TXBio Pilot Grant Program
2025 Request for Proposals

Application Deadline: March 31, 2025, 5:00 PM CT

The Texas Biologics (TXBio) Pilot Grant Program is a research initiative, jointly led by the College of Natural Sciences and the Cockrell School of Engineering, focused on the discovery, early development, clinical translation, production, and delivery of biologic therapies originating across The University of Texas at Austin (UT Austin). TXBio is supported by philanthropic gifts that are being deployed broadly to enhance the intellectual environment and infrastructure relevant to biologics research at UT Austin.

A major goal of TXBio is to strengthen and expand biomedical translational research at UT Austin. One mechanism to achieve this goal is to provide financial support for projects in biologics discovery and development.

For the 2025 competition, TXBio will consider proposals that are broadly focused on:

- new biologic therapies with novel mechanisms of action,
- technology platforms to produce biologic therapies, and
- drug delivery technologies specific to the delivery of biologic therapies.

Biologics include therapeutic proteins and peptides, nucleic acids, cell therapies and blood or tissue products. The program seeks proposals aimed at generating "lead" therapeutics, delivery technologies, and production platforms, **all focused on biologics.** For the first two topics, performing proof-of-therapeutic-concept studies *in vitro* and in animal models, and addressing other issues critical to early drug development are of particular interest. The use of AI or machine learning in project proposals is also of interest, for example, to optimize the design of a lead therapeutic candidate.

Successful proposals should:

- For development of biologics: Lead to new molecular entities (composition of matter) that are clearly differentiated from other approaches targeting the same disease pathway or targeting novel disease pathways.
- For development of delivery technologies for biologics: Lead to new compositions of matter and/or patentable process steps to address major problems such as tissue/cell selectivity, oral delivery (or delivery into the CSF), etc. of biologic drugs. Successful submissions will need to clearly explain how the proposed approach/composition of matter is differentiated from the state of the art in the field and from the investigator's on-going other research.
- For production platforms: Address what problem is being solved, how the approach addresses limitation in the state of the art and how it will enable important therapeutic modalities.
- Include an experimental plan for validating the proposed mechanism of action, the effectiveness of delivery, or the efficiency of production.
- Outline possible barriers to clinical or commercial development (e.g., medical need, toxicities, manufacturing complexity) and how they may be overcome.

Ultimately, the mission of TXBio is to make lasting contributions to human health and improve quality of life. Therefore, projects should have a long-term view toward clinical trials and commercialization with an aim to bring biologic therapies and technologies developed at UT Austin to the patient.

OPPORTUNITY HIGHLIGHTS AND PROPOSAL CRITERIA

- Awarded applications will receive a research grant up to $150,000 to be used over a performance period of two years. Grants are not subject to indirect costs; however, the **grant may be subject to a research recovery fee per the policy of the awardee's primary College or School**. This fee is accessed to support costs incurred by the CSU or department in administering the award, similar to a research gift or sponsored project. Applicants should consider such policies when drafting the proposed budget (i.e., a research recovery fee of 6% will relate to a net award of $141,000).
- Up to 3 research grants will be awarded in the 2025 competition cycle, depending on the number of meritorious proposals received.
- The review committee may request clarifications or revisions for select proposals. Proposals invited for revision may be delayed in funding, if selected. In such cases, projects will still be allowed two years for completion.
- **Only proposals related to biologic therapies will be considered**. Following FDA guidance, biologics include vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins and peptides. Proposals considering therapies or related to therapy delivery or production not meeting this definition will not be reviewed.
- Proposals to investigate the application of an existing biologic therapy for a new indication are not within the scope of this call and will not be considered.
- All therapeutic areas and diseases will be considered.

FUNDING LIMITATIONS

The following outlines allowable and unallowable expenses on a TXBio Pilot Grant:

ALLOWABLE EXPENSES

- Graduate student stipends, fringe benefits, and tuition
- Postdoc and Research Scientist salaries and fringe benefits
- Lab technicians, undergraduate researcher salaries and fringe benefits
- Materials/supplies/consumables
- Third party contract R&D services not available at UT Austin (ex. specific animal models, studies requiring BSL-3+ facilities, CRO services, etc.*) *must explain the need in the budget justification and lack of resources at UT Austin*

UNALLOWABLE EXPENSES

- Faculty salary (summer or otherwise)
- Administrative support
- Payment of salary to non-UT Austin personnel, unless for contract R&D studies
- Hosting conferences, workshops or seminars
- Travel, refreshments, or entertainment

ELIGIBILITY

Those who meet the following criteria are eligible to apply for a TXBio Pilot Grant:

- Tenure-track faculty, non-tenure-track faculty, and those with active Principal Investigator status with a primary appointment in UT Austin's Cockrell School of Engineering, College of Natural Sciences, Dell Medical School, or College of Pharmacy are eligible to apply.
- Faculty may submit only one application per cycle as the primary PI. However, an individual may serve in a Co-PI or other collaborative role on more than one application each cycle.
- Non-awarded applicants from previous cycles may resubmit their proposals once for a total of two submissions.
- PIs and Co-PIs with an active TXBio Pilot Grant are only eligible to apply in a Co-PI capacity in the 2025 competition.

APPLICATION COMPONENTS

All application components should be formatted using 1-inch margins and 11-point font. Recommended fonts are Arial, Georgia, Helvetica, and Times New Roman. The following sections are required and must be submitted as a single pdf file according to the Application Submission Instructions section below by the **application deadline of 5:00 PM CT on March 31, 2025.**

1. **Lay Summary**. In 500 words or less, describe the proposed project and its potential impact using jargon-free language that may be understandable to non-scientists and general audiences.
2. **Project Description**. Limited to 3 pages including figures, excluding citations. The project description must include the following sections, in order as listed:
    a) ***Overview and Goals***: Provide an overview of the project and its goals. Include the type of biologic therapy or technology proposed and disease target(s).
    b) ***Technical Approach or Mechanism of Therapeutic Action:*** Describe the approach (how and why) and mechanistic basis (if applicable) for the proposed technology or biologic therapy.
    c) ***Novelty and Impact***: Describe the novel aspects of the approach in comparison to current or existing approaches. Discuss the competitive landscape and impact of the proposed approach, including its potential to solve existing problems and make significant contributions to human health. Discuss how the approach addresses an unmet or difficult to meet medical need.
    d) ***Current Stage of Development***: Describe the current stage of development of the biologic therapy or technology. Consider whether the project is in the idea/conceptualization stage, if proof-of-concept data are available, and if a lead biologic therapy or technology exists. Proposals that are at the idea/conceptualization stage and have minimal supporting preliminary data can be competitive for funding as long as they describe a sound and novel hypothesis and a persuasive plan that is likely to lead to a biologic therapy or technology with translational potential. Provide data or literature supporting the likelihood of success of the proposed approach.
    e) ***Technical Approach***: Outline deliverables and project results anticipated by the end of the two-year performance period.

f) ***Barriers and Challenges***: Describe barriers or technical difficulties anticipated in developing this approach. If this is a new field of research, describe any technical assistance that may be helpful to successfully advance the project.

3. **References/Citations**. No page limit. List sources in a section separate from the Project Description.
4. **Commercialization Considerations**. Limit to 2 pages. A goal of the TXBio Pilot Grant Program is for biologics and related technologies invented at UT Austin to eventually become commercially adopted. It is understood that many years of research and development are required from conceptualization to evaluation in the clinic and that many great ideas may not lead to commercial products. Nonetheless, successful proposals need to consider and articulate perceived challenges to clinical or commercial translation. The Commercialization Considerations component should outline a plan to de-risk the proposed technology by addressing the following:
    a) ***Timeline***: Provide a brief timeline of critical steps perceived to commercialization (awardees will not be expected to complete all of these steps).
    b) ***Commercialization Path***: Describe how you envision the potential pathway(s) to commercialization. Consider how you would secure additional resources to move to the next stage of medical translation and the sources from which these additional resources may be secured (e.g., foundations, SBIR grants, private investors, venture capitalists, or companies). Describe your vision of the next stage and whether you anticipate collaborations with industry, academia, and/or private investors in the course of this project or at a later stage. Describe any intellectual property that may be generated from this work.
    c) ***Disclosure(s) and IP***: List any existing intellectual property (IP) and its status (e.g., none, disclosure filed, provisional/PCT filing, or patent granted) directly related to the proposed concept. Also list any relevant public disclosures including publications and presentations.
    d) ***Manufacturing***: Briefly describe what you envision as possible challenges to manufacturing and potential solutions for overcoming such challenges.
    e) ***Potential Side Effects/Regulatory Issues:*** For biologic therapies: Consider potential toxicities or adverse reactions the mechanism of action of the proposed therapeutic might engender and any considerations for limiting the maximum dose of the therapeutic/vaccine that could be administered. For drug delivery technologies: Consider potential toxicities, adverse reactions, or issues related to clearance/elimination of the delivery platform from the body that could lead to regulatory approval challenges. For production platforms: Consider potential side products that may be formed during production which could lead to challenges in purification or regulatory approval.
    f) ***Patient Population***: Briefly describe patient population(s) who might benefit from the biologic therapy or technology and how those patients would be selected (e.g., based on a biomarker).
5. **Budget and Budget Justification**. Submit a budget and a budget justification for project costs. Limit the budget justification to 1 page when possible. The budget should outline expected costs in appropriate categories for each year proposed. Budgets should not include PI salary (summer or otherwise) or indirect costs/facilities & administrative fees other than any research recovery fee per the policy of the CSU. Refer to the Funding Limitations section above for additional information on allowable expenses. If applicable,

outline other resources that will be committed to the effort, such as support from academic units. In the budget justification, justify funding requests for each budget category.

6. **Biosketches/CVs and Current and Pending Support**. Submit current biosketches/CVs and Current and Pending Support documents, in NIH format or equivalent, for PI and Co-PIs.

APPLICATION SUBMISSION INSTRUCTIONS

Applications must be submitted through Competition Space, UT's online submission interface. To apply:

1. Visit https://utexas.inforeadv4.com/#competitionDetail/1946006
2. Click the "Apply" button on the Competition Space page.
3. This will take you to a login screen. Applicants with an existing UT EID and password should login using the "University of Texas Web Login" button. Login using your UT EID and password to create your application.
4. You will be taken to an online application form. Complete the form and upload the required application components. Click "Submit Application" at the bottom of the page. You also have the option to save a draft and return later to submit your application.

All required application components listed in the Application Components section above should be combined and uploaded as a single pdf and submitted by the **application deadline of 5:00 PM CT on March 31, 2025.**

Note: *If this is your first time submitting a proposal through the proposal submission website, you will first need to affiliate yourself with the College before you can submit. To do this, login with your EID and password, then click on the "Hello, [Name]" link at the top right of the website. This will take you to your user profile. In your user profile, under "Primary School or Department," select "Natural Sciences, College of" and then scroll to the bottom of the page and click on the Save Changes button. You will now be able to apply.*

REVIEW CRITERIA

A faculty review panel with relevant subject matter expertise will evaluate applications based on the following criteria:

- **Significance**: The proposal outlines novelty and the potential to solve existing problems and make significant contributions to human health.
- **Approach**: The proposal outlines clear deliverables and anticipated results, and the approach is feasible for this grant performance period.
- **Commercialization Potential**: The proposal outlines a clear path to commercialization taking into consideration ways to de-risk the technology and additional resources available for moving to the next stage of translation.

POST-AWARD REQUIREMENTS

Awardees must meet the following requirements:

- Include the following acknowledgment on all publications resulting from the award: "This project was funded (fully or in-part) by The Levy-Longenbaugh Fund and Texas Biologics."

- Present an oral progress report at the end of year one. This may be in coordination with a public Texas Biologics event or symposium. However, consideration will be given to avoid public disclosure of patentable IP.
- Submit a final report at the end of the performance period. Awardees will be provided with final reporting instructions prior to the end of their project.
- Submit a completed Invention Disclosure Form at the end of the performance period, or earlier as necessary, to Discovery to Impact.

TIMELINE

Application window opens: January 27, 2025
Application deadline: March 31, 2025
Announcement of awardees: June 2025
Award start date: September 1, 2025

CONTACT INFORMATION

Program website: https://cns.utexas.edu/strategic-research-initiatives/find-funding/txbiogrants

Program and application submission interface questions should be directed to CNS Strategic Research Initiatives: CNS_SRI@austin.utexas.edu

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The form and timing of TXBio Pilot Grant awards are subject to change in subsequent years.

The content of this announcement is relevant only for the 2025 competition cycle.