April 30, 2012

- New Conflict of Interest Regulation – Charlotte Talman (30 mins)
- eRA Project – Jose Jimenez (15 mins)
- Researcher Handbook – Leslie Weatherhead & Hayley Yearian (15 mins)
- DSP Announcements – Jennifer Lassner (15 mins)
- GAO Announcements – Audra Haddy (15 mins)
- Electronic Grant Summary Reports – Audra Haddy (15 mins)
Financial Conflict of Interest Related to Research

Charlotte Talman
COI in Research Office
Office of the Vice President for Research

April 30, 2012
UI policy since 1995

Based on 1995 federal regulations of the US Public Health Service

Disclosure at UI has been on a “per project basis”
- For each project, *person completing routing form and IRB application indicates whether anyone on the study team has a conflict of interest*
It’s a New World

- Revised federal regulation released Aug 2011; must be implemented by Aug 24, 2012
- UI policy has been revised and will go into effect on Aug 24
- Disclosure will be on an annual basis and determination of linkage on a “per project basis”
Annual disclosure of financial interests

- Remuneration; stock in a public or private company; royalty payments; position with a fiduciary duty
- Required prior to submission of proposal
- Financial interests related to all University responsibilities (teaching, clinical service, research, etc.)
- Includes financial interests of spouse & dependent children
- For researchers with PHS funding:
  - Must disclose sponsored/reimbursed travel
  - Must disclose payments from non-profit entities
University determines if a financial interest is a conflict of interest

- Does the financial interest reach the new threshold?
- Monetary threshold lowered from $10K to $5K
- Is the financial interest related to the research?
- Could the interest affect (bias) the research?
Mandatory COI training

- Required prior to engaging in research
- Every four years
- More frequently if researcher is found to be noncompliant with UI policy or a management plan
Public accessibility to financial conflicts of interest

- In the case of researchers with PHS funding who are determined to have a financial COI, the University is required to respond to written requests for information within five business days.
Monitoring compliance

- For researchers funded by PHS, University must monitor researchers’ compliance with management plan annually for the life of the grant
Obligations related to subawards

- For PHS research, University must establish whether subrecipients will follow UI’s policy or their own policy (which must be compliant with the federal regulation)
- Some subrecipient researchers will need to disclose financial interests to UI and may require review/management by UI’s COI committee
- Start subaward process early!
A Tool for Implementation of the New Regulation

- A new electronic disclosure system

- Consolidates several offices’ requirements - UI Health Care, Office of Continuing Medical Education, and COI in Research Office

- Customized questions: involved in non-PHS research; involved in PHS research; not involved in research

- COI training embedded in disclosure form
March 5 to April 30: UI Health Care employees (research and non-research) must complete an annual disclosure form; >6,000 completed to date

April to August: Integrating eCOI with UIRIS and Hawk IRB system; begin to solicit disclosures from non-Health Care researchers

August 24: Revised UI Policy in place; all researchers must have disclosure on file in order have a proposal submitted to sponsor

2013: Full consolidation of COI and COC disclosure processes (?)
Who Must Complete a Disclosure Form?

Anyone involved in research at the University

- Key personnel named on a Routing Form
  - PI
  - Co-investigators
  - Other Personnel - individual(s) who have the authority to make independent decisions related to the design, conduct, or reporting of research. Also includes individuals who are likely to be authors on manuscripts or to present research findings.

- Key personnel named on a Hawk IRB application
  - PI
  - All faculty members
  - Other individual(s) who have the authority to make independent decisions related to the design, conduct, or reporting of research. Also includes individuals who are likely to be authors on manuscripts or to present research findings.
Take Home Message

I don’t want to be lonely....

Contact Information
Phone: 5-8892
Email: charlotte-talman@uiowa.edu

URL
Employee Self-Service (soon)
http://ecoi.uiowa.edu
eRA Project
Rationale

Renewing the Iowa Promise: “Great Opportunities—Bold Expectations”
The Strategic Plan for The University of Iowa, 2010-2016

Overview

Mission:
Education
Research and Creative Work
Outreach
Health Care

Expectations:
Student Success
Knowledge and Practice
New Frontiers in the Arts
Better Futures for Iowans

Opportunities: New Facilities and Comprehensive Campaign

Foundational Commitments:
Inclusion and Internationalization • Sustainability • Collaboration, Enterprise, Innovation

University Functions: Business Services • Clinical Enterprise • Development • Facilities Management •
Financial Management • Human Resources • Information Resources and Technology • Intercollegiate
Athletics • Legal & Risk Management • Strategic Communications • Student Life and Housing
Mission:

- Education
- Research and Creative Work
- Outreach
- Health Care
Revised Rules on Financial Conflicts

August 24, 2011 - 3:00am

By Doug Lederman

WASHINGTON -- For the first time since 1995, the federal government has revised its policies governing researchers' financial conflicts of interest, in ways that federal officials said would build public trust in the integrity of biomedical research by strengthening transparency and oversight.
Rationale

**COIR**
- New Disclosure system required
- Review required before submission of proposals

**DSP**
- Need to capture additional research staff on Routing Form
- Submission to sponsor blocked based on review by COIR

**IRB / IACUC**
- Protocol approvals dependent on COIR review
Rationale

- Implementation of a robust and integrated research information system for pre- and post-award administration
- An integrated system will simplify the processes and reduce the amount of effort required for grant management and administration
An innovative system that will transform research administration and enhance the University’s ability to procure, administer, and monitor research grants and contracts.
Key Partnerships

- ITS – Information Technology Services
- Provost Office
- University of Iowa Hospitals & Clinics
- University of Iowa Carver College of Medicine
- Institute for Clinical & Translational Science at the University of Iowa
Key Partnerships

- Executive Sponsors
- Executive Steering Committee
- VPR IT Advisory Committee
- Project Leadership Team
- Functional And Technical Module Leads
- Module Implementation Teams
- Campus Advisory Committees
- Stakeholder Focus Groups
Scope of the eRA project

VPR Research Information Systems Application Portfolio

Integrated Research Portal

Pre-award
UIRIS, Use424 Grants.gov

Compliance
Conflict of Interest (Emory eCOI), HawkIRB, Animal Operation, Animal Regulations (HawkLAUC), Environmental Health and Safety, Onsite-EHS Assist

Post-award
Internally Developed, Commercial

Notes:
1 – CTSA Consortium Agreement

April 2012
eRA Project Progress

- RIS – hired 6 developers in the last 9 months
- eCOI – 6,000+ faculty and staff disclosures.
- IACUC – Proof of concept prototype created.
- Portal – Researcher Handbook is being developed
Pre-Award Project Progress

- August 2011 – Electronic Routing Form released
- September 2011 – Pre/Post award integration points and process workflow
- October 2011 – Fit Gap Analysis
- January 2012 – Reporting / Data Enhancements pilot
- April 2012 – Release of new printed routing form
What is next

- eCOI – Integrate eCOI and electronic Routing Form to ensure compliance with regulations effective in August
- Pre-Award – Move additional DSP forms to a new model similar to the electronic Routing Form.
- IACUC – Planning and additional work on prototype
- Portal – Researcher Handbook
Researcher Handbook

New online resource for navigating the research enterprise

{Coming Summer 2012}
Project background

Need for “concierge” to help faculty navigate the vast research enterprise
Project team

The Core Committee is working with topic experts across the institution.
Project overview

The eHandbook will serve as a directory of the programs, policies, resources, offices, and contacts that all researchers need to know.

Target audience: New Researchers
Table of Contents

1. Transfer to campus
2. Regulatory approvals
3. Pre-award
4. Managing awards
5. Human resources management
6. Responsible conduct of research
7. Leaving the institution

+ Commonly used acronyms

Project overview

- All stages of research:
  Transferring to campus ➔ Leaving the institution

- High-level summaries and FAQs
**Project timeline**

Over the next two months, the Core Committee and OVPR will be solicit input from faculty and administrators.

**Feb – June:**
- Content development
- Solicit input and revise content.

**April – June:**
- Introduce project to various groups on campus.

**Summer 2012:**
- Go live.
- (Continue to develop content.)
Researcher Handbook - Table of Contents

This electronic guide is designed to assist all researchers (new and existing) as they navigate the complex research environment at the University of Iowa.

All sections will be completed by June 2012. If you have suggestions for new content or comments about existing content, please email research-webmaster@uiowa.edu.

1. Introduction / Welcome to The University of Iowa
2. What should I do before I come?

Website demo
• Watch for an announcement in June
• Review the website
• Talk to your faculty
• Send us your ideas

How can you help?
How can you help?
DSP UPDATES

- Staffing Changes
- eRouting
The UIRIS menu now offers a single routing-form link for initiating a Routing Form.

Once completed, the initiator will elect to either (a) eRoute through Workflow; or (b) print for paper routing.

Paper routing forms created in the Traditional system will be available for viewing via UIRIS/SPRIE search results.
eRouting FAQs

- Routing form initiator and PI work in the **UIRIS** system; all other approvers use **Workflow**
- Reviewers may edit the routing form *before* it is approved
- Personnel not editable after submission
- View Workflow path in the finish **tab**
10.2. Submission Info

Submitted: April 13 2012 05:36PM

Submitted By: Jessica L. Jensen

Disclaimer - Courier Delivery
Please remember that overnight couriers, including the one utilized by the Division of Sponsored Programs, make reasonable efforts, but do not guarantee delivery of packages at the specified time and place. As a general rule, the declared value of packages is $100. In the event of loss, damage, misdelivery or non-delivery of any such package, the courier will provide compensation.

11. Finish

11.1. This Routing Form has been Submitted.

11.1.1. Principal Investigator Workflow

- George R Bergus - Family Medicine - 17/3210
- Barcey T Levy - Family Medicine - 17/3210

Name | Approval | Org-Dept
--- | --- | ---
HOUSHOLDER, SONYA KAY | May Approve | 17DS1
ROBERTSON, ANGIE CHRISTINE | May Approve | 17DS1
BOOKER, SHARON S | Required | 173210
LEVY, BARCEY T | Approved |

11.1.2. Co-Investigator Workflow

- Kate DuChene Thoma - Family Medicine - 17/3210
- Kristi J Ferguson - Internal Medicine - 17/3215

Name | Approval | Org-Dept
--- | --- | ---
HOUSHOLDER, SONYA KAY | May Approve | 17DS1
ROBERTSON, ANGIE CHRISTINE | May Approve | 17DS1
BASSLER, LORETTA FAYE BEEDE | May Approve | 173215
MILLER, NECOLE | May Approve | 173215

- Jeanette M Daly - Family Medicine - 17/3210

Name | Approval | Org-Dept
--- | --- | ---
HOUSHOLDER, SONYA KAY | May Approve | 17DS1
ROBERTSON, ANGIE CHRISTINE | May Approve | 17DS1
BASSLER, LORETTA FAYE BEEDE | May Approve | 173215
MILLER, NECOLE | May Approve | 173215
New Staff:
- Brad Franzwa
FY11 Single Audit
  ▪ Completed in March 2012
  ▪ Results
    ▪ Questions about allowability of costs
    ▪ Confirmation of key personnel effort commitments
  ▪ No findings for second year in a row
Benefits of electronic reports:

- Eliminates use of ITS mainframe & high speed printers for all grant financial data, including elimination of:
  - FMS mainframe database
  - Report distribution (BALS)
  - University Wide Reports (FMS, SGRE, TDS)
- Provides grant financial reports within EFR Inbox
  - Portal for all university financial reports
  - Builds upon current distribution infrastructure
- Allows for integration with pre award data/information
- Utilizes management data (ePost) not previously provided
- Provides additional data summarized for award
  - Compensation
  - Subaward
- Allows download of data from any report
  - Eliminate re-keying of financial data
Replacement of Grant Paper Reports

Timeline

Data
fall 2011 - November 2012

- Review budget categories
- Data analysis
- Reconciliation

Report Development
January 2012 - November 2012

- Gather feedback
- Define data sources
- Create report specifications

Implementation & Distribution
spring 2012 - November 2012

- Communication
- Finalize distribution
- Testing
- Pilot
Finalizing FMS Category Codes

FMS category codes are the budget level categories that are used to sort and summarize grant financial data.

New categories:
- Wages (iaccts 59xx)
- Animals and Animal Supplies (iacct 6120)
- Research Participation Costs (iaccts 6045, 6046, 6240)
Replacement of Grant Paper Reports

- New report formats
  - Similar to current format, but will allow drill down from summary to lower levels of detail
  - Utilize similar distribution as TDR including the EFR inbox