Welcome to the University of Washington's Office of Animal Welfare training course for preparation and submission of grants proposing the use of live vertebrate animals. This training course was designed in order to provide you with information on grant related requirements and in order to help you avoid errors that delay the routing of grants and approval of eGC-1s by an Institutional Animal Care and Use Committee (IACUC) member in the Office of Animal Welfare.

The grant review in the Office of Animal Welfare has 2 purposes:

1. to verify that all proposed animal work has IACUC approval, or is pending approval (i.e., complete and accurate paperwork has been submitted to the IACUC but is not yet approved) and
2. to verify that any animal work described in pilot studies and progress reports was properly approved by the IACUC during the period when it was performed.

Although it is the PI's responsibility to provide correct and accurate information both to the Office of Animal Welfare and indeed to the funding agency, the federal and University compliance rules can sometimes be confusing. Guidance is available in grant instructions provided by funding agencies and on the NIH web site, but these are not always easy to find and interpret. Please carefully go through this training module and share it with others in your department who you believe would benefit from having this information (i.e., anyone who is helping process grants).

The Office of Animal Welfare operations have been significantly hampered by the frequent need to individually explain rules and regulations pertinent to grants to grant PI's, their colleagues participating in the grant, those dropping off and picking up grants from our office and non-scientists who have been assigned the responsibility for filling out forms with little or no training to do so.

For these reasons, we have developed this module. It contains information on the topics most often requiring instruction, as well as a section on frequently asked questions.

We sincerely hope that it will be helpful and that your grant's trip through the office will proceed quickly and smoothly.
make sure that the basics are understood. Many people who have been assigned grant preparation and routing duties call our office with little or no background knowledge about animal research. Here are some commonly asked questions (answers to follow):

1. What is an IACUC?
2. Who has to approve the e-GC-1?
3. Who has to approve prior to the eGC-1 approval in the Office of Animal Welfare?

Page 4. What is an IACUC?

IACUC is the acronym for "Institutional Animal Care and Use Committee". This is the "formal" name, and the name most commonly used in federal documents. The University of Washington has adopted the use of "IACUC" in order to reduce the number of different acronyms in use, and in order to be consistent with documents from other sources such as federal guidelines.

Many people call the IACUC the "Animal Care Committee" for short. No problem. We do it too. But, we use the full name or acronym on formal documents and letters.

Page 5. Who Has to Approve the eGC-1 for the Grant?

If you do not know what an eGC-1 is, you must contact your department administrator or an Office of Sponsored Programs (OSP) coordinator. Make certain that you understand the form and that you understand how to properly answer all the questions, prior to finalizing the form in SAGE.

The on-line approvals required for the eGC-1 associated with a grant will depend on exactly who is participating in the grant and what facilities will be used. An IACUC member in the Office of Animal Welfare must approve the eGC-1 if the grant proposes the use of any live vertebrate animals anywhere (e.g., at the UW, in the field, at another institution, by a private company for antibody production, etc.). The approval must take place prior to approval by OSP except for competing NIH grants, which are reviewed by an IACUC member after the PI receives their study section score (i.e., just-in-time procedures).

Although the PI is ultimately responsible for the descriptions of any animal use and for the accuracy of the IACUC approval date(s) provided to the agency, the University does have liability associated with the proposal. Funding agencies hold the grant signatories responsible for all of the contents and their accuracy. Because officials signing for the University (usually an OSP Coordinator) do not have access to IACUC approval information, an IACUC reviewer in the Office of Animal Welfare compares the grant to the IACUC protocol(s) and makes a good faith effort to verify that the information provided by the PI is correct. This process is very difficult given the complexity of many grants, especially when there are multiple IACUC protocols involved. In theory, the review by an IACUC member should be unnecessary since the PI should be verifying correctness prior to ever signing the actual grant or approving the eGC-1. However, data over the past years clearly shows that the review by an IACUC member is necessary, due to the number of grants arriving at the office with errors that require correction prior to approval of the eGC-1 by the Office of Animal Welfare.

Page 6. Who Has to Approve Prior to the Office of Animal Welfare?

With the exception of competing NIH grants, the Office of Animal Welfare approve the e-GC-1 after the PI and prior to the Office of Sponsored Programs. "Just-in-Time" rules are used by the
University for competing NIH grants. Please see the chapter in this Module for specific instructions for those grants.

**Page 7. Summary**

You have completed the introductory chapter of this module.

The next chapter will provide you with help on the information that goes on funding agency forms.
Lesson 2. Help! What Do They Want on the Grant Form?

Page 1. What Goes in the Boxes?

Granting agencies typically ask for a lot of information regarding proposed animal work. Most typically they have boxes or spaces for:

1. IACUC Approval Date
2. Animal Welfare Assurance Number

NIH also requires completion of a narrative vertebrate animals section. Five points must be fully addressed, as specified in their instructions. The NIH study sections have been instructed to do one of two things if the 5 points are not adequately addressed:

1. The study section can choose to give the grant a worse score, or
2. The study section can choose not to review the grant at all.

Page 2. IACUC Approval Date

The IACUC approval date is the date of approval of the IACUC protocol that describes the work proposed in the grant. The configuration of the NIH 398 facepage makes it look like they may be asking for the date of approval of the University's Animal Welfare Assurance. They are not. Most agencies do not request that date. If you are submitting to an agency that specifically requests the approval date of the Animal Welfare Assurance, please contact the Office of Animal Welfare for the most recent approval date.

Most funding agencies will accept competing grants without final approval of the IACUC protocol. For example, NIH will accept new and competing renewal grants with IACUC approval "pending". However, the PI must understand that NIH will not usually award such grants prior to receipt of an approval letter, signed by the Office of Animal Welfare. The old NIH rule was that in such cases the approval letter was due to them within 60 days after grant submittal (i.e., prior to study section review). That rule has changed under the "Just-in-Time" rules for competing NIH grants (see separate chapter in this module for more information).

For competing grants to agencies other than NIH, the UW Office of Animal Welfare policy is that protocols and/or Significant Changes to protocols, must be submitted to the office by the time we receive the grant during the routing process. This rule allows time for the IACUC to review the protocols so that an approval letter can be provided to the funding agency by their deadline.

If a grant is non-competing, such as a non-competing renewal of an NIH grant, then any cited IACUC protocol(s) must have current approval. If your protocol has expired then you no longer have approval to continue the animal work and so funding agencies will not authorize funds to continue the research. If you did not renew your protocol then you cannot submit the non-competing renewal until after the IACUC protocol has been re-approved. The IACUC approval date cannot be indicated as "pending" on a non-competing renewal grant.

Page 3. Animal Welfare Assurance Number
The UW Animal Welfare Assurance Number is **A3464-01**. This number refers to a document that the UW has on file with, and approved by, the Public Health Service (PHS) Office of Laboratory Animal Welfare (OLAW). It is often referred to as the "PHS Assurance" or just the "Assurance". The document provides a detailed description of the operation of the University's entire Animal Care and Use Program. It is an "assurance" to PHS that the UW follows all the pertinent laws and regulations.

Please note that the Assurance number cited on the grant should be the number for the institution administering the grant. If the UW administers the grant then use our number, even if some (or all) of the animal work will be performed at another site that has a different Assurance number.

**Page 4. Other Documents Requested**

A few funding agencies request additional documentation of the University's adherence to laws and regulations. Please contact us if you need approval dates or actual copies of approval documents pertaining to our:

1. Animal Welfare Assurance
2. AAALAC Accreditation (Association for the Assessment and Accreditation of Laboratory Animal Care, International)
3. United States Department of Agriculture (USDA) Registration

**Page 5. Summary**

You have completed the chapter on filling out funding agency forms with correct IACUC information.

Please continue with the next chapter to obtain information on Just-inTime review of competing NIH grants.

Page 1. Introduction

The NIH changed the PHS Policy on Humane Care and Use of Laboratory Animals to permit institutions with PHS Animal Welfare Assurances to submit verification of IACUC approval for competing applications subsequent to peer review but prior to award. This change in PHS Policy was effective as of September 1, 2002 (i.e., applications for the October 1 submission deadline).

This was a policy change at NIH and it did not actually require institutions to change their grant review procedures. However, in the interest of reducing the workload for faculty, as well as the IACUC members, the University of Washington has adopted Just-in-Time (JIT) review procedures for competing NIH grants.

The main effect of this change is that competing NIH grants are reviewed by the Office of Animal Welfare at a later time-point, and only if the grant received a "fundable" score from study section.

The next chapter in the module provides detailed information regarding submission of grants and a copy of the e-GC-1 to the Office of Animal Welfare. You should carefully review that chapter since all procedures still apply except where specifically noted. Again, the main change is in the timing of the UW Office of Animal Welfare review.

Page 2. UW Routing and Just-in-Time Submission Procedures

Please carefully follow the procedures below for competing NIH grants:

1. **Competing** NIH grants will not be reviewed by the Office of Animal Welfare prior to submittal to the UW Office of Sponsored Programs and then on to NIH. Because of this, Office of Sponsored Programs requires listing the IACUC approval date on the grant facepage as Pending.

2. If you are proposing use of hazardous materials, select agents, infectious agents and/or recombinant DNA, please send the Institutional Biosafety Committee (IBC) Research Project Hazard Assessment (RPHA) and required supplements to Environmental Health and Safety (EHS) at the time you are submitting the grant to NIH because their review and approval can significantly delay final IACUC protocol approval should it be needed (i.e., if the application receives a favorable score). Additional information on the RPHA can be found on the EHS web page.

3. Upon receipt of the study section summary statement, if the score indicates that funding is likely, a copy of the grant and the eGC-1 must be routed to the Office of Animal Welfare immediately. Make sure the eGC-1 correctly lists all relevant IACUC protocol numbers. There is no change in this requirement. If the grant includes use of hazardous agents then EHS must also be notified at (206) 543-7278.

4. If a new IACUC protocol is needed for the grant, or if Significant Changes to already approved IACUC protocols are needed, include the appropriate protocol paperwork when you submit the copies of the grant and eGC-1 to the Office of Animal Welfare.

5. Please be aware that if the use hazardous agents is proposed, the IBC RPHA review by EHS, other reviews and registrations such as select agent registration or environmental
compliance could take considerable time and may delay final IACUC approval.

6. As soon as all reviews are completed and all the proposed animal work is approved, the Office of Animal Welfare will prepare an approval letter that you can forward to NIH. An IACUC member reviewer will also sign the copy of the eGC-1, which you must submit to the Office of Sponsored Programs. No funds will be released unless the signed eGC-1 is on file with them.

Page 3. What if the IACUC Reviewer Finds Errors in the Grant?

Based on our records, over 50% of grants and eGC-1s routed to the Office of Animal Welfare have errors. These errors range in seriousness and in consequences.

Under Just-in-Time procedures, the IACUC member reviewer will not have the opportunity to advise you on required corrections prior to your submission of your competing grant to NIH. With this in mind, we strongly recommend that you review this entire grant module and contact the Office of Animal Welfare if you still have any questions.

However, there are several issues related to the approval letter that we would like to specifically highlight. They are:

- NIH requires that the approval letter describe any differences between animal activities in the grant and those approved by the IACUC. For example, if the grant indicates one euthanasia method and the IACUC approved a different one, then NIH requires notification of that change.
- The IACUC must note any errors in the grant that are related to animal use. Examples include:
  - some performance sites not included on page 2 of the grant – for example, a company that will be producing custom antibodies, foreign sites, etc.
  - errors in the Vertebrate Animals section– for example, indicating that all animal facilities are AAALAC accredited when some participating institutions actually are not AAALAC accredited

Page 4. Progress Reports in Competing Renewals

Because Competing Renewal NIH grants are, as the name indicates, "competing", the Just-in-Time procedures will be followed. However, we would like to remind you that when you submit the grant and eGC-1 to the Office of Animal Welfare for review (after receipt of a fundable score) the reviewer will review the Progress Report as well as new plans. With this in mind, please remember to include relevant IACUC protocol numbers on the eGC-1.

We would like to also advise you regarding the potential consequences of a reviewer finding that unapproved work is described in the Progress Report. (Also, note that the same issues apply to Progress Reports in non-competing NIH grant renewals.) Under such a circumstance, the Office of Animal Welfare is required, by PHS policy and AAALAC, to report the non-compliance both to the NIH Office of Laboratory Animal Welfare (OLAW) and to AAALAC. OLAW in turn requires a report of the non-compliance to your NIH funding Institute.
The outcomes include:

1. NIH may freeze your grant funds if the grant is currently ongoing
2. NIH may require that the University return NIH funds that were used in support of any animal related activities that were not approved at the time they were conducted

The UW Office of Animal Welfare’s experience with this issue is that these outcomes are devastating to the PI and their research program. They can also have direct consequences to others, such as students and staff, who are supported by the grant.

Please. Always double check your approved protocols and make certain that you are not about to implement a Significant Change prior to IACUC approval.

Page 5. Summary

You have completed the chapter on Just-in-Time (JIT) procedures.

In summary, please keep in mind the following points:

- Use JIT only for competing NIH applications
- Mark the IACUC approval box "Pending".
- Immediately upon being notified that funding is likely (i.e., study section summary statement with favorable score), submit to the Office of Animal Welfare a copy of your grant, eGC-1 and any required IACUC protocol forms needed to cover all proposed animal related procedures.
- Make certain that all animal related procedures in pilot studies and progress reports were approved by the IACUC, by always carefully following your approved protocols.

Please continue with the next chapter to obtain details on grant submissions to the Office of Animal Welfare.
Lesson 4. Grant Submission to the Office of Animal Welfare

Page 1. Introduction

All grants submitted through the University of Washington go through a process of review by various departments and offices. If the grant includes proposed use of live vertebrate animals then it must be submitted to the Office of Animal Welfare for review prior to being submitted to the Office of Sponsored Programs, with one notable exception. Starting with the October 1, 2002 submission deadline, **Competing** NIH grants are submitted without pre-review by an IACUC member in the Office of Animal Welfare. Please see the chapter in this module regarding "Just-in-Time" procedures for **competing** NIH grants.

The IACUC member reviewer's task is to verify that the proposed animal work is accurately described in associated IACUC protocols. After the reviewer has made a good faith comparison of the grant and IACUC protocols, he or she approves the eGC-1 in SAGE. The IACUC approval of the eGC-1 indicates that the review has been completed and that the reviewer believes that the information being provided to the funding agency is correct.

However, it is extremely important for the grant PI to understand that they are ultimately responsible for the accuracy of the information being provided to the funding agency. The IACUC reviewers read thousands of grant pages, including technical language from hundreds of research areas, and their approval of the eGC-1 DOES NOT GUARANTEE that the information is 100% accurate. For example, if the IACUC reviewer fails to discover that an unapproved procedure is included in the grant, it is still the full responsibility of the PI NOT to implement that procedure prior to IACUC review and approval. In other words, it is the PI's responsibility to uphold the terms of the certification statement they signed as part of their IACUC protocol.

Page 2. Grants, Signatures and the Federal False Claims Act

Why such scrutiny of the grants being submitted? After all, many of them won't even be funded anyway.

PHS has issued guidance that illustrates the importance of accuracy when it comes to statements made in grants. They have pointed out that incorrect information, even if it is inadvertent, is still false and is a violation of the Federal False Claims Act. The signatories on the grant (for example, the 2 signatories on the NIH 398 facepage) are attesting to the truth of all parts of the grant. PHS has stated that upon their receipt (not funding, but receipt) of an NIH grant for review, any untrue statements in the grant constitute a violation of the federal False Claims Act. Such errors, even if accidental, are subject to potential criminal and civil penalties. If the grant is actually funded, then triple damages are possible because in that case the institution will have actually received federal dollars based, at least in part, on false information.

This guidance from PHS was based on a scenario in which NIH was provided an IACUC approval date but in fact not all of the planned animal work was approved.

**Please be careful!**

The review in the Office of Animal Welfare DOES NOT relieve the PI of the responsibility for the
accuracy of the information provided to the funding agency. Again, the Office of Animal Welfare approval of the eGC-1 simply indicates that the reviewer has made a good faith effort to verify the correctness of the IACUC protocol approval information.

Please remember that under the "Just-in-Time" rules for competing NIH grants, the Office of Animal Welfare will not be checking your grant prior to submittal to NIH. The review of these grants will be postponed until your grant has been reviewed by study section and received a "fundable" score. With that in mind, you must make sure that you carefully follow the NIH instructions and properly provide correct and complete information to them. Please see the chapter on just-in-time in this module.

Page 3. Required Paperwork

The following items must be submitted to the Office of Animal Welfare. If some items are missing then the reviewer may return the grant without having approved the eGC-1:

1. **Original grant** - We really do mean the original - except for competing NIH grants, which will require submittal of a copy after review and scoring by NIH (see the just-in-time chapter for more information). For all grants other than competing NIH grants the document submitted to the Office of Animal Welfare must have original signatures. The IACUC member will generally not review a copy because of the frequency with which reviewers are having to make changes on the original that will be submitted to the funding agency. All portions of the grant describing the proposed animal work must be complete and in final form. No changes in the proposed use of the animals can be made after the Office of Animal Welfare approval of the eGC-1.

2. **eGC-1 in SAGE** with all relevant IACUC protocol(s) cited - Remember to make it clear which protocols are associated with which parts of the grant if you cite more than one. Clear information results in a shorter turn-around time. Again, in the case of competing NIH grants, a copy of the original will be submitted to the Office of Animal Welfare after review and scoring of the grant by NIH.

3. **Letter of approval from cooperating institution's IACUC** if some work is being performed at another institution.

4. **Foreign sites** - If animal work in support of the grant will be conducted at a foreign site, you must obtain an English language copy of the protocol approved by the foreign ethics committee and submit it to the UW IACUC. Federal policy requires the domestic IACUC of the awardee institution to review the work. The grant can only be funded if the UW IACUC also approves the foreign animal procedures.

Page 4. Original Grant

The IACUC reviewer must try to confirm that any IACUC approval information provided to the agency is true. In order to do that, he or she must compare the proposed animal work to the work described in the IACUC protocol(s) listed on the GC-1.

In order to accomplish that task, the reviewer must make a direct comparison between the IACUC protocol(s) and the final version of any parts of the grant associated with the animal work. (Please note that this review will be made for competing NIH grants after submittal to NIH and receipt of a "fundable" score. For all other grants this review will take place prior to submittal of the grant and GC-1 to Grant and Contract Services for their review and signature.) Regardless of whether the review is prior to submittal to NIH or prior to submittal to Grant and Contract Services, the
IACUC reviewer will concentrate on several sections of the grant including:

1. PI signature pages
2. Page(s) listing performance sites
3. Research Design and Methods section
4. Any other section describing procedures to be performed on animals - section may vary depending on agency grant format

Although other sections of a grant may not be in final form at the time of IACUC review, they must at least provide enough information such that the review can refer to them for more information if needed.

**Page 5. eGC-1**

You must submit the eGC-1 in SAGE for all grants other than competing NIH grants (see the chapter on Just-in-Time procedures). The eGC-1 must be approved by the grant PI (or their designee) prior to submittal to review in SAGE by the Office of Animal Welfare.

The accuracy of the eGC-1 is crucial. The IACUC member reviewer will not be able to make changes to IACUC protocol numbers or dates in SAGE. The Office of Animal Welfare maintains a grant log and it clearly shows that non-competing renewals are being submitted to the IACUC with carry-over errors from the previous year, even though the reviewer made the corrections previously.

Listing incorrect IACUC protocol numbers on the eGC-1 is a serious error. Remember, at the time the IACUC member is conducting the review the PI has already approved the eGC-1 and signed the original grant.

Please be careful!

All documents in the Office of Animal Welfare, including the grant log, are available to members of the public through the Office of Public Records and Open Public Meetings. The grant log clearly lists each grant with title, PI name, funding agency, IACUC protocols cited, and any issues that had to be resolved prior to eGC-1 approval. Members of the public, and others, will not understand how a University faculty member could make serious errors in protocol numbers or even what is, or is not, approved on a particular protocol.

**Page 6. Letter of Approval from Non-UW IACUCs**

If some, or all, of the animal work in your grant will be conducted at another institution, you will need to obtain an approval letter from the IACUC at the other institution. Funds for such work must usually be on a sub-contract.

The letter must include:

1. The protocol number.
2. The protocol title.
3. The protocol approval date and
4. It should indicate that the protocol includes the work proposed in the UW grant.
There are 2 exceptions to this policy. The VA Puget Sound Health Care System and the Fred Hutchinson Cancer Research Center (FHCRC) both have inter-institutional agreements with the University of Washington. University owned animals (i.e., purchased directly with UW grant funds - not sub-contracted) can be housed and used at those institutions. The University maintains copies of the IACUC protocols for those projects and therefore a separate letter from their IACUCs is not required. However, you should make sure that we do have a copy of the protocol you plan to cite. If we do not, you can turn in a copy of the VA or FHCRC protocol along with your grant.

Page 7. Summary

Well, it seems pretty simple...

but, there are really a lot of questions that come up due to the complexities of collaborations among faculty members here at the UW and indeed all over the world. The next section of this module contains the answers to frequently asked questions (FAQs). It should include almost every question that comes up during grant preparation and routing. If you have one that isn't covered, please give us a call! We'll even make calls to your funding agency for you in order to get advice, if you come up with a new situation that stumps us.
Lesson 5. Frequently Asked Questions (and answers)

Page 1. What Happens During Grant Review (other than competing NIH grants)?

Here’s what happens after you leave a grant at the Office of Animal Welfare:

For all grants other than competing NIH grants, the following procedures are followed.

1. As required by federal policy, a reviewer compares the animal work proposed in the grant to the work described in the IACUC protocol(s) cited on the eGC-1. It is a "side-by-side" review.
2. If the work described in the grant is approved under an IACUC protocol, then the reviewer checks to make sure that the correct approval date is on the grant and eGC-1.
3. If the work described in the grant has been submitted to the IACUC but does not yet have approval, then the reviewer checks to make sure that the word "pending" is on the grant and eGC-1.
4. If the work described in the grant has not been submitted to the IACUC then the e-GC1 cannot be approved and the grant cannot be submitted to the funding agency until all required paperwork has been submitted to the IACUC. This is a firm rule. It is unlikely that IACUC approval can be completed in time for agency deadlines if the paperwork is not submitted at that time. In addition, it is impossible to do a side-by-side review if part of the required paperwork is a "good intention" rather than an actual document!

Page 2. What Happens During Review of Competing NIH Grants?

Under Just-in-Time procedures, the Office of Animal Welfare will not be reviewing competing NIH grants until after review by study section and receipt of a "fundable" score. Upon receipt of the summary statement and "fundable" score, the PI must submit a copy of the grant and eGC-1 to the Office of Animal Welfare

Here’s what happens after you leave a competing NIH grant at the Office of Animal Welfare:

1. A reviewer compares the animal work proposed in the grant to the work described in the IACUC protocol(s) cited on the eGC-1. It is a "side-by-side" review.
2. If the work described in the grant is approved under an IACUC protocol, then the reviewer will check to make sure that the correct date is on the eGC-1 and will provide an approval letter for the PI to forward to NIH. The reviewer will also sign the copy of the eGC-1 and the PI must submit the signed eGC-1 to the UW Office of Sponsored Programs. The signed eGC-1 must be on file with them or funds will not be released.
3. If the work described in the grant has been submitted to the IACUC but does not yet have approval, then the reviewer will keep the grant and eGC-1 until all work is approved, at which time he or she will provide the PI with an approval letter that they can forward to their NIH Program Officer. The reviewer will also sign the copy of the eGC-1, and add the approval date to it, and the PI must submit the signed eGC-1 to the UW Office of Sponsored Programs. The signed eGC-1, with valid approval date, must be on file with them or funds will not be released.
4. If the work described in the grant has not been submitted to the IACUC then the reviewer
will request the required information from the PI and will return the grant and eGC-1 for re-review after all materials have been submitted to the IACUC.

5. **NOTE:** If the reviewer finds that incorrect information has been provided to NIH, he or she is required by NIH to include this fact in the approval letter. This would include errors such as failure to list all performance sites, differences between what the IACUC approved vs. what the PI described in the grant (for example, a different anesthetic or euthanasia method), changes in design required by the IACUC, etc.

**Page 3. More Than 1 Protocol/Approval Date - Now What!**

Granting agencies do not usually provide spaces for more than one approval date, though often the grant work is approved on 2 or more IACUC protocols. The work may even be approved on IACUC protocols from more than one institution in the case of collaborative work. In cases where all of the IACUC protocol information will not fit in the space provided, a table should be attached listing the various protocols involved along with the approval date for each one. NIH often requests such a list for large center grants or other grants involving many IACUC protocols. In that case, provide the information in the format requested by the agency. Even for an NIH 398 form it is permissible to attach a page after the facepage or refer to a specific grant section for the information. For example, in the box for the IACUC approval date, it is permissible to say "see sec....." and include the section identifier (such as "g" or "f").

**Page 4. Training Grants**

What do I do about IACUC approval for animal use on a training grant, when some as yet unidentified trainees will or may use animals?

1. For situations where grant funds are for salary only and trainees and projects are not yet identified (i.e., a new submission without a progress report), indicate "yes" for vertebrate animals on the eGC-1 and provide a statement of assurance (eGC-1 compliance section) that trainees who are recruited and decide to use animals will have their work submitted to the IACUC and approved under their mentor's protocol. Keep in mind that in such cases, the Office of Animal Welfare will need to review any animal projects and write an approval letter for NIH prior to start of animal work by a trainee.

2. Per instructions from NIH, if animal involvement is not yet determined then insert the word "Indefinite" in the box on the grant facepage where you would normally put the IACUC approval date. Please note that if an award is made, vertebrate animals cannot be used until a verification of IACUC approval date has been submitted to NIH. It is the PI's responsibility to remember that this must be done.

3. If animal projects are already known or if the training grant is a continuation and some trainees are already working with animals, cite the relevant IACUC protocol numbers on the eGC-1. On the grant you must include the relevant approval date(s). Per NIH instructions, if all approval dates will not fit in the box provided on the grant facepage you must type in "Sec. g" and list the appropriate information there (see form 398 instructions on this issue). When the grant is reviewed by the IACUC reviewer, the work of the trainees that is described in the grant will be compared to the IACUC protocols cited.

Please be careful! NIH holds the grant PI responsible. In one case a grant non-compliance issue had to be reported to the NIH Office of Laboratory Animal Welfare and the funding institute because a trainee's mentor failed to add the trainee to the IACUC protocol and also allowed the
protocol to expire. The trainee had done a project without IACUC approval. The grant PI had no knowledge of this situation until the IACUC member reviewed the grant progress report and discovered it. If you agree to be the PI on a training grant we urge you to establish measures for tracking assignment of trainees to approved protocols. If you are not willing to take on this responsibility then you should reconsider agreeing to be the grant PI and signing the facepage of the NIH grant.

Page 5. But There's No Animal Work Proposed for Year 1

Often there are plans to use live vertebrate animals in years 2, 3, or later, but not in year 1 of a grant. Accordingly, some details of the animal work may need to be revised based on findings during the prior years. What to do?

Most funding agencies, including NIH, require IACUC approval for all proposed animal work that will occur at any time during the entire grant. You must obtain approval from the IACUC for the animal work that you are proposing to the funding agency. You may, as always, submit Significant Changes to your IACUC protocol as your work progresses and you determine changes that will need to be made in your plan. If you have a particularly perplexing situation, please contact us for advice. We're happy to help and the grant trip through the Office of Animal Welfare will surely go much more smoothly if we work out a solution together.

Page 6. No Animal Work at the UW

Does the UW Office of Animal Welfare have to review my grant and approve the eGC-1 when the animal work is done elsewhere, such as under a subcontract, or by a Co-Investigator who is physically located elsewhere?

1. Yes. If the UW is administering the grant then the UW is taking responsibility for informing the granting agency of the IACUC approval date (even if the IACUC approval is from another institution).
2. The signatories on the grant (usually the PI and an Office of Sponsored Programs Coordinator) are both responsible for providing correct and true information to the granting agency. The Public Health Service has issued strongly worded "guidance" on this issue, stating that providing incorrect IACUC approval information can result in civil and criminal penalties. With that in mind, our office requires documentation of IACUC approval for proposed live vertebrate animal work in grants, regardless of the proposed site for the work.

Page 7. But the Animal Work Will be Conducted at a Foreign Site

What if some, or all, of the work will be conducted at a foreign site?

This is not an unusual situation these days. PHS policy requires that the domestic awardee institution's IACUC review and approve any animal work to be performed at a foreign site.

Here are the rules for NIH grants, and for grants to any other sponsor requiring PHS policy (e.g., NSF).

1. The foreign institution must have a Foreign Animal Welfare Assurance. However, foreign Assurances are simply "statements of compliance" indicating to PHS that the institution will follow the laws of their own country. It does not mean that the institution follows
PHS Policy, and most do not since other countries usually have a completely different set of requirements for protocol review and approval, among other things.

2. But wait a second! How can the UW IACUC really review a protocol for a foreign site when we're supposed to consider many issues such as appropriateness of animal housing, occupational health for the people involved, etc? The UW IACUC must at least review the planned animal work and must approve it. If the UW IACUC is unwilling to approve some aspect of the plan then it cannot be included in the grant. The IACUC approval procedures are exactly the same as for a UW IACUC project.

Here's what you need to do if you plan on submitting a proposal that includes animal work at a foreign site.

1. Obtain a copy of the protocol approved by the foreign institution's animal review committee.
2. If the protocol is not in English you will need to provide a translation.
3. Submit the protocol to the IACUC just as you normally would. However, attach a UW Project Review Form facepage filled out as if you are the PI. Give the protocol a title that you will recognize as the foreign protocol. We suggest starting with the country name and then the title, such as "England: Mouse Studies".
4. The Office of Animal Welfare will assign it a protocol number as usual, and the protocol will go through exactly the same review and approval process that it would were it a regular UW IACUC protocol.

Page 8. Custom Antibodies

I will be purchasing custom antibodies from a private company. While production of monoclonal or polyclonal antibodies does involve animal use procedures, these will be conducted by the private company. Does this constitute use of live vertebrate animals in the grant?

The NIH Office of Laboratory Animal Welfare has provided guidance on this issue. Since animals (usually mice or rabbits) are used, NIH requires that your grant indicate "yes" for vertebrate animal use. This is normally true for other granting agencies as well. For NIH grants:

1. Indicate "yes" for vertebrate animals on the grant face page
2. Use the UW Animal Welfare Assurance number (A3464-01) on the face page
3. Under performance sites list the name of the company from whom you will purchase the custom antibodies. Please note that you must use a company that holds an Animal Welfare Assurance with PHS (though their number is not used on the face page). Contact the UW Office of Animal Welfare if you need suggestions.
4. The IACUC approval date is the date that the chosen company's IACUC approved the antibody production. Contact the company for this information and include a copy of their IACUC approval letter when you submit your grant to the UW IACUC office for review.

Note: If you contact a company to inquire as to whether they have an Animal Welfare Assurance Number and their response is something like "What kind of insurance policy? Did you say some kind of animal insurance?", then you should pick another company. All institutions with Assurances are listed on the OLAW web site along with their Assurance number.
Page 9. Non-PHS Funding Sources (including in-house)
If the grant is going to a private agency or a UW "in-house" fund and therefore does not involve Public Health Service (PHS) funds, do the PHS rules requiring IACUC approval apply?

Yes. The University of Washington has an Animal Welfare Assurance (A3464-01) on file with the NIH Office of Laboratory Animal Welfare (OLAW). All animal work performed at the UW, or supported by UW funds, or performed by UW faculty, students or employees is covered under that Assurance, regardless of the actual source of the funds for a particular project.

"In-house" funding sources such as the Royalty Research Fund will accept your proposal without prior review in the Office of Animal Welfare. However, if they choose to fund the project you will have to submit a letter of approval to them that specifically names that project and the IACUC protocol number and date of approval. Upon notification of the award you will need to submit a copy of the proposal to the Office of Animal Welfare along with a notation as to the associated IACUC protocol number. The proposal and the IACUC protocol will be compared. Assuming that the proposed work is approved in the protocol, the IACUC member reviewer will prepare a letter of approval for you to submit to the appropriate funding office.

Page 10. Transfer of Funded Grant to the UW
If you are just joining us and you are transferring a funded grant to the UW here's what you need to do:

1. Contact your granting agency for instructions/rules from them. Some will require UW IACUC approval prior to the transfer of funds.
2. Contact the UW Office of Animal Welfare to discuss the particulars of your situation.
3. Download the IACUC protocol form (Project Review Form) from the IACUC web site so that you can begin the submittal/review/approval process even prior to coming to the UW.
4. Because we will need to do a side-by-side review of your grant and IACUC protocol in order to provide the funding agency with an IACUC approval letter, please send a copy of your grant when you submit the IACUC protocol.
5. If some of the animal work described in the grant has been completed, please note that in a memo along with your IACUC protocol. Otherwise the IACUC reviewer will not understand why the grant contains proposed animal use that is not included in the UW IACUC protocol. In other words, the grant and IACUC protocol need to match, except that you certainly do not need to apply for IACUC approval to do studies that have already been completed.

Page 11. Moving to the UW and Bringing Your Animals Too?
If you are moving your research to the UW and you will be transferring live animals to our facilities, we hope that you discussed this with the UW Attending Veterinarian, the Vice-Chair of Comparative Medicine, and the Animal Care and Use Program's Facility Manager prior to accepting a position at the UW. If not, please do it NOW - we may not have appropriate housing available for your animals.

1. Contact Dr. Mel Dennis, Attending Veterinarian, Department of Comparative Medicine, at (206) 685-1216, or dennismb@u.washington.edu, or Dr. Lillian Maggio-Price, Vice-Chair of Comparative Medicine, at (206) 685-3257, or lmprice@u.washington.edu. Contact the
Comparative Medicine Animal Purchasing Office to obtain forms for transferring animals from your institution (206) 543-0640. Contact the facility manager, Pam Morris at (206) 543-0641 or pcm252@u.washington.edu

2. Please be aware that all animals at the UW must be housed in an approved animal housing facility that is appropriate for the particular species.

3. There have been cases in the past in which hiring departments have promised unapproved space to new faculty members for housing of their animals (e.g., lab space or housing area inappropriate for the species). In fact, this is not allowed, as it violates the UW's Animal Welfare Assurance and AAALAC accreditation. The UW will not accept your animals unless there is space available that meets all federal and non-federal requirements for proper housing and care. If hazardous agents are involved, that will also impact housing and lab space requirements.

4. Please note that some new faculty members have experienced very significant delays in re-starting their research because of housing and/or lab space issues.

Page 12. Summary

You have completed the chapter on FAQ’s. The next chapter provides information on some of the frequently made errors on grants submitted to the Office of Animal Welfare for review.
Lesson 6. Frequently Made Errors
Page 1. Mismatch Between Grant and IACUC Protocol(s)

Grants submitted to the Office of Animal Welfare frequently describe vertebrate animal work that differs from, or is not included in, the IACUC protocol(s) cited on the eGC-1.

This is one of the most common errors and results in significant loss of time in processing grants through the Office of Animal Welfare. This problem comes to light when the grant is compared side-by-side with the IACUC protocol(s). If there are procedures in the grant that are not in the cited protocol(s) then the grant will have to be returned to the PI until corrections are made.

Please note that many grant PI’s ask us to contact the individual faculty members responsible for sub-projects, or trainees when the animal work in question is not their own specific project. The IACUC reviewers simply do not have time to do this because it jeopardizes their ability to review other grants that have deadlines to meet as well. The grant PI is responsible for insuring that the grant is correct prior to submittal to the Office of Animal Welfare and is responsible for resolving problems found during review. If you are a grant PI then you must take this responsibility. You can, of course, designate another person with complete knowledge of the proposed animal work to fill out the paperwork and provide correct information to the IACUC, and granting agency, but it is important to understand that the ultimate responsibility is still the grant PI’s.

If this problem is noted during IACUC review, the following steps will be followed:

1. The PI or grant contact will be notified to pick up the grant.
2. The PI or someone very familiar with both the grant and the protocol(s) must determine the discrepancy and then re-submit the grant and a Significant Change to the relevant protocol(s). The Office of Animal Welfare can supply copies of the cited protocols if the person assigned this task does not have access to them.
3. If an approval date was noted on the grant, the date must be changed to the word "pending" since the Significant Change will not yet have IACUC approval.

Page 2. Missing Non-UW IACUC Approval Letter

Approval documentation (i.e., IACUC approval letter) for work to be performed at a non-UW site is not provided.

The UW Office of Animal Welfare cannot inform a granting agency that all the work in the grant is approved (or pending) without documentation that this is true. Please see the FAQ chapter of this course for instruction on this issue.

Page 3. Agency Form Errors

Many grants come to our office with the wrong information on the granting agency form.

You really must read the form instructions carefully. Please do not list your IACUC protocol number on the facepage of an NIH 398 form in the space provided for the Animal Welfare Assurance number. Note: the Animal Welfare Assurance number is A3464-01.
Wrong IACUC Protocol Number Cited on eGC-1

Sometimes the wrong IACUC protocol number is cited on the eGC-1. In cases where more than one IACUC protocol is involved, sometimes they are not all listed.

You must list all relevant IACUC protocol numbers. Please do not expect the IACUC member to figure this out for you. The need to do so would imply that you are uncertain about what is approved on your various protocols.

Remember that the eGC-1 requires specific information for all items marked "yes". If there are multiple IACUC protocols associated with the grant, be sure to provide enough information so that the IACUC reviewer will know which protocol goes with which part of the grant. It will help the reviewer process your grant more quickly.

Note: Please remember that the IACUC protocol cited on the eGC-1 is directly compared to the grant. The PI or someone very familiar with both the grant and the protocol(s) must determine that all grant work is included in the cited protocol(s) prior to submitting the grant to the Office of Animal Welfare and prior to finalizing the e-GC1 in SAGE. If there's an error, the grant will be returned to you for this process so you will save time by making sure it happens prior to the initial submittal to the Office of Animal Welfare.
Congratulations! You have completed the Office of Animal Welfare module related to grants.

We hope that the information in this course will help you during proposal development and during routing of proposals through the UW Office of Animal Welfare.

If you have any questions regarding issues not covered in the module, please contact us and we'll be happy to help you!