
Sponsored Research Administration

A Guide to Effective Strategies and Recommended Practices

Update No. 57

April 2020

Highlights of New or Updated Material in This Update

- ◆ **New:** [12 Rules to be a Successful Research Administrator \(¶130.14\)](#)
- ◆ **New:** [How Resilience Can Lead the Way \(¶130.15\)](#)
- ◆ **New:** [Digital Transformations in Research Administration \(¶920.15\)](#)
- ◆ **Updated:** [Summary of Significant Changes to the NIH GPS - December 2019 Version \(¶1330.1\)](#)
- ◆ **New:** [Industry-Sponsored Clinical Trials: State of the Art Budgeting and Financial Management Techniques \(¶2120.9\)](#)
- ◆ **New:** [Getting Creative with Faculty Outreach at PUIs \(¶2330.5\)](#)
- ◆ **New:** [Pre-Award Compliance - Shared Responsibilities between Central and Department Offices \(¶2530.14\)](#)
- ◆ **New:** [Unintended Consequences of Six Contract Drafting Challenges \(¶2730.3\)](#)

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Overview of Sponsored Research Administration

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¶130.14 12 Rules to be a Successful Research Administrator

Lisa Mosley, Yale University and Eric Smith, Oregon Health and Science University

In 2018, clinical psychologist and University of Toronto professor Jordan Peterson published *12 Rules for Life: An Antidote to Chaos*. Dr. Peterson had the idea for this book from his hobby of responding to questions on Quora, a website dedicated to Q&A on every imaginable topic. The question that inspired the 12 Rules for Life was: “What are the most valuable things everyone should know?”

While the book is focused on the broader aspects of life, the basic principles can be applied to our professional lives as research administrators, as well. In a time when we all recognize the importance of work-life balance, shouldn't we be mirroring the concepts to improve our personal life into our professional life? This had us asking ‘What are the 12 rules that help bring success in research administration?’ Through much thought and reflection on real-life experiences, we have derived what we hope is a useful and relatable interpretation of Peterson's original 12 Rules of Life for research administrators.

RULE 1: Stand up straight with your shoulders back

What you do is important. As a Research Administrator, we are more than just pencil pushers and bean counters. Nothing gets completed without us. There's a metaphor I like to use with my colleagues, when they are feeling trodden and stymied. I tell them, research is like a car that is trying to drive across a desert. The PI is the driver and the research data and grant money are the engines. Research Administrators are the oil and the gas. What happens to a driver stuck in the desert when the car breaks down? Nothing good. Without the important work you do to keep things moving, research gets stuck in a spot that threatens to kill it. Remember how important your work is, always. Be PROUD to be the oft-unsung hero that contributes the essential ‘grease’ to keep progress moving. Let your pride in your work shine and you can be more than the oil in the engine; you can be the Italian design and the cherry red paint job on that car. With you on the team, go ahead and add flames and lightning bolts too!

RULE 2: Treat yourself like someone you are responsible for helping

A few years ago, I hired an amazing manager named Jill. In addition to having the skills to do the work well, Jill is one of those special people who always considers others and wants to ensure all of her staff has everything they need to be successful and happy. She spends large amounts of her own energy focused on advocating, checking in, and supporting. As those of you who have managed people know, all of that takes energy. It wasn't too surprising that Jill started feeling a bit of burnout herself. She started losing motivation and enjoyed coming to work less and less. Eventually, Jill's breakdown started to take its toll on her staff relationships. In focusing on what everyone else needed, Jill forgot to focus on a key member of her team: Herself.

This is a story that is all too common in the modern workplace. We recognize that our colleagues are deserving of respect and support. We offer our help and understanding, treating them with compassion when things are tough. However, we often neglect our closest colleague: Ourselves. Always remember you are worthy of the same understanding and support as anyone else. This can be a challenge for many of us, in practice. It just isn't how our minds are programmed. To get past this, we can try tricking our minds. Here is an exercise I seasonally do to foster compassion for myself. Make up an imaginary coworker who does all of the same work you do. Give them a name. Imagine how you would feel seeing them struggling without the support, training, tools, etc, that they need to do their job well. What would you want to tell them? Write that down. Then, read it back to yourself regularly. When we can see ourselves through the lens of 'other', we can break the dynamic of unrealistic self-expectation and finally allow ourselves to be compassionate and supportive of what we need to succeed.

RULE 3: Make friends with people who want the best for you

Surrounding yourself with people who motivate and support your professional development not only offers 'phone-a-friend' quick access when you don't know answers, but also gives an avenue for essential moral support and guidance to help keep your motive high and burnout low. It's important when considering this rule to think inclusively about who should be in your community. Ensuring friends at different levels and in different roles within your organization can offer valuable diversity of perspectives, limiting your blindspots. Additionally, choosing negative naysayers, while it may offer comfort, can drag you down and lead others to see you in a similar light. Remember that guilt by association is a very real part of human judgement! At the least, you should keep in mind two critical elements when building your work community:

- ◆ *Find a mentor.* We all maintain direction better with a target and having someone demonstrate successful behavior is a powerful way to focus your aim. This can be a great boss, experienced coworker, or just an inspirational colleague. Personally, I've been very lucky to have a succession of fantastic mentors throughout my career. By observing and asking guidance of each, I've learned new skills and continually refined the lessons learned from previous mentors. Each perspective has given me a more well-rounded understanding of how best to handle difficult situations. I mentor colleagues myself now, but I always know that I'll never be done learning.
- ◆ *Find a 'Sangha'.* The concept of a Sangha, or community, in Buddhism is ancient and considered one of the three essential elements of successful practice, along with the teachings (Dharma) and mentor (Buddha). It's no different for us in our work. We can have the best training and an exceptional boss/mentor and still find it a massive struggle to accomplish what we need, if we are lacking a supportive community. Colleagues that can relate and support us in achieving our goals are essential. Find others who understand your goals and struggles and connect with them regularly.

RULE 4: Compare yourself to who you were yesterday – not to who someone else is today

We so often define progress by how we do relative to other people. It is a universal temptation. However, it's a cautionary tale, because there will always be ways to justify feeling like you are doing better or worse than someone else. The problem is, this form of measurement is artificial, because there is no standard. It's akin to measuring how far you are running using the ruler you are carrying in your hand. True growth is not measured against others, but against ourselves and our own goals.

One of my colleagues is a big fan of the movie / play *Glengarry Glen Ross* and has a picture of the famous scene on his desk in which Alec Baldwin berates his staff on the 'ABCs': Always Be Closing. I took inspiration from him and now have the same picture hanging on my wall, with one modification – ABG: Always Be Growing. Our paths are not always linear. Our strengths and weaknesses will wax and wane over time and being aware of them at any given point in our lives is an important part of focusing our growth. What matters, however, is asking "Are we changing? Are we learning? Are we becoming more experienced?" This is the growth that matters.

RULE 5: Do not let your children do anything that makes you dislike them

As Gandhi famously said "You must be the change you wish to see in the world." Our workplaces are worlds of our own making and what we exhibit adds to the overall culture more than we realize. Your colleagues and staff are watching you and learning from you, just as you are with them. In this way, we are all like parents, setting an example for those who look up to us. Similar to parents with their children, we should maintain active engagement with our colleagues, setting clear expectations and helping to hold them accountable, as we do ourselves. Remember, this is a community that we are each a big part of creating. Be intentional in building something that you are proud to be a member of. Conversely, if you see aspects of your work community that you don't like, be intentional in acting to steer a new course.

RULE 6: Set your house in perfect order before you criticize the world

We've all heard the old adage "People who live in glass houses should not throw stones", but how many of us actually take the time and effort to examine our 'house' before criticizing others? Unfortunately, in our modern world, it has become all too common to sit back and point out all of the issues in other departments, University leadership, or even society as a whole as a way to avoid feeling the responsibility of improving our own work processes. Pointing out problems without suggesting solutions doesn't typically solve a thing. Luckily, there is some good news! You can use that same expertise and experience that helps you identify the problems to contribute thoughtful feedback. Taking constructive actions and suggesting potential solutions not only helps end the problems, but it's a great way to help create a collaborative culture, where everyone works to solve common problems.

It can be difficult to make the shift, if you have fallen into the problem-focused trap. Luckily, there are some activities that can help. Learn to recognize the Ladder of Inference. Actively hear the story behind your statements. When you have a criticism come up, ask "are these just the facts? Or am I adding assumptions?"

If you are making assumptions, question them. What evidence do you have that makes you assume that? Are you carrying over emotions from something in the past that is creating bias? When we recognize our biases, we can often break the self-perpetuating cycle that is the Ladder of Inference. To borrow an oft-quoted slogan, “Change begins at home”. It is our responsibility as professionals to examine our personal dynamics and ensure we are contributing to solutions, not just identifying problems.

RULE 7: Pursue what is meaningful – not what is expedient

This is an important one and can really be thought of in three ways:

- ◆ ***Remember what you want most, not what you want in the moment.*** The ‘high road’ is often described as narrow. It’s often easier to react in the moment than seeing the big picture and acting in a way that builds upon what you ultimately want. If your end goal is to build a relationship of trust and collaboration with a challenging colleague or researcher, how do you react when they may immediately blame you for something that has gone awry? It’s easy to point out why they are wrong, and it may be accurate, but is that reaction serving your ultimate goal of building the relationship? Having a long event horizon requires patience, commitment and dedication. Don’t lose sight of what you want most – instant gratification doesn’t always serve your long term goals.
- ◆ ***The easy way out, may not be that easy.*** Sometimes it’s tempting to hire someone with the right experience for the job. They could hit the ground running, you don’t have to invest as much time in training, etc. They may have the skill set to be successful, but research administration is more than just knowing the rules. The art and skill in the profession is how do you apply the rules to each unique circumstance that crosses your desk on the daily? If you make the wrong hire, you will often spend more institutional resources managing the long-term negative impact of that decision. They may have hit the ground running, but if they aren’t a good fit for the team, or don’t know they are there to support faculty in achieving their research goals, your short term ‘win’ ends up being an overall loss for the team and your institution.
- ◆ ***Don’t use a band-aid when you need a tourniquet.*** Sometimes you have to accept that the situation is more serious than you initially thought, and you are going to have to make some hard, and maybe unpopular decisions. Imagine you have a staff member who everyone loves working with, but they just aren’t able to do the job. You invest in additional training, coaching, goal setting, and a temporary reduction of performance expectations so they can be successful. They just need a little more time, a little more training, a little more support. But, the moment you take the band-aid off, the bleeding continues. What is really needed is the hard decision that they may not be the right person for the job. You may need to make the determination that despite the size of the band-aid, a more drastic measure is needed to stop the bleeding. It’s unsettling, it’s a serious decision, but ultimately, everyone benefits from the hard decision needed to solve the core problem.

RULE 8: Tell the truth – or, at least don't lie

You may not know the whole truth, but you know when you're withholding pertinent information or misrepresenting the facts. There are many situations that will cross your desk and you make the best decision you can based upon the information available to you. Sometimes you have time to collect more information – sometimes you don't. In all instances, you do the best you can with what you have. There may be instances in which if you had additional information, you may have made a different decision. But, if you are presenting some of the information you have and withholding other facts in order to support your case, protect someone or yourself, this is a form of lying. You may not always have all of the facts, but the ones you do have should be fully presented objectively.

It is imperative that you act with integrity, in all things. You're responsible for your own actions – always. There are a multitude of circumstances that can influence your decisions, but you must always be accountable for your decisions. You will make mistakes – own them. You will have successes – own those too. Be transparent – but ultimately, you have to own your behavior and your decisions.

Always remember that your reputation is your professional currency. People talk. It's human nature. We have all made poor decisions in the moment, but how you respond after the fact can be just as important – “it was *easier* to say yes/no than argue”, “It wasn't my fault, it's not my job”, etc. The list of rationalizations for doing what you did can be endless and may make perfect sense to you. But, was it the right decision for the situation? It's important to be easy to work with, but do people want to work with, and for you, for the right reasons?

RULE 9: Assume that the person you are listening to might know something you don't

Research administration is a fast-paced field, and our motto is 'it depends'. But, when you are moving fast, it's tempting to stop listening. Taking the mindset of, 'I know how this is going to play out' or 'This has been tried before and it didn't work', or 'I know better than you' eliminates an important part of the collaboration. Assuming you already know the answer robs you of learning opportunities. What if you approach each situation with the mindset that you're going to learn something new? How much might you grow in a year?

RULE 10: Be precise in your speech

Communication is key. You have to be able to succinctly communicate simple answers to very complex situations. Translating 'no' to 'what about these options' is a skill. People want answers quickly – they are coming to you for guidance and decisions. Answer the question or ask for additional information quickly and directly, but always remembering you are there to help solve the problem. It's tempting to share everything you know about why something won't work...but what they really want to know is how can they achieve their goal? And, they don't want to read 2000+ words to get their answer.

And, be open to the fact that what you think you are saying isn't what is being

heard. Try to recognize miscommunications early in the exchange. If it's a complex topic, don't be afraid to pick up the phone or set up a meeting. Email is a life saver, for all of us. It enables us to move quickly, but it isn't always a good replacement for a phone call or face to face meeting to gain a deeper understanding of the nuances of a situation.

RULE 11: Do not bother children when they are skateboarding

So, how does this relate to research administration?

- ◆ Take risks
- ◆ Practice your skills
- ◆ Plan for failure – celebrate success
- ◆ Trust others to try things that work for them

People will not always do it the way you would. Maybe they aren't wearing enough protective gear; maybe they are trying a risky new move; maybe they are trying something you've tried before but have never been able to execute. Sometimes experience is the best teacher – let them have the experience.

When you are practicing a new skill, you aren't going to be an expert the first time. This isn't reason enough to stop practicing. Not everything you do is going to be a success the first time. Sometimes you're going to fail. Sometimes you're going to fail A LOT! Learn from your mistakes, adjust your approach and keep trying. If you learn from your mistakes and apply the lessons learned, the bruises bring you wisdom of how to do (and be) better the next time.

RULE 12: Pet a cat when you encounter one on the street

Research administration is a challenging profession. To be successful, you need a combination of expertise and persuasion. You may have to be in the weeds, but never lose sight of the big picture. And, oftentimes, it is a thankless job. You are always in the way, with rules, regulations, institutional policy, etc. You have to find what brings you joy – you have to be open to new situations and approach them with an intention to have a common positive experience. We only fail, when we stop moving and stop being curious. Sure, maybe the cat will bite you. But, maybe, you gain a new companion.

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¶130.15 *How Resilience Can Lead the Way*¹

Anthony Beckman, University of Rochester; and Theresa Caban, Kaiser Permanente Southern California

Resilience can be defined as the ability to adjust easily to misfortune, change, or new paradigms. Flexible, elastic, and stretchable are all great synonyms. That's our life as research administrators. Like a rubber band, we are expected to snap back after serious setbacks and perform as required to get the job done. Resilience is our defining trait – if you can bounce back quickly, you are an ideal candidate for research administration. Why is that? Resilient research administrators are people who are deadline driven, don't shy away from holding difficult conversations, face challenges in every direction with new and different situations, and of course move with the ever-changing research landscape.

The Federal deadline is two weeks out, and you're anticipating an avalanche of applications again this cycle. The phone rings. You know who it is and what he is asking for. "Hi! It's Dr. Smith. Thanks for all your help during the last submission. It seems like this deadline sneaked up on us? Unfortunately, we're not going to be able to get you the proposal in advance of the deadline. I know there is that policy, but is it going to be okay?" Dr. Smith, a well-funded principal investigator, explains that they need this coming weekend to finalize the science and polish the application; the grant isn't due until Monday anyway. You have given Dr. Smith this flexibility previously. Yet, the very next email you get is from Dr. Simmons. She is writing to let you know that she's going to need the weekend as well.

We all have dealt with the pressure of deadlines, and the added pressure of last minute work. Are you resilient enough to stretch and accommodate? How do you respond? You could choose to get frustrated. Don't the faculty know that these internal deadlines serve a purpose, to ensure that their grants are submitted without complications? Don't Drs. Simmons and Smith know that you have several other grants going in at the same time?

It can be hard to demonstrate resilience at times like this. It is helpful to remember that PIs are generally doing the best they can and want to submit the highest quality application possible. So, we can remember that even after all the framework and structure we put in place, the behavior and actions of our researchers are not within our control.

Rather than let frustration rule the day, we can draw on the resilience we've been building as research administrators. Avey, Luthans, and Jensen (2009) found that "resilient individuals are better equipped to deal with the stressors in a constantly changing workplace environment, as they are open to new experiences, are flexible to changing demands, and show more emotional stability when faced with adversity." Despite the compressed timeline we often face around deadlines, we are responsible for doing the best job we can. When we demonstrate resilience in response to deadlines, our can-do spirit inspires those around us to do their best

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as well. This helps keep all parties focused on the larger goal of submitting grant proposals successfully.

Resilience is a perfect example of advanced Emotional Intelligence (EI). Your EI indicates how you intentionally handle your emotions in any given scenario and how you portray that to others. We are not always aware that we are being resilient. Often we are simply coping with the situation as it presents itself. Most of us are aware of the idiom, “service with a smile.” That’s what we do as research administrators. Good customer service, trust, and respect develop through interacting on a regular basis. We know that intentionally managing our emotions – no matter how crazy or surreal a situation may seem – presenting our best selves, is the most successful way to deal with these situations.

Research administrators need emotional resilience to get through those difficult conversations at work. You know the ones – the proposal is late, the budget is over the cap, or the sponsor isn’t responding. We enter these conversations with sensitivity, taking time to understand the other perspective, working toward resolution and keeping that (however tight lipped) smile on our faces. Emotional resilience isn’t easy and requires practice, but it can be learned.

Research administrators are survivors. We navigate through massive challenges: reorganizations, policy upheavals, submission snags, bad budgeting, difficult collaborators and complacent staff unwilling to communicate, to name a few. We have all gone through some form of reorganization, perhaps separating pre- from post-award. Talk about turmoil! Sometimes there are changes that feel threatening, such as reassignment of work to other departments and divisions. A pre-award research administrator may worry that his or her ability to meet immediate requests for proposal document gathering and rapid submission is in question. If there is no real understanding of why these changes are occurring or how they’ll work out, then our resilience may be more difficult to maintain. Thankfully we can receive generous support from colleagues and management reminding us to stand tall and strong, as things are bound to change again. Sure, we understand and remain very optimistic in our own abilities and purpose. But there still is the challenge and the choice before us – do we run away and get another job? Do we stay, with smiles on our faces demonstrating our value to the organization? We remind ourselves that change is simply a shift from what we used to know or do, to something new and potentially better. These kinds of challenges are opportunities to flex our resilience muscles, set new goals, and modify perspectives. Our ability to be resilient, meet these challenges head-on, accept where we are in them, and make choices to move in a positive direction lead the way for current and future success.

The only constant across the research landscape is change. Movement in priorities at the federal sponsor level, swings in popular opinion toward research (and the associated allocation decisions), and working with emboldened industry partners, we are familiar with change. A resilient pre-award research administrator can see the changes, hear the pundits yelling “the sky is falling,” and still be an effective resource for our institutions and PIs. We can embrace the reality of change, not simply tolerate it, and certainly not allow ourselves to be surprised by it, but embrace and lean into the uncertainty.

Simultaneously, a resilient research administrator will keep an eye focused above the turmoil on the bigger picture, and keep the other eye steadfastly trained on their role and responsibility to facilitate research. We demonstrate resilience in the face of these challenges by staying focused on our role and executing it with professionalism and excellence.

Will we be frustrated at times? Will it seem like there is a disconnect between policy and practical reality? Yes! The landscape will shift under our feet no matter how hard we stomp down and demand consistency. The resilient research administrator will draw on his or her experience, will reach for the end goal, and then will turn toward the challenge and perform their responsibilities as best they can.

So how do we maintain, or better yet, build resilience? Remember what your purpose is, believe in yourself and your abilities, embrace the change, strengthen your relationships, nurture yourself, set realistic goals, stay optimistic, develop your skills and problem solving, and keep learning. No matter how complicated the research landscape is, what deadlines are looming, how many difficult conversations you must have, or how complicated the challenges that materialize in your organization's pre-award environment are, the ability to be resilient will always lead the way to success.

Resources

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Chapter 900

Electronic Research Administration

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¶920.15 Digital Transformations in Research Administration¹

John Butzer, Brett Fortier, Cameron McNair, University of California, Santa Barbara; and Marcel Villalobos, University of Arizona

In our technology driven workplace, there seems to be an electronic solution to every problem. Across industries, employees look for ways to modernize their work processes by utilizing digital tools. But what does it mean to digitally transform the workflow of a research administration office? How can a completely paper-based proposal and award lifecycle be transformed into a digital process fit for the 21st century?

Recently, the central office research administration teams at the University of California, Santa Barbara (UCSB) and the University of Arizona (UA) completed the task of converting their paper-based offices to paperless operations. Though both campuses had different Information Systems (UCSB uses ORBiT for contracts and grant tracking and UA uses Quali Research), organizational structures, workflows, and differing approaches to the project, they accomplished the same goals.

Many factors served as catalysts for the UCSB and UA digitization projects. First, both campuses sought to improve efficiency by streamlining existing paper processes into electronic workflows. Second, the tremendous time and money saved by reclaiming space through the elimination of paper file storage motivated both campuses to move to electronic files. Third, electronic files enabled proposal and award file backup, searchability, and access for remote users. Lastly, the project aligned with the universities' sustainability goals.

The first step of the UCSB project was converting the existing paper proposal and award files into accessible PDF documents. This consisted of emptying eighteen 10-foot file cabinets and utilizing student workers to scan each file. These students were given written instructions and naming conventions to ensure ease of file identification and use. Closed files were scanned in a similar manner and retained as part of the campus records retention program. Once this process was complete, UCSB research administration staff were able to access any active or closed award file from their computers. As an added bonus, UCSB converted one of the previous file rooms into office space for two employees.

Similarly at UA, team members and student employees converted files using prescribed instructions and naming conventions. An essential part of the conversion was collecting feedback from team members on how the digital environment should function to best serve their duties. The files were saved in a Windows network drive. Commercial digital storage solutions were considered, but the cost savings and simplicity of a network drive supported by the campus technology team was ideal. Requirements such as record retention, backups, and permissions were also considered in the selection process. With the process complete and remote access feasible, UA's central research administration team is now implementing a telecommuting program as a means of increasing team member satisfaction and retention.

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The filing space savings was also repurposed, as UCSB has done.

The next step for UCSB was transforming the entire research administration workflow from a paper-based process to a fully electronic operation. UCSB had a collection of forms, color coded by their purpose (purple for proposal reviews, blue for award synopses, etc.). The use and purpose of each form was evaluated and considered in light of the new procedures that would be adopted once the workflow became fully electronic. Most of the existing forms were integrated into the existing electronic contracts and grants system. The remainder were converted into fillable PDF documents. Once the in-house conversion of forms was complete, the UCSB Office of Research allowed department level administrators to send over proposal documents for review electronically, instead of hand carrying hard copies to the central office. Proposal and award reviews are now conducted utilizing markup tools in Adobe Acrobat Pro. UA also migrated to an electronic operation by evaluating functions of paper-based forms and creating PDF equivalents of the forms. During the process, UA discovered some paper retention processes were relics that had since been replaced by other digital retention solutions. Conversion to a digital environment also doubled as an exercise in process review that will lead to future efficiency.

Using markup tools in Adobe Acrobat Pro was a real sea change in workflow from handwriting notes and comments on proposal and award files. With paper, it was often difficult to read a colleague's writing and identify when the comment was made. Adobe takes care of this by documenting when comments were made and by whom, all in legible text. For some staff, it was difficult to get used to this new method of markup. UCSB experimented with different equipment configurations of workstations, laptops with styluses, and dual and triple monitors to replicate a physical desktop in the digital world. UA went through similar learning curves, and created checklists to facilitate the transition of working in a digital environment. For example, a digital process comes with an optional checklist that helps the transition of completing the process in the new digital environment.

For UCSB, the last and longest mile of the project was creating the best method to save relevant email correspondence in the new electronic project folders. Saving each email as a PDF, then browsing for the correct project folder to manually place the PDF file in was tedious and time consuming. After researching different email clients and third-party browser extensions, UCSB discovered Google Apps Script. A software developer at UCSB used this resource to create a Gmail add-on that, with one click, saves the email in the proper project folder, along with any needed attachments, and renames the file using project naming convention. UA is currently exporting emails to PDF and saving in relevant project folders, but plans to explore the UCSB tool.

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Chapter 1300

Regulatory Environment

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¶1330 Practical Tools

This section contains practical resources related to the ever-changing regulatory environment. The materials are culled from a variety of sources.

¶1330.1 **Summary of Significant Changes to the NIH GPS for December 2019 Version**

National Institutes of Health

(Guide Notices Issued Before October 1, 2019)

The revised NIH Grants Policy Statement (NIHGPS, rev. December 2019) represents an update to the October 2018 version and is applicable to all NIH grants and cooperative agreements beginning on or after October 1, 2019. While the update does not introduce any new material for the first time, it incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated October 2018. The December 2019 revision supersedes, in its entirety, the NIH Grants Policy Statement (October 2018) as a standard term and condition of the award.

Notable Policy Changes: Implements new policies and clarification of existing policies announced in the NIH Guide since October 2018, and listed at Grants Policy & Guidance.

Section	Significant Changes	Reason
PART II: Terms and Conditions of NIH Grant Awards Chapter 2 – The National Institutes of Health as a Grant-Making Organization	Section 2.3.5 Types of Funding Opportunity Announcements.	Introduction of Non-parent program announcements for Notices of Special Interest (NOSI). Per NOT-OD-19-107.
	Section 2.3.7.8 DUNS Number and SAM Registration Requirements	Addition of SAM and DUNS requirements language. Per NOT-OD-19-043.
	Section 2.3.7.11 Human Fetal Tissue from elective abortions	Addition of a section on human fetal tissue from elective abortions. Per NOT- OD-19-128 and NOT-OD-19-137.
Chapter 4 – Public Policy Requirements, Objectives and Other Appropriation Mandates	Section 4.1.15.2, Certification of IRB Approval.	Removal of the Requirement for Institutional Review Board Review of NIH Grant Applications and Contract Proposals Related to Research. Per NOT- OD-19-055.
	Section 4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.	Addition of language related to informed consent. Per NOT-OD-19-050 and NOT- OD-19-110.
	Section 4.1.14.2 Human Fetal Tissue from Elective Abortions	Addition of a section on human fetal tissue from elective abortions. Per NOT- OD-19-128 and NOT-OD-19-137.
	Section 4.1.27 Research Misconduct.	Updated to clarify issues related to research misconduct. Per NOT-OD-19-020.

Section	Significant Changes	Reason
	Section 4.2.12 Appropriations Mandates.	Updated per 2019 Appropriation. Per NOT-OD-19-030.
Chapter 11 – Public Policy Requirements and Objectives	Section 11.3.13.1 Statement of Appointment	Addition of language related to ORCID ID requirements. Per NOT-OD-19-109.
Chapter 12 – Application Requirements and Submission	Section 12.4.1 Application	Addition of language related to ORCID ID requirements. Per NOT-OD-19-109.
Chapter 18 – Grants to For-Profit Organizations	Section 18.5 Small Business Innovation Research and Small Business Technology Transfer Programs.	Updated to reflect most recent SBIR/STTR Policy Directive. Per SBIR/STTR 2019 Policy Directive.
	Section 18.5.4.1 Program Levels (Total Costs). Updated numbers for program levels and hard caps.	Per SBIR/STTR 2019 Policy Directive.
	Section 18.5.5.2 Intellectual Property. Updated language to clarify data rights of STTRs as equivalent to SBIRs.	Per SBIR/STTR 2019 Policy Directive.
	Section 18.5.5.4 SBIR Life Cycle Certification. Added language requiring Life Cycle Certification Submissions.	Per SBIR/STTR 2019 Policy Directive.
	Section 18.5.5.5 STTR Life Cycle Certification. Added language requiring Life Cycle Certification Submissions.	Per SBIR/STTR 2019 Policy Directive.

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¶2120.9 **Industry-Sponsored Clinical Trials: State of the Art Budgeting and Financial Management Techniques**

Andrew Waddington, Dana-Farber Cancer Institute; Meredith Maguire, Dana-Farber Cancer Institute; and Ian Stevenson, Beth Israel Deaconess Medical Center

Introduction

The global proliferation of industry-sponsored clinical trials often led by medical centers and principal investigators in partnership with pharmaceutical companies in the United States is today one of the most exciting fields for researchers and financial analysts alike.

Advances in medicine coupled with new technologies, processes, patient expectations and financial imperatives are resulting in rapid advances in how industry-sponsored clinical trials are constructed, budgeted and financially monitored.

This brief article seeks to introduce the reader to how two leading Harvard Teaching Hospital Clinical Trial Offices, at the Dana Farber Cancer Institute and Beth Israel Deaconess Medical Center, are working to stay abreast of the changes in the field and in some respects looking to lay the groundwork for the future.

Thus, the framework for this piece will embrace both the Pre-Award component, looking at the elements and steps of clinical trial budgeting, through the Post-Award component, effectively tracking clinical trial financials and ending with what we see as some of the pressing challenges in the field today.

Our hope is by the end of the article the reader will share our passion for what we have the privilege of doing each day but also have a glimpse of a future in which they would like to invest themselves.

Pre-Award concepts:

The Pre-Award process is comprised of five basic elements: assess trial complexity, review and understand study documents, determine billing designations (Medicare Coverage Analysis), identify your institution's costs, and negotiate the total award.

I. Assess Trial Complexity

Following the feasibility review at your institution, the pre-award process begins with assessing trial complexity for budget development. There are four criteria that allow us to hone in on the study required activities and effort.

Type of Study

According to the NCI Data Table 4 Reporting,¹ there are three study categories: observational, interventional, and ancillary/correlative. For the purpose of this article, the focus will be on interventional studies, specifically therapeutic studies.

¹ "CCSG Data Guide." Data Guide - OCCWebApp 2.1.0. The Office of Cancer Centers at NCI, August 27, 2019. <https://cancercenters.cancer.gov/GrantsFunding/DataGuide>.

According to the NCI,² “Interventional Clinical Trials” means studies involving human beings (subjects) in which the investigator assigns study subjects (randomly or not randomly) to receive a specific intervention based on the applicable protocol. Such subjects may receive diagnostic, therapeutic, behavioral, and/or another type of intervention. These interventions may, but need not, be investigational or involve an investigational agent (e.g., clinical trials involving surgery, radiation, or screening tests). The subjects are then followed, and biomedical and/or health outcomes are assessed. “Interventional Clinical Trials” encompasses all types of trials in all phases including pilot trials, phase zero trials, and normal (or healthy) volunteer trials. The category provides the foundation for your review and the questions that need to be answered to develop the budget.

Study Characteristics

As our focus is interventional therapeutic trials, there are several characteristics that we need to highlight while completing our trial complexity assessment. These characteristics are not limited to: determining whether the study is investigator- or industry-initiated, the study phase, the targeted disease indications, and the number of cohorts/ drug regimens.

Investigator- vs. Industry-initiated: Determining whether the study is investigator- or industry-initiated can assist with identifying the funding source, the Investigational New Drug (IND) holder, and the capacity of the institution’s overall involvement. Typically, when a study is industry-initiated the industry study sponsor is also the funding source whereas with an investigator-initiated study there could be multiple funding sources including grants and internal funding leading to a more operationally complex study. For this article, we will focus solely on industry-sponsored studies.

Study Phase: Interventional clinical trials are categorized into phases³ from Early Phase I (formerly Phase 0) to IV. Each phase has specific objectives and enrollment requirements.⁴ Early Phase I studies are characterized by a limited subject sample size while focusing on drug interaction with the human body without the intention of providing therapeutic benefit. The primary objectives of Phase I studies are to assess safety and find the investigational product’s maximum tolerable dose (MTD) with the intent to provide therapeutic benefit. Phase II studies continue to assess safety and focus on efficacy based on the MTD with the intent to provide

² “The National Cancer Institute Policy Ensuring Public Availability of Results from NCI-Supported Clinical Trials.” National Institutes of Health. U.S. Department of Health and Human Services, January 28, 2015. <https://grants.nih.gov/grants/guide/notice-files/not-ca-15-011.html>.

³ Frost, Ruth. “Trial Phase Value Definitions - CTMS - CTRP Documentation - National Cancer Institute - Confluence Wiki.” National Institutes of Health. U.S. Department of Health and Human Services, June 29, 2017. [https://wiki.nci.nih.gov/display/CTRPdoc/Trial Phase Value Definitions](https://wiki.nci.nih.gov/display/CTRPdoc/Trial+Phase+Value+Definitions)

⁴ “Commissioner, Office of the. “What Are the Different Types of Clinical Research?” U.S. Food and Drug Administration. FDA, January 4, 2018. <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research>.

therapeutic benefit. Phase III studies are conducted with a larger subject sample size to further prove efficacy. If a standard of care drug (SOC) is already in place, the investigational may be compared to the product SOC drug in an effort to prove greater therapeutic benefit for the specific disease indication. Phase IV studies include newly FDA-approved therapies enrolling hundreds to thousands of subjects to assess short and long-term side-effects. Typically, the earlier the phase of a study the more complex the study will be. For example, Early Phase I and Phase I tend to require more research-based tests/procedures so as to collect extensive data.

Targeted Disease Indications: Enrollment for a clinical trial may be open to one or more disease populations. Identifying the targeted population(s) is essential to assessing complexity. A study is more complex when multiple disease indications are targeted, which may lead to unique enrollment requirements and increased personnel involvement that requires multiple study teams' participation.

Number of Cohorts/Drug Regimens: Understanding the study design as it relates to the number of cohorts and drug regimens is another key indicator of study complexity. For instance, a study may include multiple drug regimens where there are different dose schedules or methods of drug administration leading to more than one cohort. If the study includes several targeted disease indications this also may lead to multiple cohorts. These factors may present challenges to the study team and have significant impact on the budget and quantity of budgets that need to be developed and negotiated.

Visit Requirements

Every protocol includes an outline of the test and procedures, and central lab sample collections (if applicable) required for the study; typically, this outline is housed within the schedule of events in the protocol. In addition, the estimated study duration, cycle length (treatment and follow-up), and procurement of drug are important to note when reviewing the visit requirements.

Personnel Effort

Personnel is allocated based on the patient care associated with the protocol visits, the data entry and query resolutions in the Electronic Data Capture (EDC) system(s), and any additional core facilities involvement.

A general understanding of personnel required can be deduced from the type of study and the study characteristics. For example, Phase I studies include more tests/procedures and central lab sample collections that are solely done for research purposes thus requiring more personnel effort. Whereas with Phase III studies, most tests/procedures follow the SOC for the disease indication and there are known side effects of the investigational product thus less research billable items. More so surgical trials are far more complex than non-surgical trials from a testing standpoint. To have a well-rounded understanding of resources, a discussion with the study team and PI is important. Will there be long Pharmacokinetic (PK) collection days that need to be accounted for? How much time will the Research Nurse or the Clinical Research Coordinator (CRC) spend with the patient?

In addition to the resources for patient care, data entry and query resolutions in the EDC system(s) can be costly. Each study uses a different system and each sponsor has different requirements. Perhaps the study team has a history with the sponsor or the EDC system(s) and are aware of the requirements such as more queries, this knowledge allows for adequate budgeting and identifying trial complexity.

Core facilities involvement directly correlate to the trial complexity. Pharmacy, radiology, central lab processing, clinical trials office, biostatistics, pathology, cellular therapy lab, etc. are some examples of the cores that may be involved in an interventional study to satisfy the protocol requirements. The more core facilities involved typically translates to greater complexity. For example, engineered product studies require involvement of our Apheresis Center and Cellular Therapy Lab to fulfill the protocol requirements. When addressing complexity, these two facilities are included from the beginning by the study team in the study discussions as different facilities' costs may be dependent on the protocol.

II. Reviewing and Understanding the Study Documents

There are several study-related documents that can be of assistance when reviewing the schedule of events and identifying what is occurring: the protocol, the lab manual, the pharmacy manual, and the informed consent form (ICF), etc.

As mentioned, the study requirements are typically outlined in the protocol. When reviewing the schedule of events, the requirements should be compared to the descriptions of the visits or specific procedures in the body of the protocol. These additional details are important in the hunt for what is required of the subject and study team. For example, the schedule of events may reference a cardiac assessment at screening but refers to footnote "H" and section 9.3 of the protocol. Within the footnote and section 9.3, the protocol specifies that the cardiac assessment is a 12-lead ECG with local interpretation and blood pressure read. The schedule also lists laboratory tests and refers to section 9.4 in the protocol. Section 9.4 specifies laboratory tests are a CBC panel and TSH. There are no CPT codes associated with cardiac assessment or laboratory tests, but there are CPT codes associated with an ECG, blood pressure read, CBC, and TSH.

Additionally, the schedule of events may list a variety of central lab sample collections. It is important to know how your institution charges for central lab sample collections. Is the cost driven by timepoint or by the tubes and processing required? It is important to review the lab manual to assess for further details that may not have been specified in the protocol.

Reviewing the study related documents is a critical step to ensure that the budget captures all the institution's costs and a comprehensive Medicare Coverage Analysis (MCA) is completed.

III. Determine Billing Designations (Medicare Coverage Analysis)

A clinical trial's costs may be split between two payors: the study account, which will need to be reimbursed by the sponsor (i.e. the negotiated budget), and the patient's health insurance/self-pay. The process to determine if a trial qualifies for

third party coverage and thus what items are billable to whom is determined by completing a Medicare Coverage Analysis (MCA).

An MCA is required for all clinical trials in which tests, procedures, and interventions associated with a qualifying-clinical trial⁵ are invoiced to third party payors. Preparing an MCA involves determining the underlying eligibility of the study for Medicare coverage and reviewing clinical events specified in the protocol to determine which can be reimbursed by Medicare.

A good starting point is discussing and reviewing with the PI, the routine care associated with the specific disease indication of the protocol. Would the patient receive this procedure/test regardless if they were on this trial? For each item listed in the schedule of events, it is important to note which have a CPT code associated with it. If a CPT code can be assigned, then the charge needs to be designated to the company sponsoring the trial or to insurance/self-pay. Following the discussion with the PI, all designations need to be compared with both local and federal guidelines to confirm it is acceptable to bill to insurance. An MCA assures compliance with the CMS National Coverage Decision 310.1⁶ states, “Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials...as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.”

Figure 2120.9-1. Before the Medicare Cover Analysis

Assessments	What's Actually Happening	Screening Visit	Week 1 Visit	Week 5 Visit	Week 9 Visit	Week 13 Visit
Physical Exam	Level II Physical	X	X	X	X	X
Cardiac function	12-lead EKG	X		3X		3X
	Blood Pressure	X	X	X	X	X
Tumor Assessment	CT Scan, Chest	X		X		X
	CT Scan, Abdomen	X		X		X
	CT Scan, Pelvis	X		X		X
Chest X-Ray	Chest X-Ray	X				X
Laboratory Tests	CBC	X	X	X	X	X
	HDL	X	X	X	X	X
	LDH	X	X	X	X	X
	TSH	X	X	X	X	X
XDR11597	IV Infusion		X	X	X	X

⁵ To review the requirements for a clinical trial to be considered qualifying, please reference the CMS National Coverage Determination for Routine Costs in Clinical Trials (310.1).

⁶ “National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1).” National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). U.S. Centers for Medicare & Medicaid Services, July 9, 2007. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>.

Assessments	What's Actually Happening	Screening Visit	Week 1 Visit	Week 5 Visit	Week 9 Visit	Week 13 Visit
Effort	PI	X	X	X	X	X
	Coordinator	X	X	X	X	X
	Nurse	X	X	X	X	X

Figure 2120.9-2. After the Medicare Cover Analysis

Assessments	What's Actually Happening	Screening Visit	Week 1 Visit	Week 5 Visit	Week 9 Visit	Week 13 Visit
Physical Exam	Level II Physical	Insurance	Insurance	Insurance	Insurance	Insurance
Cardiac function	12-lead EKG	Sponsor		Sponsor x 3		Sponsor
	Blood Pressure	Insurance	Insurance	Insurance	Insurance	Insurance
Tumor Assessment	CT Scan, Chest	Insurance		Insurance		Insurance
	CT Scan, Abdomen	Insurance		Insurance		Insurance
	CT Scan, Pelvis	Insurance		Insurance		Insurance
Chest X-Ray	Chest X-Ray	Sponsor				Sponsor
Laboratory Tests	CBC	Insurance	Insurance	Insurance	Insurance	Insurance
	HDL	Sponsor	Sponsor	Sponsor	Sponsor	Sponsor
	LDH	Sponsor	Sponsor	Sponsor	Sponsor	Sponsor
	TSH	Sponsor	Sponsor	Sponsor	Sponsor	Sponsor
XDR11597	IV Infusion		Insurance	Insurance	Insurance	Insurance
Effort	PI	Sponsor	Sponsor	Sponsor	Sponsor	Sponsor
	Coordinator	Sponsor	Sponsor	Sponsor	Sponsor	Sponsor
	Nurse	Sponsor	Sponsor	Sponsor	Sponsor	Sponsor

The MCA process is one of the most important steps on the pre-award process. Billing third-party payors for services rendered on clinical trials cannot be billed if the services were paid by the sponsor. This is “double billing” and is fraudulent. Services promised free of charge in the consent form cannot be billed to third-party payors. The ICF is the institution’s contract with the patient and must be upheld for compliance. Services that are for research-purposes only cannot be billed to a third-party payor, nor can services that are part of a non-qualifying clinical trial be billed to a third-party payor.

IV. Identify Your Institutional Costs

Once the MCA process is complete, an internal budget should be created. The internal budget should reflect all the items in the schedule of events and the timepoints. The institution’s costs from the chargemaster should be applied to all the patient care items that are billable to the Sponsor and the personnel effort as discussed with the study team/PI should be included. If any external vendors and/or core facilities are being used for the study, their costs should also be reflected.

Beyond patient care costs, site level costs and applicable overhead should be applied. Site level costs, including start-ups, are dictated by the site. These fees cover the administrative and institutional costs incurred to activate and enroll to a clinical

trial. Typically, start-up costs include an administrative start-up, pharmacy fee, and IRB review fee captured in the budget. Additional fees can be added depending on the core facilities involvement and site requirements. These additional fees include, but are not limited to, amendment fees, close-out fee, storage fee, etc.

V. Negotiate the Total Award

With an internal budget complete, we now can overwrite the Sponsor's proposal and negotiate the budget and payment terms. Typically, the starting budget is offered to all sites, regardless of geographic region and the cost-of-living. Regardless of the sponsor's initial proposal, it is important that we have a blue print detailing how procedures will be billed as well as our costs (i.e. an internal budget), so we effectively convey this information to the sponsor. This will ensure that all of our costs are being captured within the final agreed upon budget. Once the site's initial proposal is returned to the sponsor for review, a fair market value analysis is completed on the revisions per procedure. If the cost is not accepted, documentation of the institution's cost may be required. Typically, negotiations are completed via email, but conference calls may be beneficial.

During the budget negotiations, the payment terms are negotiated. Payment terms may include the initial payment, subject visit payments, CRF completion timeframe, enrollment caps (if applicable), reimbursement restrictions for screen failures, timeframes for invoicing test/procedure and/or study closure payments, and holdback percentages. It is important to know how payment is being received (check or wire), how often payment will be received, and what triggers payment (eCRF completion vs. invoice). Payment terms should be negotiated following institutional policies:

Initial Payment: What costs are required to be paid upfront? This is specific to each institution and may be based on activity that needs to be completed prior to study activation. Another aspect of the initial payment that must be negotiated besides the dollar amount is what triggers the payment (e.g. at contract execution, at study activation, at initial IRB approval).

Subject Visit Payments: Will invoices or eCRF completion trigger payment? This will have an impact on how much maintenance is required during the post-award process. There is also typically a holdback (% of the total visit payment held until study completion) applied to each visit. Please consult your institution's policy as this will impact the amount of expense the institute will need to "float" until the end of the study.

Screen Failures: Will the sponsor reimburse if our study team screens potential subjects who end up being found ineligible? If so, will the sponsor reimburse for the entire cost of the visit or just the procedures performed? And if the latter, will the sponsor reimburse for the time and effort required to complete those procedures? Also, the sponsor may want to cap the number of reimbursable screen failures via a total number cap or an enrollment ratio (e.g. 1 reimbursed screen fail per every 2 subjects successfully enrolled). It is important to remember that our study team is enrolling subjects to the sponsor's study and we should not be subsidizing the cost of discovering a subject meets the sponsor's definition of eligible to enroll.

Invoice Timeframes: Invoice timing is yet another aspect of the budget that must be negotiated with consulting your institute's financial policies. Does your institute have the infrastructure required to send invoices a month after a procedure has occurred? Is your institute able to reconcile all payments and expenses in order to send a final invoice to the sponsor a few weeks after study closure? If you as an institute fail to meet these timelines, will the sponsor delay payment or have you waive your rights to receive any payment? By discussing these invoicing parameters with your institute's financial team and trying to work towards finding an institutional standard, you will be able to mitigate risk and set a precedent for future trial budgets.

Method of Payment (Check vs. Wire): How will the sponsor provide payment? Discuss this topic with your institution to find out what is the most feasible way to receive and track payments. While checks may take longer to receive, they may include a more descriptive payment advice that will assist you in reconciling payments. Wire payments should reduce delays (e.g. delivery timing, checks lost in the mail, checks being mailed to the wrong address, etc.), but you will need to make sure the wire payments can be easily identified and reconciled to each study.

Following agreement by both the institution and the Sponsor the budget/ payment terms can be considered final.

Post-Award concepts:

When the contract and budget are fully executed, the total award amount is usually included. However, with an industry-funded clinical trial all payments are fee for service, so the award amount included in the contract is not guaranteed. We are only paid as we complete milestones of work; the contract figure solely represents the maximum amount of funding per patient that the Sponsor will reimburse the institution if all visits and study requirements are completed. For an industry-sponsored study, the total award worth is not known until after the trial is over. To combat the uncertainty of the award amount, there are several databases and systems that can assist with tracking:

Clinical Trial Management System (CTMS): The CTMS provides centralized management of all protocols, billing compliance, study timeframes, submissions to institutional committees, accrual information, reporting, and tracking of milestones.

Electronic Medical Record (EMR) System: The EMRs provide a detail account of the patient visit and the direction of charges. The EMR can contain details that may not be available in the CTMS but are needed for billing to the company sponsor.

General Ledger (GL) System: Each study should have its own project account within the GL system for proper reporting of revenue and expense. Within each account record, charges for the various patient care expenses, site-level fees, and personnel expenses can be tracked.

Regulatory Database: The regulatory database can include funding information and contact information. This database is access to all submissions to the IRB and in conjunction with the CTMS houses information regarding site level costs that may need to be invoiced.

Beyond these databases and systems, Excel is of exceptional value. Each system and database provide necessary information for appropriate tracking of the status and health of individual clinical trials. This information assists with analyses and financial reporting with key performance indicators (KPIs).

Financial reporting is dependent on the individual site. At our institution, it includes reporting on individual study accruals, expenses, revenue, cash, and HR reports of staff allocated to clinical research. KPIs are included to give a more detailed understanding of the portfolio:

Total Revenue by Fiscal Year: While this figure provides the overall cash received by the institution in a specific fiscal year, it does not account for the work completed in a fiscal year. As mentioned within the payment term section, payments may be delayed based on milestone and/or eCRF completion, holdbacks, sponsor payment delays, invoice revisions, etc. To account for the work completed in the fiscal year, a per-study account overview should be provided.

Total Accruals by Month: This can be presented via a table showing month-to-month accruals, by study. This figure allows the study team to review when work occurred as well as what studies are the most and least active. If you are able to include the study phase and study sponsor for each study, it may provide an even better insight to the composition of the study team's portfolio and lead to strategic improvement discussions.

Total Accruals by Calendar Year by Sponsor Type: Accruals per year details overall enrollment by calendar year and can yield information surrounding portfolio growth. If relevant, teasing annual accruals by sponsor type (e.g. industry, grant, or cooperative group) can be beneficial when reviewing trends and financial stability of the program. This table often drives discussions regarding staff levels (e.g. ratios of clinical research staff to enrollment) as well as analyzing the number of trials that are active and open to enrollment.

This report is a collective effort by the study team and the business office involved.

Challenges of Industry Sponsored Clinical Trials

As leading pharmaceutical enterprises seek to reduce the cost of new drugs to market, utilize new technologies for direct patient interaction, meet present and future government requirements and public pressure for price controls on products, many challenges are quickly evident and are constantly evolving. Each of these challenges is different, some can be addressed by new software approaches, some by organization structure and culture some by financial models derived from other industries and some by audit techniques which gives confidence to outside parties that uphold high standards throughout.

These include issues such as:

Trial complexity: As discussed earlier, there are many factors to trial complexity. Depending on the phase(s) of the protocol, type of study, number of drug regimens/cohorts, visit requirements, vendors and/or core facilities involved, and dedicated personnel trial complexity is ever increasing. It is important that

regardless of complexity though, all trials should follow the same review process to maintain consistency.

Agreements to amendments: Does a revised protocol require a revised budget? With each protocol amendment, the review process remains the same, including the MCA process. Depending on the types of changes to the protocol (i.e. new cohorts or schedules of events) the budget negotiation process can mirror nearly the same time and effort required to negotiate a new study.

Billing compliance: With protocol amendments comes a re-review of billing compliance. It is best that an MCA is completed each time there are changes to the patient care/study visit requirements to ensure compliance, transparency, and consistency.

Staffing needs: Each study requires different resourcing needs and can be difficult to gauge as discussed in the personnel effort and post-award sections. Forecasting personnel funds is difficult as industry-sponsored trial awards are fee for service. By utilizing KPIs and consistently re-evaluating staffing needs institutionally, this challenge can be minimized.

Invoicing: Depending on the negotiated payment terms, invoicing can relate solely to site level costs, specific procedures, and/or completed study-related visits. Utilizing your institution's databases (e.g. CTMS, EMR, GL, etc.) to track these items will ensure all costs are captured and able to be billed to the study sponsor in a timely-manner that adheres to the payment term parameters within the agreed upon budget.

High volume of data to be tracked: There will always be a high volume of data to be tracked, but institutionally if there are systems, databases, and working documents that provide comprehensive tracking and the ability to run reports, tracking can be manageable. Tracking, i.e. patient visits amendments, etc., is a collective effort across the research teams at the institution. With the implementation of databases and systems though, software challenges arise.

Minimization of risk to all parties invested in the clinical trial and collecting receivables in timely fashion with minimal "leakage": What exactly do we mean by "risk" to all parties? It means different things to all involved, be the investigator, the institution by whom they may be employed, or even the sponsor themselves.

Risk can simply be the loss of revenue through "leakage" where charges or visits slip through system cracks, invoices do not get generated, or even if they do they lie fallow and do not get collected. "Leakage" is subtle in that it is hard to notice in a complex trial and may only reveal itself upon audit at the end of the trial. Some think of it like the "Angel's Share" in a Scottish whiskey barrel as the contents age and evaporation occurs!

Thus, what we have here is financial risk, but it can also have serious regulatory compliance issues if items are accidentally double billed, not billed at all, or incorrectly billed.

Risk also exists in every trial where the contract stipulates, as is common, that the sponsor retains the right of reasonable access to audit the trial. Of course, the

trial can be audited as well by the institution's independent auditors, by State or Federal auditors, and the institutions own Office of Business Conduct.

Ways of facing all these risk elements range from financial models, seen in other industries, software designed to identify billing errors, disciplined invoicing practices and rigorous audit checklists for trial closeouts, regardless of the size of the clinical trial budget.

Specifically, some technologies for modeling financial collection performance have tapped derivations of perhaps long forgotten industrial studies. An example of this is the Hawthorne Works case in Chicago (sometimes called the "Western Electric Case") in the late Twenties, early Thirties. It really at that time had nothing at all to do directly with financial performance, more a study of modified employee behavior when seen to be a part of a special group and thus increased productivity.

Today that has morphed into a financial model "owned" and shared by everyone on a given team. It focuses on invoice levels reflective of the vital few instead of the trivial many and reviewed monthly against preset team goals. This same model structure is also used to measure the risks involved in studies which have lapsed into a deficit status for whatever reason.

In parallel with this, we see closeout audits tracked through very structured linear steps, as many as thirty-two in all, which are check list controlled to a standard designed to meet any outside auditor requirements.

Interestingly though, as important as metrics, models and systems may be, there is much interest today in management theory in the culture of the institution working on the trials. This can embrace the ideas of hygiene factors, being employee incentives grasping that in today's digital workplace and "hot desk" design successful employee retention and satisfaction and thus team performance than merely pays and health benefits.

In the Clinical Trials Office of Beth Israel Deaconess Hospital in Boston a successful culture exists predicated on the "Four Cs" -- customer service, continuous improvement, collaboration and communication. It speaks to the Scottish concept, lightly, of "every penny a prisoner." It breeds trust, sound transparency and the pride of being part of a team doing purposeful and meaningful work.

Skeptics might opine that it is just one more twenty first century fad, but it is not. It fosters respect, encourages teamwork, allows team members to openly share mistakes without draconian consequence. In the latter case though, one is expected to suggest solutions and benefits to the problem or error identified!

The reader may at this point be asking, does this culture focus bring demonstrable results? Is there true ocular proof? The results appear to say it does, after close to 1000 successful clinical trial closeout audits in the past seven years and a collection rate of over 98 percent on all generated invoices.

Is it perfect? Absolutely not, but it is quite good, and the goal is to go from "good" to "great." The philosophy of the "Four C's" embraces ideas as well around a healthy restlessness of the status quo, a desire to learn something new

every day, a desire to measure what one treasures, a desire to exceed that which has been promised true to the belief that in today's complex clinical trial world that words are words, promises are promises, but only performance is reality.

It is a privilege to work in a team where one might be assisting an investigator in building a budget or closing an audit when one learns that the investigator arrives at work at 5am each day to be available to patients in the study who are construction workers with a hard 7am start time.

Such dedication is not unusual but inspires one to realize this might be the best job in the world.

Thus, as we have seen, each of these challenges is different, some can be addressed by new software approaches, some by organization structure and culture best suited to working in a sophisticated industry midst tectonic change, some by financial models derived from other industries and some by audit techniques which through hundreds of successful studies gives confidence to outside parties that processes are under solid control and are reflective of high standards throughout, all within a culture of respect and patient compassion.

Conclusion

The reality is that what has been discussed in this article as present-day practice will, beyond a doubt, be surpassed in a few short years, or sooner. But there lies the joy of being engaged in such a field.

We have been fortunate to have presented some of these thoughts at various regional and national NCURA events over the past three years and hope to be so lucky to be invited in the future. This field is one globally where the United States is demonstrating world class leadership and it is hard to imagine not being excited about being a small part of such an endeavor.

All of the material herein is solely our responsibility as authors and we welcome any and all questions the reader may have. We are grateful for the time invested by NCURA in publishing this work and hope readers at home and abroad find it of some value.

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Chapter 2300

Special Issues for Predominantly Undergraduate Institutions

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¶2330.5 Getting Creative with Faculty Outreach at PUIs

Kris Monahan, Providence College, and Stacy Riseman, College of the Holy Cross

Outreach to faculty is critical for the success for all sponsored programs offices, but particularly for offices at predominantly undergraduate institutions (PUIs). It could be said that all outreach involves marketing services, activities, and resources. Sponsored programs marketing is outreach. It is making people aware of what we can do for them, in a language they can understand. We need to tell people we’re here, explain to them how we can help, and persuade them to come in through the doors, virtual or physical. Many offices create brochures or offer traditional faculty workshops to accomplish this outreach. These activities are important however it is important to think beyond traditional avenues of outreach to examine more creative mechanisms that fit the context of an institution. This article explores strategies and more creative approaches to outreach at PUIs. It also raises a number of questions for consideration as you develop a faculty outreach approach that meets the needs for your institution.

Traditional and Modern Approaches

Traditional forms of outreach in research administration include face to face workshops and brochures. Many times traditional outreach is focused on one way communication. The “trainer” possesses the knowledge, expertise, and skills and transfers that information to the learner through one-way communication. Modern approaches, on the other hand, transcend the traditional approach by adding engagement elements to traditional approaches. In more modern or creative approaches, outreach recognizes and values that the learner has much to add to the process. Creative approaches take the perspective of the faculty member into consideration in the way that the outreach occurs and in the content of the outreach itself.

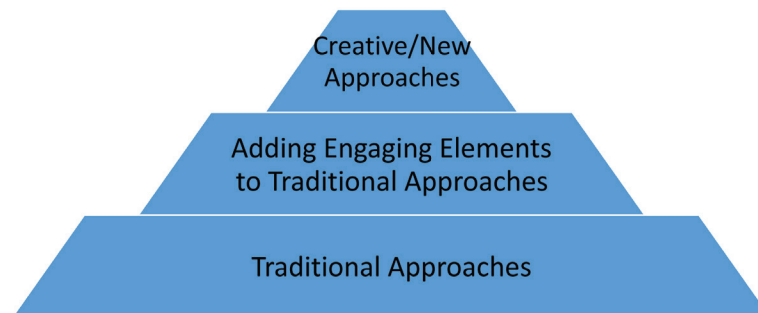
Figure 2330.5-1: Traditional vs. Modern/Creative Outreach

Traditional Outreach	Modern/Creative Outreach
One-way communication	Two-way communication
Focuses on what the RA professional wants to faculty member to know	Focuses on what the faculty member wants/needs (Mutual beneficence)
Print brochures	Pictograms, electronic resources
Didactic approach	Engaged learning
Standardized	Authentic and Flexible

Often times when people juxtapose traditional to modern approaches, there is a notion that traditional is “old fashioned” or unacceptible and modern is the desired approach. However, we suggest that traditional outreach is still critical and has an important place in research administration. We see traditional outreach as a base in a pyramid. They are important and valued activities and all research administration offices should minimally have faculty workshops and printed brochure materials. We believe the next step to mature the outreach approach is to add engaging elements to traditional approaches. An example of an engaging approach to a tradi-

tional faculty workshop would be to ensure that you are using engaged learning in the pedagogy. This means ensuring the faculty are engaged in the learning process constructively through hands on and applied activities woven throughout the workshop. At the top of the pyramid are creative and new approaches to outreach that have never been attempted before at your institution. New approaches add value and can engage different audiences. It is beneficial to have a mix of approaches to meet the needs of a broad audience.

Figure 2330.5-2: Pyramid of Outreach Approaches



Understanding the Context and Culture of Your Institution

There is a misnomer that predominantly undergraduate institutions (PUIs) are all the same. While there are clearly some common characteristics at PUIs, such as small staff and often a primary focus on other activities other than research at the institution, there are many differences. Each institution has its own culture and context. Context is the circumstances that form the setting for an event, statement, or idea, and in terms of which it can be fully understood and assessed. Institutional culture “is reflected in what is done, how it is done, and who is involved in doing it. It concerns decisions, actions, and communication both on an instrumental and a symbolic level”. It is “grounded in the shared assumptions of individuals” within the organization. (Tierney, 1988).

It is important to consider the context and culture of the PUI when determining the outreach strategy. Some questions to consider:

- ◆ Is the culture formal or informal? Formal cultures may rely on traditional approaches with engaging elements rather than truly new approaches.
- ◆ Is the research administration office view as service oriented and helpful?
- ◆ Is it a unionized faculty or a faculty that seems very engaged?
- ◆ Is it a social organization where mixers and other less-formal mechanisms would be seen as favorable?

Proposal Submission Incentives

Proposal submission incentives are extremely important, especially at a Predominantly Undergraduate Institution. At a PUI, teaching and advising are the priorities and proposal submissions come after these obligations. Faculty need to be motivated to put aside the time necessary to develop an idea, put it in to a well-written

format and submit it to a sponsor for funding. Most faculty who have done this before, and have been declined, know significant effort is involved. Those folks need a reason to try it again. There are two sides of thought regarding proposal submissions. One is, proposal incentives can be detrimental to the motivational process. The theory behind this is, if you supply faculty with motivation for doing something they are supposed to be doing anyway, once the motivation is removed all momentum is lost. Faculty proposals leading to funded research is for their own benefit. Why wouldn't folks want that for themselves? The opposite thought is, providing motivation can lead to success, which leads to more motivation. Why not build upon that? As you can imagine, it is a choice your institution has to decide how they want to proceed. At a PUI, incentives are more useful due to the large teaching schedule and less time to devote to research activities. If your institution has decided motivational incentives are important to increase research productivity, the next thoughts are the options and which ones best suite your faculty.

The best way to develop incentives that encourage proposal submissions is to access the overall needs of your faculty in relation to motivation. What exactly is the issue stopping faculty from preparing externally funded proposals? One way to find out is to send out a survey to faculty and ask. Be specific with your questions and keep them to a minimum. Timing is important so think about sending your survey in the summer or during breaks when teaching is complete for the majority of faculty. Keep in mind that surveys take time and can allow for the option to assess your office. From experience, the answer to this particular question usually results in the answer "not enough time to devote to the process". If this is the case for your institution, what are some motivational solutions?

Financial Incentives

Financial Incentives have proven to work in some cases. Small stipends to motivate faculty to set aside time to write. Usually these are paid to faculty for attending a summer writing retreat or something connected to increasing proposal submissions. In order to assess the outcome of financial incentives, it is important to track the payment to a proposal and then later to a funded award to determine if this particular incentive works for your institution.

Recognition (internal & external)

A desired outcome of outreach is faculty become involved, re-involved, or more involved with the sponsored programs office. Since the focus at many PUIs is teaching and advising, ensuring that office successes are noted in multiple ways helps put sponsored programs front and center with the campus community. There are a number of approaches to recognize faculty for their work with sponsored programs. Internal approaches are those that happen on campus, while external approaches are those which transcend the campus community. We view the ways in which an institution recognizes faculty for their involvement/successes in sponsored program as an important and creative outreach approach. These activities further engage the community in sponsored programs and make the sponsored programs office visible. Below are some approaches/techniques to consider:

Figure 2330.5-3: Recognition approaches

Recognition Approach	Internal/External	Benefits and Considerations
E-Mail from Dean/President/Provost to individual	Internal	Some institutions copy department chairs on a thank you letter. This helps message the importance of sponsored programs and the role of the sponsored programs office to the individual and department who participated
Article in alumni magazine or college/university research journal	Internal	Working with marketing and public affairs staff is critical to ensure internal printed publications feature research and sponsored programs. Some institutions will feature a “by the numbers” section in the alumni magazine so the campus community is aware of the impact of the sponsored programs office.
Campus –wide e-mail, feature on home page, or electronic “spotlight”	Internal	Ensuring that both print and electronic communications have spotlights of sponsored programs office and successes is important.
Grant Celebration	Internal	Annual grant celebration to share projects and people who are submitting proposals.
Press releases	External	Work with marketing/public affairs staff to issue press releases when new grants are received. Highlight if the grant is the first. Identify local media outlets interested in such stories.
Quarterly Meetings with Marketing /Public Affairs Staff	Internal/External	Meeting on a quarterly basis with your marketing/public affairs team and highlighting the work of the Office and the work of faculty should help yield regular integration of sponsored programs stories in multiple media
Statewide Networks/Consortiums	External	Ensure the successes of the faculty/office are shared with any statewide networks of consortiums.
Million-Dollar Club	Internal/External	Create a million dollar club for those faculty who have received more than a million dollar in funding. This is a huge accomplishment at any institution, especially a PUI.
Twitter and other social networking	External	If your faculty tweet, create an Office twitter page and share their successes via tweets.

Mixers

One idea is to create an opportunity for faculty to get together, talk and meet other faculty without calling it a workshop. A chance to attend a social event with their colleagues without a lecture. During a mixer, faculty are provided refreshments and the opportunity to talk with those they know while also meeting faculty they’ve never met before, in a social setting. Halfway through the event is a great time to say a few words about upcoming workshops, introduction office staff or campus committee members, provide upcoming funding opportunity information, in a casual format. These mixers have themes such as Internal Funding Mixer, Writing Retreat Mixer, etc. On PUI campuses, where time is an issue for faculty, it’s important to assess the types of workshops and events we do and how faculty want to spend their time. Is it something they want to use this time to attend?

Writing Retreats

Writing retreats are another excellent way to engage with faculty. The one obstacle we hear most frequently at PUIs is the lack of time to write publications and/or grants. Faculty with high teaching and advising loads often struggle to write publications early in their careers. And, they cannot be competitive with external funding without a strong scholarly track record. The sponsored programs office can reach out to faculty and collaborate with offices on campus to help create the space/time

needed to support their scholarly and grant writing. Deciding the type of writing retreat to develop and at what time of the year will depend on the needs of your faculty and the context of the institution. We have tried a number of approaches to meet the needs of faculty.

Summer Writing Retreats

Holding a writing retreat in the summer works well for faculty when announced significantly in advance, perhaps during the winter break. Faculty start booking their summer activities early in the spring so timing of the announcement is key to the successful planning of a summer writing workshop. These retreats can be two days, one night, or three days and two nights but we do not advise longer. Some faculty will want to attend during the day only, which is okay but to get the full experience to devote to writing, we encourage overnight stays. This allows for more of a cohort experience and for faculty to genuinely feel immersed in writing and away from other obligations. These writing retreats have been very successful in increasing proposal submissions, especially when combined with a financial incentive.

One-day Retreats in Intercession/end of semester

If summertime won't work for your faculty, consider one day retreats at times during the academic year on or off campus. Polling faculty in advance, collecting summaries of the writing projects in advance, and arranging a quiet place with writing support (and great coffee) is exactly what some faculty need.

Regular blocks of time with Writing Cohorts

Faculty have appreciated developing writing cohorts or teams that they can connect with and be accountable to. Creating a writing group through your Learning Management System that meets or posts virtually and regularly scheduled meetings to report on progress has proved affordable and successful.

Information Sharing

Sharing information doesn't have to be in the form of a traditional workshop. We are always trying to think of different outlets to reach faculty. Below are a few ideas we have tried on our campuses:

- ◆ PechaKucha, or a brief information sharing event, is when faculty come and share their research with a short presentation. Each person who presents has 20 slides, with 20 seconds per slide. With the small amount of time allowed, faculty are compelled to narrow their focus by using creative ways to represent themselves and their research via pictures and concise thoughts. It's a quick and interesting way to learn about other faculty research in a fun and social setting.
- ◆ Try to think of ways you can utilize what your campus already has, such as TV screens in public spaces, in order to recognize faculty and advertise your office.
- ◆ Consider a 5 minute Department presentation. Bring along the Director of Corporate and Foundation Relations, someone from the Writing Center, or an individual from Finance. Keep it short and simple and to the point. When folks

can put a face to the name, it aids in future communication. It is also important to show successful collaboration with other administrative departments on campus.

- ◆ Pictograms, like other types of visual documents, can help aid to advertise office responsibilities. For some, visual representation of information is another way to capture someone's attention.
- ◆ Other ways to share information include "Ted-like" talks, flash talks, and new-faculty poster sessions that rotate to different geographies on campus.
- ◆ "On-Location" or "On the move" or "Pop up shop" events where you geographically place a staff person in a department or school or other high traffic area is another creative approach to outreach.

Engaged Learning-New Pedagogy

There will be many pre and post award topics in research administration where faculty workshops, panels, discussions and forums are desired. We urge you to consider adding engaged learning approaches and new pedagogy to traditional didactic lectures. Higher education in the last twenty years has been focused on finding new pedagogical approaches that work for students. There are centers for engaged learning at many colleges and universities across the country, including PUIs. A Center for Engaged Learning fosters investigations of (1) how to do "high-impact" engaged learning practices well, (2) how to scale these practices to many students, and (3) how students integrate their learning across multiple high impact experiences. If engaged learning works with undergraduate and graduate students, it will also work with faculty. It is important to understand the tenants of engaged learning and incorporate those philosophies and approaches to the work that we do with faculty.

We need to build tasks within workshops that are challenging, authentic, and multidisciplinary. Such are authentic in that they correspond to information and situations that s/he may face tomorrow. Faculty will see value in the training. Collaboration around authentic tasks often takes place with other faculty and mentors. These tasks often require integrated instruction that incorporates problem-based learning. It is critical to use case studies and "what-if" scenarios in any workshop. We need to construct opportunities for faculty to come to know information and solve problems.

An engaged learning approach also involves asking faculty what they want/ need to know and using faculty peers as trainers and mentors. Students don't like "death by Power-Point" and neither do most faculty.

The most powerful models of instruction are interactive. Instruction actively engages the learner, and is generative. Instruction encourages the learner to construct and produce knowledge in meaningful ways. Some common strategies engaged learning models are individual and group summarizing, means of exploring multiple perspectives, techniques for building upon prior knowledge, brainstorming, problem-solving processes, and team teaching using other faculty who speak from sponsored programs experience.

Collaborate with Others and Consider Everything Outreach

In a small office, collaboration is essential to expand your outreach. You may be a small office of one, two or three, but through the power of collaboration your outreach can touch more individuals than you imagine. Depending on your institution, there may be many ways to collaborate with other offices on campus to take advantage of outreach they are conducting, to co-sponsor events, or to build mutually beneficial programs. We offer you some possibilities for consideration and examples of potential outreach collaborations:

Figure 2330.5-4: Collaborations to expand outreach capacity

Office	Example Collaboration/Outreach
Library	<ul style="list-style-type: none"> Work with the research librarian to develop a workshop on data management repositories and plans Work with librarians to show faculty how to use funding databases (SPIN/PIVOT etc.) Work with librarians to provide support for literature reviews
Centers for Teaching Excellence	<ul style="list-style-type: none"> Co-sponsor events with teaching centers on the balance of teaching and scholarship Co-sponsor writing resources for faculty Co-sponsor writing retreats
Writing Centers	<ul style="list-style-type: none"> Co-sponsor writing retreats for publication for faculty Ask a writing coach to conduct a training on a writing related theme
Controller/Finance Office	<ul style="list-style-type: none"> If there is a new travel policy or other College wide change, ask to be engaged with any grant-related specifics during their training events/outreach
Development/Advancement	<ul style="list-style-type: none"> Collaborate on Funding Opportunities Go to department meetings to co-present

Conclusion and Assessment of Outreach Initiatives

In order to assess your outreach initiatives, below is a number of strategies to employ in assessing your outreach programs:

Figure 2330.5-5: Assessment strategies for your faculty outreach

Assessment Strategy	Definition	Quantitative	Qualitative
Comments	Collect thoughts of participants about the outreach; can occur on paper/survey, white boards during event, or other media		X
Compiling evidence of external outreach	Gather coverage of an event through social media, newspapers, and other media outlets		X
Documentation	Save flyers, agenda, and capture photographs and anecdotes including self-reflection	X	X
Focus groups	Interview participants in groups, following the event		X
Electronic surveys (Survey monkey/qualtrix)	Collect email addresses during the event and distribute an e-survey via collected emails following the event.	X	X
Head counts/contact database	Count the number of people present at an event. Keep track of who you have reached in what ways	X	
Mini interviews during the event	Conduct very short interviews during the event, led by a staff member or volunteer. The type of interview conducted can vary, whether it asks an open-ended question or has a set list of questions to be answered.	X	X
Quick pulses	Get immediate brief feedback from participants before they leave the event (no more than a few minutes)	X	X

Assessment Strategy	Definition	Quantitative	Qualitative
Observations	Note how participants behave and respond during the event. Have an outside observer (if appropriate)		X

What is important is that you create a multitude of traditional and more engaging approaches to outreach that is carefully considered for the context of your institution. Do not be afraid to try something new. Not every outreach event will prove successful, but faculty will likely appreciate the ways you are trying to meet them where they are at.

Reference

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Chapter 2500

Pre-Award Services

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¶2530.14 ***Pre-Award Compliance - Shared Responsibilities between Central and Department Offices***

Katherine Pizer, University of Chicago and Jessica Lawrence, Deloitte Consulting, LLP

Whether you are new to research administration or you are a seasoned veteran in the profession, it doesn't take long to realize that this is not a job that can be done solely on your own. Positive working relationships between the central sponsored projects office and department research administrators is critical when it comes to providing the best possible support to faculty. Even more crucial is finding opportunities to support and assist one another when it comes to meeting increased compliance requirements.

Research administration is full of compliance and in every area of it, pre-award is no exception. From salary cap requirements and COI regulations to sponsor assurances and regulations, it often feels as though it takes a village to submit a complete and compliant proposal. Roles and responsibilities between the central and department offices will vary based on the culture, size, and/or type of your organization; however, open and honest communication will allow you to establish clear roles and responsibilities for your own institution.

Some less familiar with research administration may think that compliance-related issues are limited to post-award activities only. After all, many of us have heard reports of the consequences incurred by peer institutions because of the misuse of Federal funds. Whether a mis-allocation, charging to incorrect budget line, or blatant fraud, it is largely the issues occurring after the award has been made that are making national headlines. However, it is very important to keep in mind that research administration is a holistic process, and compliance is a major part of that process. As research administrators, we should all begin to think about managing compliance prior to proposal submission. Individuals with pre-award responsibilities should also consider the down-stream impacts their work has on their post-award colleagues, and mitigate those issues before they materialize.

But what is pre-award compliance? Compliance issues at the pre-award stage are actually quite prevalent. The first to come to mind is PI eligibility. Does your PI meet the requirements established by your institution, agency and specific funding opportunity? Consider that the proposed budget itself could be ripe with compliance issues: over/underbudgeted personnel, incorrectly applied fringe benefit or indirect cost rates, mis-executed salary cap, inclusion of unallowable expenses, etc. Does the budget align with the proposed work? There are regulatory issues to be considered and managed: COI, export control, IBC, IACUC, IRB. Consider that many proposals will also have sponsor assurances that need to be reviewed and endorsed, sometimes requiring engagement with institutional legal counsel. Additionally, pre-award research administrators have the responsibility of ensuring correct fonts, page limitations, and compliance with guideline-specific terms.

General Roles and Responsibilities

It is essential for central and department research administration staff to define and understand their roles so that they can work together in a productive and supportive way, and not in such a way that would result in finger-pointing and blaming one another for mistakes. As organizational structures change, it is important to review roles and responsibilities.

The central sponsored projects office will typically serve as the institutional source of knowledge and guidance for department administrators. Central staff are focused entirely on research administration, and likely specialize in a specific area (pre-award, post-award, contract negotiations, compliance, etc.), while department administrators have traditionally served as generalists, serving multiple faculty needs that extend outside of the research domain. Central office research administrators can provide knowledgeable guidance on Federal requirements detailed within 2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirement for Federal Awards (Uniform Guidance or simply UG). Central office research administrators also provide sponsor-specific guidance, relying on documents such as the NSF Proposal & Award Policies & Procedures Guide (PAPPG), NIH Grants Policy Statement (GPS), and published guidance from other Federal and non-Federal sponsors.

It is key for central office research administrators to be well versed on these regulations and policy guides in order to assist their department colleagues as questions arise over the course of proposal development. Serving on the front line of faculty interactions can at times place department administrators in situations where assistance and support is needed from the central office. Central research administrators should provide sound guidance to administrators and faculty, citing specific published institutional policies, sponsor specific guidelines and Federal rules and regulations.

Central research administrators are also responsible for reading sponsor guidelines for submission-specific requirements. A central administrator's read of the guidelines will likely focus on sponsor specific requirements such as: limited submissions, classified research, special terms and conditions, and any limits to institutional indirect cost rates. Central pre-award staff will also work to ensure institutional policies such as PI eligibility, PI effort, cross-departmental approvals, regulatory restrictions, and terms and conditions are acceptable to the institution. It is expected that central pre-award administrators review proposal applications and provide feedback to departments and faculty as needed, provide institutional endorsement for the proposal, and submit the final proposal to the sponsor.

Department research administration staff are the main source of support to faculty as they develop a research proposal. Like central research administration staff, department staff need to read sponsor guidelines and be well-versed in institutional policies and Federal regulations. Pre-award staff develop the budget, ensure compliance with agency imposed salary caps, and coordinate with other departments/units to obtain approval for participation of personnel involved in a project. Department staff also verify availability of space and other resources needed to conduct the work proposed. These administrators are also most knowledgeable in under-

standing any financial or personnel impacts that the proposal might have on their department. Finally, department staff are expected to provide the initial review of the proposal prior to central office endorsement. Depending on the structure of your organization, the departmental reviewer(s) may be a senior staff with authority to sign-off on behalf of a Chair and/or Dean.

Key Considerations

So, what are the key compliance considerations for staff with pre-award responsibilities in central and department offices to keep in mind as they work with faculty through the proposal process? The answer to this largely depends on the structure of your own organization. Smaller institutions may be forced to rely on one office or a handful of individuals to ensure review of compliance issues at the proposal stage. For larger research institutions, there is often a shared responsibility between department and central research administrators to review separate considerations and to provide a dual review of many items. Let's first contemplate the key considerations of department administrators.

The initial email from a PI stating his/her intention to submit a proposal begins the proposal process. It also contains many compliance related information. For example, "I want to submit an *R01* with Dr. Smith from *University of Subaward*. I need to purchase a new *microscope* and *mice*". Within these two sentences, a department pre-award administrator can identify key compliance areas for this R01 proposal; adhere to the federal sponsor guidelines, inclusion of subaward documentation, budget, budget justification, inclusion of IACUC oversight committees and associated documents. All of this may seem too easy-gathering all of the pieces of a proposal is actually a compliance exercise. Many components of a proposal can be linked to an agency and/or Federal regulation. The Uniform Guidance, establishes the administrative requirements and cost principles IHE are required to follow.

The compliance focus of central administrators is similar, but they are reviewing from an institutional perspective, so there are some differences. When a proposal is received for initial review into the Central office, it may be prioritized for review based on due date and complexity. Central research administrators will want to understand which compliance components are included within each specific proposal, and then rely on their institutional, Federal, sponsor, and RFP-specific knowledge to ensure that all compliance components are in order. Often, central staff may not have enough lead time in advance of a proposal's due date to provide a thorough review to their department colleagues. In these cases, central research administrators are often focused on a close review of compliance issues over a deep dive into the guideline-specific requirements such as page limits and font restrictions.

Turn-over in both central and department offices is inevitable. With this in mind, store guidance documents with defined roles and responsibilities specific to compliance and other areas in an easily accessible location. Seasoned staff can use the resources to maintain perspective on their job responsibility and ensure consistency with operations. Additionally, it is helpful for new staff with research administration experience to understand the roles and responsibilities within a new organization.

Establishing pre-defined roles and responsibilities of both offices can ensure that all proposal components are being reviewed for compliance prior to sponsor submission. Knowing which office is responsible for the review of specific compliance items will help to facilitate a more efficient hand-off, especially under circumstances where there is limited time for review.

Teamwork Makes the Dream Work

So far, we have discussed pre-award compliance, defined roles and responsibilities, and explored the compliance considerations made from both the department and central offices. Now let us delve into practical application of shared responsibilities and the importance of a collaborative and productive relationship between staff in both offices in order to ensure proper compliance.

Department and central research administration staff can work together to improve an inefficient or not-fully-compliant process. First, it is important for members from both central and departmental offices to identify a shared goal. Discuss the challenges, define roles and responsibilities, and identify redundant work. You may need to involve staff from multiple offices, particularly with complex processes or those that span multiple compliance offices. Begin the process with an open mind and make sure to stay focused on your original goal. Create a “parking lot” to track ideas and processes that come up for future process improvement projects. During your initial meetings look for quick wins, for example, are multiple people downloading the same document? Or, maybe there is a longstanding form or template that needs updating. To maintain momentum, establish a time frame for the project. Prior to implementation of a new or refined process, solicit feedback from colleagues who were not part of the project team. Pay particular attention to involving those with a compliance focus to ensure that those items are covered in the revised process. Formal and informal communication to all staff can alleviate uncertainty for the staff who were not part of the project team. There is also the likelihood you will need to revise your process after go-live. This is ok, and you will find that being flexible when it comes to enhancing processes will show stakeholders that everyone is committed to the best possible approach. Continue to meet and maintain open communication with the team and institutional stakeholders, and your new process will be “The Process” in no time.

Another opportunity for central and department research administrators to work together to ensure pre-award compliance involves faculty. We likely all have experienced faculty that may have challenges with understanding certain compliance requirements; or in more severe cases, may ignore those requirements altogether. It is part of our responsibility as research administrators to guide faculty toward the compliant path and keep them grounded there. If as a department administrator, you have a faculty member that is particularly difficult to manage in this area, reach out to your colleagues in the central office for support. A strong relationship between department and central offices facilitates a supportive culture where two or more individuals can make a strong case to those specific faculty. You should also work with leadership on both sides to define an escalation process for such issues.

Escalate more critical problems up the academic and administrative chain as the individual issues warrant and be sure to site available and published guidance for additional justification toward the compliant path.

Within the academic landscape of today, there are constant changes and initiatives simultaneously ongoing on many campuses across the country. These initiatives often involve the implementation of cloud systems to manage one to many aspects of business on campus. It is critical to ensure compliance is considered as central and department stakeholders work with vendors on these implementations. Clear and open lines of communication between department and central offices is imperative to ensure successful implementation of new systems, process improvements, and organizational structure changes. These close relationships will help a partnership toward ensuring compliance in every area impacted by such institutional change. If you don't have them today, consider scheduling regular meetings between divisional and central office research administration leaders, at all levels, to establish relationships and open rapport. Build relationships to create trust amongst leadership, including mid-level leadership. In fact, these mid-level relationships can often be the most important because these individuals are more entrenched in the day to day work and have direct supervision over the staff working directly with faculty, and staff that manage day to day compliance issues. Having established good-standing relationships prior to entering large institutional initiatives is ideal, but those relationships can also be built throughout.

A vital component is having the ability to disagree while understanding that ultimately, you are all working toward the same goal: building and maintaining a compliant environment while providing the best possible customer service to faculty. Communication between central and department offices must be open and clear, and all parties should be firmly committed to this. It is important for leaders to foster strong collaboration and teamwork, and should encourage positive interactions between their staff. Collaborative relationships between the central and department offices positively impact the staff working in an often pressure filled job. Defining roles and committing to open communications will help to ensure compliance in all areas of pre-award, and allow administrators to seamlessly focus on those important items while providing the best possible support to faculty.

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Chapter 2700

Administering Research Contracts

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Note: Unless otherwise indicated, material was prepared by AIS editors.

¶2730.3 **Unintended Consequences of Six Contract Drafting Challenges**

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Contracts are everywhere. People enter into them every day without reading them and even without realizing they are entering into a contract. Research administrators, however, are expected to be savvy contract reviewers and drafters. The consequences of poor contract drafting can have downstream and unintended consequences for universities, their researchers, and their contracting partners. This article exposes six of the most common drafting errors and the problems they cause.

Some terms when used in the definitions in an agreement create uncertainty or impose conditions on the conduct of a project or use of results in ways that are not intended by the parties.

“Related to” – When used in the definition of “intellectual property” or “inventions” “related to” adds uncertainty to the scope of what is being licensed or optioned in a sponsored research agreement (SRA) or other agreement (Materials Transfer Agreement (MTA), license agreement, data use agreement (DUA), services agreement) and should be avoided or clarified. “Related to” what, the project, the outcomes of the project, patentable results, the general research area, sponsor’s products? This phrase requires further specification and should be clarified or removed from the definitions in an agreement.

Investigators conduct research in defined areas that are generally relatively narrow and deep. If a university agrees to provide a sponsor a license or option to license intellectual property (IP) defined as “anything generated or developed in the course of performing the research including but not limited to methods, data, technology, technical information, know-how, and expertise **related to** the research” virtually the entire scope of the investigator’s research area is included. At the end of the project how do the parties determine what is covered by this definition and what rights the sponsor has. If the agreement provides for exclusive rights and the investigator has multiple sponsored projects with a similar clause confusing and troubling overlaps may occur. Similarly phrase like “all data”, “all information”, and “resulting from” cause the same problems.

Note a drafting problem connected to vague adjectives and qualifiers is the absence of a comprehensive retained rights clause, i.e., a clause that allows continued use of the licensed intellectual property or inventions by the university at least for research, education, and development regardless of the rights granted to the sponsor. An overbroad or vague definition of intellectual property or inventions coupled with exclusive rights to the sponsor and without a retained rights clause could lock the investigator out of their research area. However, this provision too requires some finesse as shown in the discussion of “Noncommercial purposes” below.

A well written intellectual property clause limits inventions by type, e.g., “potentially patentable”, “copyrightable” versus “all developments”, and by scope and timing of occurrence, e.g., “in performance of the Research during the term of the contract.” Of course, “Research” would also optimally be defined to reference a well described project with defined deliverables and clear descriptions of what each party is required to do.

“Data” – Research always produces information of some type which is often generically referred to as “data”. However, the abundance of data, the ability to manipulate and link data, and the importance of data to commerce, policy and other decision-making, as well as the ever increasing number of privacy and security laws dictates that data resulting from research and other projects be treated separately and clearly in agreements (SRAs, MTAs, DUA, nondisclosure agreements (NDAs)).

Consider the treatment of “data” in this contract provision that has multiple drafting errors: “Data” means “all information and other data (including without limitation, written, printed, graphic, video and audio material, and information directly related to the Study and generated in the course of conducting, or otherwise as a result of, the Study, whether generated by Institution, Investigator or Sponsor.” What if the contract goes on to say that Data is subject to an exclusive license granted to the sponsor, is required to be treated as confidential information of the sponsor, is required to be deleted from publications, or must be retained by the university for some extended period of time? The vagueness of the term would require the university to make some assumptions about what the term actually means to avoid open-ended obligations and to protect its proprietary information like business and accounting records. The scope of the definition requires the university to carefully carve out or limit the definition in other clauses, e.g., adding to the beginning of the publication provision, “Notwithstanding the definition of Data, above, the university may publish results generated by the university in the conduct of the project.....” and making sure that patient medical records are not subjected to the sponsor’s ownership and control.

If the contract requires Data to be provided to the sponsor that task may be insurmountable without further qualification, e.g., aggregate or raw Data, provided in what form and how transmitted or deposited. If the university has to curate, clean, format, store or otherwise manipulate the Data the related costs should be included in the project budget. Additionally, despite the overbreadth, the university would necessarily have to make assumptions about the scope of the Data to determine what compliance obligations were triggered. Is the Data identifiable, an education record under FERPA,¹ is it export controlled, has it been obtained from a source that restricted provision to the certain kinds of sponsors like non-profit entities or permitted uses only for certain purposes like research or education?

Most of the unintended consequences of poorly drafted data provisions can be overcome by tying the definition of Data to the statement of work and any required deliverable reports, “Data means tangible information contained in reports of the Research that are required to be generated by the university in performance of the statement of work.” Other solutions would be to tie the definition of Data to the reporting vehicle, “Data means any aggregate data contained in the research reports submitted to the sponsor using [named database submission site and process].”

Other cautionary practices include carving out Data from any grant of a license or option to obtain exclusive rights to project results (i.e., provide nonexclusive rights only), limiting access to Data that is de-identified if possible, clearly omitting

¹ Federal Education Record Privacy Act, FERPA, 34 C.F.R.99.3

financial and business records of the university from the Data definition, limiting the rights to use of the Data by the sponsor and not conveying any rights to share outside sponsor's organization. If the data is included as part of the IP to be provided to the sponsor limit the data to that necessary for the sponsor to practice any rights it acquires in the defined IP. A simple rule of thumb to keep in mind is that you can't provide or control Data if you can't define it.

Background Intellectual Property (BIP) terms – Certain projects require access to or use of IP that exists when the project starts or that is developed by a party but not as part of the sponsored activity. BIP clauses that do not clearly describe the BIP and the rights the parties have in them cause chaos for tech transfer offices if the sponsored projects office does not take care in drafting BIP provision in sponsored project agreements. Clauses that define BIP as owned or controlled by the “university” as opposed to those “on which a member of the project team is a named inventor” are difficult to for a university to implement and may subject unrelated researchers to contracts concerning projects they are not involved in. These over-broad “all university” BIP clauses require technology transfer offices to identify, flag, and reserve rights in BIP while the project is ongoing. The university needs to be able to narrow the search and the obligation to identify BIP that could affect the project. Many universities have departments and units that conduct related research but not collaboratively such as chemistry and chemical engineering departments. So, there is a possibility that research being conducted one of these units would overlap or be complimentary or even conflicting with the research being conducted by another unit. In this situation, at least limiting the definition of BIP to technologies disclosed to the tech transfer office would help them identify related BIP. Even if the definition of BIP is sufficiently limited so that the university can find it, the BIP may be subject to existing license rights. BIP provisions that are not qualified by “to the extent the university is legally able to do so” create potential breach of contract situations if rights in the agreement are inconsistent with other agreements the university has in place.

Universities should be careful about making the conduct of a project dependent on BIP of the sponsor. Limited use of the sponsor's BIP or protection of it as confidential imposes additional liability on the university to assure compliance. Limitations on disclosure may affect the publishability of results of a project that cannot be understood without access to the sponsor's BIP.

While, it may be best to avoid providing any rights to BIP in a project agreement, if it is necessary given the nature of the project the BIP clause should define the BIP as clearly and narrowly as possible and define the parties rights to use it both in the context of the statement of work as well as the foreground IP terms.

“Noncommercial purposes” – This term is often used to limit a party's use of IP, Data, BIP or other (hopefully well-defined) project result. The term, however, is confusing in describing and enforcing the permitted use for both universities and sponsors. For instance, what activities that a for-profit sponsor conducts are not commercial? The Supreme Court of the United States has characterized research

as the business of universities² thus arguably making it “commercial” if the term is defined as relating to business. If the university retains rights to use Data (again, hopefully well-defined) from clinical research for non-commercial purposes is it restricted from using it to inform decisions about patient care that is reimbursable by insurers?

There are better alternatives to “non-commercial” purposes that make the uses more explicit, e.g., for universities “research and development, education, and patient that is not subject to license rights of a for-profit entity and that does not generate profit”, for companies “use in manufacturing and design processes not including the right to incorporate the Intellectual Property into a product or service offered for sale or purchase and without the right to sublicense any of these rights.”

It should be mentioned that some statutory provisions permitting use of intellectual property are consistent with the idea of “noncommercial purposes” and do not need to be specifically invoked by a contract. For copyrighted works the doctrine of Fair Use provides a four factor test to allow a court to determine whether a particular use of a copyrighted work is non-infringing.³ The clinical research exemption provides a safe harbor for use of patented inventions for “development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”⁴

“Jointly owned inventions” – “Jointly owned” is a contractual term that is often confused with “jointly invented.” Joint inventorship cannot be contractually granted. It is legal determination made initially by patent attorneys or agents that a person’s contribution to an invention rises to the level of inventorship defined by statute.⁵ Joint ownership of patents, however, can be granted by contract. If the other party is not an inventor under law the grant of joint ownership is essentially an assignment of the inventor’s rights to the other non-inventing party. There are consequences of designating an invention as jointly owned. Joint owners are equally responsible for all decisions unless a contract between them says otherwise. This requires then that an agreement granting joint ownership also have clear patent prosecution provisions. All joint owners must join in suits to enforce the jointly owned

² *Madey v. Duke University*, 307 F.3d 1351; 2002 U.S. App., retrieved from <https://cyber.harvard.edu/people/tfisher/2002Madedeyedit.html> - researchers cannot assume a “research or experimental use exemption,” allowing use of patented inventions for purely academic and research purposes without threat of a lawsuit. Practice of a claimed invention is subject to risk of an infringement action unless expressly authorized.

³ 17 U.S.C. 107, 4 factors to consider in determining whether an intended use is Fair Use under © law: the nature of the work (factual, creative), the purpose of the use (educational, for-profit), amount of the work being used, potential impact of the use on the market for the original.

⁴ Clinical Research Exemption – safe harbor: not “infringement to make, use, offer to sell, or sell within the US or import into the US a patented invention ...Solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products” Wax Hatchman Act, 35 U.S.C. §271(e)(1)

⁵ An inventor is “one who contributes to the conception of an invention.” See 37 CFR 1.41: Inventorship

patent even if they are not practicing the invention. Patent enforcement is expensive and can be time consuming for the inventors. For inventions made with federal funds that are subject to the Bayh-Dole Act, assigning joint ownership of a federally funded invention requires approval by the relevant federal agency.⁶ Also, since laws of joint ownership differ by country the parties' obligations may be affected by the controlling law provision in the agreement. Contracts that specify defined inventions to be jointly owned should address, at least financial responsibility for obligations as joint owners and be clear about the law under which these obligations will be determined.

“And/or” – One final pet peeve of mine that is always unclear and requires the reader or contract enforcer to figure out what the drafter meant is the use of “and/or”. Courts have long hated this drafting convenience and even pervasive use has defied clarity.⁷ In the context of IP definitions “conceived and/or reduced to practice makes no sense” and should be avoided. Conception is required for inventorship and reduction to practice alone does not result in inventorship. So, by using and/or the reader will be entitled to interpret the provision as most favorable to them with vastly different outcomes. A university will generally prefer the interpretation as “and” to avoid trailing obligations to sponsor A when the university pursues further development of the conceived invention under an agreement with sponsor B to reduce the conceived invention to practice. Sponsor A's preferred interpretation of the clause would be “or” thus preempting the university from pursuing the agreement with sponsor B. The confusion from use of “and” or “or” usually can be mitigated by just adding more words however the choice of “and” or “or” in the definition of IP must be left to the negotiators who often weigh the probability or improbability of an invention against the expediency of using “and/or” thus deferring the discussion and allowing the contract to be concluded.

These six points are not necessarily all or even the most pervasive or definitive examples of drafting errors that cause issues for the parties. They do demonstrate the need to review provisions in the context of the entire agreement, including the statement of work, to assess potential impacts and strive toward consistency and clarity of agreement terms.

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⁶ 37 C.F.R.401.14 (k)

⁷ “‘And/or’, that befuddling, nameless thing. That Janus-faced verbal monstrosity, neither word nor phrase, the child of a brain of some one too lazy or too dull to express his precise meaning, or too dull to know what he did mean.” **Duhaime's Law Dictionary** retrieved from <http://www.duhaime.org/LegalDictionary/A/AndOr.aspx>

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