DIVISION OF AGRICULTURE
RESEARCH & EXTENSION
University of Arkansas System

Review Boards

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I. Introduction

All sponsored research involving human or vertebrate animal subjects conducted by the University of Arkansas Cooperative Extension Service (UACES) is subject to the approval of an applicable review board. While the UACES does not have its own review boards, the institution utilizes those of the University of Arkansas, the University of Arkansas at Little Rock, or the University of Arkansas for Medical Sciences when research warrants review.
In regard to research on humans, UACES research is guided by the requirements of the Nuremberg Code; the 1979 Belmont Report of Ethical principles and Guidelines for the Protection of Human Subjects in Research; the guidelines of 45CFR46, Protection of Human Subjects (National Institute of Health); and 21CFR50, Protection of Human Subjects (Federal Drug Administration). For animals, UACES must follow requirements of the Animal Welfare Act (AWS), the United States Department of Agriculture (USDA), the Public Health Service (PHS), and the Department of Health and Human Services Office of Laboratory Animal Welfare requirements (DHHS). Provisions of these agencies and statutes apply to all projects federally-funded or subject to federal regulations. While review board approval is not required to submit a proposal to a potential funder, approval is necessary prior to implementation of the project. It is also incumbent upon the principal investigator to receive review board approval for any modifications that may impact research subjects during the course of a project.

II. Research versus Program Assessment

According to the policies of the University of Alaska-Fairbanks, when determining the need for review board approval, the principal investigator must first decide if the proposed project constitutes research or program assessment. In general, program assessment, also involving quality improvement or assurance, includes

projects intended to measure the effectiveness of a process or program. Results of program assessment projects are typically shared only with those individuals involved in the process. Research, on the other hand, involves an investigation intended to contribute to public knowledge, the results of which will be shared with those directly and indirectly associated with the project. In simple terms, program assessment is intended for a narrow, internal audience while research is intended for broad, external dissemination.
The University of Alaska-Fairbanks has developed the following table to assist investigators in determining if a proposed project represents research or program assessment.

	Research	**Program Assessment**
Purpose	*Systematic study or probing inquiry in some field of knowledge*	*Evaluate a process, program, or system*
Starting Point	*Formal research question and literature review*	*Established set of standards*
Benefits	*Knowledge benefits more than subjects of study*	*Directly benefits process, program, or system*
Risks/Burdens	*May put subjects at risk*	*No risk with the exception of possible privacy/confidentiality concerns*
Data Collection	*Systematic or Exploratory*	*Limited to aspects of process, program, or system*
End Point	*Establish facts, discover principles that benefit public or discipline-related knowledge*	*Improve specific process, program, or system*
Testing/Analysis	*Describe frequency and importance of factors; inquire about relationships between factors; determine temporal order; establish likelihood of outcomes*	*Compare to established set of standards*

Intended Result *with those*	*Share findings with individuals*	*Share findings only*
	Involved and not involved in study, Including dissemination of information in public settings	*Involved in study*

If a project is determined to be Program Assessment, Review Board approval is not normally necessary; however, if there is a substantial risk of breach of privacy or confidentiality, the project should be reviewed.

In some cases, research projects may be exempt from review board oversight or eligible for expedited review. General determination of review requirements for DHHS can be made by consulting decision charts available at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html. For guidance with projects funded by other agencies, please consult the Office of Sponsored Programs.

Many institutions require investigators to complete human and animal subject prior to engaging in research. Both UALR and UAMS require training of all investigators involved in human subject research, while the training is voluntary at UAF (with the exception of projects funding by the National Institute of Health). UAF does require training for investigators working with animals. UACES employees can enroll in online training through the Collaborative Institutional Training Initiative at https://www.citiprogram.org. Certification renewal provisions apply at all institutions. See the following websites for additional information on certification, policies, and forms related to review boards:

http://www.uams.edu/orc/Human%20Subject%20Protection.htm

http://vpred.uark.edu/210.php

http://ualr.edu/irb/index.php/home/human-research-training/

III. Institutional Review Board

The Institutional Review Board (IRB) evaluates research involving human subjects to ensure methods, instruments, reporting, and all other aspects of the project protect research subjects as required by the Belmont Report. The components of the Belmont Report include both ethical principles and application requirements as discussed in the Research Ethics/Misconduct of Research Document. As noted, UACES does not have its own IRB; rather, it coordinates with those of other U of A institutions.

In reviewing proposed research, it is the IRB's responsibility to ensure that:

- risks (including physical, psychological, social, legal, or economic) to human participants are minimized;
- participation is voluntary;
- informed consent will be sought from each prospective participant or the participant's legally authorized representative;
- the investigator has and follows a procedure for properly documenting informed consent;
- selection of participants is equitable and recruitment method is suitable;
- there is an appropriate plan for protecting the confidentiality of identifiable data during and after conclusion of the investigation; and
- there is a plan for protecting the privacy interests of research participants during and after their involvement in the research (University of Arkansas—Little Rock).

The IRB must give special consideration to projects involving children, prisoners, people with disabilities, and other groups that may be vulnerable. Special scrutiny is also required if a project is proposed to focus exclusively on individuals of a single group (race, ethnicity, etc.).

IV. Institutional Animal Care and Use Committee

Institutions that receive federally-sponsored program funding are subject to the Animal Welfare Act (AWA) and Public Health Service (PHS) guidelines in regard to research involving vertebrate animals. Under AWA, the institution must meet several requirements, including the establishment of an Institutional Animal Care and Use Committee (IACUC). The UACES does not have an internal IACUC, with vertebrate animal-related research submitted to other U of A institutions for review.

The IACUC must review <u>all</u> research proposals involving use of animals prior to implementation of the project. The principal investigator should consider research methods, animal care and handling, and transportation while planning the project and include steps necessary to mitigate potential violations of AWA and PHS guidelines.

Federal government regulations require that an IACUC certify adherence with the following principles:

- Transportation, care, and use of animals must be in compliance with AWA and applicable federal laws, policies, and guidelines.
- Procedures involving animals should be designed and performed with due consideration of their scientific relevance to human or

animal health, the advancement of knowledge, or the good of society.

- The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on non-anesthetized animals paralyzed by chemical agents.
- Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

It should be noted that despite IACUC approval, responsibility for adherence to regulations related to vertebrate animals rests with those conducting the

research. It is incumbent upon the principal investigator to inform the IACUC of changes or modifications that may impact animal welfare.

V. Other Compliance Issues

- *Biohazardous Agents*: All researchers dealing with biohazards should be schooled in handling, treatment, and disposal of hazardous materials. Consult the following for additional information:

  http://ehs.uark.edu/PwrPt/BiosafetyTraining.pdf

  http://ehs.uark.edu/PwrPt/BloodbornePathogens.pdf

  http://ualr.edu/facilities/uploads/2009/08/Disposing%20of%20Biohazardous%20Material%208-11-091.pdf

  http://uams.edu/safety/Forms/LabForms.aspx

- *Occupational Health and Safety*: Protection of both employees and research subjects is governed by institution, the Occupational Safety and Health Administration, and several other federal agencies. For additional information on Occupation Health and Safety programs, consult the following:

  http://ualr.edu/policy/index.php/7015

  http://www.uams.edu/safety/

  http://ehs.uark.edu/BiologicalSafety.aspx

- *Environmental Protection and Compliance*: Federally-funded projects are subject to the requirements of the National Environmental Protection Act (NEPA), governed by the Environmental Protection Agency. Some agencies require completion of a NEPA-compliance form and/or environmental assessments prior to awarding funding. Information related to various forms of environmental protection can be obtained at the previously listed websites or at http://ceq.hss.doe.gov/.

- *Toxic Substances*: Investigators should be familiar with policies and procedures related to use, storage, and disposal of toxic agents. The following sites offer information related to institutional policy on these issues:

http://vpred.uark.edu/206.php

http://ualr.edu/facilities/uploads/2011/03/CHP%203%20Edit%2011-1-10.pdf

http://www.uams.edu/clinlab/Chemical_Hygiene_Plan.htm