National Association for Biomedical Research (NABR)
UDSA Inspection Management Checklist

This checklist was developed utilizing the various versions of the inspection guides used by the Animal Care Veterinary Medical Officers (VMOs) and our review and analysis of the commonly cited items of noncompliance. The checklist draws largely from information contained in Chapter 7 of the Animal Welfare Inspection Guide (AWIG).\(^1\) We encourage you to review that chapter for specific examples and situations applicable to your institution. Because USDA site visits are unannounced, this checklist should be used regularly to review your programs, facilities, and mechanisms in place so that compliance is ongoing and management has established processes and procedures for assuring compliance.

**IACUC Checklist**

**Membership**
- □ All required positions are filled
- □ There is documentation for the appointment of the members by the CEO or designated IO
- □ The veterinarian has appropriate experience and the authority and responsibility for animal care activities
- □ The nonaffiliated member represents the general public and has no conflict of interest and is not a lab animal user at another facility
- □ There are no more than 3 members from one administrative unit
- □ The members are qualified to assess the institution’s animal program, facilities and procedures
- □ IACUC members are properly trained in areas such as:
  - o the Animal Welfare Act
  - o protocol review
  - o facility and program review
  - o Institutional policies and procedures

**Note:** The USDA discourages one person filling multiple positions
For additional information on membership consult ASIG – 7-11-14

**Meetings**
- □ Meetings are held at least every 6 months
- □ All members are informed of all meetings
- □ Meetings are held at a time when all members, especially the nonaffiliated member can attend
  - o Required members are present at most meetings
- □ All members have access to the information distributed
- □ Information is sent to members in sufficient time prior to the meeting for them to be able to review it
- □ All members receive a list of protocols or the actual protocols to be reviewed
- □ There is a defined mechanism for a member to request full IACUC review
- □ If full IACUC review is requested, it is conducted

**Minutes** – meeting minutes should include
- □ Record of attendance
- □ Approval of minutes
- □ All activities conducted at the meeting
  - o Include any dissenting opinions
- □ Include the substance of the deliberations, not just the decisions reached

**Program of Humane Care and Use Review**
- □ Review conducted at least every 6 months
☐ If IACUC adopted the AAALAC assessment report, see pages 7.5 and 7.15 of the AWIG for specific requirements

☐ All members are informed of the date and time(s) of the review
  o All members are informed of the review by a subcommittee in sufficient time to request participation
  o Any members who wants to participate can do so

☐ The review addresses the criteria described on pages 7.15-16 of the AWIG

☐ Departures from the AWA regulations and standards are identified and include a:
  o Detailed description of the departure
  o The reason for the departure
  o Classification as a significant or minor deficiency
  o A plan and date for correction of the deficiency

☐ The report of the review is completed, signed my a majority of the IACUC members, contains any minority views and is sent to the Institutional Official

☐ Uncorrected significant deficiencies are reported to AC and the appropriate Federal agencies

Facility Inspection

☐ Conducted at least every 6 months

☐ If IACUC adopted the AAALAC assessment report, see pages 7.5 and 7.19 of the AWIG for specific requirements

☐ All members are informed of the date and time of the review
  o All members are informed of the review by a subcommittee in sufficient time to request participation
  o Any members who wants to participate can do so

☐ The inspection covers the facilities listed on pages 7.18-19 of the AWIG.

☐ Departures from the AWA regulations and standards are identified and include a:
  o Detailed description of the departure
  o The reason for the departure
  o Classification as a significant or minor deficiency
  o A plan and date for correction of the deficiency

☐ The report of the review is completed, signed by a majority of the IACUC member, contains any minority views and is sent to the Institutional Official

☐ Uncorrected significant deficiencies are reported to AC and the appropriate Federal agencies

Reports to the Institutional Officials

☐ Report submitted at least every six months in a timely manner after each program review and facility inspection

☐ Contains a description of how and to what extent the facility meets the AWA regulations and standards
  o Facility is in total compliance and description, or
  o Describes each item in noncompliance

☐ Departures from the AWA are contained in the report with:
- Detailed description of the departure
- The reason for the departure
- Classification of the departures as significant or minor
- A reasonable and specific plan for correction
- Date(s) for correction

☐ Recommendations to the IO regarding any aspect of the facilities animal care and use program including facilities and training issues.

☐ Signed by a majority of the committee

☐ Contains any minority reviews

Protocol Activity Suspension
- The activity was reviewed and suspended at a convened meeting of the IACUC with a quorum present
- The suspension was approved by a majority of the quorum
- The Institutional Official in conjunction with the IACUC
  - Reviewed the reason for the suspension
  - Took appropriate corrective action
  - Instituted adequate follow-up measures including monitoring of the suspended activity
  - Informed the Animal Care Regional Office
  - Informed the appropriate Federal funding agency

Compliant/Concerns
- Methods are in place for receiving complaints/concerns from sources outside the facility
- Confidential methods are in place for receiving complaints/concerns from sources inside the facility
- Complaints/concerns are reviewed and investigated for validity

Records – in addition to the reports mentioned above
- Protocols
- Proposed significant changes to protocols
- IACUC approval and/or recommendations to protocols and significant changes
- Other protocol related information

Telecommunications for IACUC Meetings
- If you conduct IACUC business by telecommunications, see page 7.9 of the AWIG for requirements

IACUC Protocol Review
Criteria – in order to approve a protocol or significant change in an approved protocol, the IACUC must:
- Review those components of the activities related to care and use of animals
- Determine that the proposed activities meet and comply with the AWA regulations and standards and internal polices and guidelines
Procedure

- A written protocol must be submitted to and approved by the IACUC prior to the start of any animal use activity.
- The IACUC must review all submitted protocols and decide to
  - Approve the protocol
  - Require modification to the protocol to secure approval
  - Withhold approval of the protocol
- The IACUC review must be conducted by
  - The full IACUC, or
  - A subcommittee of at least one member of the IACUC designated by the IACUC chair (Designated Member Review)
- Prior to IACUC review, each member of the IACUC must be provided
  - A list of the protocols to be reviewed
  - Upon request, a copy of a protocol
  - Afforded the opportunity to request and be granted full committee review
  - If an IACUC member has a conflicting interest with a protocol being reviewed, he/she does not participate in the review or approval of the protocol

Full Committee review
- Must take place at convened meeting
- Approval must be by a majority vote of the members present

Subcommittee Review (Designated Review)
- The Designated Reviewer has the authority to
  - Approve a protocol
  - Approve a significant change(s) to a protocol
  - Require modifications to a protocol/significant changes
  - Request a full IACUC review

Notification

- The IACUC must notify in writing the principal investigator and appropriate person at the research facility of its decision regarding the approval of a protocol
- If the IACUC withholds approval or requires modification in the protocol, it must
  - Include in its written notification the reason for the decision
  - Give the principal investigator an opportunity to respond in person or in writing.
- The IACUC may reconsider its decision to withhold approval
  - If the principal investigator addresses the concerns of the IACUC
  - Any change in the original decisions must be documented in the minutes

Protocol Requirements – A protocol to conduct an activity involving animals must contain and comply with the requirements/assurances detailed below

- Provide rationale for using animals
- Identify the species to be used
Provide a rationale for the appropriateness of the species

Provide the approximate number of animals to be used

Provide a rationale for the number of animals to be used – see page 7-22 for additional information

Describe the proposed use of the animals, including final disposition of the animals

Contain a written assurance form the principal investigator that the proposed activities do not unnecessarily duplicate previous experiments

Medical care will be
  - Available when necessary
  - Provided by a qualified veterinarian

The animal’s living conditions, housing, feeding and nonmedical care will be
  - Appropriate
  - In accordance with AWA standards
  - Directed by the attending veterinarian or other qualified scientist

All personnel who will be conducting the proposed activities on animals are qualified and trained

Pain/distress/discomfort are minimized
  - Contain a complete description of procedures to assure that pain/distress/discomfort are minimized

Describe the method(s) of euthanasia to be used

**Painful/Distressful Procedures** – procedures that may cause more than momentary or slight pain or distress to the animal must contain and comply with assurances that the pain/distress is necessary and will be relieved or minimized

Protocols with procedures that may cause pain or distress must meet the following requirements
  - The principal investigator has considered alternative procedures
  - The principal investigator has provided a written narrative description of the methods and sources used to determine that alternatives were not available – see page 7.23 of the AWIG for specifics.
  - Painful/distressful procedures will be performed with appropriate
    - Sedatives
    - Analgesics
    - Anesthetics
  - The justification for not using pain/distress relief must:
    - Be in writing
    - Detail the scientific reasons for withholding the relief
    - State the time period (if known) that the pain/distress relief will be withheld, or
- Have an assurance statement that the pain/distress relief will be withheld for the shortest period of time necessary
- The attending veterinarian or his/her designee was consulted and involved in the planning of the procedure and pain/distress relief
- Paralytics will not be used without anesthesia
- Animals experiencing severe or chronic pain/distress that cannot be relieved will be humanely euthanatized

**Surgical Procedures** – protocols that include surgical procedures must detail provisions for pre and post-procedural care including.
- Monitoring of recovery until animal is sternal
- Post-procedural observation and monitoring
- An appropriate recovery or post-recovery environment
- Use of pain/distress relieving drugs – should specify or refer to and follow IACUC approved procedures
  - Describe anticipated signs of pain and distress
  - Drugs to be used with dosages, routes of administration, frequency of administration and when drugs should be administered
  - Person responsible for assessing animals
- Withholding of drugs is scientifically justifies
- Specific requirements for the type surgery including multiple survival surgery can be found on pages 7-24-26 of the AWIG

**Exception/Exemptions** – to a particular AWA regulation and standard must be:
- Approved by the IACUC for scientific reasons justified in writing
- Examples of what does and does not need to be included can be found on pages 7.27-28 of the AWIG.

**Significant Changes to Animal Activities**
- The following significant changes must be approved by IACUC or a designated subcommittee must review
  - From non-survival to survival surgery
  - Resulting in greater pain, distress, or degree of invasiveness
  - Housing and/or use of animals in a location that is not part of the animal care program overseen by the IACUC
  - In species
  - In study objectives
  - In principal Investigator (PI)
- The following significant changes may be handled administratively according to IACUC-reviewed and approved policies in consultation with a veterinarian
authorized by the IACUC:
  o Anesthesia, analgesia, sedation, or experimental substances
  o Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
  o Duration, frequency, type, or number of procedures performed on an animal
☐ The following significant change that may be handled administratively according to existing IACUC-reviewed and -approved policy without additional consultation or notification is:
  o An increase in previously approved animal numbers

**Continuing Review** - All active protocols should be reviewed at least once within the same month or earlier than the date of the initial approval.
☐ The review may be conducted by the IACUC or a subcommittee
☐ All IACUC members are informed of the annual reviews
☐ All members are given the opportunity to participate in the annual reviews
☐ The IACUC reviews and decisions are documented in writing and available for inspection
☐ The review should consider:
  o New activities
  o Changes in the number and type of animal
  o New deviations from the AWA regulation and standards

**Annual Report** – The annual report should include:
☐ Reports from all animal facilities
☐ The correct number of animals should be reported in the correct columns
  o There are appropriate justifications for all Column E animals
☐ IACUC-approved exceptions not provided for in Animal Welfare Act regulations and standards are reported.
☐ IACUC-approved exemptions provided for in the AWA regulations and standards are not reported.
☐ No non-regulated species or activities are reported
Facility Inspection Checklist

This checklist was developed for facility personnel who are responsible for the day-to-day management of the animal care facilities and is intended to be used on a regular basis in the management of those facilities. It can also be used by the IACUC for its semi-annual inspections, but to be prepared for unannounced inspections regular internal inspections should be part of the management process.

Facilities – animal facilities which must be inspected include, but are not limited to:

- All sites where animals are housed and field study areas where animals are confined
- Inspections should review
  - Housing areas
  - Holding areas
  - Study areas, including equipment where animals are maintained for more than 12 hours
  - Food & bedding storage
  - Cage cleaning areas
  - Surgical suites and prep areas
  - Drug storage areas including investigators’ labs and offices
  - Loading docks and transport equipment
  - Housing areas at other facilities covered by IACUC protocols

- In addition to inspecting the facilities, the IACUC should:
  - Assess the condition of the animals
  - Assess the care of the animals
  - Review the management practices
  - Assess animal uses and animal care staff’s ability to recognize problems of animal health and behavior
  - Review the process for animal users and animal care staff to report animal health problems or concerns

Method

- The IACUC is responsible for determining the best method for conducting the review
  - Conduct a full committee review
  - Appoint a subcommittee as long as any member of the IACUC who wishes to participate can do so
  - May use ad hoc consultants

Criteria – The inspection must assess compliance with the AWA Regulations and Standards

- The findings of the report must be included in a report to the Institutional Official
- The findings should include an assessment of:
  - The condition of the interior surfaces
    - Are they clean
    - Are they well maintained – impervious to moisture and readily sanitizable
      - Have deficiencies been previously noted and scheduled for repair
  - Enclosures
    - Do they provide adequate space for the size and number of animals
    - Are they being cleaned and sanitized appropriately
      - Are their appropriate records for this
- Are they being properly maintained
  - To permit effective cleaning and sanitation
  - To prevent animal injuries
  - To prevent animal escapes
  - To comply with institutional programs for environmental enrichment and socialization.
  - Are there records to document the maintenance process
- Mechanical system systems
  - Are room conditions being maintained within acceptable limits for
    - Temperature
    - Humidity
    - Air flow
      - Rate
      - Direction
      - Dusty/dirty vents
    - Are mechanical systems being monitored and documentation of that monitoring available
      - Is there a mechanism in place when mechanical settings fall outside of established acceptable limits
- Husbandry
  - Are there written procedures for the husbandry procedures being used
    - Is the staff trained on those procedures
      - Is there a record of that training
    - Are those procedures being followed
    - Is there a system in place to document that the procedures are being followed
    - Are systems in place to address failure to perform duties as assigned
  - Is the staffing level adequate for the number of animals being maintained
  - Are staff cross-trained to deal with staff absences
  - Is staffing on weekends and holidays sufficient to maintain a consistent level of care
- Veterinary Care
  - Does the system for daily observation of animals have
    - A defined procedure for observing the animals
    - A defined procedure for reporting those observations
    - A defined procedure for reporting animals in need of veterinary care
    - A defined procedure for following up in a timely manner
    - Are there records to document the various procedures
    - Are those procedures being followed
  - Records – medical records are not required by the regulations but are useful mechanism for documenting an effective program of veterinary care
    - Medical Records
- Should contain adequate information to assess the health of the animal and the procedures to be done to assess the health status and to provide treatment when necessary
  - Should not contain extraneous information

- Necropsy Records
  - Should contain the concise observations made at necropsy and in the review of histopathology
  - Should not contain extraneous information

- Treatment records
  - Should be clearly written
  - Document administration of treatment