Instructions for Completing Assurance Statements and Certifications of Protection from Research Risks

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 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.

If a research proposal covers multiple projects in which experimental protocols vary, the AOR must provide documentation of certification, through multiple copies of Form CSREES-2008, by the appropriate committee(s) for each specific protocol utilized in the projects. Examples of multiple project/proposals may include large multi-faceted special grants, multi-institutional consortia, multi-state research projects and some large umbrella Hatch proposals.

Formula funded activities require a certification of action taken by appropriate committees, which necessitates inclusion of the date of the action; the designation of 'pending' is not an option. The designation of 'pending' may be inserted for other grant proposals in lieu of reporting a date of certification that an appropriate committee took action. However, a subsequent approval must be obtained, and a revised Form CSREES-2008 must be submitted before a final award can be made.

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. Actions by the IBC must be documented in Section A of the Form CSREES-2008.

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.

The NIH Guide for Reporting the Occurrence of Serious Adverse Events is published at:

http://grants2.nih.gov/grants/policy/recombinentdnaguidelines.htm

IBC review and approval must be documented in Section A of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section A of the Assurance Form 2008 should not be older

than 36 months.

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 must comply with the Animal Welfare Act (AWA). The AWA (7 USC, 2131-2156; Public Law 89-544, 1996, 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) pertain to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal awards:

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 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:

http://www.nal.usda.gov/awic/index.html

which is available from the Federation of Animal Science Societies, 1111 N Dunlap, Savoy, IL 61874.

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://grants2.nih.gov/grants/olaw/olaw.htm

IACUC review and approval must be documented in Section B of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section B of the Assurance Form 2008 should not be older than 36 months.

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 must agree to comply with the Department of Health and Human Services' (DHHS) regulations on the protection of human subjects:

http://ohrp.osophs.dhhs.gov/polasur.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. If a research project protocol involves the use of human subjects, one and only one of the three options outlined under section C of Assurance Form 2008 must be checked.

All nonexempt research protocols involving human subjects must be approved and undergo continuing review by an Institutional Review Board (IRB). If the performing organization qualifies for Federalwide Assurance (FWA)

status and has been approved by the Office for Human Research Protections (OHRP), DHHS, then report the assurance number along with the approval date. A list of IRBs with FWA status is available at:

http://ohrp.osophs.dhhs.gov/irbasur.htm

If the performing organization does not have MPA status, a Single Project Assurance (SPA) form may be obtained from OHRP, HHS at:

http://ohrp.osophs.dhhs.gov/humansubjects/assurance/spa.htm

and must be submitted. A SPA is a document to assure compliance and continuing review of the project being proposed, and it is limited in use and duration to this individual research activity. A SPA signed by the IRB Chairperson, AOR, and Project Director of the research project must be submitted. Also, provide additional information regarding the recruitment and selection of subjects, the proposed processes of informed consent and maintenance of confidentiality, and risk and benefit assessments for review by CSREES staff. An institution submitting a SPA may utilize its own IRB or the IRB of a neighboring institution.

The IRB approval date should reflect a timely review. The date reported in section C of the Assurance Form 2008 should not be older than twelve months, because the "Common Rule" requires annual review.

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.

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

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

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

A complete explanation of these exemptions can be found at:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance

A project may be funded but temporarily excused from IRB approval if specific protocols involving human subjects depend upon the development of survey instruments, procedures or materials, or completion of animal studies. However, human subjects may not be involved in research activities until IRB approval is obtained and a revised Form CSREES-2008 is submitted.