FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

TITLE OF INFORMATION COLLECTION:

Collection of Data to Support "Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Patient Experiences with REMS Programs."

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The Food and Drug Administration (FDA) has limited data to determine the impact of Risk Evaluation and Mitigation Strategy (REMS) programs. REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS may include one or more of the following such as: (1) A Medication Guide or patient package insert for patients; (2) a Communication Plan for healthcare providers; and (3) Elements to Assure Safe Use (ETASU), which often involve some form of restricted distribution and/or evidence of safe-use conditions.[1] REMS focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to mitigate the frequency and/or severity of an adverse event.

   FDA has contracted with Brigham and Women's Hospital affiliated with Harvard Medical School to conduct the REMS Programs to Promote Appropriate Medication Use and Knowledge - Patient Experiences with REMS Programs Study. They will conduct the study to better understand how REMS programs have operated in practice and use this information to develop actionable steps for improvement. Specifically, this study seeks to answer to what degree the terms of REMS programs have been followed, how REMS programs have impacted drug utilization, health outcomes, and patient experiences, and how effectively REMS programs translate important risk-benefit information to patients. The aspect of this study pertaining to this information collection request entails interviews with patients about their experiences with select REMS programs. Other information collection requests will be submitted subsequently that pertain to another aspect of the overall study, physician surveys and interviews.

2. **Intended use of information:**

   The contractor will analyze the data collected from participants to assess patient experiences enrolling in REMS programs and accessing the REMS program-covered drugs as well as patient knowledge of REMS program rationales and structures. By leveraging interdisciplinary expertise, the results of the findings will be used to better understand real-world experiences with the REMS programs. This information will be included with other analyses to recommend actionable steps to support and improve the REMS programs.

[1]FDA Website: **Risk Evaluation and Mitigation Strategies**, Accessed on Oct. 25, 2021

3. **Description of respondents:**

Eligible participants will constitute adult patients or adult caregivers of patients, aged 18 years or older, who started one of nine REMS program-covered drugs—alemtuzumab, ambrisentan, bosentan, clozapine, isotretinoin, lenalidomide, pomalidomide, sodium oxybate, and thalidomide—in the past year. For the REMS programs imposed because of teratogenic risks, participants will be further restricted to women of childbearing age. Up to 20 participants will be recruited for each REMS program (we will treat the REMS programs for lenalidomide, pomalidomide, and thalidomide as a single REMS program as they have the same requirements). Recruitment will be performed through patient support groups and online advertisements with voluntary measures. For each group, the contractor will ensure a reasonable degree of geographic and demographic diversity, including race/ethnicity, sex, and age. Overall, subjects participating in the research are expected to benefit from improved risk communication content and strategies of the REMS program.

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

The contractor will conduct the interview sessions between 10/01/2021 and 12/31/2022 and conduct the full study between 10/01/2021 and 06/30/2023.

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

Using an interview guide, the contractor will conduct qualitative phone interviews with each participant lasting up to one hour. Audio recordings of the patient interviews will be transcribed.

6. **Confidentiality of respondents:**

The contractor will record personal details of each participant (i.e., name and address) solely for the purpose of collecting initial screening information and providing payment. Once the testing is initiated, the contractor will use a numbering system to protect the identity of each participant and to remove the link between personal details and test data.

At no stage during the recruitment process will the recruiters seek to gain access to any medical records for any participant. The contractor will keep protected health information (PHI) and other information in a secure platform during the study and will not circulate them to any third party. The collected information will be available only to the authorized study team members through a secure mechanism and deleted upon completion of the study.

All study personnel interacting with human subjects as part of this research will have completed training on the protection of human subjects.

The contractor will present each participant with a fact sheet explaining the purpose of the study, what participation entails, the availability of a token of appreciation (a $50 Amazon gift card) for completion of an interview, the right not to participate, and contact

information for the principal investigator and IRB. Consent will be presumed based on participation. (See Fact Sheet/Consent Form).

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

As a token of appreciation, the contractor will offer a $50 Amazon gift card to patient participants. All patient interviewees will receive this token from the contractor electronically after completing an interview. In comparable prior research, Rapid Interviews and Survey of Patients Being Treated with Ambien and Lunesta or their Health Care Professionals (OMB 0910-0500; PMID: 28247279), the contractor offered an equivalent token of appreciation, yielding successful recruitment efforts. While this is above the Federal recommendation of a $40 token for a 60-minute interview, we believe that a slightly higher amount of $50 is justified in this project for three primary reasons.

First, although the contractor estimates that each remote interview will run 60 minutes, we anticipate that some interviews will last slightly longer than an hour depending on the nature of the discussion. Furthermore, due to the structure of recruitment and scheduling processes, we anticipate that interviewees will spend additional time outside of the formal interview to sign up and prepare for the interview. This includes time for signing up (5 minutes), scheduling (10 minutes), a phone screen (5 minutes), and any follow-up questions the contractor may have after the end of the interview (10 minutes). Although the amount of time each patient interviewee spends on interview-related activities will vary, we believe that it will be significant enough to merit a higher token of $50.

Second, all patient interviews will be conducted during business hours, potentially resulting in a loss of income for the time the participant spends in the interview. The Bureau of Labor Statistics (BLS) estimates that the average hour wage of employees on non-farm payrolls was $30.85 in September 2021 (Bureau of Labor Statistics, 2021). Factoring in the time a patient may spend in recruitment, scheduling, screening, the interview, and follow-up—a maximum total of 90 minutes—the equivalent average compensation should be $46.28. Our suggested token of $50 is just above this figure.

Third, $50 for a 60-minute interview is consistent with what OMB has approved in recent years for online interview participants. In a recent past study,[2] the contractor successfully used a monetary incentive of $50 for each 60-minute interview. The OMB has also previously approved incentive amounts greater than $50 for similar remote research. For example, in the CFPB's Consumer Response Intake Form Improvement Study from 2017 (OMB 3170-0042), the token of appreciation was approved at $75 for 60-minute remote interviews. This is higher than our proposed token of $50 for the same interview duration.

Considerable research has shown that the use of tokens can increase participation rates in qualitative research studies involving patient interviews. Studies have found that a $50 incentive is more likely to produce a greater willingness to participate in a qualitative interview than a $25 incentive (Kelly et al., 2017). The contractor believes that a greater incentive amount will increase willingness to participate in our study, especially given the potentially sensitive subject matter of medication usage and health history. This may also expedite the recruitment process; decrease the number of last-minute cancellations or reschedules; and increase representation of low-income and other demographics typically

[2] Kesselheim AS, McGraw SA, Dejene SZ, et al. Patient and Physician Perceptions of Drug Safety Information for Sleep Aids: A Qualitative Study. *Drug Saf.* 2017;40(6):531-542.

underrepresented in qualitative research. This saves time (and cost) on recruitment delays and on overscheduling to achieve the target number of participants. Overall, using a slightly higher monetary incentive to increase willingness to participate may save time, and therefore cost, and produce higher quality data for our project.

8. **Questions of a sensitive nature:**

   The contractor will not ask questions that are sensitive in nature. Participants will be allowed to abstain from answering if they are uncomfortable with any questions asked during this study. Additionally, participants will be notified at the beginning of the study session that they are welcome to end the session and leave at any time for any reason.

9. **Description of statistical methods:**

   We will only use descriptive statistical methods for this study. The contractor will strip transcribed interviews of personal identifiers and import them into qualitative analysis software package. After reading each transcript independently, the contractor will draw up a list of exploratory codes that best captures the ideas in the interviews and conduct an initial round of coding. The contractor will then review the text for each code and determine whether changes to the code list are needed. Using a final code list, the contractor will recode the transcripts and examine the interrelationship between the codes, the range and gravity of themes particular to each stakeholder, the diversity of responses within themes, and the nature of responses to specific REMS components.

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)
Interview	160	60	160

REQUESTED APPROVAL DATE: November 2021

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