

## NIH updates to policies affect 2018 submissions

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The NIH has released a series of policy updates that impact the submission of NIH applications due on or after January 25, 2018. Below is a summary of the relevant changes:

### New Application Forms Set “E”

The critical changes with these new forms include:

- New PHS Human Subjects & Clinical Trials Information Form
  - ◊ Consolidates human subjects, inclusion enrollment, and clinical trial information into one form.
  - ◊ Collects information at the study-level.
  - ◊ Uses discrete form fields to capture clinical trial information and provide the level of detail needed for peer review.
  - ◊ Presents key information to reviewers and staff in a consistent format.
  - ◊ Aligns with ClinicalTrials.gov (where possible) for future data exchange with ClinicalTrials.gov.
  - ◊ Includes attachment to comply with [NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#) (see [NIH-OD-17-076](#)).
  - ◊ Clarifies that the Research Strategy attachment should be used to discuss the overall strategy, methodology, and analyses of the proposed research.
  - ◊ Incorporates updated appendix policy (see [NOT-OD-17-098](#)).
  - ◊ Incorporates recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms.
  - ◊ Discontinues use of supplemental instructions for all competing applications and progress reports
  - ◊ Folds information into the application guide form instructions and/or is contained in the appropriate policy website (e.g., [NIH Grants Policy Statement](#)).

### New Funding Opportunity Announcements (FOA)

Effective for due dates on or after January 25, 2018 all applications involving one or more clinical trials need to be submitted through a Funding Opportunity Announcement (FOA) specifically designed and designated for clinical trials. For the majority of NIH applications there are two parent announcements—one for projects with Clinical Trials, and one for projects without Clinical Trials. Particular attention should be paid to ensure that the correct FOA is selected in accordance with

the proposed project. Additional details are available at

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-106.html>

### NIH Definition of a Clinical Trial

The NIH defines a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related **biomedical or behavioral** outcomes.” Please note that this definition includes Phase 1 clinical trials, and trials that do not involve any FDA-regulated products (such as trials involving only **behavioral** interventions).

In an effort to assist PIs in determining whether their proposed project is an NIH defined clinical trial (which would require submission of their project via a clinical trial specific FOA) the NIH has provided detailed guidance on their website at <https://grants.nih.gov/policy/clinical-trials/definition.htm>.

The [Office of Research and Economic Development](#) recommends that if there are any questions as to whether a PI’s proposed project falls under a clinical trial FOA or not, that they contact the NIH Program Officer listed on the FOA and confirm with them whether their project is defined by the NIH as a clinical trial.

### Additional Resources

In an effort to provide further information and resources related to clinical trials, the Office of Research Integrity has created a website <http://research.fiu.edu/irb/clinical-trials/> reminding the University research community of critical requirements related to clinical trials. Please visit this site for resources on:

- ClinicalTrials.gov registrations
- Good Clinical Practice (GCP) Training
- Submitting protocols (involving drugs, biologics, or medical devices) to Western IRB (WIRB)
- NIH and FDA Guidance on Clinical Trials

If you have any questions about these revisions by the NIH please contact your ORED Pre-Award representative at 305-348-2494 for further assistance.

# Upcoming Events

## February

- **February 2, 11 am to 12 pm, DM #100, [Type IA Topoisomerases can be “Magicians” for both DNA and RNA](#)**, presented by [Weidong Wang](#)
- **February 2, 12 to 1 pm, AHC 1 #110, [How Developmental Science can Improve Population Health and Well-Being at Birth](#)**, presented by [Kenneth Dodge](#)
- **February 7, 12 to 1 pm, AHC 1 #110, [How to Talk to your Kids about Depression and Suicide](#)**, presented by FIU’s Center for Children and Families
- **February 7, 3 to 4 pm, CP #115, [Biomolecular Sciences Institute lecture](#)**, presented by [David Clemmer](#)
- **February 9, 9 to 10 am, EC2300, [Miami Heart Month](#)** presentation, featuring [Masanori Aikawa](#), an expert in applied cardiovascular biology
- **February 12, 5:30 to 7 pm, FIU Frost Museum, [Mixtape Mondays](#)**, a compilation of ideas from FIU faculty across disciplines, using our collection as a focal point to talk about their research interests
- **February 13, 2018, 12 to 1 pm, AHC5 500, [Timothy Page](#)**, Health Informatics and Health Systems Joint Faculty & Doctoral Student Seminar
- **February 16, 9 to 10 am, EC 2300, [Miami Heart Month](#)** presentation, featuring [Frederick Schoen](#), an expert in applied cardiovascular biology
- **February 16, 9 am to 6 pm, Panther Pit at Engineering Center, [Heart Day Symposium](#)** will include a poster session from the Miami cardiovascular research community; to participate, please contact Josh Hutcheson ([jhutches@fiu.edu](mailto:jhutches@fiu.edu))
- **February 21, 8 am to 5 pm, Kovens Conference Center, [Miami International Child & Adolescent Mental Health \(MICAMH\) Conference](#)**
- **February 22, 8 am to 5 pm, Kovens Conference Center, [Miami International Child & Adolescent Mental Health \(MICAMH\) Conference](#)**
- **February 23, 9 to 10 am, EC 2300, [Miami Heart Month](#)** presentation, featuring [David Merryman](#), an expert in applied cardiovascular biology

## March

- **March 2, 12 to 1 pm, AHC1 #110, [Speaker Series: Depression and Suicide in Adolescents](#)**, presented by [Randy P. Auerbach](#)
- **March 7, 12 to 1 pm, AHC 1 #110, [Strategies to Manage your Young Child’s Challenging Behaviors](#)**, presented by FIU’s Center for Children and Families
- **March 12, 5:30 to 7 pm, FIU Frost Museum, [Mixtape Mondays](#)**, a compilation of ideas from FIU faculty across disciplines, using our collection as a focal point to talk about their research interests
- **March 13, 12 to 1 pm, AHC5 #500, Health Informatics and Health Systems Joint Faculty & Doctoral Student Seminar**, presented by [Hyeyoung Hah](#)
- **March 21, 12 to 2 pm, AHC 1 #100, [Frustrated Trying to Manage your Child’s Media Devices?](#)**, presented by FIU’s Center for Children and Families
- **March 28, 12 to 1 pm, [Raising a Bilingual Child—Dispelling Myths](#)**, presented by FIU’s Center for Children and Families
- **March 30, 1:30 to 2:30 pm, TBD, [Biomolecular Sciences Institute lecture](#)**, presented by [Laura Finzi](#)

## April

- **April 7 – 10, 2018, JW Marriott Marquis Downtown Miami, [Diversity Abroad Conference New Realities & Untapped Potential](#)**, all FIU employees and students are eligible for a 25% discounted conference

registration fee (please register as a member since FIU is part of the Diversity Abroad network; **discount codes** Main Conference: 25FIU2018; MSI Summit: 25FIUMSI2018; GSLS: 25FIUGSLS2018

- **April 10, 12 to 1 pm, AHC5 #300, Health Informatics and Health Systems Joint Faculty & Doctoral Student Seminar**

## ***Awards Received—December 2017***

FIU researchers were awarded \$6,280,968 in December 2017. Below is a listing of awards received:

### **Agarwal, Arvind**

College of Engineering and Computing

Boston University

Initial

NST ERC: Nanosystems Engineering Research Center for Directed Multiscale \$356,406

### **Ahmad, Imran**

Chaplin School of Hospitality and Tourism Management

Romans Lifesciences

Initial

Pilot Study of the Impact of Monsieur Marble in Cabernet Sauvignon Wine \$2,005

### **Almirall, Jose R**

College of Arts, Sciences & Education

National Science Foundation

Increase

RTI - Jose Almirall \$12,567

### **Baum, Marianna**

Robert Stempel College of Public Health and Social Work

Case Western Reserve University

Continuation

An unbiased OMICs approach to identify mechanisms of Cocaine regulation of the HIV \$235,834

### **Briceno, Henry**

College of Arts, Sciences & Education

National Science Foundation

Increase

FCE LTER III: Legacies \$31,339

### **Casado Zapico, Sara**

College of Arts, Sciences & Education

National Science Foundation

Increase

Rapiscan - Sara Zapico \$25,000

### **Cevallos, Fabian**

College of Engineering and Computing

City of Doral

Increase

Schedule for the FIU Trolley Route \$4,540

**Chapman, Demian D**

College of Arts, Sciences & Education  
Rockefeller Philanthropy Advisors

Initial

eDNA: a new way to access to sharks for conservation \$214,500

**Clarke, Peter J**

College of Engineering and Computing  
Florida Gulf Coast University

Increase

Using a Cyberlearning Environment to Enhance Critical Cybersecurity Education \$12,660

**Clarke, Peter J**

College of Engineering and Computing  
Florida Gulf Coast University

Initial

Using a Cyberlearning Environment to Enhance Critical Cybersecurity Education \$58,662

**Coles, Erika K**

College of Arts, Sciences & Education  
Nova Southeastern University

Initial

Behavioral Assessment Team \$33,073

**De Caprio, Anthony**

College of Arts, Sciences & Education  
National Science Foundation

Increase

Agilent - Anthony DeCaprio \$25,000

**Devieux, Jessy**

Robert Stempel College of Public Health and Social Work  
Alcohol Abuse and Alcoholism

Initial

Optimizing PrEP Utilization among Alcohol and Other Drug (AOD) Using Women of Color \$198,880

**Eirin Lopez, Jose**

College of Arts, Sciences & Education  
National Science Foundation

Initial

RAPID: Investigation of the interaction between genotype variation \$6,984

**Finlayson, Mark Alan**

College of Engineering and Computing  
University of California Los Angeles

Continuation

Narratives in the Informational Patient Society and their Association with Health \$50,000

**Frazier, Stacy Lynn**

College of Arts, Sciences & Education  
National Institutes of Health

Increase

Self-Concept Intervention for Urban High School Students \$468

**Furton, Kenneth G**

College of Arts, Sciences & Education  
 National Science Foundation  
 Increase  
 Dubai Police - Kenneth Furton

\$24,960

**Gaiser, Evelyn E**

College of Arts, Sciences & Education  
 National Science Foundation  
 Initial  
 RAPID: HURRICANE IRMA: How do ecosystem perturbations interact to influence

\$178,159

**Gaiser, Evelyn E**

College of Arts, Sciences & Education  
 National Science Foundation  
 Increase  
 LTER: FCE LTER III - Coastal Oligotrophic Ecosystems Research

\$552,793

**Gaiser, Evelyn E**

College of Arts, Sciences & Education  
 National Science Foundation  
 Increase  
 FCE LTER III: REU

\$16,000

**Georgakopoulos, Stavros**

College of Engineering and Computing  
 Georgia Institute of Technology  
 Increase  
 EFRI-ODISSEI: Novel Perpetual Reconfigurable and Multi-Band Origami Folding

\$200,000

**Hadi, Mohammed A**

College of Engineering and Computing  
 Florida Department of Transportation  
 Initial  
 Multi-Resolution Modeling Course Delivery

\$13,966

**Hadi, Mohammed A**

College of Engineering and Computing  
 Florida Department of Transportation  
 Initial  
 Data and Modeling Support of Off-Line and Real-Time Decisions

\$240,000

**Hadi, Mohammed A**

College of Engineering and Computing  
 Florida Department of Transportation  
 Initial  
 SR 924/NW 119 Street Adaptive Signal Control Technology Pilot Project Evaluation Phase II

\$47,536

**Hamid, Shahid**

Academic Affairs - Other Units  
 Florida Office of Insurance Regulation  
 Initial  
 Florida Public Hurricane Loss Model (FPHLM)

\$969,689

**Heithaus, Michael**

College of Arts, Sciences & Education  
National Science Foundation  
Increase  
FCE LTER III: Trophic Dynamics

\$67,997

**Heithaus, Michael**

College of Arts, Sciences & Education  
Paul G. Allen Family Foundation  
Increase  
Heithaus subproject to THE GLOBAL FIN-PRINT: a worldwide underwater video survey

\$16,000

**Ibanez, Gladys E**

Robert Stempel College of Public Health and Social Work  
University of California Davis  
Pre-Award  
The Acceptability and Feasibility of the iPad version of the NIH Neurocognitive

\$2,570

**Jaffe, Rudolf**

College of Arts, Sciences & Education  
National Science Foundation  
Increase  
FCE LTER III: Organic Matter

\$72,957

**Jung, Ranu**

College of Engineering and Computing  
George Washington University  
Increase  
A Naturalistic Investigation of Brain Neuroplasticity in Children Born Pre-Term

\$7,025

**Jung, Ranu**

College of Engineering and Computing  
U.S. DOD/Defense Advanced Research Project  
Increase  
Restoring Sensation with a Neural-Enabled Prosthetic Hand System

\$443,424

**Jung, Ranu**

College of Engineering and Computing  
U.S. DOD/Defense Advanced Research Project  
Pre-Award  
Restoring Sensation with a Neural-Enabled Prosthetic Hand System

\$50,000

**Khizroev, Sakhrat**

College of Engineering and Computing  
Neuroscience Centers of Florida Foundation  
Supplemental  
High specificity targeting with magnetoelectric nanoparticles

\$17,000

**Kominoski, John**

College of Arts, Sciences & Education  
National Science Foundation  
Increase  
FCE LTER III: Biogeochemistry Kominoski

\$71,583

**Malone, Sparkle Leigh**

College of Arts, Sciences & Education  
University of Alabama

Initial

Tipping the greenhouse C balance: Hurricane Irma's role in increasing \$100,180

**Malone, Sparkle Leigh**

College of Arts, Sciences & Education  
University of Alabama

Initial

Tipping the greenhouse C balance: Hurricane Irma's role in increasing \$25,000

**Maziak, Wasim**

Robert Stempel College of Public Health and Social Work  
National Institute on Drug Abuse

Increase

Carryover Year 1-Understanding tobacco flavor effects on waterpipe smokers' \$98,432

**McCord, Bruce**

College of Arts, Sciences & Education  
National Science Foundation

Increase

DEA - Bruce McCord \$25,000

**Mehrabi, Armin Barzegar**

College of Engineering and Computing  
Second Vivekananda Bridge Tollway Company

Initial

Synthesis of Inspection and Rehabilitation Activities for the External Post \$53,900

**Mohammed, Osama A**

College of Engineering and Computing  
Office of Naval Research

Increase

A Cyber Physical System/Communication Framework for Resilient Real-time \$15,318

**Montas-Hunter, Sonja S**

Academic Affairs - Other Units  
U.S. Department of Education

Increase

TRIO Upward Bound 2017-2022 \$4,728

**Montas-Hunter, Sonja S**

Academic Affairs - Other Units  
U.S. Department of Education

Increase

Subproject to 800008116 No F&A \$4,000

**Palacios, Cristina**

Robert Stempel College of Public Health and Social Work  
University of Puerto Rico

Initial

Intervention to promote physical activation and improve sleep and feeding \$30,221



**Pelham Jr, William E**

College of Arts, Sciences &amp; Education

University at Buffalo SUNY

Continuation

Enhancing Father Engagement to Promote Social, Behavioral

\$221,691

**Price, Rene M**

College of Arts, Sciences &amp; Education

National Science Foundation

Increase

FCE LTER III: Water

\$32,974

**Prospect, Sean Antonio**

College of Arts, Sciences &amp; Education

Florida Department of Education

Initial

Project IMPACT (FIU After School All-Stars) 2017-2018

\$400,000

**Raiker Jr, Joseph**

College of Arts, Sciences &amp; Education

Children's Trust

Pre-Award

After-school support program for youth at-risk for behavior problems

\$10,361

**Ross, Michael S**

College of Arts, Sciences &amp; Education

U.S. Fish and Wildlife Service

Initial

Hurricane Irma assessment: effects on forests of the USFWS Refuges of the Florida Keys

\$10,000

**Sarwat, Arif Islam**

College of Engineering and Computing

Florida Power and Light

Supplemental

FIU-EPS/MTC Engineering Lab Cooperation

\$45,000

**Sarwat, Arif Islam**

College of Engineering and Computing

National Science Foundation

Increase

REU Supplement to 800005863

\$12,000

**Scaccianoce, Monica C**

College of Nursing and Health Sciences

Humana Foundation

Initial

Intensive Nurse Directed Evidence - Based Practice Treatment Utilizing Telehealth

\$109,494

**Schreiber Compo, Nadja**

College of Arts, Sciences &amp; Education

National Science Foundation

Increase

RTI - Nadja Schreiber Compo

\$12,433



<b>Sousa, Jacqueline Bueno</b> College of Business Administration University of West Florida Initial Florida SBDC at FIU 2018	\$115,555
<b>Sousa, Jacqueline Bueno</b> College of Business Administration University of West Florida Initial FL SBDC at FIU 2018 - PTAC FED	\$8,911
<b>Sousa, Jacqueline Bueno</b> College of Business Administration University of West Florida Initial Florida SBDC at FIU 2018	\$38,739
<b>Sousa, Jacqueline Bueno</b> College of Business Administration Miami-Dade Internal Services Department Initial Miami-Dade County-SBDC Project	\$250,000
<b>Traynor, Mark</b> Chaplin School of Hospitality and Tourism Management U.S. Department of Agriculture Initial 2017 Cochran Fellowship Program on Supermarket Management	\$89,913
<b>Trexler, Joel</b> College of Arts, Sciences & Education South Florida Water Management District Increase Quantification of the aquatic faunal community	\$212,307
<b>Troxler, Tiffany</b> College of Arts, Sciences & Education National Science Foundation Increase FCE LTER III: Primary Production	\$67,211
<b>Wdowinski, Shimon</b> College of Arts, Sciences & Education National Science Foundation Increase FCE LTER III: Wetland InSAR	\$28,023

## ***Funding Opportunities***

ORED has a new, improved and interactive webpage for funding opportunities. Please visit <http://research.fiu.edu/funding/#current>.

## Limited Submissions

Current limited submission opportunities are available at <http://research.fiu.edu/funding/limited-submissions/>.

## Contact ORED Senior Leadership

Name	Title	Email Address
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