The proposed project titled "Assessment of Travelers and the Ebola CARE Kit" was reviewed by the Scientific Regulations Advisor for the EOC Ebola Response and determined to be:

PUBLIC HEALTH PRACTICE: Public Health Response and Program Evaluation

The scope of all activities should be limited to public health practice and MUST NOT INVOLVE RESEARCH.

Since the project is not considered to be research, no further action is required by CDC for human subjects protections in accordance with federal regulation for the protection of human subjects in research (45 CFR 46).

RE-REVIEW REQUIRED: Activities of this project should be monitored closely by CDC staff to ensure the activities do not involve research. The responsible CDC staff should request re-review prior to modifying the objectives or scope beyond that proposed to ensure the activities would still considered Public Health Practice.

Please save the determination form as documentation of the original determination.

Micah H. BassScientific Regulations Advisor
Ebola Emergency Response