



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

**2018**

## INTEGRATING SPECIAL POPULATIONS (ISP) PILOT AWARD

Irving Institute for Clinical and Translational Research

### GUIDELINES AND INSTRUCTIONS FOR APPLICANTS

PILOT APPLICATION DEADLINE: **NOVEMBER 1, 2017**

AWARD ANNOUNCEMENT: **DECEMBER 15, 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. **Approximately four (4) one-year, one-time funding grants of \$40,000 each will be announced in December 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. Faculty/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:**

- Junior investigators who are PIs
- New collaborations in novel areas for the PI
- Protocols that include community based research

Although senior leaders and Resource directors of the Irving Institute, as well as ISP leaders may be consulted during the preparation of the application, **they should not be included as co-investigators or collaborators**. For a list of these individuals please visit: [http://www.irvinginstitute.columbia.edu/people/executive\\_leaders.html](http://www.irvinginstitute.columbia.edu/people/executive_leaders.html) and [http://www.irvinginstitute.columbia.edu/resources/integrating\\_special\\_populations.html](http://www.irvinginstitute.columbia.edu/resources/integrating_special_populations.html)

**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 Wednesday, November 1, 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](mailto: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**: All projects involving human subject research selected for potential Irving Institute pilot funding are conditionally selected until **IRB documentation** is submitted and **NIH-NCATS prior approval** is received. IRB approval is not required at the time of application, but submission to the IRB must be completed within thirty (30) days of notification of potential Irving Institute pilot funding. In addition, conditionally selected projects must submit NIH-NCATS mandated prior approval of human subject research documentation to Irving Institute administration within thirty (30) days of notification of potential funding. Documentation of IRB and or IACUC approval, if applicable, must be submitted to the Irving Institute before dispersal of funds.

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, multidisciplinaryity, 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.**

**POTENTIAL PILOT AWARD WINNERS WILL BE ANNOUNCED BY DECEMBER 15, 2017.**

**FUNDING WILL BE AVAILABLE ON JUNE 1, 2018.**

**For any questions about the scientific content, please contact:**

General questions about ISP RFA: Karen Marder MD MPH, [ksm1@cumc.columbia.edu](mailto:ksm1@cumc.columbia.edu)

Pediatrics: Joel Lavine MD PhD, [jjw2151@cumc.columbia.edu](mailto:jjw2151@cumc.columbia.edu)

Geriatrics: Joseph Lee PhD, [jhl2@cumc.columbia.edu](mailto:jhl2@cumc.columbia.edu)

Rare Diseases: Emily DiMango MD, [ead3@cumc.columbia.edu](mailto:ead3@cumc.columbia.edu)

HIV: Magda Sobieszczyk MD, [mes52@cumc.columbia.edu](mailto: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](mailto:dcf2111@cumc.columbia.edu)

(212) 305-9315

Integrating Special Populations (ISP) Pilot Award Application

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)

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

Integrating Special Populations (ISP) Pilot Award Application

**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)


Integrating Special Populations (ISP) Pilot Award Application

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

<b>12-MONTH BUDGET (June 2018 to May 2019)</b>	
<b>SALARIES with FRINGE (Fringe rate – 29.75%):</b>	
<b>SUB-TOTAL</b>	<b>\$</b>
<b>EQUIPMENT:</b>	
<b>SUB-TOTAL</b>	<b>\$</b>
<b>PATIENT CARE COSTS:</b>	
<b>SUB-TOTAL</b>	<b>\$</b>
<b>ALL OTHER EXPENSES:</b>	
<b>SUB-TOTAL</b>	<b>\$</b>
<b>TOTAL PROPOSED BUDGET</b>	<b>\$</b>

**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

**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*