

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

# The Good Old Days

- 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”

# Major Changes in Federal Regulation Governing COI in Research

## 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**

# Major Changes in Federal Regulation Governing COI in Research

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?

# Major Changes in Federal Regulation Governing COI in 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

# Major Changes in Federal Regulation Governing COI in Research

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



# Major Changes in Federal Regulation Governing COI in Research

## Monitoring compliance

- For researchers funded by PHS, University must monitor researchers' compliance with management plan annually for the life of the grant

# Major Changes in Federal Regulation Governing COI in Research

## 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

# Timeline for Implementation

- 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](mailto:charlotte-talman@uiowa.edu)

## URL

Employee Self-Service (soon)  
<http://ecoi.uiowa.edu>



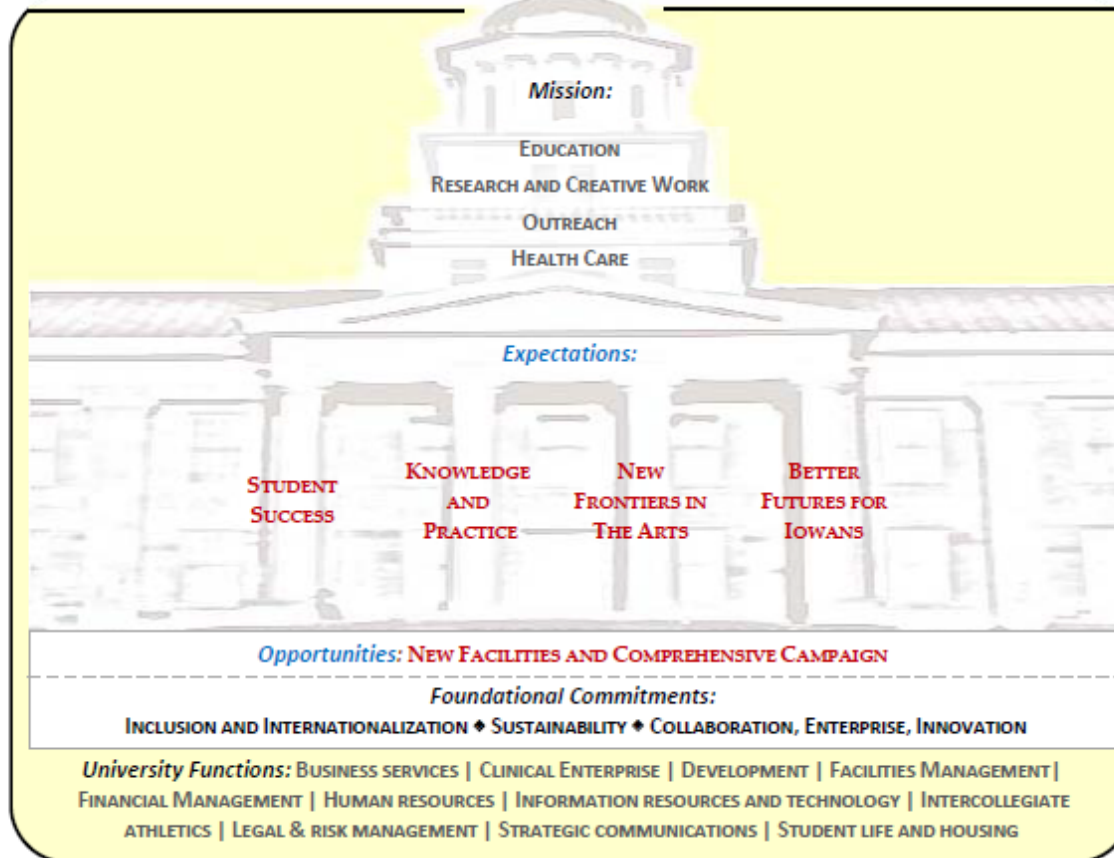
# eRA Project

# Rationale

 THE UNIVERSITY OF IOWA

RENEWING THE IOWA PROMISE:  
“GREAT OPPORTUNITIES—BOLD EXPECTATIONS”  
The Strategic Plan for The University of Iowa, 2010-2016

## OVERVIEW








# Rationale








# Rationale

## INSIDE HIGHER ED

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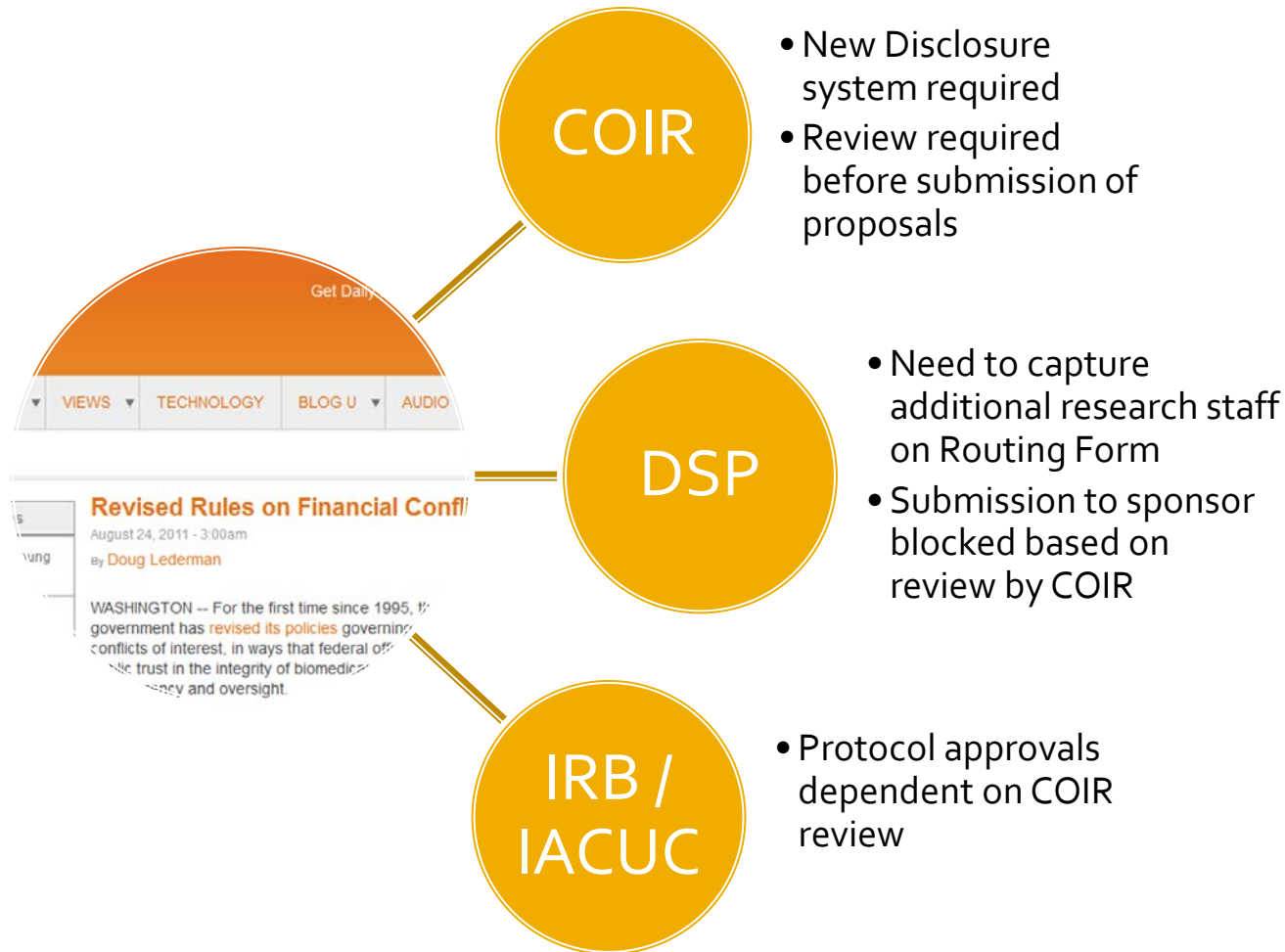
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### Revised Rules on Financial Conflicts

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





# Rationale

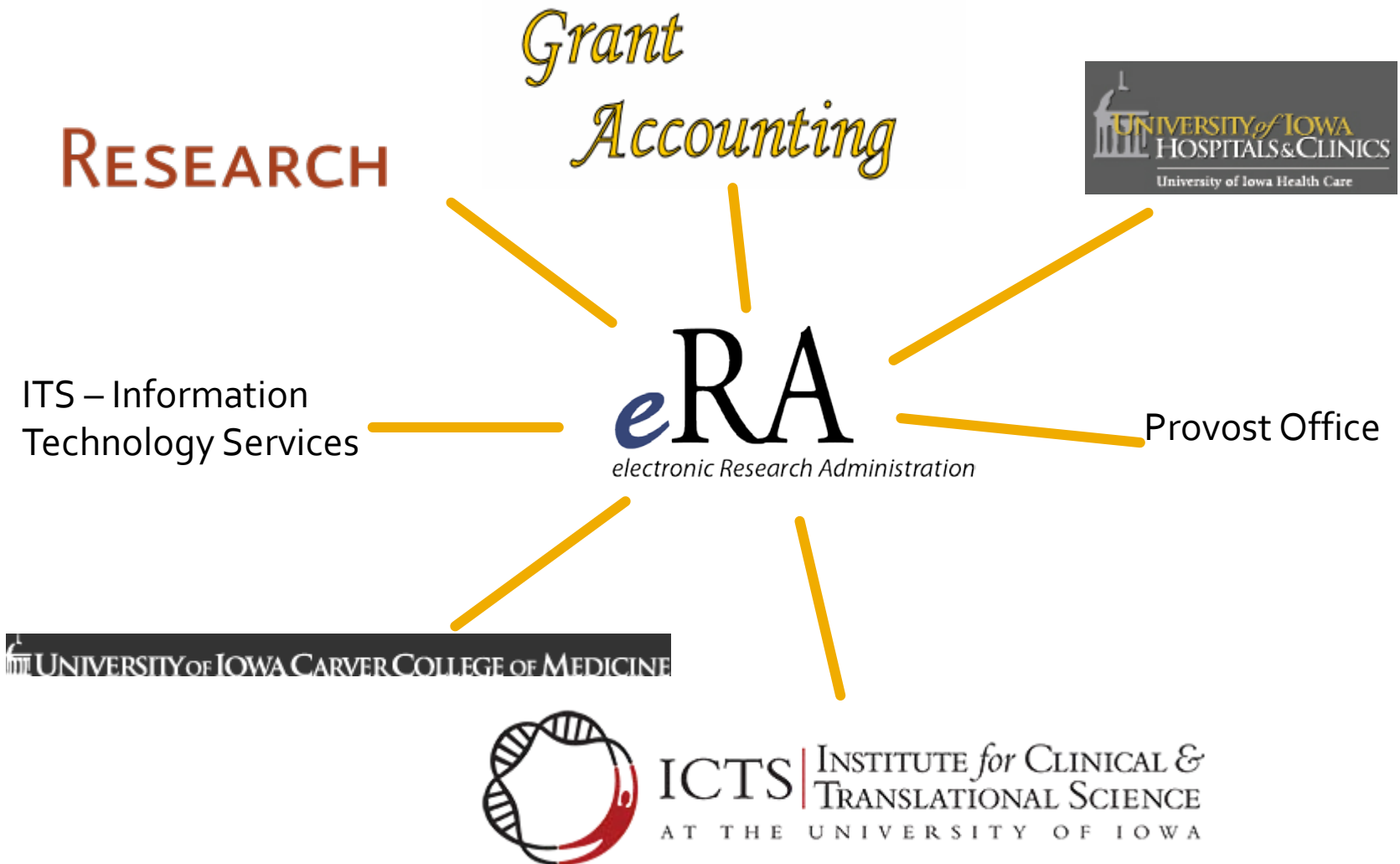
- Implementation of a robust and integrated research information system for pre- and post-award administration
- An integrated system will simplify the processes and reduce the amount of effort required for grant management and administration

# eRA Vision

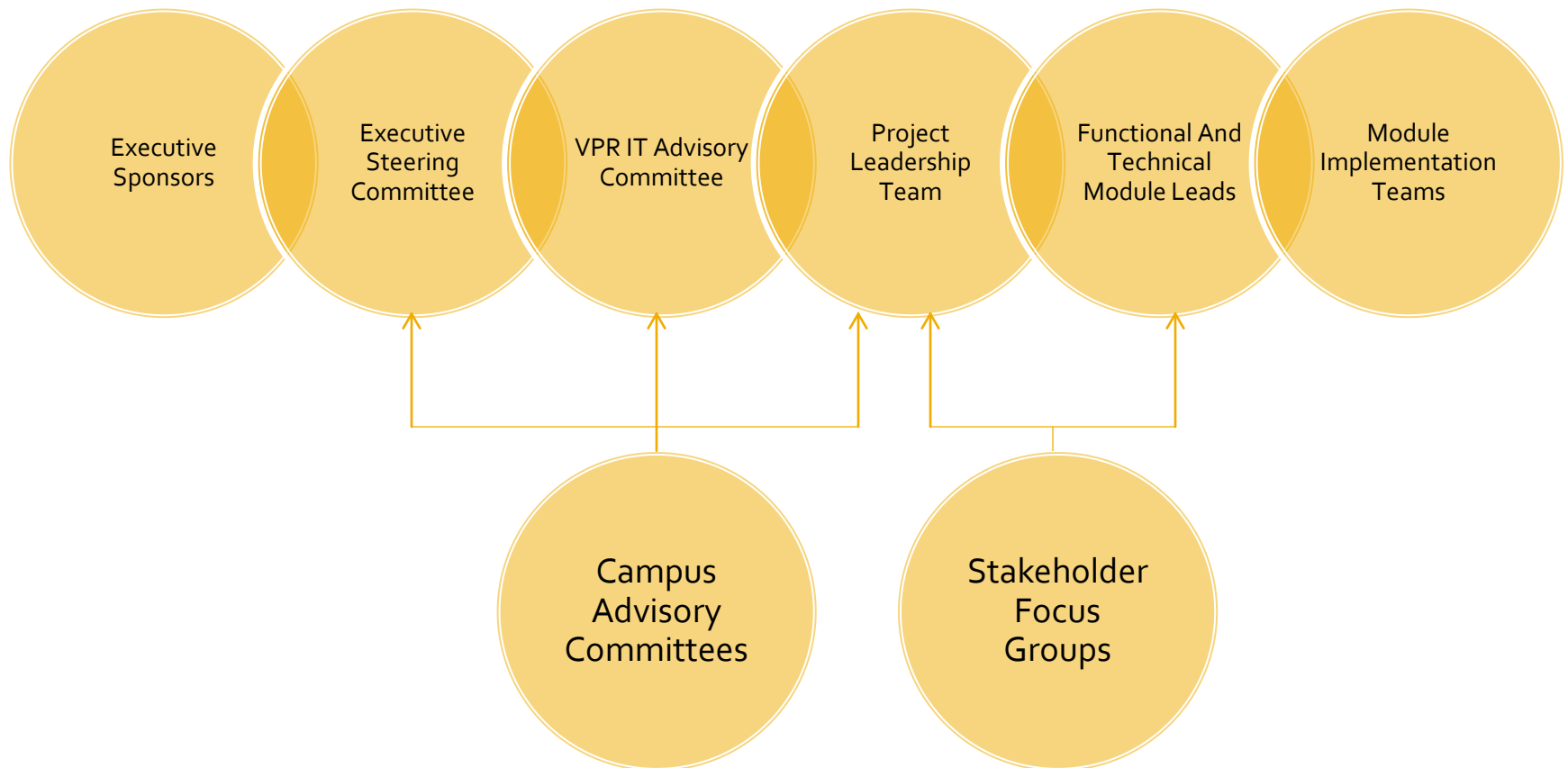
An innovative system that will transform research administration and enhance the University's ability to procure, administer, and monitor research grants and contracts.

access **administrative** awards burden  
business **collaboration** community  
**compliance** create data deliver demands departments  
developing effectiveness efficiency **enhance** ensure enterprise  
entire flexibility foundation functions funding future **grow** holistic  
**improve** information **integrate**  
investigators meet obtain offices partnerships  
process promote protocol reducing regulations  
**research** service sponsored staff  
system taking technologies timely **university** view

# Key Partnerships

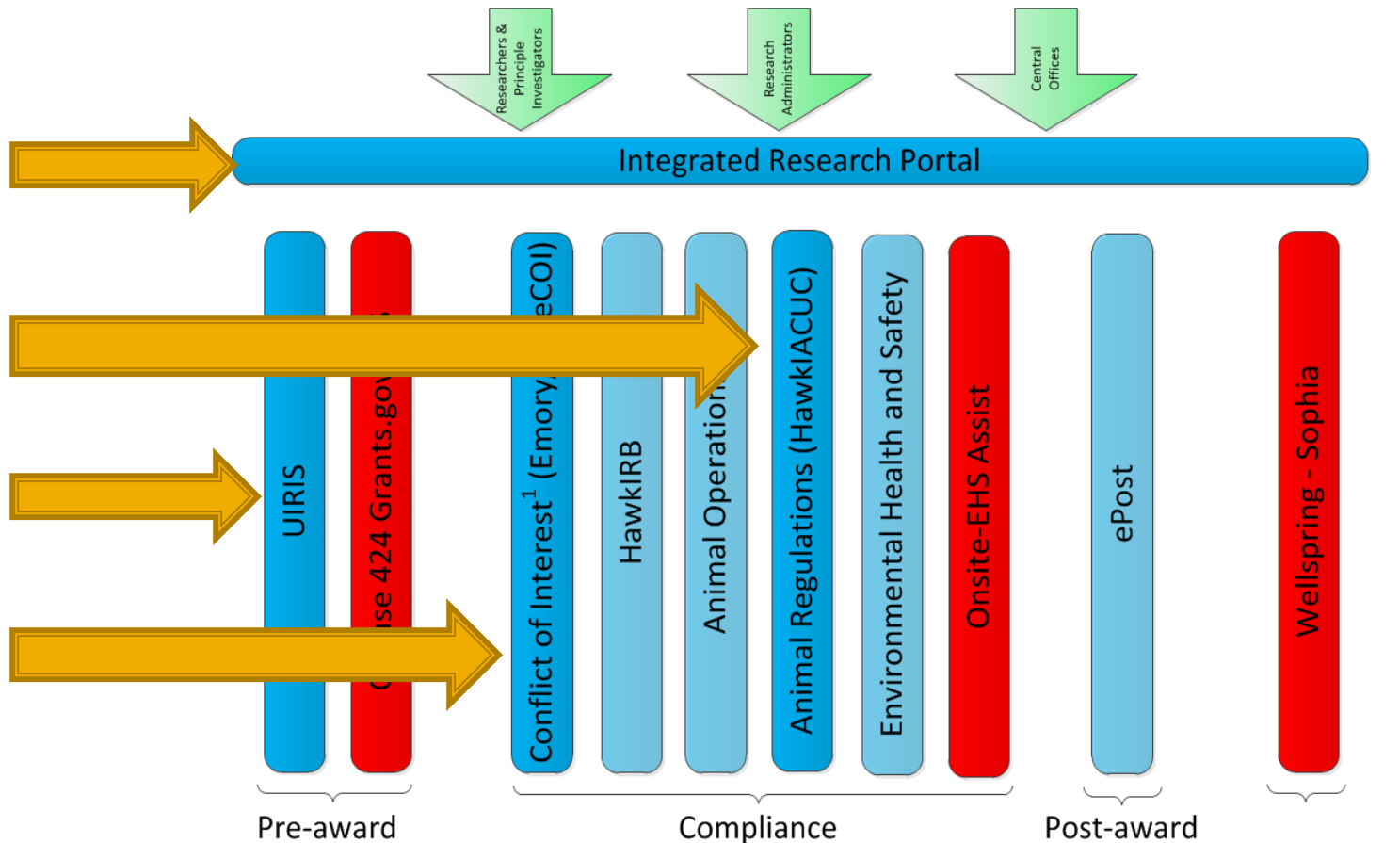


# Key Partnerships



# Scope of the eRA project

## VPR Research Information Systems Application Portfolio



Notes:

1 – CTSA Consortium Agreement

April 2012

Internally Developed ●

Commercial ●





# 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

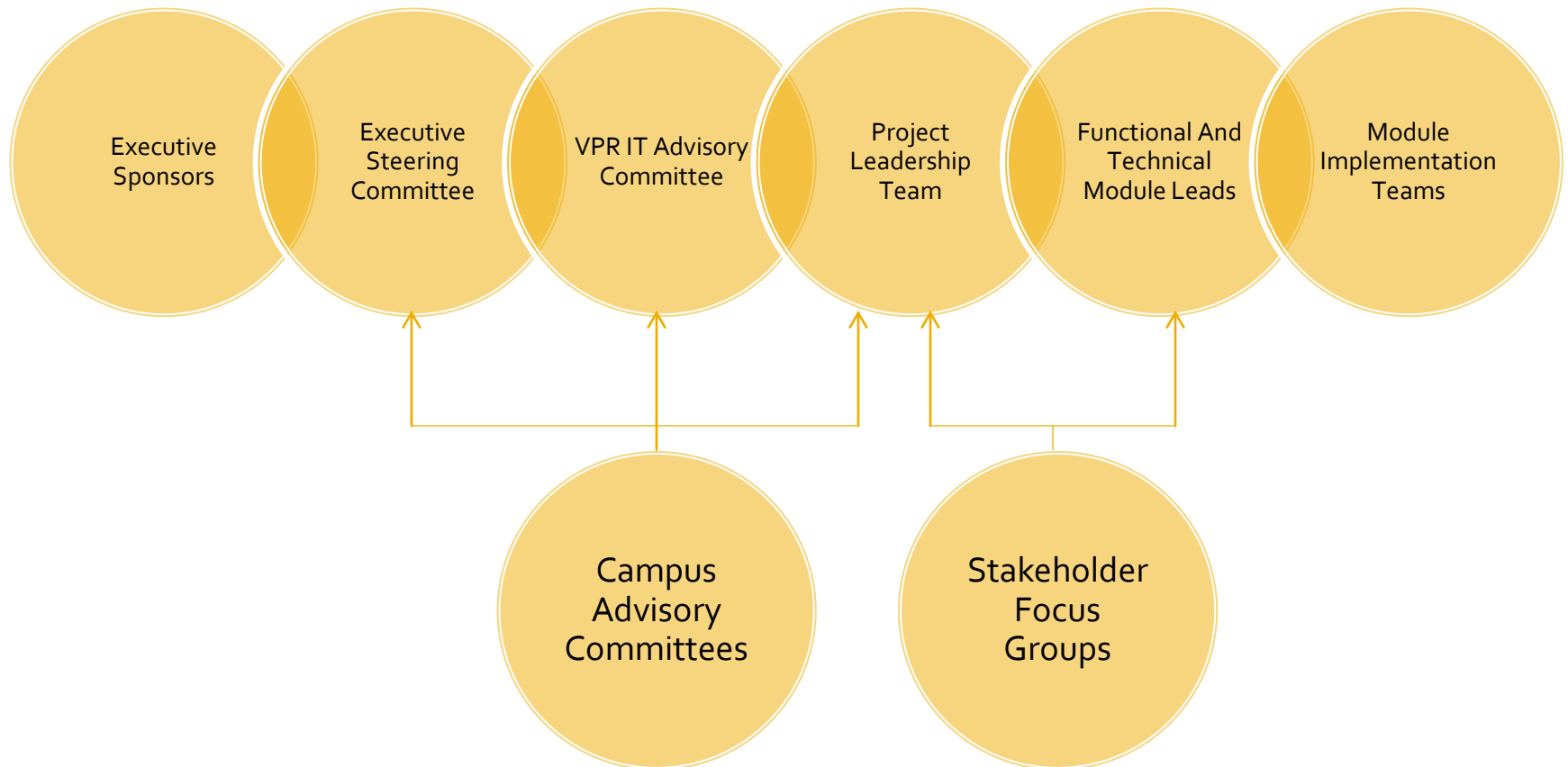
# Pre-Award Project Progress

- 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

# Involvement





# Research Handbook

New online resource for  
navigating the research enterprise  
{Coming Summer 2012}



## Leslie Weatherhead

Assoc. Director of Research Development  
and Communications

[leslie-weatherhead@uiowa.edu](mailto:leslie-weatherhead@uiowa.edu)

## Hayley Yearian

Research Webmaster

[hayley-yearian@uiowa.edu](mailto:hayley-yearian@uiowa.edu)

*Office of the Vice President for Research*





# Project **background**

**Need for “conierge” to help faculty navigate the vast research enterprise**



Audra Haddy, *Grant Accounting Office*

Jennifer Lassner, *Division of Sponsored Programs*

Charlotte Talman, *Conflict of Interest in Research Office*

Kristi Fitzpatrick, *IA Social Science Research Center*

Barb Spence, *Microbiology*

Judie Hermsen and Sean Hesler, *Human Resources*

Leslie Weatherhead and Hayley Yearian, *OVPR*

## 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

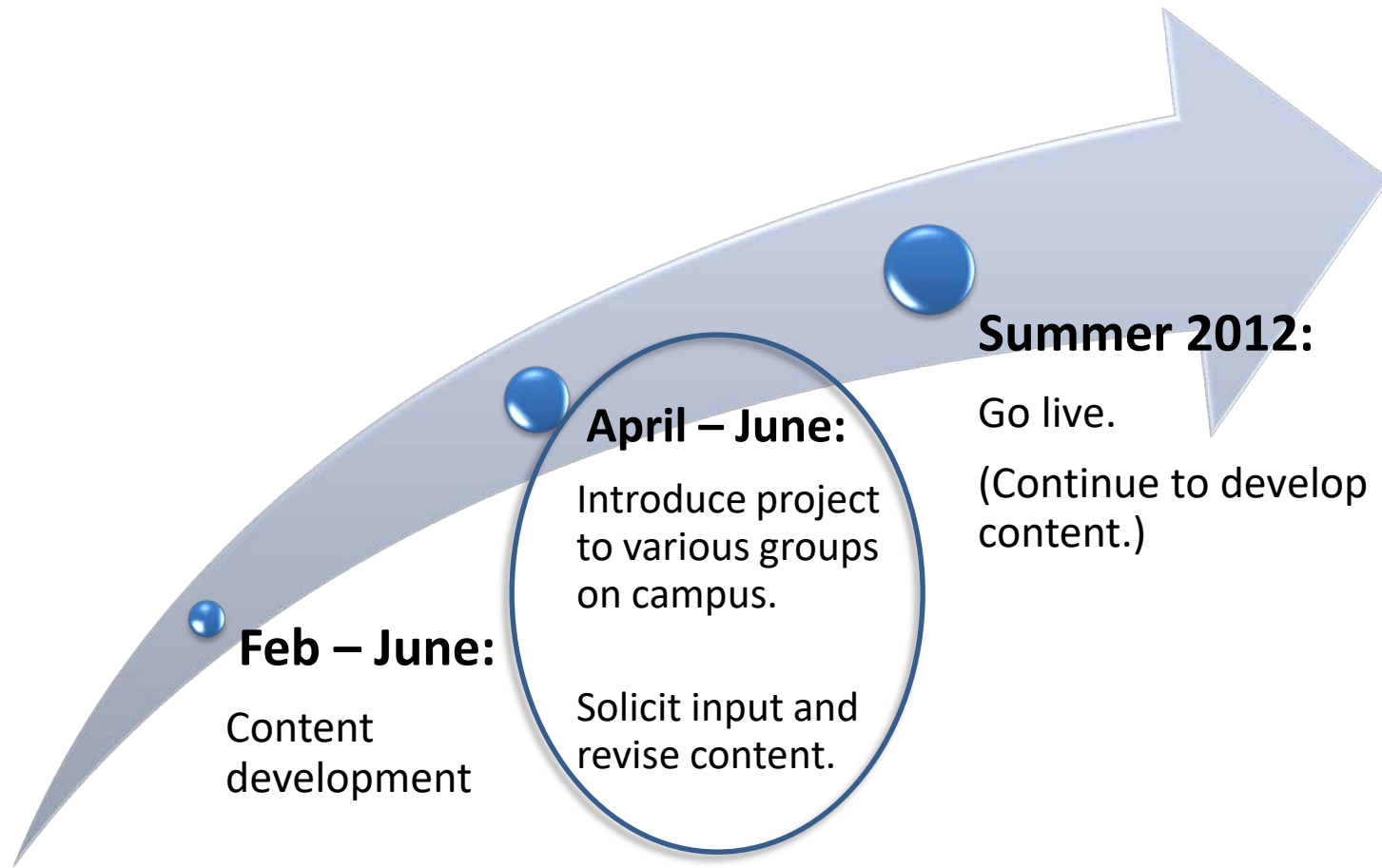
1. Transfer to campus
  2. Regulatory approvals
  3. Pre-award
  4. Managing awards
  5. Human resources management
  6. Responsible conduct of research
  7. Leaving the institution
- + Commonly used acronyms



## 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.





# Researcher Handbook

[RESEARCH HOME](#) | 
 [RESEARCH A-Z INDEX](#) | 
 [ACRONYMS](#)

<http://dev.sitenow.uiowa.edu/researcherhandbook/>

UNIVERSITY OF IOWA

Researcher Handbook

[COI](#)
[DSP](#)
[EHS](#)
[HSO/IRB](#)
[OAR/IACUC](#)
[RIS](#)
[VPR](#)
[MORE UNITS](#)

- Table of Contents

- 1. Introduction

- ▶ 2. What should I do before I come?

- ▶ 3. Regulatory Approvals

- 4. Pre-Award

- 5. Managing Awards

[View](#)
[Edit](#)
[Revisions](#)

## 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](mailto:research-webmaster@uiowa.edu).

1. [Introduction / Welcome to The University of Iowa](#)

2. [What should I do before I come?](#)

# Website demo

Transfer specimens out of the lab

3. [Regulatory Approvals](#)



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



# How can **you** help?



[research-webmaster@uiowa.edu](mailto:research-webmaster@uiowa.edu)

[hayley-yearian@uiowa.edu](mailto:hayley-yearian@uiowa.edu)

[leslie-weatherhead@uiowa.edu](mailto:leslie-weatherhead@uiowa.edu)

How can **you** help?



# DSP UPDATES

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- Staffing Changes
- eRouting

# eRouting – April 16 Announcement

- 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**

https://uiris.uiowa.edu/routing\_form/view/2878

UIRIS - Grant Log Finde... UIRIS - Grants Applicati... New Tab View - UIRIS - The U... x

File Edit View Favorites Tools Help

Google Search More >> Dav

UIRIS G UIRIS RF UIRIS Awards GAO Cayuse Commons Dates UIRIS K NIH

Scroll By: [Change 0](#) of 0 Add New Help Text

[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 nondelivery of any such package, "the courier" will provide compensation.

[11. Finish](#) [View Routing Form Tabs](#)

[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	17 3210
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	17 3215
MILLER,NECOLE	May Approve	17 3215

- ▼ Jeanette M Daly - Family Medicine - 17/3210

Name	Approval	Org-Dept
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110%

April 30, 2012

# Research Administrator Meeting



# GAO Updates

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- **New Staff:**
  - Brad Franzwa



# GAO Updates

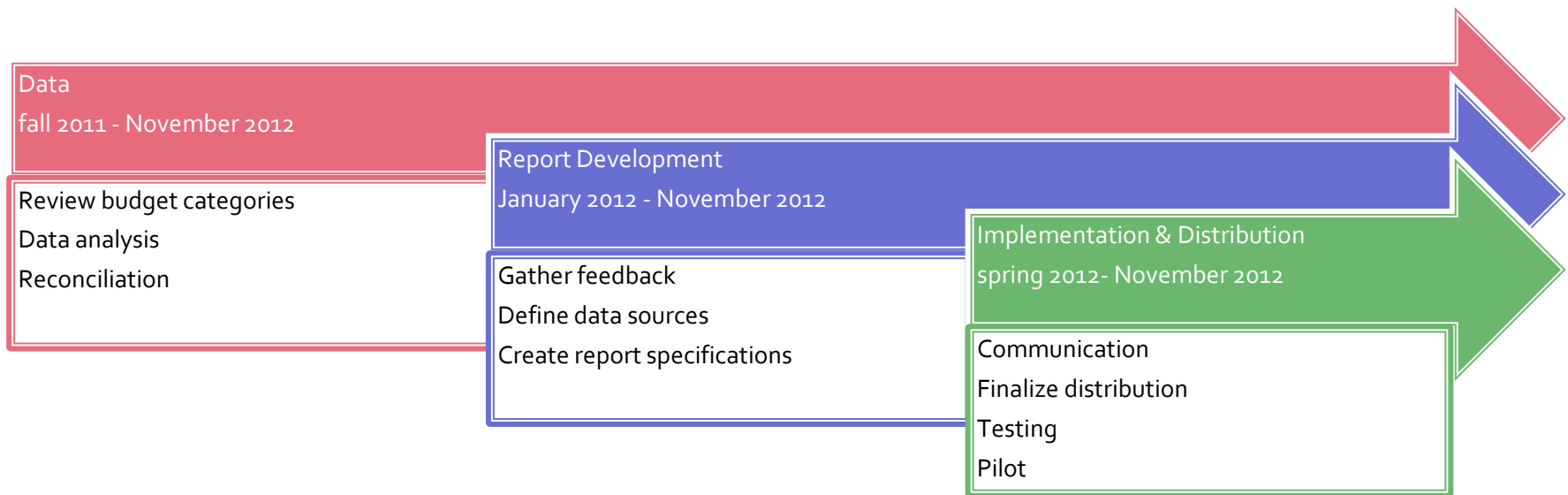
- FY11 Single Audit
  - Completed in March 2012
  - Results
    - Questions about allowability of costs
    - Confirmation of key personnel effort commitments
  - No findings for second year in a row

# Replacement of Grant Paper Reports

- 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



# Replacement of Grant Paper Reports

- 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