UNITED STATES DEPARTMENT OF AGRICULTURE COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE ASSURANCE STATEMENT(S)

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring 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 reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

NOTE: Check appropriate statements, supplying additional information when necessary.

1. INSTITUTION

2. CSREES PROJECT NUMBER OR AWARD NUMBER (if known)

3. PROJECT DIRECTORT(S)

4. TITLE OF PROJECT

A. BIOSAFETY OF RECOMBINANT DNA

- □ Project does not involve recombinant DNA.
- Project involves recombinant DNA and was either approved () or determined to be exempt () from the NIH Guidelines by an Institutional Biosafety Committee (IBC) on ______ (Date).

This performing organization agrees to assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS <u>Guidelines for Research Involving Recombinant DNA Molecules</u>, as revised.

B. CARE AND USE OF ANIMALS

- □ Project does not involve vertebrate animals.
- □ Project involves vertebrate animals and was approved by the Institutional Animal Care and Use Committee (IACUC) on (Date).

This performing organization agrees to assume primary responsibility for complying with the Animal Welfare Act (7 USC, 2131-2156), Public Law 89-544, 1996, as amended, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 CFR Parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the institution shall adhere to the principles stated in the <u>Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching</u>, Federation of Animal Science Societies, 1999.

C. PROTECTION OF HUMAN SUBJECTS

- □ Project does not involve human subjects.
- □ Project involves human subjects and

□ Was approved by the Institutional Review Board (IRB) on ______ (Date). Performing Institution holds a Federalwide assurance number ______; if not, a Single Project Assurance is required.

- □ Is exempt based on exemption number _____
- □ Specific plans involving human subjects depend upon completion of survey instruments, prior animal studies, or development of material or procedures. No human subjects will be involved in research until approved by the IRB and a revised Form CSREES-2008 is submitted.

This performing organization agrees to assume primary responsibility for complying with the Federal Policy for Protection of Human Subjects as set forth in 45 CFR Part 46, 1991, as amended, and USDA regulations set forth in 7 CFR 1c, 1992. All nonexempt research involving human subjects must be approved and under continuing review by an IRB. If the performing organization submits a Single Project Assurance, supplemental information describing procedures to protect subjects from risks is required.

SIGNATURE OF AUTHORIZED ORGANIZATIONAL REPRESENTATIVE	TITLE	DATE

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average .50 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

CSREES-2008 (12/02/00)