

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: XXXX-YYYY)

TITLE OF INFORMATION COLLECTION:

mHealth Privacy and Security Consumer Focus Group Pilot Testing

PURPOSE:

The Office of the National Coordinator for Health Information Technology (ONC) Office of the Chief Privacy Officer would like to conduct pilot testing of focus group instruments that are being developed as part of a larger research effort. The larger research effort, which is undergoing a separate clearance process, will collect qualitative data regarding the attitudes and preferences of consumers, including medically underserved populations, with respect to mobile health (mHealth) privacy and security concerns.

The purpose of this data collection effort is to pilot test focus group protocol documents that are under development and is limited to (a) accurately assessing the time allocated to the draft focus group questions and (b) cognitively testing the draft questions and refining them as appropriate prior to conducting the full scale focus groups. We will not analyze or disseminate the data or make any policy decisions with the data from the pilot testing. Our only intent is to ensure the focus group questions under development are understandable, ordered well, and can be completed within allotted time frames.

DESCRIPTION OF RESPONDENTS:

ONC proposes to conduct the pilot test with two focus groups of 10-12 participants each. One pilot group will be conducted in English with English-speaking participants. The second pilot group will be conducted in Spanish with Spanish-speaking participants. The participants will be recruited through community-based organizations. The participants for the pilot testing will be individuals (both males and females) between the ages of 29 and 65, with cell phones with texting capability and no more than a high school or vocation school education.

TYPE OF COLLECTION: (Check one)

Customer Comment Card/Complaint Form
 Usability Testing (e.g., Website or Software)
 Focus Group

Customer Satisfaction Survey
 Small Discussion Group
 Other: _____

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Penelope Hughes

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? Yes No

Community Based Organizations (CBOs) will be recruiting their members to participate in the pilot testing, relying on their internal records to contact potential participants with information about the pilot testing and reminders. The CBO will retain the first and last names of the recruited participants as well as a phone number as a means of contacting them prior to the scheduled pilot testing. The collection of this PII during the recruiting phase is necessary to ensure the focus group characteristics are met and the optimal number of participants is recruited. The CBO will hold the PII of their members on a password protected computer (if electronic) and/or under lock and key (if paper-based). The PII held by the CBO will be securely destroyed following the conclusion of the pilot testing.

Additionally, as a requirement under federal research regulations and as a condition of approval by the Institutional Review Board overseeing this research, the participants are asked to sign an informed consent form prior to the conduction of the pilot test group. The informed consent forms will be scanned, encrypted and stored on a password protected computer under the control of the project moderator. The informed consent forms will be securely retained for one year following the conclusion of the project, at which time they will be securely destroyed.

2. If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? Yes No

3. If Yes, has an up-to-date System of Records Notice (SORN) been published? Yes No

Gifts or Payments:

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

The contractor proposes to offer each focus group participant a \$40 pre-paid Visa card for their time and travel. Incentives for focus group participation are a recognized standard industry practice to improve recruitment and ensure participation in focus groups. There is extensive literature to support the use of monetary incentives, as a supplement or complement to other efforts of persuasion, to ensure recruitment of focus group participants.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden
Individuals (screening and recruitment)	72	1/6	12
Individuals (participants)	24	2	48
Totals	N/A	N/A	60

FEDERAL COST: The estimated annual cost to the Federal government is \$1,259.40.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
 Yes No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The contractor will work with various Community Based Organizations (CBOs) because they have strong networks among the target populations. The CBOs will be responsible for recruiting the participants for the focus groups according to IRB stipulated requirements. The contractor will provide the CBOs with a screening guide, which they will use to recruit and select participants. The contractor will also provide training to the various CBO recruiters and will monitor and assess the recruitment process at each site.

The screening guide includes questions about where the individual lives, the individual's age, the last grade level of school completed, whether the individual uses mobile devices, and for the Spanish-speaking pilot group, whether the individual is a native Spanish speaker. These questions are necessary to ensure that the individuals selected to participate in the pilot group represent the demographic and age categories and the minimum technology experience requirements important to ONC.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
 Web-based or other forms of Social Media
 Telephone
 In-person
 Mail
 Other, Explain
2. Will interviewers or facilitators be used? Yes No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

Instructions for completing Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback”

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g. Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a brief description of the targeted group or groups for this collection of information. These groups must have experience with the program.

TYPE OF COLLECTION: Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected per row.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)

Burden: Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.

Submit all instruments, instructions, and scripts are submitted with the request.