FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION:

Logistics Evaluation for Implementation of Ultraviolet Decontamination and Reuse of Filtering Face Piece Respirators in Hospitals

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Office of Counterterrorism and Emerging Threats (OCET), is seeking OMB approval under the generic clearance 0910-0497 to conduct focus groups / interview project to gather perceptions, opinions, beliefs, and attitudes about decontamination and reuse of filtering face piece respirators (FFRs). Currently, most FFRs are intended for single-use only.

A pandemic can place unsustainable demands on supplies of FFRs that are needed to protect health care workers from the inhalation of infectious aerosols and droplets. Ultraviolet Germicidal Irradiation (UVGI) technology promises to mitigate potential shortages by allowing for decontamination and reuse of FFRs, thereby extending FFR service life. However, very little is known about how UVGI decontamination might fit into hospitals' existing respiratory protection plans, and procedural preferences and needs of staff members who would use FFRs during a pandemic.

2. Intended use of information:

The FDA and Applied Research Associates, Inc. (ARA) expects to use the findings from these focus groups, individual interviews, and survey to explore the scope of any barriers to implementing decontamination and reuse of FFRs, and to identify key issues for further study. Focus group participants will answer questions regarding their interaction with FFRs. Results will help identify how ultraviolet decontamination might fit into hospitals' existing respiratory protection plans and to clarify the procedural preferences and needs of hospital clinicians and staff members who would use FFRs during a pandemic.

3. Description of respondents:

FDA contracted Applied Research Associates, Inc. (ARA) to conduct these focus groups / interviews.

A total of 39 individual interviews will be conducted with hospital staff most likely to use FFRs during a pandemic. This includes participants from emergency departments, as they are often responsible for patient triage in the event of an influenza pandemic.

A total of six focus groups will consist of hospital staff. This includes:

- Central supply/ Logistics staff
- Sterile Processing/Environmental Services staff
- Respiratory Therapists, Physical/Occupational Therapists
- Physicians
- Nurses, nurse educators
- Occupational Health

4. Date(s) to be conducted and location(s):

Individual interviews and focus groups will be conducted in three (3) medical facilities. Dates will depend on convenience and availability of the hospital staff.

Stony Brook University Hospital, Stony Brook, NY
101 Nicolls Rd., Stony Brook, NY 11794
Date: November and December 2016 (tentatively)

Gulf Coast Medical Center, Panama City, FL
449 W 23rd St., Panama City, FL 32405
Date: February 2017 (tentatively)

University of Chicago Medical Center, Chicago, IL
5841 S Maryland Ave., Chicago, IL 60637
Date: February 2017 (tentatively)

5. How the Information is being collected:

Recruitment Information
The hospital facilities' staff will recruit and provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will intentionally over-recruit to ensure the minimum number of participants needed come to their scheduled time slot.

Focus Group and Interview Discussions
Applied Research Associates, Inc. (ARA) staff members will serve as moderators for all focus groups and interviews.

The moderators will use the attached moderator guides to ensure that all relevant tops areas are addressed. If all participants provide consent before discussion begins, their responses may be audio recorded and transcribed.

ARA will comply with safeguards for ensuring participant information is kept private to the extent permitted by law.

Survey
Each focus group / interview participant will be asked to complete a survey during their sessions with moderators. In addition, staff for the focus group / interview facilities will recruit clinicians and support staff who are not able to participate in the focus group / interview to complete the survey using a web based service.

6. Number of focus groups, individual interviews, and surveys:

At each of 3 facilities there will be:

- Five (5) focus groups, for a total of fifteen (15)
- Twelve (12) individual interviews, for a total of Thirty six (36)
- One hundred eighty six (186) (respondents from focus groups (150) and interviews(36)) + Two thousand nine hundred 2900 (number emailed out)=3086 surveys

At 1 facility there will be an additional:

- One (1) focus group, for a total of sixteen (16)
- Three (3) individual interviews, for a total of Thirty nine (39)
- Six (6) survey participants, for a total of 3092 surveys

7. Amount and justification for any proposed incentive:

We will coordinate with each hospital point of contact to offer a $5 gift card or $5 cash as a token of appreciation.

8. Questions of a Sensitive Nature:

No questions of a sensitive nature will be asked.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):

Data will be analyzed qualitatively using systematic content analysis methods. The sample is a convenience sample. Participants will be drawn from hospital staffs that are willing to volunteer their time.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Interview Participants			
Interview	39	60 1	39
Total	**39**		**39**
Focus Group Participants			
Focus Group	160	60 1	160
Total	**160**		**160**
Survey Participants			
Survey	2900	5 .08	232
Total	**3099**		**232**

Total	**3099**		**431**

REQUESTED APPROVAL DATE: May XX, 2016

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst — Amber Sanford
301-796-8867
Amber.Sanford@fda.hhs.gov

Program Contact — Jennifer Ross
240-402-8155
Jennifer.Ross@fda.hhs.gov

FDA CENTER: Office of Counterterrorism and Emerging Threats (FDA/OCET)