

# **Division of Research**

## **Quarterly Research Administration Meeting**



**October 29th, 2013**

# AGENDA



- **Welcome and Introductions**
- **Special Updates**
- **Research Development**
- **Pre Award Update**
- **Budget & Cost Analysis Update**
- **Research Integrity Update**

Division of Research  
*Vice President's Office Update*

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- **Welcoming Remarks**
- **Introduction of Division of Research Team**
- **Introduction of New Attendees**
- **Future Quarterly Research Administrators Meeting for 2014**
  - January 28, 2014
  - April 29, 2014
  - October 28, 2014
  - All meetings are from 10:00 am – 12:00 pm in the MARC Pavilion
- **Slides will be posted on the Division of Research website after meeting**

Division of Research  
*Special Updates*

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- **OPS Conversion**
- **Patient Protection and Affordable Care Act (PPACA)**



Carolyn F. Jackson  
Division of Human Resources  
FIU

# PPACA (PATIENT PROTECTION AFFORDABLE CARE ACT)

# PPACA

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Senate Bill 1802 was signed into Florida Law which provides that any Temporary employee meeting certain criteria (working an average of 30 hours or more per week) is eligible to participate in the state group health insurance program, etc.

DSGI (Division of State Group Insurance) provided guidance to state agencies and universities to continue our efforts forward and stay on course for a January 1, 2014 implementation.

On Tuesday, July 2nd, the Federal Government announced the Employer Shared Responsibility is delayed until 2015. However, Florida is moving forward with PPACA implementation regardless of the federal PPACA mandate delay.

# PPACA

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## Temporary Employee Categories:

- Instructional Staff
  - Temporary Faculty
  - Adjuncts
- Non-Student Temporary
- Student Employees
  - Student Assistants
  - Federal Work Study
  - Graduate Assistants, Teaching Assistants and Research Assistants

# PPACA

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Eligibility for Health benefits is based on measurement periods established by the State of Florida. These measurement periods will be 1 year in length.

Employee payroll and time files will be sent to DSGI to calculate the average hours worked per week during the measurement period and establish eligibility.

**Initial Measurement Period:**

**April 1 - September 30, 2013**



# PPACA

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Additional details include:

- Should you hire an employee who is reasonably expected to work at least 30 hours per week, they must be offered the health insurance benefit upon start of employment.
- Should you hire an employee who is not reasonably expected to work 30 hours or more per week, however, they begin to do so within the first 90 days of employment, they must be offered the health insurance benefit.
- Should you hire an employee who has separated from FIU or any other State of Florida employer for less than 6 months, and they were eligible for health benefits prior to separation, they must be offered the health insurance benefit upon start of employment.

\*Seasonal employment is exempt from this legislation. Seasonal employment is defined as 10 weeks or less.

# LEGAL CONSIDERATIONS

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## Temporary Employment

- Justification of hire and tenure of temporary assignment
- Based on recent case law (Microsoft, IBM, etc.)
- Already in effect

## PPACA

- Provision of health benefits to all employees working an average of 30 hours or more per week during a measurement period
- Based on new federal legislation in Obama Administration
- Effective January 1, 2014

# HOW DOES THIS AFFECT YOU?

- Division of Research has communicated their position in regard to hiring of temporary employees for projects: **Any employee who will be hired for a period of 1 year or longer must be hired into a benefit-earning position which offers insurance and retirement benefits.**
- Grant-funded temporary positions are not exempt from PPACA legislation, which means that for every current temporary employee that works in excess of 30 hours or more per week, we will have to offer the health insurance benefit as of the Open Enrollment period.
- Initial file with employment data from April 1, 2013 – September 30, 2013 has already been sent to DSGI for review. The final file will be sent in a couple of weeks for final eligibility reports.
- Employee who choose to enroll for health benefits will have insurance effective January 1, 2013 – December 31, 2013, regardless of how many hours they work per week following eligibility determination (unless separated from university)

# NOW WHAT?

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The Division of Human Resources has already begun to look at all temporary employees on projects to better understand the impact to existing grants and the institution.

We are here to work with all academic units, chairs, and all PIs to make sure that as we help FIU remain compliant with federal legislation, we also maintain continuity and productivity in all research activity.

We will continue to work with the university community to make sure that we fully support your research endeavors in any way that we can.

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**QUESTIONS?**

Division of Research  
*Research Development Update*

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- **Overview of Services**
  - A. Research Faculty New to FIU**
  - B. Communication**
  - C. Professional Development**
  - D. Proposal Development**
  - E. Recognition**

# Division of Research *Pre Award Update*

## ▪ **Staffing Update**

**Welcome to the Pre-Award Team the following members:**

- **Christopher Beyer (Pre-Award Coordinator)**
- **Denise Medrano (Pre-Award Coordinator)**
- **Michelle Jimenez (Pre-Award Coordinator)**
  
- **Claudia Molina has been assigned to assist SIPA Faculty with all ePRAF needs. She is located in SIPA 511**
  
- **Mario Sanchez (formerly from the Robert Stempel College of Public Health and Social Work) has joined the Division of Research and will be an ePRAF Coordinator at the College of Engineering and Computing.**
  
- **Ana Ruiz, Natalie Sanchez and Reyna Hernandez are back from maternity leave.**

# Division of Research Pre Award Update

- **Federal Shutdown Impact**

## NIH Impacts -- Deadlines

<b>Activity Code</b>	<b>Original Due Date</b>	<b>New Due Date</b>
R01s, U01s (New)	10/05/13	11/12/13
Ks (New)	10/12/13	11/12/13
R03s, R21s, R34s, R36s (New)	10/16/13	11/18/13
R15s (All)	10/25/13	11/18/13
<u>Special Due Dates:</u>		
<b>Funding Opportunity</b>	<b>Original Due Date</b>	<b>New Due Date</b>
Various RFAs, PARs, PAs	Due dates not listed above	11/01/13
<u>*Exceptions:</u>		
<b>Funding Opportunity</b>	<b>Original Due Date</b>	<b>New Due Date</b>
<a href="#">PAR-13-277</a>	10/01/13	11/14/13
<a href="#">PAR-13-351</a>	10/23/13	11/14/13
<a href="#">RFA-AI-13-043</a>	10/23/13	11/14/13
<a href="#">PAR-13-086</a>	10/24/13	11/14/13
<a href="#">PAR-13-087</a>	10/24/13	11/14/13

- **The NIH Loan Repayment Program application due date has been extended from November 15, 2013 to December 2, 2013.**

- **All other November grant application due dates will not change**

- **Federal Shutdown Impact**
  - **NIH Impacts -- Rescheduling Peer Review Meetings**
    - **Most NIH peer review meetings that occurred during or immediately following the government shutdown will be rescheduled so that as many applications as possible are able to be considered at January 2014 Council meetings.**
    - **NIH scheduling complexities may prevent the evaluation of the full complement of applications for this round. There may be some applications that cannot be reviewed in time for the January 2014 Advisory Council.**
    - **These applications will be reassigned to the May 2014 Advisory Council and both the principal investigator and the signing official listed on the grant application will receive an email notification alerting them to the change during the week of November 4, 2013.**

Division of Research  
*Pre Award Update*

- **Federal Shutdown Impact on Applications**  
**NIH Impacts -- Rescheduling Peer Review Meetings**
  - **Applications reassigned to the May 2014 Advisory Council will proceed to initial peer review in February/March 2014 without any action from the applicant.**
  - **NIH is giving these applicants the option of withdrawing and submitting a refreshed application.**
  - **If any FIU submitted application will fall under this reassignment category the Division of Research will work with the affected PIs to review available options.**
  - **Additional details at:**  
**<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-007.html>**

# Division of Research Pre Award Update

## ■ Federal Shutdown Impact on Applications NSF Impacts -- Deadlines

<u>Deadlines Moved to 11/6/13</u>	
12-120 Supplemental Funding Opportunity for Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) - Phase IB Option	12-584 ADVANCE: Increasing the Participation and Advancement of Women in Academic Science and Engineering Careers (Letter of Intent)
11-509 Research Experiences for Teachers (RET) in Engineering and Computer Science	12-564 Louis Stokes Alliances for Minority Participation (LSAMP) – Bridge to the Doctorate proposals
13-574 Networking Technology and Systems: Japan US Network Opportunity (NeTS: JUNO)	13-568 Doctoral Dissertation Improvement Grants in the Directorate for Biological Sciences
11-692 Advanced Technological Education	10-1264 Algebra and Number Theory
13-543 Smart and Connected Health	
<u>Deadlines Moved to 11/12/13</u>	
11-547 SBE Doctoral Dissertation Research Improvement Grants – Sociology DDRIG proposals (can also be submitted directly to NSF 98-1331 on same date)	13-579 Computing and Communication Foundations (CCF): Core Programs -- Note change to a submission window from November 1-12
13-580 Information and Intelligent Systems (IIS): Core Programs -- Note change to a submission window from November 1-12	13-581 Computer and Network Systems (CNS): Core Programs - - Note change to a submission window from November 1-12
13-578 Secure and Trustworthy Cyberspace -- Note change to a submission window from November 1-12	

# Division of Research *Pre Award Update*

## ■ **Federal Shutdown Impact on Applications** **NSF Impacts -- Deadlines**

<u>Deadlines Moved to 11/13/13</u>	
11-7246 Physics of Living Systems	13-569 Advancing Digitization of Biodiversity Collections
12-564 Louis Stokes Alliances for Minority Participation (LSAMP) – Broadening Participation in STEM Education Research proposals	13-582 Management and Operation of the National Optical Astronomy Observatory (Letter of Intent)
12-564 Louis Stokes Alliances for Minority Participation (LSAMP) – LSAMP Alliance proposals	13-604 Research on Education and Learning (Letter of Intent)

<u>Deadlines Moved to 11/20/13</u>
13-575 Partnerships for Innovation: Accelerating Innovation Research - Technology Translation (note: Requirement for Letter of Intent has been deleted, due date for submission of full proposals is extended until November 20, 2013)

- **Federal Shutdown Impact on Applications**  
**NSF Impacts – Proposal Review Process**
  - **All panels that were canceled due to the shutdown will be rescheduled to a later date, unless a different direction is determined by the cognizant Program Officer.**
  - **Ad hoc reviews that could not be submitted via FastLane during the shutdown may now be submitted via the FastLane Proposal Review function.**
  - **In many cases, the NSF will not be able to meet their customer service standard of informing applicants whether their proposals have been declined or recommended for funding within six months of the deadline or target date, or receipt date, whichever is later.**

Division of Research  
*Pre Award Update*

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- **Federal Shutdown Impact on Applications**  
**NSF Impacts – Award Process**
  - **Issuance of New Grants and Cooperative Agreements** Grants or cooperative agreements as well as Continuing Grant Increments (CGIs) impacted by the shutdown will be awarded based on a schedule that will be determined as early as practicable.
- **Additional details at**  
**<http://www.nsf.gov/bfa/dias/policy/postshutdown.jsp>**

# Division of Research *Pre Award Update*

## ▪ **Federal Shutdown Impact on Applications NASA Impacts – Deadlines**

Responses to the RFIs on Sustainable Land Imaging Architecture Study and also Lessons Learned from Recent Planetary Science Division AOs are now both due by November 1, 2013.	NASA Astrobiology Institute CAN Step-1 proposals are now due Monday, November 18, 2013
Mars 2020 NOI are now due Monday, November 4, 2013	Earth Venture Instrument-2 (Appendix M of SALMON-2) proposals are now due November 25, 2013
Appendix C.7 of ROSES 13, Outer Planets Research proposals are now due Friday, November 15, 2013	NASA Astrobiology Institute CAN Step-2 proposals are now due Wednesday, February 19, 2014
Appendix A.11 of ROSES 13, Ocean Vector Winds Science Team, proposals are now due Friday, November 15, 2013	Mars 2020 proposals are now due Wednesday, January 15, 2014

▪ **Additional details are available at**  
**<http://science.nasa.gov/researchers/sara/grant-solicitations/>**

## Division of Research *Pre Award Update*

### ▪ ePRAF Guidance on F&A Split if awarded Question # 3

3 Will this proposal span across multiple colleges? If so, please check 'Yes' and indicate F&A percentage split between colleges in the comment box.

Yes  No

- The determination of F&A split amongst colleges for the F&A that would be returned to the colleges by the Vice President for Research is one that needs to be made amongst the collaborating colleges at proposal stage.
- The agreement should be documented in the comment box next to the question.
- DOR does not get involved in this process.
- TBD at Award Stage is not an acceptable response

## Division of Research *Pre Award Update*

- **ePRAF Guidance on F&A Split if awarded Question # 3**
  
- **A couple of common arrangements include:**
  - **Equal distribution amongst all colleges and**
  
  - **Proportionate distribution based on salaries and wages charged to the project by the respective units**
  
- **Please note that distribution of F&A is at the discretion of the Vice President for Research and any percentages stated in the ePRAF refer only to instances when F&A is returned to the colleges.**
  
- **The agreement in the ePRAF between the parties does not mandate the Division of Research to return F&A to any unit if it is determined that there will be no F&A distribution by the Vice President for Research.**

# Division of Research

## *Budget & Cost Analysis Update*

### ▪ **EFFORT REPORTING**

- Use this time in-between certification periods to check effort cards and resolve any issues before the time sensitive certification period starts. Effort cards can be monitored year round.
- We have purposely delayed the kickoff of pre-review and certification for summer 2013 as we work thru some system changes. Once these updates are finalized, we will kick off summer.
- As a result, summer 2013 and fall 2013 certifications will be possibly done back to back or concurrently, depending on the timing. We will notify users via emails once kick off begins.
- If you have questions or concerns, please contact [ecrt@fiu.edu](mailto:ecrt@fiu.edu) or Desiree Mesa 305-348-8308

### ▪ **F&A RETURN**

- College F&A Returns posted in Sept for the returns earned from Jan-Jun 2013.
- PI F&A Returns from July 2012 thru June 2013 have been communicated but are NOT available yet for spending.

### ▪ **ACTIVITY NUMBERS IN FUNDS 651/652 CONVERTING TO PROJECT IDS**

- As initially mentioned in the April meeting, the Division of Research is working with Controller's, UTS, Office of Financial Planning, and Academic Affairs to implement a completely new way of managing research F&A and miscellaneous accounts (funds 651 and 652).
- In the next few months, we will be rolling out non-sponsored project ID's in place of activity numbers. Under the current accounting structure, one activity number may have multiple independent balances at the cost PID level.
- With this new structure, balances will be available in individual project ID's and will not be shared with others at a cost PID level.
- If you'd like to volunteer to help with testing for your area, please see me after the meeting.

# Division of Research

## Research Integrity Update

- **IRB, IACUC & IBC Website Updates**
  - More User-Friendly, Expanded Content, Announcements

### IRB

[Obtaining Approval](#)

[Managing an Approval](#)

[Training & Education](#)

[Quality Assurance & Improvement Program](#)

[Committee Meetings](#)

[Western IRB \(WIRB\)](#)

[For Board Members](#)

[For Research Participants](#)

[Topaz Online Submissions](#)

[Policies & Procedures](#)

[Forms](#)

[FAQs](#)

## Obtaining Initial FIU IRB Approval

The following steps are provided to assist investigators with submitting applications to the FIU IRB for review and approval.

***Special Note:*** Studies involving a clinical trial and/or FDA-regulated drugs or significant risk devices need to be submitted through the Western IRB (WIRB) approval process (not the FIU IRB approval process). Separate instructions for WIRB submissions are available on our [WIRB web page](#).



### Step 1: Determine if You Need IRB Review

IRB approval is required for all "research" that involves "human subjects".

- **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge.
- **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction with the individual, or 2) Identifiable private information.

[Information on Determining if IRB Review is Needed](#)



### Step 2: Complete the CITI Online IRB Training Course

All research personnel that will be engaged in conducting research with human subjects (including analysis of data) are required to complete the CITI Online IRB Training Course.

[Instructions to Sign Up for CITI Online IRB Training](#)



### Step 3: Determine the Review Type

All research protocols involving human subjects will fall under one of the following three categories of review:

- **IBC Online CITI Training**
  - CITI Biosafety Training Course
  - EH&S Training Certificates – No Longer Accepted
  - Training Certificate Good for 3 Years
  
- **IACUC Online CITI Training**
  - CITI Working w/ the IACUC Course includes Animal Safety
  - Animal Safety Course from EH&S – No Longer Needed
  - Training Certificate Good for 3 Years
  
- **IRB Online CITI Training**
  - CITI Human Subjects Research Training
  - NIH IRB Training – No Longer Accepted
  - Refresher Training Required every 3 Years



Division of Research  
*Research Integrity Update*

- **Quality Assurance & Improvement Program**
  - Created to Strengthen Human Research Protections
  - Demonstrate FIU's Commitment to Continuous Improvement in Research Compliance
  - Acquire Information Necessary to Enhance Protections and Confidentiality Procedures
  
- **Mechanisms of Review**
  - Randomly Selected Reviews of Projects
  - Directed and For-Cause Reviews of Projects
  
- **Additional Information**
  - <http://research.fiu.edu/irb/pages/qa-qi-program.html>
  - Donna J. Simonovitch, ORI QA/QI Coordinator



# Division of Research Research Integrity Update

## TOPAZ Electronic Protocol Application System Author Role

Human Protocols | Main Protocols Rodriguez, Barbara

Create Original Protocol | Save Copy Compare Presubmit Submit Signoff Reports

**Outline** 47 1 53 0  
Filter Outline 1.2 +

- + 1 INSTRUCTIONS
- + 2 ADMINISTRATIVE
- + 3 REVIEW TYPE
- + 4 EXEMPTION REQUIREMENTS
- + 5 PROJECT OVERVIEW
- + 6 SUBJECT POPULATION
- + 7 SUBJECT RECRUITMENT
- + 8 METHODS & ACTIVITIES
- + 9 BENEFITS & RISKS
- + 10 INFORMED CONSENT
- + 11 CONFIDENTIALITY & PRIVACY
- + 12 AFFIRMATION OF COMPLIANCE
- + 13 OFFICE USE ONLY

**IRB Exemption Form** 1.2 -

Verdana 12 B I U

**Department**  
Select the Principal Investigator's department.

**Principal Investigator**  
Provide the name of the Principal Investigator. Students cannot serve as the Principal Investigator.  
**Please Note:** Undergraduate/Graduate student research projects are required to have an FIU faculty member with [Graduate Faculty Status or Dissertation Advisor Status \(DAS\)](#) serving as the Principal Investigator. Student researchers need to be listed separately in the "Protocol Associates" section below. Exceptions to this policy may be judged appropriate under particular circumstances and those exceptions shall be determined by the Division of Research.

Rodriguez, Barbara	bllane01@fiu.edu	305-348-8316
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**Author**  
The Author is the person that is completing this application form. This is typically the same person as the Principal Investigator unless another individual is assisting with the completion of the application form (e.g., Project Coordinator).

Rodriguez, Barbara	bllane01@fiu.edu	305-348-8316
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**Protocol Associates**  
Add all FIU Co-Investigators and FIU Key Associates that will be involved in this project. The individuals selected in this section of the form will be able to view/edit this protocol and/or receive TOPAZ system email notices (depending on the assigned role). Click on the blue "?" icon to the right for more information. Please select the green "+" icon to the right to add the individual(s).

# Division of Research Research Integrity Update

- **TOPAZ Electronic Protocol Application System**
  - Change Principal Investigator by Selecting “Human Silhouette” Icon.

The screenshot displays the TOPAZ Electronic Protocol Application System interface. On the left is an 'Outline' panel with a search bar and a list of 13 sections, each with a plus icon and a number: 1 INSTRUCTIONS, 2 ADMINISTRATIVE, 3 REVIEW TYPE, 4 EXEMPTION REQUIREMENTS, 5 PROJECT OVERVIEW, 6 SUBJECT POPULATION, 7 SUBJECT RECRUITMENT, 8 METHODS & ACTIVITIES, 9 BENEFITS & RISKS, 10 INFORMED CONSENT, 11 CONFIDENTIALITY & PRIVACY, 12 AFFIRMATION OF COMPLIANCE, and 13 OFFICE USE ONLY. The main area is titled 'IRB Exemption Form' and features a rich text editor toolbar. The 'Principal Investigator' section contains instructions and a 'Please Note' regarding student researchers. Below the text is a form with three input fields: a name field containing 'Rodriguez, Barbara', an email field containing 'bllane01@fiu.edu', and a phone field containing '305-348-8316'. A yellow 'Select Staff' button is positioned above the name field. A blue arrow points from the 'Human Silhouette' icon in the outline to the name field. A second identical form is visible below the first one.

# Division of Research

## Research Integrity Update

- **TOPAZ Electronic Protocol Application System**
  - Quick Filter Feature
  - Total Records Drop Down

The screenshot shows the 'Select Staff' dialog box in the TOPAZ system. The dialog box has a 'Quick Filter' input field at the top. Below it is a table with the following columns: Last Name, First Name, and Middle Name. The table contains 15 rows of staff members. At the bottom of the dialog box, there is a pagination control showing 'Page 1 of 15' and '1436 total record(s) found.' A red circle highlights this text. The background shows the main interface with a navigation menu on the left and a user profile in the top right corner.

Last Name	First Name	Middle Name
Abad	Carla	
Abal	Abdulaziz	
Abdelghani	Mohamed	
Abdel-Moty	Alma	R
Abdool-Ghany	Faheema	
Abdullahi	Abubakar	
Acuna	Juan	
Adam	Thomas	
Addy	Dawn	
Adjouadi	Malek	
Admin	Admin	
Agoulnik	Alexander	
Agoulnik	Irina	
Agudelo	Marisela	

# Division of Research Research Integrity Update

## TOPAZ Electronic Protocol Application System

The screenshot displays the TOPAZ Electronic Protocol Application System interface. The main window title is "Human Protocols" with a "Main Protocols" breadcrumb. The user is identified as "Rodriguez, Barbara". A "Select Staff" dialog box is open, featuring a search input field containing "Gray". Below the search field is a table with the following data:

Last Name	First Name	Middle Name
Grayson	Christopher	

The dialog box includes a "Filter" icon (funnel) and an "Export Grid" icon (calendar with arrow). At the bottom of the dialog, there are navigation controls (back, forward, search, refresh), a page size dropdown set to "1000", and the text "Page 1 of 2. 1436 total record(s) found." The "OK" and "Cancel" buttons are located at the bottom right of the dialog. The background interface shows an "Outline" panel on the left with a list of protocol steps (1-13) and a right-hand panel with various icons and text.

# Division of Research Research Integrity Update

## TOPAZ Electronic Protocol Application System

The screenshot displays the TOPAZ Electronic Protocol Application System interface. At the top, the user is logged in as "Rodriguez, Barbara". The main navigation area includes "Human Protocols" and "Main Protocols". A toolbar contains icons for "Create Original Protocol", "Save", "Copy", "Compare", "Presubmit", "Submit", "Signoff", and "Reports".

The "Outline" panel on the left lists the following sections:

- 1 INSTRUCTIONS
- 2 ADMINISTRATIVE
- 3 REVIEW TYPE
- 4 EXEMPTION REQUIREMENTS
- 5 PROJECT OVERVIEW
- 6 SUBJECT POPULATION
- 7 SUBJECT RECRUITMENT

The main content area shows the "IRB Exemption Form" (version 1.2). The form title is "IRB Exemption Form". The text reads:

**Principal Investigator**  
Provide the name of the Principal Investigator. Students cannot serve as the Principal Investigator.

**Please Note:** Undergraduate/Graduate student research projects are required to have an FIU faculty member with [Graduate Faculty Status or Dissertation Advisor Status \(DAS\)](#) serving as the Principal Investigator. Student researchers need to be listed separately in the "Protocol Associates" section below. Exceptions to this policy may be judged appropriate under particular circumstances and those exceptions shall be determined by the Division of Research.

At the bottom, a table lists the Principal Investigator details:

	Grayson, Christopher	graysonc@fiu.edu	305-348-8379
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# Division of Research Research Integrity Update

- **TOPAZ Electronic Protocol Application System**
  - E-Signature by Principal Investigator

The screenshot displays the TOPAZ Electronic Protocol Application System interface. The top navigation bar includes "Human Protocols", "Main", and "Protocols". The user is identified as "Rodriguez, Barbara". The main toolbar contains icons for "Create Original Protocol", "Save", "Copy", "Compare", "Presubmit", "Submit", "Signoff", and "Reports". The left sidebar shows an "Outline" of the application form sections, with "12 AFFIRMATION OF COMPLIANCE" selected. The main content area is titled "IRB Exemption Form" and features a rich text editor with a red circle highlighting the "E-Signature for the Affirmation and Acceptance of Responsibility" section. This section contains an important notice and a checkbox for the Principal Investigator's agreement. Below this, the "End of Application Form" section provides instructions for submission.

**Human Protocols** | **Main** **Protocols** Rodriguez, Barbara

Create Original Protocol | Save | Copy | Compare | Presubmit | Submit | Signoff | Reports

**Outline**

- Research Objectives
- Location of Research
- 7 SUBJECT RECRUITMENT
  - Recruitment/Advertising Process (Attachment)
  - Participant Compensation or Incentives
- 8 METHODS & ACTIVITIES
  - Explanation of Methods & Activities (Attachment)
  - Types of Activities
- 10 INFORMED CONSENT
  - Informed Consent in Exempt Research
- 12 AFFIRMATION OF COMPLIANCE
  - Affirmation of Compliance and Acceptance of Responsibility
  - E-Signature for the Affirmation and Acceptance of Responsibility

**IRB Exemption Form**

Verdana 12 B I U

**E-Signature for the Affirmation and Acceptance of Responsibility**

**Important:** Only the Principal Investigator is permitted to provide the affirmation below, since an e-signature is required. Therefore, if you are completing this application on behalf of the Principal Investigator, you will need to log out of the system and then ask the Principal Investigator to login and complete this affirmation.

Additional instructions are available for the Principal Investigator by clicking the blue "?" help icon to the right.

As the Principal Investigator, I agree with the affirmation and accept these responsibilities.

**End of Application Form**

At this point, you should complete the following steps to submit your protocol:

1. Save your application.
2. Click the "Submit" button at the top of this page.
3. Click the "Set Status" button in the bottom corner of the the popup window.
4. You will immediately receive an email notice, which confirms that you have successfully submitted your

- **AAALAC Accreditation**

- Stands for “Association for Assessment and Accreditation of Laboratory Animal Care”
- AAALAC International is a Private, Nonprofit Organization
- Gold Standard in Animal Care
- Enhance Funding Opportunities
- Demonstrate our Commitment to Responsible Animal Care and Use
- Site Visit - November 2013



Association for Assessment and Accreditation  
of Laboratory Animal Care International

- **Occupation Health & Safety Program (OHSP)**
  - The IACUC is working in conjunction with EH&S to ensure that all personnel that come into contact with animals are risk assessed.
- **OHSP Stages**
  - Stage 1 – Enrollment: Complete the Form A – Risk Assessment Form for Hazardous Agents and Animal Contact.
  - Stage 2 – Evaluation: EH&S reviews Form A and provides the participant with the Form B – EH&S Recommendations.
  - Stage 3 – Medical Surveillance: If deemed necessary, additional medical surveillance may be required. If so, Medical Questionnaire will need to be completed and given to medical provider for evaluation.
- **Any questions, please contact EH&S at [ohsp@fiu.edu](mailto:ohsp@fiu.edu).**



Questions?