Research Plan and Interview Guide

Task F: Logistics Evaluation for Implementation of FFR-UVDR in Hospitals

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I. Overview

A pandemic can place unsustainable demands on supplies of filtering face piece respirators (FFRs) that are needed to protect health care workers from the inhalation of infectious aerosols and droplets (Ebola, SARs, and MERs). The premise for this study is that the pandemic strain will be high in mortality, similar to past outbreaks such as the 1918-19 influenza pandemic, and that supplies of FFRs would be limited. Ultraviolet Germicidal Irradiation (UVGI) promises to mitigate potential shortages by extending FFR service life. Applied Research Associates, Inc. is conducting research on behalf of the Food and Drug Administration to explore the potential use of ultraviolet decontamination during a pandemic event. We will use interviews, focus groups, and a survey to 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.

II. Study Objective

This task 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.

III. Data Collection Sites

The University of Nebraska Medical Center's care for Ebola virus patient Rick Sacra, MD in 2014 gave their care staff expertise in caring for patients who have been infected with a high mortality disease. We will conduct conference call interviews with team members who cared for Dr. Sacra that we will use to refine this plan.

We will collect data from stakeholders at three hospitals, including a small, large-suburban, and large-metro area hospital to understand the needs and considerations associated with FFR-UVDR implementation. Collecting data from hospitals that vary in size and patient population will improve our ability to generalize our findings to other U.S. hospital systems. These three hospitals are our potential data collection sites.

1. **Gulf Coast Medical Center (GCMC):** Gulf Coast Medical is a regional medical center located in Panama City, FL. It contains 218 beds, nearly 400 physicians and a support staff of more than 900 employees. GCMC belongs to the Hospital Corp of America and thus provides a link to a large network of hospitals.

2. **Stony Brook University Hospital (SBUH):** SBUH is the university hospital of Stony Brook University located in the East Campus in Stony Brook, New York. It contains 603 beds, 5,777 employees, and 1,093 physicians. Annual inpatient admissions are ~32,000 and ~96,000 emergency room visits. SUNY-SB also has a rich history of research with annual research expenditures exceeding $95 million.

3. **University of Chicago Medical Center (UCMC):** UCMC is an academic medical center on the campus of the University of Chicago, located on the on the south side of Chicago, Illinois. It contains 617 beds, 8,500 employees, and 878 attending physicians. Annual inpatient admissions are ~ 28,726 and ~ 87,856 emergency room visits. In 2015, revenues for patient care at the University of Chicago Medicine were $1.5 billion.

While SBUH and UCMC are comparable in size, both offer different perspectives based on the populations they serve. UCMC serves an urban area on the south side of Chicago that includes a high percentage of African-American and indigent patients; SBUH is a suburban metropolitan hospital. Both facilities represent the m of U.S. hospital that may need to triage and treat patients in the event of an influenza pandemic.

IV. Methods

Our research is built around three considerations about hospitals and UVGI FFR-Decontamination/Reuse (UVDR):

- Can they do this?

  Organizational and process barriers to implementing of FFR-UVDR
  Barriers and challenges to compliance with FFR use

- Will they do this?

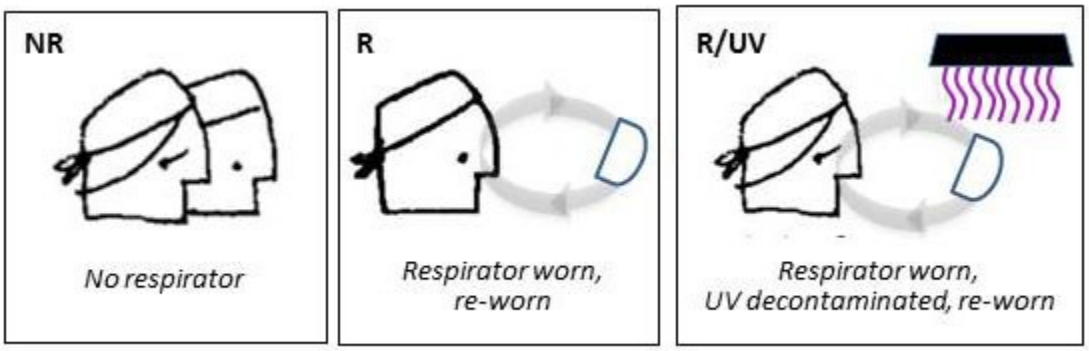
  Pros and cons of using FFR-UVDR
  Frequency of FFR reuse
  Attitudes, preferences related to successful adoption of the UVDR process

- How would they do this?

  Changes to processes as function of FFR-UVDR implementation
  Preferences among alternative mitigation strategies for FFR shortages
  Coordination and planning among staff including challenges, effective practices, etc.
  Recommended procedural considerations

To learn about clinician perceptions, we will describe the mortality threat, and what ultraviolet decontamination does, then ask for responses to “Would you feel safer?” among each of the conditions: no respirator (NR), respirator only (R), and respirator decontaminated using UV.

Options for Respiratory Protection During a Pandemic



We will use several methods to collect data on participant responses and demographics (e.g., hospital, role/position, time in role/position): Cognitive Task Analysis (CTA) interviews, focus groups, and surveys.

CTA Interviews: CTA is a family of data collection and analysis approaches used to identify and describe cognition and behavior in complex environments (Crandall, Klein, & Hoffman, 2006). These interviews will seek to capture work processes and context-rich examples of tasks and challenging situations associated with FFRs that resulted in good (or poor) outcomes. We may also use simulation interviews (Hutton & Militello, 1996) to present hypothetical decontamination and reuse scenarios that will allow participants to imagine and discuss potential behaviors and decisions in relation to FFR-UVDR use in a flu pandemic.

Focus Groups: Group interviews among 6-10 participants provide an opportunity to gather perceptions, opinions, beliefs, and attitudes about using FFR-UVDR technology and processes. While individual interviews and surveys can probe for detail, focus groups can capture the nature and scope of shared views among participants who have similar experience (e.g., nurses, or environmental service staff). We may use focus groups when individual interviews are not possible or to gather group opinions about FFRs among existing working groups.

Surveys: We will use surveys to supplement interviews by gathering information on a topics associated with FFR-UVDR use during a flu pandemic. Survey questions will focus on topics that are relevant to a large number of participants across a variety of scenarios, rather than specific to the incidents that will be discussed in the interviews.

If a participating hospital requests review through their Institutional Review Board, we will provide the support that would be needed for their approval process.

V. Participants

We plan to collect data from a variety of individuals who offer diverse perspectives on the use of FFRs. We plan to interview approximately 12 health care workers (HCWs) at each hospital, chosen from those who are most likely to use FFRs during a pandemic. We will include participants from emergency departments (ED), as they are often responsible for patient triage in the event of an influenza pandemic. We also plan to interview individuals in other roles and will identify these participants as this effort progresses. A point of contact at each hospital will recruit

participants who are willing to volunteer their time. We anticipate the following roles will participate, although actual participants may vary by hospital and staff availability.

- Health Care Workers
  - Physicians (2)
  - Nurses (6)
  - Respiratory therapists (2)
  - Clinicians who have not had FFR training (2)
- Sterile processing groups (1-2)
- Infection control (1-2)
- Hospital safety (1-2)
- Procurement/warehousing (1-2)
- Hospital administration (policy and communications) (1-2)
- Legal counsel (1-2)
- Risk analysis (1-2)
- Central Supply (1-2)
- Regulatory consultants (1-2)
- Environmental services (1-2)
- Nursing education (1-2)
- Hospital epidemiologist(s) (1-2)
- Occupational health (1-2)

VI. Interview Procedure

Two interviewers (a primary interviewer and a secondary note taker) will conduct interviews with individual participants. Individual interviews in clinical settings typically last around 45 to 60 minutes, which enables interviewers enough time to make more than one pass through topics and to probe for relevant data. Focus group interviews require time to enable participants to reflect and react to comments by others, and for more reluctant members to come forward. The methods we use and the time we take to listen thoroughly to the participants will enable us to provide richer and more insightful responses to the research question. We will coordinate in advance with each hospital POC to agree on session duration.

We will make an audio recording of the interviews with participant permission to ensure our notes are accurate. Our goal is to schedule 3 to 4 interviews/focus groups per day, allowing for 9 – 12 interviews over the 3-day data collection period. The fourth day will be used to debrief the hospital and to gather any follow-up information.

We will provide participants with a consent form to read and sign when they arrive for their session. The team will conduct interviewers using a semi-structured interview guide (see Interview Guide Draft later in this plan). We will modify the guide to fit each hospital and participant role. Following the interviews, participants will complete a brief questionnaire to collect information such as age, position, and years of experience.

VII. Schedule.

Focus Groups. We plan to schedule sessions with homogenous members (e.g., six staff members from Environmental Services):

- Supply/Logistics
- Environmental Services
- Respiratory Therapists
- Physical/Occupational Therapists
- Physicians

Individual Interview. We plan to schedule sessions with individuals to cover more in-depth information:

- Infection Control
- Management/operations
- Legal
- Procurement
- Sterile Processing
- Risk Analysis

The schedule for each facility will combine individual interviews, focus group interviews, and surveys. Sessions will be scheduled to last for 45-60 minutes, with a brief break for participant arrival and departure, and interviewer notes review and preparation. The research team will work with the hospital point of contact before and during the visit to develop and follow a schedule that is compatible with times when participants are available. Here is an example of how a schedule might be configured:

Day One		
Time	*Method*	*Role*
8:00-9:00	Set-up, survey briefing	Hospital POC
9:30-10:30	Focus Group	Nurses
11:00-12:00	Focus Group	Supply/Logistics
Break		
2:00-3:00	Focus Group	Environmental Services
3:30-4:30	Interview	Infection Control

Day Two		
Time	*Method*	*Role*
8:00-9:00	Set-up	Hospital POC
9:30-10:30	Focus Group	Respiratory Therapists
11:00-12:00	Focus Group	Physical/Occupational Therapists
Break		
2:00-3:00	Interview	Management/operations
3:30-4:30	Interview	Legal

Day Three		
Time	*Method*	*Role*

8:00-9:00	Set-up	Hospital POC
9:30-10:30	Focus Group	Physicians
11:00-12:00	Interview	Procurement
Break		
2:00-3:00	Interview	Sterile Processing
3:30-4:30	Interview	Risk Analysis

Day Four		
Time	*Method*	*Role*
8:00-9:00	TBD	[window for any remaining sessions]
10:30-11:00	TBD	[window for any remaining sessions]
Break		
1:00-2:00 themes, commonly iterated	Visit Summary	Hospital POC

VIII. Data Analysis

We will analyze qualitative data using systematic content analysis methods (Crandall, Klein, & Hoffman, 2006; Hammersley 1992; Kvale, 2006) to identify topics and themes within and across roles. We will use a 3-stage iterative content analysis process: 1) data review, 2) category coding and data extraction, and 3) synthesis and integration of findings. We will use descriptive statistics (means, standard deviations, median, mode) to analyze quantitative data from surveys. Depending on sample size, we may compare responses across roles using inferential statistics.

IX. Projected Outcomes

The outcome of this effort will describe perceptions, attitudes, considerations related to liability and logistics (e.g., resources, cost), implementation preferences, and potential barriers to implement FFR-UVDR technology in hospitals of different sizes. We will offer a representative overview by gathering a variety of perspectives ranging from administrators to clinicians.

X. References

Crandall, B., Klein, G., & Hoffman, R. R. (2006). *Working minds: A practitioner's guide to Cognitive Task Analysis*. Cambridge, MA: The MIT Press.

Hammersley, M. (1992). *What's wrong with ethnography: Methodological explorations*. London: Routledge.

Hutton, R. J. B., & Militello, L. G. (1996). Applied Cognitive Task Analysis (ACTA): A practitioner's window into skilled decision making. In D. Harris (Ed.), *Engineering psychology and cognitive ergonomics: Job design and product design* (Vol. 2, pp. 17-23). Aldershot, UK: Ashgate.

Kvale, S. (1996). *Interviews: An introduction to qualitative research interviewing*. Thousand Oaks, CA: SAGE Publications, Inc.

INTERVIEW GUIDE

March 2016

[Research team will provide form to confirm participant consent.]

INTERVIEW SCRIPT

We are from Applied Research Associates and conducting a study on behalf of the Food and Drug Administration to learn about the needs and processes surrounding the use of filtering face piece respirators (FFRs) during a flu pandemic.

A high mortality influenza pandemic can be as deadly as smaller scale infectious disease outbreaks we have seen in past years: Ebola, SARs, MERs.[6] The pandemic is likely to cause unsustainable demands on supplies such as filtering facepiece respirators. Using ultraviolet decontamination can mitigate an FFR shortage by allowing FFRs to be decontaminated and reused. We are interested to learn how this process might fit into your hospital's work practices.

We would like to make an audio recording just to make sure our notes are accurate. They will not be shared with anyone outside the project team. Are you okay with us recording this interview?

We will not report any data that identifies you as the source of the information. So please feel free to be candid. If you want to stop at any time just let us know.

We appreciate your time and contribution to this important study. Do you have any questions before we start?

GENERAL QUESTIONS

Background/Experience: We'd like to start by learning a little about your background. How long have you worked at [*hospital X*] and in what roles? What is your current role?

As we talk with you, we would like to get an understanding about [*what, how, when, and where*] in your work you interact [*select, order, manage, label, store, process, obtain, use, dispose, etc.*] with filtering face piece respirators.

- Please describe these interactions in detail by focusing on situations that require multiple tasks/steps.
- [*If appropriate given role*] Where is the FFR use process most likely to break down during a pandemic, and why? What do you see as the biggest vulnerabilities in the processes? Please describe the types of situations that require you to use FFRs.

ROLE-SPECIFIC QUESTIONS

Health Care Workers (nurses, physicians, RTs, PT)

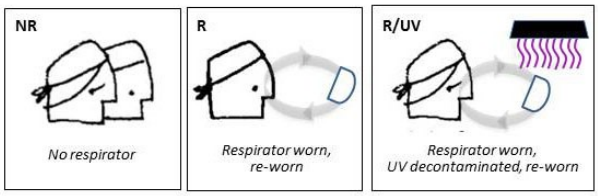
- Where do you go to get FFRs when you need them?
- What model of FFR do you use?

- Where do you dispose of used FFRs?
- What training do you receive, and how often, regarding personal protection such as FFRs and their proper use? Do you follow it in actual practice? If not, why?
- How is FFR compliance evaluated and monitored?
- What is your hospital's policy for reusing FFRs during normal operations?
- What are you expected to do in case FFRs are in short supply?
- Have you ever been in a situation of an FFR shortage? If so, please describe. How did you manage this situation? How did others here manage the situation?
- What concerns you the most about FFR supply and use during a high mortality pandemic?

"What if" questions about FFR-UVDR

[Research team provides interviewee with description of the FFR-UVDR approach, including general description of UV, how it decontaminates, tabletop device and decontamination process. Detail level TBD]

Options for Respiratory Protection During a Pandemic



- Please look over this diagram and tell me how safe (1-unsafe to 10-completely safe) would you feel going to work in each of these three conditions: (NR, R, R-UV).
- Would such a system fit in here in your hospital? Into your work flow?
- What logistical or technical barriers might affect FFR-UVDR implementation?
- Where would such a system be located?
- How far would you be willing to travel in your hospital to pick up FFRs? Do you see issues with time needed to decontaminate? Frequency?
- Would you decontaminate your FFR yourself or have someone else do it for you?
- Are you concerned about wearing an FFR that was worn by another person?
- What preferences of yours would have to be met for you to use FFR-UVDR during a high mortality pandemic?

Legal Counsel

- What are your legal considerations for maintaining an adequate supply of FFRs during a pandemic? For implementing FFR-UVDR?
- What are the legal tradeoffs for FFRs shortage versus FFR-UVDR? How do you manage this risk?
- What regulatory support would have to be in place for your hospital to implement FFR-UVDR during a high mortality influenza pandemic?
- What published research data and papers would you need to adopt FFR-UVDR?
- What FFR manufacturer considerations might be relevant?

- What preferences of yours would have to be met for you to use FFR-UVDR during a high mortality pandemic?

Support: Admin, Infection Control, Hospital Safety, etc.

- What type of FFRs does your hospital use? Do you currently stockpile FFRs? If so how often do you replenish your stockpile?
- How do you estimate need? For standard operations? Seasonal variation? Pandemic preparedness? Any other considerations?
- Do your estimates account for patients using FFRs?
- What is your current plan to maintain an adequate supply of FFRs during a pandemic? Where do you go to restock your FFR supply? Do you have a surge plan?
- What groups/divisions/departments are involved in making decisions regarding FFRs?
- What kind of training/education do you provide for FFR use? Is it the same for each unit of hospital, or different?
- How do you monitor compliance and ensure FFRs are actually used? Used correctly?
- What is your plan to communicate critical information during an influenza pandemic? Would you use different means depending on the type of information?
- Are Local, State, and Federal pandemic preparedness activities adequate?

Questions specific to FFD-UVDR

- Are you aware of and/or do you use UV decontamination? If so, what are your impressions of them? Would you consider using them routinely? Why or why not?
- How might FFR-UVDR be implemented here?
- What safety considerations matter to you regarding FFR-UVDR?
- What organizational, policy barriers might get in the way of implementing FFR-UVDR?
- What personnel, equipment and written protocols would be needed to implement FFR-UVDR?
- What are the barriers to FFR-UVDR use by frontline staff?
- What information would frontline staff need to effectively use FFR-UVDR?
- What procedures would need to be developed to ensure FFR-UVDR is used properly and FFRs are reprocessed correctly?
- What regulatory support/interactions are needed to implement FFR-UVDR?
- What published research data and papers would you need to adopt FFR-UVDR?[18]
- What considerations matter when selecting user departments? Would you target high usage departments, or implement FFR-UVDR across all hospital departments?
- What preferences of yours would have to be met for you to use FFR-UVDR during a high mortality pandemic?[15]
- How do you think FFR-UVDR would fit with current pandemic preparedness activities?
- When would/should a hospital begin to prepare to implement FFR-UVDR?

FOCUS GROUP

We will conduct interviews with groups from 6-10 participants who have similar experience:

- Nurse (ED, ICU)
- Environmental Services
- Technician
- Central Supply/Logistics
- Physician (attending , resident, physician assistant) (if possible)

The moderator will introduce and guide discussion. An observer will take notes, maintain response sheets, and manage audio recording.

SCRIPT

We are from Applied Research Associates and conducting a study on behalf of the Food and Drug Administration to learn about the needs and processes surrounding the use of filtering face piece respirators (FFRs) during a flu pandemic.

A high mortality influenza pandemic can be as deadly as smaller scale infectious disease outbreaks we have seen in past years: Ebola, SARs, MERs. The pandemic is likely to cause unsustainable demands on supplies such as filtering facepiece respirators. Using ultraviolet decontamination can mitigate an FFR shortage by allowing them to be decontaminated and reused. We are interested to learn how this process might fit into your hospital's work practices.

We would like to make an audio recording just to make sure our notes are accurate. They will not be shared with anyone outside the project team. Are you okay with us recording this interview?

We will not report any data that identifies you as the source of the information, so please feel free to be candid. If you want to stop at any time just let us know.

We appreciate your time and contribution to this important study. Do you have any questions before we start?

To start, we'd like to ask you to please enter the correct information on the sheet we have provided to let us know:

<u>Background/Experience</u>:

- How long have you worked at this hospital?
- In what roles?
- What is your current role?

Please tell us what you currently do with filtering face piece respirators:

> *Clinicians*: how do you select, process, obtain, use, and dispose of them? Any other things you do with them? It might help if you'd lead us through a typical case.

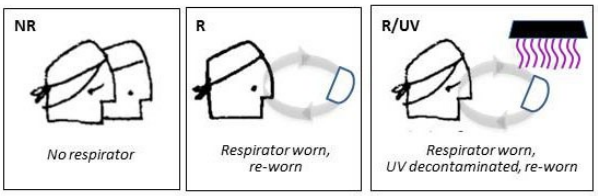
Support/Management: how do you order, manage, label, store, process, dispose of them? Any other things you do with them? It might help if you'd lead us through a typical case or process you follow.

[provide interviewee with a description of the FFR-UVDR system, detail level TBD]

Now that we have described the decontamination process that is being considered.

- Do you see any drawbacks in this decontamination process?
- What are your ideal preferences that would allow FFR-UVDR to be used during a high mortality pandemic?[15]
- Do you think the FFR decontamination process might break down during a high mortality pandemic. Why? In what way(s)?

Options for Respiratory Protection During a Pandemic



- Please look over this diagram and tell me how safe (1-unsafe to 10-completely safe) would you feel going to work in each of these three conditions: (NR, R, R-UV).
- Given that there will be an FFR shortage, which of these three FFR use options do you prefer. What other options might exist?

Is there anything we haven't covered that you would like to comment on?

Thanks very much for your time and your helpful thoughts.

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SURVEY

A brief survey will be made available using a web-based service (e.g., Survey Monkey). The hospital POC will encourage clinicians and support staff to complete the survey, particularly those who are not able to participate in interviews. The POC will send an email message to potential participants with a link to the survey, a short description of its value, and estimate of time to complete it.

We will ask to each interview and focus group participant to complete the survey during their sessions. These participants will fill out a paper version of the survey and the ARA team will incorporate their data with the online data collected from staff members that were not available for focus groups or individual interviews. The goal will be to collect as large a set of responses to the particular survey questions as possible at each facility.

The survey will be posted on line for use during the week of the research team's visit and remain available until two weeks after the visit. Web-based services are typically self-tabulating, which will help the team to develop results and findings.

QUESTIONNAIRE

Background: A high mortality influenza pandemic can be as deadly as smaller scale infectious disease outbreaks we have seen in past years: Ebola, SARs, MERs. The pandemic is likely to cause unsustainable demands on supplies such as filtering facepiece respirators. Using ultraviolet decontamination can mitigate an FFR shortage by allowing them to be decontaminated and reused. We are interested to learn how this process might fit into your hospital's work practices Applied Research Associates, Inc. is conducting research on behalf of the Food and Drug Administration to explore the potential use of ultraviolet decontamination during a pandemic event. We will use this survey, interviews, and focus groups, to identify how ultraviolet decontamination might fit into your hospital's existing respiratory protection plans and to clarify the preferences and needs of hospital clinician and staff members who use FFRs during pandemics.

1) Job title: _____

2) Years of experience in this role: _____

3) Total years of experience in hospital setting: _____

4) Have you had training on the proper use (donning and doffing) of FFRs
Yes No If yes, how often_____

5) Have you had training to decontaminate FFRs? Yes No

6) Have you used FFRs during an emergency event? Yes No

If yes, was this emergency event an influenza pandemic? Yes No

If yes, in how many emergency events have you used FFRs? _____

If you have used FFRs during an emergency event,
please circle a number to indicate your response for questions 7-9.
If you have not used FFRs in an emergency, circle "NA"

7) How easy was it to obtain an FFR?

Very easy 1------2------3------4------5------6------7 Very difficult NA

8) How easy was it to follow FFR procedures?

Very easy 1------2------3------4------5------6------7 Very difficult NA

9) How easy was it to dispose of your used FFR?

Very easy 1------2------3------4------5------6------7 Very difficult NA

10) Provide any additional comments about current FFR training, policies, and implementation procedures: _____

_____

11) Are you familiar with Ultraviolet Germicidal Irradiation (UVGI)? Yes No

Please circle a number to indicate your response for questions 12-14:

12) I would feel safe going to work during a high mortality pandemic with no respirator

Agree 1------2------3------4------5------6------7 Disagree

13) I would feel safe going to work during a high mortality pandemic with a respirator

Agree 1------2------3------4------5------6------7 Disagree

14) I would feel safe going to work during a high mortality pandemic with a respirator that had been decontaminated using FFR-UVGR.

Agree 1------2------3------4------5------6------7 Disagree

15) I would feel safe going to work during a high mortality pandemic with a respirator that I have to reuse many times without any decontamination.

Agree 1------2------3------4------5------6------7 Disagree

16) Do you think implementing UVGI FFR Decontamination/Reuse (UVDR) will help mitigate FFR shortages? Yes No

17) What would be the greatest advantage to using FFR-UVDR during an emergency:

_____

_____

18) What would be the biggest barrier to implementing FFR-UVDR during an emergency event:

_____

_____

19) What are your ideal parameters that would allow FFR-UVDR to be used during a high mortality pandemic:

_____

_____

Thank you for taking the survey! Your participation will help the US FDA to learn about issues related to FFR decontamination.

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.

The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.