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Wildlife Research Permits: What IACUCs Need to Know

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Slide 1 (Wildlife Research Permits: What IACUCs Need to Know)

>> *Swapna:* Today is March 30, 2017. I am Dr. Swapna Mohan from the Division of Policy and Education, OLAW. Before we begin with our webinar today, on behalf of everyone here at OLAW, I would like to wish our dear friend and colleague Susan Silk on her birthday this week: Happy birthday, Susan! [Laughter].

And now, it's my great pleasure to welcome our speaker for today, Ellen Paul from the [Ornithological Council](#), where she has been the executive director since 1998. The Ornithological Council is a consortium of 11 societies of ornithologists that spans the Western hemisphere and the members of those societies study birds everywhere in the world. Her role also includes assisting individual researchers with permit requirements, obtaining expertise for IACUCs, and working with other scientific societies whose members study other taxa. Ellen earned her law degree from Villanova University, and a master's degree in conservation biology from the University of Maryland. She is the co-editor of the [Guidelines to the Use of Wild Birds in Research](#) and has also co-authored the Model Wildlife Protocol.

Also with us today is Dr. Axel Wolff, Director of the Division of Compliance [Oversight], OLAW. They are going to talk today about wildlife research permits and what IACUCs need to know. Welcome to OLAW, Ellen.

Slide 2 (Permits to Study Wildlife)

>> *Ellen:* Thank you very much. And we can get started with the first slide. This is an antique permit, issued to a very famous biologist named Frederick Lincoln and this is a good illustration of one of the earliest permits. Today almost every form of ornithological research and most of the research involving other taxa requires at least one permit.

Slide 3 (Federal Permits for Wildlife Research Within the United States)

To go over the major research permits for wildlife research conducted within the United States, they are: the Migratory Bird Treaty Act, the Endangered Species Act, the Bald and

Golden Eagle Protection Act, the Marine Mammal Protection Act, and there are other non-regulatory restrictions such as the Airborne Hunting Act.

Slide 4 (Purpose of Laws Implemented Through These Permits)

The purpose of laws that are implemented through permits is primarily to protect wildlife populations by placing a limit on the number of animals that can be studied. And that limit is based on the population status of that species in that place. Place is a flexible concept because it depends on the species. Some species have very narrow or small ranges, others are nationwide.

So when you try to implement these limits, you have to consider each species to be studied. For birds, the estimation of population sizes, and as well as population estimates for any species listed under the Endangered Species Act, these estimates are derived from a wide variety of surveys and monitoring projects. For other taxa such as amphibians, invertebrates and so on, there may not be any population size estimates, except for hunted species. For hunted species we have an enormous number of very fine scale surveys, because hunting limits are set anew each year.

However, for non-hunted species, there is simply not enough funding to monitor wildlife populations other than those that are expressly protected under these laws. But the key point to be made here is that there are multiple layers of protection for wildlife populations. And those limits are based on the knowledge and expertise of the agencies charged with implementing those laws.

Slide 5 (Lethal Take: Reality Check)

Now a big reality check: in most studies there is no lethal take or permanent removal of animals from the wild. Permanent removal means one of two things, either the animals are taken live and then put into a captive situation to be studied or they are euthanized and studied in a variety of ways, most typically for museum based collections, although there are various reasons for lethal take of individuals such as toxicology studies, migration studies and so on.

I also want to note that there is occasionally some accidental mortality associated with wildlife studies. It could be one of the study animals or it could be of another animal that happens to be in the area. Accidents do happen. These numbers are extremely low. We have some studies of certain types of methodologies that show the extent of take and it is very, very low. It's almost zero for the purposes of population biology.

In all studies involving removal of individuals from the wild, the number of individuals taken is exceedingly small. Now it's also possible that a study may affect reproductive success, but many things affect reproductive success. So the likelihood that this very brief interaction that the researcher has with an individual or group of individuals is not likely to have any lasting effect, even in that particular breeding season, much less over the lifetime of the individual.

Generally, the impact associated with wildlife research is considered compensatory as opposed to additive. What this means is that the numbers are within the range of mortality that would be expected to occur from all causes.

Slide 6 (Draft USFWS Policy, 1997)

To underscore this point, in 1997, the US Fish & Wildlife Service, drafted a policy with regard to the Migratory Bird Treaty Act. In this policy they stated that “The numbers of birds collected in the United States for scientific study are extremely low compared with other categories of human-related activities and apparently have had no obvious or significant impact on species or local populations.” As of March 2017, this policy has not yet been finalized, it is still in draft.

Slide 6 (Top 10, All MBTA Species (1998-2002))

To find out how many birds are removed from the population under Migratory Bird Treaty Act permits, I requested data through the Freedom of Information Act for a 5 year period from 1998 to 2002. I counted the numbers for each species taken across all of the US Fish & Wildlife Service regions, and totaled them up. You can see that the numbers for lethal take are extremely low. Only the top 2 lines on this table show over 100 individuals taken and these are species with populations in the millions or tens of millions.

Below that are numbers in the tens of birds. In some cases, only 1 or 2 birds being taken of a given species. So you can see for yourself that these numbers are extremely low and there is no way that these numbers will have any impact on any populations, unless they were all taken from one extremely small population. But as you will see later, there are other permits, or permit conditions, that will prevent that from happening.

Slide 8 (Migratory Bird Treaty Act (MBTA))

So the basics of the Migratory Bird Treaty Act. It's 101 years old this year. It includes all native species. The name is actually misleading, and this is a very important point for IACUCs and researchers. It has nothing to do with actual migration of birds, it is a historical reference to the treaty itself, first signed with the United Kingdom, then later Mexico, Japan, and what was the Soviet Union. There is an official list of species that are protected under this law. It does change periodically [last updated in 2013], but as of 2017 it covers 1026 species. This is an official list that is published and updated by the US Fish & Wildlife Service.

The reason I say that this is a key point for IACUCs and researchers is that there are researchers, usually people who have less experience with research on wild birds, who mistakenly think that the term migratory refers to actual migration. And they believe that because the species they want to study doesn't migrate, they don't need a permit. That is NOT correct.

And if the IACUC is told that no permit is needed for a protocol that involves any form of capture of wild birds in the United States, the IACUC should question this statement. Tell the researchers to call the Ornithological Council for clarification on the MBTA.

Slide 9 (50 CFR § 21.11 General Permit Requirements)

The general provisions of the MBTA: the MBTA is implemented through a regulation in the Code of Federal Regulations. It says "No person may take, possess, import, export, transport, sell, purchase, barter, or offer for sale, purchase, or barter, any migratory bird, or the parts, nests, or eggs of such bird except as may be permitted under the terms of a valid permit..." The translation here is that you need a permit to do anything except to observe, use play back, do surveys or monitoring. If you need to capture a bird, you need a permit.

Slide 10 (Important Exception)

There is an important exception in the regulations, and that is certain kinds of institutions may acquire by gift or purchase, birds that are protected under this law, or their parts, their nests and their eggs without a permit. These are public educational or scientific institutions. This applies to permits that are issued to institutions, not to individual researchers at those institutions. So if your researcher has a permit that has been issued to the entire department, or to the university, then this exception could apply. But if it's issued in their own name, it would not apply.

It's also important to note that the term public is not used in the commonly used sense. The regulatory definition of public, as used here, is an institution that is open to the general public and either established, maintained, and operated as a governmental service or that is privately endowed and organized but not operated for profit. So it's actually a wide number of institutions.

Slide 11 (MBTA Permits)

There are different types of MBTA permits that are used for research. The first is scientific collecting, and that includes permanent removal of an individual from the population. That permit could be used to keep the bird alive to study it in captivity or it could be the take of a bird through euthanasia for various types of studies. It also includes the take of blood, feather, or tissues but only if the bird is not also being marked in some manner, such as a bird band. Scientific collecting also includes salvage of dead birds. These permits are issued by the regional offices of US Fish & Wildlife Service.

There is a separate permit needed to band or mark a bird. There are various ways to mark birds. These permits can also include blood and feather sampling if you request it. And as long as the bird is also going to be marked or banded. This permit also includes salvage of dead birds. These permits are issued by the US Geological Survey's Bird Banding Lab. Now I should note that the reason it's important that these permits include salvage is that salvaged birds are donated to museums and teaching institutions, so it

helps to further reduce the number of birds that museums and universities have to take from the wild for their studies.

There are also import and export permits issued by the US Fish & Wildlife Service. There are also special purpose permits for activities that are not covered by other specific permit types. For example, if you want to move nests or translocate eggs and young birds.

An important thing to note is that, under this regulation, the activity that is permitted may continue even if the permit expires so long as the permittee has applied for renewal at least 30 days prior to the expiration date. This is important for two reasons. The first is that we are seeing a reduction in staff in these offices, which means it will take longer to get these permits issued. We advise people to start applying for their permits or renewals in February, allowing 90 days, which is quite a while for a permit to be renewed. But with the worsening staffing shortages, it might take longer. So if somebody's permit has expired – and here we're just talking about MBTA permits – as long as they have applied for renewal at least 30 days prior to expiration, under this law, they may continue to do the work that is authorized under that permit.

The other key point that I want to make here is that we have a mismatch in terminology. It leads to researchers sometimes mistakenly thinking that they do not need a permit. Here that term is "scientific collecting". Researchers use that term to mean the permanent removal of an individual from the wild, either for study in captivity or, more commonly, via lethal take. The federal and state agencies use that same term to mean collecting anything that is part of a bird; feathers that you pick up from the ground, or nests that are no longer being used. And so we sometimes get researchers, especially those who are new to the field, thinking that since they are not taking a bird from the wild, they don't need a permit. That is entirely wrong and they do need a permit. If somebody is doing so without the permits, question them and suggest they contact the Ornithological Council. We work with individual researchers every day of the week to help prevent this kind of problem. We also have publications on our website as well and these can also answer any questions that you might have on these regulations.

Slide 12 (MBTA & ESA Permits: Euthanasia)

One thing that is important to note if you are on an IACUC, because it may impact the review of your protocol, is that neither Migratory Bird Treaty Act nor Endangered Species Act permits allow euthanasia except, obviously for lethal take under the kinds of permits that are needed for scientific research. That conflicts with a requirement in the Animal Welfare Act Regulations that says that "Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure."

The Ornithological Council has discussed this problem with the US Fish & Wildlife Service. They recognize the problem. However, they have suggested that we wait until the issue of rapid cardiac compression – which was formerly known as thoracic compression – is

resolved in terms of the [AVMA Guidelines for Euthanasia](#) [PDF]. In 2017 a research paper has been accepted, and should be published soon. While that is not a guarantee that the AVMA will reclassify this method, we hope that will be the outcome. Once this method is reclassified, we will ask the US Fish & Wildlife Service to include a condition on the permits that does allow for euthanasia.

Slide 13 (Endangered Species Act (ESA))

We now move to the Endangered Species Act which can cover all taxa of wildlife and plants. It was enacted in 1973. As of 2017, there are 81 species in the United States that are listed as endangered, 18 that are listed as threatened. Endangered species are given a higher degree of protection than are threatened species. There are also 214 species outside of the United States that are listed as endangered, and 17 outside the United States that are listed as threatened.

There are some bird species that are listed as both Migratory Bird Treaty Act and ESA, some that are listed both as MBTA and CITES, which we'll get to soon, and some that are all three. The US Fish & Wildlife Service has a procedure for issuing single permits in these cases.

Slide 14 (ESA Permits)

The Endangered Species Act permits that are needed for research are called recovery permits. In some circumstances, a researcher may need an Endangered Species Act permit even if they are not studying an endangered species, because the research methods may impact an endangered species in the area. As of 2017 there is no official guidance on this topic.

It is actually a problem because the type of permit needed for what is called "incidental take", meaning incidental to some otherwise lawful activity, has to be accompanied by a habitat protection plan. Clearly, a researcher who does not own the land can do nothing to conserve habitat. So what is needed is an in-between permit type. The Ornithological Council is talking with the US Fish & Wildlife Service about this problem and we are hoping that they will come up with some other permit type that will accommodate the problem.

Meanwhile, the US Bird Banding Lab has offered some unofficial guidance, which has so far been working well. Basically, they say that "Authorization to capture or mark species designated as endangered or threatened is granted only to persons engaged in research dealing with those species." If you band in a place where you have or are likely to catch endangered or threatened species, you should obtain an endangered species permit. If the applicant's research project is valid and feasible, and the comments received are generally favorable, a permit will be issued – here they mean a banding permit – to mark specific endangered species.

What they are basically saying is that we recognize this problem, and here's how we handle it. This is just their process, it has never been approved by the Division of

Endangered Species. So as of 2017, this is an open question. And the interesting thing from your point of view, is that the question only comes up if you happen to be studying a species for which a permit is needed. If you are studying a non-endangered mammal or amphibian, you have no interaction with the US Fish & Wildlife Service at all, and unless the researcher goes to US Fish & Wildlife Service if they happen to spot an endangered species in their area. I can assure you no one ever does that.

Slide 15 (Bald and Golden Eagle Protection Act)

The next type of permit is the Bald and Golden Eagle Protection Act, it's very straightforward. You need a permit if you want to do any of these things: shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb a bald eagle or a golden eagle. "Disturb" has a fairly broad definition. Here it means to agitate or bother a bald or golden eagle to a degree that causes, or is likely to cause based on the best scientific information available, injury to an eagle or a decrease in productivity, by substantially interfering with normal breeding, feeding, or sheltering behavior, or nest abandonment, by substantially interfering with normal breeding, feeding, or sheltering behavior.

Slide 16 (Marine Mammal Protection Act (MMPA))

The final federal permit type that I would like to discuss today is the Marine Mammal Protection Act. It was enacted in 1972. Jurisdiction is split between 2 agencies: the US Fish & Wildlife Service is responsible for manatees, polar bears, sea otters, walrus, and dugongs; and the National Oceanic and Atmospheric Administration (NOAA) handles Cetacea (which are whales and porpoises), pinnipedia, other than walrus (meaning, seals and sea lions).

Slide 17 (MMPA: USFWS Permits (IHA))

The [US] Fish & Wildlife Service has an Incidental Harassment Authorization, which is a very informal process. It allows for harassment that is incidental to otherwise lawful activity, if it's involving a small number of animals and the take is limited to harassment. That is, if you are not going to capture anything, mark anything, there will be no experimental manipulations of any kind, no biopsies, and so on. These are available for up to 1 year in duration. They do require publication in the Federal Register so that the public can comment on them, and then if they are authorized they are issued within 45 days of close of the public comment period. That's the desired length of time, but with staffing shortages, these deadlines don't hold very well anymore.

Slide 18 (MMPA: USFWS Permits)

The [US] Fish & Wildlife permits that are issued under the Marine Mammal Protection Act are covered by the Code of Federal Regulations. They are scientific research permits that are based on the need to further a bona fide and necessary or desirable scientific purpose, taking into account the benefits anticipated to be derived from the scientific research contemplated and the effect of the proposed taking or importation on the population stock and the marine ecosystem. What this means is that this permit is issued for the purpose of allowing research but also for the purpose of protecting the population.

Slide 19 (MMPA: NOAA Permits)

The permits issued by NOAA for the Marine Mammal Protection Act have 2 levels. The first one is a Letter of Confirmation (LOC). This is for low level harassment, called Level B harassment. These are activities such as photo-identification, behavioral observations, aerial surveys, and passive acoustics, which simply means listening for sound rather than trying to evoke a response to an auditory stimulus. It is a simpler and faster process than applying for a regular research permit and NOAA suggests that you apply 4-6 months before the start of the proposed fieldwork.

Slide 20 (MMPA: NOAA Permits. Not Authorized by LOC)

There are certain things that cannot be authorized under a Letter of Confirmation. These are pinniped rookeries or even observations. That's because these animals are very sensitive to having other mammals walking among them, because rookeries are where they have their young. Other activities are import and export of marine mammals or their parts, and research such as tagging or biopsy sampling that would exceed Level B harassment.

Slide 21 (MMPA: NOAA Permits)

So for those activities, the second level of a NOAA permit is called a Level A harassment, where there is potential for injury to a marine mammal or marine mammal stock in the wild. The time required to get one of these permits is longer. It is at least 6 months in advance of the intended research start date. All of these permits are for species that are not also listed as endangered.

Slide 22 (MMPA: NOAA)

NOAA will often do an environmental assessment or sometimes even a full environmental impact statement if the research is subject of public controversy based on potential consequences (underwater sonar testing is a very good example), or that have uncertain environmental impacts or unknown risks, or that may result in cumulatively significant impacts (such as, if they may impact large number of animals), or that may have an adverse effect upon endangered or threatened species or their habitats. These are not endangered species permits but only if the activity may also impact endangered species that happen to be present, and then NOAA may do these assessments.

Slide 23 (MMPA: ESA-listed Species)

Now, we have Marine Mammal Protection Act listed species that are also listed on the Endangered Species Act. For both US Fish & Wildlife Service and NOAA, the application form used is the same, but additional scrutiny is given by the agency. NOAA will take as much as a full year to issue such permits.

Slide 24 (Place-based Permits: Federal)

In addition to species-based permits, almost all research requires place-based permits.

At the federal level, a permit is required for work in any federally managed public land, including national parks, national wildlife refuges, national forests, grasslands, and many other types. The exception is the Bureau of Land Management (BLM) but it isn't that you don't need a permit from BLM. It's just that as of 2017, the BLM has a very limited system of permits that are used only for their most sensitive lands.

Most agencies have an informal authorization system for research that will have limited impact. So if you just want to go out and mist net birds and put bands on them, odds are pretty good that once you ask them if you need a permit to work in that park or work in that refuge, they will write you a letter saying that you don't. They just need to know where you are going and when you are going to be there. That's for your safety and also to prevent user conflicts, and to be sure that what you are doing doesn't interfere with their management activities.

But the permit system, the place based-permit system, assuming that you need a permit, is a very complex system and it requires a rigorous analysis by the agency.

Slide 25 (Place-based Permits: States)

Every state requires a place-based permit as well, but the purposes for these are somewhat different. Their primary purpose is to foster public safety, to limit damage to natural resources, and to prevent user conflict, and this of course is incredibly important during hunting season. The states will issue the permits and require that you give them advance notice every time you are planning to go out, and the time and location where you will be.

State agencies also analyze the impact of your activity on the wildlife. And this is particularly true for mammals and other taxa, other than birds. That's because they recognize that, for birds, you already have a MBTA permit issued by the federal agency. They are not likely to second-guess that federal permit as to be concerned about species for which no federal permits are required.

Slide 26 (Place-based Permits: Private Property)

Finally, researchers, like everyone else, require permission to enter and conduct research activities on private property.

Slide 27 (Federal Permits, Import/Export)

There are a number of permits that are issued to import and export animals, whether live animals or specimens, or parts of animals. The vast majority of research imports and exports are specimens and samples, not live animals. These include all of the permits that we have already gone over. In addition, there are the Wild Bird Conservation Act, the Convention on International Trade in Endangered Species (CITES), the Lacey Act (which is enforcement of foreign laws via permits from those countries), and APHIS has a series of permits that are issued for all birds, live or dead, and some mammals. So let's go through a few of those.

There are also, by the way, some additional non-permit requirements, such as the Nagoya Protocol, which is an international treaty intended to protect intellectual property rights. The US has never signed it so it's not clear how it will be implemented in the United States at this point. However, because it is a law in other countries, according to the Lacey Act, we have to enforce it in some manner.

Slide 28 (Imports / Exports)

For imports and exports, there are 2 basic issues. The first one is enforcement of US laws, international treaties, and foreign laws intended to protect populations. So if you are going to another country and you want to bring back wildlife samples or specimens back to your museum, you must have permits issued by the government of the country where you are working. You must also have an export permit from those countries. Often, those are combined on one permit, but sometimes they are not. It's very important that researchers know what their permits say.

The second purpose of an import or export permit is to prevent the introduction of non-native wildlife (under the Lacey Act) and pathogens (under the Animal Health Protection Act).

Slide 29 (Lacey Act)

The Lacey Act is a fairly old statute, going back to the early 1900s. It has been amended several times and it now does 3 different things. First, it prohibits import, except by permit, of listed non-native species that could be "injurious" to the interests of agriculture, horticulture, wildlife, or wildlife resources. As of 2017, there are only 3 bird species (and their eggs) that are listed and very few other animals.

The second thing it does is to protect the laws of other countries that are intended to protect wildlife populations in those countries by making it a crime to import in violation of the laws of that other country. So when somebody is at the US border, they need not only the permits that are required by the United States for import, but also permits that are required by the other country for having taken the wildlife and for exporting the wildlife. The Lacey Act also has a very rudimentary provision regarding humane transport under which the US Fish & Wildlife Service has adopted the International Air Transport Association (IATA) regulations for air transport of live animals.

Slide 30 (Convention on International Trade in Endangered Species (CITES))

There are several major statutes here that have import/export requirements that we have already gone through. So I am going to focus on the ones we haven't talked about yet. The first is the Convention on International Trade in Endangered Species. It went into force in 1977, and the United States is a member. It controls the import and export of listed species. It does not have anything to do with what happens once they are legally inside the United States. A species can be listed under the Endangered Species Act and

CITES and if they are the US Fish & Wildlife Service has a procedure for issuing a single permit for the both.

Slide 31 (CITES Basics)

The basics of CITES is that it has to involve international trade. It has nothing to do with what goes on within a country's borders. The type of permit you need and the procedures that are needed to get it and use it, depends on whether the species is listed on Appendix I, II, or III. Appendix I lists the most imperiled species, and requires both import and export permits. Appendix II lists somewhat less imperiled species, and requires only an export permit. Appendix III are species that are listed only in specific countries, and require only an export permit from those countries. Scientific institutions can register for exchanges with other registered institutions; and in those cases, no permits are needed.

Slide 32 (Wild Bird Conservation Act)

Finally, there's the Wild Bird Conservation Act and this is actually the one that most IACUCs will probably want to know about because it covers live birds. It covers all of the bird species listed under CITES except for the common parakeet, or budgie as some people call it, cockatiels, and 9 other bird families. Permits can be issued for scientific research. If you haven't heard about it, the reason is probably because it is far easier and more efficient to study them in the country of origin, particularly if the study involves questions that are best addressed in the wild. The amount of effort and money it takes to import live birds, especially in this time of highly pathogenic avian influenza, is extremely difficult. We actually advise people to study birds in their country of origin rather than try to import live birds.

Slide 33 (State Permits)

In addition to all of the federal permits, every single state has some permit requirement. Some are very basic, while some such as California are highly restrictive. With state permits, generally one permit covers all activities and they are usually called "scientific collecting". Again, I want to highlight this mismatch in terminology. Scientists do not use that term so broadly. Therefore, scientists might not realize that they require permits because they are not doing collection in the scientific sense. The Ornithological Council has the permit regulations of all 50 states on our website. There are some states that do not require banding permits if the only marking to be used is the federal bird band.

State laws and permits can be of concern to an IACUC for another reason, and that is because they almost always prohibit release of wild animals that have been taken into captivity for research. This can be a problem if you are following the ILAR *Guide* [[Guide for the Care and Use of Laboratory Animals](#)] because it specifies, "When species are removed from the wild, the protocol should include plans for either a return to their habitat or their final disposition, as appropriate." When you are talking about a healthy individual, you don't necessarily think of euthanasia as appropriate. But if the permit does not allow return to the wild, then euthanasia is often unfortunately the only choice.

Slide 34 (Keep Your Faculty and Students Out of Jail!)

It is not really the job of the IACUC to keep the faculty and students out of jail, but it boils down to a practical question. The researcher can't control the timing of the issuance of permits, so permits may not be in hand at the time the protocol is reviewed. So the question is, should an IACUC require that the researcher submit copies of the permits, once issued?

Slide 35 (Practical Issues)

OLAW does not usually recommend the conditional approval of animal use protocols. You may get the protocol approved by the IACUC but by law, you cannot start the work until you have the permit. Some institutions require the investigator to provide all permits prior to, or at the time of protocol review, or prior to approval, which may not be practical. You may not get the permit until a few days prior to the time that work is supposed to begin. For wildlife research this time is not flexible. Research is generally dictated by the season, especially for migratory species. So are you supposed to just set the protocol aside and wait?

Slide 36 (Best Practice)

The best practice to resolve this practical dilemma is for the researcher to submit the protocol, listing the required permits and giving the status for each; whether you have the permit, have applied, or will apply. If the IACUC finds the protocol to be otherwise acceptable, the best practice for the IACUC would be to indicate in writing that the protocol has been approved but that the animal work is not to begin until required permits are obtained. And according to OLAW, this practice is acceptable.

>>Axel: Yes, and let me add that OLAW recommends this practice. That is, IACUCs can review protocols, and if it is appropriate to do so, approve them. However, the work cannot begin until the permits are received. I wouldn't necessarily call this a conditional approval, because while the researchers know that they can't touch the animals without a permit, the protocol itself has been approved by the IACUC. We have similar situations where an institution gets grant money but they cannot begin any animal work until an IACUC approval is obtained.

Slide 37 (Reality Check)

>>Ellen: To put a fine point on this, it is a federal offense to conduct research involving activities that would require a federal permit if the researcher does not have a valid permit. Depending on the statute, there are civil and criminal penalties, including fines and even incarceration and at the very least, it is likely that the researcher will be ineligible for future permits for some time or even permanently.

Slide 38 (Population-level Impacts: Study Animals)

I'm going to change subjects now and address the issue of population-level impacts on the study animals. This seems to come up in protocol reviews and it may be the source of a little bit of friction. If you read the Animal Welfare Act, the Health Research Extension

Act, the Public Health Service Policy [Policy on Humane Care and Use of Laboratory Animals], the US Government Principles, and the ILAR *Guide*, there is nothing that requires an IACUC to consider the potential population-level impact of wildlife studies. All are silent on this subject. So why are IACUCs delving into this question? Arguably, it could be seen as a corollary of the requirement to use the minimum number of animals necessary to obtain valid results.

>>Axel: OLAW doesn't require IACUCs to review the population level impact of any study. However, in cases of studies on limited secluded populations, the IACUC is well within its rights to question the impact of the research activities on that population.

Slide 39 (Reality: This Inquiry is Likely to be Unproductive)

>>Ellen: Here I would like to do another reality check. This inquiry is likely to have little value. Most field research methods involve no removal of individuals from the wild or will have any lasting impact on survival and reproduction. Moreover, population-level impacts are very difficult to predict. The researcher may not have sufficient knowledge of population sizes and species interactions. There may be no published information and a census, even if possible or practical, will not yield sufficient information. The bottom line, the impacts if any are far too speculative to warrant a review by the IACUC.

Slide 40 (Population Biology, a.k.a. Considerable Uncertainty)

A single census at a given point in time will not produce useful population impact estimates because wild populations can fluctuate widely over seasons and years. You can see that living anywhere in the United States. One day you have no robins, the next day your yard is filled with robins, so which of these represents the population size of American robins? Population sizes can also change for a wide variety of reasons and it would be virtually impossible to attribute a change in population size to a given research protocol, because protocols are typically of short duration and generally involve very few animals.

Furthermore, the IACUC review of these kinds of concerns would also require that the IACUC members have sufficient understanding of quantitative population biology to assess the available data and the time to do the analysis or to review the researcher's assessment or data analysis.

Slide 41 (Permits Protect Populations)

I want to reiterate here that permits protect populations. Population level impacts are difficult to predict. The researcher may not have enough information to even be able to tell you what the impacts are, much less what the population sizes are. The population sizes change for a variety of reasons and it would be impossible to say that this population declined because of a small study that took place for 3 or 5 years. That is the duration of most studies, anywhere from 3 to 5 years.

And the ability of the IACUC to review the researcher's own analyses of population impacts is pretty limited, unless you happen to be a quantitative population biologist. They are also unique to each individual species and each research condition in which the field researcher is working. So the permits are issued by agency staffers who do have knowledge of population status and trends. Permit approval means that the officials have determined that the take needed for the study will not be detrimental to the population or that any population-level impact is justified by the value of the knowledge to be gained.

Remember, the kind of information that we are generating is the kind of information that these agencies use for conservation and management of wildlife. And where multiple permits are issued, the IACUC has even greater guarantee because these permits mean that at least 2 different agencies, generally one at a federal level and the other more local, have considered the potential impacts.

Slide 42 (Other Animals in the Study Area)

Now let's talk about other animals in the study area. Because we are out in the wild, there are other organisms out there. Therefore, there is a potential for research to impact animals not actually used in the study. They may be a part of the population from which the study animals are drawn or they may be other species in the area that may be affected by the researcher's presence or the study methods.

The classic example here would be a mist net. A mist net can catch whatever flies into, not just the species being studied. The researcher may choose to release it without putting a band on it or for other reasons, may put a band on it. But whatever the action, they have now impacted animals other than the ones they are studying in their area of unresolved problem of endangered species permits. Otherwise, the same analysis that I have been going through really applies. Most field research methods involve no removal of individuals from the wild or have no lasting impacts on survival and reproduction.

>>Axel: This is an issue that causes confusion for IACUCs. The issue of bycatch or inadvertent capture of other species should be considered by the IACUC, especially in regard to aquatic species. Often hundreds of extra fish and other water animals not needed for the research are caught and this needs to be addressed in the protocol. OLAW sometimes receives noncompliance reports on this topic. The specific problem is either the capture of species not listed on the protocol and/or the capture of many more target species than approved. Following capture, difficulties may arise with trying to release a large number of animals from traps or nets in a humane and timely fashion to avoid distress or death. From personal experience, when I was mist netting for bats, I caught owls, large tropical moths, and other species that needed to be carefully removed and released. Protocols need to be amended to account for different species or excess numbers of animals captured.

Slide 43 (APHIS Permits)

>>Ellen: Thank you, I'm going to switch now to an entirely different type of federal permit that is APHIS permits. These permits are probably not going to be of major concern to the IACUCs, because while they do cover live animals, it is becoming increasingly rare to import live animals to the United States for research, partly because of the APHIS permits. The purpose of these permits is to prevent the introduction of pathogens that can harm US livestock or agriculture. For birds, there are only 2 at the moment that they are concerned about, and these are Exotic Newcastle Disease (which is actually Velogenic Viscerotropic Newcastle Disease) and any form of highly pathogenic avian influenza (HPAI).

You may be wondering why, since we have had at least 2 outbreaks of HPAI, one currently ongoing in Tennessee. The reality is that we've had bouts of Exotic Newcastle Disease as well. The USDA has imposed a quarantine that prevents movement of animals from the affected areas, and eradicates these poultry barns by depopulation. Once they are convinced that it has been eradicated, they lift the quarantine. So even though we have had incidences of these 2 diseases in the United States, they have been contained and eradicated and so they are still considered to be foreign pathogens.

For mammals the current diseases of concern are Foot and Mouth disease (FMD), Rinderpest (which has been declared eradicated in the wild by the World Health Organization), classical swine fever, African swine fever, swine vesicular disease, and African horse sickness. APHIS regulates birds, plus all ruminants, equids, suidae (which is pigs), and tenrecs.

CDC also regulates imports of animals that carry pathogens, but the pathogens of interest there are those that can be harmful to human health, and there are really very few at the moment.

Slide 44 (USDA Quarantine Station)

Imported birds must go through USDA quarantine and testing. No live birds can be imported from any countries or regions where [highly pathogenic] avian influenza occurs, which is now almost all of Asia, most of Africa, some regions of Mexico, and some parts of Canada. For a short time, Australia as well.

APHIS has what's called an all-in-all-out system. If even one bird tests positive in any one of the tests, the entire import is euthanized. And this is part of the reason that I tell our members that it is far easier and more effective to go to that country and study the birds there. It is becoming increasingly difficult to get these birds into the United States. Moreover, quarantine space is extremely limited. It is logistically very difficult to get quarantine space for live birds. So this is something we highly discourage.

Slide 45 (APHIS: Import of Live Birds)

In addition to the quarantine procedures, the live birds must have veterinary health certificates from a government official of the country of origin. So chances are pretty good they have gone through quarantine and testing at that end as well.

Slide 46 (Specimens and Samples from Birds and Certain Mammals)

Finally, we do need permits for specimens and samples. This is not something that will involve the IACUC unless the samples were taken from live birds, of course. But specimens and samples from birds and certain mammals also require permits from APHIS. It's called an APHIS VS (which stands for Veterinary Services) 16-3 permit. The permit conditions vary depending on the disease condition and the pathogen. Just to give you one example, any bird specimen or sample coming from a country where any form of HPAI is present, must be treated to inactivate the virus using a USDA-approved treatment method.

However, if the bird is coming from a country where Exotic Newcastle [Disease] but not HPAI is present, it can be imported untreated into a USDA-certified Biosafety Level-2 lab. But if the lab is not USDA-certified as Biosafety Level-2, then the import must be treated. The only real concern here of the IACUC would be the protocol for taking these samples from live animals in the wild. I am just focusing on permits related to import here.

Slide 47 (Status of APHIS Rats, Mice, and Birds Regulation)

We're going to switch gears just a little bit here and conclude with some information about the status of the APHIS rats, mice and birds regulation. Nothing to do with permits, but I get this question all the time so we thought it would be a good idea to address it here. You may remember that in 2004, a final rule was issued by APHIS to include rats, mice, and birds that are not bred for use in research in the regulatory definition of animal. Prior to that time they had excluded these taxa. Also in 2004, they issued an advance notice of public rulemaking, which says that they are going to write rules and standards for these taxa. They took public comments; they received over 7,400 comments. In 2011 they issued a Fact Sheet.

Slide 48 (Stakeholder Notice: December 2012)

In 2012 they said that they had begun to revise their own internal documents, and were evaluating implementation issues, especially those pertaining to birds. This involved feasibility issues such as how many entities do we need to inspect, what kind of variation will we find, what type of birds will we find, what types of research facilities, and so on. There was concern at that time about the additional resources and training needed by regulated entities and by animal care personnel.

As of 2017 that situation has not changed. The USDA has been occupied with other federal regulations and there frankly hasn't been much pressure from the animal welfare community and they along with the USDA recognize the problems with the APHIS inspections that birds in captivity are not being inspected by APHIS.

Slide 49 (Let's Talk)

Finally I'm sure many of you have questions about some of the research being done at your institutions. These questions tend to be very specific and not easily applied from one situation to another. So if you or your researchers need help, please contact me directly at the email link [ellen.paul@verizon.net] or phone number [301-986-8568] provided here. I would like to thank OLAW for affording us this opportunity and I look forward to receiving many phone calls and emails from all of you.

>>*Swapna*: Thank you, Ellen. With that we have come to the end of our online seminar on wildlife permits. I would like to remind the listeners, if you have questions for us, you can submit them via the link provided on the OLAW webinars page or by email at olawdpe@mail.nih.gov. Thank you to Ellen Paul and Dr. Axel Wolff for a wonderful talk and I thank all of you for participating in our webinar. Goodbye and thank you for joining us today.

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