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 —Caregiver Tipsheet

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The purpose of this project is to conduct timely message testing of an FDA communication that aims to provide new caregivers with helpful tips for managing the medical needs of their adult loved ones. Approximately 40 million caregivers provide care to adults (aged 18+) with a disability or illness,[1] and about 34 million Americans have provided unpaid care to an adult age 50 or older in the last 12 months.[2] Over 75% of caregivers are women, and they may spend as much as 50% more time providing care than men.[3] FDA's tipsheet, developed by the Office of Women's Health, will serve as a tool for caregivers to use in developing a plan with their loved one and his/her healthcare providers. The communication objectives of FDA's tipsheet are to increase the proportion of caregivers who use their loved one's medicines and medical devices wisely, and to reduce the number of caregiver mistakes that lead to adverse events.

   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 15 U.S. adults drawn from a diverse consumer panel.

   This data collection is the second in a series of FDA rapid message testing projects. The previous message testing of a brochure about clinical trials was approved by OMB on August 4, 2017. These projects are part of FDA's effort to make consumer testing part of its routine communication development processes. In June 2016, OMB agreed to FDA flagging these projects for immediate OMB attention that reduces even the shortened generic clearance timeline.

   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.

2. **Intended use of information:**
   FDA's contractor Westat will test the caregiver tipsheet 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

[1] Coughlin, J. (2010). Estimating the Impact of Caregiving and Employment on Well-Being: Outcomes & Insights in Health Management.
[2] National Alliance for Caregiving and AARP. (2015). Caregiving in the U.S.
[3] Institute on Aging. (2016). Read How IOA Views Aging in America.

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 15 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 only recruit adults who currently help another adult manage his/her medical needs. We will recruit a variety of caregivers of parents, spouses/partners, adult children, and other family members or friends. To help ensure the tipsheet is understandable to those with lower health literacy, we will oversample those with a high school education or less. To match FDA's target audience, we will test the tipsheet with women primarily between the ages of 35 to 64, and with an oversampling of African Americans, Hispanics, and Asians. The participant pool will be regionally diverse.

4. **Date(s) to be Conducted:**
We plan to conduct interviews in September/October 2017.

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. We will also send participants a hard copy of the tipsheet by postal mail so they can see the communication in its intended form.

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. With the consent of participants, we will audio record each interview. Although the notes will be taken in real time and the majority of the details captured during the interview session itself, note takers will consult the interview recording for any information they feel they may have missed or not captured completely during the interview session.

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 confidential. 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**
We 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'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. These 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 managing other's medical needs 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.

References:

Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis practices, principles and processes. In J. Ritchie & J. Lewis (Eds.), *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	15	30	7.5
		Total	**20**

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