

A tool for semiannual review of the institutional animal care and use program

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To ensure compliance with animal welfare laws and regulations, many research institutions review their animal care and use programs on a semiannual basis. In many cases, however, review committees fail to make the most of this process, basing their evaluations on general and sometimes outdated guidelines that do not address their specific needs. The authors present a worksheet that they developed and successfully implemented at their institution, aimed at inspiring an efficient and fruitful discussion of animal care and use.

Institutions in the United States that use animals for research, teaching or educational outreach must adhere to a strict set of animal welfare laws and regulations. These laws require institutions to assume responsibility for the animals under their care and to treat them humanely and ethically. Many facilities ensure their compliance with these requirements by carrying out a semiannual review, in which the Institutional Animal Care and Use Committee (IACUC) evaluates the animal care program against standards of best veterinary, management and oversight practices. Though the semiannual evaluation should also include facility inspection, this article focuses on program review.

The Animal Welfare Act (AWA) Regulations state that a registered research facility's IACUC must review its "program for humane care and use of animals" at least once every six months, using the AWA as a standard reference¹. The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) echoes this requirement, with the modification that it cites the *Guide for the Care and Use of Laboratory Animals (Guide)*^{2,3}. The AWA Regulations and the PHS Policy direct the IACUC to identify deficiencies in the program, to categorize those deficiencies as minor or significant and to establish plans and set deadlines for correction. The policies explicitly require review committees to report their findings to the Institutional Official and in annual summaries to the Office of Laboratory Animal Welfare (OLAW)^{4,5}, and the AWA Regulations require uncorrected significant deficiencies to be reported to the USDA's Animal

and Plant Health Inspection Service, which enforces the AWA.

Though the AWA Regulations and the PHS Policy establish specific timelines for conducting program review, they do not concisely define what constitutes a "program of humane care and use of animals," rendering review of such programs a challenging task. OLAW published a sample Semiannual Program and Facility Review Checklist to assist institutions in this process (<http://grants.nih.gov/grants/olaw/sampledoc/checklist.htm>). OLAW encourages institutions to amend the checklist to fit their particular needs. The sample checklist enumerates specific requirements of the program, taken directly from the PHS Policy. One limitation of this method, if used in its original format, is that it restricts the IACUC to assigning each program item only one of the following three outcomes: acceptable, minor deficiency or significant deficiency.

Some committees carry out reviews by referring to institutional standard operating procedures for facility and IACUC operation. In AAALAC-accredited institutions, the IACUC might base semiannual reviews on the AAALAC Animal Care and Use Program Description. Committees may also use the table of contents of the *Guide* to direct discussion. Additional information about program review is available in *The IACUC Handbook*⁶ and in *The Institutional Animal Care and Use Committee Guidebook*⁷.

Our institution, a large land-grant university, has tried each of the approaches described above. In the authors' experience, none of the methods stimulated a

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sufficiently detailed evaluation, nor did they facilitate thorough review of the development of each program component over time or in relationship to the program as a whole. Most importantly, these approaches did not guide the IACUC to explore the critical links that must exist between the components of a functional animal care program. Only true integration of program elements can ensure appropriate veterinary care and animal husbandry, careful review of proposed animal activities and high-quality facility development and maintenance.

Our institution created and published a definition of an “animal care program”⁸. We used this definition as a basis to develop the Wisconsin Institutional Animal Care and Use Program Review Worksheet and have used the definition and the worksheet successfully in four consecutive semiannual program reviews. We present the worksheet below with a description and discussion of its use. We believe that other institutions may find value in this approach.

WORKSHEET USE

The complete worksheet is available for download from <http://www.rarc.wisc.edu/> as a Microsoft Word document named ‘Program Review Worksheet’. The worksheet is composed of nine sections, taken from our published program definition⁸: (I) Physical Plant; (II) Animal Environment, Housing, and Management; (III) Personnel Qualifications and Training; (IV) Occupational Health and Safety; (V) Veterinary Medical Care; (VI) Institutional Animal Care and Use Committee (IACUC); (VII) Institutional Official (IO); (VIII) Program Integration; and (IX) Support of the Institutional Mission. Each section states core requirements that the program must meet and includes blank space for the committee’s evaluation of the program’s compliance with each requirement. The nine sections and their core requirements are summarized in **Box 1**.

We organized the sections and formulated program requirements with input from IACUC members, laboratory animal veterinarians and administrative support staff, who reviewed drafts of the worksheet. Because the worksheet was developed after the 1996 revisions to the *Guide*, it includes evaluation of “IACUC training” and of the “Animal Facility Disaster Plan.” These categories are not present on the OLAW checklist.

Several weeks before a special IACUC meeting for program review, we distributed copies of our program definition and the worksheet to all meeting participants. At the meeting, the committee Chair read each statement aloud and committee members responded by discussing the program’s corresponding strengths and weaknesses, but specifically did not attempt to identify solutions to problems. Representatives from core campus services, such as Occupational Health and Safety, Physical Plant, facility management and program

training, participated in the discussion. In some cases, the committee concluded that it did not have sufficient information to respond to a particular statement in the worksheet. The responses were recorded, and a draft of the completed worksheet was presented at the next regular IACUC meeting, where committee members designated each deficiency as minor or significant, identified necessary corrective actions and established correction deadlines. The committee’s discussion and any minority opinions were recorded in the minutes, as required by AWA Regulations and PHS Policy. Finally, the IACUC Chair composed a report to the Institutional Official that summarized the minutes and the completed worksheet. All IACUC members, as well as senior deans from each school and college affiliated with our institution, viewed the report. The deficiencies and potential solutions that were identified immediately emerged as tasks to be delegated to various campus units, subcommittees or individuals. In effect, identifying these program deficiencies set the course for program discussion during the next few IACUC meetings. After the first review, we asked IACUC members to suggest changes, additions and clarifications for the worksheet itself. We did not allow deletions, to ensure that critical components would be retained. We modified the worksheet accordingly, generally by clarifying text or by adding content as our understanding of program needs evolved.

Our institution has successfully used the worksheet in four consecutive semiannual program reviews, refining the process to fit committee and institutional needs. As the committee became more familiar with the worksheet format, it could carry out reviews more efficiently. In the second and subsequent reviews, IACUC members received the previous review worksheet in advance with deficiencies and comments retained, in addition to the associated report to the Institutional Official. The committee considered whether previous deficiencies had been fully or partially corrected, whether new deficiencies existed and whether other substantial changes had occurred in the program over the previous six months. The committee determined that some deficiencies had been addressed in full. Other problems remained, though committee members acknowledged ongoing corrective efforts. The committee identified potential solutions for new and continuing deficiencies and established correction deadlines. As before, all IACUC members and senior deans viewed the report to the Institutional Official.

By the third program review, the committee was able to complete the process in a single meeting. Discussion concentrated on past and new deficiencies. Committee familiarity with the worksheet eliminated the need to read aloud each program element. This enabled committee members to track the program status efficiently, including progress made in correcting past deficiencies. Now experienced with the worksheet, the committee

BOX 1 | SUMMARY OF THE WISCONSIN INSTITUTIONAL ANIMAL CARE AND USE PROGRAM REVIEW WORKSHEET

The worksheet in its entirety may be downloaded from <http://www.rarc.wisc.edu/>. Here we present a summary of the worksheet contents, which omits the blank spaces intended for the committee's comments. The worksheet was based on refs. 3,8 and 9.

(I) Physical Plant

- A. Methods exist to assure Veterinary, IACUC, PI, and Program staff input into animal facility planning, design, and construction to ensure that new or remodeled facilities meet Program needs.
- B. The animal facilities adhere to performance standards in the areas of facility planning, design, and construction. All animal facilities meet relevant physical plant performance standards.
- C. Appropriate areas are available for:
 - animal housing
 - animal care
 - sanitation of cages and other materials
 - separation of species or isolation of individual projects when necessary
 - materials receiving and storage
 - other specialized spaces, facilities, and/or equipment required for the conduct of certain studies
 - performance of aseptic surgery
- D. Appropriate areas are available for receipt and quarantine of arriving animals, and separation and quarantine of animals if there are disease outbreaks.
- E. Methods exist to monitor and maintain the physical condition of animal facilities to ensure that it remains adequate and appropriate.
- F. Procedures exist to identify, communicate, and correct animal facility physical deficiencies.
- G. Other criteria that should be used to evaluate physical plant & the animal program.

(II) Animal Environment, Housing, and Management

- A. When providing animal housing the institution considers the appropriateness of:
 - the shape, size, and construction of the animals' primary enclosures (cage, pen, etc.)
 - temperature, humidity, ventilation, and illumination
 - behavioral management, including any needs for social housing and/or activity
- B. In assuring appropriate management of animals and animal facilities the institution considers:
 - animal husbandry, including selection, storage, preparation, and provision of food, bedding, and water
 - sanitation of enclosures and physical plant
 - integrated pest control programs
 - weekend and holiday animal care
 - population management, including animal identification (cage cards, ear tags, tattoos, etc.) and records
 - facility security and biosecurity
 - preparation of a disaster plan that takes into account both personnel and animals as well as biosecurity
- C. Methods exist to monitor and maintain the physical, procedural, and human contributions to adequate animal environment, housing, and management to ensure that they meet performance standards for all animals. That is, facilities are checked to ensure animals are fed, watered, cared for, and protected in species-appropriate ways.
- D. Facilities in which animals are housed and used are secure and provide animal and human safety. That is, access to animals in facilities is controlled, monitored, and/or documented.
- E. Procedures exist to identify, communicate, and correct deficiencies

in animal environment, housing, and management.

- F. Other criteria that should be used to evaluate animal environment, housing, management & the animal program.

(III) Personnel Qualifications and Training

- A. All categories of personnel that constitute the animal research and care community receive adequate and appropriate training, including:
 - physical plant and security staff
 - animal care staff
 - management and supervisory personnel
 - veterinarians and veterinary staff
 - research personnel, including investigators, instructors, technicians, trainees, and students
 - IACUC members
 - Institutional Officials
- B. As appropriate, each member of the animal research and care community (as listed above) understands:
 - the components of the animal care and use Program
 - his or her role within that Program
 - how that role interacts with the roles of other members of the community
- C. The institution provides initial formal and/or on-the-job training in Program goals and the humane care and use of animals.
- D. Personnel using or caring for animals participate regularly in continuing education activities relevant to their responsibilities.
- E. There are methods to evaluate the effectiveness of the initial and continuing training of all individuals working with animals.
- F. Procedures exist to identify, communicate, and correct deficiencies in training.
- G. Other criteria that should be used to evaluate training & the animal program.

(IV) Occupational Health and Safety

- A. The institution's Occupational Health and Safety Program meets the following performance criteria.
 - A1. Hazard identification and risk assessment associated with:
 - animal care
 - animal experimentation
 - teaching using animals
 - outreach using animals
 - A2. Personnel training
 - A3. Personal hygiene
 - A4. Facilities, procedures, and monitoring
 - A5. Personal protection
 - A6. Medical evaluation and preventive medicine for personnel
- B. The institution monitors the effectiveness of the Occupational Health and Safety program.
- C. Procedures exist to identify, communicate, and correct deficiencies in the Occupational Health and Safety program.
- D. Other criteria that should be used to evaluate the Occupational Health and Safety Program for the animal program.

(V) Veterinary Medical Care

- A. The Program defines and meets appropriate performance standards for animal procurement and transportation.
- B. The Program defines and meets appropriate performance standards for preventive medicine, including animal quarantine, stabilization, and separation, as well as surveillance, diagnosis, treatment, and control of disease.
- C. The Program defines and meets appropriate performance standards for management of experiment-associated disease, disability, or other sequelae.

- D. The Program defines and meets appropriate performance standards for assessment of animal well-being.
- E. The Program defines and meets appropriate performance standards for establishment of adequate surgical and post-surgical care, including proper use of anesthesia and analgesia.
- F. The Program defines and meets appropriate performance standards for proper selection and conduct of euthanasia.
- G. The Program defines and meets appropriate performance standards for veterinary participation in protocol development and review.
- H. The institution employs a sufficient number of veterinarians trained to meet Program needs.
- I. There is effective evaluation and mentoring of research animal veterinarians to meet Program and individual's needs.
- J. A mechanism exists for direct and frequent communication to ensure that timely and accurate information is conveyed to the veterinarian on problems associated with animal health, behavior, and well-being.
- K. Mechanisms exist to ensure appropriate veterinary participation in decisions regarding animal husbandry, preventive medicine, and experiment design and conduct, including surgical and post-surgical care.
- L. Veterinarians are provided with sufficient authority to carry out their duties.
- M. Records document provision of adequate veterinary care to all animals.
- N. The institution monitors the effectiveness of the Veterinary Care program.
- O. Procedures exist to identify, communicate, and correct deficiencies in the Veterinary Care program.
- P. Other criteria that should be used to evaluate the program of veterinary care within the animal program.

(VI) Institutional Animal Care and Use Committee (IACUC)

- A. The IACUC reviews and evaluates the Animal Program semiannually.
- B. The IACUC inspects facilities semiannually.
- C. The IACUC evaluates "animal activity areas" (e.g. labs where animals go for procedures, surgery areas, transport vehicles, "temporary" housing, etc.).
- D. The IACUC submits reports to institutional officials.
- E. The IACUC reviews proposed uses of animals in research, teaching and outreach (i.e., protocols), including special review requirements regarding physical restraint, multiple major surgical procedures, and food or fluid restriction.
- F. A mechanism is established for receipt and review of concerns involving the care and use of animals at the institution, including the establishment of a "Whistleblower Policy."
- G. The IACUC advises and makes recommendations to the Institutional Official on any aspect of the Program.
- H. The IACUC has the authority to suspend any animal activity that does not comply with applicable regulations and policies.
- I. The institution backs the authority of the IACUC.
- J. The IACUC has adequate administrative support.
- K. The IACUC members understand the role and responsibilities of the IACUC.
- L. The IACUC members receive suitable orientation, background materials, and specific training in understanding and evaluating issues brought before the committee.
- M. An effective mechanism exists for direct and frequent

communication to ensure that timely and accurate information is conveyed to the IACUC regarding problems in any Program component.

- N. Methods exist to monitor and maintain IACUC activities and effectiveness in support of the Program.
- O. Procedures exist to identify, communicate, and correct deficiencies.
- P. Other criteria that should be used to evaluate the IACUC's role in the animal program.

(VII) Institutional Official (IO)

- A. The IO understands Program structure.
- B. The IO monitors Program functions, including IACUC activities and membership.
- C. The IO receives appropriate and timely communications from the IACUC and other members of the Program.
- D. The IO has authority to enforce Program policies.
- E. The IO has access to necessary financial resources.
- F. Annual and other reports are submitted to federal agencies in a timely manner by the IO.
- G. The institution ensures that the IO receives appropriate administrative, financial, and legal support to develop and maintain the Program of Animal Care.
- H. Methods exist to monitor and maintain the effectiveness of the IO.
- I. Other criteria that should be used to evaluate the IO's role in the animal program.

(VIII) Program Integration

- A. There is a cadre of individuals with expertise and understanding regarding Program components who can evaluate Program adequacy.
- B. There is strong and well-informed administrative coordination of efforts to support the Program.
- C. Institution-wide there is effective and timely communication among Program administration, veterinarians, principal investigators, IACUC, and the IO so that each of these groups can carry out its designated responsibilities.
- D. There are sufficient financial, physical, procedural, and human resources to meet Program objectives.
- E. There is institution-wide recognition of the need for and practice of compliance; that is, all Program personnel and participants accept that they must follow the rules.
- F. Methods exist to monitor program integration to ensure that all Program elements function well together.
- G. Procedures exist to identify, communicate, and correct deficiencies in program integration.
- H. Other criteria that should be used to evaluate integration of the animal program.

(IX) Support of the Institutional Mission

- A. The animal care program supports and enhances research activities that involve animals.
- B. The animal care program supports and enhances teaching activities that involve animals.
- C. The animal care program supports and enhances outreach activities that involve animals.
- D. Methods exist to monitor and maintain the effectiveness of the program.
- E. Other criteria that should be used to evaluate the efficiency and efficacy of animal program in fulfilling its mission.

found that the flexible review format permitted highly focused discussion of problem areas and allowed more time to seek creative solutions. In informal interviews, IACUC members considered the process to be far more

effective than other approaches taken in the past.

The worksheet can be adapted for different organizational structures. Our institution has five animal care and use committees (ACUCs), which function as

subcommittees to an All-Campus IACUC. Each school or college ACUC works according to AWA Regulations and PHS Policy requirements and carries out semi-annual inspections of animal facilities and activity areas. The All-Campus IACUC is composed of the Chair of each ACUC, the Chief Campus Veterinarian and nonaffiliated, nonscientist members. This committee has final responsibility for the campus-wide animal care program. A single IACUC administrator coordinates the activities of all six committees. The Institutional Official has authority over the animal care program for the entire campus. For our program reviews, each school or college ACUC conducted a separate review of its part of the overall program. The IACUC administrator collected the responses of all of the ACUCs, and the All-Campus IACUC evaluated them. The members of this committee also received a summary of each ACUC's semiannual facility inspections and evaluated them from a broad institutional perspective. The committee identified positive aspects of the animal care program, noting strengths and successes. The All-Campus IACUC made final decisions regarding deficiencies, solutions and deadlines for correction. They summarized their findings in a report to the Institutional Official, which was sent to all ACUC members.

DISCUSSION

Our IACUC became quickly accustomed to using the worksheet in semiannual program review. By the third review using this format, each committee could conduct a comprehensive and detailed review of the program, including suggestions to correct deficiencies, in a single meeting. In our institutional experience, we find the worksheet to have several distinct advantages over other standard review methods. First, our approach is based on a concise yet comprehensive definition of an, "animal care and use program"⁸, ensuring that the committee does not omit any important program components from its evaluation. Second, the worksheet serves to focus discussion on problem areas and requires the committee to precisely define the nature of each problem. This precision enables the committee to identify effective solutions. Third, as determined by post-review interviews with participants, the well-defined procedure allows committee members to carry out the review with confidence, and receiving copies of the report to the Institutional Official lets them recognize the result of their efforts. The wide distribution of the summary report improved communication within our program and allowed committee members to feel that they had accomplished something valuable. Finally,

the worksheet format encourages acknowledgment of a program's strengths and successes, too often overlooked during the review process.

We recommend that committees follow certain guidelines when using the worksheet. First and foremost, they should limit the initial discussion to identification of problem areas, without trying to find solutions. Our committees each appointed one member who was responsible for interrupting meeting participants who gave in to the natural tendency to propose solutions to problems being discussed. This intervention allowed us to accomplish our first objective, the development of a comprehensive list of problems. Separating problems from solutions can also lead to more efficient discussion, allowing problems with the same solution to be considered together. Without this separation, our review process would have been far more drawn out and may even have ground to a halt, particularly during the first use of the worksheet. Second, each institution should tailor the Worksheet to fit its specific characteristics and needs, though excessive focus on details can be counterproductive. Finally, to ensure that reviews remain relevant, committee members should treat the Worksheet as a 'living' document that develops with the institutional animal care and use program and accommodates changes in regulations. The desired result is a comprehensive document that guides a natural flow to committee semiannual program review.

COMPETING INTERESTS STATEMENT

The authors declare no competing financial interests.

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