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Compliance Through Connection

Speaker:

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Title Slide

>>*Megan Clark*: Hello. I am Dr. Megan Clark, part of the NIH Office of Laboratory Animal Welfare.
I'm pleased to welcome you and our speakers to our April 2025 webinar today on Compliance Through Connection, where we will discuss bridging the gaps between didactic training and the implementation of hands-on skills. Joining us today will be several speakers from the University of Michigan Animal Care and Use Office.

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Compliance Through Connection

>>*Bill Greer*: Good day, everybody, and welcome to today's program.

Today, our program is titled “Compliance through Connection.” The premise behind this particular topic is for us to give you guys an idea on how you can make strong connections with principal investigators (PIs) and how that will help you to improve your compliance program with a group of our compliance assurance specialists that will be going through today's topics for you.

My name is Bill Greer. I'm the Director of the Animal Care and Use Office at the University of Michigan, and I'll have each do a brief introduction of themselves. And then I'll turn it over to Erin to take us through today's session. So Ashley, please.

>>Ashley Duval: Thanks Bill. Welcome everybody to the webinar. My name is Ashley as Bill just said. I've been involved in animal research for over 20 years now, starting in a lab, moving to the animal care side. And now serving as a Quality Assurance Specialist Senior in the Animal Care and Use Office. Thanks.

>>Bill Greer: Thank you, Ashley. Mike.

>>Mike Ream: Hi everyone. Thanks for attending today. My name is Mike Ream. I'm a Quality Assurance Specialist Senior. I also have over 20 years of experience in the animal care world, starting as with the animal husbandry, and then moving to compliance about 10 years ago. And I have held several different roles since being in the Animal Care and Use Office, but Quality Assurance Specialist for the last 6 or so. Thank you.

>>Bill Greer: Thank you, Mike. And Taryn.

>>Taryn Hetrick: Hello everyone. My name is Taryn Hetrick. I am a licensed Veterinary Technician with over 18 years of experience in animal care. I am currently a part of the Animal Care and Use Office as a Quality Assurance Specialist, but prior to that I was with our animal husbandry team as a technician and then shortly after that I joined the veterinary technician team. That's where I was before I got this position. Thank you for attending today.

>>Bill Greer: Thank you, Taryn. And now I'll turn it over to Erin. So Erin, a brief introduction and it's all yours.

>>Erin Czarniak: Thank you, Bill. Hi everyone. I am Erin Czarniak. I'm the Associate Director in the Animal Care and Use Office at the University of Michigan. I oversee the Quality Assurance team. I've been working in animal research for about 15 years, and I previously worked in husbandry and controlled substance compliance. Let's get started with our presentation.

Slide 3: Introduction

So during my early years in research compliance, I became frustrated with the standard training practices. Although at the time I didn't realize that the training was the problem, I felt like I was always fighting to get others in line with regulatory requirements. I tried rewording training, making training shorter, making trainings more in depth, creating what I thought were helpful guides.

I was at a loss. And it was my job to provide the expectations, but how could I make others follow them? And even if I could get them to follow the things I put on paper, how could I create a culture where when a decision that had the potential to affect animal welfare had to be made during the course of research (even if it wasn't a scenario that was written down somewhere), a researcher would know what to do or where to seek help? And they would do the right thing because they understood the implications our program faced when expectations weren't followed?

It wasn't until my work in controlled substance research compliance that I started to see what researchers wanted and what our program needed. Since that time, almost 10 years ago, I have been working with others to

change the way our compliance teams interact with the research community. Today we will specifically look at the changes we made in the Animal Research Compliance Office at U of M and the program we developed to create a culture of compliance, which all stems from how we interact with and develop and relay information to the research community.

With that, let's delve into our U of M quality assurance program and explore how collaborative work with researchers can lead to meaningful improvements in compliance efforts.

Slide 4: Overview

The essence of QA lies in fostering an environment where we focus on the understanding and capacities of our research community to enhance our research programs. This partnership not only elevates our compliance metrics, but also nurtures stronger, more positive relationships between researchers and compliance teams, creating a climate of mutual respect and understanding.

Historically, our compliance programs have heavily relied on post approval monitoring, where we would identify compliance issues and then provide scripted trainings to ensure researchers were in line with our unilateral and often self-imposed expectations. This would often feel like policing to the research community, which would inhibit open communication and erode trust, leading to a less than cooperative atmosphere. With this approach, our compliance units were mainly focused on how to better deliver the existing expectations and ensure they were followed.

In contrast, our QA approach prioritizes a natural educational experience through collaboration by researchers and compliance teams. By working together with researchers and using their insights to develop expectations, we can identify and reduce the administrative burden they face, and as a byproduct, increase compliance. This collaboration allows researchers to concentrate on conducting sound research, which includes proper animal care.

It also ensures researchers have a better understanding of why certain expectations exist and why following them is important for the future research endeavors of everyone at an institution. Essentially by working together in this collaborative manner, we're building a program where compliance is seamlessly woven into the research workflow, benefiting everyone involved and ultimately supporting the advancement of scientific research and increasing compliance.

The QA program at U of M is structured around two key components. Firstly, we conduct QA visits or meetings— not inspections— between a compliance specialist and researcher. Secondly, we offer targeted research- [correction] we offer targeted outreach and training through various means.

Slide 5: What's Next

To better understand the intricacies of our program, each of my colleagues will discuss these components in depth and hopefully provide you with ways you can promote a culture of compliance at your institution.

Ashley will start with some internal practices that support the QA process and should be considered before implementing changes. In other words, things you can learn from our mistakes.

After Ashley my colleagues Mike and Taryn will provide insight on our daily interactions and training programs. For the last portion of our presentation, I will provide an overview and specific examples of changes we experienced and the outcomes we observed after implementing a QA program. We will also have an opportunity at the end to give you our e-mail address so if you have any questions, you can reach out with those.

With that, I will hand you over to Ashley.

Slide 6: General Practices

>>Ashley Duval: Thanks Erin.

Today I'm going to discuss our quality assurance program, hereinafter referred to as the QA program, and the general practices involved in implementing a program like we have. While the setup of each program is going to vary depending on the size and the needs of each institution, I believe the key concepts I will share are essential for a successful program.

There are three key practices I'm going to cover today: 1. Gaining leadership support for change. 2. Conducting an internal review of current office practices. And 3. Making sure that you limit your QA team's involvement in any noncompliance issues. So let's break down these three practices individually. Next slide.

Slide 7: Leadership Support for Change

First, gaining leadership support for change. So how do you go about gaining support from your leadership? The first step you want is to develop a goal or a set of goals that will benefit both researchers and your program. Having a common goal helps reduce resistance to change. Some goals might include maintaining high standards of animal care, reducing burdens, making compliance standards more attainable, and being a resource for the community. Once you have a goal in place that meets your needs, present it to your leadership, which may include the Institutional Official (the IO), the Director, and the IACUC to gain their support.

Be sure to outline the structure needed to achieve this goal. While the structure may vary, it will require IACUC support and trust, leadership that is open-minded and supportive, feedback from the research community, dedicated personnel (i.e. a QA team), and an emphasis on programmatic improvements rather than focusing on researcher compliance. Highlight how establishing a QA program can advance the overall program. And if possible, gather data from other institutions that have successfully implemented similar programs. Next slide.

Slide 8: Internal Review of Office Practices

Internal review of office practices. This is an essential part of the program. If possible, consider rearranging office structures to gain the trust of the research staff. One suggestion is for the QA team to report directly to the Office Director rather than the Compliance Manager or Director to avoid any conflicts of interest. This ensures the community's trust that the QA team is not involved in any noncompliance decisions and may help remove the policing mentality they may have.

We must also review processes for consistency, accuracy, and efficiency. Consistency across the program helps reduce confusion among the research community. You may need to revise policies and guidelines to ensure they use consistent language, only include information relevant to the principal investigators, and minimize any

unnecessary text. It's helpful to have team members sit on committees that review animal care policies, guidelines, and SOPs.

This also allows the QA team to provide input in improving clarity, especially when trends emerge during QA visits. These team members can also act as liaisons to address concerns from the research community. Next slide.

Slide 9: Identify Regulatory Burden

When conducting routine QA visits, be sure the research staff understands the expectations outlined in documents that are directly relevant to their research. For example, if researchers conduct tumor studies, ensure they clearly understand your tumor policy and the specific expectations for such research. It's important to communicate and be a mentor for these expectations directly, and assuming that researchers understand them without discussion can often lead to misunderstandings.

During your review process, ensure that you're not only promoting consistency, accuracy, and efficiency, but also identifying any regulatory burden. Ask the research community for feedback on obstacles that hinder sound research. Are the compliance standards attainable while maintaining proper animal welfare at your institution? PIs want to be in compliance but are sometimes disengaged from the development of animal care and use programs, later leading to problems within the community who perform the research on a daily basis.

Additionally, ask for input on whether your current process and documents are easy to identify, navigate, and follow. For example, do the documents allow the research staff to perform their research without exceeding regulatory requirements, which could add unnecessary burden? Consider whether there are too many documents to maintain and whether any can be eliminated.

A risk-benefit evaluation of current practices can also help reduce burden on researchers. For example, if a specific form for tumor monitoring exceeds regulatory expectations, it adds unnecessary burden. If clear expectations for tumor monitoring are already outlined in the protocol, there may be no need for additional paper forms.

Programmatic improvements will arise from these early findings, leading not only to enhancements in the program, but also shaping the future direction of the QA program. Examples of programmatic evaluations include assessment of regulatory process (start to finish), evaluation of the quality and consistency of IACUC reviews, and assessing the regulatory burden on research staff. Next slide.

Slide 10: Limiting QA Involvement in Non-Compliance

The third part is limiting QA involvement in any noncompliance issues. Instead of being seen as policing researchers, the QA team should focus on providing support and acting as a mentor for them. This is the practice that will build the most trust and foster collaboration within the research community. To achieve this, ensure that someone in your office is dedicated in handling all noncompliance issues, i.e. a direct noncompliance manager, director etc. This will create clarity about who handles noncompliance concerns, freeing up the QA team to provide support when a crisis arises.

It's important to transition the mindset of researchers from seeing QA as an audit to [seeing it] it as an opportunity for constructive discussion. If your QA team is involved in non-compliance issues, it's difficult to gain

the researchers' trust. During the visits, be upfront with the PIs and lab staff about any potential issues that you find during the meeting. Make it clear that you do everything possible to avoid any noncompliance during the visits, but you cannot guarantee a noncompliance will never occur. Ultimately, the IACUC makes the final decision.

If issues are found, assess the situation based on the potential impact on animal welfare and whether the issue is individual or programmatic. If the issue is individual, take the opportunity to mentor the lab. Give them an education or training to provide improvement on the issue that you found and perhaps reduce the chance of reoccurrence. If programmatic issues arise, evaluate what you can do as a program to reduce the chance of reoccurrence also.

When labs face a crisis, the QA team should step in to offer additional support. Immerse the team into the environment of the lab by attending lab meetings, providing targeted improvements that will help avoid any future concerns. Offer training and guidance to help reduce repeat occurrences of any noncompliance. The goal is to build confidence and compliance, reassuring the research staff that the QA team is an advocate for them.

Some issues found during QA visits may arise from overly detailed or restrictive language in protocols. For example, specifying exact suture sizes or needle types, names, and sizes, increases the chance of noncompliance. Consider aligning protocols with more flexible language that will still maintain regulatory requirements.

When such issues arise, the QA team can assist the PI in amending their protocols, taking a customer service approach to help them improve their practices while meeting institutional expectations. We want the researchers to receive solutions directly targeted towards their primary needs and concerns and not receive the feeling of them just being another meeting with the QA team.

Communications between the QA team and the PIs and the IACUC is essential. The QA team plays an essential role in facilitating communication between PIs [and] IACUC members. For instance, when there's a miscommunication during an IACUC review, the process can go back and forth, frustrating both parties. The QA team can set up-- step in to clarify expectations and ensure the PI responds appropriately, aligning their responses with the lab's practices and satisfying the IACUC's review concerns.

Additionally, evaluate the amount of frequency of communications between the Animal Care Office and research community. Are you sending too much or too little? Ask yourself. Ask the research community for feedback on the amount of communication they receive and adjust accordingly to meet the needs of your institution.

In conclusion, it's clear that the word "burden" plays a significant role in this presentation. Reducing burden on the research community frees up their time to focus on conducting sound research, prioritizing animal welfare, and fostering a collaborative relationship within the animal care program. Shifting the researcher's mindset from being policed and recognizing that we are working together to solve the problems will lead to a stronger and more productive program.

Now that I've covered the basics to begin a QA program, I want to thank you all for listening and I will now hand it over to Mike to cover more details of the QA role. Mike

Slide 11: Be Visible, QA Visits

Thank you, Ashley. As mentioned, my name is Mike. I've been a -- I'm a Quality Assurance Specialist Senior here at the University and have been in the Animal Care and Use world for over 20 years. For the next few minutes, I am going to discuss being visible. Our entire team takes pride in providing great customer service to our PIs and lab staff through QA visits, lab walkthroughs, and communication.

Since the QA program was established here, we have had -- we have made a major culture shift between the Animal Care and Use Office and the animal research community. At one point, when anyone from our office associated with compliance showed up in a lab space, we were not exactly welcomed with open arms. We have made it a point to change that culture and it is not something that we that we have changed overnight. Some of the things that played a big role in impacting that culture shift are as follows.

QA visits. QA visits are something that we schedule with PI's (Principal Investigators) and lab staff on a yearly basis. One of the main goals of the visit is building a relationship with them. In our visits, we cover many topics and keep everything positive to foster that collaborative mindset. We use these visits to discuss our plans to change the culture and practices. The keys to being able to buy, or the key to being able to get buy in from the labs, is to be open about the plans that we have to make positive programmatic changes. Having a plan to promote these changes, listening to the PI and labs through their thoughts and views on these proposed changes, and then continuing to discuss the progress at each follow up visit.

Another component to our visits is helping labs with any struggles they are facing within the research program. As part of our visits, we engage with labs to understand the challenges that they are facing, collecting valuable feedback on the issues that matter most to them. These discussions often cover a wide range of topics, from PI burden and confusion around policy changes, new training requirements, or even matters related to veterinarians or husbandry. We make sure to listen carefully to all concerns and, if necessary, we follow up to ensure that solutions are found. Even if the issue is outside of the scope of our office's direct responsibilities, we act as a liaison, connecting the PIs with the relevant department to provide the necessary support.

During our visit, we gather data related to the animal research protocols and look for trends that could impact future changes in practice. We discuss their research and what projects are most active. We discuss how they are doing procedures. We do not sit there with a checklist to ensure compliance. A key note to remember is that the program is built on trust. We trust the researchers will do what they need to do in order to be compliant. We discuss future research so we can assist with changes that they may need for that future research.

A big part to reviewing the protocol with them is education. When discussing the protocol with them, we discuss where we can have flexibility in the protocol and go over those options. We discuss common programmatic findings and educate on what steps can be taken to prevent it becoming an issue for their lab. We also discuss their lab practices and training. We make suggestions and we will offer education as a service from our group if we think it will be beneficial for the lab.

We also conduct what we call “new PI visits.” These are for new researchers joining the institution, or they could be an existing person here but now moving on to have their own research protocols. During these visits, we help them through the laborsome process of starting up a protocol, along with possibly moving the entire lab to the - or possibly moving an entire lab to the institution or starting up a brand-new lab. We attempt to take as much burden off of them and make the transition as smooth as possible. This gives us the opportunity to start a

collaborative relationship with them right from the beginning. This is a crucial part to making the culture change that has happened here since the start of the QA program and ensuring it is sustained and not short-lived.

Slide 12: Be Visible, Lab Walkthroughs

Lab walkthroughs are another key thing outside of our QA visits that play a major role in the culture change and further developing those relationships. Our team makes a point to go out and walk through all our buildings and just walk through labs unscheduled. When we do our lab walkthroughs, we just show up and be seen.

I think a key thing to these walkthroughs is there is no obligation for the lab to stop what they're doing to talk with us. If we see they are busy or in the middle of an experiment, we keep it as simple as saying “Hi” and letting them know we are available to help if they need it.

We use these walkthroughs to deliver swag. Swag can be anything from a poster for program pride or new stickers for labeling. Or maybe new literature advertising upcoming changes or events. We have found these to be very beneficial in getting to see different lab members we may not get to meet in a normal QA visit.

It is not uncommon for us to talk to labs and end up helping with protocol changes or answering questions. As these have become a normal part of our program, we are typically feeling very welcome when we walk into a lab. We have been so welcomed that it has become more common that our drop in to say hello turns into a 30 to 45 minute meeting helping the lab.

During our walkthrough for lab support, even though it does not happen often, we may stumble across someone doing something that may not meet the standards. In those cases, we will address it and report it. We have a staff member in our office who handles noncompliance, which is who we would turn -- who we would turn it over to. She will guide them through the noncompliance process. Our team is often used as a PI advocate for the investigator facing noncompliance. We can do training, lab presentations, or even extra check-ins with the lab. This process has proven to be very successful. And some of our strongest relationships with certain labs are with those that we worked with in an advocate role.

One of the most important aspects of being visible to researchers is offering services - Next slide, Erin -

Slide 13: Be Visible, Other Services

- is offering services that directly benefit their teams and promoting effective communication. We provide a range of services and try to be as accessible as possible to the researchers. For instance, we offer presentations to labs and groups on the basics of compliance, highlighting its importance and explaining how noncompliance can negatively impact the entire institution. We also assist with protocol and amendment writing as well as pre-reviewing submissions to ensure flexibility and avoid potential compliance pitfalls. Additionally, we conduct lab reviews upon request, helping ensure labs are inspection ready.

We also support lab managers and implementing new practices that promote compliance. A common issue is inadequate mass communication, so we make sure it is effectively delivered, whether through visits or walkthroughs.

Another valuable tool is our Lunch and Learns. This is where we invite speakers from different program areas to discuss common compliance issues, strategies for avoidance, and other best practices in lab management.

As a QA team, we also offer virtual office hours, for instant support. We hold office hours during normal business hours, eight to five, which are manned by the entire team all day. If a lab needs assistance with protocol writing, has questions about any of our policies or processes, we can easily be reached for support.

We also have a QA team e-mail that is used to send messages to all team members. If a lab is working with a certain QA member but that person is unavailable, this is a way to assure that someone is always available.

I would like to thank you for your time and listening. I will now turn it over to Taryn who will be discussing a program that we have here that helps foster all these things that I just discussed as well.

Slide 14: Creating a Community through Training

>>Taryn Hetrick: Thank you, Mike. Hello, everyone again. My name is Taryn. I will be sharing two initiatives we've implemented at our institution to strengthen the relationship between our Animal Care and Use Program and our research community.

The LARCC program is a unique opportunity for our community to enhance their expertise in animal research practices and join a community of professionals who care about making a difference. We recognize that effective, ethical, and impactful animal research requires continuous learning and collaboration across departments. The LARCC program is designed to create just that.

LARCC, short for Laboratory Animal Research Coordinator Certification, is an optional 10-week training program that brings together researchers, animal care staff, veterinarians, the Quality Assurance team, and many other key players within the Animal Care and Use Program. Whether new to animal research or a seasoned scientist, LARCC offers the tools and connections to become an expert in animal care and research practices.

Each week of the program covers a new topic, such as husbandry and veterinary care, environmental health and public safety, training, regulations and compliance, protocol writing, and the history of animal research. LARCC is structured to keep participants engaged and connected with peers. In each weekly session, students interact with leaders from different areas of animal research and provide opportunities to ask questions, participate in hands-on activities, and share insights.

Our Quality Assurance team is present in every session, building a rapport with participants and facilitating activities. I'd like to take a moment to outline some activities here.

1. Searching relevant documents on our website: Students start by reviewing the topics listed on a worksheet. Each topic focuses on a unique subject that requires locating specific details. For each topic, students determine which documents are most likely to contain needed information. As part of the activity, we have a class discussion about the keywords students used in their research in their search process.

Reviewing our electronic Animal Research Management System: This activity engages students in exploring our electronic management system, helping them to discover new functions they may not have encountered while reinforcing their existing knowledge. Through presented scenarios, we collaboratively navigate the system to conduct searches or perform specific functions.

Discussing how IACUC might address non-compliance: This is my favorite activity. It's [an] interactive activity that helps students understand the deliberation process of the Institutional Animal Care and Use Committee (IACUC)

by engaging them and analyzing past cases of noncompliance. Students are presented with real examples of noncompliance issues from the past. Each case includes detailed descriptions of the situation, the regulations or guidelines involved, and the context of the noncompliance. Students act as members of the IACUC. They analyze the cases, consider the facts, and discuss possible outcomes, then decide on appropriate actions. After students present their decisions, the class discusses the actual outcomes that were decided by the real IACUC. The discussion focuses on the reasoning behind the real decisions, including factors such as compliance requirements, ethical considerations, and institutional policies. Students gain a better understanding of the complexities and responsibilities of IACUC decision making, as well as the importance of ethical and regulatory compliance in research.

Finally: Identifying common challenges and solutions in animal research labs. This activity, which is led by a principal investigator who is also a member of the IACUC, helps students explore real-world challenges commonly encountered in research laboratories and understand practical approaches to resolving them. The PI presents scenarios based on typical challenges faced in research labs. Each scenario includes relevant context, potential impacts, and key considerations. Students work in groups to analyze each scenario and brainstorm potential solutions. The PI guides the discussion, encouraging critical thinking and helping students explore different perspectives. They share insights from their own experience and explain how challenges like these are typically addressed in professional research settings.

At the heart of LARCC is the idea of building a community. Graduates of the program become key resources in their labs, contributing to the continuous improvement of research practices and acting as eyes and ears for the QA team. Together we can identify common lab issues, promote training where it's needed, and help improve animal research practices across the board.

Upon completion of the program, we invite key leadership from across the institution, like the Institutional Official and departmental heads, to celebrate student success. We hold a graduation ceremony where students receive a certificate and a commemorative pin as a symbol of their dedication to advancing animal research practices. As a LARCC graduate, students become part of a supportive network of researchers and professionals. After completing the program, they are kept engaged through regular touchpoints like program updates and lab issue discussions and have opportunities to reconnect through alumni reunions and networking events. Many of our graduates also go on to collaborate scientifically. LARCC graduates are also encouraged to become part of the Faculty Advocacy Committee, or ACU-FAC, a key group dedicated to improving the animal research program at the institutional level. And you can go to the next slide.

Slide 15: Faculty Advocacy

ACU-FAC members, made-up of faculty and LARCC graduates, work directly with the IO, the IACUC, and other key leadership to address concerns, promote understanding of program expectations, and identify areas for improvement. ACU-FAC plays an instrumental role in advocating for realistic and manageable program expectations, identifying and addressing barriers to compliance, clarifying confusing policies, and implementing solutions for common issues. Their goal? To make the research environment more streamlined, supportive, and effective for everyone involved.

I'd like to highlight specific examples of how this process has been successfully implemented.

Addressing non-compliance with expired substances: We identified a recurring issue where animals were being administered expired substances. After engaging in discussions with LARCC graduates and the ACU-FAC, we

realized that our existing policies and guidance on this topic were unclear and likely contributing to the confusion. Together, we overhauled the relevant documentation and improved outreach on the subject. As a result, reports of this type of noncompliance have almost entirely ceased.

Standardizing tumor burden endpoints: Cancer research involving tumor growth in rodents has been a long-standing experimental focus at our institution. Recognizing that tumor endpoints can vary based on the research, we collaborated with LARCC graduates and the ACU-FAC to develop standardized tumor burden endpoints and clear monitoring expectations. This initiative has provided consistency and clarity for researchers, enhancing IACUC policy review. During the triennial review of our IACUC policies, we actively involved the ACU-FAC to gain valuable input from research community experts. This collaborative approach has proven to be instrumental in identifying unclear language and addressing unrealistic expectations, ensuring our policies remain practical and effective.

In conclusion, both the LARCC program and the ACU-FAC committee are about empowering researchers, fostering collaboration, and continuously improving animal research practices. By working together, we'll create a research environment that is compliant, supportive, and driven by a community of experts.

Now I will turn it back over to Erin for our wrap up and thank you for joining us.

Slide 16: Process Change- Previous Expectations

>>Erin Czarniak: Thanks, Taryn. For the last portion of our presentation, I want to give some examples of processes and expectations we changed and look at the step-by-step process we went through to make this happen in a way that created a culture shift. I will also discuss some tangible and intangible changes that we continue to observe as our program develops.

We don't have enough time to delve into every process and expectation we changed, but I want to look in depth at one example that truly illustrates the benefits of collaborating with our researchers to develop expectations. My other colleagues briefly touched on this example. We love to use it not only because it was a big win for our program, but because the entire process we went through to create the change is an ideal illustration of how we feel expectations should be developed and implemented to ensure they are understood and followed by the research community.

So let's start at the beginning with our prior expectations related to tumor monitoring.

In our previous processes, any lab conducting tumor experiments on rodents was expected to: First, flag each cage with tumor bearing animals. Second, maintain a paper log in the animal room corresponding to each flagged cage. And third, document each time they examined the tumor-bearing animals on the paper log, ensuring that the monitoring frequency matched the protocol.

Slide 17: Process Change- Not Following Expectations

When this process wasn't followed, our compliance team would often send an e-mail letting the researchers know they weren't following our expectations, point them to our guideline, and remind them that failure to follow expectations could result in sanctions from the IACUC. Or for repeat offenders, we would often just refer them directly to the IACUC. We might also provide additional training, which was essentially an in-person reiteration of our expectations, or insist on repeat online training, especially if the issue persisted. We would also

develop new ways to relay the same expectation. We even created a handheld guide for measuring tumors, thinking this visual would ensure expectations were met. We spend a lot of time dressing up the same information, hoping that it would finally stick.

This all resulted in a lot of complaints from researchers during QA visits. This included, but trust me was not limited to, having to duplicate records(since they already kept their own electronic logs), an increase in emails related to incomplete paper logs even though their animals were fine (they were following their protocol and they already had their own electronic logs), having to follow time consuming processes that didn't have a clear benefit, and increased training requirements that added another level of burden.

Slide 18: Process Change- How do we fix this?

After noticing a trend with these complaints, we had extensive discussions with husbandry staff, veterinarians, compliance groups, and researchers. Each group had put forth complaints about the process, but they were all focusing on unmet expectations rather than addressing the root problem. However, conversations with researchers working with tumor models provided data showing that most rodents could be removed from a study when a specific humane endpoint was reached without compromising the collection of necessary scientific data.

We brought this feedback to our faculty advocacy group and with their input and the input of their colleagues, we were able to make recommendations to the IACUC and implement several significant changes. The discussions we had with the faculty group is really where the magic happened. Our committee was already formed, but we brought in researchers using tumor models to discuss their needs, and we had veterinary and compliance staff discuss concerns and explain regulatory expectations. We stopped focusing on how to implement the current expectations and started looking at our most basic needs related to care surrounding tumor-bearing animals.

Slide 19: Process Change- IACUC Approved

After much discussion, we brought our suggestions to the IACUC and we were able to retire our burdensome guidelines and develop a new, simpler policy that established standard humane endpoints for tumor-bearing rodents that meet the needs of most of our researchers, required scientific justification in the protocol for any deviations from the policy (and this only affects a small amount of researchers), and included the rationale for adhering to humane endpoints. The policy also removed the log in-room requirement, significantly reducing the researchers' burden.

Records were still maintained by researchers, but could be done in a way that fit their regular workflow. The changes we implemented led to several positive outcomes, including decreased burden related to monitoring records for researchers, husbandry staff, and veterinary technicians, and a reduction in compliance staff's workload with no need to develop or reiterate trainings and fewer noncompliance reports to investigate. The changes did not diminish animal welfare, and it was a process understood and accepted by the research community, which led to better compliance.

In summary, we used researcher feedback to develop expectations. The expectation was more easily understood by researchers and was easily incorporated into their work while maintaining our standard of care. This meant better compliance with the expectation, which in turn lessened our need to continually reiterate the expectation.

Slide 20: Importance of Preliminary Work

This is a good time to highlight the importance of appropriately setting up your program prior to making researchers aware of your intent to improve your program with their feedback.

Ashley discussed this at the beginning of our presentation, but let's look at the example I just gave and what could have happened if we didn't do the preliminary work before engaging the research community. Our compliance office loved the idea of using researcher feedback to develop expectations. They knew that by identifying the expectations researchers find burdensome, and rewriting those expectations, after collaboration between: 1. The research compliance community (who can explain the regulation we are trying to satisfy), 2. The researchers (who can share insight and brainstorm ideas for meeting these needs in a way that limits burden in the lab), and 3. The veterinary and husbandry staff (who can ensure animal welfare remains a priority), we could make major progress in our quest for a cultural shift. If our compliance office had collected all this feedback on the tumor monitoring process and pulled together a group of scientists who felt that this was too burdensome and should be changed, but we hadn’t engaged our husbandry and vet staff, and then we found out they weren't interested in change until after the fact, we would have wasted a lot of researcher time and probably done more harm than good.

Don't get me wrong, you won't be able to change every burdensome process in a program. I mean, most researchers think protocol writing is extremely burdensome, but this is an industry standard, and it's needed to fill a regulatory expectation. But if you promise change and then have whole sections of a program that are unwilling to seriously consider modification, the research community will not be pleased.

You may also want to consider identifying some low-hanging fruit to get your program started. Having a few wins to show off is a great way to secure more buy-in from the research community. It will make them realize you are listening and taking action. This is also one reason why we suggest QA teams report to the Office Director. If your office is structured in a way where there are multiple reporting lines, you could meet roadblocks to change in your own office.

The most difficult challenges we faced when implementing the new policy tumor policy actually came from within our office, and had our director not been completely on board, we probably would not be discussing this example today.

You may not think this will be a problem for you, but we all know change is difficult. And even with the knowledge we have gained, my staff has still routinely met with people who are territorial over certain processes and aren't willing to even consider changing. In fact, we recently made a very large overhaul to our semiannual inspection process, and we met a lot of resistance. After many discussions, we got everyone to agree on a trial run and it was a huge success. The groups who resisted were some of the first to praise the changes. We definitely needed leadership backing to push this forward.

Slide 21: Outcomes at U-M

Now let's look at the effects that all of these changes have had on our program.

Firstly, we observed several tangible changes. Most notably, there's been a significant reduction in protocol and policy noncompliance. We kept data for each of our QA visits so we could easily track compliance with our

expectations, not just [non]compliance that resulted in IACUC sanctions. We also observed that when noncompliance did occur, it was often discovered by the researchers themselves.

Although overall noncompliance was down, the issues that were coming to the IACUC were often discovered and self-reported by the labs themselves before we could identify an issue during a QA visit. We took this to mean that our researchers were paying more attention and understood our expectations. Mistakes are always going to happen, but our researchers understanding when a mistake is made and ensuring it was addressed appropriately feels like a huge win.

We also identified several intangible changes to our program. These for us are the biggest wins.

When scheduling QA visits, our PIs have over time become more willing and are sometimes even eager to schedule the visit. They express fewer complaints during the QA visit, often comment on positive changes made in our program and seem to have more faith in our ability and willingness to assist with solving any concerns they have. We do actually have some data that shows fewer complaints, but it's a hard metric to consistently track. Even behind QA visits, researchers seem more open to communicating with us. We have experienced an increase in calls, emails, and requests for guidance. They also seem more open with their questions and demonstrate less fear when seeking guidance.

Lastly, we are often met with what feels like a better and more positive reaction when walking into labs for semiannual inspections and unannounced walkthroughs. Labs are more likely to smile and not groan when we walk through the door.

Slide 22: Conclusion

We're coming to the end of our time, so I want to wrap up by reiterating that focusing on teaching by seeking to understand and collaborating to develop expectations has led to significant tangible improvements in our compliance metrics as well as fostering a more positive and cooperative culture. This approach not only enhances compliance, but also supports the overall advancement of our research initiatives.

With that, we hope to continue working together to build a robust and positive compliance culture.

Thank you for your attention today and please reach out to us at any time. Our e-mail address is on the screen. It will go to our team and one of us will respond. We love discussing our program and brainstorming with others on ways to improve, so we hope to hear from you.

End of slides