

Biotechnology Innovation Grant (BIG) Proposal Guidelines & Instructions

Deadline for Application

NOON, Wednesday, August 29, 2018

Application materials can be found on the BIG webpage at www.ncbiotech.org/big

The projected start date for BIG awardees is no earlier than February 1, 2019, depending on the terms and conditions of the award.

IMPORTANT: BIG proposals are submitted using an online application system. The submitting PI must register for an account at least 5 business days before submission of the proposal. See Step 8 page 10 for details.

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.

Purpose

The Biotechnology Innovation Grant (BIG) supports studies that explore potential commercial applications of translational research-stage university life science inventions. BIG grants 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 are intended to foster new collaborations between university scientists and commercialization advisers to explore potential of both the scientific and product development applications of inventions.

The lines of research supported by BIG awards are extensions of significant foundational research already accomplished and are intended to transition basic research

discoveries into translational research phases of development.

This program is intended to work upstream of the Center’s other technology development program for universities, the Technology Enhancement Grant (www.ncbiotech.org/teg), which supports subsequent technology licensing efforts by the university.

Program Details

A BIG project is comprised of two arms:

1. A scientific or technical research study and
2. An exploratory commercial development project

Each proposal will be evaluated on both the technology development project and the commercial development project and on the likelihood that the proposed work will advance 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 life sciences sector. The commercial development project must advance the strength of the business case for the technology.

A clear decision whether to support a university’s 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. Project outcomes that support the decision to discontinue investment of time, effort, and funds in the technology and/or related IP are viewed by NC Biotech as valid and useful.

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.

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

A BIG proposal focuses on translational research, therefore, the technology development project must focus on a single, achievable research project with clearly defined success criteria and go/no-go decision making points. The research plan must detail milestone-based objectives for each scientific aim of the study.

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, 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
- Analysis of 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

At the time of submission, the Principal Investigator (PI) must hold a full-time, tenure-track or tenured faculty appointment, or an 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:

- 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
- 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
- Representatives of local entrepreneurship support organizations

A proposed CDA who is a member of the institution's technology transfer office is strongly discouraged, except in a project management role overseeing and coordinating activities conducted by experienced commercial development experts.

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 cannot conduct any portion of the technical project.*

- ⊗ *The CDA may not have a financial relationship with any firms or contract research organizations 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 up 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 project activities.
- ⊗ *Biotechnology Center grants do not support any type of overhead or indirect costs.*
- ⊗ *Technical project activities cannot be subcontracted to any commercial firm with a financial relationship with either the PI(s) or the CDA. 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.*

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

Only one resubmission of a previously unfunded proposal is allowed.

If the proposal 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 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 based on the questions below. Review criteria include the following:

A: Solid Foundation of Basic Research (15%)

1. Has the PI established a sufficient scientific foundation to support the translational work proposed? Is the work ready to move beyond the basic science phase? Is the proposed research plan truly translational research?
2. Does the experimental design fit overall with the timelines proposed? Can the work realistically be completed within 18 months?

B. Robust Technical Study Design (20%)

1. Are the proposed technical milestones and study end-points clearly defined,

detailed, and realistic?

2. Is the research high risk/potentially high reward or incremental innovation?
3. Are there clear, precise, and concise descriptions of all aspects of the technical project, listed below, and are they described in sufficient detail?
 - a. Specific aims
 - b. Experimental protocols
 - c. Measurement methods, data generation, and statistical analysis
 - d. Milestones
 - e. End-point analysis
 - f. Definition and discussion of success metrics
 - g. Anticipated challenges and contingency plans
4. Will the project yield clear and unambiguous results that support go/no-go decisions regarding further technology development and/or IP investment?

C. Realistic and Compelling Market Potential and Commercialization Goals (15%)

1. Does this project target a verifiable unmet need?
2. Are the commercialization goals associated with deliverables well-defined, realistic, achievable, measurable, and appropriate for this stage of the project?
3. Are the goals of the commercial development and technical projects well integrated?

D. Appropriate Activities Reflected in the Budget (15%)

1. Are the proposed technical and commercialization activities an appropriate use of funds?
2. Are the budgeted line items appropriate and well justified in the proposal?

E. Effective PI/Commercial

Development Adviser Team (15%)

1. Is there evidence that the PI/CDA team(s) collaborated in writing the proposal?
2. Is there evidence that the PI/CDA team will collaborate effectively together during the project?
3. Do they have the necessary expertise and knowledge?

F. Potential Impact of Project (20%)

1. To what extent would the proposed project enhance, de-risk, or generate value in the development of a technology with commercial potential?
2. Will the project further support or clarify the IP claims and/or improve the patentability of the invention?

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

As part of our 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 university's technology transfer office (academic applicants) or an intellectual property professional for more specific counsel as necessary.

Application Instructions

Application materials are located on the BIG webpage at www.ncbiotech.org/big.

A BIG proposal is comprised of five documents:

1. Coversheet signed by the technical PI and a representative of the institution's sponsored research office representative
2. Technical proposal
3. Commercial development narrative
4. Budget form
5. 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.

It is recommended that you consider the Evaluation Criteria (page 4) when composing the content of your proposal narratives.

- ⊗ *Applications that do not follow all requirements and instructions may be administratively declined without external review.*
- ⊗ *Applications that do not have a fully signed coversheet at the time of application may be administratively declined without external review. Signatures of the sponsored research office are required and can take multiple weeks to achieve. Plan your submission accordingly.*

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.

A. Table of Contents (does not count toward page limit; should be on a separate page). Include title, PI name, institution, and page numbers.

B. Project Summary

The project summary information is entered

into the online application form rather than as a section of the Technical Narrative. See Step 8 for instructions.

C. Technical Proposal Narrative

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

1. Problem (suggested ½ page)

Define the problem that this invention addresses.

2. 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.

3. Technical Goals (suggested ½ page)

Explain the technical goals and the desired impact expected for this project.

4. Project Plan (suggested 2-3 pages)

Describe in detail the studies that will be performed to meet the stated technological goals, including study design, end points, data analysis method(s) employed, success metrics, and milestones to be achieved. This description should include the specific experimental protocols to be used.

5. Evaluation Methods (suggested 2 pages)

- a. For each specific aim, describe in detail the success metrics to be applied.
- b. For each specific aim, describe in detail the milestones to be achieved. These research milestones must be clearly defined and realistic. 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.
- c. Discuss the potential challenges with the technical project and describe alternative (contingency) plans.

D. 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.

E. Project Timeline

(does not count toward page limit)

Provide a graphic (*e.g.*, Gantt chart) that demonstrates an integrated timeline for completing the project plan milestones, including both technical and commercialization deliverables. Indicate in the graphic who will perform each step.

F. Budget Justification

(does not count toward page limit)

Describe each budget line item and provide justification for each cost. Requests for both technical (80 – 85% of total budget requested from the Biotechnology Center) and commercial development (15-20% of total budget requested from the Biotechnology Center) expenses must be itemized and explained in detail. The source(s) and use of the matching funds must be included. Personnel for whom salary is requested should be identified by name, degree, and title in the budget justification.

- ⊗ *Salary requests for a to-be-named postdoctoral fellow, research technician, or CDA are strongly discouraged. The BIG is a project-based grant and is not intended to support unspecified trainees or other individuals.*

G. 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.

H. Related Previous, Current, and Pending Grants

(does not count toward page limit)

1. Include a list of previous grants that directly provided funding for the technology that is being developed 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

I. Biographical Sketches

(does not count toward page limit)

For the Biographical Sketches, the use of the NC Biotech 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.

A. Technology under Development

Brief description of the technology being developed in this proposal (no more than one paragraph).

B. Commercial Development Adviser(s)

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.

C. Commercial Goals

Define specific commercial development goals and concrete deliverables to be performed in this project. (No more than two paragraphs)

D. 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?

E. Market

Discuss and prioritize potential commercial applications for the technology, including the unmet need, market size, and the relevant market drivers for each.

F. 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.

G. 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 and deliverable for each task?

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

H. Impact of Commercial Development Project

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.

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 into a PDF document as this causes the size of the PDF to be too large for submission.*

Step 5: Complete the Budget

Prepare your budget using the BIG Budget Form provided on the BIG webpage. Please include the title and duration of the project at the top of the Budget Form.

The Budget Form is provided in Excel format but should be converted to a PDF file for submission. Use of the BIG Budget form is required.

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 is not permitted. Detailed, itemized, commercial development project costs associated with the activities and deliverables (e.g., salary requests for CDA, consultant costs, database or market research report expenses, etc.) must be provided within the budget and in the budget justification.*

Allowable requested items include:

- Salary costs for research scientist(s)
- 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

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.
- ⊗ *Graduate student stipends may not be counted as matching contributions.*

Step 6: Supporting Documentation

Combine the following Supporting Documents into a single PDF file.

1. 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, dated, and signed by an authorized individual of the applicant institution.

2. 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.

3. 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

4. For projects involving human subjects or animal studies (Required)

- 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%
- Document that notification of the research has been made to the Institution's IRB or IACUC

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

Step 7: Complete the Coversheet

Use the Cover Sheet form provided on the BIG webpage.

The Cover Sheet must be signed by the PI and an authorized official of the Sponsored Research Office of the university or non-profit.

Step 8: Complete the Online Application Form

IMPORTANT FIRST STEP:

The PI for the BIG proposal must register for an account on the NCBiotech Funding Portal at least five days prior to the deadline in order to submit a proposal. The link is <https://ncbiotech.fluxx.io>.

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

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

The PI for the proposal must submit the proposal through her/his account. BIG proposals cannot be submitted through accounts belonging to OSR personnel or others.

Click [here](#) for more information on the registration and application process.

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

Complete all fields of the BIG online application form as instructed.

Project Summary

Enter the following project summary information into the corresponding sections on the online application. Space limitations apply.

- Brief description of the technology
- IP status
- Summary of the technical goals and deliverables
- Summary of the commercial development goals and deliverables
- Milestones to be achieved for the technical and commercial projects
- IRB/IACUC requirements

Public Information Summary

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 9: Attach the Required Documents

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

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

Step 10: 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 promptly.

Contact Information

Deborah De ("day")
Senior Director, Grant Process Operations
North Carolina Biotechnology Center

Deborah_De@ncbiotech.org
919-549-8845