



BioREACH Program

Reaching across the translational gap

Request for Proposals & Application Instructions

Round 12

RFP released:	Monday, Aug. 31, 2026
Application deadline:	Thursday, Oct. 29, 2026, by 5:00 PM ET
Award:	Up to \$50,000 in direct costs over 12 months, renewable for a second \$50,000 on a competitive basis

Center for Biotechnology

Bioengineering Building, 2nd Floor

Stony Brook University

Stony Brook, NY 11794-5280

www.centerforbiotechnology.org

About BioREACH

BioREACH — *Bio* + *REACH*, for **R**esearch **E**valuation and **C**ommercialization **H**ub — funds the translational work that stands between a Stony Brook discovery and its next stage of biotechnology development.

A BioREACH program funds the experiment that answers the question a licensee, industry partner, or follow-on funder will ask first. That may mean demonstrating performance in a relevant biological setting, validating a computational method on independent data, benchmarking against current approaches, or generating the evidence that supports a defined biomedical application. Projects typically enter BioREACH at TRL 2–3 for drugs and biologics, or TRL 3–4 for devices, diagnostics, software, and platform technologies. Then projects typically exit BioREACH at TRL 4 for drugs, biologics, devices, & diagnostics or TRL 5 for software, and platform technologies (see Appendix 1 for TRL guidelines).

What we mean by “advancing the technology”. Throughout this document, advancing a technology means work that does at least one of three things:

- **de-risks** it, by removing a specific technical uncertainty that would otherwise stop a partner or investor
- **adds value** to the translational study by creating IP, supporting claims in existing IP, make the innovation more useable or scalable
- **raises its technology readiness level (TRL)**, by producing the evidence that a higher level requires. Work that deepens scientific understanding without doing one of these is basic research, and BioREACH does not fund it

The award at a glance

Award	Up to \$50,000 in direct costs over 12 months , released in two \$25,000 tranches. The second is released on achievement of the milestones set out in your application, as approved by the External Review Board.
Renewal	Renewable for a second \$50,000 , aimed at company formation or another defined commercialization pathway. See “Award structure” in Part 1 for the conditions.
Who may apply	Stony Brook University investigators. Non-tenure-track faculty and postdoctoral fellows applying as PIs need written permission from their Chair, Dean, or Center Director.
What to submit	A 7-page application — Face Page (2), Executive Summary (1), Market Opportunity (1), Project Plan (3) — plus references, an optional appendix, and the required attachments.
Format	Single-spaced, 11-point Arial, submitted as a single PDF. Full formatting and file-naming rules are in Part 2.
Deadline	Thursday, Oct. 29, 2026, by 5:00 PM ET , emailed to center_for_biotechnology@stonybrook.edu
Not funded	Basic science research. Indirect costs. Tenured and tenure-track faculty salary. Travel. See “Costs not supported” for the full list.

Before you write We encourage you to meet with CfB staff first to confirm programmatic fit and discuss your aims and milestones. See “Program contacts” and our office hour signup link in Part 2.

PART 1

The Program

About the Center for Biotechnology

The Center for Biotechnology (CfB), a NYS Center for Advanced Technology located at Stony Brook University, advances biomedical innovation by connecting scientific discovery with the resources, expertise, and partnerships needed to move technologies toward real-world use. The Center works with faculty, entrepreneurs, industry, and investors to strengthen technology development, company formation, and commercialization across the NYS life sciences innovation ecosystem.

The CfB has helped advance some of Stony Brook University’s most impactful biomedical innovations, among them the yeast two-hybrid system, Xiaflex®, ReoPro®, Oracea®, and 3D virtual colonoscopy. These commercial successes resulted from the CfB’s investment in translating faculty innovations into technologies that addressed large unmet market needs. In total, the CfB has supported more than 475 faculty-led translational research projects and contributed to 306 license agreements generating \$51 million in royalty returns to the University. The CfB also has an active federal SBIR/STTR program that has led to 72 awards totaling close to \$40 million. Over the past decade, the economic impact of the Center’s programs has exceeded \$1 billion.

CfB focuses its resources on four areas:

- **Translational research and technology development** — providing milestone-driven funding to advance promising academic innovations;
- **Venture formation and founder development** — connecting founders with entrepreneurs-in-residence and venture-building support;
- **Translation, commercialization, and industry engagement** — advancing technologies through licensing, university/industry partnerships, and other pathways to adoption; and
- **Education and mentorship** — preparing faculty, postdoctoral researchers, and students to participate in life sciences translation and entrepreneurship.

Across Stony Brook, our scientists are at the leading edge of innovation, creating new possibilities for the future of health. CfB programs are designed to help translate that breadth of discovery into technologies and market applications with the potential for meaningful impact.

The CfB continuum of translation and venture support

CfB supports promising innovations across a continuum — from breakthrough discovery and translational development through commercialization and, where appropriate, company formation.

BioREACH, BioCATALYST, and BioNEXUS are Center for Biotechnology programs offered to Stony Brook innovators, supporting translational research, founder and venture development, and company scaling. Learn more about BioCATALYST and BioNEXUS via our [FAQs](#). **This document is specifically for BioREACH.**

BioREACH Program purpose

BioREACH advances SBU innovations that have the potential to shape the future of health and healthcare by funding translational studies that address the key scientific or technical question standing between an academic innovation and its next stage of development.

Proposed projects address one or more defined translational feasibility questions that support a clear development decision. Projects may lead to new intellectual property or generate evidence that increases the value or expands the potential application of existing IP.

Areas supported by BioREACH include biomedical innovations, computational platforms, tools, and enabling technologies shaping the future of health and healthcare. See Appendix 2 for representative technology categories and Appendix 3 for representative indications.

BioREACH-supported technologies may advance through follow-on CfB funding via BioCATALYST, licensing, industry partnerships, company formation, or other pathways appropriate to the technology.

Award structure

BioREACH provides up to \$50,000 in direct costs over 12 months, awarded in two \$25,000 tranches. The second tranche is released upon external review and achievement of the predetermined, agreed-upon milestones described in the application. Awards and funding tranches are reviewed and approved by the Center for Biotechnology's External Review Board (ERB).

All funding is intended to support the achievement of commercially relevant milestones. If the project meets the agreed milestones and remains commercially viable, the remaining funds are released. If milestones are not met, the PI will have 30 days to submit a revised project plan addressing ERB concerns. If continued development is unlikely to add commercial value, CfB may discontinue funding with 30 days' written notice to the PI.

A BioREACH award is renewable for a second \$50,000 through our BioCATALYST program, in which acceptance is contingent on the CfB's ERB review of your progress in BioREACH and your alignment with the mission of the BioCATALYST program. The purpose of the second award is to carry the technology toward company formation.

Budget guidelines

Budgets for the BioREACH award reflect one year of funding, released in the tranches described above.

Salaries

Only non-tenure-track faculty (e.g., Research Professor, Lecturer) may receive up to 20% of the direct costs for salary support, inclusive of salary and fringe benefits, and must have written permission from their unit's respective Chair, Dean, and/or Center Director. Funding is allowable for salaries of students, postdoctoral fellows, technicians, staff, and other non-faculty project personnel. Postdoctoral fellows who apply as Principal Investigators must receive written permission from their unit's Chair, Dean, and/or Center Director and are subject to the same 20% limit on salary and fringe benefits.

Students and postdoctoral trainees supported by a third-party fellowship award may need prior approval from the funding organization to accept this award.

Budgets should include the appropriate [fringe benefit rate as established by the institution](#).

Graduate students supported on the project should receive tuition reimbursement at the [current institutional rate per institutional policy](#).

Supplies, equipment, and miscellaneous expenses

Supplies and miscellaneous expenses needed to directly support and successfully achieve the project milestones are allowable. Use of funds to secure commercial testing and external development services necessary to add commercial value is allowed on a case-by-case basis with prior written approval from CfB.

External partners

Applicants proposing projects with an industry partner must discuss specifics directly with the Center for Biotechnology. Contact Anne DePietri (annette.depietri@stonybrook.edu).

Costs not supported

BioREACH funds are awarded on a direct-cost basis. The following are not supported:

- **Indirect costs.** No facilities and administrative (F&A) or indirect costs may be charged to a BioREACH award.
- **Tenured and tenure-track faculty salary.** This includes summer salary on 6- or 9-month academic-year appointments. See “Salaries” above for who may receive salary support.
- **Travel.** Travel of any kind, including conference attendance, is not supported.
- **Basic science research.** Work that extends scientific understanding without de-risking the technology, adding value to it, or raising its TRL.
- **Equipment purchased without prior approval.** Computers and other equipment require prior written approval from CfB and must be fully dedicated to the project.

If you are unsure whether a cost is allowable, ask before you submit — email center_for_biotechnology@stonybrook.edu.

Proposal evaluation

Proposals are evaluated by SBU’s Intellectual Property Partners staff and the CfB External Review Board, which is composed of industry experts. All external members sign a confidentiality agreement to protect the information provided in the application.

We evaluate each proposal individually against the following criteria, along with other factors relevant to our program goals:

- **Technical merit.** Scientific validity, innovation, technology readiness level (TRL; see Appendix 1), and technical feasibility.
- **Commercial potential.** Market opportunity, competitive advantage, and IP potential.
- **Team capability.** Domain and technical expertise, and commitment level.
- **Translational planning.** Milestone clarity, timeline feasibility, resource allocation, and risk management.

The strongest applications describe milestone-driven objectives that create or add commercial value to the innovation, and structure the Specific Aims to advance the technology toward the next TRL inflection point. If you have questions, please set up office hours with our team (see Program contacts in Part 2, page 8, for our office hour sign up links).

Award implementation and administration

Submit all required animal research, human subjects, and other compliance or regulatory documentation as early as possible. Prepare these materials in accordance with applicable NIH requirements. Amendments to existing approvals are acceptable. For projects selected for funding, funds are released once all required approvals are in place.

The CfB team provides pre-submission support and post-award support while the project is ongoing and progressing toward its milestones. PIs are expected to work closely with the CfB team and the Intellectual Property Partners Office to move their ideas and technologies along a commercial pathway.

Reporting requirements

The PI must present a progress report to the Center at the six-month point of the award period, and submit a final report within 30 days of the end of the award period. Both take the form of a PowerPoint presentation; a template with guidance on what to include will be posted on our website and is sent with the award letter.

The six-month review determines whether the second tranche of the award is released. Reports are reviewed against the aims, milestones, and go/no-go decision points stated in Section 4a of the funded application — state those in terms you will be able to report against. Projects that do not meet predetermined milestones may be suspended or terminated upon the recommendation of the External Review Board.

Submit reports as a single PowerPoint file named LastName_FirstName_BioREACHprogress.pptx to center_for_biotechnology@stonybrook.edu, copying Intellectual Property Partners at ori_ipp@stonybrook.edu, at least five business days before the review meeting.

All PIs who have received support from the CfB must continue to provide brief economic impact updates at least annually for five years after the award. Any New Technology Disclosures resulting from funded projects should acknowledge CfB funding. Acceptance of funding under this program obligates the PI to comply with these reporting requirements.

All publications resulting from this support should acknowledge the sponsor as follows:

“Research reported in this publication was supported by the Center for Biotechnology, a New York State Center for Advanced Technology, Stony Brook University.”

Export control

Faculty are reminded to refresh their training on Stony Brook University Export Control Policy P212 (stonybrook.edu/commcms/ors/export_controls). They are expected to be knowledgeable about and comply with federal export control regulations as they apply to their area of research, equipment, supplies, technology, and technical data used in their laboratories and/or research. Faculty should not share confidential or third-party proprietary information that is, or that they suspect may be, export controlled in their grant applications without first consulting SBU's Export Compliance Officer.

Disclosure of non-public, export-controlled technology or technical data to Stony Brook University (SBU) faculty, staff, or students who are non-U.S. persons may require a U.S. federal agency authorization. Companies are responsible for determining and, if necessary, securing the appropriate authorizations prior to sharing any non-public, export-controlled technology or technical data with SBU.

PART 2

Your Application

What your application must contain

The proposal has five sections and a maximum of seven pages. All sections must be completed before the application is reviewed.

- | | |
|--|---|
| 1 Face Page
2 pages | Who you are, what the project is called, and where it fits — title, PI contact information, technology & indication category, attachment checklist, and your signature. The template is located on pages 13 & 14. |
| 2 Executive Summary
1 page | The whole project in plain language: a non-confidential abstract of 250 words or fewer, followed by short answers to eight questions covering what you are trying to do, why it is hard, and what success looks like. |
| 3 Market Opportunity & Technology Differentiation
1 page | The urgent unmet market needs your technology addresses, and how it is differentiated from what is available or in development today. |
| 4 Project Plan
3 pages | The critical development question standing in the way, the aims and milestones that will answer it, the experiments that will get you there, and what the work will cost. |
| 5 References and Appendix
no limit | The citations behind your claims, plus supporting figures. |

Formatting and submission

Format	Single-spaced, 11-point Arial, with at least one-inch margins on all pages. Show the page number at the bottom of each page.
Length	7 pages maximum for Sections 1–4. References, appendix, and required attachments do not count toward the limit.
File type	A single PDF file containing the proposal and all applicable attachments. No other format will be accepted.
File name	LastName_FirstName_BioREACHapp.pdf — for example, Smith_John_BioREACHapp.pdf
Project title	Must begin with the word “BioREACH.”
Where to send it	center_for_biotechnology@stonybrook.edu
When it is due	Thursday, Oct. 29, 2026, by 5:00 PM ET

Required attachments

Attach the following to the same PDF. No attachments beyond those specified here will be accepted.

- **NIH-style biosketch** for the PI, and for the primary co-sponsor if one is named on the Face Page.
- **Current and pending research support** for the PI, in NIH “Other Support” format — active and pending awards, with project period, effort, and direct-cost amounts.
- **Project Plan Form.**
- **BioREACH Budget Form** (direct costs).
- **Research Compliance Form.**
- **Intellectual property documentation**, if any (e.g., patent applications, licenses).
- **Letter of support** from the match-funding company, if applicable.
- **Letter of permission** from Chair, Dean, or Center Director — required for non-tenure-track faculty and postdoctoral fellows applying as PI.

Primary co-sponsor. A *co-sponsor* is an external partner — typically a company — contributing funding, materials, data, or technical expertise to the project. The *primary co-sponsor* is that partner’s lead technical contact, the person named on the Face Page. Submit a biosketch or CV for that person. If your project has no external partner, this attachment does not apply.

Institutional approvals

Stony Brook University Sponsored Programs Office approval is not required at the time of submission. For projects with a corporate match, approval is required only if the project is selected for funding. Applicants with a corporate partner may contact Anne DePietri (annette.depieri@stonybrook.edu) at the Center for Biotechnology for guidance on requirements and timing. The review committee may request supplemental information during the evaluation process.

This document, along with the Project Plan Form, the Research Compliance Form, and the BioREACH Budget Form, may be downloaded from the [CfB BioREACH web page](#).

Program contacts

Applicants are encouraged to meet with BioREACH program staff at the Center for Biotechnology to discuss program objectives, application requirements, and technology-development questions. Dee Dao, PhD, and Zeld Mendelowitz, PhD, will hold three Zoom information sessions and weekly office hours in September and October.

Dee Dao, PhD

Director

dee.dao@stonybrook.edu

Office hours: Monday–Friday, 2–3:30 PM

[Sign up for Dee’s office hours](#)

Zelda Mendelowitz, PhD

Venture Associate

zelda.mendelowitz@stonybrook.edu

Office hours: Tuesday, Wednesday, Friday, 8–11 AM

[Sign up for Zelda’s office hours](#)

Zoom Info Session #1

Wed., Sept. 16, 12:30–1:30 PM: [Registration link](#)

Zoom Info Session #2	Wed., Sept. 23, 12:30–1:30 PM: Registration link
Zoom Info Session #3	Thurs., Oct. 1, 12:30–1:30 PM: Registration link
General submission inquiries	center_for_biotechnology@stonybrook.edu
Corporate partnerships	Anne DePietri — annette.depietri@stonybrook.edu
Intellectual Property Partners (technology transfer)	Valery Matthys — valery.matthys@stonybrook.edu
Sponsored Programs	Departmental grants administrators

Writing each section

Section 1. Face Page and investigator information

Use the Face Page template at the end of Part 2 (pages 13 & 14). It must include the project title — beginning with the word “BioREACH” — and the Principal Investigator’s name, title, department, telephone number, and email address, along with the technology and indication categories (see Appendices 2 and 3) and the attachment checklist. The PI’s signature is required.

Graphical abstract (optional). We prefer that you include a graphical abstract illustrating the innovation and its mechanism of action, in a format similar to graphical abstracts published in *Cell*. It is not required, and its absence will not count against a proposal — but reviewers find one helpful. AI tools such as Claude or ChatGPT, and design tools such as BioRender, may be used to create it.

Section 2. Executive Summary

Begin with a non-confidential abstract of 250 words or fewer at the top of the page. Describe the proposed work, including the unmet need, the intended end-user application, the envisioned technology, project deliverables and milestones, and team strengths.

Below the abstract, answer each of the following eight questions. Answer them in order, briefly — a bold title summarizing the key answer followed by a few sentences elaborating. Reviewers use these answers to orient themselves before reading the full proposal.

1. What are you trying to do? Articulate your objectives using absolutely no jargon.
2. How is it done today, and what are the limits of current practice?
3. What is new in your approach, and why do you think it will be successful?
4. Who cares? If you are successful, what difference will it make?
5. What are the risks?
6. How much will it cost?
7. How long will it take?
8. What is the bar for success at the mid-point and at the end of your project?

Section 2 maximum: 1 page, including the abstract.

Section 3. Market Opportunity & Technology Differentiation

Discuss the potential market fit of the product or technology, its differentiation from existing solutions, and its competitive advantage. Address the significance of the market need, the intended customer base, and a credible path to commercialization through key translational milestones.

3a. Urgent unmet market need

State the **urgent unmet market need** your technology addresses: the specific problem, who has it, how it is handled today, and what that costs them clinically, economically, or both. An *unmet market need* is a gap that someone in the market — a patient, clinician, payer, health system, drug developer, or manufacturer — would pay to close. A gap in scientific knowledge is not, on its own, an unmet market need.

Support the claim with evidence and with perspectives from relevant stakeholders (e.g., drug developers, industry researchers, patients, clinicians, and payers). Where you can, size the need: how many people are affected, what is currently spent, and what the shortfall in current practice costs.

3b. Technology differentiation

Describe current and emerging technologies in the field. Discuss how the proposed technology is differentiated from existing solutions and from other technologies in development, including the basis for its potential competitive advantage. Support with data where available.

Section 3 maximum: 1 page.

Section 4. Project Plan

This section covers project planning, methodology, and funding. BioREACH supports translational studies that advance innovations toward commercialization and technology readiness — that is, work that de-risks the technology, adds value to it, or raises its TRL to the next stage.

4a. Strategic translational feasibility plan

Technology readiness and critical development question

Identify the most consequential development question that must be answered **now** to advance the technology. In defining this question, identify the requirement that is most important to address at this stage for the technology to progress toward a viable product. This may involve intended function effectiveness, scalability, stability, delivery, integration, manufacturability, or another requirement relevant to the technology.

Focus the proposed work on the critical technology-readiness milestone that addresses this question and most meaningfully advances the innovation to its next stage. Appendix 1 gives the TRL ladder for each technology category; state your current TRL and the TRL you expect to reach. If you have questions, please sign up to speak to us (see Program contacts in Part 2, page 8, for our office hour sign up links).

Specific Aims

Define the scientific and technical objectives. Each Aim should answer a critical translational question that advances the technology.

Milestones

For each Aim, define the evidence to be generated, the quantitative or objective criteria for success, and any thresholds that will determine whether the milestone has been achieved. Explain why these criteria and thresholds are meaningful for advancing the technology to its next stage of development.

Applicants are encouraged to review the [NINDS CREATE Bio milestone examples](#) for guidance on defining development objectives, success criteria, and the evidence required to support advancement.

Development decisions and alternative approaches

Describe how milestone results will inform a decision to advance, redirect, or stop the current approach. Where appropriate, identify a technically sound alternative approach and the evidence that would trigger that shift.

Next stage of development

Describe what successful completion of the project will enable next, and how the resulting evidence will position the technology for follow-on development, funding, licensing, industry partnership, company formation, or another appropriate commercialization pathway.

We encourage you to discuss your proposed Aims and Milestones with us before you submit. Contact Dee Dao, PhD, at dee.dao@stonybrook.edu or Zelda Mendelowitz, PhD, at zelda.mendelowitz@stonybrook.edu.

4b. Experimental design and methods

Scientific rationale

Explain the scientific and technical rationale for the proposed approach and how it addresses the critical translational question.

Proposed experiments

Describe the proposed experiments, including the experimental design, materials, methods, models, techniques, and equipment required to conduct the work.

Execution risks and contingencies

Identify significant risks that could affect execution or interpretation of the proposed experiments, and how they will be addressed. Where appropriate, describe an alternative experimental approach for evaluating the same question.

4c. Funding requirements and timeline

Summarize the following. Provide detailed figures in the separate BioREACH Budget Form (see the [CfB BioREACH web page](#) for the Budget Form template).

- **Funding needs.** Identify how much funding is required to achieve key milestones. BioREACH can provide up to \$50,000 in direct costs, renewable for a second \$50,000.
- **Budget breakdown.** Summarize the distribution of funds across project needs (e.g., personnel, materials, equipment, testing). Review “Costs not supported” in Part 1 before you build the budget.
- **Project timeline.** Outline the expected duration of each phase of the project. A table may be useful but is not required.

4d. Budget justification

Justify each budgeted item by cost category (e.g., consumables, animal studies, salaries, service contracts). Explain why each expense is essential for achieving project milestones and ensuring technical success. If applicable, clarify any cost-sharing agreements or external funding contributions.

Section 4 maximum: 3 pages.

Section 5. References and appendix

Include references at the end of the narrative sections. Supporting information may be included in an appendix. Neither counts toward the page limit.

If you include an appendix, the following are useful:

- A graphical illustration of how the solution or technology works.
- A graphical illustration of the scientific mechanism of action (MOA) and the rationale for where your technology fits within it.
- One to three key supporting evidence figures.
- A brief takeaway for each figure.
- An indication of whether the data are published or unpublished, with the relevant reference where applicable.

BioREACH Application

Face Page

Page 1 of 2 · Include as the first page of your application

Project Title (must begin with the word “BioREACH”)

Principal Investigator

Name	
Title	
Department	
Telephone	
Email	

Company Co-sponsor (if applicable)

Company	
Primary contact	
Title	
Email	

Technology Category (see Appendix 2)

Indication (see Appendix 3)

Current TRL and target TRL (see Appendix 1)

BioREACH Application · Face Page

Page 2 of 2

Graphical Abstract (optional)

Optional. If you include one, show where your technology fits within the mechanism of action.

Attachment Checklist

- ☐ NIH-style biosketch of the PI (and of the primary co-sponsor, if applicable)
- ☐ Current and pending research support for the PI
- ☐ Project Plan Form
- ☐ BioREACH Budget Form
- ☐ Research Compliance Form
- ☐ Intellectual property documentation, if any (e.g., patent applications, licenses)
- ☐ Letter of support from the match-funding company (if applicable)
- ☐ Letter of permission from Chair, Dean, or Center Director (required for non-tenure-track faculty and postdoctoral fellows)

Certification and Signature

I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I accept the obligation to comply with the terms and conditions of the NIH Public Health Service if an award is made as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Signature of Principal Investigator (required)

Date

PART 3

Appendices

These appendices are illustrative, not exhaustive.

Appendix 1	Technology Readiness Guidelines (TRL) — one ladder for each of six technology categories	15–21
Appendix 2	Technology Categories	22–23
Appendix 3	Indication Categories	24–25

APPENDIX 1

Technology Readiness Guidelines (TRL)

One guideline sheet for each of six technology categories: (1) Drug / Biological, (2) Therapeutic and Interventional Device, (3) Diagnostic — Assay, Test and Imaging Hardware, (4) Software, AI and Digital Health, (5) Research Tools, Platforms and Enabling Technology, and (6) Quantum and Frontier Deep Tech. Assess your technology against the sheet that fits it, state the current TRL on the Face Page, and cite the evidence that supports it.

TECHNOLOGY READINESS GUIDELINES (TRL) · STONY BROOK VENTURES AT THE CENTER FOR BIOTECHNOLOGY

1 Drug / Biological

Small molecules · antibodies and engineered proteins · cell therapy · gene therapy and editing · RNA · vaccines and immunomodulators · delivery and formulation · radiopharmaceuticals · imaging agents · implantable regenerative medicine

The ladder — TRL 1 to 9

Discovery TRL 1–3 Development TRL 4–5 First use and evidence TRL 6–7 Authorization and market TRL 8–9

PROGRAM	TRL	LEVEL AND THE WORK THAT DEFINES IT	MILESTONE THAT CLOSES IT
BioREACH	1	Review of scientific knowledge base Target–disease link, tractability and modality fit assessed from published science	1A: product hypothesis in one sentence
	2	Development of product hypothesis Target validation dossier, TPP v0, activity assay and screening or engineering strategy	2A: candidate series identified
	3	Identification of product candidate In vitro efficacy, orthogonal target engagement, first in vivo signal	3C: lead series · 3D: patent filed
BioCATALYST	4	Optimization and initial safety Selectivity, non-GLP toxicity, endpoints defined, regulatory route determined	4E: preclinical candidate nominated
	5	Advanced characterization and GMP GLP toxicology, scalable GMP process, analytical methods, stability initiated	5C: pre-IND meeting held
BioNEXUS	6	Regulated production and Phase 1 GMP clinical supply released; first-in-human safety and dose established	6C: Phase 1 complete
	7	Scale-up and Phase 2 Efficacy in patients; process validation; end-of-Phase-2 alignment with FDA	7C: Phase 2 endpoint met
	8	Phase 3 and marketing application Pivotal efficacy, consistency lots, NDA or BLA submitted	8D: authorization granted
	9	Approved and in routine use Launch, coverage, pharmacovigilance, real-world performance monitored	Label expansions re-enter at TRL 4

 **BioREACH** TRL 2–4
 **BioCATALYST** TRL 4–5
 **BioNEXUS** TRL 5–7

Programs. BioREACH, BioCATALYST, and BioNEXUS are the Center for Biotechnology's translational and venture programs at Stony Brook University. The brackets at left mark the readiness range each program supports for this technology category.

A level is claimed only when its milestone exists as an artifact a third party could inspect — a report, a filing, a released lot, a frozen version, a signed contract.
A technology's TRL is the lowest TRL of any critical component it depends on. Readiness is not monotonic — record switchbacks.

Sources

U.S. Department of Veterans Affairs, Office of Research and Development. *Technology Readiness Guidelines: Drug/Biological*. research.va.gov/programs/tech_transfer
National Center for Advancing Innovation. *Technology Readiness Guidelines*.
NASA. *Technology Readiness Levels*. · European Commission, Horizon Europe TRL scale (baseline 1–9 definitions).

TECHNOLOGY READINESS GUIDELINES (TRL) · STONY BROOK VENTURES AT THE CENTER FOR BIOTECHNOLOGY

2 Therapeutic and Interventional Device

Surgical robotics · navigation and intraoperative guidance · OR workflow and autonomous systems · patient-specific and 3D-printed implants · active implants, neuromodulation and BCI · encapsulation devices · organ preservation and perfusion

The ladder — TRL 1 to 9

Discovery TRL 1–3 Development TRL 4–5 First use and evidence TRL 6–7 Authorization and market TRL 8–9

PROGRAM	TRL	LEVEL AND THE WORK THAT DEFINES IT	MILESTONE THAT CLOSES IT
	1	Review of scientific knowledge base Procedure, failure modes, predicate devices and their adverse-event history surveyed	1A: product hypothesis in one sentence
	2	Development of product hypothesis Simulation and virtual prototyping, user needs captured, pathway identified	2A: lead architecture selected
BioREACH	3	Prototype characterized Bench accuracy, force and latency measured; first ex vivo or cadaveric evaluation	3C: classification · 3D: patent filed
	4	Optimization and initial safety System integrated, animal model established, human factors and design inputs begun	4A: design controls opened
BioCATALYST	5	Verification and design freeze Standards testing, sterilization, ISO 10993 battery, manufacturability assessed	5B: design freeze for filing
BioNEXUS	6	QMS production, IDE and first-in-human Design V&V complete; Early Feasibility Study conducted under an approved IDE	6C: submission cleared
	7	Process validation and pivotal evidence Design transfer, surgeon learning curve characterized, multi-center clinical data	7B: trial endpoints met
	8	Market submission 510(k), De Novo or PMA filed; surveillance plan and labeling finalized	8D: clearance or approval granted
	9	Cleared and in routine use Launch, coding, complaints and CAPA, revision and explant rates monitored	New autonomy or indication re-enters at TRL 4

BioREACH TRL 3–4 **Programs.** BioREACH, BioCATALYST, and BioNEXUS are the Center for Biotechnology's translational and venture programs at Stony Brook University. The brackets at left mark the readiness range each program supports for this technology category.

A level is claimed only when its milestone exists as an artifact a third party could inspect — a report, a filing, a released lot, a frozen version, a signed contract. A technology's TRL is the lowest TRL of any critical component it depends on. Readiness is not monotonic — record switchbacks.

Sources

U.S. Department of Veterans Affairs, Office of Research and Development. *Technology Readiness Guidelines: Therapeutic Device*. research.va.gov/programs/tech_transfer
National Center for Advancing Innovation. *Technology Readiness Guidelines*.
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TECHNOLOGY READINESS GUIDELINES (TRL) · STONY BROOK VENTURES AT THE CENTER FOR BIOTECHNOLOGY

3 Diagnostic — Assay, Test and Imaging Hardware

Molecular diagnostics · liquid biopsy and multi-cancer early detection · proteomic and metabolomic tests · point-of-care and at-home testing · biosensors and continuous monitoring · infectious disease and AMR · screening · companion diagnostics · imaging hardware

The ladder — TRL 1 to 9

Discovery TRL 1–3 Development TRL 4–5 First use and evidence TRL 6–7 Authorization and market TRL 8–9

PROGRAM	TRL	LEVEL AND THE WORK THAT DEFINES IT	MILESTONE THAT CLOSES IT
	1	Review of scientific knowledge base Analyte or contrast mechanism reviewed, and the clinical decision it would change named	1A: product hypothesis in one sentence
	2	Development of product hypothesis Intended use, prevalence, truth-set and adjudication strategy, route selected	2A: TPP v0 with performance thresholds
BioREACH	3	Assay or system characterized Performance in simplified matrices or on phantoms; first real specimens or subjects	3B: sensitivity and specificity shown
	4	Integration and optimization Components integrated, pre-analytics characterized, CLSI analytical validation run	4B: decision threshold locked
BioCATALYST	5	Test methods and manufacturing Release assays, QC criteria, stability, standards testing for hardware	5C: pre-submission meeting held
BioNEXUS	6	Quality production and first clinical study Validation in the intended-use population; FDA submission or laboratory sign-out	6B: submission filed or lab validated
	7	Multi-site validation Reproducibility across sites, lots and operators; PPV reported at true prevalence	7B: performance validated across sites
	8	Pivotal evidence and market submission Consistency lots, pivotal validation, 510(k)/De Novo/PMA or IVDR filed	8C: cleared, or the test launched
	9	In routine clinical use Ordering, reimbursement, lot trending and proficiency testing operating	New analytes or claims re-enter at TRL 4

■ BioREACH TRL 3–4
■ BioCATALYST TRL 4–5
■ BioNEXUS TRL 5–7

Programs. BioREACH, BioCATALYST, and BioNEXUS are the Center for Biotechnology's translational and venture programs at Stony Brook University. The brackets at left mark the readiness range each program supports for this technology category.

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 National Center for Advancing Innovation. *Technology Readiness Guidelines*.
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TECHNOLOGY READINESS GUIDELINES (TRL) · STONY BROOK VENTURES AT THE CENTER FOR BIOTECHNOLOGY

4 Software, AI and Digital Health

Diagnostic imaging AI · digital pathology · reconstruction and acquisition acceleration · clinical decision support · prescription digital therapeutics · remote monitoring and digital biomarkers · clinical genomics interpretation · ambient documentation · trial technology · payer and provider operations

The ladder — TRL 1 to 9

Discovery TRL 1–3 Development TRL 4–5 First use and evidence TRL 6–7 Authorization and market TRL 8–9

PROGRAM	TRL	LEVEL AND THE WORK THAT DEFINES IT	MILESTONE THAT CLOSES IT
	1	Review of scientific knowledge base Task, incumbent method, data landscape and lawful access basis reviewed	1A: hypothesis with the metric to beat
	2	Development of product hypothesis Baseline of record documented; device versus non-device determination made	2B: locked evaluation set defined
BioREACH	3	Model characterized Held-out performance against the baseline, stratified by site and subgroup	3A: pre-specified improvement shown
	4	Version frozen and clinically framed Adjudicated ground truth, model card, prototype-caliber code, user feedback	4C: device status confirmed
BioCATALYST	5	Critical stage gate to deployable system External validation on unseen sites, security posture, EHR and DICOM integration	5A: external validation passed
	6	Release-controlled deployment Shadow mode then live use; clearance, laboratory validation or governance approval	6C: first live clinical use
BioNEXUS	7	Workflow integration and multi-site evidence Three or more sites, prospective or reader study, drift monitoring instrumented	7B: study endpoints met
	8	Validation complete and release Locked release, pivotal validation, submission with PCCP or commercial release	8C: cleared or fully released
	9	Deployed with continuous monitoring Drift, subgroup performance and override rates reviewed on a defined cadence	Non-device status re-confirmed each release

 **BioREACH** TRL 3–5
 **BioCATALYST** TRL 5–6
 **BioNEXUS** TRL 6–8

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Lavin A, et al. Technology readiness levels for machine learning systems. *Nat Commun* 2022;13:6039. doi 10.1038/s41467-022-33128-9
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TECHNOLOGY READINESS GUIDELINES (TRL) · STONY BROOK VENTURES AT THE CENTER FOR BIOTECHNOLOGY

5 Research Tools, Platforms and Enabling Technology

Computational drug design and simulation · screening and functional genomics · lab automation and self-driving labs · organoids, organ-on-chip and engineered test tissue · biomanufacturing and bioprocess · bioinformatics platforms · reagents and instrumentation · biomaterials · cultivated meat and materials

The ladder — TRL 1 to 9

Discovery TRL 1–3 Development TRL 4–5 First use and evidence TRL 6–7 Authorization and market TRL 8–9

PROGRAM	TRL	LEVEL AND THE WORK THAT DEFINES IT	MILESTONE THAT CLOSSES IT
	1	Review of scientific knowledge base The bottleneck removed, the incumbent method and the actual buyer identified	1A: hypothesis with the metric to beat
	2	Development of product hypothesis Baseline of record documented; business model, IP and license position set	2B: blinded validation strategy fixed
BioREACH	3	Prototype demonstrated Core capability beats the tuned baseline; reproducible by a second operator	3A: improvement over the baseline
	4	Platform characterized Configuration frozen, specification and cost per unit of work set, qualification route chosen	4A: configuration frozen
BioCATALYST	5	Prospective external validation Blinded out-of-distribution results reported in full; production process defined	5A: external validation passed
BioNEXUS	6	Design-partner deployment Partners run it on their own problems; qualification package filed where one applies	6C: partners in production
	7	Multi-customer validation Three or more customers, scaled production, partnered programs hitting milestones	7A: cross-customer validation complete
	8	Commercial-release qualification Release testing, audit-ready quality system, documentation and support model	8C: full commercial release
	9	Routine paid use Installed base, consumable or subscription pull-through, lifecycle management	An IVD or regulated transition re-enters at TRL 4

■ BioREACH TRL 3–5
■ BioCATALYST TRL 5–6
■ BioNEXUS TRL 6–8

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TECHNOLOGY READINESS GUIDELINES (TRL) · STONY BROOK VENTURES AT THE CENTER FOR BIOTECHNOLOGY

6 Quantum and Frontier Deep Tech

Quantum sensing — OPM-MEG and magnetocardiography, NV-diamond, hyperpolarization, quantum-enhanced optical imaging · AI on quantum sensor data · quantum and quantum-inspired computation for biology and chemistry · quantum-secure health data infrastructure · novel compute architectures · quantum biology

The ladder — TRL 1 to 9

Discovery TRL 1–3 Development TRL 4–5 First use and evidence TRL 6–7 Authorization and market TRL 8–9

PROGRAM	TRL	LEVEL AND THE WORK THAT DEFINES IT	MILESTONE THAT CLOSSES IT
BioREACH	1	Review of scientific knowledge base Quantum resource named; the classical incumbent's real current performance reviewed	1B: why classical cannot close the gap
	2	Development of product hypothesis Resource budget set, baseline of record documented, operating environment assessed	2C: resource gap quantified
	3	Hardware or algorithm demonstrated Runs on real hardware, not a simulator; head-to-head against the tuned baseline	3C: independent replication
BioCATALYST	4	Meaningful instance solved End to end on a problem the user recognizes, or first human signal acquired	4C: meaningful instance or first signal
	5	Independent validation and readiness Blinded out-of-distribution results; standards testing and critical supply chain	5A: externally reproduced
BioNEXUS	6	Controlled deployment First clinical, laboratory or production use under change control	6C: first real-world use
	7	Multi-site validation and scale Cross-unit reproducibility, utility re-benchmarked, production scaled	7A: multi-site validation complete
	8	Qualification or commercial release Pivotal evidence or release qualification; submission filed where one applies	8C: cleared or fully released
	9	Routine operational use Monitoring, calibration, and re-benchmarking against the current classical baseline	Advantage claims have a shelf life
■ BioREACH TRL 2–4 Programs. BioREACH, BioCATALYST, and BioNEXUS are the Center for Biotechnology's translational and venture programs at Stony Brook University. The brackets at left mark the readiness range each program supports for this technology category. ■ BioCATALYST TRL 4–5 ■ BioNEXUS TRL 5–7			

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Sources

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National Center for Advancing Innovation. *Technology Readiness Guidelines*.
NASA. *Technology Readiness Levels*. · European Commission, Horizon Europe TRL scale (baseline 1–9 definitions).

APPENDIX 2

Technology Categories

Stony Brook's strength in the life sciences is reflected in the breadth of innovation across the University. BioREACH is designed to support that diversity and advance promising discoveries toward applications that can shape the future of health.

We welcome eligible proposals across the life sciences innovation spectrum, with preference for technologies progressing beyond discovery toward an application, product concept, or use case. The areas below are illustrative, not exhaustive.

Therapeutics

- **Small molecule** novel chemotypes, targeted protein degraders, covalent inhibitors, molecular glues
- **Antibodies & engineered proteins** mAbs, bispecifics, ADCs, nanobodies, peptide therapeutics
- **Cell therapy** CAR-T/NK, TIL, iPSC-derived, allogeneic platforms
- **Gene therapy & editing** AAV/LNP delivery, base and prime editing, epigenetic editors
- **RNA therapeutics** siRNA, ASO, mRNA, circRNA
- **Vaccines & immunomodulators** novel adjuvants, mucosal delivery, cancer vaccines
- **Drug delivery & formulation** nanoparticles, hydrogels, depots, BBB-crossing, oral biologics
- **Radiopharmaceuticals & theranostics**
- **Regenerative medicine & tissue engineering**

Drug discovery & development technology

- **Computational drug design** generative chemistry, structure prediction, de novo protein design
- **Physics-based simulation** Molecular Dynamics, free energy perturbation, quantum chemistry methods
- **Screening platforms** DNA-encoded libraries, phenotypic screens, CRISPR functional genomics
- **Lab automation & self-driving labs** closed-loop design-make-test-analyze
- **Human-relevant models** organoids, organ-on-chip, microphysiological systems
- **Target identification & validation** proteomics, chemoproteomics, perturbation atlases
- **ADMET & tox prediction** in silico safety, organ tox models
- **Biomanufacturing & bioprocess** cell-free systems, continuous manufacturing, engineered chassis
- **Research tools, reagents & instrumentation**

Bioinformatics & computational biology

- **Biological foundation LLM models** DNA, protein, cell, and perturbation models
- **Multi-omics & single-cell/spatial analysis platforms**
- **Clinical genomics interpretation** variant calling, ACMG classification, polygenic scores
- **Biological knowledge graphs & literature mining**
- **Real-world data & EHR-derived evidence generation**
- **Privacy-preserving / federated health data infrastructure**

Diagnostics

- **Molecular diagnostics** NGS, isothermal amplification, CRISPR-based detection
- **Liquid biopsy & multi-cancer early detection** ctDNA, methylation, fragmentomics
- **Proteomic & metabolomic diagnostics**
- **Point-of-care and at-home testing**
- **Biosensors & continuous biochemical monitoring** wearable and implantable
- **Computational & digital pathology**
- **Infectious disease and antimicrobial resistance rapid Dx**
- **Companion diagnostics** paired to a therapeutic program
- **Prenatal, newborn, and carrier screening**

Imaging

- Novel imaging modalities
- Accessible hardware/software low-field/portable MRI, ultrasound-on-chip, handheld systems
- Molecular imaging probes & contrast agents
- Reconstruction & acquisition acceleration AI-based, compressed sensing
- Diagnostic imaging AI detection, triage, quantification, longitudinal tracking
- Intraoperative imaging fluorescence-guided surgery, margin assessment
- Advanced microscopy super-resolution, expansion, light-sheet

Surgery, simulation & medtech

- Surgical robotics including micro-scale, endoluminal, and steerable systems
- Surgical planning & anatomical digital twins
- AR/VR and haptic simulation for training and rehearsal
- Intraoperative navigation & guidance
- Biomechanical simulation FEA for implants, gait and load modeling
- Patient-specific implants & 3D-printed devices
- Active implants neuromodulation, brain-computer interfaces, closed-loop stimulation
- OR workflow, capacity, and autonomous task systems

Healthcare technology & care delivery

- Clinical decision support & risk prediction
- Ambient documentation and clinical NLP
- Prescription digital therapeutics
- Remote monitoring & digital biomarkers
- Clinical trial technology patient matching, decentralized trials, synthetic control arms
- Payer and provider operations prior auth, coding, revenue cycle
- Population health & care management

Cross-cutting deep tech

- Novel compute architectures for biological simulation

Tissue engineering & biofabrication

Implantable / therapeutic

- Engineered tissue grafts skin, cartilage, bone, cornea, vascular grafts
- Scaffolds & biomaterials decellularized matrices, synthetic scaffolds, injectable hydrogels
- 3D bioprinting cell-laden constructs, vascularized tissue
- Whole-organ engineering recellularization, xenotransplantation, organ scaffolds
- Cell encapsulation & immunoisolation islet devices, protected cell delivery
- Organ preservation & perfusion normothermic perfusion, cryopreservation, machine perfusion

Tools / non-therapeutic

- Engineered tissue for testing tox screening, cosmetics, animal-model replacement

Quantum technologies for life sciences & healthcare

- Quantum sensing & measurement optically pumped magnetometers for MEG and magnetocardiography; NV-diamond nanoscale NMR and single-cell magnetometry
- Hyperpolarization parahydrogen, DNP, and NV-based methods for large gains in MRI/NMR sensitivity; enables metabolic imaging
- Quantum-enhanced optical imaging entangled-photon and sub-shot-noise microscopy; single-photon detection for low-light and deep-tissue imaging
- AI on quantum sensor data decoding OPM-MEG and magnetocardiography signals, interpreting NV-NMR spectra, reconstructing hyperpolarized metabolic imaging
- Electronic structure simulation enzyme mechanisms, transition metal catalysis, and binding energetics beyond the reach of classical DFT
- Quantum and quantum-inspired optimization conformational search, retrosynthesis and route planning, radiotherapy treatment planning, trial design
- Quantum machine learning on biological data quantum kernel methods for high-dimensional, low-sample omics; QSAR and property prediction; generative molecular design
- Post-quantum cryptography and privacy-preserving computation over genomic and clinical data

If your technology or application is not represented here, we encourage you to REACH out to the Center.

APPENDIX 3

Indication Categories

The indications below are illustrative of areas of active unmet need. They are not exhaustive, and proposals outside this list are welcome.

Neurodegeneration

- Alzheimer's disease
- Parkinson's disease including GBA and LRRK2 subsets
- ALS SOD1, C9orf72, sporadic
- Frontotemporal dementia GRN, C9orf72
- Huntington's disease
- Dementia with Lewy bodies
- Progressive supranuclear palsy and multiple system atrophy
- Multiple sclerosis
- Friedreich's ataxia and the spinocerebellar ataxias
- Prion disease

Neuropsychiatry

- Schizophrenia including negative and cognitive symptoms
- Treatment-resistant depression and major depressive disorder
- Bipolar disorder
- Alzheimer's-related agitation and psychosis
- PTSD
- Substance use disorders alcohol and opioid, with GLP-1 crossover interest
- Obsessive-compulsive disorder
- Chronic pain, non-opioid mechanisms
- Rett syndrome, Fragile X, Dravet, Angelman genetically defined neurodevelopmental disorders

Oncology

- Prostate cancer
- Neuroendocrine tumors
- Pancreatic cancer
- Colorectal cancer
- Non-small cell lung cancer
- Small cell lung cancer
- Chronic myeloid leukemia (CML)
- Acute myeloid leukemia (AML)
- Non-Hodgkin's lymphoma
- Multiple myeloma
- Breast cancer
- Glioblastoma
- Metastatic brain tumors
- Ovarian cancer and hepatocellular carcinoma
- T-ALL

Cardiometabolic

- Obesity muscle-sparing weight loss, oral agents, amylin combinations
- MASH / MASLD
- Type 2 diabetes
- Chronic kidney disease and diabetic nephropathy
- Heart failure with preserved ejection fraction (HFpEF)
- Lp(a)-driven atherosclerotic disease and refractory dyslipidemia
- Sarcopenia and cancer cachexia
- Obesity-associated sleep apnea

Inflammation and Immunology

- Systemic lupus erythematosus and lupus nephritis
- Systemic sclerosis (scleroderma)
- Idiopathic inflammatory myopathies (myositis)
- ANCA-associated vasculitis
- Myasthenia gravis
- Sjögren's disease
- Inflammatory bowel disease Crohn's and ulcerative colitis
- Hidradenitis suppurativa
- Atopic dermatitis, psoriatic arthritis, alopecia areata, vitiligo
- Type 1 diabetes (immune-directed and beta-cell replacement)
- Celiac disease

Rare and orphan disease

- Duchenne muscular dystrophy
- Myotonic dystrophy and FSHD
- Sickle cell disease and beta-thalassemia
- Hemophilia A and B
- hATTR amyloidosis
- Alpha-1 antitrypsin deficiency
- Lysosomal storage disorders Pompe, Fabry, Gaucher
- Primary hyperoxaluria and urea cycle disorders
- Epidermolysis bullosa
- Inherited retinal dystrophies
- T-ALL

Kidney disease

- IgA nephropathy
- Focal segmental glomerulosclerosis
- Autosomal dominant polycystic kidney disease
- Alport syndrome
- Membranous nephropathy

Respiratory

- COPD
- Idiopathic pulmonary fibrosis
- Severe and T2-low asthma
- Pulmonary arterial hypertension
- Chronic cough and bronchiectasis

Ophthalmology

- Geographic atrophy
- Wet AMD durability and reduced injection burden
- Diabetic macular edema
- Dry eye disease

Women's health

- Endometriosis
- Menopausal vasomotor symptoms
- Preeclampsia
- Uterine fibroids
- Polycystic ovary syndrome