Note: text has been edited for clarity.

Transcript of OLAW Online IACUC Staff Seminar: December 4, 2008
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When Terms and Conditions Are Not Met
Speakers: Patricia A. Brown, V.M.D., M.S., Director, OLAW
Eileen Morgan, Director, Division of Assurances, OLAW
Moderator: Jerry Collins, Ph.D., Division of Policy and Education, OLAW and Yale University

Dr. Collins: Good Afternoon or good morning depending upon your local time zone and welcome to the next in our series of OLAW IACUC Staff Outreach Online Seminars. My name is Jerry Collins and I will serve as the moderator of today's session. We encourage you to submit questions online during the presentation by today's speakers. Please direct your attention to the top left corner of your monitor. If you would like to submit a question, please type it in the text field at the bottom of the "submit a Q & A Question" box - in that top left corner and press the arrow to "submit." Once submitted, your questions will appear in the upper portion of the chat box on your screen, but only seen by you and the staff here in the office. This session will be recorded and made available to all interested parties. It will be posted within a week in the Education Section (https://webmeeting.nih.gov/p69389574/) of the OLAW website (http://grants1.nih.gov/grants/olaw/).

Our speakers today are Dr. Patricia Brown and Ms. Eileen Morgan. Dr. Pat Brown currently serves as the Director, Office of Laboratory Animal Welfare (OLAW), at the National Institutes of Health. She received her Bachelor of Science Degree in Animal Science from the Pennsylvania State University and her Veterinary degree from the University of Pennsylvania. She served in the U.S. Air Force for 8 years and, while on active duty, earned a Masters of Science Degree in Laboratory Animal Medicine from Penn State. She joined the U.S. Public Health Service in 1986 and has served in a variety of positions at the NIH, within the Veterinary Resources Branch, the National Cancer Institute and the Office of Animal Care and Use. Dr. Brown is a Diplomate of the American College of Laboratory Animal Medicine (ACLAM), has served on the Board of Directors of ACLAM, is a past president of American Society of Laboratory Animal Practitioners (ASLAP), and has served on the on the Board of Trustees of AAALAC International representing ASLAP.

Ms. Morgan currently serves as the Director, Division of Assurances, in the Office of Laboratory Animal Welfare. She previously served as a Senior Assurance Officer in the Division of Assurances, within the Office of Laboratory Animal Welfare. Eileen holds a B.S. in Technology Management from the University of Maryland with a minor in Animal Health Technology. She has 24 years of experience in animal models-based biomedical research. Her experience includes service as Chief of the Facility Management Branch in the Division of Veterinary Resources, NIH Intramural Program. She has also held positions at the Johns Hopkins University School of Medicine, the

American Red Cross Holland Laboratory, Affinity Biotech, and the Cleveland Research Institute.

Dr. Brown, will you please begin the presentation on **When Terms and Conditions Are Not Upheld**?

Dr. Brown: Good afternoon. Today's seminar will focus on NIH Grants Policy as it relates to institutional oversight of animal research activities. We would like to begin first by talking a little bit about OLAW. Like many organizations, OLAW has a mission statement, which is an excellent tool to focus on OLAW's role within NIH. What OLAW is here to do - is to ensure the humane care and use of animals in PHS-supported research. Why we do what we do - is to help contribute to the high quality of the research. And how we do it - is through promoting compliance with the **PHS Policy on Humane Care and Use of Laboratory Animals** (http://grants.nih.gov/grants/olaw/references/phspol.htm), which Eileen will now describe in more detail.

Ms. Morgan: How does OLAW promote compliance? By facilitating animal welfare. Each institution receiving PHS funds has an Assurance with OLAW that describes their animal program, and the IACUC, and its oversight role; through education with workshops, online seminars -like today's, website content, and publications; by monitoring reports of noncompliance received from grantee institutions; and in evaluating allegations of noncompliance and ensuring they are appropriately investigated and reconciled.

By what authority does OLAW perform its mission? The law that required the creation of the PHS Policy was the **Health Research Extension Act of 1985** (http://grants1.nih.gov/grants/olaw/references/hrea1985.htm).
This law directed the NIH to establish guidelines for proper care and treatment of research animals used in biomedical and behavioral research. The Health Research Extension Act also mandated the creation of Institutional Animal Care and Use Committees and specifically states that the PHS Policy cannot prescribe methods of research and allows for the withdrawal of funds if an institution is not meeting the PHS Policy guidelines. We would like to now focus more specifically on what terms and conditions are involved when an institution receives a grant to conduct animal studies.

Dr. Brown: As many of you know in January 2007, in collaboration with the NIH Office of Policy on Extramural Research Administration (known by its acronym, OPERA), OLAW issued a Notice in the NIH Guide for Grants and Contracts concerning the cost that can be charged to a grant involving animal subjects when terms and conditions of the grant award are not upheld. This NIH Guide Notice (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html) can be found on the OLAW website at the address listed on the slide (http://grants1.nih.gov/grants/olaw/). Why did we issue this notice?

Ms. Morgan: OLAW and OPERA had been involved in a number of cases where basic requirements for award of a grant were not being met. In one case, a grantee had begun work involving animals without an Assurance in place to cover the work, thinking that a previously approved Inter-Institutional Assurance would cover the activity. In a second case, a prime grantee had switched performance sites for the animal activity and had not obtained an Assurance. In the third case, an institution had a number of animal protocols expire and continued to conduct the research and charge the grant. OMB Cost Principles and NIH Grants Policy do not permit charges during periods when such lapses - as described above - occur.

Dr. Brown: The essence of the Policy is that no costs may be charged to a grant award during the period of time when the terms and conditions of the award are not being upheld by the institution. These include the following situations - the conduct of animal activities in the absence of a valid Assurance on file with OLAW, or the conduct of animal activities in the absence of valid IACUC approval of the activity. Eileen will now describe the types of Assurances and the Assurance process.

Ms. Morgan: There are three types of Assurances that OLAW negotiates: Domestic, Foreign, and Inter-Institutional. There must be an Assurance in place for each performance site where live vertebrate animals will be used.

Domestic Assurances are for U.S. Institutions that control their own facilities and have a complete animal care and use program that includes an Institutional Official, an IACUC, and an attending veterinarian. Domestic Assurances remain in effect for up to four years and can be renewed.

Foreign Assurances are for foreign institutions that are grantees or subaward partners to a domestic grantee. A foreign institution must agree, in its Assurance, to comply with the **International Guiding Principles for Biomedical Research Involving Animals** of the **Council of International Organizations of Medical Sciences** (CIOMS) and the laws and regulations of the country in which it is located. Foreign Assurances remain in effect for up to five years. Foreign Institutions do not need to submit certification of IACUC approval if they are receiving a direct award.

An **Inter-Institutional Assurance** is required when the prime grantee does not have their own animal program and contracts the animal work to an Assured institution. It is a contract between the grantee institution, the contracted institution and OLAW. The organizations agree to conduct the project according to the Assurance of the covered institution. Timeframes for these Assurances are project-specific. For example, a small business subcontracting animal work to a performance site must apply for a new Inter-Institutional Assurance each time it successfully competes for a grant.

Consortium agreements have additional special considerations. For a large consortium of institutions involved with a single grant, the prime grantee must take responsibility for all consortium partners and subprojects, insuring that Assurances are in place and IACUC approval has been obtained and is dated within 3 years. For more information see the

NIH Grants Policy Statement Part 2 Terms and Conditions of NIH Grants Awards, Consortium Agreements (http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251).

For subcontracts in a consortium agreement, when the prime grantee has no animal facility and will do the work at an Assured performance site, an Inter-Institutional Assurance is required. If a performance site has no Assurance, OLAW will negotiate one when contacted by the NIH Grants Management Officer. If the prime grantee is a foreign institution, they must have a Foreign Assurance and all performance sites must have an Assurance. If the domestic grantee has a foreign performance site where the animal work will be conducted, a Foreign Assurance is required. In addition, the domestic institution must provide the IACUC certification for both the domestic and the foreign animal activities. Now we'd like to focus on when IACUC approval is absent.

Dr. Brown: Absence of IACUC approval can occur for a number of reasons. First is failure to obtain IACUC approval. Second is suspension of IACUC approval. And third is the expiration of an IACUC-approved animal study protocol. All such cases require a report to OLAW and to the NIH funding component, specifically to the Grants Management Officer who is managing the grant. The report is required when work is conducted without IACUC approval or when the animal study protocol has been suspended by the IACUC. Let's give an example of the right way - and then the wrong way - to ensure terms and conditions are being upheld.

Ms. Morgan: This flow chart shows the correct way for a PI to conduct research. It shows the PI receives the grant award, does the research, and then decides to change the scope of the animal work. The PI notifies the NIH funding component, obtains approval, amends the animal protocol, and receives IACUC approval prior to conducting the work.

The next slide shows what happens when this process is not followed. It shows that the PI receives the grant award, does the research, and then decides to change the scope of the animal work. The PI fails to notify the NIH funding component and obtain approval, does not amend the animal protocol or receive IACUC approval for the new work prior to performing the animal work. The PI has made a significant change from the aims and objectives for purposes of the approved project and has failed to obtain IACUC approval. This causes a cascade of events where the grant funds may not be drawn down for the animal work and the research stops.

Dr. Brown: Another example where institutions run into problems with the grant terms and conditions is with an expired IACUC approval – as a reminder – IACUC cannot administratively extend approval of a protocol - *de novo* review is required - at a minimum - every three years to meet the PHS Policy requirements. If a protocol does expire, the PI must discontinue research until approval is granted. However - the institution could transfer the animals to a holding protocol, as long as grant funds were not used to support the animals while the protocol was expired. If work continues on an expired protocol, this causes the same cascade of events where the grant funds may not

be drawn down for the animal work and the research must stop. This is a reportable incident to OLAW and the NIH funding component.

Ms. Morgan: A third scenario is working outside an approved protocol. This is when the IACUC suspends a protocol at a convened meeting of a quorum with a majority voting to suspend. This action should be reported to the IO who - in conjunction with the IACUC - reviews the reasons for suspension and takes appropriate corrective action and reports that action with a full explanation to OLAW. The institution must also report the suspension to the Grants Management Official at the NIH funding component. OLAW will provide a response as to the adequacy of the actions taken by the institution.

Dr. Brown: In all the scenarios we have just discussed, there are a finite number of actions that the institution must take to meet OLAW and NIH reporting requirements. First, report the noncompliance to OLAW and the funding component Grants Management Officer. Do not charge the grant during the period of noncompliance. There is an expectation that the institution will maintain the animals during this period, until the situation is resolved. The Grants Management Officer will determine, on a case-by-case basis - if funds will be allowed to cover the cost of maintaining the animals - depending on the circumstances.

An institution may report to OLAW either by phone or email, initially. This would be followed by a final formal report in writing. When in doubt about the circumstances, please call us (301-594-2061). It is always better to inquire about whether an incident is noncompliant than to not report. The outcome of a situation may be worse if an incident is not reported and comes to OLAW from another source. We do receive reports from anonymous sources, animal rights organizations and other federal agencies. We can best represent your institution in response to a Congressional inquiry, the media, or other federal agencies when we can respond that we are aware of the situation and the institution is taking proactive measures.

Ms. Morgan: OLAW and NIH look at NIH-supported research as a partnership with the grantee institution. Each organization shares the need to assure compliance and along with that go responsibilities for stewardship of public funds - with voluntary reporting of noncompliance being an essential component.

Dr. Brown: If you have more specific questions related to the NIH Grants Policy, they should be directed to OPERA at the phone number (301-435-0938) or email (grantspolicy@od.nih.gov) listed. Questions related to IACUC approval, noncompliance, or Assurances should be directed to OLAW at the OLAW phone number (301-496-7163) or to the Division of Assurances email address (olawdoa@od.nih.gov). When in doubt, please contact us.

There is a brochure available from OLAW that can be ordered from our website (http://olaw.nih.gov). This brochure highlights the investigator's responsibilities in an easy-to-follow and succinct format. It is available from OLAW- in volume- for distribution to PIs. We encourage you to take advantage of this resource to help educate

your researchers about animal issues. We've come to the end of our formal presentation but would now welcome any of your questions. Thank you.

Dr. Collins: Thank you Pat and Eileen. We will spend the rest of our allotted time responding to your questions and we would encourage you to send them in. The first two questions are somewhat similar. The first is – Who in the institution is responsible for reporting the terms and conditions have not been met? And the second one is – Who is responsible for informing the funder if a protocol has been amended and **approved by the IACUC- the IACUC or the PI?** So the first question is – **Who within an institution is responsible for reporting the terms and conditions have not been met?**
A: The Authorized Organizational Official, also known as the Signing Official in the NIH ERA Commons, is the person that assumes the obligations imposed by the NIH Grants Policy and also the Office of Management and Budget requirements. So this individual is responsible for reporting the noncompliance to the NIH Grants Management Officer.

Q: And then it sounds like that's the same answer for the other question. The question was just a little bit different, I think, in asking **who's responsible for informing the funder if something has been amended by the IACUC? Is it the IACUC or the PI?** And clearly again, it's the individual that you just indicated a moment ago, Dr. Brown.
A: That's correct. The PI and the Authorized Organizational Official are the individuals who should be in contact with the Grants Management Officer - anyone else from the institution would not be considered officially able to be making comments or statements about the status of a grant.

Q: Our next question. **If a protocol expires, and the IACUC has informed the PI that all work must stop until a new application is submitted and - work is suspended by the PI - is this a violation that must be reported?**
A: Any time the IACUC suspends a protocol - that is reportable to OLAW. However, if the suspension occurs and no animal work is conducted, the funding component would not necessarily need to know about that, although it is always better to inform them, especially if it is going to be for an extended period of time and would impact the ability for the research to be conducted during the performance period.

Q: Our next question. **Can the IACUC suspend a specific activity on a protocol?** For instance, can they suspend mouse activities on a multi species protocol?
A: The answer to that is yes, a portion of a protocol may be suspended and the rest of the activity may continue to retain to be approved.

Q: Our next question. Terms and conditions include pre approval by NIH for adding a new species. **What if a PI gets a custom antibody made in rabbits at an Assured contract lab with IACUC approval but failed to get pre approval from NIH to add rabbits to the grant? Do funds need to be reimbursed to the funding agency?**
A: Under the circumstance, it would be best to contact the Grants Management Office and inform them of the situation and they would make a determination as to how they were going to handle it. It's really the funding component that makes a determination as to how funds will need to be returned or what portion may need to be returned.

Q: **Next if a PI amends a protocol to expand its scope - without removing previous aims - should the NIH be informed?**
A: This is going into more detail about what is considered a change in scope. I did want to give some more information about what the NIH Grants Policy Statement does say about change is scope because some of you in the audience may not be familiar with this. There's a listing – a pretty long list – of change in scope examples - but the ones that involved animal activities are the ones I wanted to focus on. Examples include substitution of one animal model for another - for example - changing from a rat model to a mouse model would be a change in scope that would require prior approval from the NIH Grants Management Officer. Shifting your research emphasis from one disease area to another. For example - changing from a lung transplant study to a kidney transplant study, would be an example of a change in scope that needs to get prior approval. Application of a new technology, if you're changing from one assay type to another - in all cases - its best to contact the Grants Management Officer about the situation and have them make a determination instead of going along and doing these activities and then finding out later they required approval. Some other specific examples - if you're transferring your animal activities to a new performance site - to a third party - either through a consortium agreement or a new contract - this would rise to the level of change in scope - and this would include addition of a foreign performance site - all of those require prior approval. And as I said, you can find more information about change in scope in the NIH Grants Policy and there's a section labeled prior approval requirements, you can find it online (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm) and if you do the search under the NIH Grants Policy for "Prior Approval Requirements" you'll get that section that goes into much more detail. Any question about what's - as I said before - the need for prior approval, should be directed to the Grants Management Officer that signed the notice of grant award. And just for your information, prior approval should be made in writing and that does include email is acceptable - to be no later than 30 days before the proposed change and it should be signed by both the PI and the Authorized Organizational Official. And if you do fail to obtain prior approval, it could result in disallowance of cost or more serious actions by NIH.

Q: **If a protocol is expired (not suspended) and the PI halts work, animals are moved to a holding protocol until approval is secured, would this be reportable?**
A: No those are two separate situations. Suspension requires a convened meeting and a majority vote of the members present - whereas an expiration of a protocol, we understand in some circumstances - protocol may expire. As long as the animal work does not continue - that is not the same as a suspension - it is just an inactivity period.

Q: Our next question – for clarification - **if an NIH protocol (note: the questioner means IACUC protocol) expires, no funds from that grant can be utilized until the renewal protocol is approved by the IACUC, i.e., no funds for salary, et cetera?**
A: No funds for the animal activities – that would include anyone doing technical work associated with the animals or anyone who is associated with the animal activities –

supplies, anything like that could not be charged to the grant during the period of time when there was lack of an approved IACUC protocol.

Q: Next question. **In the case that a portion of a protocol is suspended – not the entire protocol – by the IACUC, is the IACUC supposed to report that to OLAW?**
A: Yes.

Moderator: Sorry for the delay. I was trying to read a question but there is only a portion of the question here so let me go onto another question.

Q: The question is, as follows**: Our institution guarantees congruence between what was reviewed by the IACUC in an animal protocol and what was written in a grant application by asking the PI to declare that all animal work in the grant is described in the IACUC protocols. If the PI is incorrect, is the institution at risk?**
A: Well, the answer is yes. PHS Policy and NIH Grants Policy statement - Part 2, Terms and Conditions - require the institution to verify before award -that the IACUC has reviewed and approved the components of the grant applications and contract proposals related to the use of animals. Institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application proposal. Institutions are free to devise any mechanism to accomplish this end. One method to prevent inconsistency between the information submitted to the PHS and that on the IACUC protocol is to implement a procedure for direct comparison. Some institutions have delegated this responsibility to a particular office or position such as the Sponsored Projects or a Compliance Office - others ask the departmental chairs to verify the consistency.

Q: Our next question - **is work on an expired protocol or initiation of work without approval reportable - if this occurs on a privately funded protocol and these noncompliances are not specified as reporting requirements in your institution's Assurance?**
A: OLAW requires reporting when it is related to PHS funded activities. We would not expect - necessarily - to hear concerning the situation that was described. If it is a funded activity, either from NIH, FDA, CDC - as a contract, grant, or cooperative agreement - under those circumstances - we would definitely need to have a report from the institution.

Q: Another question - again - there seems to be, perhaps, some confusion between the expiration of a protocol. This question asks - **If a protocol expires, animal work ceases and no NIH funds are used for *per diem*, is reporting needed?**
A: Reporting would not be needed under those circumstances. As I said before - if a protocol expires - the grant is not charged - and no animal activity occurs - that would <u>not</u> be a reportable event.

Q: Our next question - **Is there a requirement that all grants have their own IACUC protocol?**

A: No, there is no requirement that each grant have its own protocol. The institution has flexibility on whether there is a one-to-one relationship or not.

Q: Next - **In recent years have any institutions had to return funds because terms and conditions were not upheld?**
A: Yes….incidents. (**Moderator:** We're having some technical problem here. Hopefully, Dr. Brown will be back with you in a second.) The question was: **In recent years, have any institutions had to refund because terms and conditions were not upheld?**
A: Yes - since the Notice was issued in the NIH Guide for Grants and Contracts - we've had a number of incidents reported to OLAW and to the NIH funding component. In all of these, the circumstances are reviewed by OLAW and the funding component and the institution is instructed as to whether the funds will need to be returned. OPERA will work with the NIH funding component when the situation involves grant awards from multiple NIH funding components.

Q: This question relates to - sort of - some definitions. **What type of animal activities are likely to be considered a change in scope and require prior approval from the NIH Grants Management Officer?**
A: Examples of animal activities would include substitution of one animal model for another - and I mentioned this before - changing from a rat model to a mouse model; shift of research emphasis from one disease to another; new technology; transfer of animal activities through a third party, though a consortium agreement or a contract. And you can find more information about changes in scope on the NIH Website, The NIH Grants Policy section on prior approval requirements (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm).

Q: This next question is about timing. **Is there a standard time frame in which grants must respond to requests for preapproval of scope changes?** I'm not quite sure by the words there - its not clear to me - if it's the time frame for the institution to report or the time frame for some response to come back from NIH?
A. Well, I do know that NIH Grants Policy Statement does say that prior approval must be made in writing and it must be done 30 days before the proposed change is going to start. So the expectation from the NIH grants staff would be that the PI and the Authorized Organizational Official let the Grants Management Officer know at least 30 days before they're going to start this new activity whether its animals or some other change in the original scope of the grant.

Q: Thank you. The next question - concerning expired protocols. **May *per diem* charges be charged to Federal grants?** Again this relates to the question of funds being expended to maintain animals during that period of time.
A: During the time of a suspension or during an expired protocol, the grant cannot be charged. The institution is responsible. If the animal activities are expected to resume at a later time - the institution is expected to absorb those costs during that period of either a suspension or expiration and then at the time of reinstitution of animal activities under an approved protocol - at that time, the institution could potentially request funds - but as I

said before - its done on a case-by-case basis - and there has to be a legitimate reason as to why the situation has occurred - that the protocol was suspended. As I said - we don't want the animals to be euthanized but we also don't expect that the animals should be - as I said - euthanized - but they should be maintained during that period of time.

Q: Next question relates to possible impact on PIs as result of some of the materials we've been discussing today. **If an institution self-reports and is required to report the PHS grant involved in a violation, has the institution then affected the PI's future ability to obtain funding?**
A: I think this would depend on the seriousness of the circumstances on a case-by-case basis.
(Moderator: I apologize for the technical glitch that arose, there.)

Q: The next question. **Has there has ever been a situation in which funds recovered would have been less than the cost of the staff used to do so?** That is has NIH ever let the institution retain the funds because it was less expensive to not carry on the reporting process.
A: I am not familiar with the level of detail that's being asked in the question. As I said - its really up to the Grants Management Officer to make a determination as to the effort required and many of the recent cases that we're aware of have involved a sizeable amount of funds involved and in those cases - the determination comes down to how many animals were involved and what was the staff time involved and there's a formula used to determine how much funds need to be returned.

Q: Next question - **If there was an unapproved procedure performed on an animal, how does this affect the charges for daily *per diem* and other approved procedures?**
A: It should not affect anything other than the actual activity that was unapproved. If that was charged to the grant - that is the aspect that would be looked at in terms of return of funds. The other approved activities would be able to be done and they should not be impacted by the situation.

Q: The next question relates to some information that was on the slides and the duration of the Domestic Assurances vs. Foreign Assurances. It says that one of the slides indicated that Domestic Assurances are approved for four years and Foreign Assurances for five years**. Isn't this information reversed?** - is the question.
A: No. That's correct. At this time, Domestic Assurances are approved for up to four years. There may be some that are actually less than that timeframe. Foreign Assurances are approved for periods up to five years.

Q: This question goes back to an earlier one - in that an institution's Assurance indicates that all noncompliance must be reported to OLAW. However, we were told a few moments ago that only issues needed to be reported to OLAW - if the noncompliance was funded by a PHS agency. So the question is - **if the Assurance says that any problem that ever arises will be reported if it is a non PHS funded issue, does it still need to be reported because of that statement in the Assurance document?**

A: We would expect whatever was agreed to in the Assurance document to be the expectation of the report. Many institutions do also self-report other noncompliance just to show their good stewardship of all of their research activities.

Q: OK, the next one relates to timing. **Is the protocol considered expired if it is under review by the IACUC when the expiration has gone by?**
A: That would be an expired protocol. Protocols are approved for up to three years, so when you hit the three year expiration date, the protocol has now expired.

Q: The next one also relates to timing. **Protocols are approved after grant award. How much tweaking is allowed on the animal protocol after the award is made - without reporting?** So it sounds again as if they are saying that at the time of the award - work had started without IACUC approval. Dr. Brown? Ms. Morgan?
A: Are they asking about a change in scope? That they've amended something - you think? If we're talking about a change in scope - then you're adding additional portions to the protocol and then that would need to be reviewed and approved before that work is started. I guess I'm not quite clear on that question.
A: I'm interpreting it to mean that the protocol was approved after the grant award and I'm assuming - I don't know if they mean the award when they received notice that the award would come through - or actually the starting of the award itself - but - I think - the clarifying point here again is that if the IACUC approval had not been granted, then no animal work may begin until that granting of approval has occurred, whether or not there's funding available for that work to occur. Would you concur?
A: Yes - the circumstances are that many times at the end of the Federal fiscal year, NIH issues notices of grant awards to institutions that allows them to begin the work, but it may be a restricted award in that the animal activities cannot begin until the IACUC approval has occurred. Under those circumstances, activities that are non animal could begin under that restricted award, but the animal activities themselves would be restricted until IACUC approval had occurred.

Q: Next question - **If the IACUC suspends a person - not an activity - is this reportable to OLAW?**
A: Yes.

Q: **Can a researcher publish or present data collected during a lapse in animal activity approval?**
A: It would be strongly discouraged if it was intended to be NIH-funded research - for either data to be released or presented if it had not been done under the auspices of IACUC approval.
A: I think in this situation, we also need to recognize that many journals now request guarantee that - in fact - all the work has been reviewed and approved by an appropriate IACUC, so that would probably come into play as well.

Q: Next question. **During a suspension or expiration of a protocol, can research continue with non PHS funds, for example state funds?**
A: That would be determined based on the requirements of the state funding agency and

that - I would also say - any other funding organization may have their own requirements for approval. So you need to be familiar for what are the requirements for that individual funding organization. Say the National Heart Foundation or - a foundation of some sort - you would need to be familiar with what their requirements are. I would be surprised if they would want to allow animal activities to continue without IACUC approval.
A: Also, if it were a covered species, they would be required to have IACUC approval according to USDA regulations. So it is not likely that any work would be done - should be done on an animal activity without an IACUC approval.

Q: Two questions here that are related. First - **In the case of a reportable event to OLAW, what triggers mandatory reporting to the funding agency?** - and in the second question - **Are significant changes to animal protocols the same as in change of the scope of a grant?**
A: I'll take the second question first. Are significant changes to animal protocols the same as the change in the scope of a grant? No - not necessarily. Examples of changes to a protocol that OLAW considers to be significant include changes in the objectives of the study, changing from non survival to survival surgery, changes that would result in either greater discomfort or greater degree of invasiveness to the animal, changes in the species or in the approximate number of the animals used, changing the principle investigator changing anesthetic agents or analgesics, change in the method of euthanasia and change in the duration, frequency, or number of procedures performed on an animal. Those are all examples of significant changes to an IACUC protocol. Of these, the ones we would most likely think would meet the definition of change in scope to a grant would be change in the objectives of a study, change from non survival to survival surgery, change in the species, and change in the Principle Investigator. Those all we would encourage you to contact the Grants Management Officer and submit those as a change in scope notification. When in doubt - as I said - please contact the Grants Management Officer and the Program Official for the grant award.

Q. Next question. **Is there any hope that an activity cycle of a protocol - three years - will be changed to match that of an RO1 or other NIH grants, which are five years in length?**
A: At this time, there's no plan for that to happen that we're aware of.

Q: **A small start-up business had an Inter-Institutional Assurance with two organizations. The small business then performs animal work at a third institution. Who is responsible for obtaining an Inter-Institutional Assurance with the new site?**
A: You're talking about Inter-Institutional Assurances, so the grantee is doing the work at two performance sites - then he would have two Inter-Institutional Assurances - one with each site. If there was a third site added, then you would need to have a third Inter-Institutional Assurance added and the investigator - the PI on the grant - would be responsible to go back to the Grants Management Official and the Program Official if they are adding a third performance site and OLAW would negotiate an Inter-Institutional Assurance with the third site.

Q: We have a few more questions. **Would a strain change - for example - meet the threshold for reporting?**
A: No, because that is not a typical example of a significant change to an animal study protocol.

Moderator: Okay, and with that we seem to have ended the questions that are coming in to us here. We hope we have answered all of your questions in a way that is meaningful and helpful. We are certainly most grateful to each for taking time from your busy schedules to allow OLAW to explain its position on these issues of importance to Assured institutions. We hope that you will send your comments and suggestions about this and future seminars to the OLAW e-mail box (olaw@od.nih.gov) - which can be found at the bottom of the OLAW webpage (http://olaw.nih.gov). The link is "OLAW help." The email address can also be found in the information you received confirming your registration. We're especially interested in hearing from you about suggestions for future presentations. We are currently developing topics for the presentations during the year 2010 and would greatly appreciate any suggestion that you may have. Thank you very much and we wish you the very best of the holiday season. END