

U.S. Department of Energy
Washington, D.C.

ORDER

Approved: 12-20-07

SUBJECT

b. Solicitations

relevant to DOE employees, DOE contractor personnel, financial assistance recipients, and the public in consultation with the NNSA HSR Manager, as appropriate.

- (6) Regularly conducts institutional performance reviews to assess compliance with human research subjects protection requirements in consultation with the NNSA HSR Manager, as appropriate.
- (7) Serves as the Chair of the DOE Human Subjects Working Group and as the official DOE representative to groups with bioethics and HSR interests. The NNSA HSR Manager shall be invited to attend all such meetings.
- (8) Makes recommendations to the Secretary or the Secretary's designee regarding requests for waivers to requirements of 10 CFR 745.101 and satisfies the advance notice and publication requirements of 10 CFR 745.101(i) prior to the granting of any waiver (in consultation with the NNSA HSR Manager, as appropriate).
- (9) Concurs in HSR provisions in interagency agreements in consultation with the NNSA HSR Manager, as appropriate.
- (10) Maintains the HSR Projects Database for the Department.

d. NNSA HSR Manager.

- (1) When an NNSA element is involved, reviews requests for waivers to requirements of 10 CFR 745 and makes recommendations to the Secretary

promptly referred to the HSR Program Manager for resolution (or the NNSA HSR Manager when an NNSA element is involved).

- (3) Ensure that the contracting officer is advised when work statements for proposed agreements include HSR. The requirements of this Order will be applied to HSR conducted with DOE funding, at DOE institutions, or by DOE personnel under agreements other than site/facility management contracts, such as support services contracts, grants, cooperative agreements, work-for-others agreements, and interagency agreements.
- (4) Ensure their staffs and subordinate field elements comply with the requirements of this Order, including the notification requirements in paragraph 4e.
- (5) Actively participate in human research subjects protection educational programs.
- (6) Assure self-assessments are periodically conducted to verify compliance with the requirements of this Order.
- (7) At their discretion, conduct further review and approve or disapprove research that has been approved by the IRB. (Note: Secretarial Officers or their designees may not approve HSR that has not been approved by an IRB. See 10 CFR 745.112.)
- (8) Ensure appropriate oversight of the administration of research subjects protection programs of contractors and financial assistance recipients under their cognizance, and other parties to DOE agreements, to ensure compliance with applicable human research subjects protection requirements.
- (9) Ensure that the HSR Program Manager and the NNSA HSR Manager are involved in negotiating those portions of interagency agreements that address HSR.
- (10) Appoint a point of contact for interacting with the HSR Program Manager (and/or NNSA HSR Manager, when an NNSA element is involved) on program-related and/or Department-wide issues.

6. DEFINITIONS.

- a. Assurance. The written documentation, satisfactory to the Secretary of Energy, required from the prospective performing institution, that ensures institutional compliance with and implementation of DOE and Department of Health and Human Services (DHHS) regulations for the protection of human research subjects. The only documentation currently meeting this requirement is a Federalwide

access to classified and unclassified controlled STI is protected according to legal or Departmental requirements.

- c. DOE O 412.1A, *Work Authorization System*, dated 4-21-05, which provides the policy, responsibilities, and procedures for authorizing and administering DOE-funded work performed under DOE contracts.
- d. DOE P 443.1A, *Protection of Human Subjects*, dated 12-20-07, which defines DOE policy for the protection of human subjects in research activities.
- e. DOE O 481.1C, *Work for Others (Non--Department of Energy Funded Work)*, dated 1-24-05, which establishes the policy, responsibilities, and procedures for authorizing and administering work for non-DOE entities by DOE/National Nuclear Security Administration (NNSA) and/or their respective contractor

k. 10 CFR 605,

implementation of DOE and DHHS regulations for the protection of human research subjects. See http://www.hhs.gov/ohrp/assurances/assurances_index.html and/or contact the DOE HSR Protection Program, SC-23.2, telephone 301-903-3213, or the NNSA human subjects protection designee, as appropriate.

6. Ensure that research is reviewed at intervals appropriate to the degree of risk, but not less than once per year, to assess the risk to test subjects and to assure the risk is reasonable in relation to anticipated benefits.
 7. Periodically conduct self-assessments to ensure compliance with the HSR Program procedures and other requirements.
 8. Prepare and submit an annual report for the HSR Projects Database in accordance with directions and schedules provided by the HSR Program Manager and the contracting officer.
 9. Report the following to the HSR Program Manager (and, when an NNSA element is involved, the NNSA HSR Manager):
 - a. any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken and/or to be taken;
 - b. any suspension or termination of IRB approval of research;
 - c. any significant non-compliance with HSR Program procedures or other requirements.
- NOTE: The adverse effects of any study are to be reported to the IRB for evaluation for further action with HSR Program Manager, (and, when an NNSA element is involved, the NNSA HSR Manager)
10. Submit requests for waivers from these requirements in writing through the contracting officer to the HSR Program Manager (and, when an NNSA element is involved, the NNSA HSR Manager) with appropriate justification.
 11. Actively participate in HSR educational programs.