Subject Information and Consent Form

Name of Research Study: Logistics Evaluation for Implementation of FFR-UVDR in Hospitals

Sponsor: U.S. Food and Drug Administration

Principal Investigator Name: Mr. Brian Heimbuch

Research Site Address (es): Applied Research Associates
Engineering Sciences Division
430 West 5th Street, Suite 700
Panama City
FL 32401-6357

Daytime telephone number(s) 850-914-3188

Purpose of this Form

The purpose of this form is to give you information about the U.S. Food and Drug Administration study that seeks to understand attitudes, and identify preferences, barriers and logistic issues related to implementation of UVGI FFR-Decontamination/Reuse (UVDR) in a hospital setting during a pandemic to mitigate an FFR shortage.

If signed, this form will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your interviewers are employed by the sponsor (Applied Research Associates) to conduct this research study.

Purpose and Description of the Research Study

This study will involve up to 50 interview participants per facility at 3 different hospitals in the United States. You are being asked to take part in a research study to describe your personal experience and knowledge related to the use of filtering facepiece respirators (FFR) and logistic issues in the event of a possible future pandemic. Participation in this study will consistent of one of these three methods:

- Individual interview lasting no longer than 1 hours
- Focus group interview lasting no more than 1 hour
- Response to a survey, lasting an estimated five minutes

Study Procedures

If you agree to take part in this study, you will first sign this Subject Information and Consent Form before starting any study-related procedures. You will then be asked a series of questions about the nature of your work as it relates to the supply and use of FFRs, and issues in the event of possible insufficient FFRs in the event of a pandemic.

Subject's Initials____

Possible Benefits
There are indirect benefits to all who participate in this study, as the findings from this study will inform USFDA understanding about protection from infectious disease and FFR logistic considerations in the event of a possible pandemic.

Risks or Discomforts
There are no known risks associated with this study.

Payment to Subject for Participation
As a token of appreciation, participants in the individual interviews and focus groups may be eligible for a $5 gift card or $5 in cash.

Costs
The only cost for participating in this study is your time: up to one hour (individual interview, focus group), or 5 minutes (survey).

Confidentiality
We will protect information about you and your taking part in this research study to the best of our ability. The interview will be audio-recorded for research purposes if you are comfortable with that; otherwise, hand-written or typed notes will be taken. At the conclusion of this study, the audiotapes/notes will be stored in a secured area and only the project members will have access to the data. De-identified portions of this interview, verbatim quotations or paraphrases, may be included in the research report and related documents. Your responses will be kept confidential. We will not report your name or any other information that could be used to identify you.

Voluntary Participation
Your decision to take part in this research study is completely voluntary. There will not be any penalty or loss of benefits to you if you decide not to take part. In addition, you may withdraw from the study at any time. There will be no penalty if you decide to withdraw from the research study.

Contact for Questions
If you have any questions or concerns about your participation in this research study, or if you feel that you have experienced negative effects from the study, or have a complaint about the research study, contact:

Investigator Name: Mr. Brian Heimbuch

Daytime telephone number(s): 850-914-3188

This section applies only to the requirements of the Paperwork Reduction Act of 1995:

OMB 0910-0497 - Focus Groups as Used by the FDA

The public reporting burden time for the collection of information is estimated to average 1 hour per response for participants in individual interviews and focus groups, as well as 5 minutes per individual for survey respondents.

Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Subject's Statement of Consent

- I have been given sufficient opportunity to consider whether to participate in this study.
- My taking part in this research study is voluntary. I may decide not to take part or to withdraw from the research study at any time without penalty.
- I have been told that the interviewers conducting the research are contracted by the sponsor.
- I have had an opportunity to ask my study interviewers questions about this research study. My questions so far have been answered to my satisfaction.
- I have been told how long I may be in the research study.
- I have been told about the interview process.
- I have been told what the possible risks and benefits are from taking part in this research study. I do not give up my legal rights by signing this form.
- I have been told that prior to any study related procedures being performed, I will be asked to voluntarily sign this subject information and consent form.
- I have been told that I will receive a signed and dated copy of this subject information and consent form.

I voluntarily agree to take part in this research study.

_____

Signature of Subject Date

_____

Printed Name of Subject

I certify that the information provided was given in language that was understandable to the subject.

_____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

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