Assurances Regarding the Protection of Human Subjects, Providing Humane Treatment of Animals, and Monitoring the Use of Recombinant DNA

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring the use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational Representative (AOR) that appropriate committees in each institution have carried out the initial review of protocols and will conduct continuing reviews of supported projects.

A. BIOSAFETY OF RECOMBINANT DNA

If the project involves the use of recombinant DNA molecules, the performing organization shall assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS, Guidelines for Research Involving Recombinant DNA Molecules, as revised:

http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

This responsibility includes:

1. Ensuring that a standing Institutional Biosafety Committee (IBC) is maintained in accordance with Part IV of the NIH Guidelines and also ensuring that the research plan is reviewed and approved by the IBC prior to commencing substantive work under the project.

2. Registering with the IBC all experiments involving recombinant DNA molecules conducted with funds provided under the project and complying with the containment requirements specified in Part III of the NIH Guidelines. Records of this research must be kept in a form that is available to CSREES upon request.

In addition, the funded recipient must report the following supplemental data to CSREES and to the reviewing IBC:

a. New technical information relating to risks and safety procedures.

b. Serious accidents or releases involving recombinant DNA.

c. Serious illness of a laboratory worker which may be project related.

d. Other safety problems.

For serous adverse events, see Appendix M-I-C-4 Safety Reporting of the NIH, DHHS Guidelines for Research Involving Recombinant DNA Molecules, as revised, at:

http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_M.htm#_APPENDIX_M-I-C-4._Safety

B. CARE AND USE OF ANIMALS

The responsibility for the humane care and treatment of vertebrate animals used in any research project supported with CSREES funds rests with the performing organization. If a project involves animals, except farm animals used for food and fiber research, the personnel identified with the project, and the endorsing officials of the recipient's organization agrees to comply with the Animal Welfare Act (AWA). The AWA (7 USC 2131-2156; Public Law 89-544, 1966, as amended) and the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR Parts 1, 2, 3, and 4, and subsequent rules and regulations) that pertain to the care, handling, and

treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal awards are published at:

http://www.nal.usda.gov/awic/legislat/awicregs.htm

In the case of laboratory animals used or intended for use in research, the institution shall adhere to the principles enunciated in the Guide for the Care and Use of Laboratory Animals, (ILAR, National Academy of Sciences); 1996:

http://www.nap.edu/readingroom/books/labrats/

and to the USDA regulations and standards issued under the public laws stated above. In case of a conflict between the guidelines, the higher standard of care shall be used.

When domesticated farm animals are used or intended for use in agricultural food and fiber production research, teaching or other activities and housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 1999 which is available from the Federation of Animal Science Societies, 1111 N Dunlap, Savoy, IL 61874.

http://www.fass.org/publications.asp

Prior to commencing research activities with vertebrate animals, all protocols involving animals in CSREES funded projects must be approved by the Institutional Animal Care and Use Committee (IACUC):

http://grants.nih.gov/grants/olaw/olaw.htm

C. PROTECTION OF HUMAN SUBJECTS

The performing organization is responsible for protecting the rights and welfare of any human subject involved in CSREES sponsored research and related activities. If a research project protocol involves the use of human subjects, the institution agrees to comply with the Department of Health and Human Services' (DHHS) regulations on the protection of human subjects:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

as set forth in 45 CFR Part 46, 1991, as amended (formally adopted as The 'Common Rule'), and USDA regulations set forth in 7 CFR 1c, 1992.

Definitions pertaining to this regulation include:

Human subject means a living individual about whom the investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop generalizable knowledge. For example, some demonstration and service programs may include research activities.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject that are performed for research purposes.

Interaction includes communication or interpersonal contact (e.g., surveys) between investigator and subject.

Private information includes information which is individually identifiable and the individual can reasonably expect will not be made public.

All research protocols involving human subjects must be approved and undergo continuing review by an Institutional Review Board (IRB).

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk or be damaging.

3. Research not exempt in #2 may be exempt if, in the use of educational tests, the subjects are elected or appointed officials, or federal statutes require that confidentiality will be maintained.

1. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

2. Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs.

3. Taste and food quality evaluation and consumer acceptance studies.

Human subjects may not be involved in research activities until IRB approval is obtained and accepted by CSREES.