RE: Interim “Action Items” to go into effect immediately
These interim activities will be replaced (soon) by
   1. automated e-mails and
   2. automated interactions between COI office “screens” and DSP’s UIRIS2/GAAE “screen”

Action Items from the Tues Jan 21, 2014: 4pm meeting:

Until we can get the e-mails (etc.) automated, it was agreed that the following would go into effect immediately, in order to avoid future miscommunications between COI and DSP:

(1) The COI office would send an e-mail “manually” to DSP at era@uiowa.edu listing the UI Proposal Routing Forms in which the COI? Yes/No Question was changed from “NO” to “YES” by the COI office.

(2) The COI office would send an e-mail “manually” to DSP at era@uiowa.edu when the COI office had approved the management plan for a particular UI Proposal Routing Form (or Sequence Number). Only after this e-mail via era@uiowa.edu is received by DSP, will DSP change the UIRIS2/GAAE “Conflict of Interest Status” drop-down box to “Approved,” and thus “unblock” the award process.

(3) These e-mails from the COI office to DSP at era@uiowa.edu would be the only official record of these COI office transactions, until these procedures can be automated, which is the ultimate goal.

john m
RE: UIRIS2/GAAE #19 COI (YES/NO)

UIRIS2/GAAE Conflict of Interest Status (Pending/Not Approved/Funded)

Problem: Inadequate communication between DSP and COI when these values change, or need to change

These two solutions would fix the problem, from DSP’s perspective. (Wendy approves for DSP).

COI office may have other needs/requests.

This is all subject to change, of course, but provides some structure for the meeting.

1) SOLUTION #1: Auto-Email to DSP (and to COI office?) when COI office changes status to YES:

   Initial Situation: PI answers PRF 7.3.1 (COI?) = NO, so automatically UIRIS2/GAAE/#19 (COI?) = NO.

   When COI office changes a COI office “screen” to COI=YES, this CURRENTLY:

   A. changes UIRIS2/GAAE/#19 from NO to YES

   B. Blocks the UIRIS2/GAAE/-GAO award process by requiring UIRIS2/GAAE/“Conflict of Interest Status” box = “Approved” before the AWARD can be made.

   Also, NEW FEATURE:

   Auto-email from UIRIS2 to era@uiowa.edu saying essentially “Sequ# E123400  GAAE #19 (COI) is now YES”

PURPOSE AND BACKGROUND FOR SOLUTION #1:

When a DSP reviewer sees PRF 7.3.1 (COI?) = NO on the routing form, the DSP reviewer assumes:

   A. “COI=NO” is the correct answer, and
   B. There is, in fact, no COI, and
   C. It is OK to continue the review/negotiations through signature stage.

COI office may have turned UIRIS2/GAAE/#19 to YES at some point after routing is completed, but the DSP reviewer may not notice that change without an auto-e-mail.

Although the AWARD is blocked in UIRIS2 by UIRIS2/GAAE/#19 being YES (as long as UIRIS2/GAAE/“Conflict of Interest Status” box = “[Not Approved]”), blocking at the AWARD step is TOO LATE for DSP to notice the YES to COI, because final signatures may have been already obtained. Thus, it is currently possible for the UI and the non-UI party to sign an agreement for which the COI office has not yet approved the MANAGEMENT PLAN. (=a bad thing)

With the auto-email to DSP at era@uiowa.edu, DSP (and thus the DSP reviewer) will be alerted that UIRIS2/GAAE/#19 has been switched to YES by the COI office, and that final signatures are not appropriate until the COI office approves the MANAGEMENT PLAN.
**SOLUTION #2**: COI office should directly control UIRIS2/GAAE CONFLICT OF INTEREST STATUS (a new feature) + Auto e-mails should be sent to DSP (and COI office?) when STATUS changes.

When COI subsequently accepts the COI MANAGEMENT PLAN by editing a COI office screen to indicate acceptance, UIRIS2/GAAE should capture this change and:

A. automatically change the UIRIS2/GAAE CONFLICT OF INTEREST STATUS to “Approved.”, and

B. send an auto-mail to era@uiowa.edu (and COI office?) saying “Sequ# E123400 CONFLICT OF INTEREST STATUS is now APPROVED”

C. and/or send an auto-mail ANY TIME (?) the UIRIS2/GAAE/CONFLICT OF INTEREST STATUS box value changes.

**PURPOSE AND BACKGROUND FOR SOLUTION #2:**

As you know, UIRIS2 blocks DSP from making an AWARD until UIRIS2/GAAE CONFLICT OF INTEREST STATUS shows “Approved.”

In addition to the problem already mentioned above with SOLUTION #1 (i.e., DSP continuing to act as if “COI=NO” when that is not correct) there are currently TWO ADDITIONAL PROBLEMS with this situation:

A. Changing UIRIS2/GAAE CONFLICT OF INTEREST STATUS is currently not automated, and so depends on ad hoc DSP COI office communication. COI office must “tell” DSP to make the change of UIRIS2/GAAE CONFLICT OF INTEREST STATUS.

B. It is often not clear to DSP personnel when UIRIS2/GAAE CONFLICT OF INTEREST STATUS should be changed.

So, the best solution is to put the COI office in direct control of UIRIS2/GAAE CONFLICT OF INTEREST STATUS by having COI office screen changes automatically update UIRIS2/GAAE CONFLICT OF INTEREST STATUS.

Auto e-mails would also be needed to alert DSP (and COI office?) when these changes were made.

Thus, the simple solution (a new business practice for DP) would be that DSP personnel would never change the UIRIS2/GAAE CONFLICT OF INTEREST STATUS, simplifying the process for DSP, and greatly clarifying the process for DS/COI office interaction.
SCREEN SHOTS of PRF 7.3.1, UIRIS2/GAAE/#19, and UIRIS2/GAAE “Conflict of interest Status”

**PRF 7.3.1** - Does anyone listed in the Personnel Section (Principal Investigator, Co-Investigator, and Other Key Personnel) or any spouse or dependent children have any of the following financial interests related to this research:

- With regard to any public company (one that sells its stock to the general public), personal compensation and/or stock, stock options or other ownership interest, when aggregated, valued in excess of $5,000 in the past year
- With regard to any private company (such as a start-up company), personal compensation in excess of $5,000 in the past year or any stock, stock options, or other ownership interest
- Company position such as employee, director, officer, partner, or any other management position
- Royalty or licensing income from intellectual property (discoveries, inventions, or creative works protected by law, including patent, copyright, trademark) from a rich site entity

UI Policy on Conflict of Interest in Research

**UIRIS2/GAAE 19** - Does any investigator – i.e., the principal investigator or any other faculty, staff, or student who is responsible for the design, conduct, or reporting of this project – and/or any investigator’s spouse and/or dependent child hold financial or other interests that could give rise to a conflict as defined in Section II, Division I, Chapter 18 of the University of Iowa Operations Manual?

**UIRIS2/GAAE “Conflict of interest Status”** (Approved; Not Approved; Pending)

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