NIBIB Grant Solicitations from the Point-of-Care Technology Research Centers

Webinar
January 14, 2015
Point of Care Technology Research Network (POCTRN)

- National Institute of Biomedical Imaging and Bioengineering (NIBIB) created POCTRN in 2007
  - To facilitate the development of a pipeline of point-of-care technologies with commercialization potential
  - Utilizing a center structure that enables incorporation of clinical and user needs in the development process, and
  - Provides expertise and resources to address early barriers to commercialization and implementation

For General Information about the POCTRN contact Dr. Tiffani Bailey Lash, Program Director, baileyti@mail.nih.gov
To join the NIBIB POCT Listserv email NIBIBPOCT@mail.nih.gov
Point of Care Technology Research Network

POCTRN

Center for Future Technologies in Cancer Care
The Center for Future Technologies in Cancer Care focuses on the identification, prototyping and early clinical assessment of innovative point-of-care technologies for the treatment, screening, diagnosis and monitoring of cancers.  
Website: www.bu.edu/cftcc

Point-of-Care Technology Research Center in Primary Care
The Center in Primary Care serves as a national leader in transforming point-of-care technologies into commercially viable, clinically focused solutions for improving primary health care.  
Website: www.cimit.org

Center for Point-of-Care Tests for Sexually Transmitted Diseases
The Center for Point-of-Care Tests for Sexually Transmitted Diseases creates and tests unique methods for the diagnosis of sexually transmitted diseases, including the home delivery of over-the-counter (OTC) tests to end-users via the Internet.  
Website: www.hopkinsmedicine.org/medicine/std

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CIMIT’s Point of Care Technology Research Center in Primary Care

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Objectives

The Consortium for Improving Medicine with Innovation and Technology (CIMIT) is creating a new “center-without-walls” for rapid transformation of emerging point-of-care technologies into commercially viable, clinically focused solutions for improving primary health care. Specific aims include:

• Apply CIMIT’s innovation model to create clinically-driven point-of-care solutions that address critical areas of unmet need in primary health care.

• Identify and assess unmet primary care needs and develop performance criteria where point-of-care technology solutions would have the highest impact.

• Select the most promising point-of-care technologies and develop them into proof-of-concept prototypes.

• Test and evaluate prototype performance in simulated clinical environments and clinical “living laboratories” relative to clinical performance and implementation criteria.

• Transition prototypes that meet performance specifications into commercially licensable or start-up company opportunities.

• Train and educate relevant stakeholders – including clinicians, engineers, scientists, students and industry partners – in the innovation process as it applies to meeting health care needs.

• Disseminate “lessons learned” and best practices in innovation methodology and process both nationally and internationally in collaboration with other POCTRN Centers.
POCT Research Center in Primary Care

Unmet Needs

• As the number of primary care providers diminishes and the need for primary care increases, the fundamental unmet need is to increase the ability of providers to care for more patients without decreasing the quality of care given and without unduly burdening the providers, patients or their families.

• In general, two POC technology-enabled pathways to increase primary care capacity are:
  – To introduce point-of-care technologies that eliminate unnecessary steps and re-work to increase the efficiency of operations.
  – To offload selected testing and self-monitoring capabilities to the home or community settings for patient self-management.
• The 2015 national call is for breakthrough, disruptive innovations that transform clinic efficiency, workflow or patient/provider experience. In the future, clinical test results will be available at the time of the in-office or virtual primary care visit. Point-of-care testing from drops of blood or other body fluids or from non-invasive, non-chemical means will support clinical decision-making without testing delays or the inconvenience of off-site laboratory testing, and follow-up.

• The focus of this solicitation is to develop POCTs for
  – The most commonly used tests in primary care meeting the design requirements outlined on the next slide
  – Where results can be available within 20 minutes at the time of the visit
  – Without the need for venipuncture

• Microfluidic and nanotechnology platforms capable of multiplex testing to simultaneously measure multiple analytes are welcomed. Nonchemical sampling techniques such as optical or sonic methods or other physical modalities that expand the capabilities of primary care practices to deliver care will be considered.
POCT Research Center in Primary Care

2015 Solicitation: Design Specifications

- **Result Availability**: During the office visit (within 10-20 minutes)
- **Ease-of-Use**: Designed to ensure regulatory compliance under the clinical laboratory improvement amendment (CLIA-88) with minimal requirements for intervention by the operator.
- **Reducing Operator Errors**: The device should have built in software safeguards to ensure proper operation and reduce common errors.
- **Sample Types**: Samples that do not require a trained phlebotomist.
- **Storage of Consumables**: All consumables should be able to be stored at room temperature. The shelf life should be minimally 6 months to 1 year.
- **Device Footprint**: Designed to have as small a footprint as possible.
- **Information Connectivity**: Capable of being interfaced to the EMR.
- **Analytic Performance**: Should perform equally to central laboratory instruments with regard to analytical accuracy, reportable range and imprecision. Analytical time should be kept to a minimum (less than 5 minutes for common chemistry analytes and less than 15 minutes for immunoassays).
- **Cost**: Solutions that significantly reduce the cost of testing relative to the existing standard of care.
POCT Research Center in Primary Care

Solicitation Process and Timeline

Eligibility

- Academic Principal Investigators (PI) must hold a faculty appointment at an institution of higher education or a medical center in U.S. Industry PIs are not required to hold a faculty appointment.

Amount and Duration

- An anticipated 4 – 6 awards will be provided for up to $100,000 for direct costs for 12 months
- Indirect costs will be provided at your institution’s federally-negotiated rate

Process and Instructions – visit www.cimit.org/grants-poctrn.html

- Applicants must first submit a two page pre-proposal, which will be reviewed by Center and NIBIB scientific staff
- A sub-set of the applicants who submitted pre-proposals will be invited to submit full proposals
- Pre-proposals are due no later than 11:59pm EST, February 16th, 2015
- Pre-proposal must be submitted through CIMIT’s online system at https://cimitconnect.induct.no
- Submission site opens January 5th, 2015
- Applicants will be notified by March 16th, 2015 as to whether they are invited to submit full proposals
- Invitations and application instructions for invited full proposals will be emailed and mailed to the PI and administrative contact listed in the pre-proposal
- Full proposals must be received by 11:59pm EST, April 27th, 2015
- All full proposal applicants will be informed of review decisions by September 1st, 2015
- Earliest anticipated start date for funding is October 1st, 2015 (provided funds are received from the federal government and that all necessary IRB and IACUC approvals are in place)
- Each full proposal will be peer-reviewed on a confidential basis according to the Point-of-Care Technology Review Criteria (www.cimit.org/grants-poctrn.html)
The objective of the Call for Proposals is to identify primary care practices that are interested and willing to evaluate selected Point-of-Care Tests in their practice to address facilitators and barriers to clinical adoption, including workflow, staff and patient acceptance, practice productivity. Priority will be given to projects that have been identified as a primary care strategic priority for your institution or practice.

The needed conditions being:

- A clinical setting has articulated the need for a product or service that will enable an improved workflow, delivery of improved clinical care, compliance, etc. and/or saving money, time or resources for patients, their families or the clinics.
- A company has developed a product or service technology (approved for clinical use) that addresses this unmet need.

Up to $200K in awards may be made, each award up to $50K (direct costs). The awards will be utilized by the clinical teams to design and conduct studies to test the ability of the product or service to support a new care approach in a simulated or real-world environment (with human studies approval, if required). Monies are not available for commercial collaborators, with the exception of being used to purchase the products if required.
Boston University Center for Future Technologies in Cancer Care

Catherine Klapperich PhD, Principal Investigator
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Helen Fawcett PhD, Program Manager
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Center for Future Technologies in Cancer Care: Objectives

• Prototyping Projects
  – Funded via the annual solicitation. Additional services and funding through the Fraunhofer Center for Manufacturing Innovation.

• Alpha Prototyping Services (contact Dr. Sharon Wong, wongsh@bu.edu)
  – Machine shop and design tools.
  – Small parts fabrication.

• Clinical Needs Assessment
  – Focus Groups and quantitative research.

• Dissemination
  – Annual Hackathon Event.

• Education
  – Annual FDA Workshop.
We are particularly interested in technologies that address the following needs:

- Tools to monitor treatment toxicities more closely and adjust drug dosing to minimize side effects.
- New materials or drug delivery methods that could reduce or eliminate the need for infusion therapies.
- Tumor "aggressiveness" is currently assessed by histologic grading, staging, and invasiveness based on pathology, scans, molecular testing, etc. We seek POC imaging and/or diagnostic tools to assess these features.
- Tools that address social and behavioral barriers against scheduling, obtaining and discussing results from screening tests.
- Mobile Health technologies to improve the lives of patients and survivors.
- Technologies to enhance the delivery of palliative care.
Center for Future Technologies in Cancer Care: Solicitation

2015 Call for Proposals

Expected Due Date for Pre-proposals: November 2015

Eligibility:
Submission is open to anyone eligible to apply for an NIH R grant.

Funding Amount:
We anticipate funding approximately four to seven, 12 month grants each totaling $100,000 direct cost. Indirect costs will be covered at your institution's NIH negotiated rate.

For more information
http://www.bu.edu/cftcc/funding-opportunities/call-for-proposals/
Center for Future Technologies in Cancer Care: Events

• 19 May 2015 – Annual POCTRN CFTCC Science Symposium
  – This year the symposium features speakers and posters from all three POCTRN Centers.
  – Where: Boston University Photonics Center, Boston, MA

• 8-9 June Cancer Care for Scientists and Engineers Course at BU
  – To educate engineers and physical scientists about the key concepts in clinical cancer care, including current controversies and areas of need. The ultimate goal of the course is to provide a basis of knowledge to inspire physical and engineering scientists to work together with cancer researchers and clinicians to advance our understanding of cancer and to develop diagnostic, therapeutic and imaging tools. *No background in cancer biology is assumed*; the course is appropriate for faculty members in physics, chemistry, or engineering departments, as well as graduate students and postdoctoral scholars.
  – Where: Boston University Photonics Center, Boston, MA
The Johns Hopkins University Center for Point-of-Care Tests for Sexually Transmitted Diseases

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Center STD Point of Care Tests
Objectives

The mission of the Johns Hopkins University Center for Point-of-Care Tests for Sexually Transmitted Diseases (the Center), funded by the National Institute of Biomedical Imaging and Bioengineering (NIBIB), is to improve the health of all Americans by promoting research that will help prevent, detect, diagnose, or treat sexually transmitted diseases.

To achieve this goal, the Center facilitates the development of POCT for STIs through a number of mechanisms (discussed later) inclusive of providing TACTICAL FUNDING of POCT development efforts.

Tactical funding means that we are seeking to fund a critical path in the pipeline to develop POCT for which current funding has not been secured, but if secured, would enable the developer to obtain the larger financial support needed to fully commercialize a test.

In other words what experiment(s), if successful would be game changing or expand your current efforts toward commercialization?

Tactical funding does not fund proof of concept ideas for which no prior funding or experiments have been performed. These efforts should be directed to another award mechanism supported by the NIBIB.
The need to develop acceptable, accurate, and available point-of-care tests (POCTs) for diagnosing sexually transmitted diseases (STDs) for all at-risk populations is significant.

WHY DEVELOP TESTS FOR STDs:

- Five of the top ten reportable diseases in the United States are STDs.
- Hazardous to women since many, if not most, infections are asymptomatic
- Some STDs only detected through screening, or presentation by infected women for testing if they are notified of sexual contact with infected partner(s), or if they perceive themselves at-risk.
- About 20 million new sexually transmitted infections (STIs) occur in the United States each year.*
- STDs estimated to cost the American healthcare system nearly $16 billion in direct medical costs alone.*
- STDs effect more than 110 million total (both new and existing) STIs among women and men across the nation.*
- Stigma, privacy, and confidentiality issues make STDs/STIs optimal areas for point-of-care tests at healthcare facilities and for over-the-counter assays performed at home.
For developers of diagnostic tests, this means that STIs represent an excellent target and model for developing new POCT since:

- The need is great (100+M cases/yr).
- The financial drive to support POCT is high ($16B/yr).
- The availability of clinical specimens for test, evaluation and regulatory approval is large (20M new infections/yr).
- The market is world wide, applicable to many environments and scenarios for clinical operation and therefore open to multiple technologies fitting many unique niches.
- POCT for STIs platform can be directly transferred to new diagnostics for other infectious diseases.
Center STD Point of Care Tests
Solicitation Preferences

Current Funding Announcement is posted at:
http://www.hopkinsmedicine.org/Medicine/std/funding_announcements2014/index.html and on other Centers’ websites. While the solicitations deadlines for the 2014-2015 have passed, we anticipate posting the 2015-2016 solicitation and deadlines on or about July 2015 on Center website.

Technologies selected for funding are intended to bridge the gap between current biomedical technologies used in laboratory or research settings and those used at the bedside, in the clinic, or in the home-care scenario for STDs.

• **Priority given for POCT addressing STDs without available tests or available rapid tests such as:** Chlamydia, Gonorrhea, Trichomonas or for enumeration of HIV or Syphilis titers.

• **Scenarios will application for POCT include:**
  1) Point-of-care diagnostic tests for rapid diagnosis in the Emergency Department (ED) in which the time from sample to result is four hours or less
  2) Tests for rapid diagnosis in a community clinic, physician office or non-traditional health care setting in which the time from sample to result is less than one hour.
  3) Home testing in which the time from sample to result should be less than 15 minutes
  4) Resource-limited settings, such as found in developing countries.

It should be noted that the user (the person conducting the test) is significantly different in each of these scenarios and may encompass

1) the medical doctor      2) trained healthcare professional, or      3) lay person with no medical background.
The Center anticipates posting a new solicitation for 2015-2016 on or about July 2015.

We anticipate three submission dates from August to January dependent upon availability of funds—exact dates to be determined.

New solicitation will be posted on our website at http://www.hopkinsmedicine.org/medicine/std under the funding tab.

The solicitations generally use the following guidelines.

- Submission of concise 8 page proposal submitted by academic, industry or other organization inclusive of foreign applicants at one of three dates (as listed in the annual announcement).
- Funding limited to $50,000 with 6 month period of performance. Applicants can apply for up to two awards in a 12 month period.
- Anticipated funding goal of at least one proposal for each solicitation date.
- Proposals subject to competitive review among all applicants. The Center uses external reviewers to provide comment in combination with their own review.

Estimated Funding Timeline:

1. Proposals are reviewed by a team of external reviewers (~60 days following submission).
2. Reviewers comments are evaluated by the Center & summarized for justification to fund (~14 days).
3. A proposal is down selected for tactical funding and presented to NIBIB for approval to fund (~21 days+)
TACTICAL FUNDING IS ONE OF THE SEVEN TYPES OF SUPPORT THE CENTER OFFERS DEVELOPERS.

The other 6 types of support listed below are described in detail at: http://www.hopkinsmedicine.org/Medicine/std/funding_opportunities/index.html

1. Consultation with Center members including engineers, clinicians and other expertise related to POCT and STI.

2. De-identified clinical specimens and/or laboratory-grown organisms for testing POC devices under our IRB.

3. Collaboration for external funding providing expertise, experience and guidance on biological, laboratory or clinical needs.

4. Participation in focus groups or interactive expert panels inclusive of regulatory, clinical, market or other needs.

5. Future access to the Technology Watch Database (TWD), a comprehensive searchable database describing current and upcoming POCT technologies.

6. POC or other device testing in the research laboratory or pilot testing in clinics associated with the Center.
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