Applicants invited to submit Full Proposals for the Johns Hopkins-Coulter Translational Partnership grants must submit their completed proposals (PDF Format) to Jeffrey Healy, Coulter Program Administrator, via email attachment to jhealy5@jhu.edu. Full-Proposal submissions are due by midnight, Monday April 16, 2012.

As a reminder...

Coulter program eligibility rules require that each proposal have Co-Principal Investigators, consisting of one or more full or joint faculty member within the Department of Biomedical and one or more clinicians from the Johns Hopkins School of Medicine whose job responsibilities directly impact patient care or the management of patient care. The members of the team should be willing to devote necessary time and resources to the project, and be open to receiving mentorship and coaching related to the development of the project idea towards commercialization.

The project must relate directly improving health care. The specific objectives of the proposed project should develop a health care improvement idea along a path that takes it into full use and impact.

Evaluation of proposals will be on the basis of (1) magnitude of the potential health care impact, (2) likelihood of technical success, (3) likelihood of obtaining follow-on resources required to fully develop idea into a product that achieves expected health care impact. The latter normally pertains to likelihood of follow-on investment or licensing by a company or organization with such resources.

Full-Proposal Instructions

1. **Cover Page**
   - Please use the Cover Page Form found within the Resources Section of this website.
   - Please format all Full-Proposal documents in Arial 11 point font and 1” margins.

2. **Executive Summary**
   - One page.
   - The most important page, since most reviewers will use this page to triage their more in-depth reading, so you could lose someone here.

3. **The Team**
   - One page
   - Name, affiliation, title, role, of each team member
   - One paragraph for each team member’s experience relevant to this project
   - Please include all team members expected to play a major role in the project, including students
4. **Body of the Proposal**

- About seven pages total for the following sub-sections I – VI.

I. **Clinical Problem:**

- What is the clinical need?
- Who and how many are affected by this need?
- What are the major symptoms of this problem?
- Who are the key stakeholders negatively impacted by this problem — such as patient, payer, physician, provider — and how does it impact each?
- Summarize the clinical problem with a one-two sentence need statement that includes what you know of the performance a solution will have to have in order to successfully address the clinical need. *For example:* “There is a clear clinical need for the development of a low-cost, rapid influenza test that can reduce unnecessary diagnostic testing, decrease inappropriate antibiotic use, and reduce the duration of treatment during hospitalization compared to current solutions.”

II. **Current Solutions**

- The top two or three solutions available today or in product development that are intended to impact the same clinical need.
- For each of these, explain why it is not an adequate solution. For example, it could fail to properly achieve the required functionality, or have a complex learning curve, or exceed cost/price constraints.

III. **Your New Solution**

- Describe the product — how does it address the unmet clinical need?
- Define the end user of your technology.
- Explain how the technology will be better than the current gold standard. Be specific w.r.t. which factors it improves on.
- Preliminary testing and data to demonstrate technical feasibility of your solution
- Status of the IP of your technology. Provisional filed with JHTT? Full patents? Explain what the novel aspects of your technology are.
- Potential for platform technology or additional applications if first is successful.

IV. **Potential Risk and Mitigating Strategies**

- IP landscape: are there any concerning patents in existence that may block you from filing IP (patentability) and/or from commercializing your product (freedom to operate)?
- Regulatory strategy: what regulatory pathway will this technology require to reach the market? What is the associated time and cost?
- Reimbursement: are there existing reimbursement codes for the use of this technology, or will new codes have to be established in order for hospitals and doctors to get subsidized for using your technology?
- Other risk factors you have identified and how you will mitigate these risks.
V. Specific Aims of Proposed Project

- Describe work plan
  - Describe key milestones within the timeline of the proposed and funded project and explain the work to be done for each milestone.
  - Timeline for the project (1 year or less). Consider including Gantt chart.
  - Line item budget (all costs should be tied to a milestone)

- Describe Relevance of Work plan to Commercial Development
  - Explain how the milestones within your project fit into a larger plan to fully develop your innovation into a solution in clinical use
  - Explain how this Coulter funding will help you to convince subsequent investors (or grant reviewers or licensees) to further invest in your idea.

VI. Potential Exits

- List companies or organizations likely to have an interest in licensing your solution.
  - List company names, divisions, and why they would be interested (ex: sell similar products, sell to similar markets, a gap in their offerings)
  - If you have met or discuss project with a company/organization to gauge their interest, please mention name of company/org, title (not names) of people you met, and dates.

- List information you have obtained from any of them pertaining to this project.
  - Have any expressed an interest in your solution?
  - Have any commented on the validity of the value proposition of your technology?
  - Any quotes or letters of interest/support would greatly strengthen the application.

4. Literature Cited

5. Project Timeline (Gantt Chart preferred)

- Gantt chart template available in the Resources Section of the website.
- Show projected quarterly goals or other logical milestones within the project term
- Detail activities in the chart, and label or organize in terms of project specific aims
- Include both technical and business-related activities
- Include activities related to obtaining follow-on funding
- Timelines should start June 1, 2012

6. Curriculum Vitae

- Please provide a brief (about two page) CV for each Project Investigator.
7. **Proposed Project Budget**

- Prepare a detailed research budget including all of the direct costs for personnel, materials, supplies and equipment needed
- Major capital expenditures are not permitted. Minor capital equipment items specifically needed for conductance of the work plan are acceptable
- Funds may be used for salary support of faculty, graduate students, and other research staff, but may not be used for general staff or administrative support
- Operating supplies, minor equipment items, prototyping expenses, imaging time and travel directly associated with project activity are examples of eligible budget items
- Grant budgets are expected to be in the $100,000 range direct costs for a one-year period
- Since this is an internal JHU fund, no overhead costs should be included in the budget

8. **Supplementary Materials and Letters**

- Letters of Approval, e.g. Animal or Human Subject Testing
- Letter of interest from commercial partners or other organizations stating strong potential interest in the results of this project “if successful”
- Letter describing resources available (including funds) that will be employed alongside Coulter funds to further the aims of this project or closely related aims
- Statement from JHU Tech Transfer staff managing the IP related to this work stating the status of that IP and key upcoming decision points (such as filing deadlines)

**ADDITIONAL INSTRUCTIONS**

- Please highlight in bold sentences in your proposal that **direct address comments or issues brought up by the Oversight Committee reviews**. OC members will be looking for these as specific responses to their questions and/or concerns.
- We’re here to help – please feel free to contact us for help in understanding this format and in developing the content.
- For the May 8 oral presentation, please see guidelines for those slides and presentations. Presentations to the OC should be rehearsed with the program director and deputy at least once.
## Johns Hopkins-Coulter Translational Partnership

### Full-Proposal Cover Page

**Project Title:**

**Total Amount Requested for Proposed Period of Support:** $  

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**Signatures:**

The Undersigned accepts responsibility for the scientific and technical conduct of the research project and agrees to all terms and conditions of the Johns Hopkins-Coulter Translational Partnership Grant from the Wallace H. Coulter Foundation.

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**Reviewer Notes/Comments**