Request For Applications (RFA)

UofL-ExCITE Product Development Grant – Cycle #4

Background:

The REACH (Research Evaluation and Commercialization Hub) program is a National Institutes of Health (NIH) initiative that has created three proof-of-concept product development hubs. The goal of the program is to accelerate the translation of biomedical innovations into commercial products that improve patient care and enhance health. For more information, see ncai.nhlbi.nih.gov.

ExCITE (Expediting Commercialization, Innovation, Translation, and Entrepreneurship) is the name of the REACH hub at the University of Louisville (UofL). The ExCITE hub will administer $1M per year for 3 years to support approximately 5–10 product development projects per year. In addition to funding translational research, the ExCITE hub will provide commercialization-related education and training, as well as feedback from various experts, including the NIH and their partners (see louisville.edu/excite).

It is important to note that the ExCITE 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 a mentor to develop a product development plan and timeline. Receipt of funding for selected projects will be milestone-driven and ExCITE staff will monitor project progress. There will be a continuation evaluation (go/no-go decision) about every 6 months and non-progressing projects may be terminated and replaced with new projects. ExCITE-funded projects may require a commitment to return a portion of any subsequent income back to the program.

Eligibility:

This RFA is open to all UofL faculty, staff, trainees, and students. Non-faculty applicants must identify a UofL faculty member who is willing to sponsor their application. Applications must focus on developing products that have the potential to improve patient care or enhance human health. All types of products (e.g. therapeutic, preventative, device, test, software) are eligible. There is no disease-specific requirement, but some funds are restricted: of the $1M/year available, at least $150,000 must support lung cancer-related projects and at least $200,000 must support projects focusing on plant-produced pharmaceuticals. Applications should involve ideas that originate from UofL (making them potentially eligible for patent protection or some other mechanism that will return income to the program) or UofL-derived technologies with pending/issued patents or copyright. 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:

Requests for up to $200,000 total per project, over a period of up to 2 years, will be considered.

Important Dates (anticipated):

- Pre-application deadline: August 8, 2016
- Full applications invited: August 23, 2016
- Full application due: October 3, 2016 (by invitation only)
- Full application presentations: October 27, 2016
- Award notices: January 2, 2017 (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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Format</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cover page</td>
<td>Part of fillable pre-application form.</td>
<td>1 page</td>
</tr>
<tr>
<td>Demographic information</td>
<td>Part of fillable pre-application form.</td>
<td>No limit</td>
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<tr>
<td>Product description</td>
<td>Part of fillable pre-application form.</td>
<td>2 pages (including any figures and tables)</td>
</tr>
<tr>
<td>Response to previous reviews (if applicable)</td>
<td>Part of fillable pre-application form.</td>
<td>300 words (about half a page)</td>
</tr>
<tr>
<td>References cited</td>
<td>Part of fillable pre-application form.</td>
<td>10 references</td>
</tr>
<tr>
<td>Other Support</td>
<td>Part of fillable pre-application form.</td>
<td>No limit</td>
</tr>
<tr>
<td>OPTIONAL: PI &amp; key personnel biosketch(es)</td>
<td>Any (e.g. NSF, NIH 4- or 5-page)</td>
<td>5 pages per person</td>
</tr>
</tbody>
</table>

In addition to these application forms, please submit a non-proprietary abstract (maximum of 250 words) as a Word document. The abstract may be shared with representatives of industry, so please insure that the abstract does not contain any proprietary information. If you have questions or need assistance composing your abstract, please contact sarah.andres@louisville.edu.

Submission Deadline: Submit your pre-application as a single PDF file to sarah.andres@louisville.edu by 5:00 PM (Eastern time) on Monday, August 8, 2016.

Questions & Assistance: The ExCITE hub staff 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. If necessary, we may be able to help find a suitable collaborator and/or faculty sponsor (for non-faculty applicants). Email sarah.andres@louisville.edu with questions or to set up an appointment to discuss the ExCITE 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. Does it address an unmet clinical need?
2. Describe the market for this product and any competitive products currently in use or development.
3. How is your product unique and is it patentable? If not patentable, is other proprietary protection likely?
4. In broad terms, what do you plan to use the funds for?
5. Briefly explain any specific expertise and experience the PI and/or team have that will help this project.

**Response to previous reviews**: Indicate if you have previously submitted this project (or a related project) to the ExCITE program for funding. If you have, please describe briefly how you have addressed any concerns raised in previous reviews, using 300 words or less.

**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 may be included, but is optional.

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**Pre-application Review Procedures**

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**Administrative review of pre-applications:**

The ExCITE hub staff will review pre-applications to determine if they are responsive to the RFA and may exclude any that are unsuitable for this program.

**Scientific and commercialization review of pre-applications:**

Responsive pre-applications will be reviewed based on various criteria, including scientific merit, clinical relevance, intellectual property (IP) position, market potential, time to market, and ExCITE portfolio diversity. Pre-application reviewers will include faculty with scientific, clinical, and/or entrepreneurship expertise, plus Office of Technology Transfer (OTT) staff who will assess patentability and commercialization potential.

**Next steps:**

All applicants who submit a pre-application will be notified of the outcome (invited or not invited to submit a full application) on or around August 23, 2016. Those who were not invited will receive a brief description of why their pre-application was not selected and will be encouraged to meet with ExCITE hub staff to discuss the possibility of resubmission. Invited applicants will receive further instructions regarding preparation of the full application. Submission of a full application will involve additional training in research commercialization and working with mentors to create a detailed product development plan. While a UofL Research Disclosure Form is not required to submit a pre-application, completion of this form will be required prior to full proposal submission. Final funding decisions will be made following review by the ExCITE External Review Board (ERB) and from the NIH Technology Review Committee (TRC).