Biotechnology Innovation Grant (BIG)
Proposal Guidelines & Instructions

Deadline for Application

The Biotechnology Innovation Grant (BIG) program has two proposal cycles for fiscal year 2017-2018.

Cycle 1 Deadline:

NOON, Wednesday, July 19, 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*.

The projected start date for Cycle 1 awardees is no earlier than November 1, 2017, depending on the terms and conditions of the award.

Program Requirements

Purpose

Every day, North Carolina researchers make 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) is intended to support studies that explore potential commercial applications of early-stage university life science inventions, enable strategic "go/no-go" decision-making regarding the further development and/or pursuit of intellectual property protection, and strengthen the entrepreneurial culture within a university or non-profit research institute. BIG awards allow university scientists to advance research discoveries from the theoretical to the conceptual product stage of development.

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.

Program Details

A BIG project is comprised of two arms - a scientific or technical research study and an exploratory commercial development project. Each proposal will be evaluated on the underlying technology and the commercial development project 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 clear decision whether to support continued investment in further intellectual property protection and commercialization efforts or not (i.e. go/no-go) is considered a successful outcome of a BIG project.

Technical Project

A technology or scientific discovery is poised for BIG funding when the basic research phase has been completed and is entering the translational research or preliminary product phase of development. At a minimum, an invention disclosure **must** have been submitted to an institution's tech transfer office prior to submitting a BIG proposal.

Examples of technical project studies include:

- Proof-of-concept and feasibility studies
- Compound screening against a validated target
- Prototype development
- Scale-up pilot studies

- Optimization studies
- Other studies designed to achieve commercially relevant milestones

Commercial Development Project
Simultaneously, and in close co-ordination with the scientific/technical researchers, a partner referred to as the Commercial Development Adviser (CDA) undertakes the commercial development project. The CDA is responsible for writing and executing the Commercial Development Narrative, a project plan that details preliminary commercial development tasks to be achieved during the project.

The Commercial Development Project may include, but is not limited to, any or all of the following tasks:

- Examination of the market for the discovery/invention/product
- Analysis of the intellectual property (IP) landscape
- Creation of a commercial technology development plan (distinct from the technical development plan) that addresses specific product development milestones
- Clarification of the regulatory path necessary to gain market approval
- Assessment of a product's potential impact on the market
- Competitive analysis of the market
- SWOT (strengths, weaknesses, opportunities, threats) analysis
- Studies designed to assess commercial feasibility and guide further IP protection
- Other factors influencing commercial development

Applicants are encouraged to review the Evaluation Criteria section for more details. Please refer to the *FAQs* on our website for information regarding general and BIG program-specific questions.

Who May Apply

Eligible Institutions
Proposals may be submitted by any North Carolina university or non-profit research organization.

Intellectual Property Requirements
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.

Principal Investigator Eligibility
The Principal Investigator (PI) must hold a full-time tenure-track or tenured faculty appointment, or an equivalent appointment as full-time research faculty with a dedicated independent lab at the applicant institution.

⊗ The PI may not have a financial relationship with the Commercial Development Adviser or with any firms funded by this award. Any potential conflicts of interest **MUST** be disclosed in the application.

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

Commercial Development Adviser Eligibility
The CDA role allows for a wide variety of relevant 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 CDAs. See the *FAQs* for examples of qualified advisers and information on resources available for entrepreneurs in North Carolina.

The CDA is independent of the technical PI. The CDA will design, execute, and/or coordinate

specific commercial development tasks and is responsible for writing the Commercial Development Narrative portion of the proposal.

⊗ The CDA or a potential licensee cannot conduct the technical project experiments. These arrangements carry the risk that the project may appear as subsidized R&D for a company, which is not consistent with the objectives of the program.

⊗ The CDA may not have a financial relationship with any firms funded by this award. Any potential conflicts of interest **MUST** be disclosed in the application.

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. A minimum of 15 – 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.
- Review by an advisory panel consisting of NC Biotechnology Center internal staff and external professionals with significant experience with commercializing life science technologies.
- Final approval by the designated committee of the Biotechnology Center's Board of Directors.

Evaluation Criteria

BIG proposals are evaluated by reviewers on a 100-point scale based on the questions below. Review criteria include, but may not be limited to, the following:

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 technical aspects of the project, listed below, described in sufficient detail?

- Clear, precise description of the specific aims
- Clear, concise descriptions of the experimental protocols
- Measurement methods and data generation
- End-point analysis
- Discussion of success metrics
- Anticipated challenges, and contingency plans

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 and Commercialization Goals
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, achievable, measurable, and appropriate for this stage of the project? Are the goals of the commercial development and technical projects well integrated? (15 points)

D. Appropriate Activities and Budget
Are the proposed technical and commercialization activities an appropriate use of funds 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? Is there evidence that the PI/CDA teams will collaborate effectively? (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 advance 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 periodic 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:

1. Technical Proposal
2. Commercial Development Narrative
3. Budget Form
4. Supporting Documentation

Please use the checklist provided on the website 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 2-3 pages)
Describe in detail the studies that will be performed to meet the stated technological goals, <u>including study design, end points, measured data analysis method(s) employed, success metrics, and milestones to be achieved</u>. This description should include the specific experimental protocols to be used.

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 describe 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 key 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)
For the Biographical Sketches, the use of the **NCBiotech Biographical Sketch** form provided on the NC Biotech Center website is required. (www.ncbiotech.org/big). Limit each biographical sketch to one (1) page. Include the biographical sketch(es) at the end of your proposal.

For the PI, co-PIs, postdoctoral fellows, non-tenure-track researchers, or senior technicians and all other key personnel, include a list of publications that documents each investigator's expertise in the proposed project.

Step 3: Prepare the Commercial Development Narrative

The Commercial Development Adviser must prepare this document.

The Commercial Development 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 proposal (no more than one paragraph).

Commercial Development Adviser
State the name(s) of the personnel who will serve as the CDA and others contributing to the commercial development activities. Describe their roles and the expertise that these individuals/team bring to the project. Discuss any potential conflicts of interest.

Commercial Goals
Define specific commercial development goals and concrete deliverables to be performed in this project.

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

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?

Regulatory
If regulatory agency approval may be needed to market the technology, provide a rationale for how this project contributes to or clarifies the achievement of regulatory milestones and the pathway towards approval.

Project Plan
Describe in detail the individual steps and the overall plan for meeting the commercial development objectives and deliverables described in the Commercial Goals.

Detail each task to be performed: How will each task be accomplished? Who will complete each task? What is the expected outcome for each task? How does each task fit within the overall commercial development project goals?

Tasks should be achievable, measurable, and have concrete endpoints and deliverables.

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.

Step 4: 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 5: Complete the Budget

Prepare you budget using the BIG Budget Form provided on the BIG webpage. The Budget Form 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 duration of the project must be included 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 - 18 months may be requested.

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

- It is advisable that up to 20% of the requested funds be directed toward meaningful and stage-appropriate commercial development projects.
- 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 at reduced cost through the NC Biotechnology Center library)
- Minor lab equipment and equipment fees
- Lab supplies
- Travel costs only if *directly related* to achieving technical or commercial goals or only for a *limited number* of face-to-face meetings between the PI and the CDA (see unallowable travel expenses below)
- Contractual and consultant fees, including CRO costs
- Commissioning an independent professional assessment of the patent landscape or patentability opinion.

Unallowable items as requested or matching funds include:

⊗ Legal fees including licensing or litigation fees
⊗ Salary for the CDA, if the CDA works for the University in a tech transfer/innovation/ entrepreneurship/business development role
⊗ Patenting costs
⊗ Publication costs
⊗ *Salary, tuition support, or stipends for students* (This program is not intended to be a support mechanism for students.)
⊗ Indirect costs/overhead/facilities and administrative (F&A) costs
⊗ Travel by **ANY** personnel to scientific or business conferences or meetings for any reason
⊗ Graduate student salaries may not be used for the matching contribution.

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 6: Gather Supporting Documentation

Combine the following Supporting Documents into a ***single*** PDF file.

- **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. The Cover Sheet must be signed by the PI, the CDA, and the Sponsored Research Office of the university or non-profit.

- **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 the Commercial Development Adviser (Required)
    - This letter should include a brief statement summarizing the activities that this individual/team will perform on the project and the deliverables to be produced.

  - Letter(s) of Support from the Technology Transfer Office or appropriate authorized institutional official (Required)
    This letter should include:
    - evidence of invention disclosure and
    - current status of any efforts to establish IP protection of the invention

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

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

Step 7: 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 8: 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 9: 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.

Submission Notification

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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