Columbia University Medical Center

Irving Institute for clinical and translational research

INTEGRATING SPECIAL POPULATIONS (ISP) PILOT AWARD APPLICATION

Irving Institute for Clinical and Translational Research

2017

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GUIDELINES AND INSTRUCTIONS FOR APPLICANTS

PILOT APPLICATION DEADLINE: **FEBRUARY 13, 2017**

AWARD ANNOUNCEMENT: **MAY 2017**

The Integrating Special Populations (ISP) Resource of the Irving Institute for Clinical and Translational Research provides pilot funding and seminar series to foster collaborations at Columbia University within and across designated special populations. Our goal is to develop an interactive cadre of established and new investigators ranging from pediatrics to geriatrics, bridging CUMC and our surrounding community.

The ISP consists of four special populations:

- Pediatrics (infants, children, and young adults)
- Geriatrics (≥65 years)
- Rare Diseases (e.g., as defined by NIH a rare disease affects <200,000 people in the US or 1/1500)
- HIV

The ISP goals are to:

1. Foster collaborations both within each special population and across special populations that will:
   a. Provide expertise necessary to study diseases across the lifespan
   b. Utilize rare diseases as tools to study more common diseases
   c. Increase the breadth of dissemination of the results of these efforts, with the goal of further increasing collaborations among investigators within and across the special populations
2. Create culturally sensitive engagement, recruitment, and educational tools to facilitate ISP-based research in Northern Manhattan

Pilot Award Program

The ISP Pilot Award program provides funding focused on four special populations: Pediatrics, Geriatrics, Rare Diseases and HIV, to support the formation of newly-configured investigative teams aimed at studying diseases across the lifespan and utilizing rare diseases as tools to study more common ones, at CUMC and within the community. **Up to four (4) one-year, one-time funding grants of $40,000 each will be announced in May 2017**, to assist in the activities of novel, cross-disciplinary collaborations involving at least two investigators.

Eligibility: **Each team is limited to six (6) investigators. At least one applicant must be a junior investigator (i.e., Instructor, Assistant Professor, or Associate Research Scientist) at CUMC. F**aculty/investigators from the Morningside campus and community collaborators may be a part of the investigative team. Applicants will be expected to propose studies that address a problem affecting at least one of these special populations, with the overarching principle of examining diseases across the lifespan, e.g. an adult disease such as Type 2 Diabetes now prevalent in children, a pediatric disease such as Down's syndrome, or a rare disease like cystic fibrosis, that now extend into adulthood. Community based research is encouraged. Proposals may identify gaps in processes related to transition of care across the lifespan, focus on disease mechanism or consequences that change with age, e.g. genetic determinants of age of onset and phenotype, or development of culturally sensitive tools needed to engage patients and their families at different stages of life and of the disease. During the application cycle, only

one submission is permitted per principal investigator. **Preference will be given to new collaborations.** Irving Institute and ISP leaders may be consulted during the preparation of the application and included as co-investigators.

APPLICATION DIRECTIONS:

1. Prepare all parts of the application form (contact information, abstract, current funding sources, submitted applications, 12-month budget, budget justification, regulatory approvals and research areas, and signature page). Attach the application (detailed in direction item #4) and NIH-style biosketches for all project team members, including eRA Commons usernames.

2. Convert the entire packet into a single PDF file that must be submitted electronically no later than 5:00pm EST on Friday, February 13, 2017, to:

Dianne C. Frederick
Program Manager
Clinical Research Resource (CRR) and Integrating Special Populations (ISP)
Irving Institute for Clinical and Translational Research
Email: dcf2111@cumc.columbia.edu

3. The body of the application (i.e., Goals, Rationale, Methods, and Future Plans) may not exceed five (5) single-spaced, typed pages (11 or 12 point font required; Arial typeface preferred), excluding references. It should include:

A) *Goals:* What are you planning to achieve/ what is your desired result/expected outcome?

B) *Significance and Premise:* Why is it worth doing? What prior research will this new proposal build upon? What gaps in knowledge will be filled by the proposed work? How is the proposed work interdisciplinary?

C) *Methods:* How will the study be conducted?

- We strongly encourage applicants to seek consultation with relevant Irving Institute Resources prior to submission of this proposal (e.g., Design & Biostatistics, Regulatory and Ethics, Community Engagement, Biomedical Informatics). *Note that requests for Irving Institute Resources to help with grant submissions MUST be submitted at least 4 weeks prior to the proposal due date; otherwise, a request for consultation could be delayed or possibly denied.* Requests must be made online at the following URL: http://irvinginstitute.columbia.edu/. Our Service Request form may be found by clicking any one of three buttons on our Web site – **RESOURCES, RESEARCH or LINKS,** and then selecting **SERVICE REQUESTS**. To access these services and log in your request, a Columbia UNI and password are required.
- Will services of Irving Institute Resources be requested/used/needed for carrying out the proposed work?
- Discuss the statistical analysis plan, including sample size and power estimates. Pilot proposals that are being used to collect data to generate effect size and/or power estimates for future studies are acceptable.

D) *Future Plans:* What is the next step after the completion of the pilot project?

- What specific grant application(s) do you plan to submit and when? Provide a detailed plan and timeline for grant applications to the NIH, private foundations, or other external funding sources. This response will be *heavily weighted*.

4. References: Reference pages do not count toward the five (5) page limit.

5. NIH-style biosketch for each investigator including collaborators and/or consultants: Maximum of 5 pages per investigator (including Other Support).

6. Budget: This one-time award is in the sum of $40,000. Your detailed budget should directly support your protocol. Each item must be justified in the budget justification section of the application. Expenses may include salary, equipment, computer costs, etc., but the justification must be clearly stated.

NOTE: IRB/IACUC approval is not required at the time of application. However, if a candidate is awarded a grant and the project involves the use of data from human and/or animal subjects, an IRB/IACUC approval number must be forwarded prior to receipt of funding (June 1, 2017). In order to avoid any delays if funding is awarded, candidates are encouraged to apply and obtain IRB/IACUC approval in advance.

Review Process: Reviewers will use a scoring system based on a 5-point scale (1 = highest) and judge each application on the basis of scientific merit, multidisciplinarity, potential impact of the pilot findings and potential of the junior investigator for independent research career.

FAILURE TO FOLLOW THESE DIRECTIONS WILL RESULT IN THE PROPOSAL BEING RETURNED TO YOU, WITHOUT REVIEW.

JUNIOR INVESTIGATORS ARE STRONGLY ADVISED TO REVIEW APPLICATIONS WITH SENIOR FACULTY MEMBERS PRIOR TO SUBMISSION.

DO NOT INCLUDE APPENDICES.

PILOT AWARD WINNERS WILL BE ANNOUNCED IN MAY 2017.

FUNDING WILL BE AVAILABLE ON JUNE 1, 2017.

For any questions about the scientific content, please contact:
General questions about ISP RFA: Karen Marder MD MPH, ksm1@cumc.columbia.edu
Pediatrics: Joel Lavine MD PhD, jjw2151@cumc.columbia.edu
Geriatrics: Joseph Lee PhD, jhl2@cumc.columbia.edu
Rare Diseases: Emily Dimango MD, ead3@cumc.columbia.edu
HIV: Magda Sobieszczyk MD, mes52@cumc.columbia.edu

For any questions about the application process and format, please contact:
Dianne C. Frederick
Program Manager, Clinical Research Resource (CRR), Irving Institute for Clinical and Translational Research
dcf2111@cumc.columbia.edu
(212) 305-9315

To learn more about the Irving Institute, please visit: http://irvinginstitute.columbia.edu

CONTACT INFORMATION PAGE – *Please include contact information for the PI and co-investigators, collaborators and/or consultants. Please add as necessary (maximum total 6)*

PI NAME:
ACADEMIC TITLE:
HOME DEPARTMENT:
LOCAL ADDRESS:
EMAIL ADDRESS:
COLUMBIA UNI:
NIH eRA Commons user name:
TELEPHONE NUMBER:
CO-INVESTIGATOR NAME:
ACADEMIC TITLE:
HOME DEPARTMENT:
LOCAL ADDRESS:
EMAIL ADDRESS:
COLUMBIA UNI:
NIH eRA Commons username:
TELEPHONE NUMBER:
CO-INVESTIGATOR NAME:
ACADEMIC TITLE:
HOME DEPARTMENT:
LOCAL ADDRESS:
EMAIL ADDRESS:
COLUMBIA UNI:
NIH eRA Commons username:
TELEPHONE NUMBER:

PROJECT TITLE:
SYNOPSIS OF PROPOSAL: (use only space provided below – minimum 11 point font)

ALL CURRENT SOURCES OF RESEARCH FUNDING (include begin/end dates and total direct costs)

PENDING APPLICATIONS FOR RESEARCH FUNDING (include proposed begin/end dates and total direct costs)

12-MONTH BUDGET (May 2017 to May 2018)	
SALARIES with FRINGE (Fringe rate – 28.9%):	
SUB-TOTAL	**$**
EQUIPMENT:	
SUB-TOTAL	**$**
PATIENT CARE COSTS:	
SUB-TOTAL	**$**
ALL OTHER EXPENSES:	
SUB-TOTAL	**$**
TOTAL PROPOSED BUDGET	**$**

DETAILED BUDGET JUSTIFICATION: (use only space provided – minimum 11 point)

REGULATORY APPROVALS AND RESEARCH AREAS

If this proposal involves human subjects and/or animal research, the Irving Institute requires documentation of Institutional Review Board (IRB)/Institutional Animal Care and Use Committee (IACUC) approval before pilot funds can be released. These approvals are not required at the time of application, but must be in place at the time of the award.

IRB Approval

Does this proposal involve human subjects?	Yes/No
Does this proposal require IRB approval?	Yes/No
Is this proposal approved by the IRB?	Yes/No
IRB number:	
IRB last approval date:	
IRB expiration date:	

IACUC Approval

Does this proposal involve animal research?	Yes/No
Does this proposal require IACUC approval?	Yes/No
Is this proposal approved by IACUC?	Yes/No
IACUC number:	
IACUC last approval date:	
IACUC expiration date:	

Clinical Trials Information

Is this proposal a clinical trial?	Yes/No
Is this a Phase III clinical trial?	Yes/No
Is this registered in ClinicalTrials.gov?	Yes/No
If registered, what is the NCT number?	
If registered, who is the NCT sponsor?	

Research Areas

Does this proposal involve AIDS research?	Yes/No
Does this proposal involve PEDIATRIC research?	Yes/No
Is this registered in ClinicalTrials.gov?	Yes/No
If registered, what is the NCT number?	
If registered, who is the NCT sponsor?	

Team Assembly

Did you meet any members of your team at the ISP sponsored seminar series? (List seminars will have occurred prior to the RFA deadline)	Yes/No Name(s) of faculty:
Have you previously worked with any of the members on your team?	Yes/No Name(s) of faculty:
If yes to the question above, describe previous collaborations (3-5 sentences):	

SIGNATURES OF APPROVAL

A. I certify that the information presented in this proposal is, to the best of my knowledge, complete, accurate, and developed according to practices commonly accepted within the scientific community.

_____

Signature of Principal Investigator *Date*

B. I hereby take responsibility for ensuring that the necessary space, personnel, and facilities which are mentioned in the application pertaining to my Department will be available for this project should it be funded. I recommend that this application be submitted.

_____

Signature of Department Chairman *Date*