NIH updates to policies affect 2018 submissions

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 (j hutches@fiu.edu)
- February 16, 8 am to 5 pm, Kovens Conference Center, Miami International Child & Adolescent Mental Health (MICAMH) Conference
- February 17, 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

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**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

For updates, corrections, suggestions, and/or general comments, please email Mercedes.rodriguez@fiu.edu
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<tr>
<th>Name</th>
<th>Institution</th>
<th>Amount</th>
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<tr>
<td>Chapman, Demian D</td>
<td>Rockefeller Philanthropy Advisors</td>
<td>$214,500</td>
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<td>Clarke, Peter J</td>
<td>Florida Gulf Coast University</td>
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<tr>
<td>Clarke, Peter J</td>
<td>Florida Gulf Coast University</td>
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<td>Coles, Erika K</td>
<td>Nova Southeastern University</td>
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<td>De Caprio, Anthony</td>
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<td>Devieux, Jessy</td>
<td>Alcohol Abuse and Alcoholism</td>
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<td>Eirin Lopez, Jose</td>
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<td>Finlayson, Mark Alan</td>
<td>University of California Los Angeles</td>
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<td>Frazier, Stacy Lynn</td>
<td>National Institutes of Health</td>
<td>$468</td>
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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 & Education
University at Buffalo SUNY
Continuation
Enhancing Father Engagement to Promote Social, Behavioral $221,691

Price, Rene M
College of Arts, Sciences & Education
National Science Foundation
Increase
PCE LTER III: Water $32,974

Prospect, Sean Antonio
College of Arts, Sciences & Education
Florida Department of Education
Initial
Project IMPACT (FIU After School All-Stars) 2017-2018 $400,000

Raiker Jr, Joseph
College of Arts, Sciences & 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 & 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 & Education
National Science Foundation
Increase
RTI - Nadja Schreiber Compo $12,433
Sousa, Jacqueline Bueno  
College of Business Administration  
University of West Florida  
Initial  
Florida SBDC at FIU 2018  
$115,555

Sousa, Jacqueline Bueno  
College of Business Administration  
University of West Florida  
Initial  
FL SBDC at FIU 2018 - PTAC FED  
$8,911

Sousa, Jacqueline Bueno  
College of Business Administration  
University of West Florida  
Initial  
Florida SBDC at FIU 2018  
$38,739

Traynor, Mark  
Chaplin School of Hospitality and Tourism Management  
U.S. Department of Agriculture  
Initial  
2017 Cochran Fellowship Program on Supermarket Management  
$89,913

Troxler, Joel  
College of Arts, Sciences & Education  
South Florida Water Management District  
Increase  
Quantification of the aquatic faunal community  
$212,307

Troxler, Tiffany  
College of Arts, Sciences & Education  
National Science Foundation  
Increase  
FCE LTER III: Primary Production  
$67,211

Wdowinski, Shimon  
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.

For updates, corrections, suggestions, and/or general comments, please email Mercedes.rodriguez@fiu.edu
Limited Submissions
Current limited submission opportunities are available at http://research.fiu.edu/funding/limited-submissions/.

Contact ORED Senior Leadership

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