EPA New England
Human Subjects Research
Implementation Plan
Revision 1.1
5/23/07

I. Background

EPA has national policies and procedures to safeguard subjects of human research. In 1977, EPA issued its "Policy and Procedures on Protection of Human Subjects." In 1991 EPA, along with 16 other federal agencies adopted the "Common Rule." The "Common Rule" outlined ethical principles and procedures that must be followed when conducting or supporting Human Subjects Research (HSR). On July 30, 1999, EPA updated the 1977 Policy document with EPA Order 1000.17 Change A1, "Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research (the Order)." On April 7, 2006, EPA's final rule (40 CFR Part 26), to provide expanded protections for subjects in human research, became effective.

In its diligence to comply with the requirements of the Common Rule and EPA Order 1000.17 Change A1, the Region has developed and is implementing this Regional plan. It is the policy of EPA New England to comply with EPA Human Subjects Research requirements. Further, EPA New England supports the expanded protections for subjects in human studies research and its objectives to protect the safety, confidentiality, privacy and respect of research volunteers.

II. General Approach

EPA New England is using a multi-faceted approach to comply with EPA's HSR requirements. Important principles in the development of this plan include:

- Clearly identifying roles and responsibilities of management and staff.
- Creating a process analogous to, and coordinated with peer review.
- Making the process as self-sustainable as feasible.

The key components of the Regional HSR plan include training and a three-part process:

- Identify potential HSR activities.
- Make HSR determinations for activities that may be human subjects research.
- Meet Agency requirements for all HSR activities.

Attachment 1 illustrates the Regional procedures for human subjects research.

Implementation of this three-part process will include:

- Designating a Regional HSR Coordinator.
- Providing office-specific contacts for HSR.
- Establishing an HSR Committee affiliated with the Regional Science Council (RSC) to identify potential HSR activities and to provide advice to make HSR determinations. At a minimum, the Committee will include the Regional HSR Coordinator, the Regional Science Advisor, the Regional Peer Review Coordinator, the Regional Information Quality Guidelines Officer, and HSR Contacts for Offices that may oversee or fund HSR activities (ORA, OEP, OES, OSRR, and OEME).
- An annual region-wide survey to identify potential HSR activities and significant public health practice activities.
- A semi-annual HSR "awareness" email to managers and selected staff to remind them of HSR obligations.

- Training management and key staff and documenting the training via the Regional START system.
- Utilizing the Regional Science Council to communicate and coordinate with the EPA Regional scientific community.
- Establishing grant conditions for potential HSR activities.
- An intranet-based HSR information and resource web page linked to the RSC site.
- Conducting an assessment of the Region's implementation of this plan in 2008.

III. Training

EPA New England has developed and will deliver mandatory on-line HSR awareness training to managers and targeted personnel. Personnel will have 30 days to complete the on-line training**.** The training is intended to help managers and staff:

- Be knowledgeable of our Regional process.
- Identify potential HSR activities.
- Understand and fulfill HSR requirements.
- Understand their HSR roles and responsibilities
- Know how to access and use HSR information resources.

In addition to all Regional Managers, the target audience for training is personnel who are most likely to have an involvement with potential HSR and PHP activities such as grant project officers; tribal, environmental justice, urban, and children's health staff; risk assessors; grant and contract award officials; and others.

In addition to the on-line training, it is likely that several "open house" sessions will be available to provide the opportunity to supplement their knowledge of HSR. These open house opportunities are voluntary.

All projects officers who are actually involved in supporting, conducting, or funding an HSR activity are required to also immediately complete the National Cancer Institute's "Human Participant Protections Education for Research Teams" on-line course. The link is: http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

Should EPA develop or make available other mandatory HSR training in the future, the Region will substitute that training for the NCI course.

IV. Identifying Potential Human Subjects Research Activities

Annual HSR Survey

On an annual basis and coordinated with the call for peer review products, the Regional HSR Coordinator will survey (Attachment 2) each Office to identify activities that EPA is planning, or is already, conducting, funding, or supporting that may be HSR activities. The survey may include activities, such as public health practice, that are eventually determined not to be human subjects research. For each activity identified in the survey, a tentative HSR determination will, subsequently, be made by the Regional HSR Coordinator.

Offices that may oversee or fund HSR activities (ORA, OEP, OES, OSRR, and OEME) shall designate an HSR contact who will be a member of the HSR Committee. The Committee is affiliated with the Regional Science Council. The HSR Committee will also include the Regional Peer Review Coordinator, the Regional Information Quality Guidelines Officer, and the Regional Science Advisor. The Office Contacts will assist the Regional HSR Coordinator by conducting the survey within their respective Office. The survey response will identify new

or on-going potential HSR activities or affirmatively state that, to the best of the Office Director's knowledge, no new HSR activities are ongoing or planned.

On-going HSR Vigilance

Front line regional personnel involved in the day-to-day business of the Agency are critical to the Region's ability to identify potential HSR activities that EPA may be conducting, funding, or supporting. On an ongoing basis, and especially during project planning, regional personnel should be aware of potential HSR activities. Immediately upon receiving information that EPA may be planning to be involved in, or is already, conducting, funding, or supporting potential human subjects research, that has not been identified in the Annual HSR Survey, regional personnel shall inform their direct supervisor of this activity and complete an HSR Tentative Determination Form (Attachment 3). The supervisor will immediately notify the Office Director and the Regional HSR Coordinator regarding the potential HSR activity. The potential HSR activity must then follow the Regional HSR process described in Section VI and Attachment 1 of this Plan.

If any HSR activities were started before approval or exemption, they must immediately stop until they are approved or determined to be exempt by the Agency's Human Subjects Research Review Official (HSRRO, or Review Official).

A semi-annual HSR "awareness" email will be sent by the Regional HSR Coordinator to remind regional personnel of their HSR obligations.

V. Making HSR Determinations

Staff have the primary responsibility to identify and document potential HSR activities. The project officer prepares, with input from the Regional HSR Coordinator, and signs the Tentative Determination Form and submits it to his/her supervisor for signature.

The supervisor, within whose unit a potential HSR activity is being planned, funded, conducted, or supported, is responsible for ensuring that the HSR Tentative Determination Form is completed. This form must be completed for all potential HSR activities, including those HSR activities discovered outside of the annual HSR survey process. The supervisor will sign and submit to the Regional HSR Coordinator all HSR Tentative Determination Forms. The Coordinator will make a tentative determination and will submit all tentative determinations to the Agency's Review Official for a final determination, approval, or exemption.

EPA Order 1000.17 Change A1 requires that all HSR activities must either be approved or be determined to be exempt research by the HSRRO before any funding agreements can be awarded or entered into. All human research studies conducted by EPA must also be approved or determined to be exempt by the HSRRO before work can start.

The Regional HSR Coordinator maintains the originals of HSR surveys and Tentative Determination Forms, including forms that document public health practice activities.

VI. Process for HSR Activities

When the HSRRO makes a determination that an activity is HSR, EPA staff/project officer requests required documentation from the Project Manager/Principal Investigator (PM/PI) and submits it to HSRRO for review, through the Regional HSR Coordinator. Required documentation includes:

- Study design and protocols
- Consent forms
- Principal investigator contact information
- Local Institutional Review Board (IRB) approval letter and Federal Wide Assurance number.

If the HSR project involves a grant or contract, staff works with grants/contract office to record project as HSR in Integrated Grants Management System and with the Regional HSR Coordinator for entry in the Regional HSR database.

The Agency HSRRO reviews the documentation package. If the HSRRO concurs with local IRB decision that HSR project conforms to the Common Rule, the project may be funded and begun. If HSRRO does not concur, Regional HRS Coordinator, the Office HSR Contact, and staff/project officer organize a conference call to discuss basis for non-concurrence and required corrective action. If necessary, staff submits revised documentation to HSRRO through Regional HSR Coordinator. If concurrence is not achieved, the project may not be funded or begun.

The Regional HRS Coordinator maintains records of all Region 1 HSR projects, coordinates the annual poll of HSR projects conducted by R1 Office/Program Contacts, and conducts periodic audits of HSR projects for compliance with EPA Order 1000.17 Change A1 by reviewing staff records on HSR projects. Staff/project officer shall maintain individual project records and are responsible for enforcement of EPA Order 1000.17 Change A1.

VII. Grant Condition

All grant agreements that may involve HSR activities must include the following language:

> **Human Subjects:** The grant recipient agrees to meet all EPA requirements for studies using human subjects prior to initiating any work with these subjects. These requirements are given in 40 C.F.R. 26. Subpart B of 40 C. F. R. 26 prohibits intentional exposure studies in children and pregnant or nursing women. For observational studies, refer to C. F. R. 26 Subpart C for pregnant women and fetuses and Subpart D for children. No work involving human subjects, including recruiting, may be initiated before EPA has received a copy of the applicant's Institutional Review Board's (IRB) approval of the project and the EPA has also provided approval. Where human subjects are involved in the research, the recipient must provide evidence of subsequent IRB reviews, including amendments or minor changes of protocol, as part of annual reports.

VIII. Roles and Responsibilities

Regional HSR Coordinator:

The HSR Coordinator serves as the primary point of contact with Headquarters, the HSRRO, and other Regions regarding HSR matters. The HSR Coordinator is responsible for ensuring that the annual HSR survey is conducted and, in conjunction with the Peer Review Coordinator, coordinated with the annual peer review product inventory. The Coordinator will also send a semi-annual "HSR awareness" email to all Regional personnel. The HSR Coordinator assists in the preparation of, and signs, the Tentative Determination Forms.

The HSR Coordinator maintains the originals of HSR surveys and Tentative Determination Forms and develops and maintains, if needed, an HSR tracking system. He/she submits all Regional Tentative Determination Forms to the HSRRO for a final determination, approval, or exemption. The Coordinator also maintains records and conducts periodic audits.

Office Directors:

Office Directors are responsible for their Office's conformance with this plan and EPA HSR policies and regulations. Office Directors will ensure that the annual HSR surveys are completed and sign their Office's HSR survey form.

Supervisors:

Supervisors sign the HSR Tentative Determination Forms for all HSR activities within their unit and submit the forms to the Regional HSR Coordinator. The supervisor will inform their Officer Director of any potential HSR activities that are identified outside of the annual HSR survey. Supervisors are encouraged to consult with the Regional HSR Committee when reviewing HSR Tentative Determination Forms

HSR Contacts and Committee:

The HSR Office Contacts and Committee provide HSR technical advice to management and staff. The Office Contacts also help coordinate the HSR process and activities within the Region especially within their respective Offices. Specifically, the Office Contacts conduct the annual HSR survey within their respective offices and submit the results to the HSR Coordinator.

Staff/Project Officers:

Staff have the primary responsibility to identify and document potential HSR activities. The project officer prepares, with input from the Regional HSR Coordinator, and signs the Tentative Determination Form and submits it to his/her supervisor for signature. The supervisor submits the form to the Regional HSR Coordinator.

Under Section 6.b.(3) of the Order: The project officer is responsible, *inter alia*, for monitoring the conduct of the study for compliance with the agreed upon procedures and methods for the protection of the rights and welfare of human subjects. Such monitoring may involve various management techniques such as site visits, review of documentation, and communication with the researchers. Should the project officer discover material noncompliance with the assurance or with the IRB approved methods and procedures, the project officer shall notify his/her management, Office Contact, HSR Coordinator, the Award Official/Contracting Officer (when applicable), and the Review Official at once.

All HSR projects officers are required to immediately complete the National Cancer Institute's "Human Participant Protections Education for Research Teams" on-line course. The link is: http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

EPA Award Official/Contracting Officers:

Section 6.c.(1) of the Order provides the following: The EPA Award Official/Contracting Officer is responsible for ensuring that the written approval or exemption determination from the Review Official is submitted as part of the funding package prior to awarding or entering into any contract, grant, cooperative agreement, CRADA, interagency agreement, or any formal agreement involving research covered by this Order. He/She is responsible for including within the contract, grant, cooperative agreement, CRADA, or other formal agreement, except interagency agreements, a clause or special condition requiring compliance with EPA's

regulations, policies and procedures for the protection of human subject research and described and referenced in this Order. For interagency agreements he/she is responsible for including a clause or special condition requiring protection of human subject research subjects as per that department's or agency's own version of the Common Rule. Should the department or agency not be a signatory to the Common Rule, the clause or special condition will require compliance with EPA's regulations, policies, and procedures as described or referenced in this Order. If the project has human subjects, but is not research he/she must assure that an explanation of why the project is not research is included in the funding package.

IX. Access to HSR Information Resources

An important component to the successful implementation of this plan is the use of information technology resources to communicate, educate, and provide HSR-related information to all personnel. They include:

- Web-based training described in Section III., above.
- An HSR intranet page [http://r1-gis-web.r1.epa.gov:9876/rsc/hsr.htm] with content and web links, including:
  - The Regional Plan, including HSR documentation
  - EPA's Human Subjects Research Regulations
  - EPA Order 1000.17 Change A1
  - EPA's HSR web page [http://www.epa.gov/oppfead1/guidance/human-test.htm]
  - Training materials
  - U.S. Health and Human Services Office for Human Research Protection web page http://www.hhs.gov/ohrp/
  - Other appropriate information.

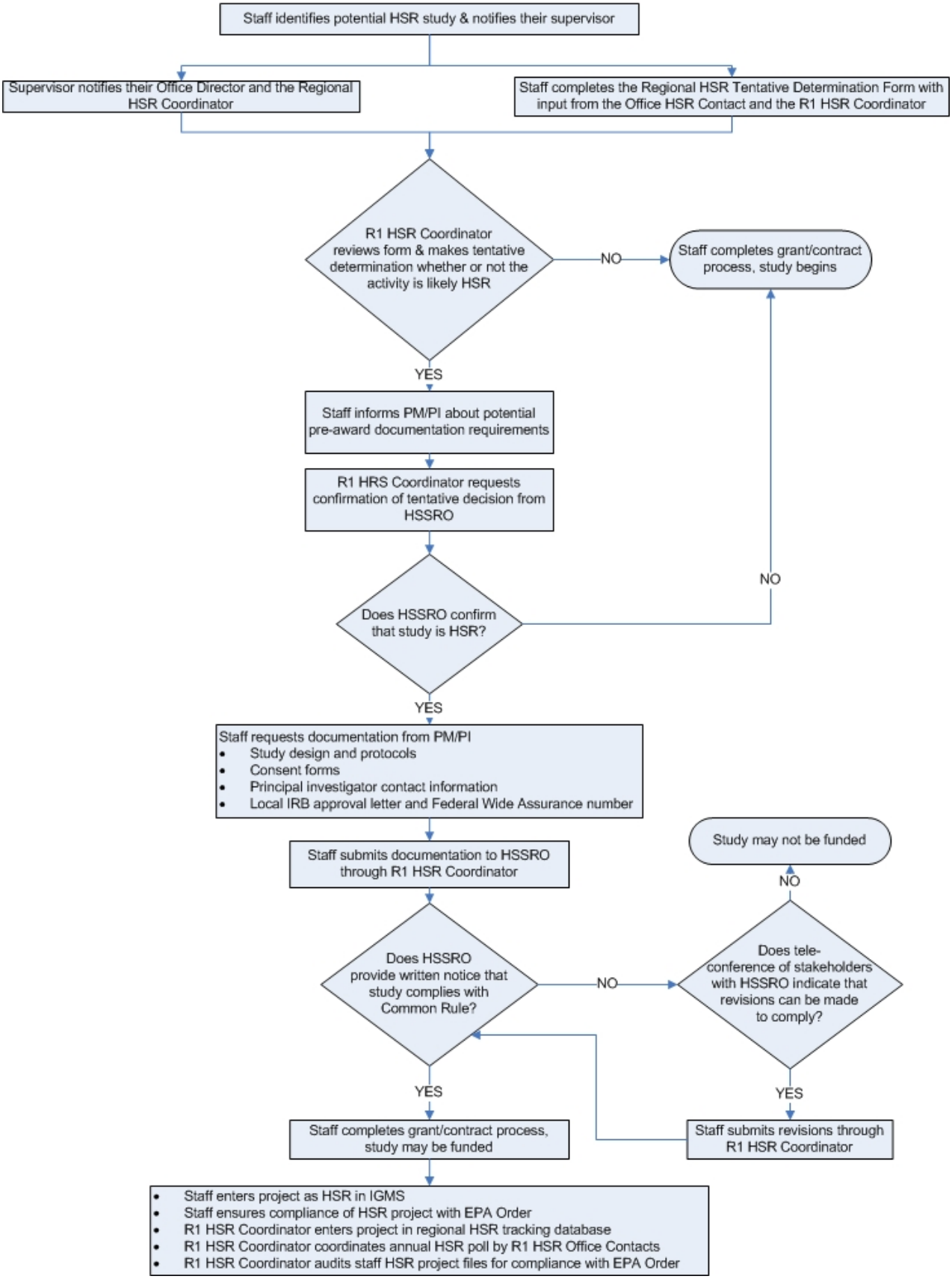
X. Regional HSR Contacts and Committee Members

The following Regional personnel have been designated as HSR Contacts and/or HSR Committee members and should be contacted for additional information pertaining to HSR.

ORA – Jerry Minor-Gordon
OSRR & Regional HSR Coordinator – Rick Sugatt
OES – Lucy Casella
OEP – Marybeth Smuts
OEME & Regional Peer Review Coordinator – Ann Jefferies
Regional Science Advisor - Bob Hillger
Regional Information Quality Guidelines Officer - Gerry Sotolongo

Attachment 1

EPA New England's HSR Process



Attachment 2
EPA New England Annual Survey to Identify
Activities that <u>May Be</u> Human Subjects Research (HSR)

Instructions: Identify all planned or on-going projects/activities that <u>may be</u> potential human subject research in the appropriate location below. Include any activities where there is any question or doubt as to whether the activity is public health practice or human subject research. Every potential HSR project/activity listed must have an HSR Tentative Determination form (attached) on file with the Regional HSR Coordinator. A new form must be completed only for those activities/projects identified below that do not have a completed form on file.

Office Director signs the survey and returns it to the Regional HSR Coordinator.

New activities/projects including activities not previously identified in an annual survey (If no new potential HSR activities are identified, check the last box.)**:**

List HSR activities that have been completed in the previous 12 months.

☐ Based upon current information, to my knowledge, there are <u>no new</u> potential human subject research projects/activities planned, conducted, funded, or supported by this office.

_____ _____

Office Director **Date**

Attachment 3

EPA New England
Human Subjects Research
Tentative Determination Form
(Use a separate form for each activity/project)

1. Project Officer's Name:

2. Project Officer's Office/Unit:

3a. Description of activity/project. Include specific details of any activities that may be human subjects research*. Explain whether or not the activity may involve human subjects and whether or not it is research (versus public health practice). **It is highly recommended that you consult with the Regional HSR Coordinator to provide assistance in completing this form.**

_____ _____

Project Officer's Signature / Date Supervisor's Signature / Date

4. Tentative Determination* - Based upon the currently planned or on-going activities, and the information presented, it is probable that this project or activity DOES/DOES NOT involve human subjects research.
Rationale:

_____

Regional Human Subjects Research Coordinator / Date

cc: Office Director

*See next page for additional, explanatory information on human subjects research and public health practice. Also, see [web page] for additional information.

Items 1-3 are completed by the Project Officer.
Item 4 is completed by the Regional HSR Coordinator.

Brief Overview of
Human Subjects Research and Public Health Practice*

Human subject means a living individual about whom an investigator conducting research obtains:
(1) Data through intervention or interaction (including survey or interview) with the individual, or
(2) Identifiable private information.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Identifiable private information: The identity of the subject is or may readily be ascertained by the investigator or associated with the information. Examples of subject identifiers:

Names
Telephone numbers/fax numbers
Any geographic subdivisions smaller than a state, including street addresses, city, zip code
Any elements of dates for dates directly related to an individual including birth date
Electronic mail addresses
Social security numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Web universal resource locators (URLs) and internet protocol (IP) address numbers
Biometric identifiers, including finger and voice prints
Full face photographs or any comparable images
Any other unique identifying number or characteristic or code
Occupation or profession

Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Public health practice: The collection and analysis of identifiable private information or data by an authority for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community. The information is not designed or planned to be used for a wider community.

What's the difference between human subjects research and public health practice?

- The intent is a determining factor!
- The intent of human subjects research is to generate or contribute to generalizable knowledge.
- The intent of public health practice is to prevent or control disease or injury and improve health of a particular community; or to improve a public health program or service to a particular community.

There are difficult and complex matters to interpret, so please consult with the Regional Human Subjects Research Coordinator.

See [http://r1-gis-web.r1.epa.gov:9876/rsc/hsr.htm**] for additional information.**

*This summary information is based upon 40 CFR Parts 9 and 26; EPA's "Expanded Protections for Subjects in Human Studies Research" web pages (http://www.epa.gov/oppfead1/guidance/human-test.htm); and the proceedings from EPA's September 26 – 29 2005 HSR Workshop in Seattle, Washington titled "Protection of Human Subjects in EPA's Research and Non-Research Studies."