

Changes in Institutional Review Board (IRB) Regulations



Federal Regulation 45 CFR 46 “Protection of Human Subjects,” referred to as the “Common Rule,” is an anchor regulatory text on which investigators and IRBs rely and must comply to protect human subjects in research.

The U.S. Department of Health and Human Services (HHS) issued revisions to the Common Rule, which were originally slated to go into effect on January 19, 2018, but were later delayed until July 19, 2018.

However, significant uncertainty remains about the implementation of the revised Common Rule. On April 19, 2018, HHS announced a proposal to further delay the general compliance date until January 21, 2019 – a proposal whose fate has not yet been determined.

If the federal government takes no action on the proposed delay between now and July 19, 2018, the revised Common Rule takes effect on July 19, 2018.

In the face of this uncertainty, the ORED’s Office of Research Integrity (ORI) has moved forward with preparations to implement the necessary changes. This will ensure that FIU will be compliant if the revised Common Rule becomes effective on July 19, 2018.

ORI has developed a web page, which highlights the key changes to the Common Rule and also provides guidance to FIU researchers on what to expect during the transition over the coming

weeks. The web page will be updated as additional guidance becomes available.

<http://research.fiu.edu/irb/revised-common-rule/>

Considerable preparation will be required by ORI staff to prepare for the new regulatory requirements. In order to facilitate a smooth transition, there will be a **“freeze” period on all new IRB protocol submissions during the period of July 1, 2018 – July 18, 2018.** Please take this time frame into account when planning your upcoming IRB submissions.

In addition, **all pending (already submitted) IRB protocol applications will need to receive IRB approval by July 16, 2018.**

If a pending submission does not receive IRB approval by July 16, 2018, it will need to be withdrawn and resubmitted on the latest version of the IRB application (to comply with the new regulatory requirements).

If you have any questions, please contact Chris Grayson at 305-348-8379 or graysonc@fiu.edu.

Did you know ORED has specific email accounts that are monitored centrally?

- ◆ preaward@fiu.edu – requests for proposals’ submission assistance
- ◆ doraward@fiu.edu – incoming awards and award-related actions
- ◆ oredagremnts@fiu.edu – sub-award requests, consulting agreements, MTAs, NDAs and other non-funded research agreements

If someone is out sick or on vacation, your email will still be read!

Awards Received—May 2018

FIU researchers were awarded **\$13,822,443** in May 2018. Below is a listing of awards received:

Adler, Jessica Lee

Steven J. Green School of International & Public Affairs

History

National Endowment for the Humanities

Initial

War and Healing: A Century of Veterans' Reintegration

\$91,309

Afanasyev, Alexander

College of Engineering & Computing

Computer Info Sciences

University of California Los Angeles

Initial

ICN-WEN: Collaborative Research: ICN-Enabled Secure Edge Networking

\$95,000

Agarwal, Arvind

College of Engineering & Computing

Mechanical and Mat Engineering

Boston University

Supplemental

NST ERC: Nanosystems Engineering Research Center for Directed Multiscale

\$69,631

Allen, Timothy

College of Arts, Sciences & Education

Psychology

National Institute of Mental Health

Initial

The role of the nucleus reuniens in the temporal organization of memory and behavior

\$307,357

Azzam, Diana Jehad

Robert Stempel College of Public Health & Social Work

Environmental Health Sciences

Florida Department of Health

Initial

Personalized Ex Vivo Drug Screening and Genomics Profiling to Guide Individualized

\$700,000

Bagner, Daniel

College of Arts, Sciences & Education

Psychology

Child Health and Human Development

Increase

Effect of Parent Emotion-Related Talk on Infant Behavior and Regulation

\$480

Baum, Marianna

Robert Stempel College of Public Health & Social Work

Dietetics and Nutrition

National Institute on Drug Abuse

Continuation

Cohort Studies of HIV/AIDS and Substance Abuse in Miami

\$1,052,827

Beck Sague, Consuelo Maria

Robert Stempel College of Public Health & Social Work

Health Promotion and Disease Prevention

Health Resources & Services Administration

Continuation

Mother and Children FIRST! Fresh Ideas and Resources for Scholar Training

\$33,144

Boeglin, Werner

College of Arts, Sciences & Education

Physics

U.S. Department of Energy

Continuation

Hadronic Physics with Electromagnetic Probes

\$200,000

Boswell, Kevin

College of Arts, Sciences & Education

Biology

University of Miami

Initial

Developing acoustic classification methods for reef fish species in the Gulf of Mexico

\$111,578

Brewster, Luther G

Herbert Wertheim College of Medicine

Humanities Health and Society

FIU Foundation

Pre-Award

Herbert Wertheim College of Medicine: Innovation in Education and Healthcare Delivery

\$106,700

Brewster, Luther G

Herbert Wertheim College of Medicine

Humanities Health and Society

FIU Foundation

Initial

Herbert Wertheim College of Medicine: Innovation in Education and Healthcare Delivery

\$87,300

Briceno, Henry

College of Arts, Sciences & Education

SERC

Islamorada, Village of Islands

Increase

Water Quality Monitoring Program for the Village of Islamorada, Florida Keys

\$75,671

Briceno, Henry

College of Arts, Sciences & Education

SERC

Pennsylvania State University

Increase

Response of carbon cycling to climatic and anthropogenic perturbations in two North

\$35,070

Burke, Shanna L

Robert Stempel College of Public Health & Social Work
 School of Social Work
 Dan Marino Foundation
 Increase

The effectiveness of Virtual Interactive Training Agents (ViTA) software \$38,932

Campa, Adriana

Robert Stempel College of Public Health & Social Work
 Dietetics and Nutrition
 Minority Health and Health Disparities
 Initial

FIU Center for Reducing Health Disparities in Substance Abuse & HIV in South Florida \$62,310

Chambers, Jeremy Wayne

Robert Stempel College of Public Health & Social Work
 Environmental Health Sciences
 Baptist Health South Florida
 Initial

Targeting JNK signaling in patient-derived glioblastoma stem cells \$40,000

Cheng, Michael

Chaplin School of Hospitality & Tourism Management
 U.S. Department of Agriculture
 Initial

2018 Cochran Fellowship Program - Brazil Culinary Educators @ FIU \$83,747

Choi, Young Rae

Steven J. Green School of International & Public Affairs
 Global and Sociocultural Studies
 Social Science Research Council
 Initial

The Yellow Sea: A Window onto the Anthropocene \$42,500

Coles, Erika K

College of Arts, Sciences & Education
 Psychology
 Children's Trust
 Initial

A Summer Program for Children with or at risk for serious behavior problems \$601,005

Comer, Jonathan S

College of Arts, Sciences & Education
 Psychology
 National Institute of Mental Health
 Initial

Improving Satisfaction, Engagement and Clinical Outcomes Among Traditionally \$39,968

Crowl, Todd Alan

College of Arts, Sciences & Education
 Institute of Water and Environment
 University of Puerto Rico
 Increase

LTER: LTER5: Understanding Ecosystem Change in Northeastern Puerto Rico \$30,000

Crowl, Todd Alan

College of Arts, Sciences & Education
 Institute of Water and Environment
 University of Puerto Rico
 Increase

LTER: LTER5: Understanding Ecosystem Change in Northeastern Puerto Rico \$10,000

Cyrus Cameron, Elena Antonia

Robert Stempel College of Public Health & Social Work
 CRUSADA
 National Institutes of Health
 Initial

To Reach Unrestricted Services for Transgender Women (TRUST) \$128,034

Dinehart, Laura H

College of Arts, Sciences & Education
 School of Education
 Business & Leadership Institute for Early Learning
 Initial

2018-2019 BLI Coordinating and Research Services, year 2 \$68,555

Elawady, Amal Mohamed Kamel A

College of Engineering & Computing
 Civil and Environ Engineering
 National Science Foundation
 Initial

Collaborative Research: Downburst Fragility Characterization of Transmission \$307,752

Fernandez Lima, Francisco Alberto

College of Arts, Sciences & Education
 Chemistry
 National Science Foundation
 Increase

CAREER: Development of gas-phase, post-ionization structural tools for the study of DNA \$8,000

Finlayson, Mark Alan

College of Engineering & Computing
 Computer Info Sciences
 Smart Information Flow Technologies
 Initial

PERFECTA: Politeness-based Evaluation of Regard for Finding Efforts to Create \$50,000

Frankovich, Thomas A

College of Arts, Sciences & Education
 SERC
 South Florida Water Management District
 Initial

Light Attenuation Study in Manatee Bay, Barnes Sound and NE Florida Bay \$78,500

Friedman, Rebecca

Academic Affairs - Other Units
 European Commission
 Increase

BILAT USA 4.0 \$3,454

Furton, Kenneth G

Academic Affairs - Other Units

Association of Public & Land-Grant Universities

Increase

University Transformation through Teaching (UT3) Phase II

\$2,324

Gaiser, Evelyn E

College of Arts, Sciences & Education

SEAS

FIU Foundation

Initial

FIU for Everglades Student Research Fund

\$15,000

Gan Chowdhury, Arindam

College of Engineering & Computing

Civil and Environ Engineering

University of Florida

Initial

Full-Scale Experimentation and Computational Modeling to Mitigate Wind-Induced

\$26,095

Gann, Daniel

Academic Affairs - Other Units

GIS Center and Digital Collection

National Park Service

Initial

REMAP IV (2014) -- Phase II Data Distribution System

\$40,000

Gardinali, Piero

College of Arts, Sciences & Education

Chemistry

National Park Service

Increase

Laboratory Services for Florida Bay Seawater Chemical Analysis

\$10,000

Graziano, Paulo

College of Arts, Sciences & Education

Psychology

Children's Trust

Initial

Summer Treatment Program for Pre-kindergarteners (STP-Pre-K)

\$217,941

Guilarte, Tomas R

Robert Stempel College of Public Health & Social Work

Dean's Office

Minority Health and Health Disparities

Initial

FIU Center for Reducing Health Disparities in Substance Abuse & HIV in South Florida

\$56,571

Harborne, Alastair

College of Arts, Sciences & Education

Biology

Nature Conservancy

Initial

Mapping and modeling fishing pressure and fish standing stocks in the Florida Keys

\$20,000

Harborne, Alastair

College of Arts, Sciences & Education

Biology

Nature Conservancy

Initial

Mapping and modeling fishing pressure and fish standing stocks in the Florida Keys \$20,000

Hospital, Michelle

College of Arts, Sciences & Education

SISH

Gang Alternative Inc.

Pre-Award

Evaluation of the Gang Alternative Minority Violence Prevention Project 88 (MVP 88) \$5,076

Ibarra, Julio E

Academic Affairs - Other Units

CIARA

National Science Foundation

Continuation

IRNC: RXP: Atlantic Wave-SDX: a distributed intercontinental experimental SDX \$999,456

Jiao, Shuliang

College of Engineering & Computing

Biomedical Engineering

National Institutes of Health

Increase

Imaging the functional biomarker of photoreceptors \$46,611

Khizroev, Sakhrat

College of Engineering & Computing

Electrical and Computer Engineering

University of California Berkeley

Continuation

Physics of Spin Switching in Sub-10-nm Spin-transfer-torque Magnetic Tunneling Junctions \$53,483

Kolishetti, Nagesh

Herbert Wertheim College of Medicine

Immunology

FIU Foundation

Initial

Development of Brain Targeted and Biodegradable Polymeric Nano-Formulations for Delivery \$50,000

Lagos, Leonel

Academic Affairs - ARC

Office of Environmental Management

Increase

FIU's Research Support to the Department of Energy's Office of Environmental Management \$675,000

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Academic Affairs - ARC

Office of Environmental Management

Increase

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Academic Affairs - ARC

Office of Environmental Management

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Academic Affairs - ARC

Office of Environmental Management

Increase

FIU's Research Support to the Department of Energy's Office of Environmental Management \$675,000

Lau, Kingsley

College of Engineering & Computing

Civil and Environmental Engineering

U.S. Department of Transportation

Increase

ABC-UTC Proposal FY 16-17 \$60,000

Lee, Seung Jae

College of Engineering & Computing

Civil and Environmental Engineering

Texas A&M University

Initial

Uncovering Potential Risks of Wind-induced Cascading Damages to Construction \$157,387

Lee, Seung Jae

College of Engineering & Computing

Civil and Environmental Engineering

U.S. Department of Transportation

Increase

ABC-UTC Proposal FY 16-17 \$60,000

Liu, Hong

College of Arts, Sciences & Education

Earth and Environment

Pew Charitable Trusts Fellows Program

Initial

Conservation of illegal-traded marine wildlife in South China \$150,000

Lundy, Debra

Chaplin School of Hospitality & Tourism Management

Miami Beach Visitor & Convention Authority

Initial

2018 Annual South Beach Wine & Food Festival (MBVCA) \$59,500

Lyons, Lisanne Elizabeth

Robert Stempel College of Public Health & Social Work

Dietetics and Nutrition

Tweed Charitable Foundation

Initial

Sound Reinforcement Request \$4,000

Madhivanan, Purnima

Robert Stempel College of Public Health & Social Work
 Epidemiology
 University of California Berkeley
 Pre-Award
 Global Health Equity Scholars Program

\$4,786

Maziak, Wasim

Robert Stempel College of Public Health & Social Work
 Epidemiology
 Fogarty International Center NIH
 Continuation
 Translating evidence and building capacity to support water pipe control

\$345,482

Maziak, Wasim

Robert Stempel College of Public Health & Social Work
 Epidemiology
 Minority Health and Health Disparities
 Initial
 FIU Center for Reducing Health Disparities in Substance Abuse & HIV in South Florida

\$102,550

McMakin, Dana Lynn

College of Arts, Sciences & Education
 Psychology
 National Institute of Mental Health
 Initial
 Sleep-dependent negative overgeneralization in peri-pubertal anxiety

\$651,413

Mebel, Alexander

College of Arts, Sciences & Education
 Chemistry
 U.S. Department of Energy
 Continuation
 Theoretical Studies of chemical reactions related to the formation and growth

\$110,000

Mehrabi, Armin Barzegar

College of Engineering & Computing
 Civil and Environmental Engineering
 U.S. Department of Transportation
 Increase
 ABC-UTC Proposal FY 16-17

\$80,000

Mills, De Etta kay

College of Arts, Sciences & Education—Biology
 National Institutes of Health
 Increase
 FIU MARC U*STAR Program

\$1,633

Murray, Edward P

Steven J. Green School of International & Public Affairs
 Metropolitan Center
 North Miami Community Redevelopment Agency
 Initial
 City of North Miami Workforce & Affordable Housing Needs Assessment

\$36,000

Nair, Madhavan P

Herbert Wertheim College of Medicine

Immunology

National Institute on Drug Abuse

Increase

Nano-delivery of methanandamide across BBB to block cannabinoid induced effects \$12,788

Nair, Madhavan P

Herbert Wertheim College of Medicine

Immunology

National Institute on Drug Abuse

Continuation

Nanotechnology Based Gene Editing to Eradicate HIV Brain Reservoir in Drug Abusers \$638,630

Nair, Madhavan P

Herbert Wertheim College of Medicine

Immunology

National Institute on Drug Abuse

Increase

Cocaine in the Neuropathogenesis of HIV infection: Role of HDAC-2 \$36,583

Nikkhah Moshai, Roozbeh

Herbert Wertheim College of Medicine

Immunology

Baptist Health South Florida

Initial

Low Energy External Magnetic Stimulation of Nanoparticles to Disintegrate Amyloid \$39,980

Noriega, Fernando

College of Arts, Sciences & Education—Biology

National Institutes of Health

Increase

Regulation of juvenile hormone titers in mosquitoes \$504,327

Ozgen, Mesut

College of Communication, Architecture + The Arts

Music

Miami-Dade County Cultural Affairs

Initial

2018 Guitar Festival TDC Grant \$5,000

Palacios, Cristina

Robert Stempel College of Public Health & Social Work

Dietetics and Nutrition

University of Hawaii

Initial

Preventing excessive gestational weight gain via short mobile messages in WIC \$8,062

Papastamatiou, Yannis Peter

College of Arts, Sciences & Education

Biology

Earthwatch Institute

Pre-Award

Shark and ray conservation in Belize \$34,562

Papastamatiou, Yannis Peter

College of Arts, Sciences & Education

Biology

Earthwatch Institute

Increase

Shark and ray conservation in Belize

\$9,426

Pomeroy, Jordana

Academic Affairs - Frost Art Museum

Miami-Dade County Cultural Affairs

Initial

FY 2017-2018 Dangerous Women

\$12,000

Premo, Bianca Caroline

Steven J. Green School of International & Public Affairs

History

American Council of Learned Societies

Initial

The Smallest Subject: Peru's Youngest Mother and the Rise of Modern Research Ethics

\$50,000

Prospect, Sean Antonio

College of Arts, Sciences & Education

Community Engagement

Florida Department of Education

Supplemental

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

\$148,475

Pulugurtha, Markondeyaraj

Robert Stempel College of Public Health & Social Work

Dietetics and Nutrition

Georgia Institute of Technology

Initial

Advanced Components and Integration for Systems Packaging

\$75,000

Raymond, Andrea D

Herbert Wertheim College of Medicine

Immunology

National Institute on Drug Abuse

Continuation

Role of exosome extracellular vesicles in opiate abuse and HIV neuropathogenesis

\$212,000

Rishe, Naphtali

College of Engineering & Computing

Computer Information Sciences

National Science Foundation

Increase

I/UCRC Phase II: Center for Advanced Knowledge Enablement

\$50,000

Ross, Michael S

College of Arts, Sciences & Education

Earth and Environment

U.S. Fish and Wildlife Service

Initial

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

\$55,788

Ross, Michael S

College of Arts, Sciences & Education

Earth and Environment

U.S. Fish and Wildlife Service

Increase

Hurricane Irma assessment: effects on forests of the USFWS Refuges of the Florida Keys \$10,000

Sanchez, Mariana

Robert Stempel College of Public Health & Social Work

Health Promotion and Disease Prevention

Pacific Institute for Research & Evaluation

Initial

Pre- to Post-Immigrant Drinking and Driving Trajectories among Recent Latino Immigrants \$298,773

Sarwat, Arif Islam

College of Engineering & Computing

Electrical and Computer Engineering

National Science Foundation

Continuation

CAREER: Cyber Physical Solution for High Penetration Renewables in Smart Grid \$87,317

Sheehan Delgado, Diana Montserrat

Robert Stempel College of Public Health & Social Work

Epidemiology

HIV Prevention Trials Network

Increase

Perceived network sexual norms and HIV sexual risk behavior among drug users \$26,473

Sibley, Margaret

Herbert Wertheim College of Medicine

Psychiatry and Behavior Health

National Institute of Mental Health

Initial

Integrative Data Analysis of Psychosocial Treatment Studies for Adolescent ADHD \$73,250

Sinicrope, Joseph Daniel

Academic Affairs - ARC

U.S. Army Corps of Engineers

Initial

Research and Development Initiatives in support of ERDC's Coastal Hydraulics Lab (CHL) \$29,511

Soares Quinete, Natalia

College of Arts, Sciences & Education

SERC

Academy of Marine Sciences Inc.

Initial

Non-targeted screening of emerging contaminants in surface and tap waters \$2,000

Standiford, Lester

College of Arts, Sciences & Education

English

Eckerd College

Initial

Writers in Paradise 2019 \$38,325

Theobald, Jamie

College of Arts, Sciences & Education

Biology

National Science Foundation

Initial

CAREER: Image speed and visual acuity during fly flight \$168,350

Theobald, Jamie

College of Arts, Sciences & Education

Biology

National Science Foundation

Initial

CAREER: Image speed and visual acuity during fly flight \$1,650

Trepka, Mary Jo

Robert Stempel College of Public Health & Social Work

Epidemiology

Minority Health and Health Disparities

Initial

FIU Center for Reducing Health Disparities in Substance Abuse & HIV in South Florida \$108,892

Troxler, Tiffany Grace

College of Arts, Sciences & Education

SERC

South Florida Water Management District

Initial

Benchmarks for coastal vulnerability \$2,500

Trucco, Elisa

College of Arts, Sciences & Education

Psychology

Minority Health and Health Disparities

Initial

FIU Center for Reducing Health Disparities in Substance Abuse & HIV in South Florida \$98,339

Tsoukias, Nikolaos M

College of Engineering & Computing

Biomedical Engineering

University of Vermont

Increase

K⁺ sensing & electrical signaling by Kir channels in brain vasculature \$30,000**Wagner, Eric**

Robert Stempel College of Public Health & Social Work

School of Social Work

Minority Health and Health Disparities

Initial

FIU Center for Reducing Health Disparities in Substance Abuse & HIV in South Florida \$111,917

Zhang, Yuying

College of Arts, Sciences & Education—Biology

National Oceanic and Atmospheric Admin

Increase

A decision-support tool for evaluating the impacts of short- and long-term management \$198,393

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/>.

Upcoming deadlines include:

AGENCY	PROGRAM	INSTITUTIONAL SUBMISSION LIMITS	DEADLINE FOR NOTICE OF INTENT TO APPLY	AGENCY DEADLINE
Oak Ridge Associated Universities (ORAU)	ORAU Travel Grants:	Only two proposals per fiscal year. Contact Maureen Pelham (mpelham@fiu.edu) for additional information before applying.	Open	Prelim deadline: Open Agency Deadline: 9/30/2017
National Film and Video Foundation	National Film and Video Foundation Fund (Marketing and Distribution)	Only one application per organization	Open	The NFVF will receive proposals for film funding throughout the year.
National Film and Video Foundation	National Film and Video Foundation Fund (Production Funding)	Only one application per organization	Open	The NFVF will receive proposals for film funding throughout the year.
National Film and Video Foundation	National Film and Video Foundation Fund (Development Funding)	Only one application per organization	Open	The NFVF will receive proposals for film funding throughout the year.
National Film and Video Foundation	National Film and Video Foundation Fund (Education and Training)	Only one application per organization	Open	The NFVF will receive proposals for film funding throughout the year.

Contact ORED Senior Leadership

Name	Title	Email Address
Andrés G. Gil	Vice President for Research & Economic Development	Andres.gil@fiu.edu
Tonja Moore	Associate Vice President, Strategic Planning & Operations	Tonja.moore@fiu.edu
Luis P. Salas	Associate Vice President, International Research, Space Optimization and Compliance	Luis.salas@fiu.edu
Mirtha Alberto	Director, Budget & Cost Analysis	Mirtha.alberto@fiu.edu
Henry Artigues	Director, External Partnerships & Economic Development	Henry.artigues@fiu.edu
David Driesbach	Assistant Vice President, Research Information Systems	David.driesbach1@fiu.edu
Christopher Grayson	Director, Research Integrity	Christopher.grayson@fiu.edu
Emily Gresham	Assistant Vice President, Innovation & Economic Development	Emily.gresham@fiu.edu
Robert Gutierrez	Assistant Vice President, Research Development & Pre-Award	Robert.gutierrez@fiu.edu
Pedro Hernández	Director, Technology Management & Commercialization	Pedro.hernandez7@fiu.edu
Regnier Jurado	Director, Research Management Solutions	Regnier.jurado@fiu.edu
Donna Kiley	Director, Post-Award	Donna.kiley@fiu.edu
Lidia Kos	Associate Vice President for Research, Associate Dean— University Graduate School	Lidia.kos@fiu.edu
Maureen Pelham	Director, Research Development Director, Postdoctoral Scholar Services	Maureen.pelham@fiu.edu
Horatiu Vinerean	Director, Laboratory Animal Research ; Attending Veterinarian	Horatiu.vinerean@fiu.edu
Susan Webster	Assistant Vice President for Research, Assistant Dean— University Graduate School	Susan.webster@fiu.edu



OFFICE OF RESEARCH AND ECONOMIC DEVELOPMENT
 11200 SW 8th Street—MARC 430
 Miami, FL 33199
<http://research.fiu.edu>