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The Research Animal Coordinator: A Tool to Foster a Culture of Compliance

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Slide 1 (The Research Animal Coordinator: A Tool to Foster a Culture of Compliance)
>>*Babcock:* Hello, today is September 18, 2014. Welcome to the OLAW Online Webinar, **The Research Animal Coordinator: A Tool to Foster a Culture of Compliance**. The 8th Edition of the *Guide for the Care and Use of Laboratory Animals*, on page 33 says, "Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance." Today several of your colleagues will share their institution's methods of researcher training and conducting post approval monitoring of animal activities. It is now my pleasure to introduce our speakers.

Dr. Ron Banks has served as the Director of the Office of Animal Welfare Assurance at Duke University and Duke University Medical Center since 2004. He is a graduate of Auburn University, College of Veterinary Medicine. Dr. Banks has over 29 years of biomedical program experience, first in the US Army and then at state

and private academic research institutions. He is Board Certified with the American College of Animal Welfare, the American College of Veterinary Preventive Medicine, and the American College of Laboratory Animal Medicine. He is a Fellow of the National Academies of Practice, and a Certified Professional IACUC Administrator (CPIA). At Duke, the Office of Animal Welfare Assurance (OAWA) provides IACUC administrative support, performs compliance monitoring and investigator training, and assists researchers with protocol preview. With over 30 publications and many more scientific and professional seminars and presentations on his *CV*, Dr. Banks brings a career of experience and dedication to humane animal care and use, especially as it relates to today's topic of tools to extend the concepts of programmatic compliance and welfare to the bench-top.

Tracy M. Heenan, DVM, is the Director of the Office of Animal Care and Use and Associate Professor in the Department of Pathology at the University of North Carolina at Chapel Hill, North Carolina. Prior to entering the laboratory animal science field, Dr. Heenan was a small animal practitioner for 4 years. Dr. Heenan earned her veterinary medical degree from North Carolina State University and has extensive experience in Institutional Animal Care and Use Committee function. She is a Certified Professional IACUC Administrator and currently serves on the Council for the CPIA. Dr. Heenan also serves as an ad hoc Consultant for AAALAC International.

Emily Hearne, MS, is the Training and Compliance Manager for the Office of Animal Care and Use at the University of North Carolina at Chapel Hill. Emily earned her undergraduate degree in Poultry Science from North Carolina State University where she continued on to complete her Master of Science in the Department of Animal Science. Throughout her career she has held a wide range of animal care and management jobs with many different species, in both academic settings and the pharmaceutical industry. At UNC, she manages the Training and Compliance Team, which is responsible for coordinating all IACUC inspections, providing training, protocol pre-review, and animal welfare reporting.

Susan Silk, the Director of the Division of Policy and Education at the NIH Office of Laboratory Animal Welfare, will also be joining us today. Susan.

>>*Silk:* Hello everyone. The *Guide* says, on page 34, that the level of formality and intensity of post approval monitoring or PAM should be tailored to institutional size and complexity, and in all cases should support a culture of care focusing on the animals' well-being.

Ron, Tracy, and Emily will describe the methods used at their universities to include their research community in their animal care and use training and PAM programs.

OLAW is pleased to present this information as one of many best practices. Your institution is NOT required to have a similar program. Institutions are free to determine the best methods of continuing assessment of animal activities. I encourage you to listen to this webinar with an open mind. Look for ideas that may be relevant or helpful to your program. You may determine to use a similar program at your institution, or to use selected portions or ideas from these programs, or you may determine that continuing monitoring at your institution is best conducted by an entirely different method. Back to you, George.

>>*Babcock:* UNC folks, why have you developed the specialized program you are going to present to us today?

Slide 2 (UNC-CH Statistics in 2002)
>>*Heenan:* Hello, this is Tracy, I'll answer this first question about UNC. Prior to 2002, UNC-Chapel Hill offered voluntary rodent hands-on training to researchers. In 2002, we decided to institute a campus-wide, mandatory hands-on training program for our researchers working with rodents. We wanted to provide useful and consistent training to a substantial number of animal handlers. UNC is a large, decentralized institution and about 90% of our research animals consist of mice and rats. In 2002, when we started assessing our needs, we had approximately 350 investigators and a total of 1,400 researchers working with animals, mostly mice and rats. There were approximately 100 investigator laboratories where animal work was conducted and which required semiannual IACUC inspections.

Slide 3 (IACUC FTE Personnel Support Statistics in 2002)
We wanted to institute our training program as efficiently and quickly as possible, but we knew it would be a big challenge to train all of these individuals at once. Our Office of Animal Care and Use at that time included 8 staff positions and only 2 of those positions were Training and Compliance Coordinators, the folks who conducted our hands-on training.

Slide 4 (Desirable Qualities in an Animal Handler Training Program)
Our goal was to provide our researchers with manageable, consistent, reliable rodent-based training in the common handling techniques and basic procedures such as injections, blood withdrawal, euthanasia, and aseptic surgical technique. We considered the assets we had to work with to meet this challenge. We only had 2 Training Coordinators but we had a wealth of talented and trained researchers in our 350 investigator laboratories. We wondered how we could utilize this knowledge base to spread and share the training burden.

Slide 5 (UNC Laboratory Animal Coordinator Certification Program)
So, in 2002 we developed and implemented the Laboratory Animal Coordinator Certification Program to help relieve some of the training burden on the Office of Animal Care and Use and to utilize this valuable researcher resource to provide uniform and consistent training to personnel working with lab rodents.

Slide 6 (What is a Laboratory Animal Coordinator?)
The Laboratory Animal Coordinator or LAC is a trained and certified member of the research team responsible for coordinating animal activities in the laboratory, training lab members in proper animal handling, communicating animal welfare rules and regulations, and serving as a liaison between the laboratory, the IACUC, and animal support services.

Slide 7 (Initial Steps)
The UNC LAC program is based on the premise that every Principal Investigator with an active animal use application appoints a qualified and active member of the laboratory who, once fully trained and certified, can then train and certify other members of the laboratory. The Principal Investigator can serve as the LAC. However, the LAC is typically a research technician or other permanent member of the laboratory.

Slide 8 (IACUC Ambassador)
As the LAC program developed, we realized that, in addition to training, the LACs also operate as IACUC ambassadors, helping to teach the research community about IACUC and animal care policies, practices, and procedures. Similarly, LACs serve as the laboratory point-person for communicating with the IACUC, participating in semiannual laboratory inspections and procedural observations, and assisting the IACUC in gathering details regarding animal welfare or noncompliance issues. Further, the LACs network with each other to share resources, extra animals, and best practices. In essence, the LAC serves as the liaison between the laboratory and the IACUC, providing hands-on training and disseminating IACUC policies, guidelines, and best practices to members of the laboratory and the UNC research community. It is perhaps these last two outcomes of the LAC program which have resulted in the most benefits to the institution and its animal researchers.

Slide 9 (Numbers)
Since the formal initiation of the LAC Certification Program in 2002, the UNC Office of Animal Care and Use has trained and certified a total of 1,262 LACs. During the 12 years the program has been in effect, 13,171 individuals have been trained and certified with 40% of these being trained by LACs. So, although the numbers of researchers trained by the Office [of Animal Care and Use] outnumber those trained

by LACs, the 40% reduction represents a significant training relief to the Office. Initially, in order to get the entire campus trained and certified, we were training between 250 and 330 LACs a year. In recent years, however, we've leveled out to an average of 86 LACs trained annually. As an example of an average current year, in 2012, a year in which we collected data for a PRIM&R presentation, LACs trained 474 students and the Office trained 624. This represents approximately 43% of training performed by LACs.

At UNC all researchers must be trained and certified in the basic handling techniques before working unsupervised with animals. If an application indicates a researcher as an animal handler, that individual must be certified in all associated techniques before the application can be approved. This certification may be done by the LAC or the investigator may choose to have the individual attend one of the classes offered by the Office of Animal Care and Use. Certified techniques are maintained on the IACUC online training database which communicates directly with the online application.

Slide 10 (Duke University and Duke University Medical Center)
>>*Babcock:* Ron, I'll ask you the same question. Would you describe your program and explain why Duke developed the specialized PAM program that you use?

>>*Banks:* George, the Duke program is not all that dissimilar from our UNC colleagues, or any other research program for that matter. We have several animal facilities, numerous species of animals, and quite a few personnel working with those animals. We, like many, receive federal and nonfederal funding for research, are PHS-Assured, USDA-registered, and AAALAC-accredited. Our species distribution includes aquatic, terrestrial, and airborne animals.

Slide 11 (Who Are We?)
What is most significant about our program is our belief that we are not unique. While larger than some institutions and smaller than other institutions, we have the same rules and regulations, the same challenges of program oversight, the same need to educate, the same desires to communicate, and the same corrective expectations when bad things happen to good people or to good animals. In other words, we're just like the institutions represented on today's webinar attendee list. We want to do the best we can for our animals, our researchers, and our institution.

Slide 12 (Progress?)
Our journey began in 2004 at a time when our researchers were frustrated, the IACUC was overburdened, and the administration decided something needed to change, as long as change meant progress and not just doing the same things in a

different way. The IACUC began the discussion with the question, what do we want our program to look like in 10 years? And after a period of reflection certain characteristics of our desired program emerged. These same characteristics served as the basis for our strategic plan and our ultimate course selection. And we've used the strategy as a beacon to keep us on course and our characteristics as milestones to use as metrics [by which we have charted] our progress. What was our ultimate goal? To develop a mature and dynamic *Culture of Compliance*.

Slide 13 (Culture of Compliance or New Strategy?)
George, we think this is a critical point. Why choose culture over strategy? Of all things, why should an animal program focus on culture? Well, at Duke we had seen several strategies come and go for program improvement, and each time the strategy was effective only as long as it was being enforced. We determined that culture was not what we wanted people to do but what we wanted people to become. We wanted colleagues to recognize that the animal care committee, veterinary staff, and oversight personnel were research partners rather than animal police. We wanted a culture where the first decision was always compliant animal use and the right decision was also always animal welfare centric. That [meant cultural decisions] would be the right research decision and it would be simply the right thing to do. We realized that a culture would take time to develop but if we had the patience and [continued focusing effort] in the right direction, why couldn't we build a culture? Bottom line, we believed "culture would beat strategy every single time."

Slide 14 (Duke's Culture of Compliance)
The IACUC concluded there would be 3 important characteristics of our culture of compliance:

- The first of which being a running monthly average of greater than 90% compliant audits. The running monthly average meant we tracked progress over the last 6 months, each month adding the current and dropping the oldest month. This process balanced individual monthly ups and downs due to the number of audits being performed, species differences with findings, and other aspects of the auditing process. We chose 90% because we just didn't believe 100% compliance was a realistic goal. After all, neither animals or people are ever 100%. We are talking about humans and biologic systems which sometimes don't respond like the books say they will. By the same token, 60, 70 or 80% compliance was viewed as not reflective of a quality program and too low of a standard for a culture of compliance. So, we settled at 90% as being an achievable standard to aspire to and an appropriate indicator of cultural performance.
- The second cultural characteristic was a research community which would self-identify, self-correct, and self-report unanticipated outcomes or adverse

events to the IACUC and do so in a timely manner. We're all aware of the self-management strategy expectations from the federal agencies to the institution, and we decided to extend that same expectation of self-management from the institution to the researcher and the laboratory.

- The third cultural characteristic was no significant animal welfare noncompliant items, which might be interpreted as a few to no OLAW-required reports. Why? If we're communicating well, training properly, monitoring effectively, and exercising our research partnership, issues, when they occurred, would be captured at a more minor level, would have lesser of an impact upon animals and research outcomes. We saw this as a practical outcome of making the right choices.

The overall plan and process for our journey to the culture of compliance was ultimately approved by the IACUC and the institutional official and with that clear programmatic direction, we set sail on a new programmatic course.

>>*Babcock:* Ron, was it smooth sailing at Duke for the animal program?

Slide 15 (Changing a Program)
>>*Banks:* Well, George, we set the rudder to establish a new direction for the animal program and we expected the ship to turn, but instead we waited – and we waited – and we waited a bit more. We discovered that the Duke program was much like a supertanker on the open seas and we learned it takes a long time to turn a supertanker. During the anxious early days, we were filled with anticipation but also discouragement. The promise was great, but it wasn't happening very fast. It would have been very easy to terminate the plan because there were few indications early on that things were going to work. But with persistence, patience, a firm hand on the programmatic rudder, and the confidence of the IACUC leadership that the program had made the right course correction, we stayed on course and, indeed, things did start to slowly change.

Slide 16 (Changing Duke's Animal Care and Use Program)
Late 2004 was a bit discouraging, but in early 2005 we started seeing improvement. Some of the noncompliance numbers started to fall, some of the protocols started to look a little better, but we were not getting any self-reports. Late in 2005 things improved significantly – far fewer NCIs, far less significant NCIs, much better protocols, and our first self-report. We started feeling pretty good about our efforts.

Slide 17 (What Drove Us onto a Sandbar?)
Then in 2006 it appeared our program had hit a sandbar. Our progress slowed. We had made changes, we had seen progress but we were just not getting to where we

thought we needed to be. In other words, we were going nowhere fast. PIs were pleased with the new review and processing efficiency but they were starting to get frustrated with the continuing changes and the slow progress [of change]. They wanted to prevent rather than report NCIs.

The IACUC was happy to see better protocols, mostly attributable to the robust pre-review process that had been started, but the IACUC started to get impatient as well. While many PIs were writing better protocols, there were still many protocols which were not any better. The Office of Animal Welfare Assurance staff, especially the Director, was exhausted. We were trying to be everywhere, help everyone, and solve every problem. We just didn't have any more capability. We were max'd out on capacity. So it was time to reassess.

Slide 18 (Options?)
We realized the institutions' resources of 2004 to build the Office of Animal Welfare Assurance were just that, and there would not be additional resources coming or new personnel to solve the current sandbar problem. We also knew we would have to find a solution or we ran the risk of serious programmatic stagnation.

We considered the notion that maybe we had done enough – after all, things were not as bad as they used to be. The program had changed a lot in 2 years. Maybe we had just set our goals too high? Maybe we were good enough?

Slide 19 (The Key)
But, the IACUC concluded that it was not enough, to be good enough. We had set our sights on building a culture of compliance, and it was going to take more than good enough to get there. We would need to use existing resources more effectively. We would need to *work smarter, not harder*. That phrase – "work smarter, not harder" – became an Office [of Animal Welfare Assurance] slogan in the months ahead.

I started looking outside for solutions to our dilemmas. I talked with colleagues around the country, including the folks over at UNC. We ultimately decided that we would leverage our existing skills and resources, remember, "work smarter, not harder". The result of those efforts were what we would call the Research Animal Coordinator, or our RAC program.

Dr. Anna Hampton, currently our Associate Director in the Office of Animal Welfare Assurance, was [in the Office on an externship from her laboratory animal residency] at that time. [I assigned her the project of guiding] an effort to craft into a working document the backbone of the program we enjoy today.

Slide 20 (5 Pillars of RAC-dom)
The Duke Research Animal Coordinator program was founded upon 5 central pillars. These included:

- The Research [Animal Coordinator] participation was not a requirement, but was voluntary. We wanted the research community to join us, and besides we didn't have the resources for a massive training initiative with no new staff or no new resources.
- Secondly, the RAC graduates would serve as an extension of the animal program oversight activity. They would be trained and validated by the Office of Animal Welfare Assurance.
- Thirdly, the RACs would serve as the IACUC's ears, eyes, and voice. They would have a good understanding of the "why" in a process or in a decision.
- Fourth, the RACs would (we hoped) bring practical solutions to programmatic issues – assisting the IACUC with understanding the problem from the bench-top perspective and assist with determining the information necessary to resolve the issue and disseminating that information when the issue was resolved.
- And fifthly, the RACs could be the institution's first responders for program-related activities. They would know the institution's expectations and how to initiate an immediate corrective response. They would also know whom to call for an answer when there was an unexpected dilemma.

If we were successful, we would create a partnership from which successful research outcomes, assured animal welfare, and effective corrective actions would naturally flow. We would have an extraordinary programmatic tool for the IACUC to use as a measure of the program, indeed, a pulse of the program. And we could leverage the RACs for their energy to get us off the sandbar and help us reestablish progress toward our culture of compliance.

>> *Babcock:* Ron, it seems like you view your program as a living organism?

Slide 21 (Dynamic)
>>*Banks:* Absolutely, George. Any effective program is a living entity. We believe anytime a program becomes static, or stops growing, or ceases to change, it is dying. Anytime program leaders stop considering ways to be more effective, more humane, more efficient, the program is dying. Have you ever heard the last 7 words of a dying institution? Here they are: "We've never done it that way before." Those who choose to maintain status quo, those who believe there's no reason to consider change because it won't work or it's too hard, those are the folks who are uttering for their institution the words "We've never done it that way before."

That's not to suggest our journey was easy. In fact, it really was not and we're still on our journey today. And we've been tempted several times to say things are good enough, but good enough should never be used as an excuse for failing to seek a better institutional course, securing animal welfare, assuring the institution's good name, and assisting the forward discovery of research.

Slide 22 (Moving Forward)
George, I learned something a few years ago watching the ducks on the river down the way. Those that were not paddling upstream were floating downstream. It occurred to me that animal programs are much the same. We needed program participants, all of them, researchers, administrators, veterinarians, and support staff – the community, if you will, of institutional ducks – all paddling upstream together, if we're going to make progress against suboptimal animal welfare, regulatory ignorance, and inefficient research performance. When we started thinking about our program as a living entity that had to move forward or float downstream, it was then that we started to master the dynamic nature of the process. Never allow a suggestion for improvement to be met with those words, "We've never done it that way before."

Slide 23 (Judging Program Effectiveness)
Let me give you an example. Like all institutions, we have training modules for new animal program participants that the IACUC has reviewed and approved. They're good modules, right? The IACUC has approved them, therefore they must be good. Well, after our first group of Research Animal Coordinators graduated, we asked them what they thought about the training program at Duke for new faculty and new researchers. Many RACs said, "It's okay, kind of dull, pretty routine stuff really, but it's okay." Then we asked them how effective were our training modules at achieving the goals of our training? Our RACs suggested that we might not be getting the message as intended out to the community. In other words, we had stopped paddling and had started floating down the training stream and had been there for some time.

In response to the RACs' assessment the IACUC said, "Okay, write us a better training module," and the RACs did just that. Their product was better than the one the IACUC had approved and had in use for many years. As an institution we discovered the value of asking the "how" question. Absolutely, George, any effective program is a living, growing, and changing entity and matures through the contributions of all.

>>Babcock: Tracy, could you compare your program to the Duke program?

Slide 24 (Laboratory Animal Coordinator)
>>*Heenan:* Certainly, at UNC, the primary focus of the Laboratory Animal Coordinator is to train laboratory members in hands-on rodent techniques. However, we have also realized many of the benefits that Ron described. One unanticipated benefit has been the result of creating an IACUC liaison in every laboratory. The LAC program fosters a working relationship between a key member of the laboratory and the IACUC and the Office of Animal Care and Use. This relationship enhances communication between the lab and the IACUC, provides a point person for arranging inspections and other interactions, facilitates education, and increases the comfort level of lab members when working with the IACUC. Having this personal connection with a laboratory helps inspections be more educational and interactive rather than threatening or nerve-wracking. We believe this LAC-IACUC relationship has also contributed to researchers being more comfortable self-reporting animal welfare issues. A majority of our animal welfare and noncompliance self-reports are made by LACs.

Ron mentioned that his RAC program is voluntary. Having an LAC is mandatory at UNC. It is required for each laboratory to have its own LAC and for every protocol to identify the LAC. The program was developed to provide more uniform and consistent training to personnel working with lab rodents, as rodents make up about 90% of our animal population. LACs who work with species other than rodents receive the training they need to work with that species and are certified by our veterinary staff or an outside consultant, as needed.

>>*Babcock:* So a large laboratory at UNC with many protocols could have numerous LACs?

>>*Heenan:* Yes, sometimes that does happen. We prefer that the PI have just one LAC that coordinates all animal activities for the lab. However, some large laboratories have multiple LACs who work together to coordinate activities. Also, some smaller laboratories share LACs or one LAC may coordinate the activities of multiple labs with similar research. We currently have about 400 investigators that work with animals at UNC and we do have more than 400 LACs.

Slide 25 (Building Consistency)
>>*Babcock:* Tracy your institution has obviously trained a lot of individuals and as we all know there is turnover of personnel in science. How to you keep the information consistent within a laboratory and do different LACS give conflicting information?

>>*Heenan:* Although the investigator may appoint any member of the laboratory as the LAC, we encourage PIs to select permanent lab members such as research

technicians rather than students or post-docs. This lends greater consistency and permanency rather than having the role constantly handed off to a new lab member. Also, during semiannual inspections and procedural observation, the office spends a significant portion of that visit with the LAC reviewing the protocol and associated records, identifying possible protocol drift, and going over new IACUC policies, guidelines, and animal care procedures in order to maintain consistency among LACs. In addition to serving the purpose of a semiannual inspection or post approval monitoring, much of the visit is dedicated to establishing a working relationship and fostering a culture of compliance. Our coordinators serve as educators and facilitators of humane animal care and use rather than the IACUC police.

>>*Babcock:* How do you train your LACs and who does the actual training?

Slide 26 (The Training of a LAC)
>>*Hearne:* Hi, this is Emily. I manage the training program for animal handlers at UNC, so I'll describe our program. LACs are trained and certified by Office of Animal Care and Use Training and Compliance Coordinators, who also have their own acronym, we call them TCCs. As a team, we offer hands-on mouse, rat, and aseptic techniques courses which registrants sign up for depending on what is needed to conduct their research. These are face-to-face didactic sessions held in our training laboratory and are offered to all animal handlers.

Slide 27 (Proficiency Rating System)
Folks are trained and then certified according to proficiency at Level I, II, or III. Individuals must be certified at the proficiency Level I to be eligible to train lab members as an LAC. While highly encouraged, the ability to train others is not a requirement of the LAC.

>>*Babcock:* So if I understand this correctly, the same training is offered to many individuals at UNC, but to become an LAC, you must achieve a higher score or a higher level of proficiency?

>>*Hearne:* Yes, and there is an additional course that is required to achieve LAC status.
>>*Babcock:* What is that course?

Slide 28 (Required LAC Lecture)
>>*Hearne:* The LAC lecture is a requirement prior to becoming an LAC. The lecture is presented one time per month and is also available by appointment with a Training Compliance Coordinator to facilitate timely approval of protocols. While the hands-on training is focused on the species that the LAC will actually be working

with, the lecture covers all species, including USDA covered species. The lecture is comprehensive as it prepares the LAC to be an integral part of the animal care and use program for the institution by introducing them to the people, places, and policies they may need while engaged in animal work at the university. The topics covered in this lecture include the training and duties of the LAC, an introduction to our online training certification system for LACs who do certify lab personnel, and an introduction to our online protocol application system (ACAP).

We also take this time to cover the basics of grant congruency, our process for conducting lab and facility inspections, and our post approval monitoring practices. During the lecture we go over many basics related to IACUC and Department of Laboratory Animal Medicine or DLAM policies as well as required monitoring and documentation in the laboratory. The lecture ends with a listing of resources available at UNC Chapel Hill and any important compliance issues or recent policy updates. You can find a link to this lecture on our IACUC website, which will be presented at the end of this webinar. We have found that real-life examples are a great way to illustrate why certain polices are in place, and to draw attention to what can go wrong if people to not adhere to them. In addition to all the information we provide in the lecture, we reserve time for audience questions so we can ensure that we address any specific questions related to their work on campus. We think this helps foster a more facilitative relationship with our researchers rather than an adversarial one.

Slide 29 (Other Training at UNC-CH)
In addition to the LAC lecture, a mouse breeding policy lecture is required for at least one person per lab if mouse breeding is included on the protocol. A mouse colony management lecture is also available, but is not required. We also have one-on-one training sessions for 3 hours per week by appointment, to accommodate those that have already gone through one of our classes or have experience handling rodents and need a quick turnaround. This training facilitates faster approval times and is tailored to the individual's needs.

>>*Babcock:* So you are really describing most of the animal training available at UNC and you coordinate this training to provide different levels of certification at UNC and LAC is one of those levels.

>>*Hearne:* Yes, George, exactly.
>>*Babcock:* Ron, do you have a lot of RACs at Duke?

Slide 30 (Duke RACs)
>>*Banks:* At present, George, we have 85 active RACs. We graduate 25 or 30 every 10 months or so. Our current iteration has 31 candidates presently enrolled,

8 of those in 3 classes and 7 in the fourth. I wish we had one active RAC per lab, and we will get there, but RACs at Duke are not as commonplace as they are at UNC, at least not yet. And several of our RACs have moved to other institutions, which has also reduced the number of active RACs from Duke from what it could have been. We view the movement of RACs to other campuses as a good thing for the greater research community, so in the end it's all good.

Part of the reason we have so few at present is simply a matter of philosophy – not to suggest that either campus is more right or more wrong – but our approach is RAC training as a relational activity. In other words, we want to build a relationship with each and every RAC and that is not easy on a large campus. It takes time. The relationship is our foundation for partnership and a compliant culture and that's what we seek. Partnership is the means by which we build our culture of compliance.

The other reason is simply a matter of available time to facilitate classes. When we started our RAC process we thought if we could get 6 PIs to recommend an RAC candidate, we'd be happy, we would have a class of 6 candidates. And yes, we had those naysayers who said no PI will buy into that. Others said PIs will see this as creating a police state on campus, and still others said, lab staff are already too busy and don't have the time for what you folks are designing.

Well, to introduce the RAC program to campus, we held a noon-time [campus-wide] seminar describing our plans. I ended the session by asking that the PIs and lab managers consider our proposal and consider recommending one of their senior lab staff to participate as a RAC candidate. I noted that we were looking for 5 or 6 candidates for our first class. If we attained that many, we would have an RAC class. The walk from the lecture hall back to my office was about 20 minutes. By the time I got to my desk, there were 37 emails from PIs recommending one of their lab members as one of our first RAC candidates. We had a real problem! Our RAC program plan was to have small classes, yet we had 6 times the number of folks we wanted for the first class. We had 37 PIs wanting to partner with the program, and we were not, absolutely not, going to turn folks away. But that's a great problem to have, George.

>>*Babcock:* Ron, how are the RACs trained? Is the training for these individuals specialized or is it a part of the general training offered to the animal care staff and the research teams?

Slide 31 (Investment and ROI [Return on Investment])
>>*Banks:* The Duke RAC training process begins with a recommendation from the PI for a specific lab member to become a candidate RAC. That gets PI buy-in from

the start. On the one hand, when the PI completes the application, he knows the lab member will have training requirements each month for the next 10 months and they can expect a more skilled lab member when their RAC graduates. The new RAC skills and authorities may include:

- Serving in the lab as a skilled specialist to help more junior lab members;
- An assistant for protocol preparation and protocol submission;
- An in-lab trainer for animal handling or animal procedures;
- Someone skilled in compliance monitoring, and also reporting to the IACUC when those actions are necessary; and
- Someone who is skilled with completing necessary corrective actions properly and accurately.

The PI and the RAC determine how these new skills will be employed in the laboratory.

Slide 32 (RAC Training Program)
One of our Compliance Liaison staff in the Office of Animal Welfare Assurance, Mr. Bill Wade, laboratory animal technologist [LATG], serves as our course facilitator. He assists the RAC candidates through the class process and coordinates instructors from the animal care committee, from Office of Animal Welfare Assurance, safety, employee heath, lab animal resources, other campus activities, according to the course topic for each small group, presentation or discussion. AALAS Learning Library modules provide the core background information and small group sessions are used to familiarize RACs with the Duke aspects of animal care and use expectations including safety requirements, employee health concerns, vivarium issues, and many more.

Our colleagues at UNC have a fine program, but one difference between our two programs is that the Duke program is more inclusive in terms of training. We look at things in terms of Phase I or Phase II. For example, all RAC candidates who work in mouse-only labs also receive the USDA training module part of the Phase I curriculum. The same is true for controlled substance training. Not all labs use controlled substances, but all RACs receive controlled substances training so they are aware of the expectations and stipulations of using controlled substances in animals on campus. The driving principle is that RACs need to know the world of animal care and use is larger than what goes on in their laboratory. Remember, we're building a culture. In Phase II of our training program the RAC focuses upon the species used within the laboratory.

>>*Babcock:* Ron, how does each Phase work?

>>*Banks:* Each month, the RAC candidates complete an assigned set of AALAS Learning Library modules online. You could use any training modules, but we have an institutional subscription to the AALAS group, so we have chosen to use that resource. Then the RAC candidates attend a class that covers the topic area that's been addressed in the AALAS module. We keep class sizes small, 6 to 8 candidates per class, so we can have a discussion more than a lecture. One of our RAC goals is to develop a relationship during training, and we can maximize relationship with small classes and lots of discussion. We also recognize folks learn best from their peers, in other words, discussion again rather than lecture, so we try to leverage the learning preferences of our learners, building the community's knowledge base, and also building relationships. Turns out it's a win, win – win!

The effort required for this segment of the training becomes significant for the instructor as well as the candidate. Since we generally are running 4 RAC classes concurrently with 6 to 8 candidates per class, the instructor will facilitate an RAC class every Tuesday of the month, but the candidate will only attend one of those Tuesdays. For example, Animal Welfare Assurance compliance liaisons, Dr. April Kolstad, and laboratory animal technologist, Sonya Doss, [LATG], teach a session on performing in-lab compliance audits, or how to do a lab audit using PAM [principles]. They will lead the RAC class every Tuesday, with the PAM topic for PAM topic month. Each class is scheduled for about 2 or 3 hours, but often the discussion runs longer so we block out 4 hours for each class. The same process occurs with each module segment and each module construction. That describes the process for Phase I, which we look at as core knowledge for all RACs.

In terms of lab-specific curriculum, or Phase II training, each RAC candidate will identify the species they work with in their lab. We partner with the lab animal resources group, who provide individualized animal care and use training based upon the common issues or concerns associated with the species that are used in that RAC's lab.

Our RAC basic training process ends with a graduation ceremony. The Institutional Official, or designee if the IO is unavailable, attends and provides a word of congratulation and encouragement to the RACs. The IO and the IACUC Chair present each RAC with the RAC lapel pin, as seen on this slide, and RAC certificate of completion. And we snap a photograph for later presentation in the institution's e-newsletter called Animal Tracks. Immediately afterwards we hold a reception for the RACs and include their PIs, lab members, and all IACUC members. It becomes a time of recognition and a great send-off as a representative of the animal program, serving their PI and lab mates as a Research Animal Coordinator.

George, the time on our webinar today is limited, but as a means to allow more substantive review of what we're doing at Duke our Senior Compliance Liaison, Dr. Deb Vanderford, has assembled a PDF file of our RAC curriculum, teaching plans, and other program documents. We've provided those to OLAW, and Webinar attendees will be able to download those [documents] from the OLAW Web site in a bit. Do please remember we annually reassess and modify our program to meet the changing needs of our campus – remember the dynamic nature of a program. Next year the RAC curriculum may look a tad different than it does today, but the PDF file describes what we have currently engaged and what has worked for us. And everyone is welcome to use the parts and pieces that might be useful in their program.

>>*Babcock:* Participants in this Webinar can find material and other resources for this Webinar in the Educational Resource section of the OLAW Web site. The URL for those resources will be provided on a resource slide at the end of this presentation. If you look there, you can also find a PDF of the slides, and as soon as the OLAW staff can prepare them, you will also be able to find a recording of this Webinar and a transcript of this Webinar. Now let's find out how UNC's training compares to Duke's. Emily, how is your training structured?

Slide 33 (Training Structure at UNC-CH)
>>*Hearne*: We currently offer 2 mouse handling and techniques classes, one rat handling and techniques class, and one aseptic techniques per month. Each class can hold up to 12 students and they last about 2.5 hours, utilizing all 3 Training Compliance Coordinators. We also offer our lectures once a month, each one lasting about an hour. In addition to these classes and lectures, one TCC per week holds a 3-hour block of time for one-on-one training sessions by appointment. These sessions are available on a first come-first served basis to accommodate those that cannot attend our normally scheduled classes, or have an urgent training protocol need, or are seeking additional help. If an LAC does not earn a Proficiency of I during their initial training, they may use these one-on-one sessions to demonstrate improved ability after practice and earn a higher proficiency rating.

>>*Babcock:* Emily, how are people selected for your programs?

Slide 34 (Who's Your LAC?)
>>*Hearne:* The PI appoints an LAC. The role of LAC must be selected on the IACUC animal use application and the individual who is designated as LAC must attend the LAC lecture before the protocol can be approved.

>>*Babcock:* How about in the RAC program at Duke, Ron?

Slide 35 (RAC Community)
>>*Banks:* Since our program is voluntary, the PI recommends rather than appoints the candidate RAC. We haven't refused a recommended candidate to date, but we do retain the option of not accepting a candidate if we need to manage participation in the program. That could happen, if, say, a PI wants all their lab staff to be RACs, and we have several labs wanting one RAC, or maybe a junior-level person is recommended as an RAC candidate as a means of gaining experience with the intention of attending grad school or medical school. It's not a bad idea, but if we're tight we'll select middle management and senior lab leaders as candidates because these more senior folks have the experience we have found necessary to make good RACs and they typically tend to remain in the laboratory for longer periods of time. On occasion the IACUC may encourage the PI to select an RAC candidate and especially if that lab has a checkered history of suboptimal performance.

>>*Babcock:* Yes, that brings up the subject of performance. What have been the benefits of these programs, Ron?

Slide 36 (RAC Benefits)
>>*Banks:* George, this could be a Webinar in and of itself! I think it's fair to say that the Duke RAC program has exceeded our initial outcome expectations. The entire campus, from the IO to the IACUC, the PI and the RACs, all believe this has been a good experience for Duke.

PIs have benefited from having an RAC who may act on behalf of the PI, submitting forms/reports and generally making the life of the PI much less "form heavy." PIs have a skilled resource to assist with internal training, procedure monitoring, and lab preparation for IACUC inspections, PAM visits, safety audits. All these things are covered in the RAC training.

Secondly, RACs have benefited because the institution views completion of the RAC program as documented evidence of advanced training – in fact, some of our RACs have received raises after completing the course. Most of our RACs have been assigned greater authority and responsibility in the lab. All of our RACs see completion as a matter of self-actualization and validation of the quality professional that they already know they are. Best of all, our RACs know how the animal program works, they have talked to the wizards behind the curtain and the program wizards are not as scary as they happen to think (if that doesn't make sense, colleagues, you might need to watch an episode of the Wizard of Oz). They know how the campus works, they've met the animal program leaders and have the direct phone numbers for the people they will need to talk to, in safety, employee health, lab animal resources, and even in the

IACUC. A face and a phone number, does it really get any better for Research Animal Coordinators?

Lab members have benefited from having someone in the lab they can immediately trust, someone who knows what the campus expects and how to accomplish the task most effectively.

The IACUC has benefited from receiving protocols which are more complete and better written than in the pre-RAC days. There are fewer significant noncompliant issues to review since problems are frequently identified by the RAC while minor and then reported to the IACUC usually with a corrective action already engaged. Talk about taking responsibility for lab activities! It really works. The IACUC also benefits from direct advice regarding what is working and what may not be working at the bench-top level.

From the Office of Animal Welfare Assurance, we see a partner in the animal program care and use assurance process. We've been able to take our very small staff and we have "worked smarter, not harder." And we've leveraged program reach by using RACs as adjunct staff, if you will, into the labs of 85 different researchers, and growing each year. The RACs know that our programmatic focus in animal welfare is as a partner, not as a police.

A benefit to the program is the RAC Advisory Committee which consists of all graduate RACs. The Advisory Committee meets quarterly to review program updates, discuss potential program changes, or serve as a beta test group for new software, policies, or procedures. The RAC Advisory Committee attends the IACUC semiannual program review and provides a report to the IACUC on matters of interest to the RACs. Remember how the RACs rewrote our initial training modules? Partnership does indeed work!

And let's not forget the most important participants in the research and training enterprise, the RAC program has also benefited our animals. RACs are individually trained by lab animal resources staff to know the care expectations, the anticipated outcomes, the means for humane animal use, and the methods for immediate clinical veterinary or veterinary technician contact, if needed. The animals receive more eyes, more trained eyes assuring their well-being. It's the right thing to do for the animals. As our friends at the NIH say, good animal care equals good research outcomes.

Yes sir, from a Duke perspective the RAC activity has benefited all sectors of the campus and of the program.

>>*Babcock:* How about at UNC? Emily and Tracy, what benefits have you realized from your LAC program?

Slide 37 (Post Approval Monitoring and the LAC: The Procedural Process)
>>*Hearne:* This is Emily. We have seen many of the same benefits that Ron described in our program since its creation back in 2002. In addition to the training aspect of our LAC program, one of the most important side benefits we've all gained is that the LAC serves as a liaison between our office and the laboratory.

Slide 38 (Animal Welfare Concern Communication and the LAC)
We contact the LAC when scheduling laboratory inspections, during animal welfare investigations, and for many protocol related questions. We recently had our AAALAC site visit and during the months leading up to the visit, the LACs were instrumental in helping us plan for and organize our lab and satellite visits. While our PIs were involved as well, it was incredibly helpful to know that we had a point person in each lab that was able to meet with the site visitors with very short notice and provide documentation as requested. Overall the program has developed many individuals on our campus into assets for their lab and for us as IACUC administrators.

Slide 39 (NLAC)
>>*Heenan:* This is Tracy. One of the most useful offshoots of the LAC certification program is the Network for Laboratory Animal Coordinators known as NLAC. This network consists of LACs from all across the UNC-Chapel Hill campus and from all of the different schools and departments working with animals. Members of NLAC participate in NLAC quarterly seminars which cover pertinent topics such as IACUC policies and guidelines and tips about talking to the public. We also have vendors who come on campus to talk about new techniques and procedures.

Also, NLAC members can sign up for the NLAC listserve which has been extremely useful in promoting best practices, training tips, locating other researchers who are proficient in techniques not taught by the Office [OACU], and sharing animals, thereby reducing the overall numbers of animals that are used. These helpful resources regarding the UNC LAC program are included at the end of this presentation and they're also available on the UNC IACUC Web site.

>>*Babcock:* Thank you Emily, Tracy, and Ron for this wonderful presentation. These programs appear to really benefit all those involved, the IACUC, laboratory animal medicine, the PIs, the lab animal workers, and the lab technicians. On page 34 of the *Guide*, it says, "Regardless of the methods used or who conducts and coordinates the monitoring, PAM programs are more likely to succeed when the

institution encourages an educational partnership with investigators." I think that the programs at UNC and Duke certainly have met this goal and should be a model for others, a true partnership.

Slide 40 (Resources)
[Duke

- http://grants.nih.gov/grants/olaw/educational_resources.htm

UNC-CH

- All class handouts, certification sheets, lectures: *Lab Animal* Vol. 39, No. 4 | April 2010 LAC article
- http://research.unc.edu/offices/iacuc/training/]

Slide 41 (Question 1)
>>*Babcock:* Now we're going to address some of the questions that we've received from the audience. First question, Ron, what is the percentage of laboratories at Duke that have RACs?

>>*Banks:* George, we haven't assessed the actual percentage of all campus labs. I would estimate that probably 20% or so. The good news is even minor campus percentages can have significant impact on overall campus performance, in part because the lab staff and PIs talk and the trained RAC on the 4th floor may very well provide guidance beyond their home laboratory, and certainly with the PI's consent. We believe that sharing knowledge and assisting others is consistent with building a community, and a lab with an RAC is an encouragement to the other labs on the same floor to do better and potentially even recommend a candidate for RAC participation.

Slide 42 (Question 2)
>>*Babcock:* To whom do the RACs and LACs report?

>> *Heenan:* This is Tracy. At UNC the LACs report directly to the principal investigator. Although the investigator is the one that is ultimately responsible for all activities in the laboratory, the LAC serves as the point person and the coordinator for animal activities in the lab.

>>*Banks:* For the Duke response, it is important to recognize a distinction between our understanding of the RAC's responsibilities and hierarchical authorities. RACs are paid by and work for the PI. There are those who may argue that such a relationship would interfere with RAC responsibilities and transparent communication with Animal Welfare Assurance or IACUC. If that were the case, then we would not have a culture. Since our goal is a culture, we encourage transparency and we commit to partner toward a solution whenever a

problem occurs. We are less concerned with who committed an infraction and more concerned with how the infraction occurred. In fact, most of our corrective measures have a personnel component and a system component. So we look at things from individual behavior changes as well as enhanced systemic protections to keep those things from occurring again. Remember, we're going for a programmatic culture shift not hierarchical strategy because we believe culture beats strategy every time.

Slide 43 (Question 3)
>>*Babcock:* Do RACs or LACs serve on the institution's IACUC?

>> *Hearne:* This is Emily again. At UNC, two of our IACUC members are research associates who are also LACs. In addition several of our scientist members who are investigators also serve as their own LAC.

>>*Banks:* At Duke, there is no association between IACUC membership or RAC status. But there is also no prohibition from being a RAC and IACUC member. It is just not a specified affinity either way. We do empower RACs as a program player by maintaining the RAC Advisory Committee, by RACs attending semiannual programmatic meetings, and by a request from the RAC Advisory Committee for a report of the IACUC every time there is a programmatic meeting.

Slide 44 (Question 4)
>>*Babcock:* Do LACs or RACs participate in IACUC investigations and formulating corrective actions to a noncompliant animal activity?

>> *Heenan:* This is Tracy. At UNC, LACs take an active role in assisting the IACUC with an animal welfare or noncompliant investigation. They help gather records, identify animals, and participate in interviews. Typically, the PI will suggest corrective actions which the IACUC may consider. The LAC may work with the PI to identify these corrective actions. In some cases, the sanction may involve the noncompliant party being supervised during animal activities. The LAC may be asked to participate in this way by supervising or shadowing the lab member.

>>*Banks:* At Duke the answer is, yes, sort of. RACs have not served on an IACUC investigation subcommittee per se. But by virtue of their presence in the laboratory, their partnership with the PI to immediately address the issue, and their assistance to the PI with formulating an appropriate corrective action as well as reporting the issues to Animal Welfare Assurance and the IACUC, yes, the RACs do participate in the investigative and corrective action process.

Slide 45 (Question 5)
>>*Babcock:* When in labs or procedure rooms and interacting with PIs and animal users, do coordinators point out and suggest corrections of observed activities that are contrary to protocol descriptions? Or, do they report those noncompliances to someone else who then advises PIs and animal users that changes need to be made? If they report to someone else, is that someone else the IACUC? The compliance component? Or some other person?

>>*Hearne:* This is Emily again. At UNC, it's part of the LAC's responsibility to identify activities in the laboratory which may be straying from the protocol or institutional policy. Outside of the laboratory in the animal facility or procedure rooms, LACs often point out best practices or correct policy and procedure to their colleagues. If the LAC is not comfortable approaching an individual in the facility, they often apprise the IACUC of possible noncompliance or breaches in policy. Additionally, during PAM observation the LACs are instrumental in identifying protocol drift and suggesting corrections via amendments. Typically LACs will know of proposed changes to the protocol and are able to facilitate amendments quickly.

>>*Banks:* It is our opinion that the welfare of the animal, prevention of animal pain or suffering, and animal wastage are important considerations in an observation of a noncompliant event. It's possible an RAC may observe a practice that might be better enhanced or modified, and that action may occur while the action is in progress. It is our expectation that there will very quickly be a report to the IACUC as soon as possible for consideration of the potential NCI; and amendment to the approved protocol if the modified procedure is anticipated to occur more than once.

Slide 46 (Question 6)
>>*Babcock:* How did the UNC or Duke researchers buy in? Was it willingly?

>>*Heenan:* At UNC, at first there was some resistance to the mandatory hands-on training. There was especially push-back at implementing it quickly and across the board. However, several years into the process, the benefits we've seen far outweigh any negative. It's also now just an established and expected part of working with animals at UNC.

>>*Banks:* Early on at Duke there was some suspicion but there was also significant buy-in as I described in the story of our first seminar and resultant emails. At this point, our PIs are highly supportive of the process as they have seen how the RACs have made their research lives easier. Our focus is partnership and not creating a police state, and PIs have warmed to that thought very well.

Slide 47 (Question 7)
>>*Babcock:* Did the senior administrators embrace these plans? If so, what was responsible for administration buy-in?

>>*Heenan:* This is Tracy. At UNC, implementing the hands-on rodent training at our institution at the time was an important institutional commitment, supported by the Institutional Official, our senior administration, and the IACUC. The institution actually provided valuable wet lab space so that our training and compliance team had a place to hold their hands-on classes in the one-on-one training sessions.

>>*Banks:* The Duke experience may be better described as senior administration giving us the rope we had asked for, that the IACUC had approved. So either we could build a bridge to get ourselves where we needed to go or we were going to be tied up in a mess. But now the buy-in from administration is indeed quite real. As an example, our institutional official recommended and now her lab manager has gone through the RAC program. Probably the greatest enticement for the administration was a "no additional cost institutional insurance policy" against institutional risk factors, people not knowing what they should be doing. The belief that we hold is that folks who know what the expectations are and know how to achieve the desired outcomes will choose the right opinion and make the right choices. We had our office slogan made into an institutional commitment, we're all going to "work smarter, not harder" – and from the administrative perspective also less expensively.

Slide 48 (Question 8)
>>*Babcock:* UNC and Duke both have large animal care and use programs. Do you think this sort of PAM program is best for a large campus?

>>*Hearne*: This is Emily again. The UNC LAC model can work at any institution no matter the size. It actually seems as though it would be easier to accomplish at a smaller institution. Compliance issues and animal welfare policies are the similar at most institutions. We all know that PIs are stretched very thin, regardless of the size of the institution, so any additional support IACUC administrators can offer, without asking them to spend more money, is generally a positive addition to an existing program.

>>*Banks:* George, I begin by responding regardless of program size the rules are all the same. For example if you're PHS-Assured or USDA-registered, there's an agency that expects a certain level of programmatic performance and compliance. The only real difference between our programs is how we craft our solutions with personnel policies and processes. For example, we all have

IACUCs, some of us have 5-member IACUCs and some have 53-member IACUCs. Program size drives intensity or maybe investment. But IACUC is still an IACUC. Any sized campus can have an effective RAC program. It simply takes a philosophy of believing that people will do the right thing if they're trained and if they know the institution's expectations and if they're held to the standards of performance and if the program and the researchers partner transparently. For us, regardless of program size, we believe the RAC process maximizes the IACUCs educational outreach opportunities while offering clear guidance on how to choose the right thing.

Slide 49 (Question 9)
>>*Babcock:* Do you have people who drop out of the process? Or maybe get encouraged to stop?

>>*Hearne:* This is Emily again, at UNC it seems that most individuals drop out of the program simply because they are leaving the institution, changing careers, or moving on to a different type of laboratory that might not work with animals.

>>*Banks:* At Duke, on a rare occasion we have found the candidate that seems to be more interested in learning how to avoid what they perceive as IACUC persecution rather than trying to learn how to partner with the IACUC. We will try to morph their vision to one that recognizes the value of partnership, but if unsuccessful, yes, George, I have asked for a candidate to withdraw from our RAC training program, and they did.

Slide 50 (Question 10)
>>*Babcock:* How many campuses do you know are looking toward something like this?

>>*Heenan:* At UNC, we have had a number of our UNC sister institutions visit us to attend our classes and to learn how to implement this at home. We have also hosted other non-UNC universities to show them how our program works.

>>*Banks:* I want to reiterate things you and Susan said earlier on. None of this is required by OLAW or anyone else for that matter. It's a process we have chosen to help us be a great program instead of just a good enough program. And I think there are many institutions that believe similarly and many are accomplishing this desire using a variety of methods. We've had several institutions ask us about specific program processes and policies and we've shared these with other colleagues. I'm aware of several institutions in the US, and also outside the US, who have chosen to do things like we are and embarked on a similar path. An important point here, George, I never suggest an institution take our program as it

is and make it theirs, although we'll provide the documents to them and let them craft their own. The Duke animal program is not interested in making other Dukes. That would be a fool's exercise, as no two programs are exactly alike, so the solutions should not be exactly the same. We're interested in sharing our journey and, if possible, smoothing the road for others who are on a similar journey. For us it seems the most humane thing to do, so that others may be successful in their program management and so that animals and researchers may benefit from program enhancement efforts.

Slide 51 (Upcoming OLAW Webinar)
>>*Babcock:* At this time we have no time for further questions. So I'd like to remind you to please send your questions in and the speakers and the staff will answer them as soon as possible. I'd like to thank Tracy, Emily, Ron, and Susan for their participation in making this a wonderful Webinar, and I'd like to encourage everyone to join us for our next Webinar, December 4. Thank you.

Additional Submitted Questions Not Addressed During the Webinar

Question 11. **Has this program been considered approaching the departments on your campuses as opposed to recruiting someone from the lab level?**
>>*UNC:* We have not considered that for the LAC program. It is specifically intended for the laboratory level. Perhaps institutions interested in a step-wise implementation approach could start with one person per department. Once that phase of LACs are ready to go and PIs see the benefits of having an expert in the department, perhaps the institution could begin a second phase requiring one LAC per lab.

>>*Duke:* Sure, and it works just as well. There are some departments with less animal work and having a single RAC with shared similar duties but for the department rather than the PI is just as effective.

Question 12. **What is the online protocol system used at UNC?**
>>*UNC:* It is a home grown online application system which is currently used by several sister UNC institutions. It's called ACAP for Animal Care Application.

Question 13. **What is the timeline for becoming a LAC or RAC?**
>>*UNC:* LACs can be certified and approved on a protocol after attending the one hour LAC lecture. If they would like to train others, they need to be certified as an LAC at a Proficiency of 1 to do so, therefore, they'd need to come to either a hands on class or one-on-one session to be certified by a TCC. The entire process could be

done in one day if the person is proactive in seeking training, or one month if they chose to wait for our normally scheduled classes and lecture. We ensure a quick turnaround on amendment approvals to facilitate personnel and other minor changes in protocol so once an LAC is trained, approval on a protocol could happen within 24 hours.

>>*Duke:* RAC, 10 months.

Question 14. **For the hands-on courses, what is the source of the animals? (i.e., Are they donated to the IACUC, provided by the lab, purchased?)**
>>*UNC:* All animals used for training purposes in the LAC program have been donated from researchers on campus who cannot use the animals. We have not yet had to order animals for this purpose. Many of our animals are donated by LACs and through the NLAC list serve.

>>*Duke:* For Phase II RAC Training, the animals may originate from several sources; they may be excess research animals, or may be animals managed by the lab resources staff as part of the training animal colony. For RAC training of their internal research staff, our protocol includes an option (Section B11: USE OF ANIMALS FOR PERSONNEL TRAINING) that reads: Is personnel training the primary purpose of this protocol? One of the four options is: "No, this is not a training protocol. However, I may use small numbers of the approved experimental animals to train my research staff the procedures approved on this protocol." When the protocol is IACUC-approved, in-lab training may occur using experimental or lab colony animals.

Question 15. **How has UNC dealt with LAC's that were dealing with a perceived conflict of interest, e.g. dealing with compliance, but on the payroll of the PI?**
>>*UNC:* Typically, LACs work with their PIs to self-report to the IACUC. We have an anonymous reporting Ethics Hotline which allows the identity of the individual reporting an animal concern or noncompliance to be totally anonymous. I suppose there may have been LACs which used this method to report a concern. However, the method is not used often. Typically, LACs and their PI approach us to let us know about non-compliance or animal welfare issues.

Question 16. **How can a small research facility with less than 20 PIs and less than 50 protocols benefit from LAC where PI staff share lab space?**
>>*UNC:* Without knowing the reporting structure or lab organization it would be hard to say. Each PI or each group, depending on the reporting structure, could

have their own LAC, or if it makes more sense, perhaps an LAC could be assigned 5-10 protocols for which they are responsible.

>>*Duke:* Maybe a single RAC? Or possibly two? Maybe send their candidate to a larger program having an RAC program and then upon graduation, the graduate returns home to serve under the IO's approval/IACUC's oversight as a facility RAC (rather than a lab RAC). Programs should seriously consider sharing skills sets and training resources. Where possible, ask institutions nearby if they could include 1 or 2 people in their RAC/LAC training program. I know we would welcome that request.

But the conditions described in this question – 20 PIs and 50 protocols – can be the most concerning of all institutional styles. There are lots of folks in a small space who need to work well together, assuring animal welfare and positive research outcomes for all! This sort of environment can be a perfect place for an RAC to coordinate, guide, assist, and assure.

Question 17. **How do you deal with smaller labs that consist mostly of graduate students and post-docs? Who serves as RAC/LAC if there isn't a dedicated staff member?**

>>*UNC:* We do have a number of graduate students and post-doctoral fellows serving as LACs. This is allowed. It's just not preferred. It does result in higher turnover of the LAC for those labs and sometimes requires more "retraining." The best part about having grad students and post-docs as LACs is that the experience they gain from being an LAC helps prepare them to be more mindful PIs with a better understanding of the behind-the-scenes processes involved in maintaining an animal research lab.

>>*Duke:* Yep – that can be a challenge. There is nothing wrong with a grad student or post-doc being a RAC; in fact we have several of these. You just have to be prepared that this individual will be leaving sooner rather than later. So, get the PI to commit that the year their RAC leaves, they recommend a new candidate – which gives us time to get them trained and ready to go. This question speaks directly to the dynamic nature of many programs – we need to be nimble and able to respond to changing conditions at the program. While the easiest solution is a 10 year employee, getting a good year or three from a post-doc RAC is good for the present, and provides a trained post-doc for their future PI/faculty duties! It takes effort, but it can be guided into a "win" for the present and a greater "win" for the future!

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