CHECKLIST-Modification of the Human Environment			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-421	5/7/19	E. White/C. Hautala-Bateman	1 of 3
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314-WORKSHEET-Criteria for Approval when research involves modification of the human environment. For the IRB, this checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.

- For initial review using the expedited procedure and modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Designated Review" activity.
- For initial review using the convened IRB and for modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB complete the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB complete this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB uploads this checklist in the "Submit Committee Review" activity.

1 Applicability

Examples of Studies to Which this Checklist Applies:

- Generalizable studies in human environments (e.g., occupied homes and offices, classrooms, and transit centers like subway systems and airports) that use tracer chemicals, particles, and/or other materials, such as perfluorocarbons, to characterize airflow.
- Generalizable studies in occupied homes and/or offices that:
  - manipulate the environment to achieve research aims, e.g., increasing humidity and/or reducing influx of outside air, through new energy-saving ventilation systems.
  - involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy saving behaviors through surveys and focus groups. Some surveys may be online surveys administered through providers such as Amazon Mechanical Turk and Survey Monkey.

What is DOE's philosophy regarding such studies?

In all research, potential risks must be evaluated and mitigated to the extent practicable. When:

a) people are included in research or experiments, voluntarily or involuntarily* and/or

b) people have their environment intentionally changed or manipulated for the purposes of the research, with or without their knowledge*, and/or

c) research can only be validly conducted with people present (other than those conducting the research), regardless of whether personally identifiable information is collected about them, the potential risks to those individuals must be considered by the appropriate IRB.

*Typically researchers conduct the research and do not participate in the research, but when they do, the potential risks to the researchers must also be considered by the IRB.

2 Research Involving Modification of the Human Environment
(Check if **"Yes"**. All must be checked or completed.)

☐	Is there is a compelling and credible case for anyone not on the research team to be present during the experiment? *Provide any supporting comments*:
☐	There are no other ways to achieve the research aims. *Provide any supporting comments*:
☐	All the risks and discomforts have been identified and considered. For example: • All chemicals/materials to be used have been evaluated for potential human health and safety effects; • All devices have had appropriate safety testing; • Other potential risks have been identified in the population group(s) to be exposed. *Provide any supporting comments*:
☐	Appropriate mitigations have been taken to minimize the risks, and risks are considered minimal for all involved. *Provide any supporting comments*:
☐	Those involved in the study, but not part of the research staff, will be informed of the research (unless the IRB waive consent). *Provide any supporting comments*:
☐	Subjects can "opt out" if they wish without any repercussions.

	Provide any supporting comments:
☐	The PI will monitor the research and measure outcomes. *Describe*:
How and from what sources will data be collected? Will characteristics of the subject population be determined and/or required for the research? *Provide any supporting comments*:	