Policy Regarding Research Involving the Use of Human Subjects

Applicants requesting research funds from HEI-Energy are asked to indicate in their application whether human subjects or derived materials will be used in the course of their study. Applicants indicating that they would use human subjects or materials are asked to provide additional information about their studies in their application and to complete OMB form 0990-0263. HEI-Energy also informs them that they would need to obtain IRB approval, or exemption (as defined in article 40 Code of Federal Regulations (CFR) Part 26.101(b), and submit relevant documents to HEI-Energy, including any correspondence between the IRB and the researchers. All IRB approval is contingent on whether the study is in accordance with 40 CFR Part 26 and EPA Order 1000.17A. HEI-Energy will in turn obtain approval from an on-site, EPA-approved Human Subjects Officer (HSO) if available, and from a Human Subjects Research Review Official (HSRRO) before signing a contract for the study. Each HEI-Energy contract for research will include the required contractual language at the end of this policy. No work may begin, including recruitment of subjects, before both the IRB and EPA processes have been completed satisfactorily.

For each study involving human subjects, the materials HEI-Energy submits to EPA for review and approval include: (1) OMB form 0990-0263, (2) application to IRB (including all supporting documentation submitted to the IRB, such as the study protocol, questionnaires, informed consent document [if applicable], etc.), (3) approval from IRB or a statement from the IRB that the study is exempt, and (4) approved informed consent document (if applicable). EPA may, at its discretion request additional information or clarification. HEI-Energy also requires that investigators submit copies of their yearly IRB renewal applications and approvals, including evidence of subsequent IRB review following amendments and minor protocol changes; HEI-Energy submits these materials to EPA.

In cases where HEI-Energy intends to fund a study whose application does not indicate that human subject or derived material will be used, HEI-Energy Staff working with experts on its Research Committee, make an evaluation as to whether they agree with the applicant's determination; this evaluation involves a review of all aspects of the proposed study, including the methods to be employed, origin and source of materials or data to be used, sampling and other approaches to obtaining data, etc. If HEI-Energy determines that human subjects or materials will not be involved (such as for animal, atmospheric chemistry, or certain air monitoring studies), no further action is taken. In cases where HEI-Energy disagrees with the applicant's assessment, HEI-Energy asks the investigator to obtain a determination from his/her IRB. Whether the IRB approves or exempts the study, HEI-Energy follows the procedures described above. In cases where the use of human subjects is not clear cut, HEI-Energy submits the proposal from the investigator to the EPA and requests a determination, and takes further steps as indicated by that determination.

HEI-Energy's Required Contractual Language regarding the use of human subjects in research conducted by Universities and Other Research Institutions funded by HEI-Energy:

Use of Human Subjects

A. The Institute and the University hereby agree that the protection of the rights and welfare of human subjects involved in the work under this Agreement is the sole responsibility of the University. The University and any assignee or subcontractor (at whatever tier) shall comply with all governmental requirements relating to such protection.

B. Because the research to be funded under this Agreement will include funding from the U.S. Environmental Protection Agency, the University and any assignee or subcontractor (at whatever tier) involved in such research will consult EPA Regulation 40 CFR 26 ***(Protection of Human Subjects)****,*

available from EPA's Program in Human Research Ethics (http://www.epa.gov/osa/phre/index.htm). 40 CFR 26 includes the Common Rule at subpart A, and additional protections for pregnant women and fetuses, nursing women, and children at subparts B, C, and D. Particularly noteworthy is that research meeting the regulatory definition of intentional exposure research found in subpart B is prohibited by that subpart in pregnant women, nursing women, and children. Human exposure research includes any intervention that modifies (i.e., increases, decreases, or otherwise changes) a participant's exposure as part of the research project, and these activities are therefore prohibited in pregnant women, nursing women, or children who participate in HEI-Energy-sponsored research.

C. Furthermore, it is the sole responsibility of the University to determine whether or not the work under this Agreement involves research with human subjects as defined in the Common Rule. If the University determines that such work does not involve research with human subjects, a statement to that effect, signed by an authorized representative of the University, must be delivered to the Institute prior to beginning work under this Agreement.

D. If the University determines that work under this Agreement involves research with human subjects, then before commencing such research:

(i) *The University and any assignee or subcontractor (at whatever tier) engaged in such research shall have an assurance on file with the U.S. EPA pursuant to the Common Rule. The U.S. EPA accepts the Federalwide Assurance filed with the Office for Human Research Protections of the U.S. Department of Health and Human Services for this purpose; and,*

(ii) *The University and any assignee or subcontractor (at whatever tier) engaged in such research shall obtain an approval or exemption determination from an institutional review board (IRB) designated on its assurance with certification to the U.S. EPA and confirmation of the approval or exemption determination by the EPA Human Subjects Research Review Official.*

E. In addition to meeting the above listed requirements, the University shall submit to the HEI-Energy:

i. Copy of the Investigator's IRB application as approved or exempted by the IRB, including the protocol and informed consent form, if applicable; and

ii. Documentation of the IRB's final approval or exemption determination. This may be provided either by a copy of the IRB's approval or exemption determination letter or by submission of OMB Form 0990-0263, aka HHS Optional Form 310.

If at any time HEI-Energy determines that the investigator is not working within the requirements or standards of 40 CFR part 26, EPA Order 1000.17A, or the principles set forth by the Scientific and Ethical Approaches for Observational Exposure Studies (SEAOS), HEI-Energy may immediately suspend the contract until the investigator corrects any evidence of noncompliance. It is HEI-Energy's general practice to have a Quality Assurance Plan and to review its implementation, using an external QA contractor, for all research studies that involve human subjects. Details of the QA policy are provided in a separate document.