Research Administration Advisory Council (RAAC)
Committee-at-Large

Tuesday, April 16, 2019, 3:00 – 4:30 pm
6050 ISR Building
Minutes

Attendees:

Meenu Baxendale – Taubman College of Art & Architecture	**Karen Durigon** – Engineering	**Becky O'Brien** – Information
Steve Beach – LSA	**Nicole Dyer** – LSA	**Carolyn Pappas** – ITS
Beth Brant – Medical School	**Linda Forsyth** – Engineering	**Nicole Sleight** – SSC
Amy Brooks – Engineering	**Stephanie Hensel** – Education	**Yvonne Sturt** – ORSP
Constance Colthorp – ORSP / Sponsored Programs	**Teresa Herrick** – SEAS	**Danielle Smith** – LSI
Kerri Cross – ISR	**Jennifer Huntington** – Business	**Debbie Talley** – Sponsored Programs
Cindy Dames – ORSP	**Meredith Ingram** – Social Work	**Michelle Terrell** – SMTD
Lauren Danridge – ACUO	**Melissa Karby** – Dentistry	**Traci Trimmer** – SSC
Lori Deromedi – UMOR	**Charlie Mattison** – ISR	**Pat Turnbull** – Dearborn
Kathy Devereux – UMOR	**David Mulder** – ORSP / Sponsored Programs	**Bryan VanSickle** – Sponsored Programs
Chris DeVries – RAAC		

Debbie called the meeting to order at 3:00 p.m.

1.   **Introductions of Members and Guests** (*Debbie Talley*)

Debbie welcomed everyone and we went around the room and phone for introductions. Debbie introduced Amy Brooks who is presenting the updates for the RAAC Training Subcommittee.

2.   **Presentation:** RAAC Training Subcommittee Update (*Amy Brooks*)   Attachment #1

Amy Brooks from the College of Engineering provided the update for the RAAC Training Subcommittee for Judy Carrillo. New members added to the Training Subcommittee:

- Amy Brooks, CoE – replaced Christine Oberly
- Lark Haunert, ORSP – replaced Tricia Haynes
- Terri Maxwell, ORSP – replaced Amy Holihan

Navigate courses and offerings:

- Budgeting Basics – Will be held on May 2 & 20. Registration is closing April 19. Had 19 participants in the last class, 96% satisfaction.
- RAMP↑ – In it's 5th cohort. There are 16 mentor/mentee pairs. The 6th cohort will begin in summer this year.

- Advanced Budgeting – Internal Proposals. Was scheduled for April 16 and 30th. The course was canceled. Had 11 participants in the last class with an overall satisfaction of 89%.
- Advanced Budgeting – Task-Based Budgets. Was scheduled for April 5 and 12th. The course was canceled. Had 15 participants in the last class with an overall satisfaction of 98%.
- Lunch & Learn – next session is scheduled for April 19 on BusinessObjects. This is the second session for BusinessObjects and the team is considering offering as part of the Navigate curriculum.
- Fundamentals – is currently underway and will end May 21. Fall course had 31 participants with a satisfaction rate of 98%.
- Uniform Guidance – Scheduled for June 4 with registration closing on May 13.
- E-ssentials Elearning Modules – Came out in November 2018 and 7 modules have been completed to-date:
    - Proposal Prep & Submission
    - Understanding Effort
    - Cost of All Kinds
    - Cost Share
    - Pre-Closeout Analysis
    - Project Closeout
    - Financial Status Report (FSR) Overview.
- Advanced Budgeting – DoD - Scheduled for May 23 and June 6. The pilot course had 16 participants with an overall satisfaction rate of 95%.

Work in Progress:

- Useful BusinessObjects reports – developing a list of useful BusinessObjects reports to be housed in one location. Started with the list that is shared in Fundamentals and expanding.
- Research Administrator (RA) Competencies:
    - To help identify training gaps and provide RAs and supervisors with tools that outline knowledge, skills, and abilities needed to perform their job.
    - Currently working on description and mapping to available professional development opportunities (internal and external)
- Progress to Date:
    - List of key competencies including descriptions.
- In Progress:
    - Mapping key competencies to job levels.

Faculty Resources – Development of Training Programs:
- David presented the latest mockup of the portal page to the RAAC Faculty Advisory Committee. Received good feedback with the question of where it will be located. Suggestions included: Wolverine Access or the Research Resources page on the UMOR website.
- Did find some technical issues and working with web vendor (Boxcar) to fix.
- Content is being developed and reviewed.
- When completed, the focus will turn to an onboarding training program for new/junior faculty.

RA Complex Projects – Instructor-Led Training:
- Developing as an intermediate/advanced course.
    - Co-leads are Amy Brooks and Patrick Lagua
- Complex projects attributes include:
    - Large dollar amount
    - Multiple funding sources
    - Subcontracts
    - Others.

- Timeline:
  - Design phase - April 2019
  - Material Development: May - September 2019
  - Practice (demo) session: October - November 2019
  - Implementation: Winter 2019/early 2020

Kathy D. asked if there has been any feedback on the E-ssentials modules. David responded that there has not been formal (survey) feedback but anecdotally he has received very good feedback.
Yvonne asked if the Navigate team has numbers on who has taken the E-ssentials courses? David responded that they do have numbers, but he does not have them with him nor recall them at this time.

3.   **Sponsored Programs Update** (*Debbie Talley*)

Debbie alerted the group that the SPG related to Effort Certification was recently updated. If you are not getting updates from University Audits, you may sign up on the SPG website. What has changed? Previously, if you were paid from multiple shortcodes (whether sponsored or non-), certification was required. Now, if you are paid from multiple shortcodes, but none of them are sponsored, you do not need to certify.

Single Audit:
- Submitted on March 28 (due on March 31). Waited to submit due to an issue on how we handled 2% program fee for the Strategic Supplier Program.
- Earlier in the year, an internal review indicated we should be passing the 2% fee on to the federal government. Auditors determined with the amount of time it had gone on, it was a significant deficiency and reflected in the report how we were handling discount going forward.
  - For federal sponsored projects, it will start on April 1, 2019.
  - For non-federal sponsored projects, it will start on May 1, 2019.
- All affected groups have been notified. Constance sent out RAPid, and Procurement Services has information on their website.
- One challenge is the costs transfers for charges incurred prior to April 1, as these will not have the 2% discount and will need to adjust. We are working with Procurement on a solution. If you are preparing journal entries for moving costs for activity prior to April 1 and have not seen it, that is why.
- If you have people in units asking about this process, direct them to Procurement Services. If sponsors call with questions, send them to Bryan VanSickle or Debbie Talley. Working with DHHS on how we are going to return these funds to the federal government.
- The amount we owe back will not impact the units.
- We have to go back six years for the money we owe for the 2% discount.

Yvonne asked where the money will come from to pay back the federal government. Debbie responded that it will have to come from central office funds.

David asked where the six-year number came from. Debbie responded that this was a recommendation that came about as a result of working with the Office of General Counsel and our external counsel. Six years was recommended to start – we could be asked to go past six years, but hopefully not.

Staffing:
- In May we will a new cohort starting. It will consist of five accountants and three interns.

4.   **ORSP Update** (*Yvonne Sturt*)

Yvonne presented the ORSP update for Craig, who could not be here today.

Personnel:
- We have hired a new PR. Raymond Cluckey, with Private Sponsors Blue Team (non-health related school/colleges) started on April 1, 2019, and is going through training.
- Maggie Swift is out on maternity leave for 2 months and will come back on a part-time basis.

Foreign Entities:
- The federal government (NIH and other agencies) has changed their requirements on reporting related to foreign entities and institutions. A RAPid went out on February 18, 2019, including a reminder for NIH PIs on NIH sponsored project to report foreign entities.
- Jack Hu established a working group in March 2019 - International Research Security Working Group. The focus is on research security.

Another working group has been established related to Support for Public Access to Research Data. Members have been selected. The focus is to make recommendations for supporting U-M researchers and making their data publically available. The group has not yet met. The group's deliverable is a report detailing recommendations of next steps, and the goal is to have the report completed within six months.

Danielle asked if Yvonne could share who is on this new working group? Yvonne answered with the following individuals: Jake Carlson, Nick Wigginton, Maya Kobersy, Sol Bermann, Lois Brako, Craig Reynolds, Myra Kim, Sharon Broude, Erin Kaleba, Jason Garr, Margaret Levenstein, Tracy Pattok.

There was a question about the members of the International Research Security Working Group. Yvonne provided the list of participants: Brad Orr, Lois Brako, Pat Ward, Nick Wigginton, Krista Campeau, Kristina Ko, Bill Greer, Richard Vanden Heuvel. Craig Reynolds, Tiefei Dong, David Grimm, Sol Bermann, Patrick Morgan, John Godfrey, and Brodie Remington.

This Thursday, April 18, ORSP will be having a Staff Appreciation event in the morning from 8 a.m. - 1:00 p.m. The ORSP main phone line will be forwarded to Yvonne's cell phone.

5.   **ITS / Award Management Update** (*Carolyn Pappas*)   Attachment #2

Changes in eRPM that will be in place on April 29:
- Award enhancements
- Compliance Changes:
  - New question for use of controlled substances
  - Splitting existing Export Controls/Classified Research into two questions.
  - Changes to Biosafety questions on PAF and UFA.

Award Enhancements:
- Updating Award Unit Info tab to accommodate additional Terms & Conditions. Will be a read-only field. Will carry over on special Terms & Conditions that are entered by ORSP and will show up on both.
- Email notifications updated with a list of email recipients:
  - Manage Hold (on or off hold)
  - Deliverables reminders (14 and 21 days past due)
  - Email sent when ORSP initiates a modification.

- Temporarily turning off the 35-day past due deliverable reminder message (alerting Deans/Directors). Will turn back on when the pilot is over and we have a better understanding of functionality. These are only deliverables from eRPM.
- Adding Primary Post Award Contact to appear the PAF Workspace in all states.
- Adding Title of the P/G # on $$$ tab. The title also includes the shortcode and is hand entered so don't rely on it.

ORSP:
- New options for compliance hold evaluation.
    - The system will not evaluate compliance hold(s) on early terminations.
- New option on award and award mod for ORSP to indicate compliance work (human, animal, biosafety) is done or not applicable. ORSP has a way to bypass it.

Compliance Changes:
- New question for the use of controlled substances.
- Export controls, Classified Research & Enhanced IT Security:
    - Splitting existing Export Controls/Classified Research into two questions
    - A new question to cover the need for security review
    - A new activity to request a security review on a project.
- Changes to Biosafety questions on PAF and UFA

New questions: In Section 5 of the PAF
- Controlled Substances: added to PAF and UFAs.
- Export Controls & Security – split into 2 questions.
    - New PAFs and PAFs in Progress:
        - If new security questions are answered "yes" or unsure, it will be sent to U-M Security Officer (Steve Dawson) for review.
        - ORSP can also use new activity to request a Security review.
- Institutional Biosafety (IBC):
    - U-M updated policy in 2016. Catching up in eRPM - Section 5 of PAF.
    - Changes to:
        - Proposal Approval Form (PAF) - Section 5 - Research Activity
        - Unfunded Agreements (UFAs) and Material Transfer Agreements (MTAs) and other.
        - PAF Summary
        - UFA Summary
        - Update Research Activity activity.
- Currently, there are four questions related to IBC. There will now be one new high-level question. If you say no, you're done. If yes, you will have more questions to answer.

When is an IBCA required?:
- The current process is an approved IBCA will be required at the time of Award or Award Modification if the rDNA/SNA question is answered "yes" and the PI/PT indicates a Biosafety Level or 2 or more.
- The new business process is the IBCA is required at the time of Award or Award Modification if the rDNA/SNA question is answered "yes" for all Biosafety Levels.

PAF/Award Workflow Impacts:
- For PAFs in Progress:
    - ITS will automatically fill in the new biosafety question with "Yes" if any of the four existing questions are answered "Yes" and ITS will map the existing answers to the appropriate sub-questions.

- ○ Export Controls: The answer to the existing question will be mapped over to the revised Export Controls question.
  - ○ New questions (Biosafety & Security): left blank.
- PI/PTs will be required to answer new compliance questions at the time they route the PAF for unit review and/or when they submit PAF changes.
- If the proposal is submitted to the sponsor there is no requirement to answer the new compliance questions unless a PAF revision is started.
- Update Research Activity – If either human or animal subjects have been indicated and the proposal has not been submitted to the sponsor, the questions may be answered..
- Updated Research Activity is available when the PAF is editable by the project team up until the time when ORSP has created the Award.
- ORSP awarding a PAF – may elect to ask PI/PT to use Update Research Activity to complete the compliance information.
  - ○ ORSP will do similar work to what they do today to determine whether appropriate compliance items are provided.
  - ○ No requirement for ORSP to complete the new compliance questions - just need the IBCA.
- IBC Approval line on the Award Compliance Meter will appear if any of the biosafety sub-questions are marked "yes." The indicator will be marked red:
  - ○ If rDNA/SNA is indicated at any biosafety level and IBCA is not approved, or
  - ○ If IBC was indicated for future use and that date is in the past.

- RAPid went out on update of all compliance job aids.

6. **Closing and Future Meetings** (*Debbie Talley*)

Our next meeting is May 21 at LSA and June 18 at Laurie Engineering. No meeting in July.
May 30 is a joint meeting with RAAC Faculty Advisory Council and Executive
Committee – the meeting time is going to change.

Thanks to ISR for hosting.

RAAC Committee-At-Large Meeting Dates
- Tuesday, May 21, 2019, 3:00 – 4:30 pm @ LSA Building (*Becky O' Brien*, RAAC Communications Subcommittee)
- Tuesday, June 18, 2019, 3:00 – 4:30 pm @ Lurie Engineering Center (*Chris Allan*, RAAC Metrics Subcommittee)
- *No July meeting*

Executive Committee Meetings
Wolverine Tower, Conference Room 1025 (unless noted)
- Tuesday, May 14, 2019, 3:30 – 5:00 pm
- Tuesday, May 30, 2019, 3:00 – 4:30 pm (Joint meeting – RAAC Faculty Advisory Council) – location TBD
- Tuesday, June 11, 2019, 3:30 – 5:00 pm

Research Administration Advisory Council
Committee-at-Large
Training Subcommittee Update
April 16, 2019

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Amy Brooks
College of Engineering

Current Subcommittee Membership

- **Judy Carrillo,** Chair, Medical School

- **David Mulder**, ORSP/Sponsored Programs

- **Dave Nassar**, ORSP/Sponsored Programs

- **Chris DeVries**, ORSP/Sponsored Programs

- **Raquel de Paula Silvius,** ORSP/Sponsored Programs

- **Lyn Fyfe,** ORSP/Sponsored Programs

- **Kim Angelopoulos**, LSA

- **Amy Brooks**, CoE

- **Lori Deromedi**, UMOR

- **Cathy Handyside**, ITS

- **Emily Hamilton**, CoE, UMTRI

- **Lark Haunert**, ORSP

- **Sue Kelch,** Medical School

- **Patrick Lagua**, Dental

- **Terri Maxwell**, ORSP

- **Melinda LaRocca**, Public Health

- **Susan Powell**, CoE

- **Cathy Seay-Ostrowski**, Biomedical Eng

- **Amanda Simon**, Sponsored Programs

- **Pat Turnbull**, U-M Dearborn

Agenda:

- Update: Navigate Training Opportunities

- Work in Progress

Navigate Courses & Offerings

BUDGETING BASICS
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

ADVANCED BUDGETING
SELECTED TOPICS: DOD PROPOSAL
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

ADVANCED BUDGETING
SELECTED TOPICS: TASK-BASED BUDGETS
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

FUNDAMENTALS
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

LUNCH & LEARN
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

ADVANCED BUDGETING
SELECTED TOPICS: INTERNAL PROPOSALS
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

E-SSENTIALS eLEARNING MODULES
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

RAMP↑ RESEARCH ADMINISTRATION MENTORING PROGRAM
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

UNIFORM GUIDANCE
NAVIGATING RESEARCH ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN

M | NAVIGATE

All Training Opportunities available on Navigate Portal Website:

orsp.umich.edu/**navigate**

Also includes video recordings of Lunch and Learn

Upcoming Navigate Offerings:

- Fundamentals - Spring 2019 - Closed
- Uniform Guidance - Summer 2019
- Budgeting Basics - Spring 2019
- Advanced Budgeting: Internal Proposals - Spring 2019
- Advanced Budgeting: Task-Based/Hourly Budgets - Spring 2019
- E-ssentials Elearning Modules
- Lunch and Learn - April 2019
- Advanced Budgeting: DOD Proposal - Early Summer

WORK IN PROGRESS

Useful Business Objects Reports

- Coming soon; list of useful BO reports for RAs to be housed in one location

M-Pathways Financials & Physical Resources System (FinProd)		
Report	**Report Details**	**Navigation**

Project/Grant Report	- Shows how to find details about history and changes to your P/G made by Sponsored Programs - Has the status of some of the reports submitted to the sponsor per the award requirements - Tip: Save to your Favorites as you may use this one often	>Main Menu
		   >Set Up Financials/Supply Chain
		   >Common Definitions
		   >Design Chartfields
		      >Define Values
		     >Chartfield Values
		      >Project/Grant

Parent Summary PBSR	- Useful because it pulls the parent project as a whole and also each individual Shortcode under that parent - This report is different than the PBSR report, which only pulls one project at a time - Can be long but has everything in one place vs. M-Reports where you can only look at each one individually	>Main Menu
		   >Reporting Tools
		   >Budget Reports
		   >Parent Summary Budget Status

Research Administrator Competency Roadmap

To help Training Committee identify training gaps and provide research administrators and supervisors with tool that outlines knowledge, skills and abilities needed to perform job.

Work Group Members: David Mulder, Sponsored Programs and ORSP; Sue Kelch, Medical School & Judy Carrillo, Medical School

Deliverables:
- List of Key Competencies for Research Administrators, including descriptions
- Mapping of Key Competencies to available professional development opportunities (both internal and external)

Under Development

Progress to Date

☑ List of key competencies for Research Administrators, including descriptions (completed)

In Progress; mapping of key competencies to available professional development opportunities (both internal and external)

(Lifecycle Phase)	Suggested Competency	Suggested Tasks	Additional Details	Tools/Systems	Resource
Overview	Identify Internal U of M Research Administration Resources	Get started in research administration at U-M.			http://orsp.umich.edu/research-administrators-toolkit http://orsp.umich.edu/navigate
Develop Proposal	Understand, interpret, and communicate sponsor guidelines	Navigate sponsor systems (e.g., grants.gov) Correctly interpret sponsor guidelines Inform project personnel regarding key guideline elements	i. Terms and conditions a. Publication restrictions b. Data monitoring ii. Budgetary guidelines iii. Formatting guidelines iv. Submission guidelines v. Proposal body guidelines	grants.gov Fastlane	NIH application submission policies: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/submission-policies.htm NSF: https://www.nsf.gov/pubs/policydocs/pappg18_1/nsf18_1.pdf

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Faculty Resources - Development of Training Programs

Create a robust research administration training and information resources for faculty

- **Currently under development**
  - Website resource for senior faculty

- **Once above completed, focus will turn to:**
  - Onboarding training program for new/junior faculty

Workgroup members
- Corey Turner (Engineering), Lori Deromedi (UMOR) John Christiano (U-M Dearborn); Erin Kingsley (U-M Flint); Amanda Simon (Sponsored Programs), Lark Haunert (ORSP); Patrick Lagua (Dentistry). Lead; David Mulder (Sponsored Programs/ORSP)

Website Prototype for Senior Faculty Resource

New Instructor-Led Training Opportunity Under Development - RA Complex Project Management (pre- and post-award)

Co-Leads: Amy Brooks, CoE; Patrick Lagua, Dental

Complex project attributes include
- Large dollar amount
- Multiple funding sources
- Subcontracts

Timeline *(tentative)***:**
- Design phase (course agenda, learning objectives): April 2019
- Material Development: May 2019 - September 2019
- Practice (Demo) Sessions: October-November 2019
- Implementation: Winter 2019/early 2020

Questions?

eRPM April 2019 System Preview

RAAC Committee-at-Large

April 16, 2019

Coming April 29, 2019

- Award Enhancements
- Compliance Changes
    - New question for use of controlled substances
    - Splitting existing Export Controls/Classified Research into two questions
    - Changes to Biosafety questions on PAF and UFA

Award Enhancements - Units

- Updating Award Unit Info Tab to accommodate additional T & C
  - Includes display of Institutional T&C and function to allow unit-defined T&C

Main	Mod/ACR	Activity Log	$$$	Deliverables	Terms	Contacts	Compliance	SUBKs	Unit Info

Unit Documents:

Name	Version Number	Modified Date
Test File	0.02	4/9/2019 11:05 AM

Special Terms & Conditions: *(See Terms tab for full text)*

Federal Research Terms and Conditions (RTC)

Unit Comments:

Additional place for unit comments.

Additional Special Terms & Conditions:

PI effort is committed at 1.20 months (10%). Any reduction to 0.90 months (8%) or less, requires sponsor prior approval.

The budget period anniversary start date for future year(s) will be December 1.

Unit-Defined Terms & Conditions:

This is where the project team can add additional terms.

Award Enhancements - Units

- Additional Award email notifications updated with list of email recipients
  - Manage Hold (on/off hold)
  - Deliverables Reminders: 14 and 21 day past due
  - Email sent when ORSP initiates a mod

- Temporarily turned off 35-day Deliverables reminder message

Award Enhancements

- Adding Primary Post Award Contact to PAF workspace in all states

Main	Contacts	Change Tracking	Activity History	Attachments	Hardships	Subcontracts	Unit Comments	Posted Comments	Project Notes	

Title:
Promoting Long-Term Physical Activity in COPD: A Scalable Multi-Level Intervention for Patients and Healthcare Providers

PAF #:
18-PAF05534

ORSP Staff Note: 2/21/18: Sue, The signed pages have been added to the final proposal document and it's ready for submission. Tks, KA

Contract Admin Notes:

Principal Investigator(s):

| Caroline Richardson | UM Principal Investigator | caroli@umich.edu | 734-998-7120 |

Deadlines
FOA Deadline:
Sponsor Deadline: 2/21/2018
Early Deadline: no
Time:
ORSP Deadline:
School/College Deadline: 2/8/2018
Department/Unit Deadline:

Primary Research Administrator:
Judy Connelly , 734-998-7124, jconnell@umich.edu
Primary Post Award Contact:
Judy Connelly , 734-998-7124, jconnell@umich.edu

Project Has Indirect Cost Waiver:
No

Project Administrative Home:
Family Medicine (235500)

Project Has Subcontracts:
No

Related Award (For Renewal/Continuation or Supplemental Request):

Project Representative:
Karen Alameddine , 734-615-5309, alamkar@umich.edu

Project Has UM Cost Sharing:
No

Award Enhancements

- Adding Title to P/G information on $$$ tab

Main	Mod/ACR	Activity Log	$$$	Deliverables	Terms	Contacts	Compliance	SUBKs	Related

M-Reports Award Link: AWD010637

Project/Grants (P/G):

P/G	Title	P/G Short Code	Cost Share P/G Short Code
F052044	096384-MIP - Child Parent Psychotherapy Train-the-Trainer and Implement	096384	120055

Award Enhancements - ORSP

- New options for compliance hold evaluation
  - System will not evaluate compliance hold on early terminations
- New option on award and award modification to indicate compliance work (human, animal, biosafety) work is done or not applicable (linked awards, training grant, etc.)

Compliance Changes

- New question for use of controlled substances
- Export Controls, Classified Research & Enhanced IT Security
  - Splitting existing Export Controls/Classified Research into two questions
  - New question to cover need for security review (Classified Research, FISMA, CUI, etc.)
  - New activity to request Security review
- Changes to Biosafety questions on PAF and UFA

New Controlled Substances Question

- New question added to PAF (Section 5) & UFAs
  - Use of controlled substances (as defined by the Federal Controlled Substances Act) or Propofol in a U-M research laboratory?

Export Controls & Security

Existing PAF Question:

- Does the research project involve classified research or possible export controls?

Updated Export Controls Question:

- Does the research project involve possible export controls or delivery of a physical item, such as a product or material, including models and prototypes?

New Security Question:

- Are there any enhanced security requirements for this project (e.g., CUI, FISMA, or classified research)?

Export Controls & Security

- New PAFs & PAFs in Progress:
  - If new Security question is answered "yes" or "unsure", a request will be sent to U-M Security Officer (Steve Dawson) for review when the PAF moves to Negotiation in Progress or Award Processing
  - ORSP can also use new activity to request Security review

Institutional Biosafety (IBC)

- Changes related to Biosafety questions and expanded requirement for Institutional Biosafety Approval
  - U-M Policy updated in 2016
  - Changes to:
    - Proposal Approval Form (PAF)
      - Section 5 - Research Activity
    - Unfunded Agreements (UFAs) - Material Transfer Agreements (MTAs) and Other
    - PAF Summary
    - UFA Summary
    - Update Research Activity activity

IBC - Current PAF Questions

IBC - New PAF Questions

- New high-level question:
  - Does this project involve research in a UM laboratory with biological materials?
    - If no, fewer questions to answer...

IBC - New PAF Questions

- If yes, additional questions are required:
  - Use of recombinant DNA (rDNA) or synthetic nucleic acid (SNA) molecules?
  - Use of infectious agents (i.e., bacteria, viruses, parasites, fungi, prions)?
  - Use of biological toxins (i.e., toxic substances produced by bacteria, fungi, protozoa, insects, animals, or plants)?
  - Use in a U-M research laboratory of human-derived substances (including cell/cell lines, blood products, body fluids, tissues, pathology materials, organs, body parts, cadavers)
  - Use of animal derived substances (i.e., cells, tissues, fluids from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal)
  - Use of transgenic animals
  - Will any of the following be administered to vertebrate animals (rDNA, SNA, infectious agents, biological toxins, human-derived substances (including cell/cell lines, blood products, body fluids, tissues, pathology, materials, organs, body parts, cadavers), animal-derived substances (including cells, tissues, fluids from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal)?

When is an IBCA required?

Current business process

- An approved IBCA is required at the time of Award or Award Modification if the rDNA/SNA question is answered "yes" and the PI/PT indicates a Biosafety Level of 2 or more

New business process:

- An approved IBCA will be required at the time of Award or Award Modification if the rDNA/SNA question is answered "yes" **for all Biosafety Levels**

PAF/Award Workflow Impacts

- **PAFs in Progress:**
  - ○ Answers to existing questions will map over
    - ■ For Biosafety: If any of the four existing questions are answered "yes", the new high-level biosafety question will be answered "yes" and existing answers will be mapped into the appropriate sub-questions
    - ■ For Export Controls: The answer to the existing question will be mapped over to the revised Export Controls question
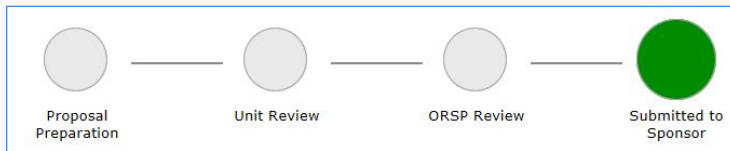   - ■ New questions (Biosafety & Security): Left blank

PAF/Award Workflow Impacts

- **PAFs in Progress:**
  - ○ PI/PTs will be required to answer new compliance questions at the time they route the PAF for unit review and/or any time they submit PAF changes

PAF/Award Workflow Impacts

- PAFs in Submitted to Sponsor:
  - No requirement to answer new compliance questions unless a PAF Revision is started
  - PI/PT could use Update Research Activity activity on PAF to update answers to new compliance questions and/or add HUM, PRO, IBCAs

Update Research Activity

- Existing PI/PT activity used to add HUMs and PROs to PAFs prior to award
- Updating to include new compliance questions
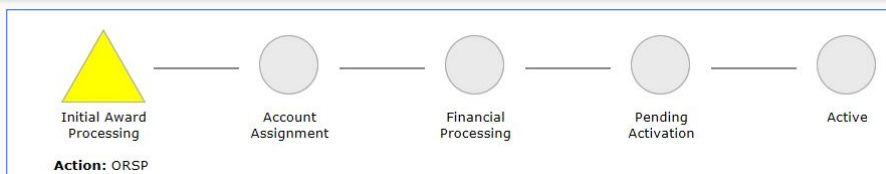
# PAF/Award Workflow Impacts

- At time of Award:
  - **On PAF:**
    - If time permits, ORSP may elect to ask the PI/PT to use the Update Research Activity activity **on PAF** to complete compliance information
    - This activity will now be available on the PAF in the state of Processing Award prior to creating the award

PAF/Award Workflow Impacts

- **On Award and Award Modifications**:
  - ORSP needs to confirm that appropriate compliance items are provided (HUM, PRO, IBCA, etc.)
    - If rDNA/SNA is indicated **at any biosafety level**, an IBCA is required
      - There is also an option to indicate that IBC work will start at a future date
  - No requirement to complete the new compliance questions at this time
  - If the appropriate compliance items are present, PR can complete signoff

PAF/Award Workflow Impacts
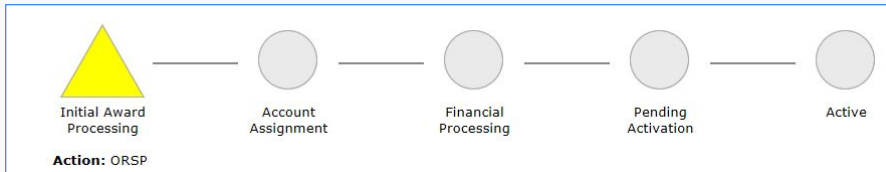
- **On Award and Award Modifications**:
  - The IBC Approval line on the Award Compliance Meter will appear if any of the Biosafety sub questions are marked "yes"
  - The indicator will be marked red:
    - If rDNA/SNA is indicated **at any biosafety level** and IBCA is not approved, or
    - If IBC was indicated for future use and that date is in the past
  - The indicator will be marked yellow if IBC will be in the future
  - The indicator will be marked green for all other biosafety conditions

Summary & Next Steps

- eRPM Update Scheduled for April 29
  - Updates to Compliance Job-Aids

- Questions?