FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "Testing Communications on Drugs" (0910-0695)

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TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel —Public Service Announcements (PSAs) about Safe Disposal of Opioids

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The purpose of this project is to conduct timely message testing of two storyboards that FDA plans to develop into short video PSAs. The storyboard titled "The Medicine Cabinet" will be tested in English, whereas the storyboard titled "The Nephew" targets the Hispanic population and will be tested in Spanish.

As part of FDA's ongoing work to address the opioid crisis, including exploring options for the improved packaging, storage, and disposal of opioids, this campaign will focus on the proper disposal of unused opioid medications. The goals of the campaign include:

1. Increasing awareness about the danger/risk of keeping unused opioids in the home;
2. Increasing awareness about methods for safe disposal of unused opioids;
3. Creating a sense of urgency for disposing of unused opioids; and
4. Empowering audiences to leverage roles as caregivers to help address the opioid crisis by safely disposing of unused opioids in the home.

Communications science tells us that we must test messages with our intended audiences before communicating them. Thus, FDA plans to test this communication using online cognitive interviews with a small sample of 16 U.S. adults drawn from a diverse consumer panel.

This data collection is the sixth in a series of FDA rapid message testing projects submitted under 0910-0695. These projects are part of FDA's effort to make consumer testing part of its routine communication development processes.

Project #	Communication Tested	OMB approval date
1	Clinical Trials Brochure	August 4, 2017
2	Caregiver Tipsheet	September 26, 2017
3	Public Service Announcement Video about Generic Drugs	October 25, 2017
4	Opioid Analgesics Patient Counseling Guide	November 27, 2017
5	Vaccines and Seniors brochure	May 10, 2018

This project is in keeping with the spirit of the 2015 Executive Order to improve how information is presented to consumers by applying behavioral science insights, and it meets repeated calls from FDA's Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public. In June 2016, OMB

agreed to FDA flagging these projects for immediate OMB attention that reduces even the shortened generic clearance timeline.

2. **Intended use of information:**

   FDA's contractor Westat will test the PSA storyboards with a small sample of target audience members to ensure the message meets its objectives without causing unintended negative effects. FDA will use the collected interview data to refine its messaging by improving the comprehensibility, enhancing the cultural appropriateness and sensitivity, and improving the personal relevance for a higher public health impact.

   The data collected will not be statistically representative of the target audience population. Therefore, the data will not be used for making policy or regulatory decisions.

3. **Description of respondents:**

   We will conduct 16 30-minute interviews with U.S. adults. Westat has partnered with Research Now Group, Inc., a global leader in digital data collection, to recruit respondents from its general population research panel and avoid "professional" panelists through proprietary recruitment and enrollment techniques.

   We will use a participant screener to recruit women between the ages of 35 to 64 who are mothers, grandmothers, or unpaid caregivers of adults over age 65 who have been prescribed opioids in the last three years. The storyboard titled "The Medicine Cabinet" will be tested with ten participants in English, and the storyboard titled "The Nephew" will be tested with six participants who speak Spanish as their first language. The participant pool will be diverse in terms of education and geography.

4. **Date(s) to be Conducted:**

   We plan to conduct interviews in July 2018.

5. **How the Information is being collected:**

   We will conduct all interviews remotely using telephone and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, tablets or mobile phones. We will ensure that any materials provided to the participants for the test are compatible with all devices.

   For each 30-minute interview, a trained interviewer will lead the discussion using a semi-structured interview guide that ensures consistency in major topics but allows flexibility in probing each participant on particular questions.

   Note takers will chart their findings into a standardized reporting template so that all notes are organized in a consistent manner. Interviewers will review the notes to ensure accuracy. With the consent of participants, we will audio record each interview.

FDA staff will have the ability to listen to the interview sessions, and this will be made known to participants as part of the informed consent.

6. **Confidentiality of Respondents:**

We will provide all respondents with informed consent language that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. As part of the consent procedure, respondents will be asked to allow audio recording of the interview. Recording will not begin before participants have had the opportunity to ask for any clarification and provide consent. Participants will be asked to again confirm their consent when recording begins.

No participant's identifiable information such as name will be included in the interview notes. All interview materials will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. Interview notes will be zipped electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to FDA, Westat will destroy all names and contact information of participants to protect their personal identity. Additionally, the interview notes and interpretive report delivered to FDA after message testing will omit all information that could be used to identify respondents.

All electronic data storage media that contain confidential, private, or proprietary information will be maintained within secure areas. Data collected in hard copy will be kept in locked cabinets when not in use.

7. **Amount and justification for any proposed incentive**

For this project, Research Now will provide $35 incentives to participants at the end of each 30-minute interview in the form of virtual currency. The virtual currency is redeemable for a wide range of award items, vouchers, and publications.

Research Now uses a "by-invitation-only" recruitment methodology, and incentivizes panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time. Research Now's incentive scale is based on set time increments and panelist profiles and is applied equally across all study topics, sponsors, and data collection modes. Research Now's incentive scale is proprietary and FDA has no control over the incentive amounts promised to participants upon signing up with Research Now. Research Now's rates are also in line with those used by government agencies conducting cognitive testing studies documented in the QBANK5 at CDC.

8. **Questions of a Sensitive Nature**

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' experience with prescription pain relievers and their reactions to the messages and material.

Nevertheless, respondents will be told that they may skip any question that they do not want to answer or may stop participating at any time.

9. **Description of Statistical Methods**

We do not plan to use formal statistical methods in this study but rather qualitative analysis methods. Our analysis approach is based on the Framework method, as described in Spencer et al (2003). Framework is a matrix-based approach to data management, which facilitates both case and theme based analysis. The Framework method allows for data reduction through summarization and synthesis yet retains links to original data, in this case the interview notes. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The software will allow us import interview notes, create links between the notes and the Framework matrices, and develop new queries or matrices as needed.

The Framework method will allow us to recognize patterns within the data. Findings will be supported with verbatim participant quotes and grounded in accepted principles of health communications.

Bibliography

Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis practices, principles and processes. In *Qualitative research practice.* London: Sage Publications.

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)
Screener	250	3	12.5
Interviews	16	30	8
		Total	**21**

REQUESTED APPROVAL DATE: July 27, 2018

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