

# **Request for Applications (RFA)**

12P Product Development Grant

#### **Historical Background:**

The National Institute of General Medical Sciences (NIGMS) funded creation of Regional Technology Transfer Hubs (Hubs) for IDeA States in 2018 to accelerate the translation of biomedical innovations into commercial products that improve patient care and enhance health. In the Southeast IDeA States Region, XLerateHealth (the SBC on the grant) in collaboration with a consortium of 24 academic institutions across all 6 Southeastern IDeA states and Puerto Rico are working to create one of four hubs - the Southeast "XLerator Network". In 2019, NIGMS has provided funding to develop a program to specifically support pilot projects that would help advance innovations by quickly and clearly demonstrating whether a technology or product is worthy of advancing through the commercialization process. Many of these projects are anticipated to become future candidates for NIH SBIR/STTR funding.

I2P ("Ideas to Products") is the name of the program for the Southeast XLerator Network Hub. The I2P program will administer \$200,000 for 1 year to support approximately 4-7 product-development projects, with individual awards generally ranging between \$25K and \$40K.

It is important to note that the I2P program is not a traditional grant program; it is product focused and requires business-case project management. Applicants who are invited to submit a full application will work with the Program Manager to develop a product development plan and timeline. Receipt of funding for selected projects will be milestone-driven and I2P staff will monitor project progress. There will be an ongoing continuation evaluation (go/no-go decision), and non-progressing projects may be terminated and replaced with new projects. I2P-funded projects may require a commitment to return a portion of any subsequent income back to the program if the project did not achieve agreed upon milestones.

#### **Eligibility:**

This RFA is open to all participating institutions which includes any public or private academic or research institutions in the Southeast IDeA States. Non-faculty applicants must identify an institutional faculty member who is willing to sponsor their application. Applications must focus on developing products that are intended for commercialization and have the potential to improve patient care or enhance human health. All types of products (e.g. diagnostics, medical devices, therapeutics, preventative medicine, clinical decision support tools, digital health products, Al support tools for imaging, and other clinical applications, etc.) are eligible. There is no disease-specific requirement, as long as the project is within the scope of NIH-supported, human-health related research. Applications should involve ideas with protectable IP that originate from participating institutions. Technologies that are already licensed to a company are not eligible. Having multiple Principal Investigators (up to three) is optional but permitted.

## **Budget and Duration:**

We plan to fund 4-7 grants in 2020 generally ranging from \$25K to \$40K each for product development projects of up to 12-months in duration. No-cost extensions will be permitted.

# **Important Dates (anticipated):**

- Letter of Intent (Pre-application) deadline: November 20, 2019
- Pre-applications reviewed and invitations for selected applicants to submit full proposals:
   December 5, 2019
- Full proposal submission deadline: January 15, 2020
- Presentations to EAC via Zoom: January 27 February 7, 2020 (by invitation only)
- Award notices: February 10, 2020 (estimated)

# **Pre-application Instructions**

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## Format:

The pre-application must be submitted as a single PDF document consisting of the sections shown in the table below. Please prepare the documents in Word, convert to PDF, and compile into a single document.

Section	Format	Limit
Cover Page	Part of fillable pre-application form.	1 page
Demographic Information	Part of fillable pre-application form.	No Limit
Product and Market Description	Part of fillable pre-application form. Must have at least 0.75-inch margins, 12-point Calibri font, and single spacing in main text.	2 pages (including any figures and tables)
Technology Transfer Statement (Status of protectable IP)	Part of fillable pre-application form. Must have at least 0.75-inch margins, 12-point Calibri font, and single spacing in main text.	Up to 500 words (about 1 page)
References Cited (optional)	Part of fillable pre-application form.	10 references
Other Support	Part of fillable pre-application form.	No Limit
PI & Key Personnel Biosketches (optional)	Any (e.g. NSF, NIH 4- or 5-page)	5 pages per person

In addition to these application forms, please submit a **non-proprietary abstract** (maximum of 250 words) as an editable **Word document**. The abstract may be shared with representatives of industry, so please ensure that the abstract does not contain any proprietary information. If you have questions or need assistance composing your abstract, please contact Dr. Adam Gifford at <a href="mailto:adam@xleratornetwork.com">adam@xleratornetwork.com</a>.

#### **Submission Deadline:**

Submit your pre-application as a single PDF file to I2P Program Manager Dr. Adam Gifford at adam@xleratornetwork.com by 6:00 PM EST (5 pm Central) on Friday, November 20, 2019.

#### **Questions & Assistance:**

Dr. Adam Gifford can answer questions about this RFA and assist you with various aspects of the pre-application preparation. We encourage informal inquiries about whether an idea or product would be suitable for this program. Email <a href="mailto:adam@xleratornetwork.com">adam@xleratornetwork.com</a> with questions or to set up a time to discuss the I2P grant pre-application or your idea.

#### **Cover page:**

Complete the form as indicated. A detailed budget and timeline are not required at this stage, but please indicate your estimated budget and duration.

## **Demographics:**

Complete the form as indicated.

#### **Product description:**

This section should be 2 pages or less. Answer each question below:

- 1. Describe the product/idea you are proposing.
- 2. Describe the size of the market for this technology and any competitive products currently in use or development. Describe how the product/solution solves a market need/pain point or clinical unmet need.
- 3. Describe how your technology is unique. Note if it is patentable, and if not patentable options for other proprietary protections (if applicable).
- 4. In broad terms, describe how you plan to use the funds.
- 5. Briefly explain any specific expertise and experience the PI and/or team have that will help this project.

# **Technology Transfer Statement:**

Your Institution's Technology Transfer Office should prepare a brief statement on the protectability and commercialization potential, including: (1) a summary of patentability (or other protectability) review, (2) progress towards protecting the intellectual property, and (3) a one-paragraph synopsis of a marketing analysis. This statement should be a short summary only, not the full assessment. If your University does not have a technology transfer office, this statement must be provided by whatever office or entity is responsible for patenting or protecting research from your Institution.

#### References cited:

Up to 10 literature references may be listed, but this is optional.

## **Other support:**

List past, present, and pending support relevant to the proposed product. Or state "none".

#### **Biosketches:**

A biosketch or resume for the PI and other key personnel is optional, but may be included.

#### **Submission Instructions:**

<u>Completed pre-applications (in PDF format, as a single document) should be submitted through the XLerator Network website.</u>

# **Pre-application Review Procedures**

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# **Review of pre-applications:**

The Southeast XLerator Network leadership team will review pre-applications to determine if they are responsive to the RFA and may exclude any that are unsuitable for this program. It will also select a subset of applicants (up to 10 is expected) to be invited to prepare a full application, to be presented to, and reviewed by, the Southeast XLerator Network External Advisory Committee (EAC). The criteria for selection include scientific merit, clinical relevance, intellectual property (IP) position, market size, commercial potential, time to market, and I2P portfolio diversity.

# <u>Particular preference will be given to pre-applications with a high potential of leading to competitive</u> SBIR or STTR proposals.

Matching (including through in-kind and partnered approaches) is encouraged for all applicants.

#### Next steps:

All applicants will be notified of the outcome on or around December 5, 2019. Those who were not invited to submit a full proposal will be encouraged to contact I2P Program Manager Dr. Adam Gifford to discuss the application.

Invited applicants will receive further instructions regarding preparation of the application and the process of submission. Development of application presentations will require a detailed product development plan. While an exhaustive invention disclosure (or an equivalent) is not required to submit a pre-application, it will be required prior to the full application submission. If disclosure has not been filed already, a Disclosure Form will be provided to you by your technology transfer office or, if your university does not have one, by the office responsible for protection of intellectual property at your university. Final funding decisions will be made following review by the Southeast XLerator Network Hub's External Advisory Committee (EAC), followed by the NIGMS final review and approval.