**HRP-103-SOP-Appendix A-5:**

**Additional Requirements for Department of Energy (DOE) Research**

1. Research that involves one or more of the following is considered by DOE to be human subjects research and requires IRB review:
   a. Intentional modification of the human environment
   b. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
   c. Study in occupied homes or offices that:
      i. Manipulate the environment to achieve research aims.
      ii. Test new materials.
      iii. 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.

2. You must complete and submit to the IRB the DOE “Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements” (http://humansubjects.energy.gov/other-resources/documents/IRB-template-for-reviewing-PII-protocols-2010_ac.pdf) if your research includes Personally Identifiable Information. Please indicate with each item in the checklist where this is addressed within the protocol you have submitted to the IRB for review.

3. You must report the following within ten business days to the Department of Energy human subjects research program manager:
   a. Any signification adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken
   b. Any suspension or termination of IRB approval of research
   c. Any significant non-compliance with HRPP procedures or other requirements.

4. You must report the following within three business days to the Department of Energy human subject research program manager.
   a. Any compromise of personally identifiable information must be reported immediately.

5. Research involving human participants also includes studies of the intentional modification of the human environment; generalizable includes the study of tracer chemical, particles or other materials to characterize airflow.

6. Generalizable also includes studies in occupied home or offices that:
   a. Manipulate the environment to achieve research aim;
   b. Test new materials;
   c. Involve collecting information on occupants’ views of appliances, materials; or
   d. Devices installed in their homes or their energy-saving behaviors through surveys and focus groups.

   Generalizable should be viewed in terms of the contribution to knowledge with the specific field of study.

7. Other specific requirements of the Department of Energy (DOE) research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in the IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”