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

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel — Transmucosal Immediate Release Fentanyl (TIRF) Patient Prescriber Agreement Form (PPAF)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The purpose of this project is to conduct timely message testing of a Patient-Prescriber Agreement form that aims to inform patients and caregivers of the most serious risk of Transmucosal Immediate Release Fentanyl (TIRF) medicines–the potential of life-threatening respiratory depression in patients not already taking and tolerant to chronic opioid analgesics. In addition, TIRF medicines can be abused and are subject to misuse, addiction, and criminal diversion.

The form to be tested is part of the TIRF Risk Evaluation and Mitigation Strategy (REMS) Program. The REMS Program uses risk minimization strategies beyond approved labeling to help ensure that the benefits of the drug outweigh its risks. The form is being revised from a version previously approved in 2011 to improve patient understanding of the risks of TIRF medicines and the safety rules that must be followed to protect patients and others from serious harm or accidental death. The form provides information to educate patients and caregivers that:

- TIRFs medicines can cause breathing to stop which can lead to death.
- Patients must be opioid tolerant before taking TIRFs. Patients must continue to be opioid tolerant while taking a TIRF medicine.
- Patients must properly store and dispose of TIRF medicines to avoid accidental overdose in others.

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 panel of patients and caregivers.

This data collection is the tenth in a series of FDA rapid message testing projects submitted to OMB under generic clearance. These projects are part of FDA's effort to make consumer testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order[1] 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.

[1] https://obamawhitehouse.archives.gov/the-press-office/2015/09/15/executive-order-using-behavioral-science-insights-better-serve-american

2. **Intended use of information:**

FDA's contractor Westat will test the form with a small sample of target audience members to ensure the message meets its objectives without causing unintended negative effects. FDA's Risk Communication and Advisory Committee includes renowned experts and researchers in social sciences, marketing, health literacy, and related fields. From its very first meeting in 2008, the Committee has consistently advised and reaffirmed that testing communications with the target audience is necessary for FDA, and that using small samples is an effective approach for testing and communicating in a timely manner. In fact, research has shown that "saturation," or the point at which no new information or themes are observed, can occur with as few as 12 interviews, as described in Guest et al (2006).

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. Specifically, FDA is asking Westat to gain insight to the following questions:

- Is the Patient-Provider Agreement form clear and understandable?
- What are the key messages that participants get from the form?
- Do participants understand that TIRFs can cause their breathing to stop, which may lead to death?
- Do participants understand that because of the serious risk of death, they have to follow certain safety rules?
- Does the language about storing patient information in a database concern participants?
- Do participants understand they can only get a TIRF medicine from a special pharmacy?
- Do participants understand the information about the TIRF REMS program?

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 45-minute interviews with U.S. adults. Westat has partnered with Rare Patient Voice, LLC, a company specializing in difficult to reach patient and caregiver recruitment. Rare Patient Voice tracks and stores all panel member activity and assigns a unique ID number which stays with the panelist throughout their entire panel membership. These tracking records consist of profile information provided during enrollment, profile updates, and client feedback. Rare Patient Voice monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include individual vetting of contact information, and review of IP addresses, and enrollment data, as well as review of screener questions and past survey response.

We will use a participant screener to recruit a mix of patients and caregivers. We will recruit 10 patients who are currently taking prescription medicines around-the-clock to treat non-cancer pain since they might be eligible to take a TIRF medicine at some point. We will also recruit 5 non-professional caregivers of cancer patients taking prescription medicines around-the-clock to treat pain. To the extent possible, the participant pool will be diverse in terms of race/ethnicity, education, and geography.

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

We plan to conduct interviews in April 2019.

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 postal mail materials to participants who do not have access to screen sharing technology.

For each 45-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 whether they 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. Participants who do not allow audio recording may still participate in the interview. In these cases, Westat will take notes that are more detailed than when relying on the audio recording.

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.

FDA's IRB, the Research Involving Human Subjects Committee (RIHSC) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

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

For this project, Rare Patient Voice will provide $50 incentives to participants at the end of each 45-minute interview in the form of a check.

Rare Patient Voice 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. Rare Patient Voice's incentive scale is based on set time increments and is applied equally across all study topics, sponsors, and data collection modes. The table below details the previous incentives approved by OMB for this series of rapid message tests.

Project #	Communication Tested	Interview Length/Incentive	OMB approval date
1	Clinical Trials Brochure	45 min/$50	August 4, 2017
2	Caregiver Tipsheet	30 min/$35	September 26, 2017
3	Public Service Announcement Video about Generic Drugs	30 min/$35	October 25, 2017
4	Opioid Analgesics Patient Counseling Guide	45 min/$50	November 27, 2017
5	Vaccines and Seniors Brochure	30 min/$35	May 10, 2018
6	Public Service Announcements about Safe Disposal of Opioids	30 min/$35	July 26, 2018
7	Nicotine Dialogue Campaign Branding	30 min/$35	August 23, 2018
8	Testosterone Medication Guide	45 min/$50	October 12, 2018
9	Asthma Fact Sheet	30 min/$35	February 12, 2019

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 treating pain 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.

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. Field methods, 18(1), 59-82.

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	400	3	20
Interviews	15	45	11
		Total	**31**

REQUESTED APPROVAL DATE: April 5, 2019

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