PI: **Jaramillo Zuluaga, Andres**	Title: Implementing strategies for Building Capacity in Research Administration at CIDEIM, and subsequent dissemination within Colombia and the Latin American region	
Received: 07/31/2019	FOA: PAR18-335 Clinical Trial:Not Allowed	Council: 01/2020
Competition ID: FORMS-E	FOA Title: Global Infectious Disease Research Administration Development Award for Low-and Middle-Income Country Institutions (G11-Clinical Trial Not Allowed)	
1 G11 AI152214-01	Dual:	Accession Number: 4334176
IPF: 2474901	Organization: CENTRO INTERNACIONAL (CIDEIM)	
Former Number:	Department:	
IRG/SRG: ZAI1 AMC-D (J1)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: [redacted] Year 2: [redacted]	Animals: N Humans: N Clinical Trial: N Current HS Code: 10 HESC: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Andres Jaramillo Zuluaga	CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG	PD/PI
Cindy Montero	CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG	Co-Investigator

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

c. Previous Grants.gov Tracking Number

2. DATE SUBMITTED | **Application Identifier**

5. APPLICANT INFORMATION **Organizational DUNS*:** [redacted]

Legal Name*: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
Department:
Division:
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
ZIP / Postal Code*: [redacted]

Person to be contacted on matters involving this application
Prefix: First Name*: Andres Middle Name: Last Name*: Jaramillo Suffix:
Position/Title:
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: Email: [redacted]

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 44-4444444

7. TYPE OF APPLICANT* W: Non-domestic (non-US) Entity

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Implementing strategies for Building Capacity in Research Administration at CIDEIM, and subsequent dissemination within Colombia and the Latin American region

12. PROPOSED PROJECT
Start Date* Ending Date*
05/01/2020 10/31/2021

13. CONGRESSIONAL DISTRICTS OF APPLICANT
00-000

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Andres Middle Name: Last Name*: Jaramillo Zuluaga Suffix:
Position/Title: Coordinator Research Promotion and Developmen
Organization Name*: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
Department:
Division:
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: Email*: [redacted]

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	[redacted]
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	[redacted]
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Nancy Middle Name: Last Name*: Gore Saravia Suffix: Ph.D
Position/Title*: Director
Organization Name*: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
Department:
Division:
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: Email*: [redacted]

Signature of Authorized Representative*
Nancy Saravia

Date Signed*
07/31/2019

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

424 R&R and PHS-398 Specific
Table Of Contents

OMB Number: 4040-0010
Expiration Date: 10/31/2019

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
Duns Number: [redacted]
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
Zip / Postal Code*: [redacted]
Project/Performance Site Congressional District*: 00-000

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
DUNS Number: [redacted]
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
Zip / Postal Code*: [redacted]
Project/Performance Site Congressional District*:

Additional Location(s) File Name:

Funding Opportunity Number: PAR-18-335. Received Date: 2019-07-31T17:26:48.000-04:00

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ❍ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ❍ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ● **Yes** ❍ **No**

6.a. If yes, identify countries: COLOMBIA

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Project_summary.pdf
8. Project Narrative*	Project_narrative.pdf
9. Bibliography & References Cited	Bibliography_References.pdf
10.Facilities & Other Resources	Facilities_and_Resources.pdf
11.Equipment	

Funding Opportunity Number: PAR-18-335. Received Date: 2019-07-31T17:26:48.000-04:00

PROJECT SUMMARY

The Centro Internacional de Entrenamiento e Investigaciones Medicas, CIDEIM, is recognized by COLCIENCIAS as a research center within the National System of Science, Technology and Innovation of Colombia. CIDEIM originated in Colombia in 1961 as an International Center for Medical Research and Training awarded to Tulane University by the United States National Institutes of Health and hosted by Colombia as a bilateral Technical Assistance Mission. Successive renewals of this program were followed by funding through the US NIAID ICIDR program until 1989. In 1990 at the initiative of COLCIENCIAS, CIDEIM was established as a Colombian non-profit foundation and in 1991, successfully competed for a Tropical Medicine Research Center TMRC award from the US NIAID. Since then, CIDEIM investigators have developed collaborative research and training programs with U.S. universities through subawards within projects supported by NIAID and the Fogarty International Center, as well as receiving direct awards from the US NIAID. Our current NIAID funding includes a TMRC U19 award and sub-award within a U19 award to the University of Connecticut, which have increased our institutional role in, and responsibility for the management of USNIAID grants.

The overall goal of this project is to strengthen the capacity of CIDEIM to develop and implement institutional policies and practices for grants management that are compliant with NIH guidelines and requirements for administration of NIH grants, and to share this capacity with other institutions in the region. To achieve this goal, we will first address critical gaps in CIDEIM grants administration for current and future grants funded by the USNIH, by training CIDEIM management leaders at Yale University. Senior administrators trained in the U.S. will then transfer and implement these policies and practices including oversight of updated NIH guidelines, in CIDEIM. Second, we will design, implement and evaluate an internal training plan, curriculum and materials that will provide the bases for institutionalization of sustainable grants management and administration capacity through continuing education and updating of training in accordance with changes in NIH guidelines. This training curriculum and corresponding materials will be adapted for external training and transfer of capacity to other institutions in Colombia and the region. Our management leaders and their teams will review and adjust Institutional policies, procedures and standard operating procedures (SOPs) to meet good management practices in compliance with NIH requirements throughout the pre-award, award and post award phases of the natural history of programs and projects. Adaptation of training to internal and external online access and development of an in-house grant tracking system will promote sustainability of these practices.

PROJECT NARRATIVE

The mission of CIDEIM is to reduce the impact of infectious diseases and thereby improve the quality of life of those affected. In pursuing this mission, NIAID support has been fundamental to our research and training for prevention and control of transmissible diseases. Training of CIDEIM management leaders in the administration of USNIH grants will be sustainably implemented in CIDEIM and shared with other national and regional institutions, thereby benefitting current and future NIAID supported projects and research priorities, and optimizing the investment of NIH.

CIDEIM FACILITIES AND OTHER RESOURCES

GOVERNANCE AND OPERATION

CIDEIM has established external and internal advisory committees, as well as institutional review boards (IRBs), to define policies, instruments and mechanisms to ensure compliance with national and international standards and regulations for biomedical research. The committees include: Board of Directors, Science and Research Training Advisory Committee and the Ethical Review Committee. In addition, internal operations are supported by Directive, Scientific, Authorship and Training Committees. Independent external audit of financial management is conducted permanently since 1990 when CIDEIM was instituted as a Colombian non-profit foundation.

Board of Directors: The Board of Directors is the governing body of CIDEIM. The principal function of the Board is to guide and to promote the organization in the fulfillment of its mission. The Board of Directors operates in compliance with the legal guidelines for non-profit organizations and the statutes of the institution, names and receives the reports of the external auditor, and the reports of the Director. The members of the Board of Directors include leaders in the scientific, clinical, academic, productive, and science and technology policy arenas in Colombia.

Executive Committee: This committee is constituted by the leaders of the research Units and the Director. This committee participates in the governing responsibility of CIDEIM together with the Board of Directors in developing strategic plans and policies, policy decisions, and their implementation.

Science and Research Training Advisory Committee: This committee includes the participation of the Director of CIDEIM and leading external scientists and directors of national university post graduate programs in biomedical sciences. The principal function of this committee is to provide insight and guidance in scientific and technical scope, and identify opportunities and challenges for research innovation in accordance with their collective knowledge and experience. Daniel Colley, Director for Tropical and Emerging Global Diseases at the University of Georgia, with a distinguished career in parasitology dealing especially with the immunology of schistosomiasis and Chagas' disease, is the current Chair of the Committee. This committee recently convened in CIDEIM in September of 2017.

Scientific Committee: This Committee is constituted by the Director, leaders and coordinators of each research and support unit. The principal function of the committee is to assure the scientific standards of the research program, define the research priorities and promote the scientific and technological development of the institution.

Training committee: The Training Committee was instituted at CIDEIM as a strategy to support higher education institutions in the country, in particular graduate programs and the young researcher program as well as undergraduate students that want to carry out their thesis in CIDEIM´s areas of research. One of the main functions of this committee is the follow-up and oversight of the training program defined for each trainee in bi-annual follow-up meetings. The committee also promotes and coordinates internships in clinical research, and promotes courses, seminars and workshops.

Authorship Committee: This ad-hoc committee is responsible for assurance of adherence to internal standards and policy for authorship of the communication of research results deriving from the projects of CIDEIM investigators and their collaborators. The committee promotes and facilitates compliance with internal and external norms through internal and external peer review of the communications to be presented in professional meetings or submitted for publication. The committee is also responsible for updating authorship standards in accordance with those of the international scientific community, including ethical standards and relevant processes for presenting and publishing intellectual material. CIDEIM publication and authorship policy adheres to the guidelines of the International Committee of Medical Journal Editors

Ethical Review Committee for Protection of Human Subjects: The constitution of the CIDEIM Ethical Review Committee for Protection of Human Subjects adheres to universal guidelines that stipulate the importance of participation by different professional groups, institutions and the community. The IRB consists of 8 members, 7 external members with vote and one institutional member without vote. This committee is guided by national and

international guidelines as follows: 1) the Colombian National Resolution 8430/93, which establishes the scientific, technical, and administrative norms and guidelines for health research; 2) the National Resolution 2378/2008 which establishes good clinical practices; 3) the principles of the World Medical Assembly presented in the Declaration of Helsinki revised version 2013; 4) the International Ethical Guidelines for Biomedical Research Involving Human Subjects developed by the Council for International Organizations of Medical Sciences (CIOMS revised version 2016) and 5) the Code of Federal Regulations Title 45 Part 46, for the protection of Human Subjects of NIH of June 18th, 1991.CIDEIM has Federal Wide Assurance approval by the Office for Human Research Protection (OHRP; FWA # [redacted]) valid through November 16, 2021.

Institutional Research Compliance and Oversight: Diverse research support units including the biostatistics and data management unit, clinical research unit, research ethics office, administrative unit and the Direction are involved in compliance and oversight in accordance with their functions and expertise. Compliance with regulatory, legal and financial requirements is managed by the administrative unit under the authority of the Director. Scientific, technical and ethical compliance is managed by the data management and biostatistics unit, the clinical research unit, research ethics office and the Direction, which together support investigators and research staff in understanding good research practices and standards and their application to research activities. CIDEIM has developed policies and procedures in terms of the ethical conduct of research, assurance of participant confidentiality, ethical review and approval of research proposals and protocols, monitoring of projects and reporting of adverse events and scientific integrity including research misconduct, conflict of interest, authorship and publication, and material transfer agreements. Institutionalization of compliance procedures and good research practices is promoted and monitored in collaboration with the Training Unit.

ADMINISTRATIVE UNIT

The following support processes are managed by this unit.

Financial Management: Since 2010, the Financial Management office of CIDEIM works collaboratively with the Accounts Department of ICESI University to track all grant expenditures and develop financial status reports for each project, both for institutional purposes and funding agencies. This new arrangement allows the Financial Manager, Mrs. Luz Divia Villa, APC (authorized public accountant) to focus on the monitoring and troubleshooting of project accounts, and the development of financial strategies for the institution.

The Financial team uses the accounting software UNO-EE (Sistema Integrado de Información Empresarial), and uses the payroll and health software UNO85C, which allows integrated analysis of data regarding accounting, financial, purchasing, salary, health and other benefits for a portfolio of projects in different currencies. Additionally internal Apps have been developed to manage purchases and travel logistics which have facilitated the internal operation, control of activities and services. Since 2015, CIDEIM has adopted the International Financial Reporting Standard (IFRS).

CIDEIM manages financial resources though the national banking system in Bancolombia and Banco de Occidente. International transactions in foreign currencies are conducted through Bancolombia Internacional and its subsidiary in Panama City, “Bancolombia Panama S.A”.

The Financial Manager coordinates presentation of relevant internal reports to project PIs and the Board of Directors, as well as external reports for funding agencies, accounting records to the Chamber of Commerce and federal and state tax returns. In addition, the Financial Manager interacts with the External Auditor, Gonzalo Millán Associates, which conducts monthly day-long monitoring visits and comprehensive audits every trimester. The External Auditor also provides continuous assistance to the financial team regarding tax regulations and issues and accounting procedures.

Human Resources: The Human Resources office coordinates activities related to development of job descriptions and announcements, candidate interviewing and selection, hiring and payroll. This office maintains and updates employee files and promotes the organization and conduct of employee safety and welfare activities as well as access to benefits.

Quality Assurance: The Quality Assurance Office disseminates key information regarding institutional, national and international quality requirements and ensures that quality initiatives in the different areas and

units of CIDEIM are integrated. CIDEIM is GCP certified by INVIMA (national institute for oversight of medications and food products) and has a Quality Management System that responds to the requirements for health research in Colombia such as: habilitation of health services, management of human samples and biological collections, and access to genetic and biological resources, among others.

Purchasing: The Purchasing Office negotiates, in close partnership with CIDEIM investigators, the acquisition, importation and nationalization of all necessary materials and equipment. The Purchasing Officer also maintains price estimate databases which inform the development of research proposal budgets. Recently, CIDEIM has developed and implemented a user-friendly application accessible via the institutional intranet that expedites purchase requisitions.

Maintenance: The Maintenance Office, which employs a full time coordinator and a full-time repair technician, conducts regular prevention maintenance of medical and laboratory equipment, as well as all activities regarding computer maintenance, including the installation, upkeep, repair and security of computer equipment and networks. In addition, the Maintenance Office directs the selection and supervision of any external maintenance providers.

IT Services: IT and Communication Services are provided jointly by the CIDEIM Administrative Unit and ICESI University. The IT & Communications Officer at CIDEIM coordinates all institutional videoconferences using the ZOOM teleconferencing software, and designs and conducts training in these and other IT educational and communication tools. In addition, this officer supervises the IT troubleshooting services by ICESI to CIDEIM personnel.

RESEARCH PROMOTION AND DEVELOPMENT UNIT

The following support processes are managed by this unit.

Project Support in the pre-award phase: The unit maintains all institutional registrations (such as DUNS, SAMS, eRA Commons and others) required for application to national and international funding agencies up to date, assists investigators in identifying and understanding funding opportunities and in complying with the funding agency instructions and requirements for applications, and manages the internal review for obtaining institutional approval and authorization to submit the application.

E-Learning:

CIDEIM has developed institutional capacity to interface with content and curriculum designers to create and use virtual learning methodologies. CIDEIM IT staff deliver web- based courses through the ZOOM platform to the National Postgraduate Training Network. IT staff and the course coordinators in each of the institutions participating in the National Postgraduate Training Network have received training to assure that each institution has the capacity to troubleshoot and manage the videoconference sessions. CIDEIM IT personnel have experience in the use of Moodle and have employed this open-access platform to create templates for post graduate Web-Based courses, the blended learning course on Statistics Applied to Biomedical Research and short courses on Good Clinical Practices and Effective Project Planning and Evaluation in Health Research offered each year by CIDEIM. The CIDEIM Learning Management System (Moodle) allows for storage of course materials, videoconference recordings, forums and quizzes, as well as interaction among course participants from the different cities, between course sessions.

Training and Career Development in Science, Technology and Innovation (STI): Research training is a core activity of CIDEIM and is conducted within the framework of ongoing research and technical services. Research capacity is built through a diverse portfolio of training modalities, which support and extend undergraduate and postgraduate programs in health sciences available at national and regional universities. The unit oversees all internal and external training activities and manages a database to track all applicants and participants. Descriptions of training opportunities and course offerings are posted on the CIDEIM website and announcements are distributed to target institutions via email. CIDEIM welcomes national and international trainees to participate in the institution's ongoing research and training programs. The training program is directed to students interested in scientific and technological innovation through research, and includes the following training modalities: 1) Supervised undergraduate, master's and doctoral thesis research; 2) Young

Investigator mentored research training for outstanding recent graduates; 3) Social service and internship training for medical graduates and health professionals; 4) Health sciences post-graduate courses offered in-person and through web-based modalities.

Research Capacity Strengthening: The unit applies, manages and conducts institutional research capacity strengthening projects/programs funded by national and international funding agencies. One of these is that of CIDEIM as Latin American and Caribbean Regional Training Center supported by the

https://www.who.int/tdr/news/2015/regional_training_centers/en/ .

Communications: The unit provides professional support for the development and implementation of communication strategies to reach different audiences at the project and institutional levels with the effective use of available resources.

FACILITIES

CIDEIM headquarters have been strategically designed based on the specification for the research, training and service mission of CIDEIM. Interior space is 2,300 m2. A unique feature of the center is that it is essentially self-contained, comprising outpatient clinical facilities and full time medical staff for routine clinical diagnosis and management of the diseases under investigation, research laboratories, insectary, and administrative and technical support infrastructure and personnel. The outpatient clinic, pharmacy, research laboratories and core facilities [redacted]. The library, documentation and communications center, biostatistics and epidemiology laboratory, clinical archive, investigator cubicles, computer systems, administrative offices and meeting rooms [redacted].

A. Laboratories:

a) ***Biochemistry and Molecular Biology****:* This research Unit has the infrastructure to conduct proteomic and functional genomics research. This laboratory is equipped with multiple thermocyclers, hybridization ovens, heating blocks, DAN/RNA concentrator, refrigerators and freezers, extraction hood, electroporator, analytical balance, water bath, vertical and horizontal electrophoresis chambers and microcentrifuges, which support the performance of nucleic acid and protein extraction, cloning, PCR, real time qPCR, Southern/Northern/Western hybridization techniques, SDS and 2D-SDS-PAGE, constructions of RNA libraries for RNAseq analyses and gene knockdown using short hairpin interference RNA.

b) ***Immunology and Cell Biology*:** This research Unit has the capability to evaluate the immune response at the local, systemic and cellular level using technologies such as cytometric analysis, phenotypic and functional markers and products of leukocytes, real time PCR of gene products and transcription factors, and *ex vivo* analysis of cells of the inflammatory and immune response. Primary peripheral blood monocytes, macrophages, neutrophils, eosinophil, NK, fibroblast and dendritic cells can also be cultured and functional analysis conducted. This laboratory is equipped with three Thermo Scientific refrigerated tabletop centrifuges, two inverted microscopes one provided with a video cam and three light microscopes, two ELISA plate readers and printers, water baths, refrigerators, minimacs and quadromacs magnetic cell separator equipment, dedicated computer with Flowjo software for cytometric analyses. The laboratory has a dedicated and independent space for cell culture equipped with culture flow hoods with five simultaneous working spaces, and incubators coupled to CO_2 influx system. An independent dark room has been adapted exclusively for immunofluorescence microscopy and image analysis with Nikon imaging software.

c) ***Biostatistics and Epidemiology:*** This unit collaborates with the research teams in the planning, execution and analysis of research studies, with the overall aim of ensuring valid traceable data and quantitative analysis. Activities include: sample size calculations, sampling methods, statistical analysis, preparation of reports and publications. This unit has responsibility for data management which incororates development of databases and custom data entry screens, maintenance of data quality by double data entry and interactive checks, and provision of data in the form needed for reports and analysis. Available software includes STATA, Microsoft Office, Epi Info, R and SQLServer.

d) ***Microbiology:*** This Unit has the infrastructure to type and phenotypically characterize clinically-relevant microbial pathogens (bacteria and parasites), using conventional culture methods and PCR-based techniques. Also the capacity to do molecular epidemiology using pulse field electrophoresis (PFGE), PCR and MLST typing of bacterial genomes. This information is used to diagnose and monitor patterns of nosocomial infections in hospital settings. Host-pathogen interactions and mechanistic studies of bacterial infections in the context of drug resistance and persistence is another focus of the Unit. The Microbiology Unit also includes the infrastructure required for working with Biosafety Level III pathogens such as *M.tuberculosis* i.e. negative-pressure room and biosafety hood.

e) ***Vector Biology and Control:*** The Unit´s physical infrastructure includes a general research area and insect colonies, consisting of three spaces for individual colonization of vector species, each of these with independent areas for experimental infection. All areas are equipped with physical barriers avoiding insect escape between and outside of the colonies (BSL 2+). This unit is equipped with all elements necessary for entomological research (insect capture traps, microscopes, stereos, etc.), as well as equipment for capture of small mammalian species (National and Sherman traps), microphotography, microinjection, and dissection, molecular assays and insect cellular cultures. The unit has the capacity to use computational tools for statistical and geospatial analyzes in order to identify risk variables that allow the design of prevention and control strategies for vector transmitted diseases.

B. Core Facilities:

a) Culture Facilities: Four laboratories are dedicated to aseptic culture of cells and microbial pathogens. These are equipped with biosecurity level II and III facilities for working with high risk microorganisms such as multidrug resistant *Mycobacterium tuberculosis*, dengue virus, and HIV positive clinical samples as well as human cell and parasite cultures. Within these controlled- access areas the following equipment is available: standard, CO2, and low temperature (25°C) incubators, light microscopes, inverted microscopes, and laminar flow bio-safety hoods with gas outlets.

b) PCR -qPCR facility: This facility is equipped with 5 conventional PCR thermocyclers with capacity to do temperature gradients, 96 well plate runs and independent block runs, among others. In addition the facility is equipped with a Real Time thermocycler (CFX96BioRad) with analytical software for Gene expression and Precision Melt Analyses, a Nanodrop spectroscopy and a BioAnalyzer-Agilent 2100 for quantifying micro quantities of nucleic acids and proteins and for verifying quality. Designated and segregated areas have been established for the conduct of the different steps of molecular amplification, in order to avoid carryover and contamination of samples. An external sample analysis and imaging area has been established equipped with a GelDoc EX(BioRad) imaging system.

c) Flow Cytometry facility: This facility is equipped with a Becton Dickinson Accuri C6 Flow Cytometer and FlowJo, Summit and other specialized analysis software tools. This facility is temperature-controlled, guarantying the ideal functioning of the equipment.

d) Cold Room*:* This facility has been designated to contain ultrafreezing equipment including -80°C, -45°C and -20°C freezers. This area is temperature-controlled and supervised with a central temperature control and monitoring system for all the equipment in the facility.

e) BioBank*:* CIDEIM's biobank has currently more than 3,000 strains of *Leishmania* spp., 260 *Trypanosoma* spp., 630 isolates of *Plasmodium falciparum*, 4,600 *Mycobacterium* spp. isolates and > 3,600 of Gram(-) bacteria, with their susceptibility/resistance profiles characterized. In addition, DNA and plasma samples are preserved from patients with tuberculosis, malaria, syphilis and leishmaniasis, and skin biopsies from patients with secondary syphilis and leishmaniasis. The biobank is equipped with 5 Liquid Nitrogen Storage Vessels with a capacity of 4800 vials each and 2 ultrafreeezer (-80°C) with a capacity of 45000 vials. Management of the biological material stored in the biobank is supported by the **Biobanco CIDEIM®** software, according to ethical and legal guidelines.

f) Autoclaving Facility*:* Materials are washed, sterilized and packaged and disposed in this area. Equipment includes two autoclaves, balances, glassware, washing and drying facilities and general use for reagents and supplies required for solution and culture media preparation.

C. Clinical Infrastructure:

a) CIDEIM-Cali: Members of the Clinical Unit team include the Unit Leader and Coordinator, one Clinical Research Assistant, two Clinical Research Fellows, a laboratory specialist and a clinical technician. The assistant, research fellows and clinical specialists participate heavily in the design of necessary research documents (CRFs, SOPs, informed consent forms, etc.), manage patient records and other clinical research documentation. They guarantee ethical conduct, enrollment, treatment and follow-up activities. The clinical laboratory specialist carries out parasitological diagnosis of study participants, and ensures that samples are collected, processed, stored and shipped according to GCLP guidelines.

Clinical facilities include two consulting offices, a room equipped for basic diagnostic procedures, a separate area for phlebotomy, an independent patient waiting room, two offices and a reception room. The diagnostic laboratory is equipped to process samples and perform diagnostic tests for syphilis, HIV and leishmaniasis, and isolation and identification of different species of *Leishmania*. The diagnostic unit has the capability of training and advising other laboratories in the use of different methods for the diagnosis of Leishmaniasis, syphilis and malaria, and has been contracted by the Pan-American Health Organization to conduct training in diagnosis of leishmaniasis in the reference laboratories of the countries of the Americas reporting the most cases.

Importantly, the Clinical Unit has the support of infectious disease specialists from the Fundación Valle del Lili, a level 4 hospital, and a dermatology specialist (Dr. Adriana Cruz), who provide support for the clinical management of complicated or unusual cases.

b) CIDEIM-Tumaco: Considering that the large proportion of current CIDEIM study participants come from the South Pacific area of Colombia, the Clinical Research Unit includes a clinical and laboratory facility in Tumaco-Nariño, a recognized endemic area for dermal leishmaniasis, malaria, dengue and other vector borne diseases, where CIDEIM has conducted clinical research activities since 1980. Members of the CIDEIM-Tumaco clinical team include a medical coordinator and two laboratory specialists. This clinical facility is fully equipped to provide primary care (level 1) attention, outfitted with all the necessary equipment and supplies to perform diagnostic procedures (i.e. direct smears, culture of lesion aspirates, skin biopsies) and research sample collection. The facility has an independent power generator to assure back up of equipment during power outage. Electronic medical records and e-CRFs have been designed according to GCP standards and national regulations, and implemented to allow timely availability of data and improve security. Biological samples are regularly shipped for storage and processing in CIDEIM-Cali. Regular supervisory visits are made by CIDEIM-Cali clinical and laboratory staff for monitoring and improvement of the operation in accordance with good practices and public health licensing to operate.

In addition to the outpatient clinical facilities available in CIDEIM, tertiary level hospital facilities for research requiring hospitalization and clinical support are available at the nearby Fundacion Valle de Lili Clinic and COLSANITAS Clinica Sebastián de Belacazar in Cali. A Level 2 clinical care center is available at study sites in the Regional Hospital San Andres in Tumaco.

D. Additional access to research technologies and infrastructure through national interinstitutional collaborations

Through our network of collaborators and partnering institutions, CIDEIM has broaden its access to current technologies and infrastructure that support the development of biomedical research. This “technology network” creates an important standpoint for joint research, promoting collaboration and non-redundant acquisition of large scale state-of-the-art infrastructure that supports high quality research. Among these are:

Confocal Microscopy: CIDEIM researchers have access to an imaging facility equipped with a Zeiss LSM 700 microscope and image analysis software (including capacities for 3D reconstruction co-localization, marker quantitation, among others) at Universidad del Valle. User training sessions and staff are available for new users.

Luminex: Universidad del Valle has recently acquired a Luminex system, ideal for the evaluation of complex samples and multiparamenter analysis. Through our continuing collaboration, CIDEIM research staff has access to this technology and applications.

Experimental Animal Breeding Facility: Through our partnership with Universidad ICESI we have access to the Animal Facility which has capacity to house 600 small laboratory rodents (Mus musculus: Swiss Albino; Mesocricetus auratus, inbred Chester Beaty, MHA and outbred hamsters; Merionis unguiculatus; Rattus sp: wistar rats), 48 White New Zealand Rabbits, and 5 pigs or sheep in four separate temperature controlled rooms. A laboratory for surgical and sampling procedures, with a level II laminar flow hood, electronic balance, light microscope, and CO2 apparatus for euthanasia, as well as room for cage washing and a storeroom are located within the vivarium.

INFORMATION AND COMMUNICATION

***Library and Documentation Center*:** In support of the different academic, scientific and research programs, the CIDEIM library offers a computerized bibliographic information system. In addition, the library provides guidance to users on bibliographic searches, bibliographic reviews, lending of journals and books, and electronic bibliographic consulting. An online database has been developed by the CIDEIM library: SCCOT (general collection books, final reports, CIDEIM publications). Additionally, through the partnership with ICESI University, CIDEIM has access to the university library, which is part of a larger Services and Resources Unit.

Computer Resources: The 180 node network operates under a star-format and is controlled by a Windows server 2016 Standard controlling computer access to internet and internal ftp. The network and computer configuration allow sharing of resources such as desks and printers located at different sites of the institution, thereby facilitating remote access to information located at each site. These resources are protected with [redacted]

Ninety computers are currently available to users of CIDEIM ICT service. These are provided with Microsoft Office software, browsers and some with applications for data analysis. Six printers (1 dot matrix, 5 laser) and one photocopier are available for use according to printing needs. Full time internet connection is achieved through a dedicated internet service. All computers are connected to a domain server. Importantly, CIDEIM has a Volume Licensing with Microsoft that facilitates use of software including Microsoft Office 365 by a large number of users at a modest cost.

Document Management: CIDEIM has implemented Sharepoint online, this tool is a collaborative plataform web based that allows sharing news, SOPs and procedures registered in the Quality System Management, communication of internal orders and requirements to the Administrative Unit and log in to Institutional Databases. In addition, CIDEIM has implemented OneDrive for all users, this tool is a file hosting service that allows users to create, edit, share, and sync files in their computers and to access them from a web browser or mobile device. This tool strength the collaborative work.

Videoconferencing Resources: Videoconferencing facilities are available on site within CIDEIM, with three appropriately furnished conference rooms. The larger conference room is equipped with video projector, an audio system (amplifier, speakers and microphones), and a dedicated desktop computer with Microsoft software. The other two conference rooms, meant to be used for videoconferences with small groups of local participants, are equipped with 42” Sharp LCD flat screen television with appropriate video and audio connections to laptop. Transmission of web-based courses, connecting international collaborators and the members of the Colombian Postgraduate Training Network, is achieved through ZOOM platform. CIDEIM employs a dedicated laptop for videoconferencing needs, including archiving session recordings. In addition, the recordings are loaded in the YouTube private channel of CIDEIM. In addition to its internal resources, CIDEIM has access to the conferencing and other facilities of ICESI University.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Andres Middle Name Last Name*: Jaramillo Zuluaga Suffix:

Position/Title*: Coordinator Research Promotion and Developmen
Organization Name*: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
Department:
Division:
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number:

E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: PD/PI Other Project Role Category:

Degree Type: MBA Degree Year: 2014

Attach Biographical Sketch*: File Name: Jaramillo_Andres_Biosketch.pdf

Attach Current & Pending Support: File Name:

Funding Opportunity Number: PAR-18-335 . Received Date: 2019-07-31T17:26:48.000-04:00

PROFILE - Senior/Key Person

Prefix: First Name*: Cindy Middle Name Vanessa Last Name*: Montero Suffix:

Position/Title*: Administrative Coordinator
Organization Name*: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG
Department:
Division:
Street1*: [redacted]
Street2:
City*: Cali
County:
State*:
Province:
Country*: COL: COLOMBIA
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number:

E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Montero_Vanessa_Biosketch.pdf

Attach Current & Pending Support: File Name:

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Jaramillo Zuluaga, Andres

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: Coordinator Research Promotion and Development Unit

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Universidad Icesi, Cali, Valle del Cauca	BBA	02/2005	Management
Universidad Icesi, Cali, Valle del Cauca	MBA	08/2014	Strategic Management
Colombia Stock Exchange, Cali	Other training	07/2005	Diploma - Operation of Colombia Stock Exchange
Universidad Icesi, Cali	Other training	07/2008	Diploma - Project Management

A. Personal Statement

My undergraduate and graduate training in Business Administration and Management, subsequent research management experience as Assistant to the Scientific Direction, Coordinator of the Research and Training portfolio and currently, as Coordinator of the Research Promotion and Development Unit have allowed me to understand and to bridge the research program and administrative requirements of the Centro Internacional de Entrenamiento e Investigaciones Medicas (CIDEIM). In this capacity, I serve as Administrative Official with responsibility for grants administration. These roles and responsibilities have given me the opportunity to interact at national and international levels with researchers and trainees, university faculty and administrators, and funding agencies. Within CIDEIM, I engage and support scientific and administrative personnel in the coordination of pre and post award activities, update grants management policies and procedures, and ensure policy implementation and compliance. Additionally, together with the Research Promotion and Development Unit team members I provide administrative support for the development of proposals and administrative oversight of active projects. I also conduct in-house and external, including international training, in Effective Project Planning and Evaluation in Health Research.

B. Positions and Honors

Positions and Employment

2004 - 2005 Financial Administrative Assistant, Fiduciaria FES, Cali
2005 - 2006 Administrative and Financial Consulting, “Estudio Abierto” Architects, Cali
2007 - 2011 Assistant to the Scientific Direction, Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM), Cali
2011 – 2018 Coordinator, Research & Training Portfolio, Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM), Cali
2018- Coordinator of Research Promotion and Development Unit, Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM), Cali

Other Experience and Professional Memberships

2009 - Secretary of the Board of Directors, Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM)
2009 - 2009 WHO Temporary Adviser. Meeting on Harmonization of Short Training Courses on GCP-

GCLP/Basic research/Bioethics/PPM/Social Sciences/Data management/Product Research and Development- Thammasat University, Bangkok Thailand, 9-17 February 2009, Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization.

2011 - 2011 Participation in the NIH, Grants Policy and Management Training, Panama City, Panama, November 30 - December 2, 2011., National Institute of Allergy and Infectious Diseases (NIAID),

2013 - 2013 Invited facilitator for EPPE (Effective Project Planning and Evaluation in Biomedical Research) Skill Building training for Erasmus Mundus Scholars for the tropEd Masters of Science Programme in International Health. Bordeaux Segalen University, Bordeaux, France, 4-14 March 2013., Erasmus Mundus Scholars for the tropEd Masters of Science Programme in International Health

2013 - 2013 Attendance of the annual meeting of the Society of Research Administration (SRA) and pre-congress workshop “Introduction to Research Administration and Management”, New Orleans, United States, October 27-30, 2013, Society of Research Administration (SRA)

2013 - 2013 Invited facilitator for Implementation Research (IR) Training Workshop in Accra, Ghana from 25-29 November, 2013, hosted by the Dodowa Health Research Centre, Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization.

2014 - 2014 WHO Temporary Advisor. Review committee for the selection of a Regional Training Center supported by TDR in the WHO-AFRO region, Geneva, Switzerland, 22-24 September 2014., Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization

2015 - 2015 WHO Temporary Advisor. Review committee for the selection of a Regional Training Center supported by TDR in the WHO-EMRO region, Geneva, Switzerland, 5-6 February 2015., Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization.

2015 - 2015 Participation in TDR Consultation on promoting implementation / operational research in countries receiving Global Fund grants. Domaine de Penthes, Geneva, Switzerland, 9-10 December 2015., Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization.

C. Contribution to Science

1. During the past ten years I have participated in diverse strategies to build research and research training capacity in CIDEIM and its collaborating institutions. Almost immediately after I joined CIDEIM I was trained in the TDR short course “Effective Project Planning and Evaluation in Biomedical Research (EPPE)” in February 2007. Afterwards, I was trained as a trainer in May 2007. Since then, I have led seven Skill-Building and two Train-The-Trainer courses, disseminating the TDR EPPE methodology in Quito, Ecuador; Bordeaux, France; Rio de Janeiro, Brazil; Bogota and Cali, Colombia. Additionally, I participated as a facilitator for the Implementation Research course conducted in Accra, Ghana in 2013. I have worked to assure the permanent institutionalization of these project planning and evaluation tools and other research skill building courses within CIDEIM. I have promoted and participated in the organization of web-based courses and seminars offered through the research training program that CIDEIM and Yale University have collaboratively developed with national and regional doctoral programs in biomedical science through the Global Infectious Disease (GID) Research Training program supported by the USNIH Fogarty International Center. Currently, I coordinate the dissemination of training by CIDEIM as the Latin American Regional Training Centre supported by the WHO TDR programme in collaboration with the WHO Regional Office for the Americas (WHO-AMRO).

   a) Alger J; Gómez L; **Jaramillo A**; Saravia NG; Cuervo LG; Halpaap B. 2010. Reunión de la Red Inter-Regional de Centros de Referencia para capacitación en cursos de planeación y evaluación efectivas de proyectos de investigación para la salud; Cali; Colombia. Rev Med Hondur. 78(2):97-100

   b) Tulloch-Reid MK; Saravia NG; Dennis Verano RJ; **Jaramillo A**; Cuervo LG; Walker SP; Salicrup LA. 2018. Strengthening institutional capacity for equitable health research: lessons from Latin America and the Caribbean. BMJ. 362: k2456. doi: 10.1136/bmj.k2456. PMID: 30012634. PMCID: PMC6046649

c) Gomez L; **Jaramillo A**; Halpaap B; Launois P; Cuervo LG; Saravia NG. 2019. Building research capacity through “Planning for Success”. August 1, 2019. Plos Negl Trop Dis. 13(8): e0007426. https://doi.org/10.1371/journal.pntd.0007426

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

[redacted] 11/2013-12/2019
[redacted]
Role: Project manager

D43 TW006589 (Christian Tschudi PI/PD, Nancy Saravia Foreign PI/PD) 01/2007-12/2019
Fogarty/NIH
Translational Research Training on Leishmaniasis & Emerging Infectious Diseases
Fogarty International Center Global Infectious Disease Training Program to increase research capacity to identify, evaluate and implement strategies to interrupt the transmission and pathogenesis of leishmaniasis and other vector-borne and emerging infectious diseases in Colombia and the Latin American Region.
Role: Project manager

1U19AI129910 (Nancy Gore Saravia PD/PI) 04/2017-03/2022
NIH/NIAID
Optimizing Surveillance and Treatment for Control of Cutaneous Leishmaniasis
This program undertakes three interrelated research projects that focus on improving control of CL through the use of different approaches that target P-1) populations at risk requiring access to diagnosis and treatment, P-2) parasites having a wide range of variation in drug susceptibility, and P-3) innate host defense mechanisms that can impair or promote therapeutic response.
Role: Admin Core - Program coordinator

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Montero, Vanessa

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: Administrative Coordinator

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Universidad Icesi, Cali	M.ENG	02/2019	Industrial Engineering (Thesis: Knowledge management in human resource processes in a research center)
Universidad del Valle, Cali	B.ENG	04/2012	Industrial Engineering
ICONTEC, Cali	Other training	12/2012	Diploma in Integrated Management Systems HSEQ
CIDEIM supported by WHO-TDR, Cali	Other training	10/2018	Train-The-Trainer Good Clinical Laboratory Practice (GCLP)
CIDEIM Developed with the support of UNICEF / UNDP / World Bank / WHO, Cali	Other training	03/2015	Effective Planning and Evaluation in Health Research Projects

A. Personal Statement

My educational background in industrial engineering and my work experience have been developed in relation with performance analysis, quality assurance, and human resource and administrative management. Early in my career I worked at Universidad del Valle, a large public university considered to be the principal institution of higher education in southwestern Colombia. There, in the Office of Institutional Planning I supported quality assurance and audit processes of various administrative units of the institution. I also had the opportunity to work in the Human Resources Division providing support to the structuring of procedures, action plans, programs and tools for measuring the organizational climate. During this experience at the Universidad del Valle I had the opportunity to learn about its administrative, training, research and personnel benefits processes.

As Administrative Coordinator of the Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM), I am responsible for the design and support of a wide range of organizational processes including the development and implementation of policies and procedures, as well as compliance with institutional and government guidelines and regulations including the recent re-certification of

CIDEIM by our food and drug agency INVIMA, in Good Clinical Practices. Since 2016 I support the area of Human Resource Management and have worked together with the Direction of the CIDEIM on policies in relation with organizational structure, and compensation and benefits received by institutional personnel. In accordance with my role in quality assurance of all administrative processes, I have had the opportunity to participate in training courses on Good Laboratory Practices, Good Clinical Practice, Effective Project Planning and Evaluation, and in the Train-the-Trainer course Good Clinical Laboratory Practice (GCLP), all of which has allowed me to understand and interact with the laboratory area and gain an integral view of the research process.

B. Positions and Honors

Positions and Employment

2015 -	Administrative Coordinator, Centro Internacional de Entrenamiento e Investigaciones Médicas - CIDEIM, Cali
Mar- May 2014	General Coordinator, Politécnico Empresarial Colombiano, Cali
2012 - 2014	Professional Contractor, Quality and Improvement Area, Universidad del Valle, Cali
2012 - 2012	Professional Contractor Human Management, Universidad del Valle, Cali
2010 - 2012	Facilitator analyst, Corporación para el Desarrollo de la Ecología, Calidad y Tecnología, Cali

Other Experience and Professional Memberships

2011 - 2013	Internal Quality Auditor under the NTCGP1000 Standard, Universidad del Valle
Oct – Dic 2010	Professional Consulting, Project for the Implementation of a Public Management Indicators System for the city of Cali

Honors

2008 - 2010	Administrative Fellow of the Quality and Improvement Area, Universidad del Valle

C. Contribution to Science

At the Universidad del Valle and at the Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM), I have supported the research and training missions of these institutions in the structuring of policies, procedures and actions that facilitate, sustain and improve the capacity for the development and dissemination of knowledge. Some of the institutional documents in which I have participated in developing and writing are the following:

Universidad de Antioquia, Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, Cooperative Agreement between Universidad de Antioquia y CIDEIM, 2019.

Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, Annual Report 2018.

Universidad Icesi, Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, Interinstitutional Framework Agreement between Universidad Icesi y CIDEIM, 2018.

Framework Agreement for Academic and Scientific Cooperation between Universidad Libre Sectional Cali (Colombia) y la Corporación Centro Internacional de Entrenamiento e Investigaciones Médicas CIDEIM, 2018.

Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, MAN01015 Manual for Administration and Control of Fixed Assets, Version 01, 2018.

Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, MAN01005 Manual of Responsibilities and Functions in Research Projects, Version 03, 2017.

Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, MAN01016 Conflict of Interest and Commitment Policy, Version 01, 2018

Centro Internacional de Entrenamiento e Investigaciones Médicas – CIDEIM, SOP01007 Control of documents, Version 11, 2018.

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Technical Report: User Satisfaction, 2013.

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Executive and Technical Report: Organizational Climate at the Universidad del Valle, 2013.

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Institutional Report: Analysis of results and data of Internal Quality Audits 2012: Fifth and Sixth Cycle of Audits.

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Institutional Report: Consolidation and analysis of results of process performance indicators. 2012

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Institutional Report on the status of corrective, preventive and improvement actions by process. 2012

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Internal quality audit program and prioritization factors: Eighth cycle of audits. 2014.

Universidad del Valle, Office of Institutional Planning: Area of Quality Assurance and Improvement. Executive and Technical Report: Diagnosis of the implementation of Comprehensive Quality Management System of the Universidad del Valle, according to the subsystems, components and elements of the standard Internal Control Model. 2013

Support and advice to those responsible for processes of the Universidad del Valle in the consolidation and updating of policies, procedures and formats for: Institutional Planning, Institutional Communication, Management of Goods and Services, Human Resource Management, Management of Technological Resources, Management of Improvement, Quality Management, Control Management, Financial Management, Training and Research and Knowledge Generation. August 2010 to February 2014.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG

Start Date*: 05-01-2020 **End Date*:** 04-30-2021 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .		Andres		Jaramillo Zuluaga		PD/PI	[redacted]	3.0			[redacted]	[redacted]	[redacted]
2 .		Cindy Vanessa		Montero		Co-Investigator	[redacted]	3.0			[redacted]	[redacted]	[redacted]

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** [redacted]

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Financial Officer	3.0			[redacted]	[redacted]	[redacted]
1	**Total Number Other Personnel**					**Total Other Personnel**	[redacted]
						Total Salary, Wages and Fringe Benefits (A+B)	[redacted]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-18-335 . Received Date: 2019-07-31T17:26:48.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG

Start Date*: 05-01-2020 **End Date*:** 04-30-2021 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	[redacted]
2. Foreign Travel Costs	[redacted]
Total Travel Cost	[redacted]

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Tracking Number: GRANT12913604 Funding Opportunity Number: PAR-18-335 . Received Date: 2019-07-31T17:26:48.000-04:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG

Start Date*: 05-01-2020 **End Date*:** 04-30-2021 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Other: Materials translations in Spanish	[redacted]
9 . Other: Development of Online components for the grants management training program	[redacted]
10 . Other: Distance learning - webinar training or videoconferencing	[redacted]
Total Other Direct Costs	[redacted]

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	[redacted]

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	8.0	[redacted]	[redacted]
		Total Indirect Costs	[redacted]

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	[redacted]

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	[redacted]

L. Budget Justification*	File Name: Budget_justification.pdf
	(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Tracking Number: GRANT12913604 Funding Opportunity Number: PAR-18-335 . Received Date: 2019-07-31T17:26:48.000-04:00

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG

Start Date*: 05-01-2021 **End Date*:** 10-31-2021 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .		Andres		Jaramillo Zuluaga		PD/PI	[redacted]	3.0			[redacted]	[redacted]	[redacted]
2 .		Cindy Vanessa		Montero		Co-Investigator	[redacted]	3.0			[redacted]	[redacted]	[redacted]

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** [redacted]

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Financial Officer	3.0			[redacted]	[redacted]	[redacted]
1	**Total Number Other Personnel**					**Total Other Personnel**	[redacted]
						Total Salary, Wages and Fringe Benefits (A+B)	[redacted]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PAR-18-335 . Received Date: 2019-07-31T17:26:48.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG

Start Date*: 05-01-2021 **End Date*:** 10-31-2021 **Budget Period: 2**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	[redacted]
2. Foreign Travel Costs	
Total Travel Cost	[redacted]

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Tracking Number: GRANT12913604 Funding Opportunity Number: PAR-18-335 . Received Date: 2019-07-31T17:26:48.000-04:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*:

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: CORPORACION CENTRO INTERNACIONAL DE ENTRENAMIENTO E INVESTIG

Start Date*: 05-01-2021 **End Date*:** 10-31-2021 **Budget Period: 2**

F. Other Direct Costs	**Funds Requested ($)***
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Other: Materials translations in Spanish	
9 . Other: Development of Online components for the grants management training program	
10 . Other: Development of a new in-house grants management Grant Tracking System	
Total Other Direct Costs	

G. Direct Costs	**Funds Requested ($)***
Total Direct Costs (A thru F)	

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	**Funds Requested ($)***
1 . MTDC	8.0		
		Total Indirect Costs	

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)***
Total Direct and Indirect Institutional Costs (G + H)	

J. Fee	**Funds Requested ($)***

K. Total Costs and Fee	**Funds Requested ($)***

L. Budget Justification* File Name: Budget_justification.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Budget justification

A. Senior/Key Person

Jaramillo, Andres BS in administration and MBA will devote 25% effort (3.0 calendar months) as PD/PI of this Global Infectious Disease Research Administration Development project. He will be responsible for the overall leadership and coordination of the project and communications with the U.S. host institution. He will work with Ms. Montero in the planning, preparation and conduct of training activities at the U.S. host institution Yale University Schoolog Public Health and in CIDEIM, and in implementing research grants administrative changes to improve oversight of NIAID grant awards, compliance with NIH funding policies and Federal research funding requirements for NIAID-supported foreign institutions.

Montero, Vanessa, B.Eng. and M. Eng. in industrial engineering, will devote 25% effort (3.0 calendar months) to this project. She will receive training in the U.S. with Mr. Jaramillo and will work with him in the planning, preparation and conduct of training activities at the Yale School of Public Health and in CIDEIM, and in implementing research grants administrative changes to improve oversight of NIAID grant awards and compliance with NIH funding policies and Federal research funding requirements for NIAID-supported foreign institutions. She will be involved in developing institutional policies and processes for sustainable implementation of research management practices that are compliant with NIH guidelines and requirements.

Senior/Key Personnel costs for year 1: [redacted]
Total Senior/Key Personnel Costs: [redacted]

B. Other personnel

Villa, Luz Divia, Certified Public Accountant (CPA) with a specialization in finance, will devote 25% effort (3.0 calendar months). Mrs. Villa is the Financial Officer of CIDEIM since 1993 and will be responsible and highly involved in the implementation of financial management and reporting practices in accordance with NIH guidelines and requirements at CIDEIM and instrumental in their dissemination to other institutions.

Other Personnel for year 1: [redacted]
Total Other Personnel Costs: [redacted]

Total Personnel Costs for year 1: [redacted] **Total Personnel Costs – 18 months:** [redacted]

C. Equipment
None requested.

D. Travel

International Travel:

Hands-on training in grants administration at the Yale School of Public Health
Costs for airfare between Colombia and the U.S. estimated at [redacted] trip and per diem (including hotel costs) estimated at [redacted]/day x 15 days are included for two senior administrator(s) from CIDEIM for each year of the program. Total: [redacted]

NIH regional workshop on program funding and grants administration or a NIAID post-award grants policy and management training event
Costs for round trip airfare between Colombia and the U.S. estimated at [redacted] and per diem (including hotel costs) estimated at [redacted]/day per 5 days are included for two senior administrator(s) from CIDEIM for the first year of the program. Total: [redacted]

In-house training with the Grants Management Program (GMP) at NIAID in Rockville, MD
Costs for round trip airfare between Colombia and the U.S. estimated at [redacted] and per diem (including hotel costs) estimated at [redacted]/day per 5 days are included for two senior administrator(s) from CIDEIM for the second year of the program. Total: [redacted]

Visit to CIDEIM (Personnel of the Yale School of Public Health Research Administration office)
Costs for airfare between U.S. and Colombia estimated at [redacted]/trip and per diem (including hotel costs) estimated at [redacted]/day x 5 days are included for one professional from Yale University for first year of the program. Total: [redacted]

Total international travel for year 1: [redacted]
Total international travel: [redacted]

F. Other

Products/services:

As part of sustainability initiatives:

- Costs for preparation and translation of materials]in Spanish at [redacted] for each year of the program. Total [redacted]
- Costs for development of Online components for the grants management training program at [redacted] for first year and [redacted] for second year of the program. Total: [redacted]
- Costs for development of a new in-house Grant Tracking System at [redacted] for second year of the program.
- Costs for webinar training and videoconferencing are included at [redacted].

Total Products/services for year 1: [redacted]
Total Products/services: $[redacted]

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		[redacted]
Section B, Other Personnel		[redacted]
Total Number Other Personnel	2	
Total Salary, Wages and Fringe Benefits (A+B)		[redacted]
Section C, Equipment		0.00
Section D, Travel		[redacted]
1. Domestic	[redacted]	
2. Foreign	[redacted]	
Section E, Participant/Trainee Support Costs		0.00
1. Tuition/Fees/Health Insurance	0.00	
2. Stipends	0.00	
3. Travel	0.00	
4. Subsistence	0.00	
5. Other	0.00	
6. Number of Participants/Trainees	0	
Section F, Other Direct Costs		[redacted]
1. Materials and Supplies	0.00	
2. Publication Costs	0.00	
3. Consultant Services	0.00	
4. ADP/Computer Services	0.00	
5. Subawards/Consortium/Contractual Costs	0.00	
6. Equipment or Facility Rental/User Fees	0.00	
7. Alterations and Renovations	0.00	
8. Other 1	[redacted]	
9. Other 2	[redacted]	
10. Other 3	[redacted]	
Section G, Direct Costs (A thru F)		[redacted]
Section H, Indirect Costs		[redacted]
Section I, Total Direct and Indirect Costs (G + H)		[redacted]
Section J, Fee		0.00
Section K, Total Costs and Fee (I + J)		[redacted]

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OMB Number: 0925-0001

Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

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3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

5. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	
Research Plan Section	
2. Specific Aims	Specific_Aims.pdf
3. Research Strategy*	Research_Strategy.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	Letter_of_Support.pdf
10. Resource Sharing Plan(s)	
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Tracking Number: GRANT12913604
Funding Opportunity Number: PAR-18-335. Received Date: 2019-07-31T17:26:48.000-04:00

SPECIFIC AIMS

Centro Internacional de Entrenamiento e Investigaciones Medicas, CIDEIM, is recognized by COLCIENCIAS as a research center within the National System of Science, Technology and Innovation of Colombia. CIDEIM is dedicated to biomedical and health research on transmissible diseases, and training of investigators and health personnel. In order to achieve our mission, we work in concert with the public health, industrial and academic sectors at the national and international level. (http://www.cideim.org.co)

CIDEIM originated in Colombia in 1961 as an International Center for Medical Research and Training awarded to Tulane University by the United States National Institutes of Health. Successive renewals of this program were followed by funding through the US NIAID ICIDR program, also awarded to and administered by Tulane University with the co-direction of COLCIENCIAS until 1989, when Tulane culminated its program in Colombia. In 1990 at the initiative of COLCIENCIAS, CIDEIM was established as a Colombian non-profit foundation and in 1991, successfully competed for a Tropical Medicine Research Center TMRC award from NIAID. Since then, CIDEIM investigators have developed collaborative research supported by subawards as Co-PD/PI of ICIDR, R01, D43 Fogarty Global Infectious Disease Research Training awards several internationally-funded grants with Yale University, as well as R21 awards with colleagues at University of Massachusetts and University of California San Diego, R03 awards with the University of Connecticut and University of Massachusetts. Direct awards to CIDEIM and hence, responsibility for grants administration have been limited to the past and current TMRC awards, an R03 and IRIDA R01 award. We currently lead a U19 TMRC program (2017-2022), are subawardee for a U19 Consortium (2019-2024) led by University of Connecticut and have just submitted renewal for the first time as Primary applicant, of our Fogarty Global Infectious Disease research training program in partnership with Yale University.

Some of the challenges in grants administration encountered recently are: updating institutional registrations during the pre-award phase (Grant.gov, SAMS, eRA Commons), preparation of budget and institutional research training grant data tables; In the award-phase, collecting Just in Time (JIT) information and reviewing the Notice of Award with PD/PIs; and in the post-award phase, time management and effort report, subrecipient management and monitoring, prior approvals request, changing an established budget, financial reporting and closeout and public access for publications; and in general for all phases keeping track with NIH policies changes.

The overall goal of this project is to strengthen the capacity of CIDEIM to develop and implement institutional policies and practices for grants management that are compliant with NIH guidelines and requirements for administration of NIH grants, and to share this capacity with other institutions in the region. To achieve this goal, we will first address critical gaps in CIDEIM grants administration for current and future grants funded by NIH by training of CIDEIM management leaders at Yale University. Senior administrators trained in the U.S. will be responsible to transfer and implement these policies and practices and oversight of updated NIH guidelines. Second, we will design, implement and evaluate an internal training plan and curriculum that will provide the bases for institutionalization of sustainable capacity through continuing education and updating in accordance with changes in NIH guidelines; and adapt and pilot the training materials and curriculum for external training. Thirdly, we will review and adjust Institutional policies, procedures and standard operating procedures (SOPs) to meet good management practices in compliance with NIH requirements where certain functions do not currently have detailed instructions to support a policy or guideline (how, who, when, what and why) and to provide clarity of roles and responsibilities for these functions across CIDEIM as a whole. Lastly, we will adapt an On-line modality for components of the training program and develop a Grant Tracking system application.

Specific Aims:

1. **To institutionalize at CIDEIM Grants Management Best Practices for NIH grants.**
   Specific Objectives:
   a) Implementation of a continuous Institutional grants management training program on NIH policies and requirements
   b) Revision of Institutional policies and SOPs to be in compliance with NIH requirements
   c) Development and implementation of ICT tools for good business practices for managing awards
2. **To disseminate Grant Management Best Practices for NIH grants in the region.**
   Specific Objectives:
   a) Adaptation and piloting of the training materials and curriculum for external training
   b) Conformation of an interinstitutional community of managers of NIH grants in the region

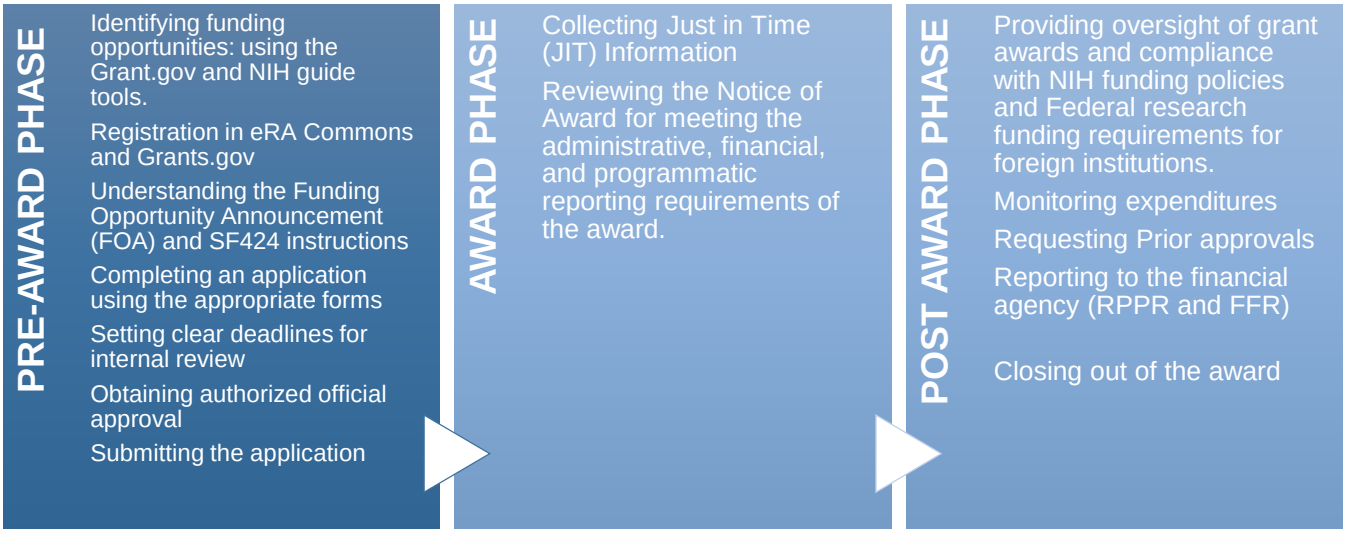
RESEARCH STRATEGY

RESEARCH GRANTS ADMINISTRATION/FINANCIAL MANAGEMENT PLAN

Current grants administration/financial management process at CIDEIM

The application of policies and procedures for the grant administration process is currently managed and administered by two units of the organization, the Research Development and Promotion Unit and the Administrative Unit (including the services of the accounting office of Universidad Icesi), these two units provide support to researchers during the different phases of the grant life cycle. The activities that these Units support in each phase are described in Figure 1.

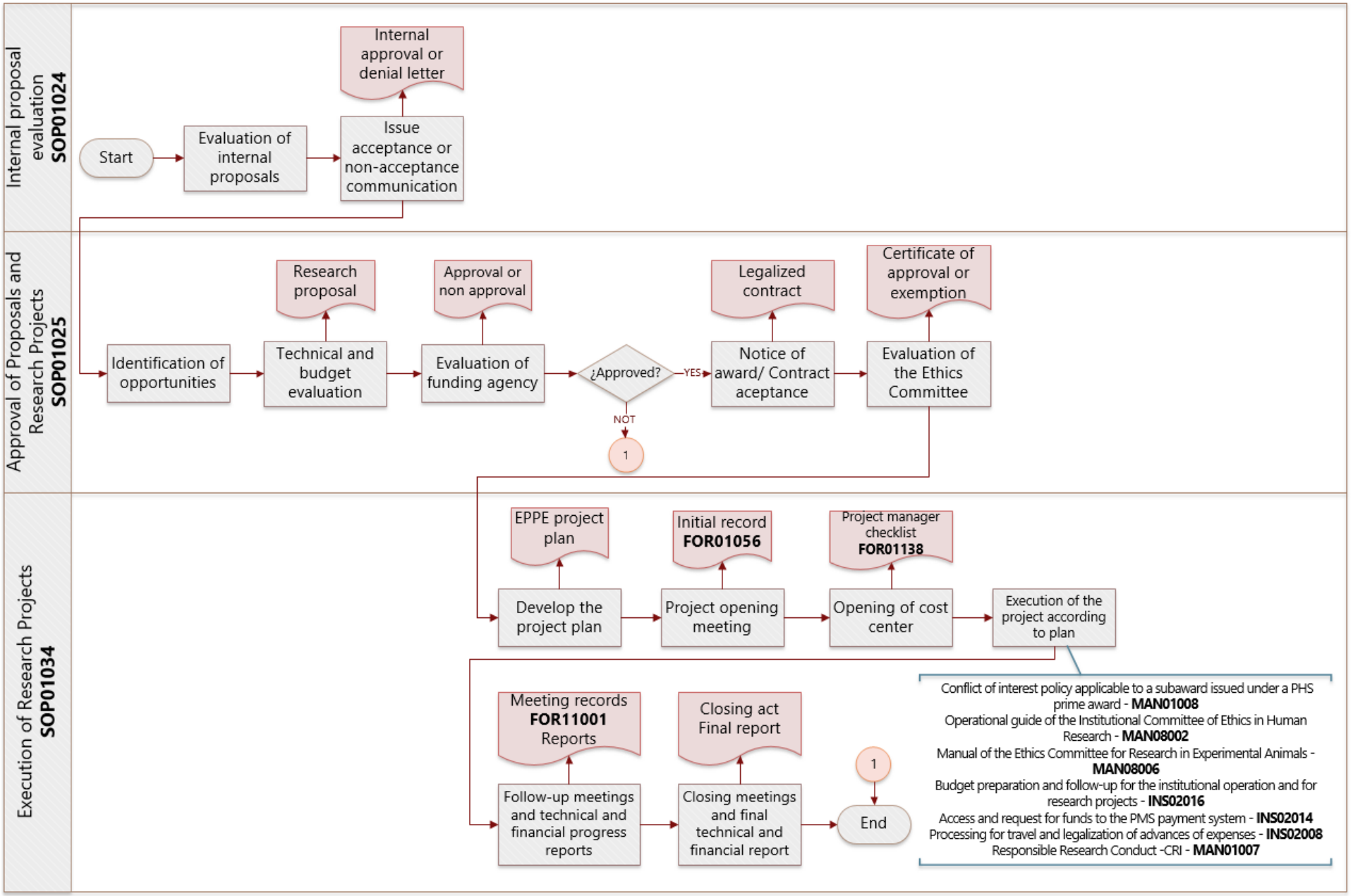
Figure 1. Support on the Grant Cycle in CIDEIM Adapted from: Grants.gov. (2019) (1)



To carry out the activities of the grant administration process, the organization has a Quality Management System, supported by manuals, procedures and formats that provides guidance for researchers for the development of their proposals and projects. The current schematic description of this process and the relevant documents and active records are summarized in Figure 2.

The current administrative / financial grant management process of the institution starts with an internal evaluation of the pre-proposal, to determine its alignment with institutional objectives and mission and compliance with scientific and ethical standards. After the pre-proposal is approved the identification of opportunities begins. When an opportunity has been identified for which the proposal is responsive, the full proposal documentation is presented according to the technical and budgetary requirements of the funding agency. If the funding agency approves the proposal and after completing the procedures for formalizing the award and ethical committee approval of the protocol, consent forms and other relevant project documentation, the execution of the project is initiated in accordance with the project plan and approved budget. An initiation meeting is convened to review the project plan, responsibilities and commitments followed by signature of the project initiation form by the Principal investigator and all Co-investigators. Follow-up meetings are convened for technical and financial monitoring. During the development of the project, the different activities established in the project plan and budget are carried out according to the policies established by the funding agency, the relevant national regulations and institutional policies, with the support and advice of the different administrative units (Purchasing, Financial management, Quality assurance and Human resources). When the execution of the project is completed, technical and financial closure is conducted through a closing meeting and signature of close-out form by the Principal investigator.

Figure 2. Current grants administration/financial management process at CIDEIM (2).



Aspects to be improved

One of the main sources used to identify the process gaps in CIDEIM was the Foreign Organization System (FOS) Visit carried out in 2016 by Mrs. Clover Cobb. During this visit Mrs. Cobb identified gaps and areas of improvement in the process for changing an established budget, time management follow up and procedure of public access for publications and made recommendations that have been applied by CIDEIM and are retaken in this project in order to strengthen the proposed action plans and provide sustainability to these activities (3).

Another source of identification of the process gaps are the daily situations and experience of the organization that have been addressed in the grant management process by the organization's administration and direction. The gaps or processes identified for correction or improvement are the following:

In the pre-award phase

- Keeping institutional registrations up to date (Grant.gov, SAMS, eRA Commons)
- Budget and institutional research training grant applications data tables preparation

In the award-phase,

- Collecting Just in Time (JIT) information and reviewing the Notice of Award with PD/PIs

In the post-award phase

- Effort reporting
- Subrecipient management and monitoring
- Prior approvals request
- Financial reporting and closeout
- Clarity in the roles and responsibilities related to the grant management process, especially the functions that support the policies and guidelines (how, who, when, what and why) associated with financial and administrative monitoring and supervision of projects.

A review of the procedures and tools currently available in the organization for these specific processes will be carried out in order to identify improvement points. This review will be done through the analysis of the activities, the flow of information of the process and the analysis of causes, and the correction or improvement plans will be framed in the cycle of continuous improvement.

Also, during the visit to the US host institution, CIDEIM administrators will identify and learn University best practices and tools in grants management and explore their applicability and adaptation and implementation at CIDEIM.

The changes to be incorporated into the process will be formalized through institutional policies and procedures, that will later be shared and communicated to the members of the organization, through institutional communications and the structuring of material and tools for incorporation into continuing training activities. The application of technological tools will also be sought in order to make information available for later consultation and for new staff entering the organization.

Regarding the roles and responsibilities related to the grant management process, these will be included in the relevant job descriptions and these functions will be communicated to all members of the organization involved.

U.S. host institution

The Yale School of Public Health (YSPH) is the partner U.S host institution where the two senior CIDEIM administrators will receive hands-on training in grants administration for up to 1 month during the award period (2 weeks in the first year and 2 weeks in the second year). CIDEIM has developed collaborative research and training supported by NIAID and NIH Fogarty Center with Yale University since 2003. YSPH is a leader in improving health across the globe through research, education and community engagement and has appropriate expertise in the management and administration of NIH grants.

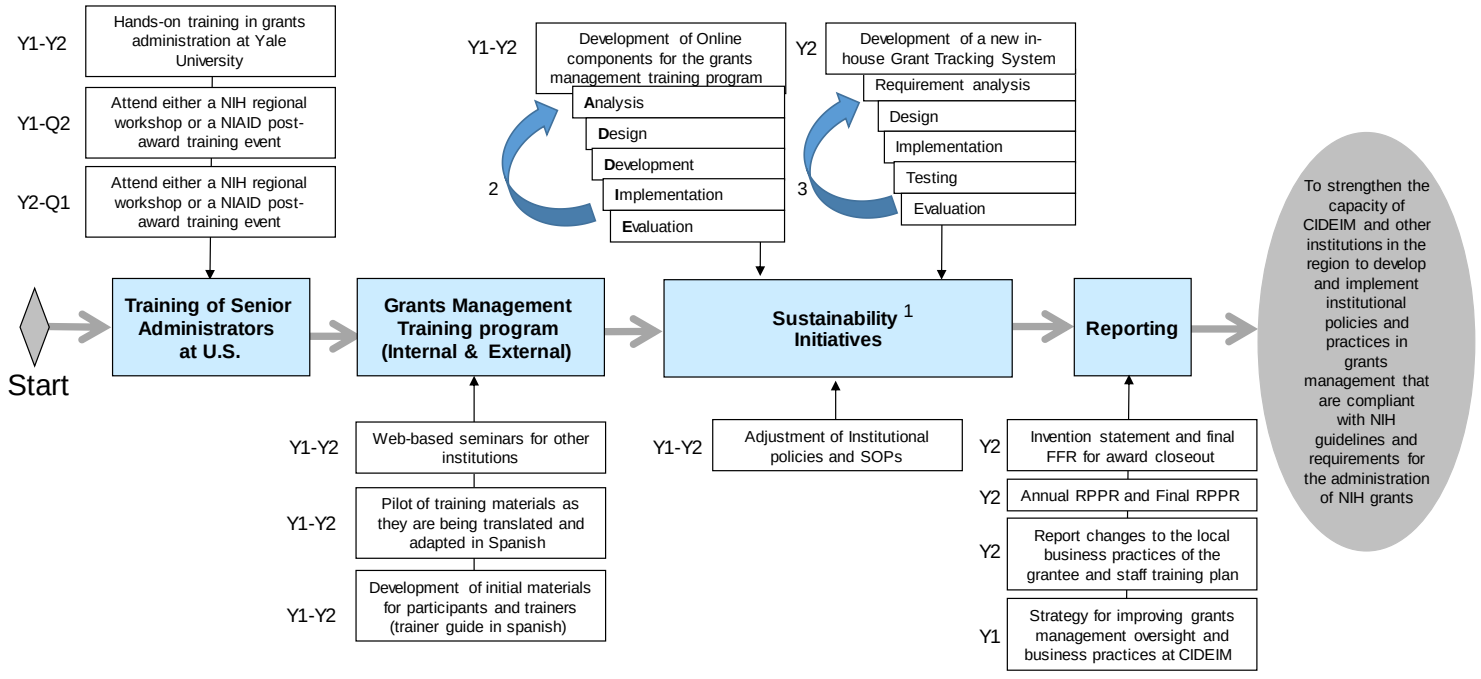
Mrs. Kathleen Fisher, Director Research Administration at Yale School of Public Health will oversee all the training related to this opportunity and bring over twenty-five years of experience in research administration at both central and departmental levels to the program.

In order to achieve the training and business practices goals of the program, the administrators from CIDEIM will have monthly meetings with Ms. Fisher to review and follow up training activities and management/business plans. At the end of month 10, it's expected that Mrs. Fisher would visit CIDEIM to review the progress in situ and together with the two senior administrators set up a strategy for improving grants management oversight and business practices at CIDEIM, this document would be signed and sent to NIH following the report instructions.

Overall strategy and methodology

To achieve the proposed objectives we will follow the route shown in Figure 3, starting with the training of two Senior Administrators in the U.S. who will be responsible to transfer to CIDEIM members involved in the grant management process what they learned, in order to identify and implement with them the necessary adjustments to institutional policies, procedures and tools, and also, to develop a grants management training program for sustainable compliance of NIH guidelines and requirements and help the transfer of this capacity to other institutions to form an interinstitutional community of individuals managing NIH grants in the region. Additionally, the development of a Grant Tracking system will start during the project period to support the grants management process.

Figure 3. PERT chart of the overall strategy



1 Activities that would be initiated during the grant funding period and will continue after the funding has ended
2 Instructional system design model called ADDIE that comprises 5 dynamic and interdependent steps: Analysis, Design, Development, Implementation and Evaluation
3 The systems development life cycle (SDLC), or software development process

TRAINING PLAN

The training plan is composed by three main phases that include: training of senior administrators from CIDEIM at the U.S hosting institution, Yale University School of Public Health, implementation of training at CIDEIM (internal) and training offered to other local or regional institutions (external).

Training of senior administrators from CIDEIM at U.S. (Yale University)

Mr. Jaramillo visited the Office of Finance and Administration at Yale School of Public Health in November of 2018, within the framework of the NIH Fogarty Global Infectious Diseases research training grant NIH/FIC D43 TW006589 collaboratively developed by Yale University and CIDEIM since 2003. This visit was coordinated with Mrs. Kathleen Fisher, Director Research Administration at Yale School of Public Health, in order to review and discuss the training program in grants administration and management available at Yale and how this program could provide the bases for this G11 application. After his visit and during the following months Mr. Jaramillo and Mrs. Montero developed a competency model for their respective jobs (Coordinator of Research Promotion and Development Unit and Coordinator of the Administrative Unit, respectively) as well as for Mrs. Luz Divia Villa, CPA, the Financial Officer of CIDEIM, taking as a reference the competencies framework for administrative employees at NIH (4). Based on these competency models, priority training needs were identified as bases to plan the training programs of Mr. Jaramillo and Mrs. Montero at Yale University. Although not traveling to receive training in the U.S., Mrs. Villa will be highly involved in the implementation of financial management and reporting practices in accordance with NIH guidelines and requirements at CIDEIM and instrumental in their dissemination to other institutions.

During Mr. Jaramillo and Mrs. Montero training at Yale University, for up to 1 month (2 weeks in the first year and 2 weeks in the second year), the two identified senior administrators from CIDEIM, will receive training organized and supervised by the Office of Finance and Administration of the School of Public Health and the Office of Sponsored Projects (OSP). The CIDEIM administrators will receive a training curriculum that includes online training modules as well as instructor-led sessions that OSP already offers periodically to their faculty and administrators (5). A Yale NetID will be set up for the CIDEIM administrators to have access to the online training modules as well other online resources that the University offers to its community for conducting and administering research. The training curriculum includes an Introduction to Sponsored Project Administration, and specific sessions on, Research Compliance Principles for Administrators, Allocating Allowable Costs, Effort Reporting Principles, Fly America and Open Skies Agreement, Cost Transfer Principles, Financial Reporting and Closeout, Cost Sharing on Sponsored Projects and Subrecipient Basics and Monitoring. Although, these courses and modules are offered across the calendar year, the OSP will accommodate the training to be achieved during their visit at Yale, as proposed in the timeline for this training summarized in Table 1. Other training needs that have been identified such as Changes in Project and Budget, Research Misconduct policy, Public Access requirements will be addressed by arranging specific meetings with people who have experience in those topics at the University. These CIDEIM senior administrators will also take two elective courses from Yale leadership Development training: InsideOut Coaching and Leading with Influence.

Courses and module descriptions

Introduction to Sponsored Projects Administration

This 1-day program is designed to be an overview of the sponsored projects process from pre-award to post award. This course is intended for those who work in business offices and have the responsibility of managing sponsored awards or some part of the award process. The course is designed for Research Administrators who are new to the profession, for those who have been administering awards for years and would like a refresher, or for those responsible for a piece of the award management process and want an understanding of the entire life-cycle of an award. Successful completion of this course includes attending the class and passing the quiz administered at the end of class. Topics covered include: Regulatory compliance; Award basics and terminology; Proposal preparation, submission, negotiation and acceptance; Award setup and managing the award; Reporting obligations, award closeout and audits.

Research Compliance Principles for Administrators

This 1/2 day program is designed to walk attendees through the principles of research compliance concentrating on what business administrators need to know when managing sponsored awards. Main topics covered include: Conflict of Interest (COI) disclosure requirements; Human Research Protection Program (HRPP) and IRB reviews; Regulations, guidance and policies regarding Animal research; the university department of Environmental Health and Safety (EHS) and how they monitor safety concerns on campus; Policies and regulations regarding Export Controls of technologies and information.

Allocating Allowable Costs
The purpose of this module is to increase participants' understanding of the difference between allowable and unallowable costs and what constitutes an acceptable allocation methodology.

Effort Reporting Principles
This module provides administrators with a comprehensive understanding of the principles of effort reporting and documenting activities as it relates to sponsored awards. Topics include: Key terms, policies, procedures and regulations; Effort management activities from proposal through closeout; Key roles and responsibilities; Understanding the effort reporting lifecycle, with case studies e.g., appointing faculty and staff, proposing effort, charging salaries.

Fly America and Open Skies Agreement
This course is designed for anyone involved with travel arrangements charged to sponsored awards including: Research Administrators, Administrative Assistants, Principal Investigators, Lab Technicians, Researchers, etc. There are regulations that must be adhered to, and restrictions that must be followed, when making foreign flight reservations that will be charged to federal awards.

Cost Transfer Principles
This module provides individuals with an understanding of university policies and procedures regarding labor and non-labor cost transfers associated with sponsored awards. This instructor-led course is for individuals who prefer interactive classroom learning; for those who took the online course but would like to discuss questions related to the course; or for those looking to review updated information and refresh their knowledge. Course objectives are to increase participants' understanding of: Federal regulations related to cost transfers; Sponsor and University Policy; The process to properly and efficiently prepare, document, approve and submit a cost transfer; and available tools and templates for these processes.

Financial Reporting and Closeout
This course is designed for administrators responsible for the financial reporting and closeout of sponsored awards. In this class participants will learn about: The roles and responsibilities of those involved in financial reporting and closeout; Policies and procedures related to these functions; University processes supporting sponsor requirements; The closeout process cycle; The steps necessary to properly close sponsored awards. This class is recommended for those who have experience working with Financial Status Reports (FSRs) and have been dealing with financial reporting for a minimum of 6 months.

Cost Sharing on Sponsored Projects (video)
This short video reviews the rules regarding mandatory cost-sharing, voluntary cost sharing, voluntary uncommitted cost sharing, in-kind/matching and charging effort commitments to an award.

Subrecipient Basics and Monitoring – Online
The content of this online module addresses the difference between subawards and procurement actions, requirements for establishing and monitoring subawards, and roles and responsibilities of the PI and administrators throughout the subaward process. Upon completion of this course participants will: Understand the roles and responsibilities of individuals involved in the subaward process; Be able to differentiate between a subrecipient and a vendor relationship; Gain a greater awareness and understanding of university policies and procedures regarding subrecipients; Understand the requirements and expectations for subrecipient monitoring and the processing of invoices; Know where to find resources to assist in the subaward process within the university.

InsideOut Coaching
InsideOut Coaching is a one-day program that offers a different way of looking at coaching. It provides a practical and proven process for coaching others to improve and sustain enhanced performance. In this workshop you will learn concepts and practices that will help you and others discover your innate ability to respond to the performance pressures of today.

The goals of the workshop are to:
- Explore ways to improve performance in yourself and others

- Apply a process to help you make faster and directionally sound decisions
- Use a simple coaching process that:
    1. Compliments current skills
    2. Involves the subject matter expert in the decision-making process
    3. Treats others with respect and dignity
    4. Moves people to action
- Move the process to practice and apply it to real situations

Leading with influence

Leading with Influence recognizes the fact that individuals often need to use their ability to "enlist, persuade, and engage" others, in order to obtain results. In fact, without the ability to influence, individuals can end up working hard and long to strategize, innovate, and achieve their goals – and still not get the payoff they deserve from their efforts! In this fast-paced, hands-on workshop you will hone your influencing skills as you learn:

- How power, relationship, and influence methods. all affect your ability to influence
- The different influence approaches available to you, and which ones you currently use most
- An influence model that lets you choose your approach, set your plan, and enhance your results

TABLE 1. Timeline - Training at Yale University	**Year 1**		**Year 2**	
Instructor-Led Modality	**W1**	**W2**	**W1**	**W2**
1. Introduction to Sponsored Project Administration (SPA)				
2. Effort Reporting Principles				
3. Leading with Influence				
4. Allocating Allowable Costs				
5. Research Compliance Principles for Administrators				
6. Fly America and Open Skies Agreement				
7. Direct Charging of F&A Costs on Sponsored Awards				
8. Cost Transfer Principles				
9. Financial Reporting and Closeout				
10. InsideOut Coaching				
Online Modality				
11. Subrecipient Basics and Monitoring				
12. Cost Sharing on Sponsored Projects				
13. What Research Staff Need to Know About Spending Sponsored Projects Funds				
14. Principle Investigator Eligibility: Who Can Be a PI?				

Training at CIDEIM (internal)

Although most of the researchers at CIDEIM understand English, the majority of the administrative staff do not, and this is a barrier for implementing NIH requirements. This situation extends to other research institutions in the local and regional context. Therefore, a curriculum in Spanish adapted for research administrators and staff from institutions in the region to fulfill NIH requirements for foreign institutions is needed.

The two senior administrators from CIDEIM will adapt a curriculum in Spanish based on the training at Yale and the curriculum of training received by Mr. Jaramillo at the annual meeting of the Society of Research Administration (SRA) in October 2018 to obtain the "National Institutes of Health (NIH) Grants Fundamentals" certificate, and the NIH regional workshop (or a NIAID post-award training event) and the In-house training with the Grants Management Program (GMP) at NIAID that are included in this training grant . This Spanish language curriculum will deliver the information and corresponding sources for what research administrators and staff in CIDEIM need to know about NIH requirements for foreign institutions. This curriculum will be pertinent and applicable to other institutions in the region.

An initial curriculum will be prepared including adaptation and translation of an introductory session/workshop on the National Institutes of Health (NIH) fundamentals session received by Mr. Jaramillo at and the sessions mentioned previously from Yale University, in the following order as follows:

1. National Institutes of Health (NIH) fundamentals
2. Introduction to Sponsored Project Administration (SPA)
3. Research Compliance Principles for Administrators
4. Effort Reporting Principles
5. Financial Reporting and Closeout
6. Allocating Allowable Costs
7. Fly America and Open Skies Agreement
8. Subrecipient Basics and Monitoring
9. Cost Sharing on Sponsored Projects
10. Cost Transfer Principles

The session on the National Institutes of Health (NIH) fundamentals will be required to be undertaken by all the administrative and support staff of the Promotion and Development of Research Capacity Unit (PDRC), and the Administrative Unit of CIDEIM, which manages the pre and post award aspects of grants management at the institution. All investigators involved in projects funded by NIH and postdoctoral investigators and project managers will be required to complete this session. The session "Introduction to Sponsored Project Administration" will be required for all administrative and support staff. Similarly Administrative and support personnel and investigators will fulfill training sessions on topics related to specific procedures and policies (3 to 10) essential to preparing successful applications to and managing grant awards from the National Institutes of Health. Audiences will vary depending on the topic and job description.

The sessions InsideOut Coaching and Leading with influence will be incorporated into the training curriculum and a program for administrators, support staff and investigators interested in deepening the development of their competences and also the development on others competencies will be designed and tested during the project period. All the junior staff from the PDRC and Administrative units at CIDEIM will receive mentorship led by Mr. Jaramillo, Mrs. Montero and Mrs. Villa in their

Initial materials in Spanish for participants and a trainer guide will be developed. Pilot versions will be tested as they are being developed. This curriculum will be extended and adjusted according training needs and policy changes at the institutional level and by NIH.

Training offered to other local or regional institutions (External)

Using the Research Portfolio Online Reporting Tools (RePORT) https://report.nih.gov/index.aspx, the institutions receiving NIH awards in Colombia and in the region will be identified and invited to participate in some of the training activities proposed in this application, including training on site at CIDEIM and web-based seminars on specific topics of NIH grants administration. Also, institutions that are part of CIDEIM's Regional Training Center Network that may not have NIH grant support but are interested in applying for NIH grants will be invited to participate in activities focused on preparing for successful applications.

Training activities on site at CIDEIM (described previously)

Web-based seminars
Specific topics of NIH grants administration will be addressed in 20 minutes presentations followed by 20 minutes for questions and answers. Presenters will vary depending on the topic selected and the participation of the grants administrators from institutions in the region managing NIH funds directly or indirectly (subawards) will be encouraged to participate as presenters or participants. The recorded sessions and post seminar forum will be posted in the virtual campus of CIDEIM and registered participants will have access.

SUSTAINABILITY INITIATIVE

Institutional oversight will be strengthened within its grants management processes, especially functions that do not currently have detailed instructions to support a policy or guideline (the how, who, when, what and why), to provide clarity of roles and responsibilities for these functions across CIDEIM as a whole, as well as to facilitate research grants administration activities. The sustainability initiatives to be pursued through this project include 1) adjustment of institutional policies, procedures and standard operating procedures (SOPs) to effectively manage NIH research grants, 2) the development of Online components for the grants management training program described in the Training plan 3) the development of a new in-house grants tracking system. The timeline for these activities are presented under Sustainability Initiatives in Table 2.

TABLE 2 - TIMELINE OVERVIEW	**Year 1**				**Year 2**			
1. TRAINING PLAN	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
1.1. Training of Senior Administrators at U.S.								
1.1.1. Hands-on training in grants administration at Yale University								
1.1.2. Attend either a NIH regional workshop or a NIAID post-award training event								
1.1.3. In-house training with the GMP at NIAID								
1.2. Grants Management Training program (Internal & External)								
1.3. Development (adaptation and translation in Spanish) of initial materials for participants and trainers (trainer guide)								
1.4. Pilot of training materials as they are being translated and adapted in Spanish								
1.5. Web-based seminars for other institutions								
2. SUSTAINABILITY INITIATIVES								
2.1. Adjustment of Institutional policies and SOPs								
2.2. Development of Online components for the grants management training program								
2.3. Development of a new in-house Grant Tracking System								
3. REPORTING								
3.1. Strategy for improving grants management oversight and business practices at CIDEIM*								
3.2. Report stating what changes have been initiated or made to the local business practices of the grantee and staff training plan**								
3.3. Annual RPPR and Final RPPR								
3.4. Invention statement and final FFR for award closeout								

Adjustment of institutional policies, procedures and standard operating procedures (SOPs)

Institutional policies, procedures and SOPs will be revised in order to assure and harmonize their compliance with Federal requirements. These include: Public Access Policy, Policy on Financial Conflicts of Interest, Procedure for Research Misconduct, Procedures for Human Subjects, Policy and Procedures on Monitoring of Performance by Consortium Institutions, Procedures describing the process required to change an established budget, Human Subjects Research Training SOP, Grants Administration/Financial Management SOPs, etc. Although, CIDEIM has revised some of these in the past and this is a continuing process, during the project period Mr. Jaramillo and Mrs. Montero will have the opportunity to learn from Yale policies and procedures for grants management during their visit in year 1 and 2 and to consider these in implementing policy and procedural changes in CIDEIM.

Development of Online components of the grants management training program

An online version of the 1 day course “National Institutes of Health (NIH) fundamentals” will be developed, in order to offer it regularly both internally and externally to national and regional institutions. An instructional system design model denominated ADDIE that comprises 5 dynamic and interdependent steps: Analysis, Design, Development, Implementation and Evaluation will be used for its development. This activity will begin at the end of year 1. After evaluation this strategy, the feasibility virtualizing other courses will be determined.

Development of a new in-house Grant Tracking System

CIDEIM has in-house capacity to develop web and mobile applications for research projects and also tracking systems for institutional purpose and use, among the tracking systems are:

1) Administrative Tracking System: allows monitoring of administrative requirements / services such as purchasing, travel, per diem and other expenses that are budgeted in research and capacity building projects.

2) Training Tracking System: allows monitoring and storage of registration data of participants in the training programs offered by CIDEIM, facilitating the generation of statistics and analysis of the outputs of the training programs within the Institutional monitoring and evaluation framework.

Additionally, an IT tool to monitor study progress (dashboard) was developed as part of a re-entry grant supported by the Special Programme for Research and Training in Tropical Diseases (TDR) for Dr. Maria del Mar Castro, Leader Clinical Research Unit at CIDEIM. This dashboard was developed using Metabase®, an open-source software and it can be tailored to the needs of any clinical research project. It uses data collected through different apps at CIDEIM to generate indicators presented to the PI and Project Manager, some of the indicators include enrollment rate and total number of enrolled versus sample size, project budget (by budget lines) and overall budget execution.

Taking into account the experience in software development, it is proposed within the framework of this project to develop a new in-house Grant Tracking System that will allow the integration of previous developments, figure 1, for managing the Pre-Award and Post-Award processes at CIDEIM. This system will be used by all administrators, support staff and researchers involved in the grants management process in the institution.

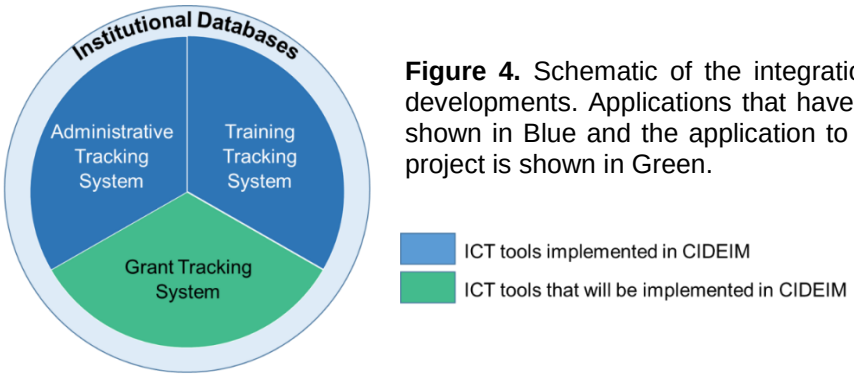


Figure 4. Schematic of the integration of institutional management application developments. Applications that have already been implemented in CIDEIM are shown in Blue and the application to be developed within the framework of this project is shown in Green.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	❍ Yes ● No
Is the Project Exempt from Federal regulations?	❍ Yes ❍ No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Does the proposed research involve human specimens and/or data	❍ Yes ● No

Other Requested information

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