

CONFLICT OF INTEREST SYSTEMS FOR MULTI-PURPOSE USAGE

BY: DAVID PROPEN AND ALLISON SHAH

KEY TAKE-AWAYS

- Institutional alignment of policy and process should precede system implementation
- Some process areas can vary, while others should be standardized across an institution,
- If an organization cannot standardize certain areas (for example because of local/state requirements), multiple systems may be a better option

CONFLICT OF INTEREST SYSTEMS FOR MULTI-PURPOSE USAGE: OPTIONS AND CONSIDERATIONS FOR ALIGNMENT

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Introduction

When implementing conflict of interest (COI) systems, institutions often want their system to be able to accommodate multiple purposes. These purposes may include, but are not limited to:

- Annual certifications of disclosures and financial interests
- Certifying financial interests for specific purposes at various times, e.g.
 - Funding proposals
 - IRB submissions, or at time of award
 - Board of directors or trustee-related questions
- Prior Approval Requests
 - Conflict of commitment and others

These different purposes are often managed by multiple owners or stakeholders such as research offices, compliance committees, legal departments, academic units and affiliates.

For multiple-purpose COI systems to be successful, the different purposes and stakeholders must be addressed thoughtfully and related considerations planned in advance of implementation. Several options and approaches to system implementation can be employed depending on institutional drivers.

This white paper explores these key options and considerations, providing recommendations as to best practices for multi-purpose COI systems based on experience across a variety of higher education institutions.

Options for Multi-Purpose Implementation Approach

When implementing COI systems for multiple purposes, offices or organizations, there are a number of options that can be employed. The two options presented below have been proven successful and provide for a greater likelihood of strong, positive outcomes. Other options, such as implementing a system without alignment, introduce more risk and are less advisable:

- 1. IMPLEMENT ONE SYSTEM:** Aligning key elements completely and other elements as much as possible, to manage long-term costs
- 2. IMPLEMENT MULTIPLE/SEPARATE SYSTEMS FOR DIFFERENT PURPOSES, USES OR ORGANIZATIONS:** More achievable when discloser populations don't align and/or requirements cannot be reconciled (for regulatory, cultural or other reasons)

1. Implementing One System

ALIGNING PROCESSES COMPLETELY

Aligning processes completely implies that all (or most) of the considerations for alignment listed below have been discussed amongst the multiple purposes, offices or organizations. It also implies that agreement, compromise or alignment has been reached regarding the approach and design to achieve multiple purposes.

We recognize that establishing consensus can be challenging, but a strong alignment and analysis effort can allow a wide range of purposes, offices or organizations to operate harmoniously within a single system.

Aligning processes successfully within a single COI system means an institution must start alignment work early. In one case, a director of research integrity ensured, a full year and a half in before the client engaged with Huron, that reporting, definitions and workflow were aligned between the primary institution and its secondary institutions with which the primary would be sharing its system. Major compromises were brokered and questions, such as whether department review will occur within or outside of the system, were addressed and agreed upon.

ALIGNING KEY ELEMENTS OF THE SYSTEM

Successful implementation of a single COI system for multiple purposes can be achieved without total alignment if key system elements and definitions are aligned. This model can accommodate some differences in areas such as routing, access, reporting or notifications, but the extent of differences will impact system complexity and maintenance.

The most important elements for alignment are definitions for disclosure reporting, such that a complete set of disclosed interests can be shared across purposes, offices, or organizations, and sharing the majority of the workflow.

For one hospital client, multiple offices were able to align mostly on disclosure definitions, workflow and business processes but less so on security. The client was able to collect the necessary information for each office through different system-secured viewer roles and even have different triage/routing logic, by office, for certifications that required administrative review, all while remaining in one system.

This option has its merits, specifically in enabling the institution to remain within a single system; however, risks associated with this approach

can include:

- Greater design and development effort
- Long-term support
- Potential for insoluble differences
- Increased timeline and budget

Indeed, establishing the details of alignment, across the multiple purposes or offices, during the course of an implementation — even if the high-level elements are previously agreed upon — can require additional coordination, time and effort that must be accounted for.

2. Implementing Separate Systems

In some cases, alignment of multiple purposes is neither possible nor desired by either one or more offices or organizations which are interested in an automated COI solution.

For one client, very different requirements between annual certifications and research-initiated certifications resulted in the institution implementing one system for annuals only. The client recognized that requirements were different, specifically, public health service (PHS) research requirements and state requirements were largely incompatible. Because reporting for each was different and the client only intended to capture data necessary to each purpose, the institution elected to have different systems. Another university decided to implement two different systems for state annual versus federal research regulations to great success.

IMPLEMENTING ONE SYSTEM WITHOUT ALIGNMENT

When institutions force alignment where there is no agreement, or when different purpose-groups compromise where key elements cannot or should not be compromised, a lack of user adoption and potentially noncompliance can result. For example, in cases where alignment is not established across definitions, disclosure data entry, and reporting and/or business process/workflow, noncompliance risks such as disclosers not completing their certifications in a timely manner are increased. Similarly, nonalignment amongst these items can introduce audit risks as well. Finally, increased risk of investigator burden, e.g. risks of seemingly duplicative data entry by disclosers can accompany misalignment associated with definitions or disclosure data entry and reporting. In these cases, implementing two separate systems would be advisable.

In cases where alignment was not established between multiple purpose-

groups or organizations, this has also led to budget overruns, project delays and, subsequently, recognition of mistaken approach. Implementing a second system to accommodate such differences should be viewed as a valid approach and considered for any multi-purpose implementation where considerations for alignment begin to point to significant differences or complexity.

At one university, significant differences in research certification and state certification requirements led the client to try to force alignment of these two purpose areas into a single system, first by creating a new data model and data entry approach for the state forms and later leveraging this new approach for the PHS research requirements. Approaching such disparate requirements, in the absence of robust upfront alignment efforts, introduced significant risk to the project, including risks of budget overruns, timeline extensions and rework. Thus, it necessitated a more complex technical approach. Ultimately, the project timeline was extended from four to six months and later to over two years; the project ran out of budget, forcing the client to request additional funds, some of which were not provided; and significant rework was indeed required. Such stressors on the timeline and budget also led to turnover amongst the client's project personnel.

CONSIDERATIONS FOR ALIGNMENT: HOW MUCH IS "ENOUGH"?

When determining which of these approaches best suits an institution and the multiple stakeholders who will utilize a system, it is important to consider a number of areas where alignment is critical and necessary to successfully "live" in a single system. These include:

- Definitions of financial interests
- Disclosure data entry and reporting
- Business process/workflow

Table 1 below, includes a number of questions to help an institution determine whether the degree of alignment between the multiple offices/purpose areas is sufficient to “live” in a single system.

TABLE 1. AREAS CRITICAL TO ALIGN

ID	AREA	PRIMARY QUESTION	FOLLOW-UP QUESTIONS	SUMMARY
1	Definitions of Financial Interests	Is there alignment across disclosure definitions and timelines?	<ol style="list-style-type: none"> 1. Are purpose-, office or organization-specific definitions equivalent or do they differ significantly? 2. Will the purposes, offices or organizations interpret regulations in the same way? 3. Are the time periods associated with the disclosures for the multiple purposes, offices or organizations equivalent? For example, federal regulations indicate that PHS researchers need to report everything in last 12 months; however, many clients prefer to use the last calendar year. 	<p>If offices or organizations are not willing or able to share a common set of disclosures, alignment within a single system will be difficult to achieve and less beneficial to disclosers.</p> <p>The time periods of disclosure data collection, specifically, should be aligned to avoid introducing undue complexity into the system.</p>
2	Disclosure Data Entry and Reporting	Are forms for the disclosure agreed upon?	<ol style="list-style-type: none"> 1. Are the values for disclosures that the multiple purposes, offices or organizations report on agreed upon, e.g. dollar values, dollar ranges, only entity names, etc.? 2. Will the multiple purposes, offices or organizations require/collect the same data/information around the disclosures? 3. Are there state-level requirements that will collect significantly different data than other purposes, offices or organizations? 4. What is the degree of difference between the reporting requirements? 	<p>Collecting different data on the disclosure forms by purpose, office or organization introduces significant complexity into the system, is not recommended and is a good indicator of misalignment.</p>
3	Business Process/ Workflow	Is workflow, for the most part, aligned?	<ol style="list-style-type: none"> 1. If there are multiple purposes (e.g. research-initiated certifications and annual hospital certifications) do the workflows differ significantly? 2. Will different workflow states or activities be required dependent on the purpose? 3. Are there state level requirements that will necessitate significant customizations and require significant deviation from the other purposes, offices or organizations? 4. How many steps are in the workflow, e.g. does the purpose, office or organization have department review or not? 5. Does your purpose, office or organization have additional reviewers outside the responsible office? Do these reviews stop workflow from proceeding to the next step? 	<p>Overall workflow must be well aligned in order for multiple purposes, offices or organizations to “live” successfully in a single system.</p> <p>While there are exceptions to this rule — e.g. some institutions have department review; and an institutional review board (IRB) office may have different review processes than a pre-award office — if customization are required, there are still certain elements that should remain unchanged. These include, but are not limited to: administrative determinations/central office toutings and approvals that dictate large portions of the workflow as well as the project statuses which are utilized in the product. If an office/purpose area is necessitating a new custom project type or state not required by the others, this is a good indicator of misalignment. Differences in where the management plan should be “housed” within the data model is also a good indicator of mis-alignment.</p>

CUSTOMIZATIONS

There are some variations across multiple stakeholders that can logically be accommodated within a single system. To the degree that such variations require customization, long-term support costs, associated with the complexity variations carry with them, should be considered. Areas where variances can be accommodated, include:

- Certification data entry and reporting (or other data entry not specific to the disclosure/ financial interest)

- Notifications and communications strategies
- Security and visibility
- System access

Table 2 below includes a number of questions to help an institution determine the degree of customization that may be required to support nonalignment between multiple purposes, offices or organizations; and to facilitate discussion around what level of complexity these customizations may add to future upgrades and long-term cost of ownership.

TABLE 2. AREAS THAT CAN VARY

ID	AREA	PRIMARY QUESTION	FOLLOW-UP QUESTIONS	SUMMARY
4	Certification Data Entry and Reporting	Are there significant differences in the certification forms by purpose, office or organization ?	1. Can these differences be captured by hiding/showing questions in the context of existing forms?	<p>The certification forms can often be customized to accommodate multiple purposes, offices or organizations utilizing multiple types of certification and thus alignment is less critical.</p> <p>However, if the answer to this follow-on question is no, then it is likely that new custom views and branching will be required. While this is not an obstacle to multiple purposes, offices or organizations “living” in a single system it will increase the complexity of the system and impact the ease of future upgrades.</p>
5	Notifications and Communications Strategies	What differences exist in the notifications and communication strategies by purpose, office or organization?	<ol style="list-style-type: none"> 1. Will initial notifications of new certifications vary by purpose, office or organization? 2. Will draft status reminder schedules vary by purpose, office or organization? 3. Will new notifications outside of the solution be required by purpose, office or organization? 	<p>Notifications are very customizable, can vary by purposes, offices or organizations with often minor configurations to existing activities or scheduled background operations, and thus are less critical to align.</p> <p>However, as more customizations accumulate, the complexity of the system and ease of future upgrades will be affected.</p>
6	Security and Visibility	Is there alignment on security, user roles and who can see what within the system?	<ol style="list-style-type: none"> 1. Is there alignment regarding who, across the multiple purposes, offices or organizations, needs to see the name of the disclosure entity? 2. Is there alignment regarding who, across the multiple purposes, offices or organizations, needs to see the values of the disclosure entity? 	<p>Differences in security across purposes, offices or organizations can be accommodated and thus alignment is less critical.</p> <p>However, security often requires some level of change to the product that will require repeated changes as part of future upgrades.</p>

7	System Access	Is there alignment on a single point of access to the system?	<ol style="list-style-type: none"> 1. Will the approach to proxies vary by purpose, office or organization? 2. Will authentication types vary by purpose, office or organization? 3. Will login URL vary by purpose, office or organization? 	<p>Both approaches to proxies and authentication types can vary across purposes, offices or organizations; however, it is important to note that it is critical for there to be alignment on a single point of access, or a single URL/“Login Page”.</p> <p>From this point users can choose their office/purpose area/login method, and be directed to the appropriate authentication method. Having multiple login URLs for different purposes, offices or organizations in a single system is not recommended.</p>
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Looking to the Future: Upgrades

When making determinations around accommodating or reconciling differences between different purposes, offices or organizations, an institution should understand how each setting, extension and customization is made to support nonalignment, ultimately impacts the upgrade-ability of your system and its long-term cost of ownership. Some questions for consideration around this topic include:

1. Do the customizations required to align your purposes, offices or organizations take your institution/system significantly off the upgrade path?
2. Is the business requirement necessitating a customization something that applies to other clients and are there immediate or long-term plans to build this enhancement into the Huron product?
3. If the requirement does not apply to other clients and/or this is not on the Huron product roadmap, should this business requirement be re-examined or simplified?

Single or Multiple Systems?

As these areas for alignment are considered, eventually a determination must be made as to whether these multiple purposes, offices or organizations are currently aligned or if they can reach sufficient alignment. Some additional

considerations that should be accounted for include: discloser population and culture.

- **DISCLOSER POPULATIONS:** If the intersection of discloser populations is large, the benefits of using a single aligned system will be greater. Conversely, if there are differences between the requirements that subsequently require alignment, will these differences be easy, moderately difficult or difficult to manage across the populations?
- **CULTURE:** Organizations must also ask whether their culture will allow them to reach alignment. Do constituents have the drive to align on key system elements and do the resources and bandwidth exist to dedicate to this effort? Regardless of the level of alignment, if the intent is to align, the next-level question is: Can the organization design a single system that reasonably accommodates the differences and can the organization afford the long-term cost of supporting them? Alternatively, if the differences cannot be supported in one system, how does the institution approach the need for multiple systems?

Conclusion

Huron recognizes that clients often desire a single system to cover all of their multi-purpose requirements around COI. However, this entails often difficult alignment efforts on everything from definitions and data collected to reporting and workflow. Huron recommends that clients,

when considering multiple purposes, offices or organizations within the context of a COI system, attempt to align processes, or, failing that strongly consider separate systems. Either approach can be successful but the effort to create alignment can be significant.

A thorough review and strong understanding of the COI product's current capabilities and future roadmap will help clients level-set on what settings and extensions the product can currently accommodate "out-of-the-box" as opposed to what will require client-specific customizations.



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For more information and to contact us please contact:

Allison Philabaum Shah, Director
apshah@huronconsultinggroup.com

David Propen, Manager
dpropen@huronconsultinggroup.com



huronconsultinggroup.com

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