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VPRS Administrative Updates

September 27, 2022

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Agenda

- ORA Leadership Updates
- ORA Post-Award Restructure
- Ancillary Review Reminders
- IBISResearch Proposal Information Accuracy
- Jackson ONENESS Update
- Grants.gov Unavailable
- NIH Forms E and H
- Research.gov Updates
- Award Close Out Time Frame Reminders
- RQA Transition
- New IRB system
- AAHRPP reaccreditation update/upcoming site visit
- Huron Solutions & New Intake Report Form
- Increased Enforcement by FDA and NIH
- Civil Penalties Assessed by FDA

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ORA Leadership Updates

Laura Kozma

Associate Vice President
Research Administration

Edwin Bemmel Leaving UM

- Edwin Bemmel, Executive Director of Research Administration who leads Post-Award has accepted a position as Associate Vice President, Research, Grants and Contracts at Emory University.
- Effective immediately, list “Laura Kozma, Associate Vice President, Research Administration” as the Financial Officer on all documents where Edwin would normally be listed.
- If you have any questions or concerns, please contact me (lkozma@miami.edu).

Edwin Bemmel
Executive Director, Research Administration

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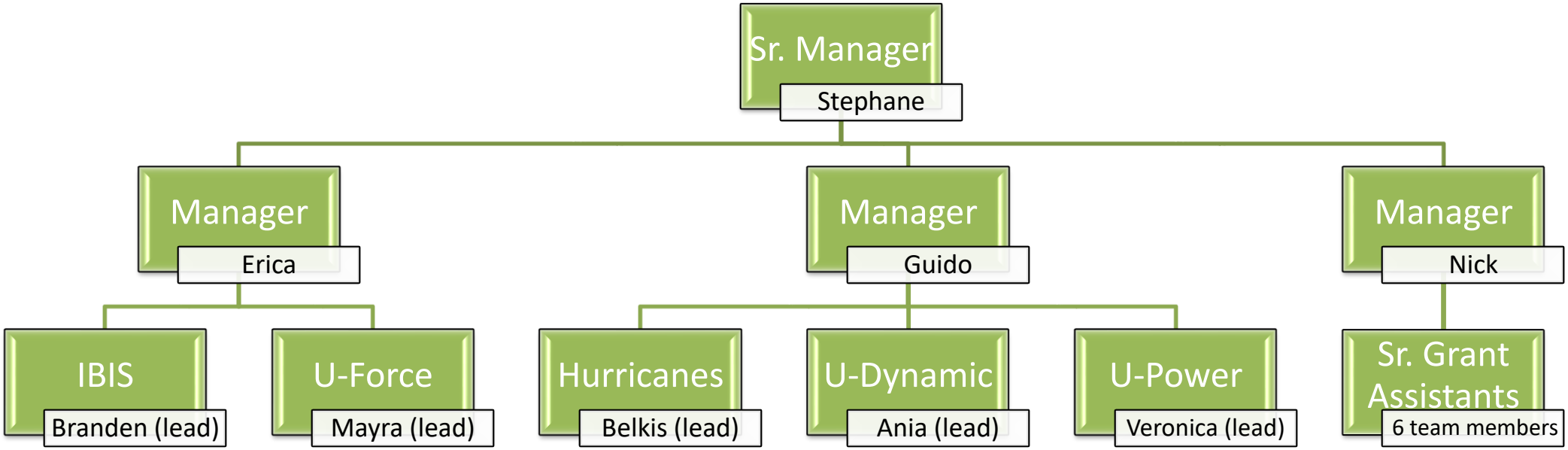
ORA Post-Award Restructure

Laura Kozma

Associate Vice President
Research Administration

ORA Post-Award Restructure



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Ancillary Review Reminders

Laura Kozma

Associate Vice President
Research Administration

Ancillary Review Reminders

- Make sure you are sending to the right person
- Include all relevant documents (cost sharing form, supporting letters, etc.)
- Route early!

This job aid provides information on how to submit an ancillary review in IBISResearch.

How to Submit an Ancillary Review ›

Ancillary Review Guide ›

Ancillary Review Matrix ›

F&A Waiver/Cost Share Form ›

Last Revised: 06/01/22

IBISResearch

Ancillary Review Matrix Grants

Ancillary Review Type	Initiator	Approver	Response Required?	Required Documents/Information	Person or Organization	Selection
Compliance (COI)	ORA	VPR/EDR	Y	Read and follow the Conflict of Interest in Research Policy. • Include a letter disclosing the potential conflict • Attach to Ancillary Review	N/A	This is for SBIR/STTR only and generated by ORA.
Cost Share	Department	VPR/EDR	Y	Read and follow the Cost Sharing Policy. • Completed Cost Share Budget • Justification letter for the Cost Share • **NEW REQUIRED:** Cost Share Form *(must be included on attachments)* **Note: When requesting cost share voluntary or mandatory please include sponsor details in addition to the waiver and NEW required cost share form in the attachments.*	Person	Gables or RSMAS: Laura Kozma Medical: Patricia Wahl for Dr. Schulman
Department Chair/Center Director (as PI)	Department	Dean/Dean Designee	Y	• Include a justification comment for approval in the ancillary review. ** Note: If an approver noted here is the PI, the Proposal requires approval from a higher level.*	Person	Medical: Carl Schulman RSMAS: Roni Avissar A&S: Leonidas Bachas Engineering: Fabrice Manns
Export Controls	Department/ORA	William Collins	Y	Read and follow the Export Control Policy. • Letter disclosing export control concerns • Attach to Ancillary Review	Person	William (Bill) Collins
Indirect Cost Waiver	Department	VPR/EDR	Y	Read and follow the F&A Waiver Policy. • Justification letter • **NEW REQUIRED:** Indirect Cost Waiver Form *(must be included on attachments)*	Person	Gables or RSMAS: "Provosts Office" (CC00372) on the Organization Medical: Carl Schulman
Late Proposal Submission	Department	VPR/EDR	Y	Required documents/Information: • Read and follow the Proposal Exception Process • Include a justification and supporting documentation • Request must be submitted **in advance** of the ORA deadline	Person	Medical, Gables and RSMAS: Laura Kozma
Nepotism/Familial Relationship	Department	VPR/EDR	Y	Read and follow the Nepotism in Research Policy. • Include a Nepotism Memo • Attach to Ancillary Review	Person	Medical, Gables and RSMAS: Laura Kozma

https://www.research.miami.edu/systems/education-and-resources/job-aids/indexhtml

IBISResearch Proposal Information Accuracy

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Laura Kozma

Associate Vice President
Research Administration

IBISResearch Proposal Information Accuracy

- Accurate data is everyone's responsibility
- Review prior to submitting to ORA
- Consult with the PI
- Inform ORA of inaccurate data

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Jackson ONENESS Update

Laura Kozma

Associate Vice President
Research Administration

Jackson ONENESS Update

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Jackson
HEALTH SYSTEM

ONENESS

Mission Statement

To advance research through a collaborative effort, built on a shared foundation of diverse and unique patient data and resources integral to the broader missions of UHealth and JHS.

Clinical Research Workgroup

Streamline Process

Reduce Turnaround Times

Maximize Enrollment

Highlighted Achievements

- ✓ Taskforce created
- ✓ End to end process documentation
- ✓ Initiatives identified
- ✓ UM reorganization of contracting team
- ✓ Inclusion of UM in CRRC

Current Initiatives

Short Term	**ClickUp**	Provide transparency about the status of clinical trials pending activation at JHS by implementing a software solution
	Confidentiality Agreements	Leverage the master agreement to reduce the number of confidentiality agreements required
	UM Budget Structure	Evaluate and reorganize the budget team at UM to streamline budget and coverage analysis development
Medium Term	**DEF Initial Streamline**	Complete DEF process in parallel with existing processes to reduce burden
	Signature Process	Review and streamline signature process
	Regulation Alignment	Determine where UM and JHS are not aligned on interpretation of regulations, draft position papers and agree on interpretation
Long Term	**Single Budget Development**	Create budget and coverage analysis as a single unit utilizing master rate sheets and unified decision making
	DEF Overhaul	Evaluate current master agreement, needs of each institution to eliminate all unnecessary steps, amend the master agreement and streamline process
	Feasibility	Create JHS feasibility review utilizing CRRC and new budget process to decrease review turnaround times

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Administrative Updates

Tonya Sautier

Sr. Business Officer, Finance and Administration, OVPRS

New Hires

Name	Title
Amanda Monzon	Bookkeeper

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ORA Leadership Updates

K. Brandon Strickland, J.D.

Executive Director, Research Administration

Brandon Strickland New Hires

Name	Title
Evgueni Trepaline	Contract and Grants Analyst
Jairo Lazo	Contract and Grants Analyst
Eliana Valdes	Contract and Grants Analyst
Amy Gonzales	Contract and Grants Analyst
Leydis Sales	Contract and Grants Officer
Holly Kasem-Beg	Associate Director Research Administration
Deborah Musgrove	Associate Director Research Administration

Departures

Name	Title
Alonso Antunez de Mayolo	Contract and Grants Analyst
Cristina Serafini	Contract and Grants Officer
Magalys Hernandez	Contract and Grants Officer
Marco Chin	Contract and Grants Analyst

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Grants.gov Unavailable

K. Brandon Strickland, J.D.
Executive Director, Research Administration

Grants.gov Unavailable

- Planned outage: September 23, 2022 at 12:01 AM ET to September 29, 2022 at 11:59 PM ET.
- Consider this when planning a proposal submission through Grants.gov.
- During the outage you will not be able to create a new proposal for S2S submissions
- Work can be continued on proposals where the FOAs were downloaded prior to Grants.gov outage, but the proposal must be created with the FOA prior to the downtime
- NIH and AHRQ due dates that fall on or between September 22 and September 30, 2022 will move to October 3, 2022.

Grants.gov Unavailable

Grants.gov Cloud Migration

Overview

Training environment downtime: **August 30 – September 19, 2022**

Production environment downtime: **September 23 – 29, 2022**

Grants.gov's maintenance schedule is available here:
https://www.grants.gov/web/grants/support/calendar.html

- Grants.gov's cloud migration is part of a 4 - 5 year effort to modernize the Grants.gov system.
  - After successful migration, Grants.gov will focus efforts on:
    - ❑ UI updates that support a modern and responsive design driven by human centered activities
    - ❑ Redesign web services to transition to REST API from SOAP services (**targeting 2023**)
- Grants.gov has been providing updates about the cloud migration and system downtime to the Applicant and Grantor communities through listservs, the Grants.gov blog, and banners on the Grants.gov site.

Grants.Gov Cloud Migration

Impact to SF424 and other systems connecting to Grants.gov

✗ Users will not be able to do the following during the Grants.gov downtime:

- Download or update FOAs
- Submit SF424 applications
- Retrieve status updates on submitted applications

✓ Users will be able to do the following during the Grants.gov downtime:

- Create SF424 applications from FOAs that were downloaded prior to the Grants.gov system going offline
- Edit existing SF424 applications
- Validate SF424 applications
- Generate the PDF for SF424 applications

Grants.Gov Cloud Migration

Questions from the community

Q If a user starts an application prior to the Grants.gov system going offline, will the data still be available when the system comes back online?

A Yes, the data will still be available as it is entered, edited, and stored in the Huron system, not the Grants.gov system.

Q If an SF424 application is submitted before the downtime, will the application remain intact when the system comes back online?

A Yes, the reason that Grants.gov will be down for the extended period of time is to ensure that everything migrates over successfully.

Q If something happens and the application is lost, how will users be able to tell, and will the applications be allowed to be submitted again without penalty?

A If there is a problem with an application related to the migration, users will need to contact the Grants.gov and federal agency help desks for guidance on what steps to take next.

Grants.Gov Cloud Migration

Questions from the community (continued)

Q Have agencies besides NIH extended their deadlines for submissions that have deadlines during the downtime?

A Grants.gov has been reaching out to the agencies to inform them of the downtime so that they can adjust their deadlines if they fall within the migration period, but there is not a list of agencies contacted or a list of adjusted deadlines available.

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NIH Forms E and E

K. Brandon Strickland, J.D.
Executive Director, Research Administration

NIH Adjusted Deadlines

Overview

NIH has adjusted due dates to accommodate Grants.gov downtime to **October 3, 2022**.

Guidance for adjusted deadlines can be found here: https://nexus.od.nih.gov/all/2022/08/03/extended-grants-gov-downtime-impacts-september-22-30-due-dates/

- NIH has adjusted due dates that fall during the Grants.gov migration period, September 22-29, 2022, to an extended due date of October 3, 2022.
- Be sure to read the NIH announcements regarding the Grants.gov downtime and the extended due date as there are caveats.

NIH FORMS-H Update

Overview

NIH will begin posting FORMS-H application packages **October 25, 2022**, for submissions due on or after **January 25, 2023**

Details for NIH FORMS-H can be found here:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-195.html

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- The FORMS-H update is being implemented to support the 2023 NIH Data Management and Sharing Policy. You can find details about this policy here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html
- During the transition period from FORMS-G to FORMS-H, both sets of forms will be active, and the user will need to select the correct form set based on the due date for the opportunity.
  - For due dates before January 25, 2023, use FORMS-G application packages
  - For due dates on or after January 25, 2023, use FORMS-H

NIH FORMS-H Update

Impact to SF424

- SF424 will need to be upgraded to SF424 10.5.0 and 10.5.1
  - SF424 10.5.0 will include the following updated forms:
    - PHS Career Development Award Supplemental Form V6.0
    - PHS 398 Research Plan V5.0
    - PHS 398 Research Training Program Plan V5.0
    - PHS Fellowship Supplemental Form V7.0
  - SF424 10.5.1 will include the following updates:
    - Updates to the forms where only the OMB expiration date is being updated (waiting on OMB approval). See https://grants.nih.gov/grants/electronicreceipt/files/high-level-form-change-summary-FORMS-H.pdf for a high-level summary of changes to the forms.
    - Text updates to the following forms:
      - PHS Cover Page Supplement V5.0
      - PHS 398 Modular Budget V1.2

NIH Forms Retirement Update

NIH Forms Retirement Update

Overview

NIH will retire form versions prior to FORMS-E in ASSIST on **August 31, 2022**

Details for the retirement of these forms can be found here:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-182.html

- Form versions prior to FORMS-E will be retired in ASSIST as the government has fully transitioned from DUNS to UEI.
- Applicants will not be able to copy data from retired form versions to applications that use active FORMS-G forms.

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Research.gov Updates

K. Brandon Strickland, J.D.
Executive Director, Research Administration

NSF Fastlane to Research.gov Transition

Overview

Grants.gov integration will migrate from Fastlane to Research.gov on **October 31, 2022**.

Last day to submit new proposals in Fastlane will be **January 27, 2023**.

Last day to submit proposal file updates, budget revisions, or download submitted proposals in Fastlane will be **September 29, 2023**.

- NSF is in the final phases of fully transitioning to Research.gov and retiring Fastlane.
- Fastlane will be removed as a submission option in all solicitations in January 2023.
- Applications submitted through Grants.gov will begin going to Research.gov instead of Fastlane.

NSF Fastlane to Research.gov Transition

Grants.gov integration

- Proposals submitted through Grants.gov on or after October 31, 2022, will be available in Research.gov for file updates and budget revisions.
- Proposals submitted through Grants.gov prior to October 31, 2022, will be available in Fastlane for file updates and budget revisions until September 29, 2023.
- NSF will continue to pick up applications from Grants.gov every 5 minutes.
- Submissions through Grants.gov will go through the following 3 steps:
  - Data will be converted to data elements accepted by Research.gov.
  - Data will go through a pre-check process.
  - Data will go through a post-check process.

NSF Fastlane to Research.gov Transition

Grants.gov integration pre-check process

- The pre-check process checks for the minimum requirements to be accepted in the Research.gov system.
  - If the application does not pass the pre-check process, the applicant will be notified by email and will be required to correct the application in the source system (Huron SF424, Grants.gov, etc.) and then resubmit the application.
- The pre-check process checks for the following:
  - If the FOA has a due date more than 1 year from the current date.
  - If the FOA is on the solicitation exclusion list for Research.gov.
  - If the solicitation has multiple UOCs and a UOC is incorrect. If there is only one UOC, the system will auto-correct the UOC.
  - If the UEI entered for the primary organization is not valid.
  - If the NSF ID for the PI is not valid.

NSF Fastlane to Research.gov Transition

Grants.gov integration pre-check process

- The pre-check process checks for the following (continued):
  - If prime organization is a P-type institution, but the proposal type is not Fellowship or if the prime organization is not a P-type institution, but the proposal type is Fellowship.
  - If the zip file received from Grants.gov is empty or has any attachments that are 0 bytes.
  - If the zip file received from Grants.gov fails to open.
  - If the zip file cannot be retrieved from Grants.gov.
  - If the XML is malformed, the data mapping cannot be completed.

NSF Fastlane to Research.gov Transition

Grants.gov integration post-check process

- The post-check process happens when the application has passed the pre-check process and checks for Research.gov compliance validations.
  - If the application does not pass the post-check process, the PI, SPO, and AOR will be notified by email and the submitting organization will be required to correct the application in Research.gov and then resubmit the application.
  - An application that fails the post-check process can be found in the in-progress list in Research.gov and will be considered as a pending submission.
- The post-check process checks for the following:
  - If the application fails any of the validations in the current validations found here:

    https://www.nsf.gov/bfa/dias/policy/autocompliance.jsp
  - If FOA has the nearest due date that is in the past.

NSF Fastlane to Research.gov Transition

Email notifications for Grants.gov submissions

- NSF will send the following email notification for a successful submission:
  - Subject line will be "Proposal XXXXXX Submitted" and the notification will include the following details.
    - Confirmation that the submission was successful with proposal number
    - Grants.gov ID
    - Date/time of submission
    - Proposal title
    - Date/time received by NSF
    - Organization
    - SAM legal business name
    - Guidance on where to access the application
  - This email notification will be sent to the PI, co-PI(s), OAU(s), AOR associated with the prime organization.

NSF Fastlane to Research.gov Transition

Email notifications for Grants.gov submissions

- NSF will send the following email notification for a submission that does not pass the pre-check process:
  - Subject line will be “Proposal Errors Need Correction in Grants.gov” and will include the following details.
    - Grants.gov ID
    - Date/time of submission
    - Errors that need to be corrected
  - If you receive a notification with the subject line “Proposal Errors Need Correction in Grants.gov, you will need to make your corrections in the source system that submission originated from.
  - This email notification will be sent to the PI email that corresponds with the NSF ID. If the NSF ID is not valid, the email notification will be sent to the email address for the PI in the SF424 (R&R) form.

NSF Fastlane to Research.gov Transition

Email notifications for Grants.gov submissions

- NSF will send the following email notification for a submission that does not pass the post-check process:
  - Subject line will be "Proposal Errors Need Correction in Research.gov" and will include the following details.
    - Grants.gov ID
    - Date/time of submission
    - Temporary ID number
    - Proposal title
    - Organization
    - SAM legal business name
    - Guidance on where to access the application
    - Errors that need to be corrected
  - If you receive a notification with the subject line "Proposal Errors Need Correction in Research.gov, you will need to make your corrections in Research.gov.
  - This email notification will be sent to the PI, SPO associated with the primary organization, and the AOR associated with the primary organization.

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Administrative Updates

Edwin Bemmel

Executive Director, Research Administration

Edwin Bemmel New Hires

Name	Title
Andres Quinta	Sr. Grant Assistant
Stacy Machado	Grant Accountant
Tatyana Dauphin	Sr. Grant Assistant
Xiomara Morales	Grant Accountant

Edwin Bemmel Promotions

Name	Title
Ania Cabrera	Sr. Grant Accountant
Isabel Samper	Grant Accountant
Veronica Wong	Sr. Grant Accountant

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Award Close Out Time Frame Reminders

Edwin Bemmel

Executive Director, Research Administration

Award Close Out Time Frame Reminders

Deadline Timeline

Direct federal (includes all awards where the funding is provided from the federal agency to the University):

Financial Reporting and Invoice Due Date:	Department close out:	ORA submission deadline date:
120 days after award/budget end date	60 days after award	90 days after award/budget end date

All non federal, and federal funding provided to the University through a subaward:

Financial Reporting and Invoice Due Date:	Department close out:	ORA submission deadline date:
>60 days after award/budget end date	30 days after award/budget date	60 days after award/budget end date
60 days after award/budget end date	30 days after award/budget date	45 days after award/budget end date
45 days after award/budget end date	15 days after award/budget date	30 days after award/budget end date
30 days after award/budget end date	15 days after award/budget date	21 days after award/budget end date

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Administrative Updates

Mikki O'Neal

Associate Vice President, Research Operations & Infrastructure

New Hires

Name	Title
Alejandra Quinones	Project Manager

Promotions

Name	Title
Daniel Auguste	Data Management Coordinator
Kanchan Sakhrani	Sr. Business Systems Analyst
Kristine Martinez	Sr. Project Manager

Departures

Name	Title
Allen Mora	Executive Director, Research Intelligence & Capacity (RIC)
Leah Bamford	Project Manager

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RQA Transition

Scott Streibich
Executive Director, Research

RQA Transition

is changing

RESEARCH COMPLIANCE AND QUALITY ASSURANCE

RQA Transition

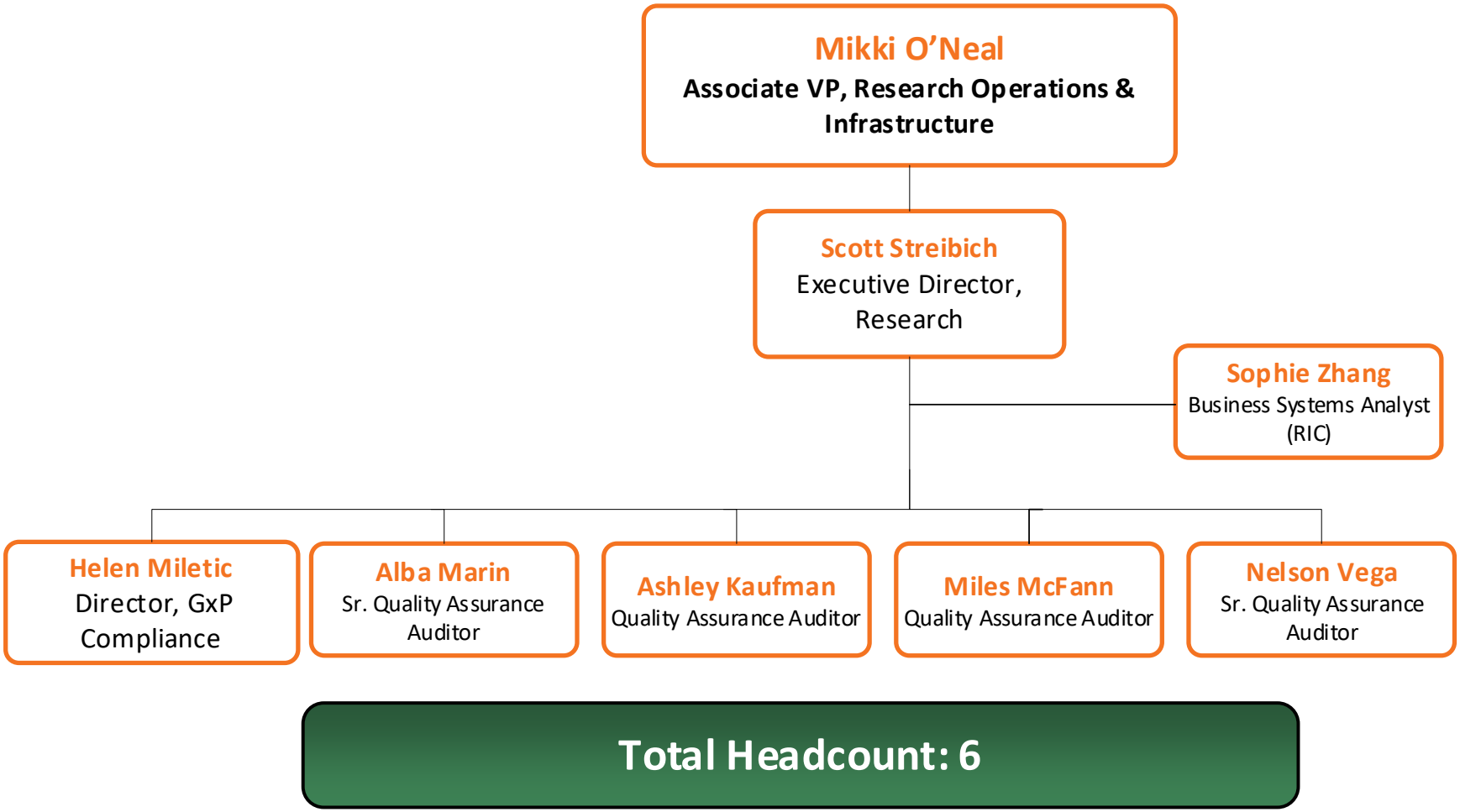
From September 27th onward

RESEARCH QUALITY ASSURANCE

Research Quality Assurance

- Reporting structure now under Research Operations and Infrastructure
- Quality Reviews Continue Unchanged
- Continuous Quality Improvement supports Collegiality and Collaboration
- Participant Safety during research conduct is still paramount
- “Partners, Not Police”
- Focus on Leveraging Data to Educate and Support GCP
- Collaboration for Continuous Improvement
  - RQA alongside study teams
  - CAPA Facilitation
  - Study Improvement Tools (e.g. Study Conduct Checklist)

Research Quality Assurance



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Administrative Updates

Kenia Viamonte

Director, Human Subject Research (HSRO)

Promotions

Name	Title
Denise Dimitriu	IRB Regulatory Analyst
Di Ding	Sr. Manager, Research Support
Karen Legagneur	Sr. IRB Regulatory Analyst
Karla Fongyee	Sr. IRB Regulatory Analyst
Vivienne Carrasco	Associate Director, Regulatory Affairs
Yaslaime Fraga	IRB Regulatory Analyst
Anthony Fernandez	Sr. IRB Regulatory Analyst
Angel Gallusi	IRB Regulatory Analyst

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New IRB System

Kenia Viamonte

Director, Human Subject Research (HSRO)

New IRB System

Purpose of re-implementation: To continue to enhance the University's commitment to a comprehensive Research Administrative System. IBISResearch was expanded to include the re-implementation of the ***IRB system with a soft go live on 8/12/2022 and official go live on 8/29/2022***. *[Access to the legacy system read-only]*

Benefits:

✓Integration with the other research solutions Grants, Agreements, Udisclose
✓Reduced administrative burden
✓Intuitive and simplified smart forms for submissions

Current Project Phase - Stabilization:

✓Issue resolution ongoing (i.e., visibility to studies)
✓Operational report build
✓IRB system enhancements (i.e. new research billing question)
✓IRB-Velos integration re-implementation go live 9/10/2022

New IRB System

To learn more about the IRB system such as system access, training material, new features, visit the OVPRS IBISResearch website: https://hsro.uresearch.miami.edu/researchers/irb-system-upgrade/index.html

For Support:

- *Human Subjects Research Office* (305-243-3195; hsro@miami.edu)
- *OVPRS Help Desk* (305-243-2314; OVPRShelpdesk@miami.edu)

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AAHRPP Reaccreditation Update/Upcoming site visit

Kenia Viamonte

Director, Human Subject Research (HSRO)

AAHRPP Reaccreditation Update

Step 1 – of application was approved with (0) revisions

Step 2 – was submitted; now only pending site visit scheduling

Site visit – anticipated for early 2023

AAHRPP® Association for the Accreditation of Human Research Protection Programs, Inc.®

Upcoming Site Visit

The accreditation process is an institution wide initiative

The site visit, specifically, draws in key partners from all areas of our Human Research Protection Program (HRPP)

- Communication, preparation and training materials
- Responsibilities are grouped by Domain

What makes it all come together is our mutual commitment and dedication to our mission and to our program. THANK YOU!

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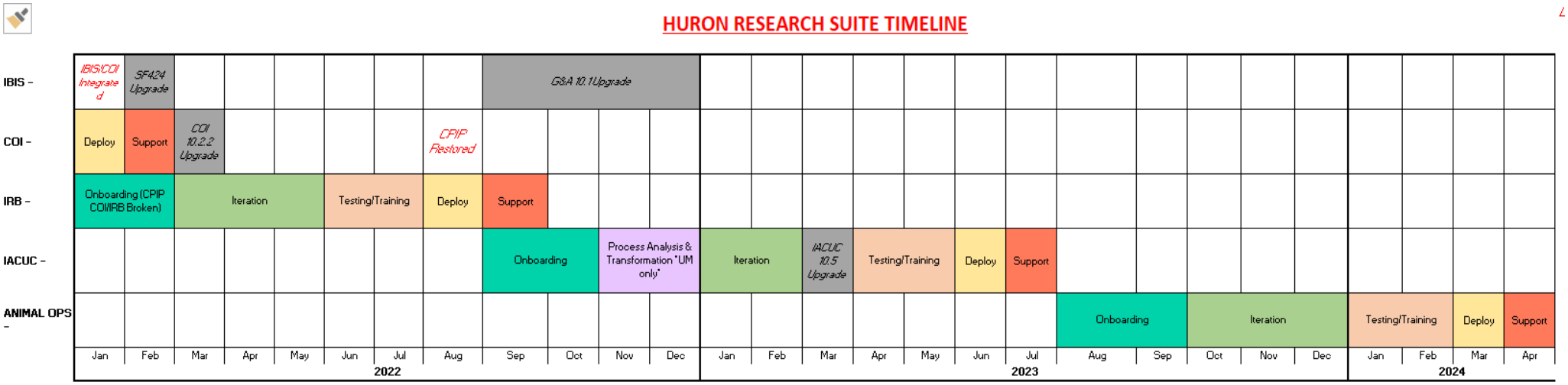
Huron Solutions and New Intake Report Form

Raquel Zamora/Kristine Martinez

Sr. Manager IT, Sr. Project Manager

Huron Solutions Roadmap



What's Next?

- Grants upgrade in the new year
- IACUC Implementation, target go live July '23
- Animal Operations Implementation, target go live April '24

New Intake Report Request Form

Purpose: This form is to be used to submit research report requests to the Office of the Vice Provost for Research and Scholarship.

Benefits: Report requests processed centrally by the team who serve as data custodians and knowledge experts of research applications (i.e., IBISResearch Grants, IRB, UDisclose, Velos), who also work intimately with the business system owners for accuracy and integrity of data delivered.

Where:

- Information Technology Self-Service Portal
  - Order Items and Services
    - Click on the Office of Research and Scholarship Data/Report Request (OVPRS)

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Administrative Updates

Yolanda Davis
Director, Clinical Research
OVPRS

New Hires

Name	Title
Letty Ginsburg	Manager, Clinical Research, Clinical Research Management and Support Office (CRMSO)

Increased Enforcement by FDA & NIH

Non-Compliance of ClinicalTrials.gov Records

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Yolanda Davis

Director, Clinical Research

OVPRS

FDA Requirements

- Register Applicable Clinical Trials (**ACT**) within 21 days of enrollment of the first participant
- Updating your ClinicalTrials.gov record within 30 days of any of the below occurring.
  - Change in responsible party (contact information, official title or the name of the individual)
  - Change in overall recruitment status
  - Change in study start date, study primary completion date, and study completion date
  - Human Subject Review Board Status
  - Name of Intervention
- Report Results for ACTs within 12 months of the last participant reaching the primary completion Date

FDA Enforcement

FDA U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE

July 26, 2021

Accuitis, Inc.
Attention: Rick Coulon
1005 Alderman Drive, #104
Alpharetta, Georgia 30005

Accuitis, Inc.
Attention: Rick Coulon
150 Technology Parkway, Suite 173
Peachtree Corners, GA 30092

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "Efficacy of ACU-D1 in the Treatment of Acne Rosacea" (NCT 03064438)
FDA Reference Number: CDER-2021-105

Dear Mr. Coulon:

The United States Food and Drug Administration (FDA) sent you a letter dated October 26, 2020, alerting you to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank operated by the National Library of Medicine (a part of the National Institutes of Health) for the above-referenced clinical trial. Accuitis, Inc., is the "responsible party"[1] for the above-referenced clinical trial, which is an "applicable clinical trial"[2] that is subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date of the applicable clinical trial, unless the responsible party has submitted a

[1] *See* section 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."
[2] *See* section 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."

FDA U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE AND E-MAIL

August 31, 2021

Andrey Petrikovets, M.D.
1513 South Grand Avenue, Suite 400
Los Angeles, California 90015

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "ICE-T Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Same Day Vaginal Pelvic Reconstructive Surgery: A Randomized Controlled Trial" (NCT03052816)
FDA Reference Number: CDER-2020-109

Dear Dr. Petrikovets:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 20, 2020, alerting you to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine (a part of the National Institutes of Health), for the above-referenced clinical trial. You are the "responsible party"[1] for the above-referenced clinical trial, which is an "applicable clinical trial"[2] that is subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date of the applicable clinical trial, unless the responsible party has submitted a certification of delay, a request for an extension of good cause, or a request for a waiver of the requirements for submission of results information.[3]

In our previous letter, we requested that you review your records for this clinical trial and submit all required results information promptly. We also stated that we intended to further review and assess this clinical trial beginning 30 calendar days after you received our previous letter, and that we might take regulatory action if we determined that you were not in compliance at that time.

[1] *See* section 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."
[2] *See* section 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."
[3] *See* section 402(j)(3)(E) of the PHS Act (42 U.S.C. 282(j)(3)(E)) and (H)) and 42 CFR part 11, subpart C for results submission requirements.

NIH Requirements

- **All of the FDA requirements plus**
- Registration of all federally funded studies that meet the below definition

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.

NIH Enforcement

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Bethesda, Maryland 20892

March 23, 2018

To: [redacted]
V. Whittemore, Program Officer

From: E. R. Rosenberg

RE: Grant #[redacted]

All National Institutes of Health funded clinical trials are to provide information to the public through the ClinicalTrials.gov web site, and keep their study details updated concluding with study final results submission (link to policy). To this end, the National Institutes of Neurologic Disease and Stroke (NINDS) conducts a quarterly database review of its funded trials for compliance.

During this review, the trial associated with grant identified above, was found to be out of compliance. You are asked to open the page to update the status and add the findings if the study is closed.

If there are questions about accessing your page for updating the information, refer to the National Library of Medicine's "frequently asked questions for Investigators" (ClinicalTrials.gov link), or contact the customer support (register@clinicaltrials.gov). For questions related to the quarterly review, contact this office at rosenbeel@nih.gov.

RESULTS

Date: July 18, 2022 at 6:51:43 PM GMT+5:30
[redacted]
Cc: ORA Award <Nihaward@med.miami.edu>, "NIDDK DK eRA Notifications (NIH/NIDDK)" <dkeranotifications@niddk.nih.gov>, "Gunter, Tommy (NIH/NIDDK) [E]" <tommy.gunter@nih.gov>
Subject: [EXTERNAL] Re[redacted]

CAUTION: This email originated from outside the organization. DO NOT CLICK ON LINKS or OPEN ATTACHMENTS you know and trust the sender.

[redacted]
Some of the Information provided in your RPPR on the study [redacted] (Enrollment of the first subject (Study Start Date)) does not match the information in Clinicaltrials.gov for the Clinicaltrials.gov identifier provided [redacted]
Please correct this at your earliest convenience in order not to delay the issuance of your award.
Thank you.
ziya

Ziya Kirkali, M.D. (he/him)
Senior Scientific Advisor
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Room # 6121, MSC 5458
Bethesda, MD 20892
Phone: 301-594-7718

MAINTENANCE

Public View

Additional Criteria:

Phase: ☐ Early Phase 1 ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ Not Applicable

Funder Type: ☐ NIH ☐ Other U.S. Federal agency ☐ Industry ☐ All others (individuals, universities, organizations)

Study Documents: ☐ Study Protocols ☐ Statistical Analysis Plans (SAPs) ☐ Informed Consent Forms (ICFs)

FDAAA 801 Violations: ☐

Results Submitted: [ ] x

Study Start: From [ ] x To [ ] x (MM/DD/YYYY)

Primary Completion: From [ ] x To [ ] x (MM/DD/YYYY)

First Posted: From [ ] x To [ ] x (MM/DD/YYYY)

Results First Posted: From [ ] x To [ ] x (MM/DD/YYYY)

Last Update Posted: From [ ] x To [ ] x (MM/DD/YYYY)

Search Help **Sort studies by:** Relevance

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Public View

Sponsor:
University Hospitals Cleveland Medical Center

Information provided by (Responsible Party):
Andrey Petrikovets, Case Western Reserve University

Study Details | Tabular View | Study Results | FDAAA 801 Violations | Disclaimer | How to Read a Study Record

Information on FDAAA 801 Violations

More Information: Notices of Noncompliance [FDA]

Available on ClinicalTrials.gov	Issued by FDA	Study Record Submitted	Notice Type	FDAAA 801 Notice
January 6, 2022	December 20, 2021	October 3, 2021	Correction Confirmed by FDA	The responsible party has corrected the violation.
September 3, 2021	August 31, 2021	December 15, 2018	Violation Identified by FDA	Failure to Submit. The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.

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Civil Penalties Assessed by FDA

Non-Compliance of ClinicalTrials.gov Records

Yolanda Davis

Director, Clinical Research

OVPRS

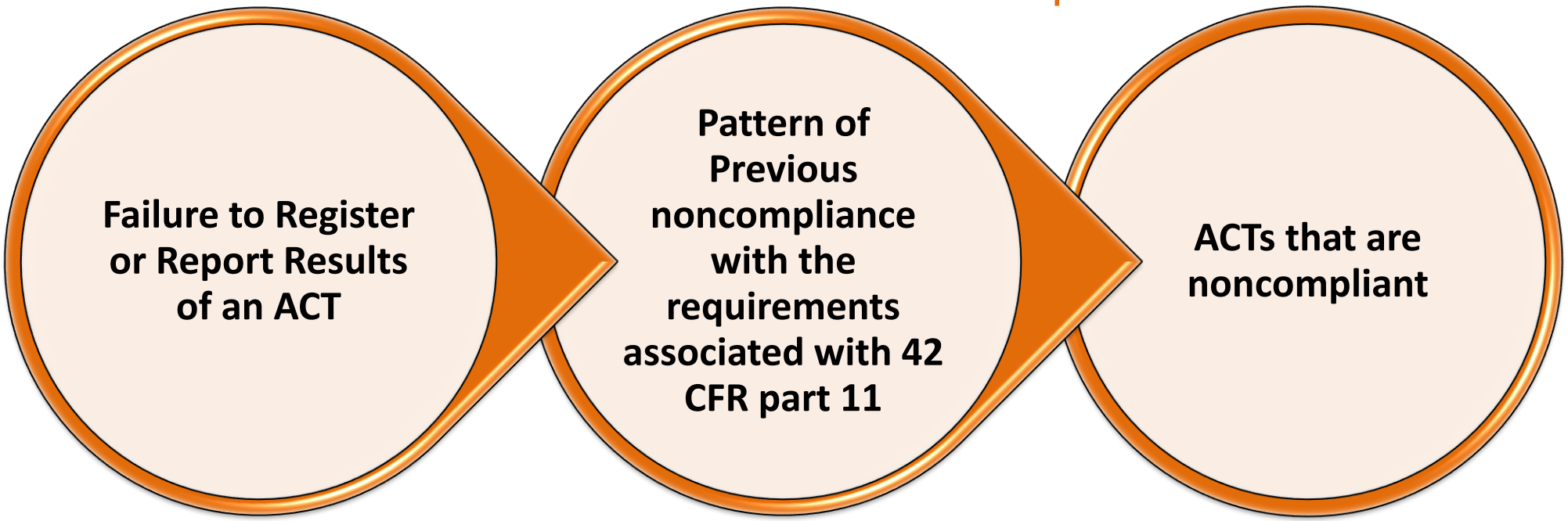
How FDA Identifies Non-Compliant Studies

FDA Bioresearch Monitoring Information (BIMO)

Evaluations of Complaints Received

What Generates a Non-Compliance Notice

What Circumstances Generate a Non-Compliance Notice?



What Amount are you Assessed?

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Open Forum Questions