Translational Research Grant (TRG)
Proposal Guidelines & Instructions

Deadline for Application

FY2021 Cycle 2 Proposal Deadline

NOON, Wednesday, February 10, 2021

At-A-Glance Overview

- A maximum of $100,000 may be requested.
- Projects may last up to 18 months.
- In addition to a written proposal, a pitch presentation will be required for selected, highly reviewed proposals.
- Any request for a single piece of equipment costing over $25,000 requires a 25% cash match.
- No other match is required.
- Biotechnology Center grants do not pay any type of overhead or indirect costs.

See 'Budget Guidelines' (p. 13) for budget details and allowable/unallowable costs.

Pre-Submission Information

Application materials can be found on the TRG webpage at *www.ncbiotech.org/TRG.* Read these TRG Program Guidelines & Instructions thoroughly prior to preparing an application. If you have any questions about the program, use the contact information at the end of this document.

Online Submission Portal

TRG 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 7, page 16 for details.

Pitch Presentation

For those proposals selected to pitch, pitch Presentations will be scheduled for **March 31–April 2, 2021** (see page 6 for details).

Eligibility

Eligible Institutions

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

⊗ Projects that appear to be subsidized R&D for any commercial entity may be administratively declined. Direct funding of R&D expenses for commercial firms, except contracted services, even if they have ties to NC-based universities and research institutions, is not consistent with the objectives of the program.

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 more than two active awards from the North Carolina Biotechnology Center at the same time.*

TRG applicants seeking to further develop an innovation that has been previously funded with any NCBiotech grant must schedule a pre-submission consultation.

Intellectual Property Eligibility

Eligible projects support inventions that, at a minimum, have been disclosed to the university's technology transfer office at the time of application.

The applicant must attest that the IP rights are assigned to the applicant's institution and have not been committed through license, option, or letter-of-intent to license to any third party at the time of application.

Purpose

North Carolina's technology-based economy is fueled by the innovative research taking place in universities and research institutions across the state, but groundbreaking ideas are just the beginning. The results of basic research must successfully undergo the "translational" phase of development in order to result in the new technologies and products that solve problems and foster economic growth. NCBiotech is committed to supporting North Carolina's life sciences researchers through this critical stage and to maximizing the impact of university research in the marketplace.

TRG projects explore potential commercial applications or initiate the early commercial development of university-held life sciences inventions. The technology must have the potential to solve a real-world problem as a commercial product in the life sciences sector.

The goals of the TRG program are:

- Transform basic research discoveries into product-focused translational research development;
- Generate data that addresses important product development milestones, addresses the concerns of potential licensees or investors, or otherwise de-risks the technology for a specific commercial application;
- Enable strategic "go/no-go" decision-making regarding further technology development and/or pursuit of intellectual property protection;
- Enable technology licensing efforts by the university;
- Establish goal-oriented partnerships between university scientists, product development professionals, and key stakeholders.

Program Details

Key attributes of the TRG program are **projects that are team-driven and milestone-based**, with post-award oversight by NCBiotech staff, as described below. Please review the evaluation criteria beginning on page 6 for more information on the features of a successful TRG project.

Team-Driven Research

The TRG application should clearly identify the contributing team members and define how the efforts of each will be coordinated to achieve the proposed project outcomes. A TRG team is comprised of four required core members and one optional member.

Required Team Members

A. Principal Investigator (PI) – The faculty researcher responsible for oversight and execution of the technical project.

⊗ *The PI may not have a financial relationship with the project manager or business case adviser(s), whose roles are described below. Any potential conflicts of interest pertaining to financial relationships among team members and/or commercial firms subcontracted through any grant award **MUST** be disclosed in the written proposal.*

B. Project Manager - **The applicant is required to identify and obtain a commitment from a project manager prior to submission of the written proposal. *TBD* project managers are not allowable.**

Evidence points to the active participation of an experienced project manager as the best predictor of the success of academic translational research projects.

The project manager is expected to be an integrated member of the project team and is responsible for driving the efficient and timely completion of project tasks and achievement of defined milestones. This person will be responsible for coordinating team activities, scheduling regular team meetings/calls and submitting quarterly project reports to NCBiotech.

The TRG project manager will preferably have direct experience with managing technology or product development projects in industry or other non-academic settings.

In the event that qualified project managers are not available at the applicant's university or through other sources, NCBiotech staff can provide a list of resources for identifying qualified individuals, if requested at least three weeks before the submission deadline.

NCBiotech will not be responsible for any communications, contacts, or recommendations in selecting the project manager. The choice of the project manager is wholly the responsibility of the applicant.

⊗ *Research personnel working in the PI's laboratory are ineligible to serve as Project Managers.*

To ensure that the project management component is addressed, supplemental funds of up to $10,000 may be requested to engage the services of a qualified project management consultant. These funds are in addition to the $100,000 maximum for the base grant. More details are provided in the Budget section, page 12.

C. End-User (Potential Licensee, Clinician, or Practitioner)

A representative target customer of the proposed commercial product who:

- Provides an independent "voice-of-customer" confirmation of the potential usefulness of the technology from a technical perspective
- Guides the determination of specific technical features necessary to be impactful in practice
- Confirms a market need for the technology
- Is not involved in day-to-day activities but advises technical development, as needed

The specific requirements and activities associated with the end-user role vary depending upon whether this team member is a potential licensee, clinician, or practitioner of the targeted use for the technology, as described below.

1. <u>Potential Licensee</u>

   Representative of an independent third-party commercial entity that has expressed an interest in licensing the technology being developed.

   a. Provides a non-binding letter of interest that corroborates the potential of the technology, indicates preliminary interest in licensing the technology, and attests to the value of the outlined translational project.

   b. Provides guidance re: performance specifications or other specific technical milestone(s) required to generate licensing interest.

   We recognize that many TRG-funded technologies may eventually be licensed to a university startup company involving the faculty inventor and/or other founders. In these situations, we encourage applicants to also include a letter from an entirely independent and established company in the target market which provides credible corroboration of the commercial potential of the technology, and corroboration of the

value of the project and milestones proposed.

2. Clinician

   Certified healthcare provider (M.D., P.A., R.N., D.V.M., *etc*.) who has clinical expertise in the proposed application field of the technology (*e.g*., surgery, treatment of autoimmune diseases, *etc*.). Key opinion leaders are welcomed.

   a. Corroborates how this technology could impact the practice of medicine, confirms potential interest in testing or using the technology, and attests to the value of the translational project proposed.

   b. Provides guidance regarding the performance specifications or other specific technical milestone(s) required to be impactful.

3. Practitioner

   Practicing potential end-user (farmer, researcher, *etc*.) in the associated target market (*e.g*., crop production).

   a. Corroborates how this technology will impact her/his work, confirms potential interest in testing or using the technology, and attests to the value of the translational project proposed.

   b. Provides guidance regarding technical requirements, performance specifications or other key product features necessary for the technology to solve real-life problems experienced by the practitioner.

D. Technology Transfer Officer

(or senior administrator responsible for the intellectual property (IP) and licensing interests of the university)

a. Corroborates the current status of IP protection related to the technology

b. Confirms the university's intent to continue investing in the protection and/or licensing of the associated IP

c. Not involved in day-to-day activities but participates in team progress calls/meetings

E. Optional Team Member - Business Case Adviser (BCA)

The BCA is an optional team member who contributes independent commercial guidance to the team as needed.

⊗ *The Business Case Adviser may not have a financial relationship with the PI, nor may the BCA be a member of the PI's laboratory*.

⊗ *The Business Case Adviser may not be employed by or have a financial relationship with any commercial entities acting as the End User or as a potential licensee*.

Up to $15,000 of the TRG budget may be used to undertake a well-defined business case project that results in one or more of the deliverables listed below. The proposal should describe how the BCA project will complement the technical project and how the BCA will be integrated into the project team.

The BCA role allows for a wide variety of relevant experiences and backgrounds, including but not limited to:

- Business expert associated with the university, such as an entrepreneur-in-residence (EIR), business school faculty member, or university staff responsible for new venture development
- Commercial experts outside the university, such as industry-experienced product development consultants, serial entrepreneurs, or investors with experience funding and/or serving on the boards of life sciences companies
- Representatives of local entrepreneurship support organizations

Examples of appropriate Business Case activities for which funding may be directed include, but are not limited to:

- Creation of a product development plan that defines critical technology development milestones and presents a logical sequence of activities (beyond the proposed TRG project) to definitively address them
- Market research intended to assess the commercial opportunity for the invention/product
- Analysis of the intellectual property (IP) landscape within the intended application
- Clarification of the regulatory path necessary to gain market approval
- Competitive or SWOT (strengths, weaknesses, opportunities, threats) analyses of the market
- Studies designed to assess commercial feasibility and guide further IP protection or investment
- Analysis of other factors influencing commercial development

Many organizations throughout the state provide business or product development assistance and could potentially serve as BCAs. See the FAQs for examples of qualified advisers for life sciences researchers in North Carolina.

Milestone-based Project Plan

A TRG project operates in the translational research phase of development and, therefore, must be centered on a focused, achievable research project with clearly defined milestones, success criteria, and go/no-go decision-making points. The research plan must include one or more milestone-based objectives for each scientific aim of the study.

Milestones will be proposed by the project team; disbursements of project funds will be dependent upon the achievement of these set milestones. A 50-40-10 disbursement strategy will be employed by NCBiotech to encourage meeting the milestones in a timely fashion. Upon execution of the award agreement, a brief kick-off team meeting with a member of the NCBiotech staff will be required to initiate the project. Afterward, 50 percent of the funds will be released up-front. Written reports and several meetings/calls with NCBiotech staff will be required throughout the duration of the project (see Post-Award Oversight below for details).

Translational Research Activities

Examples of project studies include:

- Proof-of-concept and feasibility studies
- Compound screening against a validated target
- Prototype development
- Scale-up pilot studies
- Optimization studies
- Studies designed to independently reproduce or confirm crucial preliminary findings
- Other studies designed to achieve commercially relevant milestones

Data that leads to 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 TRG project.

⊗ *Technical project activities cannot be subcontracted to any commercial firm that has a financial relationship with either the PI(s) or the BCA. 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 TRG program.*

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

Post-award Oversight

The TRG program includes several post-award activities that are intended to facilitate the timely and successful completion of the awarded project.

Kick-off meeting

An in-person or conference call kick-off meeting with NCBiotech staff is required before the first tranche of money is released to the university. The purpose of the meeting is to review roles and responsibilities, to discuss the milestones and the steps to be taken to achieve those milestones, and to review the reporting requirements for the award.

Quarterly written reports

Quarterly reports written by the project manager are required to keep team members and NCBiotech staff apprised of the progress towards achieving the milestones. These reports will be a brief (2 pp.) summary of technical and business case (if applicable) activities to date, approximate timelines towards completion of milestones, changes to team composition, challenges faced, *etc*. The reports should include key findings and data when available.

Mid-term report and meeting; Release of funds

Mid-term reporting requirements are similar to those for quarterly reports, but also include:

1. Evidence that the established mid-term milestone(s) has been achieved, and
2. A current financial report that presents an accounting of the project funds expended and remaining.

Upon receipt of the mid-term report, NCBiotech staff will schedule a meeting/call with the project team to discuss the report contents. If it is determined that the mid-term milestone(s) has been achieved, NCBiotech staff will authorize the release of the second tranche of funds.

Final technical and financial reports

Final technical and financial reports are required for the release of remaining grant funds. The technical report provides a final analysis of the project, including achievement of proposed milestones, and data to support the successful completion of each aim. The final report will also include updates from each team member re: current IP and licensing status, the business case adviser project (if applicable), and a discussion of next steps.

Follow-up impact surveys

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.

Review Process and Evaluation Criteria

Review Process

Upon intake, all submitted proposals will be examined by NCBiotech Center Staff to ensure the proposed project meets program requirements and goals.

Written Review

Each proposal meeting the basic requirements will be reviewed in writing by 2-3 members of an advisory panel consisting of NCBiotech staff and external professionals with significant industry experience in developing and commercializing life sciences technologies.

Pitch Presentation

The TRG teams with top-scoring written reviews will be invited to present their projects in a pitch-style format of no more than 30 minutes to NCBiotech staff and members of the advisory panel. Following the prepared presentations, TRG teams will answer follow-up questions.

Invitations to present will be emailed to the selected teams approximately one to two weeks prior to the presentation date. All members of the team are expected to participate in the presentation, except with prior approval of NCBiotech staff.

For this cycle (FY2021 Cycle 2), the pitch presentations will be held from March 31 – April 2, 2021. A selection of morning and afternoon times will be available from which invited teams may choose. Teams submitting TRG proposals should be fully prepared to present during one of those days if invited.

Final decision

Final decisions will be made by the designated sub-committee of the Biotechnology Center's Board of Directors.

Notification

Notification of awards will be made within approximately two weeks of the final decision date. For this cycle (FY21 Cycle 2), notification is anticipated to be made by June 15, 2021.

Evaluation Criteria

Each proposal will be evaluated on the likelihood that the proposed work will advance the technology toward intellectual property protection and/or commercialization.

TRG proposals are evaluated by reviewers based on the questions below. Review criteria include the following:

A. Effective Team

1. Is there evidence that the project team(s) collaborated in writing the proposal?
2. Is there evidence that the project team will collaborate effectively together during the project?
3. Does the team collectively have the necessary expertise, knowledge and resources for the project to succeed?

B. Stage of Translational Research

1. Has the PI established a sufficient scientific foundation in advance of the TRG submission to support the translational work proposed?
2. Is the proposed research plan truly translational research?

C. Translational Research Study Design

1. Is the study well-designed?
2. Will the study as designed generate the necessary data to advance the line of translational research to the stated goals?
3. Are there clear, precise, and concise descriptions of all aspects of the technical project, and are they described in sufficient detail?
   a. Experimental protocols/tasks
   b. Measurement methods, data generation, and statistical analysis
   c. Milestones
   d. End-point analysis
   e. Definition and discussion of success metrics
   f. Anticipated challenges and contingency plans
4. Are the proposed milestones and end-points clearly defined, detailed, and realistic?
5. Do the project aims suggest a high risk/potentially high reward opportunity or incremental innovation?
6. Will the project yield clear and quantifiable results that support go/no-go decisions regarding further technology development and/or IP investment?
7. Does the study design and sequence of tasks fit with the timelines proposed?
8. Can the work realistically be completed within the proposed timeframe?

D. Milestones and Success Metrics

1. Are there clear, precise, and concise descriptions of each task linked to the advancement towards each milestone?
2. Are the success metrics clearly defined for each milestone?
3. Is the first proposed milestone achievable within the first 6 – 9 months of the project?
4. Will achievement of the mid-point milestone(s) warrant release of the second tranche of funding?
5. Are these milestones critical to the long-term product development plan?
6. Does the team have a plan in place to continue development beyond the completion of this project?

E. Realistic and Compelling Market Potential and Product Goals

1. Does this project target a verifiable unmet need?
2. Where applicable, are the business-case activities associated with deliverables that are well-defined, realistic, achievable, measurable, and appropriate for this stage of the project?
3. Where applicable, are the business-case activities and the technical project well integrated?

F. Budget

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

G. Potential Impact of Project

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?

Other Program Information

Preliminary Consultation

A pre-submission consultation is required for all applicants who have been previously funded with any NCBiotech grant, such as a Flash Grant, BIG, and/or TEG award.

For all others, a pre-submission consultation is strongly encouraged.

Please contact NCBiotech program staff 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 TRG proposal is allowed. If this is a resubmission of a previously submitted TRG 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 the resubmitted proposal.

- *Resubmitted proposals must follow the current guidelines and include up-to-date letters of support and other documentation.*

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 TRG webpage at *www.ncbiotech.org/TRG*.

A TRG proposal is comprised of five documents:

1. Coversheet signed by the PI and a representative of the institution's sponsored research office
2. Team Composition Form
3. Translational Research Project Narrative
4. Budget Package
5. Supporting documentation

Please follow the steps below and 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 TRG Program Guidelines & Instructions thoroughly prior to preparing an application. If you have any questions about the program, use the contact information at the end of this document.

It is recommended that you consider the Evaluation Criteria (pages 6-8) when composing your proposal.

⊗ *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 several weeks to obtain. 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 Team Composition Form

Use the form provided on the NCBiotech TRG website (*www.ncbiotech.org/TRG*) to describe the specific roles and responsibilities for the Principal Investigator, Technology Transfer

Officer, End User, Project Manager, and any other key personnel (*e.g.*, the Business Case Adviser).

Step 3: Prepare the Translational Research Project 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 sections of the proposal with page numbers.

B. Project Overview

(1 page maximum; does not count toward page limit; should be on a separate page)
Summarize the entire project as it relates to the purpose/problem to be addressed, methodology, anticipated results, and potential impact towards commercialization of the technology.

C. Translational Research Project Narrative

The technical narrative should be no more than 10 pages long and should include all sections below. Use the headings provided.

1. ***Technology/Product in Development***
   (suggested 1 paragraph)
   Briefly describe what you envision your "product" to be and how it will be used.

2. ***Expected application for technology/product***
   (suggested 2-3 sentences)

   Define the problem or unmet need that your technology/product will address. Reference the current "gold standard" solution and explain how your technology/product is superior.

   If possible, provide information about the competitive landscape and size of intended market. Include a summary of any market research) that quantifies the market opportunity, if available.

3. ***Intellectual Property Position***
   (suggested ½ page)

   The minimum IP eligibility status for TRG projects is an invention disclosure submitted to the university's technology transfer office at the time of application.

   The applicant must include a statement indicating that the IP rights are assigned to the applicant's institution and have not been committed through license, option, or letter-of-intent to license to any third party at the time of application.

   Describe the intellectual property held by the university surrounding this technology or line of research. This description must include:

   - Current type of IP protection (invention disclosure, provisional patent application, patent application, PCT application, issued patent, trademark, copyright, trade secret, *etc*.)
   - Title and brief summary of claims
   - Patent application numbers/patent number and issue date if applicable
   - Filing dates
   - Assignee name(s), inventor name(s), *etc*.

   Describe how the proposed research will influence, support, and/or clarify the IP claims, improve the patentability of the invention, improve the licensing position, or other considerations related to the IP.

4. ***Foundational Research***
   (suggested 1-2 pages)

   Describe the status of foundational research that has been done to date, both as the state-of-the-art for the field and in the laboratory of the PI. Explain why this

collective knowledge base is sufficient to support translation towards the innovative solution advanced by this project.

5. Current Stage of Development (suggested ½ page)

Describe where your technology is in the translational research/product development process (*e.g*., prototyping, feasibility testing, pre-clinical testing, *etc*.).

6. Milestones (suggested 1 page)

Provide *clearly defined and realistic* milestones that align with the Translational Research Project Plan (below). Milestones indicate the completion of key project tasks and are different than goals, aims, or deliverables.

Establishing well-defined, realistic, and appropriate milestones with clearly defined success criteria for each, is crucial, as release of award fund tranches are based on timely achievement of these milestones.

For this project, list each milestone(s) to be achieved and for each milestone list:

- The objective(s) for completing the milestone(s)
- The tasks to be performed to complete the milestone
- The milestone success criteria (*e.g.*, How do you define success? How do you know when you have hit a milestone?)
- One or more contingency tasks to be completed if the original tasks are unsuccessful at reaching the milestone

Indicate which milestone will serve as the mid-point milestone. When this milestone is successfully achieved, this will trigger the release of the second tranche of funding.

7. Translational Research Project Plan (suggested up to 5 pages)

a. Describe in detail the tasks and experiments that will be performed in order to meet the project milestones. Include study design, protocols, measurement methods, end points, and data analysis methods.

b. Discuss any potential challenges and provide contingency plans for each experiment or protocol.

c. Explain how the research plan will:

- Provide clear and unambiguous results that support go/no-go decisions regarding continued development of the technology, and/or
- De-risk the technology for potential licensees.

d. Describe the critical next steps for translating your invention, including those steps that will be achieved after completion of this project.

D. Business Case

(does not count towards overall page limit, 2 page maximum)

1. General commercialization information (required for all proposals, even if the team does not include a Business Case Adviser)

Describe the anticipated path towards commercialization or towards a market.

Include details on:

- Who is your customer? Who will buy your product/technology?
- Who/what/where is your target market?
- What regulatory approvals will your technology/product need to achieve in order to enter the market?
- What competition is present in the target market?
- What is the size of the target market?

Please indicate which, if any, of the questions above will be addressed by a Business Case Adviser.

2. Business Case Development Activities
(required only if the project team includes a Business Case Adviser)
Describe in detail the scope of work for which the BCA will be responsible, including:

- The specific activities and deliverables
- The methods and sources used to develop the business case, technology development plan, etc.
- Other information to be gathered that will assess and guide the commercial product development strategy.

E. Project Timeline
(does not count toward page limit)

Provide a graphic (*e.g.*, Gantt chart) that depicts the timeline and sequence of steps to complete the research plan, including both technical steps and business case deliverables (if applicable). Indicate in the graphic which team member(s) will perform each step.

F. Bibliography
(does not count toward page limit)

Give full citation including title and complete author list for publications cited in the project narrative. If the complete author list is extensive, include the first three (3) authors listed.

G. Conflicts of Interest Statement
(does not count toward page limit)

Disclose all potential conflicts of interest, including financial relationships among team members, research staff, potential licensees, etc. Disclose team member involvement in any start-up company with interest in the proposed technology. If there are no conflicts of interest, state this in one sentence in this section.

H. Related Previous, Current, and Pending Grants
(does not count toward page limit)

List of previous, current, and pending grants that directly provided funding for the technology that is being developed in 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)

Provide a biographical sketch for each member of the TRG project team, using the NCBiotech Biographical Sketch forms provided on the NCBiotech Center website (*www.ncbiotech.org/TRG*).

Please note that the Project Manager Biosketch form is unique to the project manager and is different from the other Biosketch form.

Limit each biographical sketch to two (2) pages.

Convert Your Proposal into a PDF Document

Once items A-I are created, merge all technical proposal documents into one Technical Project document. Then, 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 4: Complete the Budget Package

The Budget Package consists of one (1) PDF document that encompasses three parts. The three parts of the Budget Package include:

1. **Budget form**: Prepare you budget using the TRG Budget Form provided on the TRG webpage (*www.ncbiotech.org/TRG*). Use of the TRG Budget form is required.

   Please include the title and duration of the project at the top of the Budget Form.

   The Budget Form is provided in Excel format and should be converted to a PDF and merged with the other PDF documents in the budget package.

⊗ *Proposals with budget components uploaded as separate files are subject to administrative declination.*

2. **Budget Justification**: All funds requested on the Budget Form must be justified in a separate document and then included within the Budget Package PDF. Describe each budget line item and provide justification for each cost. Personnel for whom salary is requested should be identified by name and title in the budget justification.

3. **Quotes**: Quotes must be provided for all contracted services or equipment listed on the budget form, which includes:
   - core facility fees,
   - business case development materials,
   - consultant services (including business case adviser costs),
   - contracted research costs
   - commercialization research costs,
   - equipment costing over $5,000

   Limit quotes to a maximum of 3 pages each.

   All quotes or statements of work from individuals must be on letterhead, dated, and signed by the vendor.

   If you are not sure which items on the budget require quotes, please seek a consultation on your budget.

   If a business case adviser is utilized for this project: A statement of work (SOW) or quote for services, which includes an itemized list of tasks to be performed and associated costs, must be included in the budget package.

Budget Guidelines

- A maximum of $100,000 for project periods up to 18 months may be requested.
- Any single piece of equipment costing over $25,000 requires a direct 25% cash match.
- No other match is required.
- Up to $15,000 may be budgeted for Business Case Activities.
- Up to $10,000 in supplemental funds can be requested for project management services. See details below.

Funds can be allocated toward technical and business case aspects of the project. Requests for Business Case Advisor expenses must be itemized on the budget form, explained in the budget justification, and documented in a quote from the BCA.

Please review each budget line item amount for consistency with the project narrative and the accompanying letters of support.

⊗ *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), the BCA, or the End User. 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.*

⊗ *Funds cannot be requested for university technology transfer office representative or the End User team members(s).*

Supplemental Funds for Project Management Expenses

A project manager is a required member of the TRG project team (see page 4) If the services of this individual are not available to the project as a free university resource, applicants may request up to $10,000 in supplemental funds designated for the salary or fees for project management services.

Refer to the Project Manager qualifications specified previously.

These supplemental funds are in addition to the $100,000 maximum for the base grant. These supplemental funds may not be requested for expenses other than project management services.

Allowable requested items

- Salary costs for research scientist(s)
- Salary costs for technical or commercial personnel directly conducting work on the project
- Business Case Activities Expenses (up to $15,000)
  - BCA consulting fees
  - Market reports (some reports may be available at reduced cost through the NC Biotechnology Center library)
  - Commissioning an independent professional assessment of the patent landscape or patentability opinion
- Minor lab equipment and equipment fees
- Lab supplies
- Contractual and consultant fees, including fee-for-service contract research costs
- Project management expenses (see above)

Unallowable requested items

⊗ Indirect costs/overhead/facilities and administrative (F&A) costs

⊗ Salary, tuition support, or stipends for <u>any</u> student(s) (This program is not intended to be a support mechanism for students.)

⊗ Travel by <u>ANY</u> personnel to scientific or business conferences or meetings for any reason

⊗ Legal fees, including licensing or litigation fees

⊗ Salary for the BCA, if the BCA works for the University in a tech transfer/ innovation/entrepreneurship/business development role

⊗ Salary for Technology Transfer Office Representative or End User team member(s)

⊗ Patenting costs

⊗ Publication costs

⊗ *Salary requests for a to-be-named postdoctoral fellow, research technician, or project team member are strongly discouraged. TRG applications are evaluated on the collective strength of the project team; applications requesting funding for unspecified trainees or team members may not be competitive.*

Step 5: Supporting Documents

Please note: Quotes for contracted services and consultants are required, if applicable. All quotes should be included within the Budget Package PDF document, not in the Supporting Documents listed below.

Combine the following Supporting Documents into a single PDF file.

⊗ *Proposals with letters uploaded as separate files are subject to administrative declination.*

All letter(s) must be on letterhead, dated, and signed.

- ***Letter of Commitment from the End User*** (Required)

The letter provided by the End User should:

- Strongly corroborate the potential utility of the technology
- Indicate the necessary specifications or features that the technology must exhibit in order to be of commercial value
- Attest to the significance of the project aims to the overall development of the desired product.

In the event that the End User is a potential licensee, this letter of support should be a non-binding letter indicating general interest in potentially licensing the technology as well as indicating the specifications or features that the technology must meet in order to be of further interest. This letter should specifically indicate the value of the proposed project aims to subsequent licensing discussions.

- ***Letter(s) of Commitment from the Technology Transfer Office*** or appropriate authorized institutional official (Required)

  This letter should:

  a. Confirm the current status of intellectual property (IP) protection relating to the core technology (minimally, an invention disclosure)

  b. Confirm the university's commitment to continued IP development

  c. Describe the university's broader IP strategy to be pursued related to this technology

  d. Summarize all licensing discussions to date relating to the technology, if any

  e. Indicate how the proposed project will support continued IP development and licensing efforts

  This letter should align with the activities described in the roles/responsibilities section of the team composition above.

- ***Letter(s) of Commitment from the Project Manager*** (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, as described in the roles/responsibilities section of the team composition above.

- ***Letter(s) of Commitment from the Business Case Adviser*** (Required, if applicable)

  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 as described in the roles/ responsibilities section of the team composition above.

  This Letter of Commitment from the BCA is separate and different from the quote or statement of work to be included with the Budget Package.

- ***For projects involving human subjects or animal studies***

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

  - Provide a power analysis indicating that the studies proposed have the correct number of human or animal subjects required to achieve an *a priori* confidence level of at least 80%,

    Or

  - For proof-of-concept studies, provide the rationale for why a power analysis is not warranted.

- ***For projects requesting a single piece of equipment costing more than $25,000, a letter of commitment of matching funds is required.***

  The letter should come from an individual authorized to commit the matching funds

and should include the dollar amount of the match (25% of the cost of the piece of equipment).

Step 6: Complete the Coversheet

Use the Cover Sheet form provided on the TRG 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 7: Complete the Online Application Form

Important First Step

The PI for the TRG 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 TRG 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. TRG 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 TRG online application form shown below as instructed

A. 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 business case activities, goals, and deliverables (if applicable)
- Milestones to be achieved for the technical project
- IRB/IACUC requirements

B. 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.

C. Start Date

The earliest projected start date for TRG awards is **June 15, 2021**, depending on the terms and conditions of the award.

Step 8: Attach the Required Documents

Follow the instructions for attaching the required documents to the online application

(Coversheet, Team Description, Translational Research Project Narrative, Budget Form/Justification, 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 9: Review and Submit

Carefully review your application package for completeness and consistency throughout, using the checklist provided on the website. Then, submit your TRG application prior to the Program Deadline.

Submission of your grant application indicates that:

1. You have read and understand the information and directions in this Application Package and agree to be bound by the conditions stated herein.
2. You release the North Carolina Biotechnology Center from any claim for damages caused by:
   a. Disclosures required under the provisions of any North Carolina or United States law, statute, or regulation
   b. Disclosures made in connection with the North Carolina Biotechnology Center's funding review and approval process
   c. Disclosures required by rule or order of any court of competent jurisdiction
   d. Any other non-negligent, inadvertent, unintentional, unknowing, or immaterial disclosure.
3. All research conducted during the proposed project is performed in accordance with established university policies and procedures, including—but not limited to—policies and procedures applicable to research involving human subjects, laboratory animals, or hazardous agents and materials.
4. If the project proposed involves vertebrate animals, the project complies with federal guidelines for vertebrate animal care and experimentation.

Submission Notification

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

Contact Information

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