

**NCURA Neighborhoods Online Chat**  
Organizational Models for Research Compliance  
May 30, 2007

Featured Guests: **Alice Tangredi-Hannon**, Research Compliance Officer, Yale University; **Steve Erickson**, Director, Office for Research Compliance and Intellectual Property Management Boston College

Moderator

Welcome to today's chat on Models for Compliance with Alice Tangredi-Hannon and Steve Erickson, sponsored for the Compliance Neighborhood

Moderator

Alice Tangredi-Hannon is the Research Compliance Officer (ICO) in the Office of Research Administration at Yale University. With over 30 years experience in the field of research administration, Alice has a breadth of knowledge that range from pre-award activities, contract negotiations (including clinical trials), human subjects management and policy development, to preparing F&A cost rates and property management. She has served as the functional program manager in the implementation of a web-based effort reporting system and has developed and implemented a sponsored projects compliance certification program. In 2003, Alice received the NCURA Distinguished Service Award.

Moderator

Stephen Erickson has been involved in sponsored programs administration for more than 28 years. He was employed at Harvard University for 13 years and has now been at Boston College for the past 15 years, 11 years as Director of the Office of Research Administration and the past 4 years as the Director, Office for Research Compliance and Intellectual Property Management. Dr. Erickson is a past President of the NCURA, and is a recipient of NCURA's Distinguished Service Award. He has been a program chair of two conferences at the national level. He has participated in professional development training sessions on the national and regional level. He served as one of the faculty for NCURA's first online tutorial "A Primer on Subawards Under Federal Prime Assistance". In addition, he has served on the faculty for the Fundamentals of Sponsored Projects Administration and the Sponsored Project Administration Level II workshops.

Steve Erickson

Good afternoon. Alice Tangredi-Hannon and I are pleased to be here to discuss alternate organizational models of research compliance.

Steve Erickson

We have to be creative in thinking about the best ways our institutions can be responsive to sponsor compliance requirements while at the same time developing a model that will fit within our institutional culture. There are no right or wrong models; rather we need to adapt workable models to our own institutional needs. For this chat to be successful, we will depend on your input so that we can all draw on a variety of ideas.

Moderator

If you have comments/questions please share them in the rectangular box

Steve Erickson

Perhaps we can begin by discussing how your institution defines research compliance...what issues are covered at your institution?

Frannie Nuttall

I am from a PUI and am wondering what are some good examples of monitoring research compliance. I don't have an electronic system and find it difficult to monitor all that is required. Any suggestions?

Alice Tangredi-Hannon

Frannie, how do you define research compliance?

Joe Rosse

For us, research compliance includes IRB, IACUC, Biosafety, Rad Safety, research misconduct and export controls

Sheri Walls

I was about to ask the same question. I'm going to be responsible starting in July for our IRB, IBC and IACUC. I need some guidance...

Frannie Nuttall

Alice--Insuring that the IACUC, IRB et.al are completed and followed up when it is time, effort reporting -

Angelique Dorsey

At my institution, research compliance covers financial compliance through the office of research administration, human research, animal research, biosafety, radiation safety, research misconduct, and export controls.

Steve Erickson

I think we can see one common element...that IRB and IACUC are pretty common component.

Ellen Hyman-Browne

Here at CHOP we define research compliance across the entire spectrum of regulatory committees, conflicts of interest, and grants management. We have 2 functions for compliance - one within research administration and a second that's part of corporate compliance.

Alice Tangredi-Hannon

In this chat we will not be focusing on corporate compliance which incorporates a variety of additional issues. Our focus will be on research compliance including sponsored projects administration and management.

Jeanne Mattern

Here at CCF, compliance is not centralized which makes it difficult to operationalize. It comes at researchers from operations as well as corporate compliance. We are beginning to work together.

Jeanne Mattern

CCF defines compliance as encompassing all aspects of grant management and project management including subject protections and lab safety.

Steve Erickson

I think what we can see are some common areas, but there are major differences as well --- which confirms the idea that we have to develop models that meet our individual needs.

Frannie Nuttall

Steve, at my institution there are faculty members who sit on these committees and don't always understand the importance of their responsibility. They understand the ethical issue but the annual checks and some of the paperwork is frustrating. I agree with the models.

Steve Erickson

Not only do we have to recognize the differences in issues covered, but also whether our institution is centralized or decentralized.

Kelly Hochstetler

Research compliance is defined differently by different user groups within our university. For our office (Research Integrity) it involves animal subjects, human subjects, conflict of interest, research misconduct, biosafety, radiation safety, export compliance, etc. Out grant/contract administrators and internal auditors are more likely to say fiscal accountability, fly America act, etc. I'm curious about how those of you who also have this arrangement, handle post approval/award compliance monitoring... Do you conduct simultaneous audits/assessments or function independently?

Joe Rosse

I'd have to say they operate quite independently in our case.

Alice Tangredi-Hannon

Kelly, Frannie et al for many of us we view compliance in the form of performing assessments (not audits). Some of us have started by identifying the areas and regulations with which we must comply. At Penn I called it the Universe Document. After that was developed we started to identify who was responsible for the particular area.

Elaine Fluder

I am interested to know the "typical" reporting lines for Research Compliance Officers. The report line may actually dictate the scope of the research compliance program. The scope of research compliance includes IR, IACUC, Conflicts of Interest in Research as well as IBC and Safety. In addition, research billing compliance has been an area of focus both in my office and Corporate Compliance.

Jeanne Mattern

Alice: So you monitor -- do you do conduct these on an issue-basis or on a project-scheduled basis?

Mike Burnett

Kelly, at some institutions where I have worked, central offices, most especially post award admin and financial offices are in a good position to audit and review for compliance issues.

Steve Erickson

The reporting lines often depend on the issues involved. In an effective program, I would say that either there is some central oversight or at least some coordination via a compliance committee.

Alice Tangredi-Hannon

Good question Jeanne. I would have loved to have scheduled the assessments but usually other "events" would interfere. Here at Yale, I am scheduling the compliance areas that I will assess.

Ellen Hyman-Browne

Our Director of Research Compliance reports to the Chief Scientific Officer. Our Research Compliance Officer reports up through the Chief Compliance Officer to the Board and CEO.

Monica VanBuskirk

At MGH my impression (I'm at the departmental level) is that they operate independently. This includes auditing. There has recently been an effort to centralize some, but not all components of compliance under Research Management. For example, Research Finance is moving to be under the CFO and the Finance office's umbrella.

Steve Erickson

Ellen, your point is well taken, i.e. irrespective of the type of institution, the research compliance function must be taken seriously at the highest levels and report as high as possible.

Kelly Hochstetler

Steve: Are you talking about IACUC, IRB etc or a committee that has more general oversight of compliance? What is the composition of this committee?

Steve Erickson

Kelly, the research compliance committee we have at BC has EHS, the IACUC, IRB, Vice Provost, RCR and my office as members. We are considering expanding it a bit. We also have OSP on our committee as well.

Ellen Hyman-Browne

We are having some difficulty gaining acceptance of the research compliance function that reports up to the Board and CEO, however.

Steve Erickson

Ellen if it reports that high, then how is it not gaining acceptance?

Jeanne Mattern

What does the best practice model look like? I am just forming a program here at CCF and having some difficulty identifying structure.

Moderator

Thanks Jeanne, sounds like others can certainly chime in as well

Ellen Hyman-Browne

Well, research administration is guarding the hen house.

Joe Rosse

At the University of Colorado, I report to the Vice Chancellor for Research. Rad Safety reports to EH&S, who reports to the Vice Chancellor for Administration. IBC has a shared responsibility between the VC-Research and VC-Administration.

Alice Tangredi-Hannon

Jeanne, since you are starting a program I think you will need to get buy in. My current institution has formed a research compliance committee. This committee includes all of the research compliance areas of the university including billing compliance. We determine as a group what areas should be reviewed.

Ann Pollack

At UCLA we do not have a compliance office or officer per se but we are concerned with research compliance. We differentiate between regulatory offices (e.g. protection of research subjects, conflict of interest, biohazards, etc.), and research compliance. The latter is much broader and includes some central offices with responsibility only for research-related issues (e.g. contract and grant administration, office for the protection of research subjects, extramural fund management, etc.) and others that have broad responsibilities some of which affect research (e.g. purchasing, accounts payable, audits and advisory services, etc.). About a year ago we formed what we call a Research Compliance Roundtable which is really a compliance committee. It is convened by the Vice Chancellor for Research to whom I report and who also serves as the Institutional Officer for most of our regulatory issues - Select Agents, Research Integrity and others.

Frannie Nuttall

I have a similar situation, certain committees report to different VPs and once outside our VP we lose input etc.

Steve Erickson

Ann, that seems like a reasonable model...it incorporates the independence needed by particular functions, but also has the crucial element of coordination.

Rashonda Jefferson

At Temple University our compliance office is new and we are exploring new ways to be more accepted by the community, any suggestions?

Mike Burnett

At some level seems like having the CFO or Controller in the chain would be useful.

Jeanne Mattern

We have a compliance committee that is undergoing some changes as clinical and basic research were separate and now are coming together. My job has expanded and we are undergoing some growing pains as we restructure. That's why I decided to attend today.

Jeanne Mattern

Steve, what about IBC? With the mandates for monitoring rDNA, we are strengthening the oversight responsibilities of this committee to become equivalent to the IRB and IACUC in importance. We are currently implementing ways through OSP to make sure that approvals of these bodies are present at proposal submission.

Steve Erickson

At BC, our EHS office staffs the IBC. There are a lot of cross links between the IBS, OSP, IRB, and IACCUC, all of which need coordination. That's why I think some form of roundtable or compliance committee is vital.

Alice Tangredi-Hannon

Rashonda, I think you need to market yourself in such a way that you are partnering with the various groups. I would definitely form a compliance committee chaired by your senior research officer. It would be advisable to interview the various entities to determine what assistance they need in complying with policy and regulation. They don't want to be audited they want to be assisted.

Frank Ingiosi

We're also new at our institution and have been running into similar levels of resistance throughout the research community. Despite our best efforts to educate the community at large we still feel as if we're "spinning our wheels."

Ann Pollack

I think the issue of acceptance is a difficult one. As I said earlier our Roundtable has been meeting (about once every 2-3 months) for about a year. Among the members I believe there's acceptance because the discussions have focused on cross-cutting issues that have proven to be of interest and which have helped everyone at the meeting understand that we cannot continue to think of ourselves as an organization made up of separate silos. However, other than creation of a research compliance matrix that was intended as a tool to help the research community understand who to go to for what, (and which is now posted on the Office of Research Admin website), we have not done too much that would require "acceptance" by the community.

Frannie Nuttall

With the roundtable scenario would the assessments be reported back to the committee and they determine how to handle any problems?

Joe Rosse

One way we've tried to enhance coordination among IRB, IBC and IACUC is to have some shared membership on the committees. I also generally attend meetings of all the committees as a way to increase coordination.

Moderator

Joe--can you clarify "coordination"?

Steve Erickson

To some extent we all do some wheel spinning in terms of acceptance. It is important the upper levels of the administration give active support to the research compliance program...by making it clear to deans, department chairs, and faculty that research compliance is important and needs serious consideration.

Ann Pollack

Frannie - Our Research Compliance Roundtable has not done any assessments of individual projects. Rather we have focused on broader issues, trying to figure out where there are gaps in policy, where guidance is needed, how to solve general problems. As Steve just said, we are focusing on clarifying certain issues and our next step will be communicating to deans, chairs, etc, issues that are of importance.

Steve Erickson

For most of us, we are talking in terms of changing the culture of the institution -- whether to gain "acceptance" or to get folks to understand the importance of the research compliance program...So, what ways can we think of to get the culture evolving?

Frannie Nuttall

Thanks that is great information!

Anita Mills

Can you share examples of what gets research compliance on the radar screen of the higher ups?

Steve Erickson

By the way, at BC, I am responsible for performing assessments of compliance functions.

Moderator

Anita: good question--the old newspaper headline usually works

Alice Tangredi-Hannon

Oh Anita, since we have worked together you know that an audit by the feds. can do it. Even an audit of a sister institution can do it.

Elaine Fluder

I try to make myself as "visible" as possible. Like Joe, I attend as many meetings as possible which has helped me to understand the various academic and clinical cultures. The most important thing that I have done is start Community of Research Coordinators Committee that meets regularly. The members of this committee are my eyes and ears so to speak and as a result when I need to make a change to enhance research compliance I have the perfect starting point.

Christina DeVries

We have a Compliance Officer for the entire institution as well as a compliance function in the research administration office. I like the idea of having a research compliance committee to bring all of the compliance components together with members from each committee. Then they can determine how to assess the risk in areas of compliance and where to focus effort to strengthen controls and policies. It seems the only way to get everyone on the same page.

Frannie Nuttall

Steve, I am interested in what type of assessments you do specifically. What you assess and how you complete them.

Joe Rosse

A good example of what I meant by coordination is that the Biosafety Officer is a member of both the IACUC and IRB. As such she can flag biosafety issues that come up in protocols being reviewed by either committee and ensure that they are resolved. We do not do gene transfer research, so for the most part the IBC-IRB connection has to do with blood-borne pathogens, biowaste, etc., and again she can make sure that PIs are complying with these requirements, which the IRB sees as

outside of its purview. I've also noted a couple cases of COI at IACUC, IRB or IBC meetings, which I can then refer to the COI Compliance Officer.

Steve Erickson

I am authorized to assess any compliance function...I just completed a major administrative assessment of our Animal Care and Use Program I also have cost-sharing, cost transfers, and effort reporting on my schedule. I will also be looking at two cost centers to ensure they are following their own procedures.

Steve Erickson

Ellen, I have no staff for the assessments. We are hiring a full-time education person who will relieve me of the education programs and focus on assessments.

Ellen Hyman-Browne

Steve, what kind of staff do you have to assist you with these assessments?

Alice Tangredi-Hannon

Joe, thanks for the clarification. As soon as i read your email I was thinking of COI which you also mentioned. Could be valuable to have the COI person on IRB or IRB on COI which I experienced at another institution.

Jeanne Mattern

Our problem is that there are people "doing" compliance at our institution but it does not appear in their job title. I know there are folks to bring to the table, but finding out who does what is an issue.

Steve Erickson

Another question to consider -- How can we develop an effective research compliance program without being burdensome to researchers?

Ellen Hyman-Browne

Steve, I'm afraid that an unburdensome research compliance program is an oxymoron.

Anita Mills

Are there different approaches to compliance for a Medical School verses a University setting?

Moderator

Anita--good question.

Steve Erickson

Ellen, I actually don't see an oxymoron...compliance, if effective can be flexible and responsibilities allocated so that researchers can get their work done as well as fulfill their compliance responsibilities....it takes some planning and consensus, as well as a broad agreement on roles and responsibilities.

Jeanne Mattern

Steve, that's my number one issue -- researcher just want to be left alone to do research -- that's what I hear daily. However, reality is that PIs are "solely" responsible. They may have help with the administration, etc. but they have received the funding. I know this as for many years I was a PI and did not have the benefit of

an OSR, Compliance Office, etc. I was on my own getting grants, running projects, hiring, budgets, contracts, reports, etc.

Alice Tangredi-Hannon

Jeanne, I laughed when I saw your comment because i have experienced the reverse, people having the word compliance in their title but not certain what the compliance role actually is. That is why I think if all of the areas of compliance are identified including the responsible individual, interviewing that person can give you a better idea of what is done within that office. Frankly, we are all doing some form of compliance the roles and responsibilities need to be articulated and accepted by all.

Anita Mills

Burdensome to researchers?? My mind compliance is about education about doing the right thing and having the knowledge to manage the research projects effectively. I have a hard time understanding the tug of war.

Ann Pollack

Jeanne (and others). Hopefully a lot of people will "do" compliance without it being part of their job title if, as we hope, compliance really means raising consciousness about being responsible stewards of research monies, of disclosing, of conducting research ethically, and all those other good things we strive to do. The issue of how to not be burdensome or intrusive is another issue. The UC Regents recently decided that everyone should take an on-line Ethics course. That's been followed by a conflict of interest modules - one for designated officials and one for researchers. Many people think that half an hour of so is not much time to spend on such things. Others feel that even that much is too much time if the module is not useful.

Kelly Hochstetler

A recurrent issue we find at our institution is that research staff and students (grad and undergrad) are getting little or no education or training in compliance. By incorporating more educational opportunities targeted to those groups we're creating more people who can play a role in monitoring and assuring compliance within each program. We are also insuring a more consistent message gets out to staff and students in all disciplines (institutes and colleges) that way...

Alice Tangredi-Hannon

I agree Kelly. I am fortunate in that I am at an institution that believes compliance is everyone's responsibility including students involved in research. We have a very aggressive educational program.

Steve Erickson

Ann and Kelly, you are pointing out the two main aspects of an effective compliance program --- assessments/monitoring and education. I really don't think a program that does not have both components can succeed in the long run.

Ann Pollack

One of the big differences about Medical School vs the rest of campus is the special concern about safety of human research subjects. Our Medical School has an Office of Clinical Trials and they together with the corporate compliance officer have been thinking about how to augment the for-cause audits of clinical trials done by the IRBs.

Elaine Fluder

One thing that we have done recently is to revamp our electronic applications process so that the researcher has a one stop shopping experience. Issues related to COI, human subjects protection, radiation safety, grants administration and the like are all addressed at a single starting point. The object is to address compliance matters as part and parcel of the research process.

Steve Erickson

Elaine, I am developing a one-stop shopping element in that my compliance website will have a matrix of all policies, procedures, and forms for all compliance related offices -- and all hyperlinked.

Alice Tangredi-Hannon

Elaine, great comment. Some institutions are currently developing research portals that will have everything a researcher needs when they open their portal, from COI, human subjects protocols, current and pending support pages and yes even current effort reports.

Moderator

Alice, you mean a PIs website, right?

Alice Tangredi-Hannon

The portal is specific to the individual PI. Truly one stop shopping as Elaine mentioned.

Moderator

Thanks for your comments and sharing today. Compliance as we know is everyone's business. Steve/Alice, any closing comments?

Steve Erickson

I would like to take this opportunity to refer everyone to the Chapter Alice and I wrote on developing compliance programs in NCURA's "Sponsored Research Administration: A Guide to Effective Strategies and Recommended Practices."

Moderator

The book is available at the NCURA bookstore at

<http://www.ncura.edu/bookstore/default.asp>

Another item of note is the Report on Research Compliance available at

<http://www.reportonresearchcompliance.com/>

Moderator

Thanks for your time and participation. Special thanks to Alice and Steve (with a broken finger). Join us for the next chat on Export Compliance at the Proposal Stage on 6/27, 2-3pm with Kay Ellis. Good Afternoon.