



I³ MORNINGSIDE CENTER FOR INNOVATIVE AND AFFORDABLE MEDICINE: REQUEST FOR LETTERS OF INTENT IN CANCER

BACKGROUND: The current ecosystem around medical innovation focuses on unmet medical needs, but rarely prioritizes ideas on the basis of affordability and accessibility. Expensive new drugs result, yet only a fraction of patients globally has access to and can afford these treatments. Ideas that could rapidly result in inexpensive new treatments lie unexplored largely because of a lack of financial incentive to do the research necessary to bring these treatments to market. We have referred to them as financial orphans (<https://www.healthaffairs.org/content/forefront/financial-orphan-therapies-looking-adoption>). Emory's Morningside Center for Innovative and Affordable Medicine focuses on financial orphans aiming to generate both pre-clinical, biomarker and clinical data for affordable, effective, safe and readily accessible medical treatments that will reduce global disease burden. This RFA will entertain cancer proposals. The awards will be administered through the Emory SOM Imagine, Innovate, and Impact (I3) awards program with funding support provided by the Morningside Center for Innovative and Affordable Medicine.

I³ MORNINGSIDE CENTER RESEARCH AWARDS AND FUNDING AVAILABILITY: The Morningside Center anticipates awarding up to \$1M across three areas and is soliciting proposals for studies in the following:

1. **PRECLINICAL WORK CRITICAL TO SUPPORT CLINICAL STUDIES:** We anticipate 3-5 awards totaling \$200-300,000
 - The goal of this award is to fund preclinical studies (ideally animal studies in disease models) that will lend strong supporting evidence for future clinical trials. The interventions should include one or more of the following financial orphan categories: generic drugs approved by the FDA that are being explored for a new indication (drug repurposing), readily available natural products/supplements, lifestyle changes (diet, exercise, etc.). Preference will be given to interventions that are affordable, safe, likely to give a large efficacy signal, and which shed light on mechanisms of action of the intervention. Studies that employ approved drugs that are still on patent will not be entertained, nor will studies that will ultimately require drug reformulation for extrapolation to human studies. An example of a study that might be funded involves the modulation of stem cells with a repurposed drug in an animal model of glioblastoma to disrupt its aggressive growth pattern.
2. **BIOMARKER DEVELOPMENT FOR FINANCIAL ORPHAN STUDIES:** We anticipate 1-2 awards totaling \$60-150,000.
 - The goal of this award is to promote the development of novel CLIA-approved biomarkers that augment conventional assessments of response to therapies. The biomarkers could be useful for stratification, monitoring or decision support for a study that uses repurposed drugs, supplements, or lifestyle change interventions. The biomarkers might be blood or tissue based but should be easily measured and (ideally) correlate with other assessments of response such as imaging, clinical measurements, or conventional histologic analysis.

3. **CLINICAL TRIALS READY FOR IMPLEMENTATION:** We anticipate 2-3 awards totaling \$600-700,000
- The goal of this award is to increase the number of innovative financial orphan interventions tested in clinical studies. The interventions may include one or more of the following: generic drugs approved in the US by the FDA that could be explored for a new indication i.e., drug repurposing, readily available natural products/supplements, lifestyle changes (diet, exercise, etc.). Preference will be given to interventions that are cheap e.g., generic drugs, safe, and likely to give a large efficacy signal. Preference will also be given to interventions that might boost the efficacy of checkpoint blockade while also being affordable and safe. Studies that employ approved drugs that are still on patent will not be entertained. The majority of studies that will be funded will be early-stage clinical trials such as Phase 0 micro- or sub-therapeutic-dosing studies; Phase 1 single ascending dose and multiple ascending dose studies to assess safety and feasibility; Phase 2a biomarker-based proof-of-concept or proof-of-mechanism studies. These studies can validate novel molecular targets in humans and de-risk novel therapeutic approaches earlier in clinical development by assessing the potential efficacy of therapeutic interventions using pharmacodynamic outcomes. Phase 2b single-arm or randomized studies assessing early efficacy (response and/or survival) signals of interventions alone or in combination with conventional therapeutics.

Eligibility – I³ Morningside Center Awards:

- Faculty PI with a primary appointment in the Emory WHSC at the rank of Assistant Professor or above at an FTE of 0.5 or higher
- Cannot be duplicative of current funding at the time of award
- Faculty may participate in more than one proposal but may only serve as PI on one proposal

Timeline

10/25/2023 – RFA released

12/15/2023 – Letter of Intent due by 5:00 pm

02/01/2023 – Full proposal invitations will be sent by the Morningside Center. Full proposals are expected to be in the range of 15 pages.

Application Information-Letter of Intent

Applicants should submit the Letter of Intent to: Krista Charen, MPH, krista.charen@emory.edu **no later than 5:00 p.m. (no exceptions) on 12/15/2023.**

Attachments – Please attach the Letter of Intent as a single PDF document following this naming convention: PI last name.first name.I3.LOI23.pdf

- Example: Hill.Beth.I3.LOI23.pdf

The Letter of Intent single PDF should not exceed 3 pages and must address each of the following items, in this order:

- Title of the proposal/innovation
- Category: Preclinical, Biomarker, or Clinical Trial
- Length of project: 1 year or 2 years
- PI name, credentials, title, and department/division
- If applicable, Co-PI name, credentials, title, and department/division

- Co-Investigators' names, credentials, titles, and departments/divisions
- Concise description of the proposed project with specific aims addressed by the research
- Brief explanation of how the proposal will meet each of the review criteria: 1) Fit within a scientific framework or known mechanistic background (particularly relevant for clinical studies); 2) Magnitude of impact if project were to succeed (i.e. potential for significant vs. incremental impact); 3) Time to impact (preference given to projects with well-defined time plans and with early and clear go-no-go points); 4) Creativity and novelty of the idea/approach; 5) PI qualifications and team readiness; 6) Feasibility of carrying out the proposed project (i.e. competing trials and potential for patient enrollment); 7) Chances of a successful outcome; 8) Potential to generate extramural funding
- Proposed total budget (in increments of \$5,000)

Application formatting:

- Use paper size no larger than 8 ½" x 11"
- Provide at least one-half inch margins (top, bottom, left, and right) for all pages
- Font size must be 11 points or larger (smaller text in figures, graphs, diagrams, and charts is acceptable as long as it is legible when the page is viewed at 100%)
- Text color must be black (color text in figures, graphs, diagrams, charts, tables, footnotes, and headings is acceptable)
- The following fonts are acceptable: Arial and Calibri

Review Criteria for LOI-The following Review Criteria will be used to score proposals:

- Fit within a scientific framework or known mechanistic background (particularly relevant for clinical studies)
- Magnitude of impact if project were to succeed (i.e., potential for significant vs. incremental impact)
- Time to impact (preference given to projects with well-defined time plans and with early and clear go-no-go points)
- Creativity and novelty of the idea/approach
- PI qualifications and team readiness
- Feasibility of carrying out the proposed project (i.e., competing trials and potential for patient enrollment)
- Chances of a successful outcome
- Potential to generate extramural funding

For content questions related to the I³ Morningside Center Award programs, please contact:

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