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ORA Quarterly Meeting

April 19 2017

Agenda

1. **Workday Grants Implementation Items**
   - General Information
   - Blackout Period
   - Sub K's - Set-up and Invoicing
   - Advance Accounts
2. **Jackson/ UM Partnership**
   - Master Agreement for Research Activities
   - Processes
3. **Reporting**
   - RRS Changes
   - Workday Reporting
4. **Upcoming Effort Reporting Changes – Fall 2017**
5. **PCRF Updates**
6. **Conflict Of Interest – Dr. Lory Hayes**
   - Software Implementation
   - Change in PHS Non-Competitive Renewals
7. **Greenphire ClinCard**
8. **Export Control – New Director William Collins**

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Workday Grants Implementation

General Information

Go-live June 1, 2017

Key Terminology for Grants

Key Terminology for Grants

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With Workday's implementation, some of your terminology will change. Here is a list of terms that you will be used during today's Webinar:

Term	Definition	Yesterday's Term
Award	Captures all the sponsor's terms and conditions. A Workday award is used to define the business rules necessary to capture cost, calculate facilities and administration expense, and bill your sponsor. Example of Award: AWD-001908	Award/Grant/Contract
Award Line	Determines the applicable revenue recognition rules for the award, ties the award to a specific grant, F&A rate application, establishes an effective date range for determining eligible expenses, and assigns the sub-awardee (if applicable).	None
Line Type	Key Mechanisms for receiving grant funding: • Cost Reimbursable - Approved budget, bill sponsor based on how much you spend as you spend it. • Fixed Amount – Scheduled payment amounts over a series of dates or milestones • Pre-Paid - Upfront funds or one-lump sum funds	Reimbursement Method and LOC Number (e.g. YFP,YPF, YSP, BCR)
Award Schedule	Life of the award (how is it broken down into budget periods), configured each time for each award.	Budget Years
Purpose Codes	Used to explain the purpose or focus of the award. For example: Clinical Research, Instruction, Organized Research, and Sponsored Programs.	Research Type (e.g. Instruction/Clinical Trial)

Key Terminology for Grants

Key Terminology for Grants *(cont.)*

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Term	Definition	Yesterday's Term
Grant	Workday uses the grants worktag as the primary cost and revenue collector for an award. If you want to charge against a grant on a purchase order, you use the grants worktag. Example of Grant ID: "GR001234 Smith Natl Institute of Health 1R01CA12345 Melanoma Spec……"	FRS Account Number
Object Class	Translation between the internal reporting classifications and how a sponsor views costs by mapping spend categories into the Sponsor's invoicing/reporting requirements.	None
Award Types	Used to identify various types of Awards for reporting purposes. For example, Contract, Cooperative Agreement, and Grant.	Grant or Contract
Worktag	Keywords assigned to transactions and supporting data to facilitate business process routing and enable reporting	None/attribute

General Information

- Sponsored projects setup as award consisting of one or more award lines
- Award lines are assigned a grant number

General Information

- Transactions are posted to a grant and reflected at an award line level
- Existing FRS numbers converted to Awards & Award lines
- Worktags used to capture transactional and related data

FRS to FDM Conversion Tool

FRS to FDM Conversion Tool

Deployment

- The Workday Implementation team is working on the deployment schedule
  - There will be a 1 - 3 day blackout period in FRS beginning April 26, 2017
  - Accounts created prior to April 26 will be available in Workday on June 1
  - All accounts will continue to be available in FRS through the FY17 year end close

Deployment

- Accounts created in FRS after April 26 may be used in FY17, but will not be available in Workday for about 2 weeks beginning June 1
- ORA is working proactively to create non-competing accounts prior to April 26, 2017, where possible

Deployment

- Contact Marie Grimes in ORA at 305 284 3871 to direct your questions on specifics related to Workday
- Other departments will have transactional cutoffs (requisitions, procurement and travel card, AP processing, etc.) through May
- Additional announcements with exact dates and instructions will follow

Deployment

Balances will not be available until UM has closed FY17 books

Sub Awards

- WD's sub recipient's module will be utilized
- Each sub award will be issued against a unique award line (ie: grant number)
- Supplier Contracts initiated by ORA upon receipt of budget and scope

Sub Awards

Dr. XXX,

Congratulations on the attached New XXX Award. As noted in the attached, this award is for (Award Amount) with the anticipation of three additional years of funding totaling XXX. This pertains to UM Proposal #XXXXXXX. Please review the attached terms and conditions. Please note, in addition to the standard terms and conditions, this award includes the following:

- An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.
- NIH is currently funded through a Continuing Resolution. Therefore, this non-competing award has been made at a level below that committed for FY2017 in the previous Notice of Award.

Sub Awards

This award/contract includes the anticipation of a subaward to XXX University for YYY dollars. Please confirm you still intend to subaward to this entity for this dollar amount. If so, please submit the following materials to ORA as soon as possible via mra@med.miami.edu to initiate the outbound subaward process: Scope of Work, Budget, Justification and deliverables (if applicable). Please refer to the above UM Proposal # and below grant # when submitting these documents to ORA.

The grant for this award is GRXXXXXX

Thank you

Sub Awards

- Supplier Contracts rather than PO's will be issued
- A unique Supplier Contract number will be issued and incorporated in the sub award
- The Supplier Contract will route to department for approval

Sub Awards

- WD functionality removes the need to split the sub award between the first $25k and additional funds over $25k
- Agreements with Jackson Memorial will be handled similarly

Advance Accounts

- UM encourages the use of Advance Accounts
- Upon notification from sponsor that funding is imminent
- Written justification is required

Advance Accounts Form

Advance Accounts

- Request must be signed by the PI and Dean, Chair, or Center Director
- If higher approval is required, ORA will obtain
- Advance accounts cannot be created for non-governmental contracts

Advance Accounts

- For governmental contracts, the draft contract must be attached to assess start date and pre-award spending
- Advance Account can only be set up if COI has been approved

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UM/JHS Partnership

Master Agreement

- Fully executed on 2/23/2017
- All sponsored and/or funded research studies that use JHS facilities and resources

Process in the Past

- Process was unclear, not streamlined
- Depended on the type of project/study on how it needed to be processed and reviewed
- Required three party agreement between UM, sponsor and JHS
- Duplicative efforts reviewing (UM & JHS)
- Caused delays

Process Now

- Eliminates the need for 3 party clinical trial agreements
- Consolidates all study types into one process

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Recap

- Be proactive
- JHS involvement must be identified at the proposal/contract stage
- This avoids additional work and delay in study start up

Moving Forward

- Starting in May, any new project submitted will use this process
- Will continue to improve the process
- In-house training/discussion available

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Reporting

Research Reporting System

Please login with your Cane ID and password to view various research-related reports.

Login ›

https://rrs.Miami.edu

Workday Reporting

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Data Warehouse

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Systems

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Project Confirmation

- Currently collecting data for last period of Effort Certification
- UG removed all reference to Effort Certification

Project Confirmation

- FDP Pilot – Project Confirmation
- Only PI and each faculty member paid from grants needs to certify
- No need for each person to certify
- June 1 – Rollout of ECRT v5.1

Project Confirmation

- Periods will remain the same with the first period opening December 15 (June 1-Nov 30)
- Project Confirmation document at closeout
- Currently 3,000 certifiers
- Only 850 faculty members

Date Table

	Begin Payroll Collection	End Payroll Collection	Certification Period Open	Certification Period Closed
Current System (v4.6) Workday HR/Legacy FRS	12/01/2016	05/31/2017	07/21/2017	09/19/2017
Project Certification (v5.1) Workday HR and Financials	06/01/2017	11/30/2017	12/15/2017	02/15/2018

Training

- Training will be rolling out in the Fall
- UG focuses on internal controls; salary charges carefully scrutinized

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PCRF Updates

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PCRF-L

PCRF-L Highlights

- Shifted to Workday vernacular
  - Project Type is now Purpose Code (applied/basic/development research NEW)
  - Account is now Grant/Legacy Value
  - Department is either Academic Unit or Employee Cost Center

PCRF-L Highlights

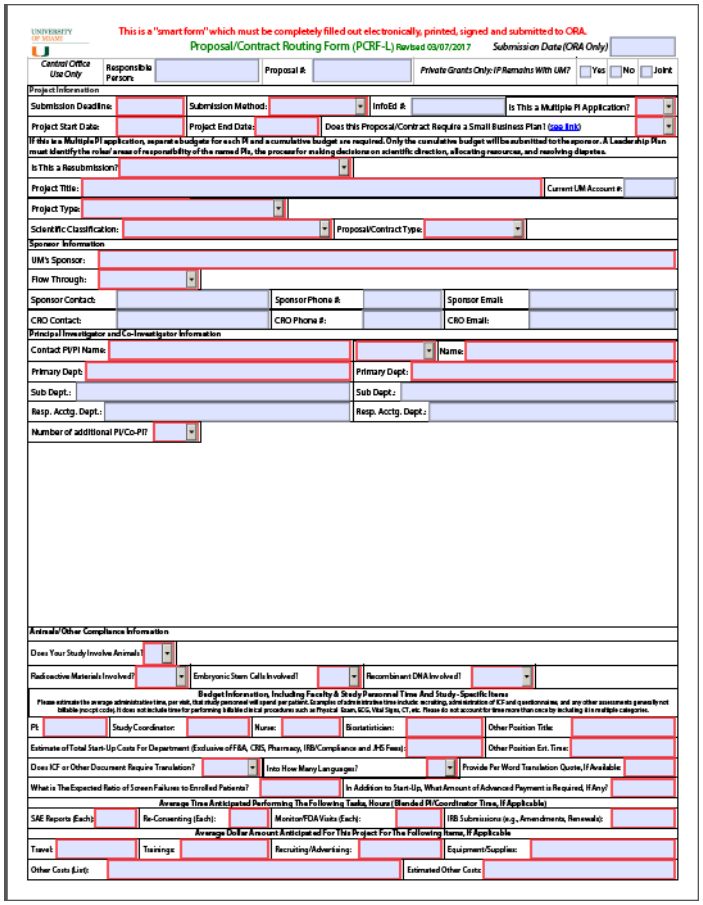
- Non-Compete Renewals will no longer be handled via the PCRF-L
- Separated UM from JHS and added a SCCC question
- Added new data points
  - Workday Short Title
  - Intellectual Property questions

PCRF-L Highlights

- Form is reorganized
  - Page 1 is study specific information, including animals and export compliance
  - Page 2 is primarily human subjects information plus research/performance locations and subcontracting
  - Page 3 is financial – budget, cost sharing, F&A waiver
  - Page 4 is IP and certifications, assurances, approvals

PCRF-L Form

PCRF-L Form



This is a "smart form" which must be completely filled out electronically, printed, signed and submitted to ORA.

Proposal/Contract Routing Form (PCRF-L) Revised 03/07/2017 — Submission Date (ORA Only)

Central Office Use Only | Responsible Persons | Proposal #: | Private Grants Only: IP Remains With UM? ☐ Yes ☐ No ☐ Joint

Project Information

Submission Deadline: | Submission Method: | InfoEd #: | Is This a Multiple PI Application?

Project Start Date: | Project End Date: | Does this Proposal/Contract Require a Small Business Plan? (see link)

If this is a Multiple PI application, separate budgets for each PI and a cumulative budget are required. Only the cumulative budget will be submitted to the sponsor. A Leadership Plan must identify the roles/ areas of responsibility of the named PIs, the process for making decisions on scientific direction, allocating resources, and resolving disputes.

Is This a Resubmission?

Project Title: | Current UM Account #:

Project Type:

Scientific Classification: | Proposal/Contract Type:

Sponsor Information

UM's Sponsor:

Flow Through:

Sponsor Contact: | Sponsor Phone #: | Sponsor Email:

CRO Contact: | CRO Phone #: | CRO Email:

Principal Investigator and Co-Investigator Information

Contact PI/PI Name: | Name:

Primary Dept: | Primary Dept:

Sub Dept.: | Sub Dept.:

Resp. Acctg. Dept.: | Resp. Acctg. Dept.:

Number of additional PI/Co-PI?

Animals/Other Compliance Information

Does Your Study Involve Animals?

Radioactive Materials Involved? | Embryonic Stem Cells Involved? | Recombinant DNA Involved?

Budget Information, Including Faculty & Study Personnel Time And Study-Specific Items

Please estimate the average administrative time, per visit, that study personnel will spend per patient. Examples of administrative time include: recruiting, administration of ICF and questionnaires, and any other assessments generally not billable (except coding). It does not include time for performing billable clinical procedures such as Physical Exam, ECG, Vital Signs, CT, etc. Please do not account for time more than once by including it in multiple categories.

PI: | Study Coordinator: | Nurse: | Biostatistician: | Other Position Title:

Estimate of Total Start-Up Costs For Department (Exclusive of F&A, CRIS, Pharmacy, IRB/Compliance and JHS Fees): | Other Position Est. Time:

Does ICF or Other Document Require Translation? | Into How Many Languages? | Provide Per Word Translation Quote, If Available:

What is The Expected Ratio of Screen Failures to Enrolled Patients? | In Addition to Start-Up, What Amount of Advanced Payment is Required, If Any?

Average Time Anticipated Performing The Following Tasks, Hours (Blended PI/Coordinator Time, If Applicable)

SAE Reports (Each): | Re-Consenting (Each): | Monitor/FDA Visits (Each): | IRB Submissions (e.g., Amendments, Renewals):

Average Dollar Amount Anticipated For This Project For The Following Items, If Applicable

Travel: | Trainings: | Recruiting/Advertising: | Equipment/Supplies:

Other Costs (List): | Estimated Other Costs:

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PCRF-S

PCRF-S Highlights

- Shifted to Workday vernacular
  - Account is now Grant/Legacy Value
  - Department is Academic Unit or Employee Cost Center
- Purpose now includes Submission of Sponsor-Required Progress Reports
  - No more PCRF-Ls, budgets, justifications, etc. for Non-Compete Renewals
  - You only need to process a PCRF-S when sponsor REQUIRES a progress report

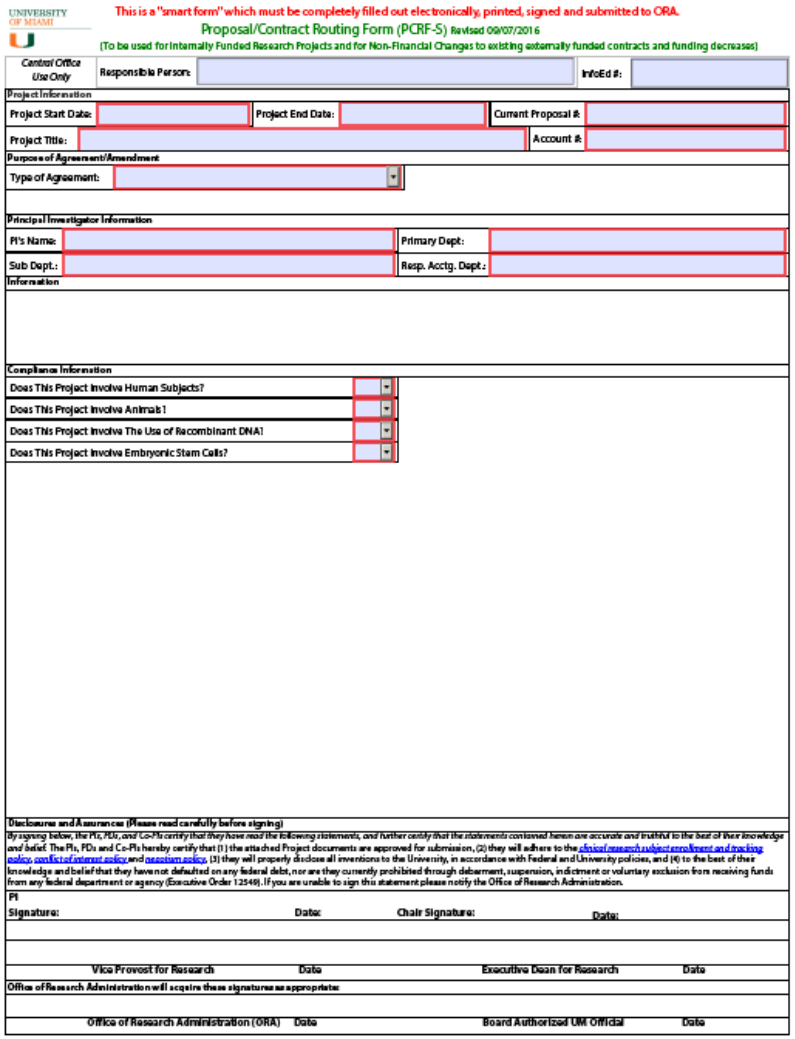
PCRF-S Highlights

- You must identify Submission Type (system versus hardcopy)
  - If system, you must identify the system
  - If hardcopy, you must attach the final documents
- PI certifies that the uploaded/attached submission is accurate and in final format

- Chair or Center/Institute Director signature is NOT required for:
  - Master Agreement
  - Sponsor Required Progress Report

PCRF-S Form

PCRF-S Form



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This is a "smart form" which must be completely filled out electronically, printed, signed and submitted to ORA.

Proposal/Contract Routing Form (PCRF-S) Revised 09/07/2016

(To be used for Internally Funded Research Projects and for Non-Financial Changes to existing externally funded contracts and funding decreases)

Central Office Use Only	Responsible Person:		InfoEd #:	
Project Information				
Project Start Date:		Project End Date:	Current Proposal #:	
Project Title:			Account #:	
Purpose of Agreement/Amendment				
Type of Agreement:				
Principal Investigator Information				
PI's Name:		Primary Dept:		
Sub Dept.:		Resp. Acctg. Dept.:		
Information				
Compliance Information				
Does This Project Involve Human Subjects?				
Does This Project Involve Animals?				
Does This Project Involve The Use of Recombinant DNA?				
Does This Project Involve Embryonic Stem Cells?				

Disclosure and Assurances (Please read carefully before signing)

By signing below, the PIs, PDs, and Co-PIs certify that they have read the following statements, and further certify that the statements contained herein are accurate and truthful to the best of their knowledge and belief. The PIs, PDs and Co-PIs hereby certify that (1) the attached Project documents are approved for submission, (2) they will adhere to the clinical research subject enrollment and tracking policy, conflict of interest policy and nepotism policy, (3) they will properly disclose all inventions to the University, in accordance with Federal and University policies, and (4) to the best of their knowledge and belief that they have not defaulted on any federal debt, nor are they currently prohibited through debarment, suspension, indictment or voluntary exclusion from receiving funds from any federal department or agency (Executive Order 12549). If you are unable to sign this statement please notify the Office of Research Administration.

PI Signature:	Date:	Chair Signature:	Date:
Vice Provost for Research	Date	Executive Dean for Research	Date

Office of Research Administration will acquire these signatures as appropriate:

Office of Research Administration (ORA)	Date	Board Authorized UM Official	Date

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Conflict of Interest (COI)

Dr. Lory Hayes

Introduction to the UDisclose System

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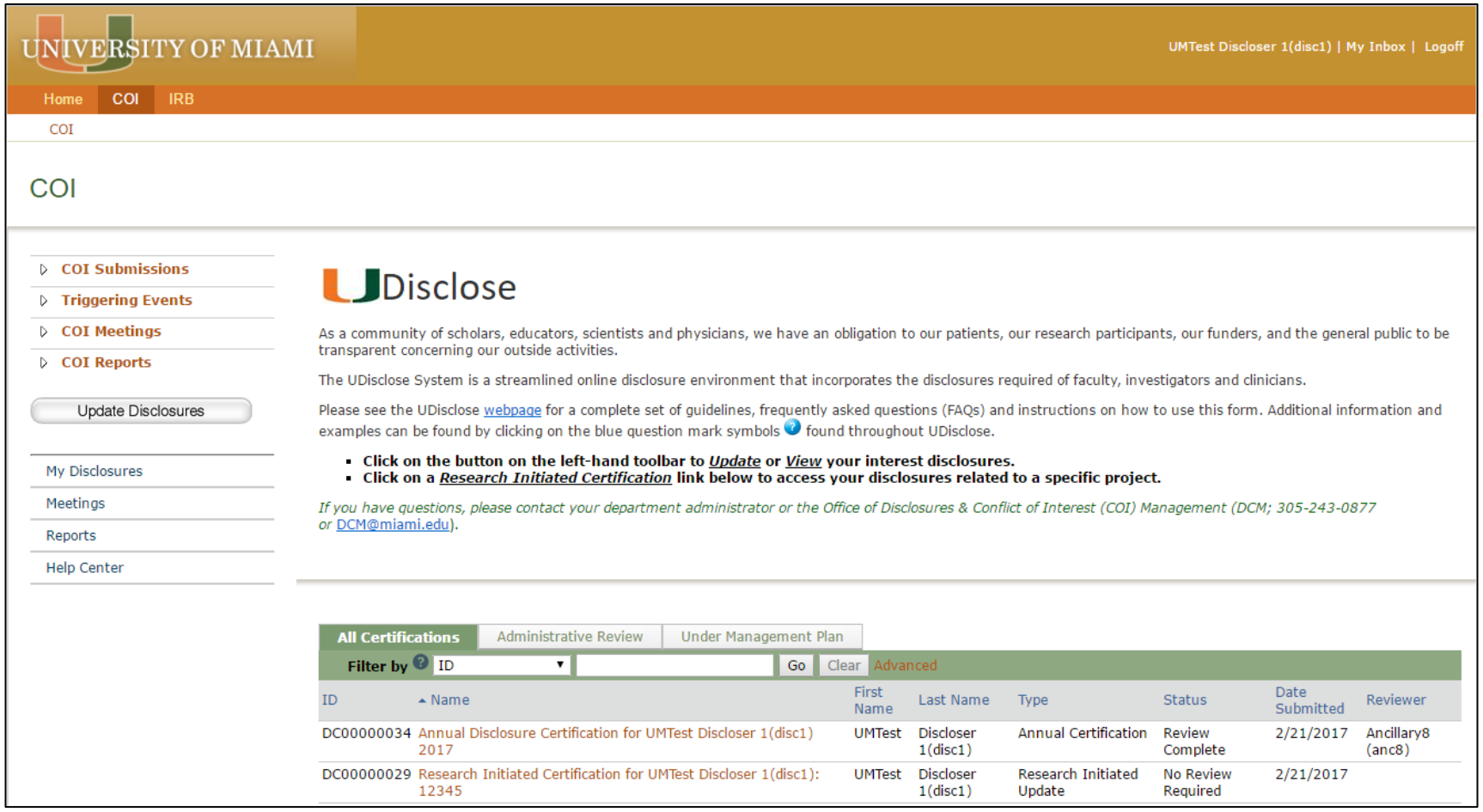
Lory A. Hayes, PhD, CHRC
Associate Director,
Disclosures and Conflict of Interest Management (DCM)
Office of the Vice Provost for Research

April 2017

The U Disclose System

- COI disclosure software from Huron
  - Similar look and hierarchy to IRB7
- UDisclose System advantages
  - reduce administrative burden
  - simplifies the disclosure process
- DPS will remain available as read-only

COI Workspace



Benefits

- Eliminates redundancy
- Increases transparency
- Compatibility with all web browsers
- Streamlines disclosure certification
- Integration with the IRB7 and CITI
- Ability to designate a proxy to assist with disclosures and team member designation
- C Numbers are no longer needed to designate team members
- Clear indication of status of team members on projects

Comparison of DPS and UDisclose

In DPS, we had:	Which were:	DPS Profile
Questionnaire	How disclosers reported information that was used to determine what they needed to disclose	Separate sections certified on separate dates
Interests (FOIs, OPAs, and Travel)	Outside interests, activities, or relationships with an external organization	
Sponsored Projects/Awards/Contracts	List of projects on which team members were designated	

Certifications

- A submission in the UDisclose System that confirms a set of a discloser's interests and other information at a certain point in time.
  - **Annual Certification** - A **Disclosure Update** is created/submitted any time a discloser's interests change during the year.
  - **Research Certification** - A Disclosure Certification that is required to be submitted for each funded project and IRB study

	For Annual Certification	For Research Certification
Institutional Responsibilities	X	X
COI Training and Education	X	X
What to Disclose	X	X
Disclosure Details	X	X
Research Information		X
Assurance	X	X

UDisclose: New Terms

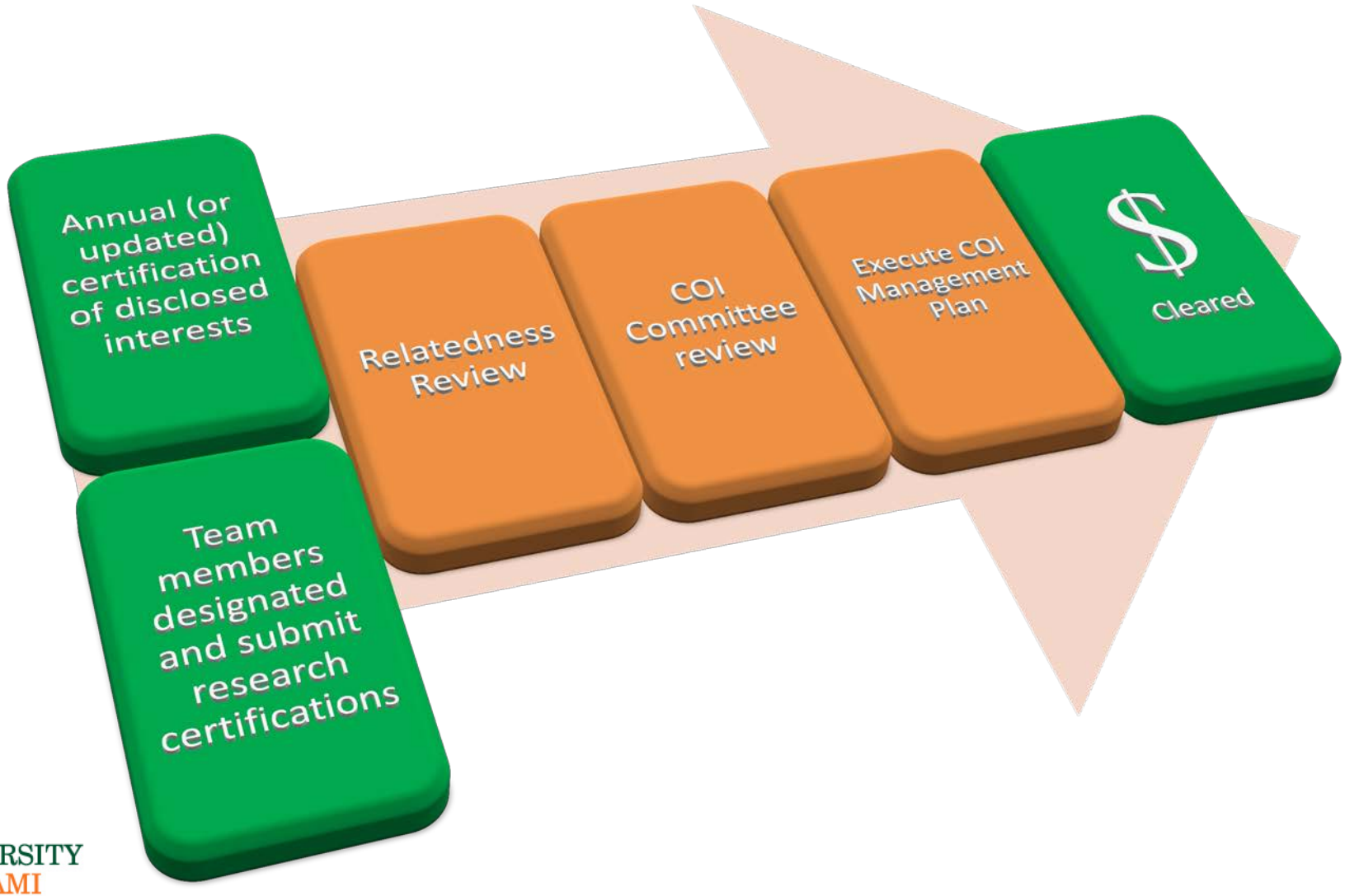
UDisclose term	Definition
Triggering Event	A Triggering Event is created when a new funding proposal (new and competing renewals) is ready for COI disclosure review. When a Triggering Event is created, a Research Certification will be created for the PI. The PI adds his/her team members to the Triggering Event, which in turn generates Research Certifications for each team member.
UDisclose Inbox	List of all disclosure certifications pending some action by the logged-on user. Disclosure certifications that are already reviewed, do not require review, or are currently under review but pending someone else's action will not appear in the inbox.
Proxy	Designated to create and update an individual's disclosures, but a proxy cannot submit disclosure certifications on behalf of someone else; these must be submitted by the actual discloser. Will be able to designate team members on behalf of PIs.

Grants and Contracts

InfoEd numbers will be grouped into projects

- UDisclose will use the InfoEd number active when the project is imported into the system
- Team member designation:
  - New and competing awards will require team designation
  - Supplements and non-competing will not require team designation
- PD/PI can designate a proxy to assist with team designation
  - Proxy will have access to **ALL** information in the UDisclose System (including disclosure data)

Review Process: Interests and Research



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Next Steps

- Launch date: May 2017
- Training:
  - Deans, Dept Heads, Faculty, Investigators
  - Will need to identify and train Proxies
  - Departmental focused; webinars; open office hours; monthly trainings on each campus
- Partner with DCM

Thank You!

Lory A. Hayes, PhD, CHRC
Associate Director, DCM
lhayes@med.miami.edu
Office: 305-243-5036
Help line: 305-243-0877

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Greenphire ClinCard

Greenphire ClinCard Program

What is the ClinCard?

- A method to reimburse patients in clinical trials
- A debit card, backed by MasterCard
- Reloadable for multiple payments to patient
- Card is managed through ClinCard web-based software

What is the ClinCard?

- ORA is doing a 60-day pilot with up to 25 users
- Pilot departments are Psychiatry/Psychology
- Adding users beyond 25 will require a one-time setup fee
- A user is a person with access to the portal, i.e. software.

UM Fees

- To be built into study budget
- Card cost: $3.65-$4.00 per card, depending on volume
- Loading fee: $1.00 per load, $50 minimum monthly. Loading fee includes initial load, reload, edit load and void load.
- Shipping fee: $20 per card order
- Management fees: $100 or more monthly, depending on number of users

ClinCard Funding

- Accounts Payable will use a petty-cash like system to replenish initial fund, financed by ORA
- Necessary costs must be estimated budget: Cards cost, loading fees and other fees to UM
- Cards need to be ordered 7-10 days ahead of time
- Dedicated site computer must be used for loading card – UMIT requirement

Patient ClinCard Uses and Fees

- Card balance is available within minutes of loading, unless approver required
- Card usage options:
  - Signature POS: like a credit card. Swipe at register. Free
  - PIN based: like a debit card, cash back option. Call MasterCard for PIN. Free
  - ATM access: cash redemption. Fee: $3 domestic, $4 international
  - Bank withdrawal: cash redemption at any MasterCard accepting bank. Free
- Inactivity fee: $4.50 per month after 6 months, from card balance. Can be reversed with phone call to Greenphire
- Lost card fees:
  - Site coordinator transfers the balance to new card. Fee: cost of card
  - MasterCard replaces card. Fee: $7 from card balance

ClinCard Card Management

- ORA will keep blank cards
- Cards sent to site administrators upon formal request
- Site coordinators register patients for study
- Site coordinators load and issue cards to patients upon completion of first milestone
- Site coordinators reload cards for subsequent milestones, if any
- Preloaded payments and manual payments do not require secondary approver
- Manual payments require comment
- All travel reimbursement require secondary approver – ORA

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Export Control

Export Control – New Director

Export Control Compliance

William J. Collins

Director, Export Control Compliance

- Email: Wjc59@miami.edu
- Phone: 305-284-9558

www.ora.miami.edu

Questions