

Research Innovation and Pilot Funding Guidelines

January, 2017

CCHMC has established this funding vehicle for projects that are unusual (Innovation) or alternatively, are essential (Pilot), and are therefore good candidates for external funding after preliminary data has been obtained.

Eligibility for RIP funding

Open to all faculty. Only one application per submission deadline. You may not hold two RIP grants at the same time. Trustee and Proctor awardees may receive RIP funding only after Trustee and Proctor award budgets have ended. Collaborative projects that include investigators at the University of Cincinnati College of Medicine with the primary PI at CCHMC will be accepted. See special eligibility criteria for clinical trials proposals in the document Clinical Trials Eligibility.

Application documents:

1. Proposal. This should consist of three pages of text (not including references) that outline the hypothesis, aims, and briefly, the proposed experimental work. The reasons that this work should be considered innovative and of high impact or essential and should be stated explicitly.

2. NIH Biosketch.

3. Other Support page.

4. Budget justification. Half page max. Each award budget will be less than \$75,000. No PI salary coverage.

5. Resubmissions. Include a one page response to reviewers.

Submit application to Mary.Kinsella@cchmc.org by email as a single pdf document. Please call 636-8854 for questions.

Application deadlines will be three times a year on the First Monday of March, July, and November by 5pm. Principle investigators should anticipate a response within 5-6 weeks. RIP funding is not renewable.

Review process and criteria

Proposals are reviewed by internal reviewers who are members of an NIH style study section. Reviewers are instructed to use NIH scoring criteria. Applications are ranked according to average score and then funded from the best score downwards. The program committee has the option to request that part or all of a budget recommended for funding is sourced divisionally. If you obtain CCHMC Gap funding but your application is subsequently funded from an external source, we will require that any duplicative funding is returned.

Research Innovation and Pilot Funding: Special eligibility criteria for clinical trials

Applications that seek to enroll human subjects should be reviewed prior to submission by the Office of Clinical and Translational Research (OCTR) at CCHMC. Proposals must be received at least 5 business days prior to the submission date to allow time for review. At the conclusion of the review, a feasibility assessment letter will be generated by OCTR for inclusion in the proposal's application packet. The OCTR review will focus on feasibility, particularly the feasibility of interventional trials. Information important to this review is covered in the checklist below:

Clinical Trial Review Checklist

#1. Does the project include a prospective trial that enrolls human subjects?

If not, do not continue with question #1.

- a. Has the protocol been drafted?
 - i. Did the investigator collaborate with a team (statistician, regulatory, CRCs, monitor, other investigator) to design the protocol?
- b. Has the protocol been approved by the applicant's Divisional Scientific Review committee?
- c. Has the protocol been submitted to the IRB?
- d. Has the IRB approved the protocol and informed consent?
- e. Have the investigators and staff completed CITI training?
- f. What is the desired total number of participants?
- g. What is the estimated rate of enrollment?
- h. What is the proposed enrollment strategy (who, where, when, how)

#2. Will the study include administration of a drug or use of a device (or combo product)?

If not, do not continue with question #2 but proceed to question #3.

- i. Will the study article/drug/device require an IND or IDE ?- i.e. Will the study article/drug/device be used outside the scope (population, dosing, disease state) of the package insert? IF YES:
 - i. Does the project require a pre-IND meeting with the FDA? (60-90 day process)
 - ii. Has the investigator submitted the IND to the FDA or IDE to the IRB/FDA? (30 day review process)
 - iii. Has the sponsor-investigator received clearance from the FDA to initiate the study?
 - iv. Is the study currently on clinical hold by the FDA, post IND submission?
- j. Is the investigator working with the OCTR to meet FDA/regulatory obligations or to market/recruit for the study?
 - i. Does the investigator have trained staff to develop and operationalize the project?
 - ii. Will the study article/drug/device require submission to the IBC or RAC?
 - iii. Has the investigator reviewed regulatory obligations for holding an IND/IDE?
 - iv. Has the investigator completed a pharma-sponsored trial or participated in an IND or IDE study as an investigator or sponsor-investigator?

#3. What is the estimated timeline for study startup, study enrollment and study close?

- k. Will the current study be a single site?
- l. Will the current study include one or more sites in addition to CCHMC?
- m. Does the investigator have trained staff available to conduct the study?
- n. Does the project require a DSMB?
- o. Have potential members of a DSMB been identified?
- p. Who handles the data?
- q. Is there a data management plan?