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# **SBIR/STTR 101**

Jim Bray

NUCATS Institute

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[www.nucats.northwestern.edu/sbir](http://www.nucats.northwestern.edu/sbir)

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# Introduction

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- Two programs that encourage commercialization of scientific innovations:
    - Small Business Innovation Research ("SBIR"); and
    - Small Business Technology Transfer ("STTR");
  - Challenges and special considerations
  - State of Illinois support programs
  - Entrepreneurial resources you can take advantage of at NU
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# Why Bother?

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- \$2.5 BILLION in new funding each year
  - Review process adds credibility to your technology in the commercial marketplace
  - Significant risk reduction:
    - Funds projects too early to attract investment capital;
    - Unlike loans or equity infusions, no need to repay; and
    - Awards often easier to get than other gov. grants
      - Ex: NIH success rate is around 20% for Phase I
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# What Gets Funded

- Two general types of funding opportunities:
    - Contracts based on specific agency wants/needs; and
    - Grants for “good ideas” that fit the agency mission.
  - Three approaches:
    - Development of new technologies that solve a problem;
    - New applications of existing technologies; and
    - **Significant** advancement of existing technologies.
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# SBIR Overview

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- Set-aside program for small business concerns to engage in federally funded R&D with potential for commercialization
  - Applies to certain Federal agencies and departments-
    - External research & development budgets above \$100 million; and
    - Total SBIR funding generally equals 2.5% of total agency budget.
  - Established in 1982 with three major goals-
    - Increase private-sector commercialization innovations derived from federal R&D;
    - Use small business to meet federal R&D needs; and
    - Foster and encourage participation by minorities and disadvantaged persons in technological innovation.
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# Recent Changes

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- Congress reauthorized an expanded SBIR program in 1992 with additional objectives-
  - Greater emphasis on increasing private sector commercialization;
  - Further increase small business participation in federal R&D; and
  - Improve dissemination of information on the program.
- Further reauthorization in 2000 created existing program-
  - Extended until September 2008;
  - Created a public database of award information <http://technet.sba.gov>;
  - Authorized expanded Phase II program with larger grants and commercialization plan requirements; and
  - Phase III follow-on funding agreements.

SBIR is a well-established and consistent  
source of funding

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# Program Scope

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- Eleven cabinet departments and agencies offer SBIR grants-
  - Agriculture;
  - Commerce;
  - **Defense;**
  - Education;
  - **Energy;**
  - **Health & Human Services;**
  - Homeland Security;
  - Transportation;
  - Environmental Protection Agency;
  - **National Aeronautics and Space Administration;** and
  - **National Science Foundation.**

\$2.5 Billion in SBIR/STTR funds are  
awarded each year!

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# Award Phases

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- Phase I (feasibility studies)-
    - Generally from \$70,000-\$100,000 but can be much higher for NIH (avg \$180k);
    - Generally six month term, but can be as long as two years.
  - Phase II (research activities)-
    - Must be a continuation of a Phase I award (multiple continuations allowed);
    - Generally \$500,000-\$750,000 but can be higher for NIH;
    - Generally for two years.
  - Phase III (commercialization)-
    - Generally private money;
    - **Except** DoD, EPA and NSF offer Phase IIb - match money from outside investor;
    - **And** NIH has Ph II competing renewals for drug/device preclinical evaluation;
    - **And** contract agencies provide opportunity for sole source, "no bid" contracts.
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# Eligibility

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- Grants must go to a “Small Business” (less than 500 employees)
  - Only U.S. companies may participate as grantees
  - Company must be a “for profit” enterprise
  - Majority (51%) owned by individuals
    - U.S. citizens or resident aliens.
  - Company must be significant employer (51%) of primary investigator
    - P.I. need not be same as inventor; and
    - Required to have sufficient technical and scientific expertise (PhD NOT required).
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# Award Criteria

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- Eligibility is determined at **time of award**-
    - No previous company operating history required; and
    - Sufficient time to set up many things between notification and award.
  - Participation by the University as a research partner/subcontractor is allowed-
    - Up to **one-third** for Phase I grants; and
    - Maximum of **half** of Phase II awards.
  - Company must administer the grant-
    - **Retains intellectual property developed under the grant;**
    - Accounting (outsourced acceptable); and
    - Reporting.
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# Typical SBIR Phase I Process

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## Solicitation Topics

- Agencies describe targeted research topics in published solicitations.

## Proposal Submission

- Small Businesses prepare short (usually 25-page) proposals. Unsolicited proposals not accepted.

## Evaluation

- Agencies evaluate based on technical merit, firm's qualifications, and commercial potential / societal benefit.

## Award

- Granting agency makes and funds awards.
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# Each Agency is Unique

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- Number and Timing of Solicitations
  - R&D Topic Areas -- (Broad vs. Focused)
  - Communication
  - Size of Award
  - Proposal Preparation Instructions and Electronic Submissions
  - Financial Details (e.g., Indirect Cost Rates, Gap Funding)
  - Due Dates and Delivery Requirements
  - Review Process
  - Type of Award (Contract or Grant)
-

# Current Programs



	DOD	NASA	DOT	EPA	DOE	DHS	DOC	NSF	USDA	DoED	NIH
<b>Award Type</b> <i>Contract</i> <i>Grant</i>	C	C	C	C	G	C	C	G	G	GIC	GIC
<b>Award Amount</b> <i>Phase I</i>	70K-100K <sup>a</sup> <u>Options<sup>c</sup></u>	70K SBIR 100K STTR	100K	70K	100K 9 mos	100K	75k	100K	80K	100K	100k <sup>b</sup>
<b>Award Amount</b> <i>Phase II</i>	750K	600K	720K	225K <sup>c</sup>	750K	TBD	300k	500K <sup>c</sup>	325K	750K	750K <sup>b</sup>
<b>Review Process</b>	I	I	I	I	E	I	I	E	E	I	E
<b>Research Topics</b>	S	S	S	S	S	S	S	B	B	S	B
<b>Gap Funding</b>	Y	N	N	N	Y	N	N	Y	Y	N	Y
<b>Communication</b>	R	R	R	R	R	R	R	O	O	O	O

**C - Contract**                      **G - Grant**  
**I - Internal Review**            **E - External Review**  
**S - Specific**                        **B - Broad**  
**R - Restricted**                    **O - Open**

<sup>a</sup> Varies among DOD subcomponents.  
<sup>b</sup> Deviations permitted with justification  
<sup>c</sup> Some agencies offer Ph II options

# STTR Overview

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- Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions to engage in federally funded R&D with potential for commercialization
  - Broad definition of “research institution” -
    - Universities;
    - Federally Funded Research & Development Centers (e.g. Argonne); and
    - Other non-profit research institutions.
  - Uses same definition of “small business” as SBIR
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# STTR Program History

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- Created in 1992 to-
  - Stimulate and foster scientific and technological innovation through cooperative research and development; and
  - Foster technology transfer between small business concerns and research institutions.
- Reauthorized in 2001 with enhancements-
  - Extended until September 2009;
  - Increased to 0.30% of agency budgets;
  - Mandated additional outreach efforts; and
  - Authorized expanded Phase II program with larger grants.

STTR is a smaller (\$200+ Million) but more  
flexible source of funding

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# Program Differences

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- MANDATORY participation by research institution.
  - Minimum participation levels-
    - Small business must do **at least 40%** of work; and
    - Research institution must have **minimum 30%** participation.
  - Principal Investigator flexibility-
    - Primary employer NOT stipulated; but
    - Policy varies by granting agency.
  - Intellectual property sharing rights must be established BEFORE grant is awarded.
  - Many agencies provide 1 year to complete Phase I (vs. 6 months).
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# Granting Agencies

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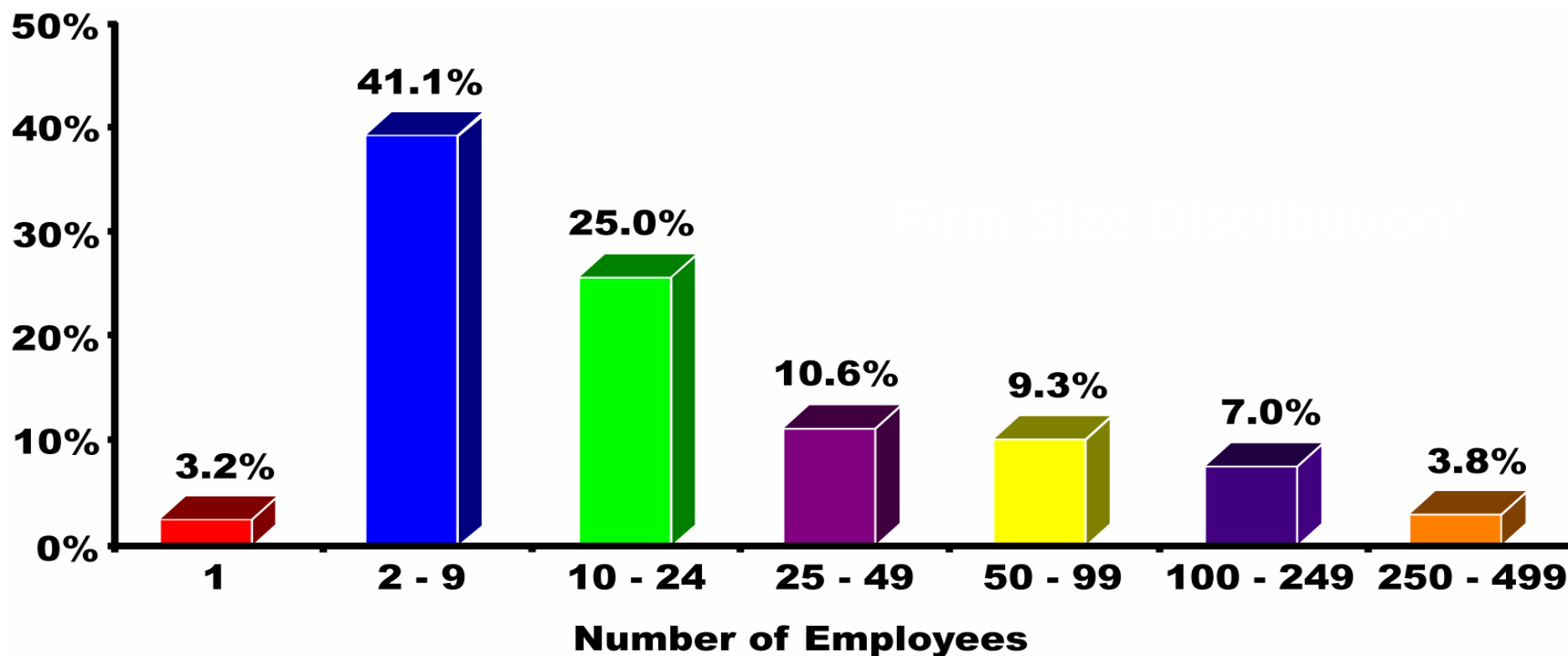
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- Only five departments and agencies offer STTR grants-
    - Defense;
    - Energy;
    - Health & Human Services;
    - National Aeronautics and Space Administration; and
    - National Science Foundation.
  - Most of the agencies have combined SBIR and STTR management processes, blurring the distinction between the programs.
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# Grantee Profile

- About one-third of Phase I grantees are first-time winners.
- Most are very small companies.





# The Funding Gap

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- There can be a 6 month gap between Ph I and Ph II awards
    - Hard to keep employees if this is main source of revenue.
  - Agency Solution: Fast Track
    - NIH:
      - Apply for Ph I and Ph II together;
      - Requires full business plan;
      - Need to carefully plan milestones and hit them to continue;
    - DoD and Homeland Security:
      - File for near the end of Ph I
      - Requires matching money from outside investor
      - Grants interim money between Ph I and II
    - Success rate?;
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# Special Support Programs

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- NIH:
    - Pipeline to Partnerships
    - Commercialization Assistance Program
    - Niche Assessment Program
    - Manufacturing Assistance Program (Pilot)
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# Tips and Tactics

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- Get to know the granting agency-
    - Don't judge an agency solely by its name;
    - Understand its mission and needs; and
    - Build a relationship with the Program Manager.
  - Follow a controlled grant application process-
    - **Start early** (especially first timers):
      - Up to 6 weeks to complete registrations
      - Multiple errors common at submission; can take a week or more to fix
      - Traffic jams near deadline
    - READ the solicitation and FOLLOW instructions to the letter;
    - Use support systems such as consultants and grant writers;
    - Get and review evaluations, win or lose; and
    - If you lose, reapply!
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## Tips and Tactics (cont.)

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- Clearly describe the R&D plan-
    - Plan entire technology development process BEFORE writing any single grant;
    - Have clear outcomes that are simple to evaluate;
    - Think about and describe what you will do in Phase II;
    - Include a timeline/Gantt Chart; and
    - Remember there are multiple paths to success.
  - Don't forget your profit
    - 7% fee for profit allowed (may need to use 6.99% on NIH forms to avoid error)
    - No strings attached to use – other SBIR/STTR funds can't be used for legal, marketing, large equipment purchases, etc
    - **No reason** to ever turn down
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# Sample SBIR Abstracts

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## Title: A minimally invasive cardiac assist device

### Abstract:

The purpose of the proposed Phase I research is to demonstrate feasibility of a new minimally invasive blood pump to provide mechanical circulatory assistance to the failing heart. Over 4.8 million Americans suffer from congestive heart failure (CHF), with 550,000 new cases appearing annually. Generally progressive, CHF is characterized by the inability of the heart to pump adequate blood to meet physiologic demands. Existing devices for mechanical circulatory support require open chest surgery, cardiopulmonary bypass and cannulation of the heart and major vessels for device implantation, and are associated with high morbidity and mortality. Consequently, their clinical use has been very limited and the event of an implantation is extraordinary rather than routine. Unique to the proposed device is the ability to be implanted by means of a minimally invasive approach, i.e., using techniques currently available to interventional cardiologists. A steerable catheter is introduced through the right brachiocephalic vein and into the right atrium via the superior vena cava. A needle positioned distally on this catheter creates a transeptal hole through which a dilator or dilatation catheter can be used to enlarge the opening. Use of a guide catheter or wire permits the pump to be advanced through this opening into position in the left atrium. The outflow cannula provides a transvalvular (mitral and aortic) conduit for antegrade flow through the left ventricle to the ascending aorta. A novel dual-impeller design will allow for lower speed operation, which is expected to reduce hemolysis due to shear gradients. The development team is experienced in the design of innovative blood pumps, particularly those amenable to minimally invasive techniques (i.e., the Hemopump).

**Phase I goals: 1) design and analyze prototype using finite element analysis of hydraulics and electromechanical coupling, 2) build working models and test fixtures, 3) conduct bench evaluation of pump performance, efficiency and thermal management, and 4) test for hemolysis using standard protocols.** The success of this project will lead to a breakthrough technology that will provide a significant new treatment option in the management of CHF, likely reduce the morbidity and mortality associated with current device implantation, and reduce the cost of mechanical cardiac support.

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# Sample SBIR Abstracts

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## Title: Polymer Coatings for Prevention of Bacterial Contamination of Dental Waterlines

**Abstract:** Copious amounts of water are used for rinsing and cooling purposes in restorative and surgical dental procedures. Bacterial fouling of dental unit waterlines that deliver this water is a persistent problem in clinical dentistry and dental surgery. While the risk of bacterial infection is slight in most healthy patients, those patients with compromised immune systems due to disease or drug therapy are at elevated risk. Additionally, dental healthcare professionals are subjected to chronic exposure to contaminated water and aerosols generated from the dental unit. Existing approaches to combat bacterial contamination and biofilm formation are typically not effective in reducing bacteria counts to levels recommended by the American Dental Association. Finally, the majority of the existing approaches rely on healthcare workers to adhere to specific maintenance schedules that, if not followed, render the approaches largely ineffective. New approaches to dental waterline antifouling that would significantly reduce or eliminate the need for routine decontamination maintenance are of great interest to the dental healthcare community. Surface coatings which repel bacterial attachment on dental waterlines and biofilm formation would significantly reduce these health risks. If bacteria cannot attach to the surfaces of dental waterlines, they will not be able to form biofilms to allow them to reproduce in large numbers and contaminate the water supply. Coatings will be developed and evaluated that prevent bacterial attachment to surfaces of materials commonly used in the manufacture of dental waterlines. **In stage 1, surface coatings will be developed that adhere tightly to these materials and form coatings covering these surfaces. In stage 2, these coated surfaces will be evaluated for their ability to prevent bacterial attachment to the surfaces of these materials under both static and dynamic conditions. In future research, the coatings that have been developed will be evaluated for their effective on actual dental unit waterlines.**

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# Online Resources

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- SBIR/STTR granting agencies support a central online resource for the programs-
    - <http://www.sbir.gov>
  - Alternative non-government site (SBIR Gateway):
    - <http://www.zyn.com/sbir/>
  - NIH Specific Advice:
    - <http://www.niaid.nih.gov/ncn/sbir/pres.htm>
  - Proposal Advice from Greenwood Consulting:
    - [http://home.att.net/~g-jgreenwood/sbir\\_proposal\\_writing\\_articles.htm](http://home.att.net/~g-jgreenwood/sbir_proposal_writing_articles.htm)
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# Challenges

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- Universities must-
    - Develop common goals between faculty-initiated business and the mission of the institution;
    - Protect the intellectual property of the university; and
    - Establish policies to manage or eliminate conflicts of interest.
  - Researchers need to-
    - Balance academic and commercial initiatives;
    - Respect student and post-doc participation; and
    - Follow conflict of interest policies.
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# After Careful Consideration. . .

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- Positives-
    - No need to repay or give up equity
    - Generally easier to obtain than money from investors
    - Provides technology validation
  - Negatives-
    - There is no free lunch: opportunity cost
    - “Funding Gap”
    - Easy to fall into grant addiction
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# Illinois Innovation Challenge Grants

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- Proposal Preparation Assistance
    - Science Applications International Corporation (SAIC)
      - For NIH subcontract to Biotech Business Consultants (BBC)
    - Complete help with Ph I and Ph II proposals and a track record of success
  - Phase I Grant Match
    - Matches 50% of Phase I award, up to \$50,000
    - May be used for things unallowable by SBIR (legal, marketing, equipment, etc)
    - State may provide a letter of support if application early enough
    - Eligible source of FastTrack matching money
    - Application must be made within 30 days of submission due date
    - Two stage application
    - Company must remain in IL for 2 years and agree to reporting requirements
  - <http://www.commerce.state.il.us/dceo/Bureaus/Technology/Technology+Grants+Programs/Innovation+Challenge+Program.htm>
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# Upcoming Event

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- iBIO Institute SBIR/STTR Workshop
    - January 28-29<sup>th</sup>
    - Intensive, NIH focused workshop by BBC Consultants
    - \$150 NU rate to attend
    - More details at: [http://www.ibio.org/NEWS\\_EVENTS/ev-detail.lasso?e\\_id=1753](http://www.ibio.org/NEWS_EVENTS/ev-detail.lasso?e_id=1753)
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# Entrepreneurial Resources Here at NU

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- Student Specific–
    - InNUvation: [www.innovation.org](http://www.innovation.org)
  - Faculty, Staff and Students–
    - NUCATS: [www.nucats.northwestern.edu](http://www.nucats.northwestern.edu)
    - Homeland Security Innovation and Entrepreneurship Center (HSIEC): [www.hsiec.org](http://www.hsiec.org)
    - Kellogg (Levy Institute): [www.kellogg.northwestern.edu/entrepreneurship](http://www.kellogg.northwestern.edu/entrepreneurship)
    - McCormick Center for Innovation and Entrepreneurship
    - McCormick Office for Corporate Relations: [www.industry.northwestern.edu](http://www.industry.northwestern.edu)
    - Small Business Opportunity Center (SBOC): [www.sbo.org](http://www.sbo.org)
    - Technology Transfer Program (TTP): [www.northwestern.edu/ttp](http://www.northwestern.edu/ttp)
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# Northwestern University Clinical and Translational Sciences (NUCATS) Institute

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- Pilot Funding Programs
  - Information Aggregation
  - Research Database
  - Education
  - Clinical Trial Support
  - Biomedical Informatics
  - Community Engagement
  - Team Development and Support
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**Thank you!**

**Questions?**

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## Contact Information

Jim Bray

NUCATS

312-50(3-1941)

[j-bray@northwestern.edu](mailto:j-bray@northwestern.edu)

[www.nucats.northwestern.edu](http://www.nucats.northwestern.edu)

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