

United States Food and Drug Administration
Generic Clearance: Focus Groups as Used by the FDA
OMB Control Number 0910-0497
Gen IC Approval Request

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 Gen IC: Usability Testing of Virtual Reality for Opioid-Sparing Pain Management Among Diverse Patients

1. Statement of Need:

Almost half of all patients report pain in the hospital setting, and 12% call it ‘unbearable.’ In the inpatient setting, pain is typically managed pharmacologically. However, opioids, a common pain treatment approach in the United States, can lead to serious harm. Previous reports indicate that disparities in opioid access, use, and related morbidity and mortality by income and race/ethnicity exist. (Refs. 1–6) Therapeutic virtual reality (VR) provides an alternative approach for managing pain non-pharmacologically, and randomized trials demonstrate its effectiveness in reducing pain among hospitalized patients. (Ref. 7) However, VR therapeutic products are primarily tested in well-resourced, controlled settings serving mostly white, non-Hispanic patients with high educational attainment. (Refs. 7, 8) It is not clear if VR is a feasible or effective approach for pain management in real-world settings serving diverse, low-income patients. Therefore, we propose to conduct usability testing of VR for opioid-sparing pain management in a safety-net health care system serving diverse patients using an implementation science framework.

2. Intended Use of the Information:

Usability testing, which includes in-depth interviews, will be used for the following purposes:

- a. Examine the usability of VR therapeutic products among diverse, low-income patients
- b. Examine the usability of VR therapeutic products among health care workers in safety-net settings, who may deliver the intervention to potential end users

3. Description of Respondents:

The respondents for this collection are: (a) patients receiving care in primary care and pain clinics at an urban, integrated, safety-net hospital; and (b) health care workers (e.g., providers, front-line staff, information technology staff) who are involved in the delivery of care to diverse, low-income patients.

Under Section 3003 of the 21st Century Cures Act (Public Law 114-255, December 13, 2016), the voluntary responses provided by patients receiving primary care and pain clinics at an urban, integrated, safety-net hospital are exempt from the Paperwork Reduction Act. Section 3003 states that “Chapter 35 of title 44, United States Code, (the Paperwork Reduction Act), shall not apply to the collection of information to which a response is voluntary...” Therefore, for the collection of information from patients for this individual generic submission under OMB No.

0910-0497, we are not listing the patients as respondents in Item 3 and are not seeking OMB approval under the PRA and will not add the burden to the burden table in Item 9.

4. How the Information is Collected:

Usability tests and interviews will be conducted by trained research staff based at the University of California, San Francisco (UCSF). Each session will include one member of the study team and one participant. Interviews will be audio recorded and transcribed.

Given the ongoing COVID-19 pandemic, study activities will be conducted after receipt of OMB approval and when it is safe to do so.

5. Number of Focus Groups:

We intend to recruit 12-20 patients and 12-20 health care workers for a total of 24-40 usability tests and interviews.

6. Amount and Justification for Proposed Incentive:

Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? Yes No

Patient participants will be provided with \$25 for participation in a usability test and interview (approximately 60-90 minutes). Health care workers will be provided with \$100 for participation in a usability test and interview (approximately 60-90 minutes). These amounts were determined based on average hourly wages among residents of the Bay Area and among health care professionals.

7. Questions of a Sensitive Nature:

The usability tests and interviews will elicit participants' perceptions about VR and digital therapeutics for pain management. The majority of the questions will not be sensitive in nature, but some questions may be considered personal or sensitive to participants. For example, patients may be asked about their experiences with pain and pain management. Researchers will communicate to participants prior to commencing the usability test and interview that participants may be asked questions that make them feel uncomfortable, and that participants can skip any question they do not wish to answer and discontinue the usability test and interview at any time. Additionally, all members of the study team are trained conducting human subjects research.

8. Description of Statistical Methods:

The study team will conduct a qualitative analysis of interview transcripts using a deductive and inductive reasoning approach to characterize usability barriers and facilitators. The overall conceptual model that will guide the evaluation is the Consolidated Framework for Implementation Research, CFIR. (Refs. 9,10) A synthesis of several evidence-based implementation frameworks, CFIR comprises a set of constructs designed to guide theory development and empirical verification of which practices work, where, and why, across different contexts. The CFIR model takes into account the multiple, interacting domains and processes that must factor into successful implementation.

9. **Burden:**

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)
Adult Patients	20	75	25
Health Care Workers	20	75	25
Totals	40		50

10. **Date(s) to be Conducted and Locations:**

Usability tests and interviews will take place in private offices at Zuckerberg San Francisco General Hospital and Trauma Center in San Francisco, California.

11. **Requested Approval Date:** August, 2020

12. **FDA Contacts:**

Program Office Contact	FDA PRA Contact
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13. **Certification:** In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
- c) The collections are noncontroversial;
- d) Personally identifiable information (PII) is collected only to the extent necessary and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.

Name: Christine Lee

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