

**Standard Operating Procedures (SOP) Manual  
University of Maryland, School of Pharmacy**

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## I. **New Protocol Submissions**

Any investigator involved with the use of animals in research, teaching or other activities, regardless of where the work will be conducted must submit a protocol for Institutional Animal Care and Use Committee (IACUC) review.

If the work is being conducted at another assured institution, our IACUC will review the approved protocol to make sure that the procedures are acceptable. If acceptable, we will defer all oversight responsibilities to that institution (i.e. accept their review). If concerns are identified, a letter will be sent to the PI to revise the protocol to address those concerns, and have it re-reviewed and approved at the other assured institution. Once this process is complete, we will accept the assured institution's review. If the work is being conducted at this institution, our IACUC is responsible for ensuring compliance with all federal laws and regulations.

### **Principal Investigator Eligibility**

Only full time School of Pharmacy (SOP) faculty members qualify to serve as PI on a project. The faculty member's appointment must be as a Full Professor, Associate Professor, or Assistant Professor. Exceptions may be made for Full time (FT) Instructors and Research Associates or FT faculty members from other schools if SOP facilities are being used.

### **Submission**

Completed protocol forms must be submitted by the first Wednesday of each month. The IACUC meets on every other odd month on the last Wednesday in the month. All applications received on the deadline day are pre-reviewed by the IACUC Coordinator and logged into the IACUC database prior to the assignment of an IACUC member(s).

### **Full Committee Review Procedures**

Routinely all protocol submissions undergo full committee review. Our IACUC utilizes a primary and secondary reviewer system such that at least two committee members with the appropriate expertise are responsible for an in depth review of a proposal and subsequently lead the discussion at the meeting. In rare instances, only a primary reviewer (usually the chair or veterinarian) may be assigned if a study involves minimal animal manipulations such as an euthanize and harvest protocol. In both cases, the full committee participates in this discussion and votes on the outcome of the review. [A quorum (>50%) of the members must be present at the meeting and the majority of the members present must vote in favor of the outcome for any action to be taken].

The potential outcomes of review are:

**Full Approval:** The Committee has approved the protocol without question.

**Conditional Approval:** The Committee has approved the protocol contingent upon receipt of additional clarification before the project can be initiated.

**Request More Information:** The Committee has neither approved nor disapproved the protocol. Clarification, revisions and/or additions are needed to properly assess the proposed research. The revised protocol must come back to full committee review.

**Disapproval:** The Committee did not approve a protocol due to significant deficiencies and concurred that the Principal Investigator (PI) should start over.

### **Protocol Distribution Procedures**

A copy of each protocol along with a meeting agenda, protocol assignments, discussion and education materials, etc is distributed to all members one week in

advance of the meeting. If a new protocol is added to the agenda following distribution of the packet, the materials are hand delivered or sent electronically to all members in advance of the meeting.

### **Post Meeting**

Following the meeting, draft minutes are composed. Minutes include pre-protocol review discussions (training, updates, etc) and detailed comments for each protocol reviewed. For each protocol, the following information is recorded in the minutes: PI Name; PI Department; Title; Species and Number Requested; Reviewers; Committee Decision; Committee Vote and Comments to the PI. IACUC number will be assigned to the protocol once approval has been received. Comments from each reviewer and IACUC Coordinator's notes for a given protocol are combined. The draft minutes are reviewed by the IACUC Chair. The minutes are revised to include any corrections/additions/deletions made by the IACUC Chair. From the minutes, letters are composed and sent to the PI for action as follows.

Full Approval: A full approval letter is sent to the Principal Investigator (PI). Animals may be purchased through Veterinary Resources and used in the approved protocol only. Approval is given for a maximum of three years from the meeting date with a continuing report of progress/status required annually.

Conditional Approval: A query letter is sent to the Principal Investigator (PI) indicating the study had been conditionally approved and includes those issues that must be addressed prior to final approval. The PI is advised to submit the requested information within fifteen (15) working days and is reminded that no animals may be ordered and no research may begin until final approval is granted by the IACUC. Upon receipt of the PI's response to queries, a review (by the chair and/or other members as warranted) will take place to determine if the response is adequate. If the information is satisfactory, a final approval letter will be sent to the PI. Approval is given for a maximum of three years, with a continuing report of progress/status required annually.

Request More Information: A query letter is sent to the Principal Investigator (PI) indicating that the committee requires further information to render a decision and includes those issues that must be addressed prior to further review. The PI is advised to submit the requested information to the IACUC as soon as possible and is reminded that no animals may be ordered and no research may begin until the final approval is granted by the IACUC. Upon receipt of the PI's response to queries, the protocol will be assigned to the original reviewers and put on the agenda for re-review at the next Committee meeting.

Disapproval: A letter is sent to the PI indicating that the committee had disapproved the study, the reasons for disapproval, any comments the committee had that must be addressed in the next version, and recommend consultation with the IACUC Chair and/or IACUC Coordinator or Veterinary Resources for guidance and assistance prior to submission of a new (revised) protocol. The letter also indicates that no animals may be ordered and no research may begin until the final approval is granted by the IACUC.

Minutes are to be sent to the committee within three working days after the committee meeting. Any comments/suggestions are to be returned to the IACUC Coordinator. Revised minutes will be presented at the next scheduled meeting.

## **Designated Review Procedures**

The designated review mechanism is not routinely used by the IACUC, although the following methods are implemented when the IACUC Chair has determined this method is appropriate. The IACUC has determined that they prefer to review all protocols involving the use of animals at a fully convened meeting to discuss details of the proposed animal procedures.

The identified protocol can be submitted on the deadline date or at any point during the month. The protocol will be pre-reviewed by the IACUC Coordinator, and logged into the IACUC database prior to the assignment of an IACUC member(s). The protocol will be submitted to all members of the IACUC (in hard copy or electronically) identifying the two or more designated reviewers and providing a deadline for the opportunity for any member to request full committee review. The same procedures as noted above in the outcome section for full approval or conditional approval will be implemented. If the reviewers or committee request full board review, a letter will be sent to the PI notifying him of the decision and the rationale for that decision.

The IACUC Chair will summarize for the committee the results of the designated review at the next upcoming bimonthly meeting for informational purposes only and this discussion will be documented in the minutes.

## **Specifics: Meeting Log In, Agenda Preparation & Packets**

1. Send RSVP to members to find out who will be attending.
2. Organize new studies, more information studies and amendments
3. Amendments
  - a. Find IACUC # in database
  - b. Click in MISC field & input A01 (Amendment for January Mtg.)
  - c. Pull file and put in cart.
4. New Studies
  - a. Assign number using new study cover sheet. Attach this sheet to the original copy for the protocol file. Pull copy, write # on top corner and put aside.
5. Compose an agenda cover sheet documenting any discussion items. Print out, attached to agendas and copy number needed for packets. (*Order: cover memo, new protocol agenda, more info agenda, amendment agenda*)

### **NOTES:**

- **AMENDMENTS:** Reviewers get a copy of the fully approved protocol in addition to the amendment request.

### **Addendums**

New Protocol Forms  
Approach Log In Screen  
Log in Cheat Sheet  
Minutes Template  
Letters of Determination Template  
Approval Letters (new projects)

## II. AMENDMENTS

Any modification to the approved protocol must be submitted for IACUC review and approval. When an amendment is submitted to the IACUC, it is classified as either an administrative, minor or significant amendment.

### Administrative Amendments

An administrative amendment is one that can be approved by the IACUC Chair. Examples of administrative amendments include changes to the protocol title, deletion of research personnel, change in office / laboratory location, etc.

If the administrative amendment is approved, the approval date for the amendment will be the date of approval. The "Minor Amendment" approval letter will be issued.

If a clarification is needed, an email will be sent to the principal investigator. Once a response is received and approved, the "Minor Amendment" approval letter will be issued.

A copy of the approval letter and amendment is maintained in the protocol file.

### Minor Amendments

A minor amendment is one that can be approved by the IACUC Chair, a Veterinarian or any full voting member of the IACUC. Examples of minor amendments include a change in animal numbers (<10%), a change to an anesthetic or analgesic as recommended by Veterinary Resources, etc.

If the minor amendment is approved, the approval date for the amendment will be the date of approval. The "Minor Amendment" approval letter will be issued.

If a clarification is needed, an email will be sent to the principal investigator. Once a response is received and approved, the "Minor Amendment" approval letter will be issued.

A copy of the approval letter and amendment is maintained in the protocol file.

### Significant Amendments

A significant amendment must be reviewed via full committee or designated review, if warranted. Examples of significant amendments include change in objective of study, new species / strain, new procedures / experiments, a change in animal numbers >10 %, change in Principal Investigator, etc.

#### 1. Full Committee Review of Significant Amendment

The amendment is pre-reviewed by the IACUC Chair, assigned to the original reviewers (or reviewers with the appropriate expertise) and put on the agenda for review at the next Committee meeting. Our IACUC utilizes the primary and secondary reviewer system such that two committee members with the appropriate expertise are responsible for providing a brief summary of the approved study and an in depth review of the proposed modification. The full committee participates in this discussion and votes on the outcome of the review. [A quorum (>50%) of the members must be present at the meeting and the majority of the members present must vote in favor of the outcome for any action to be taken].

The potential outcomes of review are:

Full Approval: The Committee has approved the proposed modification without question.

Conditional Approval: The Committee has approved the proposed modification contingent upon receipt of additional clarification before the modification can be initiated.

Request More Information: The Committee has neither approved nor disapproved the proposed modification. Clarification, revisions and/or additions are needed to properly assess the proposed research.

Disapproval: The Committee did not approve the proposed modification due to significant deficiencies and concurred that the Principal Investigator (PI) should submit as a new study.

#### Protocol Distribution

A copy of each proposed significant modification is included in the meeting packet that is distributed to all members one week in advance of the meeting. If a modification is added to the agenda following distribution of the packets, the materials will be hand delivered or sent electronically to all members in advance of the meeting. NOTE: A copy of the currently approved protocol is provided to both of the reviewers in addition to the amendment request.

#### Post Meeting

Following the meeting, draft minutes are composed. Minutes include pre-protocol review discussions (training, updates, etc) and detailed comments for each protocol reviewed. For each protocol, the following information is recorded in the minutes: PI Name; PI Department; Title; Species and Number Requested; Reviewers; Committee Decision; Committee Vote and Comments to the PI. IACUC number will be assigned to the protocol once approval has been received. Comments from each reviewer and IACUC Coordinator's notes for a given protocol are combined. The draft minutes are reviewed by the IACUC Chair. The minutes are revised to include any corrections/additions/deletions made by the IACUC Chair. From the minutes, letters are composed and sent to the PI for action as follows.

Full Approval: A full approval letter is sent to the Principal Investigator (PI).

Conditional Approval: A query letter is sent to the Principal Investigator (PI) indicating the proposed modification had been conditionally approved and includes those issues that must be addressed prior to final approval. The PI is advised to submit the requested information within fifteen (15) working days and is reminded that the research proposed in the modification cannot begin until final approval is granted by the IACUC. Upon receipt of the PI's response to queries, a review (by the chair and/or other members as warranted) will take place to determine if the response is adequate. If the information is satisfactory, a final approval letter will be sent to the PI.

Request More Information: A query letter is sent to the Principal Investigator (PI) indicating that the committee requires further information to render a decision and includes those issues that must be addressed prior to further review. The PI is advised to submit the requested information to the IACUC as soon as possible and is reminded that the research proposed in the modification cannot begin until final approval is granted by the IACUC. Upon receipt of the PI's response to queries, the proposed protocol modification will be assigned to the original reviewers and put on the agenda for re-review at the next Committee meeting.

Disapproval: A letter is sent to the PI indicating that the committee had disapproved the proposed modification, the reasons for disapproval, any comments the committee had that must be addressed in the next version, and recommend consultation with the IACUC Chair and/or IACUC Coordinator or Veterinary Resources for guidance and assistance prior to submission of a new protocol. The letter also indicates that that the research proposed in the modification cannot begin until final approval is granted by the IACU

Minutes are to be sent to the committee within three working days after the committee meeting. Any comments/suggestions are to be returned to the IACUC Coordinator. Revised minutes will be presented at the next scheduled meeting.

## 2. Designated Review of Significant Amendment

The designated review mechanism is not routinely used by the IACUC, although the following methods are implemented when the IACUC Chair has determined this method is appropriate. In order for a modification to undergo this method of review, the Principal Investigator must provide documentation justifying the request. The IACUC has determined that they prefer to review all proposed significant modifications involving the use of animals at a fully convened meeting to discuss details of the proposed animal procedures.

The identified modification can be submitted on the deadline date or at any point during the month. The proposed modification will be pre-reviewed by the IACUC Coordinator and distributed to all members of the IACUC (in hard copy or electronically). The IACUC Chair will designate two or more reviewers and deadline will be provided for the opportunity for any member to request full committee review. Designated reviewers will review the proposed modification and either grant full approval, conditional approval or require full board review at the next convened meeting (or an emergency meeting may be convened if warranted). The same procedures as noted above in the outcome section for full approval or conditional approval will be implemented. If the reviewers or committee request full board review, a letter will be sent to the PI notifying him of the decision and the rationale for that decision.

The IACUC Chair will summarize for the committee the results of the designated review at the next upcoming monthly meeting for informational purposes only and this discussion will be documented in the minutes

### Specifics:

All specific details for meeting log in, meeting minutes, etc for significant amendments are already included within the details noted under New Protocol Submissions.

### Addendums

Letters of Determination  
Approval Letters

## III. ANNUAL REPORTS

### Reminders

An email is sent to the Principal Investigator (PI) at least one month in advance of the protocol's anniversary date as a reminder that an annual report is due. The PI is required to report on the progress made to date, whether any complications have been

observed and to address various questions regarding any proposed changes for the upcoming year. The completed form is to be submitted to the IACUC Coordinator prior to the anniversary date. [Delinquency in submitting an annual report will result in an administrative hold being placed on the protocol.]

#### Annual Report Review

The annual reports are reviewed by the IACUC committee and forwarded to the next committee meeting for informational purposes only. If complications or modifications are proposed, the IACUC Chair and/or other members, as needed, will review the annual report. An annual report requesting significant modifications will undergo full committee review or designated review.

#### Approvals

Once the annual report is approved, the "Annual Report Approval" letter is sent to the principal investigator. A copy of the approval letter and annual report is placed in the protocol file.

#### Meeting Minutes

Any annual report with a significant modification undergoes committee review, and the discussion and comments are noted in the minutes. See procedures for committee review of significant modifications.

An annual report agenda noting all annual reports approved since the last meeting is included in the final minutes.

#### Addendums

Annual report form  
Annual reminder letter  
Annual approval letter

### **IV. FINAL REPORTS / THIRD YEAR RENEWALS**

#### Reminders

All studies are approved for three years. Three months in advance of a study's expiration date, the PI is sent an email reminder indicating that a final report is due and if he/she wishes to continue the research a new protocol must be submitted for review prior to the current study's expiration date (noted on the reminder).

#### Final Report Review

The final report is reviewed and approved by the IACUC committee. Any final report noting complications is reviewed by the IACUC Chair. New protocols undergo full committee review.

#### Closure / Approval

Once the final report is approved, the study is closed. The expiration date is removed from the database and a "Final Report Approval" letter is sent to the investigator. A copy of the approval letter and final report is placed in the protocol file.

#### Procedures if no final report is submitted

Final report review takes place on the date of expiration, unless otherwise requested by the PI (e.g. early closure). All final reports are reviewed, approved and the study is closed. All studies for which a final report has not been submitted are identified and

administratively closed. A "Close" letter is sent to the investigator. A copy of this letter is placed in the protocol file.

All closed / completed protocols are placed in the closed drawer in the IACUC and later archived.

#### Addendums

Final report reminder

Final report

Final report approval letter.

Closure letter

### **Reporting:**

The IACUC reports to the I.O., who is the Dean of the School of Pharmacy.

1. Minutes:
  - a. Minutes of meetings are provided to IACUC members prior to the next scheduled convened meeting.
  - b. Changes or additions to the meeting minutes will be made during regularly scheduled meetings and will be approved by the IACUC members.
2. Semi-Annual reports:
  - a. Semi-annual reports are sent to the I.O.
    - i. Any minority reports will be attached.
  - b. Copies of all semi-annual report will be kept on file in the IACUC Coordinator's office
3. Deficiency Memos
  - a. Will be issued by the IACUC Coordinator and signed by the IACUC chair.
  - b. All deficiency memos will be sent to the I.O., the PI and the PI's Department Chair's
    - i. If same or identical deficiency is found on subsequent three (3) inspections the IACUC has the right to remove or suspend the active protocol until the deficiencies are corrected.
    - ii. Notification will be sent to the I.O., the PI, PI's Department Chair, and Vet Service of the removal or suspension.
  - c. Timetable for correcting deficiencies.
    - i. Deficiencies affecting animal health and being will corrected immediately
    - ii. All others deficiencies will be corrected with three days of notification.
    - iii. Copies of all deficiency memos will be kept on file in the IACUC Coordinators office

### **V. SEMI-ANNUAL INSPECTIONS**

Every six months, all facilities in which animals are housed or used are inspected by representatives of the IACUC. Inspection teams consist of at least two IACUC members accompanied by the IACUC Coordinator. The inspections are assigned by building and then broken into laboratories, animal housing facilities or satellite facilities. The IACUC database includes the location of animal usage for each protocol. Prior to each semi-annual inspection, the database is queried for each building and a report is printed out to assist inspectors in assuring all areas have been seen. Each room inspected is documented on the inspection form noting room number, PI, species used, whether surgery is conducted and if so surgical procedures and logs are inspected, drug inventory inspection, vermin control, cleanliness of room and a section to note any

deficiencies or guidance, etc. When an apparent deficiency is noted, it will be discussed with the principal investigator or research staff. The principal investigator may choose to send a formal letter to the IACUC noting what corrective action he/she has taken or they may wait to respond to the IACUC letter documenting a deficiency was found in his/her lab, etc. If immediate veterinary care is warranted, the IACUC Coordinator will contact Veterinary Resource to follow up and provide a report back to the IACUC Office of their findings, discuss actions taken, etc.

#### Inspection Report and Deficiency Notices

The IACUC Coordinator gathers information recorded on the inspection forms and composes a formal inspection report. The report briefly summarizes the IACUC's responsibilities set forth in the PHS Policy, what guidance was used as a basis for evaluation, what areas were inspected and how. The report is separated into two sections: facility inspections and program review. Under facility and lab inspections, a brief summary is included addressing whether any significant deficiencies were noted and a description of the information to follow. This section of the report is broken into sections: labs / satellites and animal housing facilities. Each section is further divided to address deficiencies, comments, or recommendations per building. Items identified in the report include building, room, principal investigator, significant or minor deficiency and its corrective action. Under program review, each element reviewed is documented noting version date. The draft report is reviewed and approved at a monthly IACUC meeting and documented in the minutes. Upon approval, corrective action letters are sent to the principal investigators, as well as those parties responsible for the animal housing facilities noting the deficiency, the corrective action to be taken and the deadline for correction.

The final report is forwarded to the Institutional Official for review, discussion as needed and sign off.

#### Addendums

Specifics: Inspection Packet Preparation & Contents

Blank Inspection Forms

Cover Letter to Inspectors

## **VI. SEMI-ANNUAL PROGRAM REVIEW**

Every six months, during monthly IACUC meetings, a review is done of the Institution's program for humane care and use of animals. The committee utilizes the OLAW Semi-Annual Program Review Checklist to aid in this evaluation. This checklist and a detailed list of the reviews including the date of the IACUC meeting in which it was reviewed and approved are included with the semi-annual inspection report and in the monthly minutes for that month.

Additionally, the IACUC conducts a review of its program on a continuing basis throughout the year. As modifications are made, review and final approval by the full IACUC is required and is documented in the meeting minutes.

#### Pre-Meeting Procedures

The IACUC Coordinator pulls all necessary documents. Each responsible party is asked to review the document(s) and ascertain that the current version on file in the IACUC is still applicable. If a document is updated, the revisions will be discussed and approved at the meeting. The updated version(s) will replace the current version on file in the IACUC.

## Addendums

OLAW Semi-Annual Program Review Checklist

Listing of items routinely included in program review.

## **VII. GRANT APPLICATIONS**

### Grant / Protocol Congruency

Per PHS Policy, the institution is required to provide assurances that the protocol approved by the IACUC is consistent with the information contained in the grant. This process occurs by one of two mechanisms:

1. If an IACUC protocol is already in existence at the time of routing, the Research Administrator in the SOP will review the grant and assure that all procedures are contained within the animal use protocol on file in the IACUC. The Research Administrator will initial the appropriate space on the second page of the routing form. If the grant is being submitted to NIH, the Research Administrator will initial the face page of the submission attesting that the latest approval date is correct and the assurance number for the School of Pharmacy is included in the appropriate space. If the grant is being submitted to an agency other than NIH and this agency requires an IACUC letter of approval for this submission, the Research Administrator will provide this letter for the grant.
2. If "just in time" procedures are being implemented, the Research Administrator in the SOP will mark the IACUC verification sections of the routing form and certification pages (e.g. NIH face page) as to be submitted. This shifts the responsibility of assuring grant / protocol congruency to the IACUC. As such, a copy of the final funded grant must be submitted to the IACUC either at the time of initial review, in response to the committee's queries, or as soon as the final version of the grant is available.

### To Be Submitted Tracking Procedures

All SOP grant applications are routed through the SOP and logged into a database. The database contains a field for IACUC information (IACUC #, status, and latest approval date). A copy of the grant must be included in this IACUC submission.

### IACUC Review

The grant / protocol comparison is conducted by the IACUC Coordinator, and reviewed by the IACUC Chair, as needed. If the animal procedures in the grant are included in the animal protocol, then the grant is filed with the protocol. No further action is taken. If there are any discrepancies, the investigator is emailed for clarifications. The clarification will be filed with the grant in the protocol. The investigator may or may not need to submit an amendment depending on the situation.

### Notes

1. The following statement regarding information on the veterinary care of the animals should be included in all grants:

Animals are maintained in the animal facilities of the University of Maryland School of Pharmacy. Animals are housed, cared for and used strictly in accordance with the NIH Guide for the Care and Use of Laboratory Animals. The University of Maryland School of Pharmacy Veterinary Resources Program is fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC). The program of animal care is directed by a full-time, specialty-trained (American College of Laboratory Animal Medicine, ACLAM), laboratory animal veterinarian. This institution has an Animal Welfare Assurance on file with the NIH Office of Laboratory Animal Welfare (OLAW), Assurance Number A3198.

2. An IACUC protocol may include additional procedures which are not included in the grant, but must include at a minimum the animal work proposed in the grant.
3. One IACUC protocol may be used for multiple grants, as long as the scientific aims are related and all the animal work proposed in the grants is approved under the specified IACUC protocol.

## **VIII. ANIMAL CARE CONCERNS**

Individuals can report any concerns regarding animal research procedures and/or animal care to the IACUC via the following methods: telephone followed by written documentation, email or a written correspondence. The IACUC prefers that the initial contact be made via telephone so that the appropriate action to ensure the well-being of the animal(s) in question can be taken immediately. Subsequently, a written description of the concern should be submitted for further action.

When a concern is reported to the IACUC Coordinator is the first point of contact. The IACUC Coordinator will obtain as much information as possible from the party lodging the concern, and contact the IACUC Chair immediately. (Anonymity of the individual initiating the concern will be respected if requested.) The chairman will follow up to obtain any additional information necessary from the individual initiating the concern and from all individuals involved in providing care or responsible for the animals in question. If warranted, visitation to the location or immediate veterinary care will be initiated. If it is decided that further action should be taken, the Chair may call an emergency meeting of the IACUC to discuss the issue at hand and whether to suspend the investigator's research until all issues with relation to the concern have been resolved.

If the latter action is necessary, the IACUC will inform the Institutional Official, OLAW and any other federal agency as required of the initial allegation and plan to move forward, consult with all parties as needed during the process and then follow up with all parties regarding the final outcome.

In general, all issues affecting the care and use of animals are brought to the attention of the IACUC at its regular bimonthly meeting, or on an emergency basis as noted above when necessary. Issues are discussed, and resolutions are documented in the IACUC minutes.

In an attempt to protect the complainant from possible reprisal, the IACUC will maintain anonymity of the individual initiating the concern, if at all possible. The individual will be kept informed of the final findings of the investigation relative to the concern of the event.

## **IX. PROTOCOL SUSPENSIONS**

Studies can be suspended as result of noncompliance with the IACUC approved protocol, with the federal regulations and/or university policies, etc., or as result of jeopardizing animal health and well-being.

The IACUC Chair and Attending Veterinarian have been given the authority to initially suspend a study utilizing their best judgment if animal health or well-being is being jeopardized or as a result of noncompliance with the IACUC approved protocol, etc. Following such action, the members will convene for a meeting to discuss the initial suspension, devise a plan to move forward, and vote to determine whether the suspension should remain in effect until the issue is resolved. The suspension could put

the whole study on hold, or certain procedures on hold. Alternatively, the IACUC Chair may call a meeting of all members to discuss an issue at hand and to decide whether a suspension is warranted.

Once a determination has been made to suspend the study, the PI, the Institutional Official, OLAW and other agencies as required will be notified. The contact with the PI and Institutional Official will be in person or via telephone. OLAW and other agencies as required will be notified by telephone or email. All conversations will be followed up with a written correspondence.

In order for a suspension to be lifted, the PI must address all committee concerns, as well as establish and implement a plan to avoid any such problems in the future. The committee will meet to vote on whether the suspension should be lifted and whether any additional stipulations should be implemented.

A final report documenting reasons for suspension, procedures followed, corrective actions taken, timelines, etc will be kept and a copy forwarded to OLAW and other federal or accrediting agencies as required.

## **X. ANIMAL ACTIVIST**

Scheduled protest must be approved by UMB Administration via the Assistant Dean for Public Affairs. The Assistant Dean determines which university officials must approve the event and determines the final approval for the event. The University Police and Veterinary Resources must also be informed of any proposed protest against animal research. The Dean of the School of Pharmacy will be notified of all protests against animal research.

If an unscheduled protest, notice of an unapproved protest, or animal activist threat occurs, the University Police Department must be immediately notified. The University Police Department will determine what action should be taken in the event of a protest / animal activist threat.

REFER TO "UM SCHOOL OF PHARMACY DISASTER PLAN FOR VETERINARY RESOURCES" FOR FURTHER INSTRUCTIONS CONCERNING THIS ISSUES. (Section entitled: Protest Against Animal Research / Animal Activist Threat)

## **XI. FILMING**

An investigator who desires media coverage of their research that involves animal usage must contact the School of Pharmacy Office of Marketing and Communications Public Affairs to coordinate coverage, or to issue a press release. A copy of the press release must be forwarded to the IACUC with a cover memo indicating the approved IACUC protocol under which the research was accomplished.

Investigators must immediately notify the Office of Public Affairs of any request by the news media to view, photograph, film or videotape animal usage. Concurrently, the investigator must immediately notify the IACUC Coordinator to inform the IACUC of any such requests. Any request by the news media to view, photograph, film or videotape animal usage must be approved in advance by the IACUC and the Associate Dean for Graduate Studies and Research. No filming by the news media may take place without prior approval.

Any filming, photographing or videotaping of animal usage must be coordinated with the Office of Associate Dean for Graduate Studies and Research. The IACUC must also be informed of the filming schedule. A member of the IACUC and a representative from the Office of Associate Dean for Graduate Studies and Research must be present during filming. In addition, a veterinarian must be present if the filming involves a surgical procedure, or if it is recommended by the IACUC.

Stock video footage of several species is/or will be available for media use. If you cannot use this stock footage, please provide justification for the necessity of additional filming. Please contact the IACUC for information regarding all stock video footage.

## **XII. RECORD KEEPING**

All animal use protocols and IACUC documents are kept on file in the IACUC Coordinator's office. All files are secured within an internal office under separate lock and key. During non-working hours, the external office is alarmed with motion detectors.

All record keeping procedures are in accordance with PHS Policy, AWA and other applicable laws, regulations or policies.

All documents such as semi-annual inspection and program review reports, USDA site visits, meeting minutes, AAALAC program description, OLAW Assurance are maintained on site for at least three years, after which point they are archived and shipped off site.

All protocols are maintained on campus while active. Once a protocol is closed, it is archived and sent off campus. All closed protocols are maintained off site for 4 years following its closure.

All files can be retrieved from archives in a timely fashion. No files are destroyed without prior consent issued by the IACUC Chair or Associate Dean for Graduate Studies and Research and the Dean of the school

## **XIII. IACUC COMMITTEE MEMBERSHIP**

Committee membership is evaluated at least once every six months. The IACUC will determine whether there is a need for additional expertise. If needed, the IACUC Chair will discuss it with the committee at the next convened meeting. If the committee is in agreement, a candidate will be pursued.

Potential committee members are identified as follow:

- a. Contact the Department Chair for recommendation of a faculty member,
- b. The committee identifies a specific faculty member, or
- c. Follow-up with a faculty member that has expressed interest in serving on the committee if and when a need arises.

If a current member resigns, he/she will be asked to recommend another faculty member from their department if possible.

The IACUC Coordinator will contact the identified member, discuss the responsibilities, expectations, and the amount of time required to serve as an IACUC member. If the faculty member is willing and able to commit to serving on the IACUC, the following information is obtained: updated CV and confirmation of willingness to serve on the committee.

The following information will be forwarded to the Associate Dean of Graduate Studies and Research and then to the Dean of the School of Pharmacy for consideration and final approval / disapproval:

1. A formal letter including the need for the additional member and a brief description of the faculty member's qualifications and training.
2. A copy of the updated CV,
3. An IACUC appointment letter for the Dean's signature.

*\*\*\*The School of Pharmacy is considered its own entity with the University of Maryland Baltimore system. All faculty appointments within the SOP are approved by the Dean of the School of Pharmacy. The SOP IACUC is specific to this school and as such all committee members are appointed by the Dean, who also serves as the Institutional Official.\*\*\**

Once a faculty member's appointment has been approved, the appointment letter is sent out. As soon as an acceptance letter is received, the faculty member will be scheduled to meet with the IACUC Coordinator and/or IACUC Chair for new committee member training. Please reference IACUC Education, Training and Resource Manual for training and orientation details.

#### **Committee Attendance**

It is the Institutional Official's expectation that all IACUC members be present at each meeting unless unforeseen circumstances arise. If a member has been assigned a review and cannot attend at last minute, the review must be faxed or emailed to the IACUC Coordinator so that the other reviewer and the chair can present the review to the committee.

#### **Membership**

Members of the IACUC are appointed by the IO, generally for 2-year terms, except as indicated below.

1. Chairperson.
  - a. Appointment:  
The Chairperson will generally serve a term of 2 years, but may serve a term of 1 year if approved by the I.O. The Chairperson's appointment is renewable by the I.O. for additional terms, and may be extended to provide continuity leading up to, and during, an AAALAC site visit.
  - b. Qualifications:
    - i Knowledgeable and effective leader;
    - ii Has been a member of the IACUC for at least two years and has served on the IACUC during an AAALAC site visit.
    - iii Responsibilities:
      - a. Works with School Administration to ensure compliance with all applicable regulations and standards and to assist in maintaining the University's AAALAC accreditation.

- b. Recommends membership changes to the I.O.;
- c. Reviews and writes policies and SOP as needed;
- d. Reviews all incoming protocols and amendments and assigns committee members as appropriate;
- e. Convenes/chairs meetings; designates acting chair if unable to attend meetings or inspections;
- f. Acts as spokesperson on behalf of the IACUC.

## 2. Members

### a. Terms

- i Faculty members may be reappointed by the I.O. as deemed necessary and for one additional consecutive term. Staff members representing specific campus units may serve multiple two (2) year terms. Non-Affiliated Members representing the interests of the community at-large may serve multiple two (2) year terms.

### b. Alternate Members

Alternate members will be appointed to the IACUC by the I.O. in accordance with PHS policy. An IACUC member and his/her alternate may not count toward a quorum at the same time or act in an official member capacity at the same time.

### c. Ad Hoc

Non-voting attendees may be invited as needed. Examples of such attendees include, but are not limited to, representative(s) from Environmental Health and Services, I.O. or designee.

## **Meeting Attendance Requirements:**

The IACUC Office will maintain IACUC member attendance records based on the calendar year

All members are required to do the following:

1. Attend approximately in total 75% of the regularly scheduled meetings and inspections.
  - a. Notify the IACUC Office if attendance at a meeting or inspections is not possible. This notification does not preclude the member from meeting the 75% attendance requirement.
2. All IACUC members are expected to participate in the required IACUC inspections and IACUC subcommittees.
3. Removal of Delinquent Members
  - a. If a member does not meet the 75% attendance requirement his/her membership on the committee can be suspended.

