these discoveries into innovations that will yield useful commercial products.

The Biotechnology Innovation Grant (BIG) provides funding that enables university researchers to explore commercial applications of their inventions. Each BIG award funds a technical project in parallel with a commercially-focused project designed to contribute to early product milestones, demonstrate a clear path to commercialization, and inform subsequent development. The technical project extends beyond the existing foundational research base to test some aspect of the product potential of the invention. The commercial development project is undertaken by a partner Commercial Development Adviser and examines the market, intellectual property (IP) landscape or other factors determining commercial potential.

A successful BIG project can uncover technical and commercial opportunities or weaknesses; inform go/no-go decisions regarding continued development and IP protection; enhance IP value; or position the invention for further commercial development. More broadly, the BIG program helps nurture an entrepreneurial culture within the university by pairing technologists with commercial development expertise at the earliest stages of product development.

Program Details

Eligible projects support inventions that have been disclosed to the university's technology transfer office but have not yet been converted to a full non-provisional or PCT patent application. Note that the filing of a provisional patent application is allowable but not required.

Funds are awarded for technology and commercial development activities, including early proof-of-concept studies, compound screening against novel targets, prototype development, scale-up pilot studies, and studies designed to assess commercial feasibility and guide further IP protection.

This program is intended to work upstream of the Center's other technology development program for universities, the *Technology Enhancement Grant,* which supports subsequent technology licensing efforts by the university.

Applicants are encouraged to review the Evaluation Criteria section for more details. FAQs are provided at *www.ncbiotech.org/grantfaq* to 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 engage with a qualified Commercial Development Adviser (or Team) for the execution of the commercial development project.

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

Commercial Development Adviser Requirements:

- The Commercial Development Adviser will recommend and execute specific commercial development goals for the project and be required to complete the Commercial Development Narrative portion of the proposal.

- The Commercial Development Adviser role allows for a wide variety of experiences and backgrounds, including but not limited to:

  1) business expert(s) outside of the lab but within the university, such as an entrepreneur-in-residence, business school faculty or university staff responsible for new ventures development; or

  2) commercial experts outside the university, such as serial entrepreneurs, industry-experienced product development consultants, or investors with experience serving on the boards of startup companies or venture capital funds; or

  3) representatives of local entrepreneurship support organizations.

There are a number of organizations throughout the state that provide assistance to entrepreneurs and could potentially serve as Commercial Development Advisers. See the *BIG FAQs* for examples of qualified advisers and information on resources available for entrepreneurs in North Carolina.

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 required from the university.
- In addition to the minimum 10% match, any equipment costing over $40,000 requires a direct 25% cash match.
- Funds should be allocated toward both the technical and commercialization aspects of the project. Up to 20% of the requested funds is expected to be directed toward commercial development activities.

⊗ *Biotechnology Center grants do not support any type of overhead or indirect costs.*

Preliminary Consultation

Although not required, a pre-submission consultation is strongly encouraged. 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.

Review Process

- Examination by Biotechnology Center staff to ensure the proposed project meets program

requirements and goals and has potential for success.

- External review by an advisory panel consisting of professionals with significant experience with assessment and commercialization of life science technologies.
- Final approval by the designated committee of the Biotechnology Center's Board of Directors.

Evaluation Criteria

Each proposal will be judged on the underlying technology and the proposed 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 a commercial product in the biotechnology sector. *A project plan that leads to a clear decision whether a technology should move forward toward further intellectual property protection and commercialization* <u>*or not*</u> *(i.e. go/no-go) is considered a successful outcome.*

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

A: Solid Foundation of Basic Research: Has the PI established a sufficient scientific foundation to support the translational work proposed? Is the work ready to move out of the basic science phase? (15 points)

B. Robust Technical Study Design: Are the important aspects of the project (i.e., aims, study design, data analysis, thresholds for success, anticipated challenges and contingency plans) described in sufficient detail? Will the project yield clear and unambiguous results that support go/no-go decisions regarding further technology development and/or IP investment? (20 points)

C. Realistic and Compelling Market Potential: Does this project target a verifiable unmet need? Does the technology offer features that improve upon existing solutions? Does the proposal demonstrate a realistic approach to understanding and addressing the market potential for the technology? Are the commercialization goals associated with deliverables that are 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 and well justified in the proposal? (15 points)

E. Effective PI/Commercial Development Adviser Team: Is the team appropriate for moving the technology forward on the developmental continuum? Do they have the necessary expertise and knowledge? (15 points)

F. Potential Impact of Project : To what extent would the proposed project enhance the invention, mitigate risk, or generate value in the development of a product with commercial potential? Will the project further support or clarify the IP claims and/or improve the patentability of the invention? Will the proposed activities serve to uncover or confirm a potential commercial application for the technology or otherwise move the technology along a commercialization pathway? (20 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, licenses, publications, jobs, companies created, 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.

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/big*.

The BIG proposal is comprised of four documents: the Technical Proposal, the Commercial Development Narrative, 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.*

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.

Step 2: Prepare the Technical Proposal

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.

Project Summary (no more than one page):
Provide information on the project in the following order:

- Brief description of the technology,
- Name of the Commercial Development Adviser
- IP status
- Summary of the technical goals and deliverables
- Summary of the commercial development goals and deliverables

Technical Proposal Narrative: The technical narrative should be no more than **6** pages long and include all sections below. Use the **headings** provided below.

-Problem (suggested ½ page)
Define the problem that this invention could address.

-Current Status of Research (suggested 1 page)
Describe the work that has been done to date, both in the lab of the scientist and the state-of-the-art for the field. Describe why your solution is technically superior.

-Technical Goals (suggested ½ page)
Explain the technical goals and the desired impact expected for this project.

-Project Plan (suggested 2 pages)
Describe in detail the studies that will be performed to meet the stated technological goals, including study design, end points, measured data analysis method(s) employed and milestones to be achieved.

-Evaluation (suggested 2 pages)
1) Define the criteria established for project outcomes that will be used to assess whether each study aim has been successfully completed and how each will contribute to go/no-go decision-making.

2) Discuss the potential challenges with the technical project and alternative (contingency) plans.

Roles and Responsibilities *(does not count toward page limit)*
1) Describe the specific roles and responsibilities for the Principal Investigator, Commercial Development Adviser and any other pertinent personnel.
2) Describe the management plan for coordination of the technical and commercialization goals and accountability for the deliverables of the project.

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

Budget Justification *(does not count toward page limit)*
Describe each budget line item and provide justification for each cost. Requests for both technical and commercial development expenses must be itemized and explained in detail. 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 relating 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, Commercial Development Adviser, 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.

Step 3: Prepare the Commercial Development Narrative

The Commercial Development Adviser must prepare this document.

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

-Technology under Development
Brief description of the technology being developed in this project (no more than one paragraph).

-Commercial Development Adviser Expertise
State the name(s) of the personnel who will serve as the commercial development adviser and others contributing to the commercial development activities. Describe their roles and the expertise that this individual/team brings to the project.

-Commercial Goals
Define specific commercial development goals and deliverables to be accomplished in this project.

See the *FAQs online* for examples of commercial development goals.

-Market
Discuss and prioritize potential commercial applications for the technology, including the unmet need, market size, and the relevant market drivers for each. Identify potential licensees or commercial partners for each application, if known.

-Intellectual Property
Discuss the current status of any IP relating to the technology. How will this project contribute data that will be used to strengthen existing IP or generate additional IP claims?

-Project Plan
Describe the plan for meeting the commercial development objectives and deliverables described above.

-Evaluation
1) Explain how the results of the commercial development deliverables will contribute to go/no-go decisions with respect to continued product development and/or IP protection.

2) Discuss the anticipated challenges within the commercial aspects of the project and present any alternative (contingency) plans.

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 4: 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. *Use of the BIG Budget form is required.*

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).

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.

- It is expected that up to 20% of the requested funds be directed toward meaningful and stage-appropriate commercial development milestones.
- Requests for commercial development expenses must be itemized on the budget form and explained in the budget justification.

⊗ *Assigning a single, flat rate for commercial development costs on the budget form without providing a detailed itemization in the budget justification of the costs associated with the activities and deliverables is not permitted.*

Allowable requested items include:
- Salary costs for research scientist
- Salary costs for technical or commercial personnel directly conducting work on the project
- Commercial Development Adviser fees
- Market reports (Some reports may be available through NC Biotech library)
- 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
- Commissioning an independent professional assessment of the patent landscape or patentability opinion.
- Graduate Student salary – up to 25% of the student's salary may be requested. (This program is not intended to be a support mechanism for students.)

Unallowable items as requested or matching funds include:
- Legal fees including licensing or litigation fees
- Patent costs
- Publication costs
- Tuition (This program is not intended to be a support mechanism for 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 costing over $40,000 require a direct 25% cash match.

Step 5: 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 Commercial Development Adviser This letter should include a brief statement summarizing the activities that this individual/team will perform on the project. (Required)

  - Letter of support from the Technology Transfer Office or appropriate authorized institutional official which includes: 1) evidence of invention disclosure and 2) any formal efforts to protect the IP. (Required)

  - Letters of interest from potential licensees, partners, or other relevant entities. (Encouraged)

  - For projects involving human subjects or animal studies: Documentation demonstrating that notification of the research has been made to the Institution's IRB or IACUC.

Step 6: 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 7: Attach the Required Documents

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

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

Step 8: Review and Submit

Carefully review your application package using the checklist provided on the website then submit your BIG 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, 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

Deborah De ("day")
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North Carolina Biotechnology Center

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