

United States Food and Drug Administration
Generic Clearance: Testing Communications on Medical Devices and Radiation-Emitting Products
OMB Control Number 0910-0678
Gen IC Request for Approval

Title of Gen IC: CDRH Rapid Message Testing with Consumers and Caregivers—Web Content About Recently-Approved Medical Devices

1. Statement of Need:

The FDA currently regulates more than 190,000 different medical devices. On average, the FDA approves about 45 devices every year that include some of the newest medical technology available. Many of these devices are important to diagnosing and treating illness and injury and bring enormous benefits to patients. We at the FDA take seriously our role in communicating about both the benefits and risks of medical devices, to support an informed public and strong health care system. As part of these communications, we post information about certain recently-approved devices to our website to help increase public awareness of some of the newest medical technology available.

The FDA’s Center for Devices and Radiological Health (CDRH) has received stakeholder feedback that the information we provide on our website about recently-approved devices sometimes emphasizes the benefits of using the device more than the associated risks, which could be misperceived as being promotional on the behalf of device manufacturers. CDRH wants its communications about new medical devices to reflect the public’s information needs and interests, while also providing balanced information about both the benefits and the risks.

The purpose of this project is to test consumer website content produced by CDRH about recently-approved devices. Specifically, we will test the recently-approved devices [landing page](#) (Attachment A) and the following examples of information about recent consumer-focused or implantable devices:

- [Eversense E3 Continuous Glucose Monitoring System - P160048/S016](#) (Attachment B)
- [RHA Redensity – P170002/S012](#) (Attachment C)
- [MiSight 1 Day \(omafilcon A\) Soft \(Hydrophilic\) Contact Lenses for Daily Wear - P180035](#) (Attachment D)

We will obtain feedback from participants on whether the questions provided in Q&As about each new device are those they want answered, whether the information about benefits and risks are balanced, and whether they have any suggestions for improving the clarity or format of the information.

Communications science tells us that we must test messages with our intended audiences. Thus, the FDA plans to test these communications using cognitive interviews with a small sample of 18 U.S. adults drawn from a diverse consumer panel.

This data collection is the second in a series of rapid message tests CDRH plans to submit to OMB under generic clearance 0910-0678. These projects are part of CDRH’s effort to make target audience testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order (White House, 2015) to improve how information is presented to consumers by applying behavioral science insights, and it meets repeated calls from the FDA’s Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public.

2. **Intended Use of the Information:**

The FDA is not seeking quantitative data or generalizable findings; it is only interested in pretesting communications with small samples of target audience members for understandability and to avoid unintended negative effects.

The FDA's contractor, Westat, will test the communications with a small sample of target audience members to ensure the messages meet their objectives without causing unintended negative effects. The 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 the 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).

The FDA will use the collected interview data to refine its messaging by improving the comprehensibility for a higher public health impact. Specifically, the FDA is asking Westat to gain insight to the following questions:

Main Landing Page and Approvals by Year Page

- How well does the landing page meet participants' expectations?
- Is the landing page text clear, understandable, and well organized?
- How would participants attempt to find a one-pager for a specific device?
- What improvements do participants suggest for the landing page?

Information About Recently-Approved Devices

- What are the main message(s) that participants get from the information?
- How well do participants think the information explains both the benefits and the risks?
- How clear and understandable is the text to participants? What words or phrases are confusing and what suggestions do participants offer for replacing them?
- What information do participants find useful? Not useful? Repetitive?
- What information do participants say is missing or would be helpful to add?
- Are the question headers the ones that participants want answered?
- How well do participants think the content is organized?
- How do participants' reactions differ across the one-pager examples?
- What suggestions do participants offer for improving the information?

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 18 45-minute interviews with U.S. adults. Westat has partnered with PRC, a recruitment specialist, to recruit respondents from its general population panel. PRC tracks and stores all database member activity and assigns a unique ID number which stays with the member throughout their entire membership. These tracking records consist of profile information provided during enrollment, profile updates, and past focus group or in-depth interview involvement. PRC 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 enrollment data, as well as review of screener questions, rescreening of participants before participation, and client feedback on past focus group and interview response.

We will use a participant screener (Attachment E) to recruit a mix of six consumers who have diabetes or high blood sugar (to review a webpage about a recently approved glucose meter), six consumers who have considered or had injections to give their face a smoother or fuller appearance (to review a webpage about a recently approved dermal filler), and six participants who wear eyeglasses or contacts (to review a webpage about recently approved contact lenses). We will primarily recruit lower education consumers for feedback on literacy and comprehension. To the extent possible, the participant pool will be diverse in terms of gender, age, race, ethnicity, and geography.

4. How the Information is Collected:

We will conduct all interviews remotely using online software (e.g., ZoomGov) and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, or tablets. We will ensure that any materials viewed by the participants for the test are compatible with these devices.

For each 45-minute interview, a trained interviewer will lead the discussion using a semi-structured interview guide (Attachment F) that ensures consistency in major topics but allows flexibility in probing each participant on particular questions.

With the consent of participants, we will audio record each interview. We will produce a written transcript of the discussion and use the transcript for the analysis.

FDA staff will be able to observe unobtrusively and will not be visible on screen, and this will be made known to participants as part of the informed consent.

5. 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 will not be invited to participate in the interview.

The recruiter, PRC, will send regular recruitment updates to Westat via email. These updates will contain no personally identifiable information (PII), such as the recruits' last names or contact information. Therefore, the FDA and Westat will not have full names or contact information for any participants and there will be no link between the data collected and participants' identities. No participant's identifiable information such as name will be included in the transcripts. 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. Transcripts will be zipped electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to the FDA, Westat will destroy all personally identifying information to protect each participant's personal identity. Additionally, the transcripts and interpretive report delivered to the 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.

The FDA's Institutional Review Board (IRB) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

6. Amount and Justification for Proposed Incentive:

For this project, PRC will provide \$50 incentives to participants at the end of each 45-minute interview in the form of a digital gift card. PRC 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.

The proposed incentive amount is significantly below market rate for an effort of this type. Recruiting firms determine market rates for research participation based on what other comparable studies in the field are offering and what rate will incentivize the required population to participate. PRC and other vendors estimate that other studies being conducted with similar populations and levels of effort in this market at this time pay incentives of \$100-\$175. For example, it is not uncommon for companies to pay \$150 for 45-minute remote consumer interviews (Lai et al, 2017).

We estimate that participants will spend approximately 60 minutes of their time on this task, which includes time for screening (3 minutes), time for scheduling an interview (7 minutes), the time involved in logging in early to confirm the technology is operating correctly (5 minutes), and time to participate in the interview (45 minutes). The Bureau of Labor Statistics calculated that the average hourly wage of employees, including benefits, in June 2022 was \$41.03 (BLS, 2022). But there are additional factors requiring an incentive for this study that is higher than the BLS average hourly rate. Participants are required to join the interview from a location where there are no distractions, which may require coordinating childcare, finding a private and quiet location, or special accommodations during that time. BLS calculated in May 2021 that the median hourly wage of childcare workers is \$13.22, an additional expense for some participants that will be offset by the incentive (BLS, 2022). Also, the interviews will be conducted online, and participants must have a computer and broadband Internet to participate; participating will use approximately one hour of data on their Internet plans.

The proposed incentive rate is in accordance with standard practice and based on our experience with specific consumer populations, the amount of time the participant spends in the study, what is required of them, recent consultation with our recruiting vendor, and OMB-approved incentives on recent FDA projects and projects for other clients. This token of appreciation is intended to provide enough incentive to participate in the study rather than another activity, improve data quality, reduce the number of cancellations, recognize the burden of childcare costs, and convey appreciation for contributing to this important activity (Russell et al, 2000). Incentives must be high enough to equalize the burden placed on respondents in respect to their time and cost of participation. Offering an incentive below these rates may result in increased costs exceeding the amount saved with a lower incentive. Consequences of insufficient incentives include increased time and cost of recruitment, and increased probability of cancelled or postponed interviews.

7. Questions of a Sensitive Nature:

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals’ reactions to the messages and materials.

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.

8. 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 transcripts. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The software will allow us to import interview transcripts, create links between the transcripts 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.

9. Burden:

| Type/Category of Respondent | No. of Respondents | Participation Time (minutes) | Burden (hours) |
|-----------------------------|--------------------|------------------------------|----------------|
| Screener | 450 | 3 | 22 |
| Interview | 18 | 45 | 14 |
| Totals | | | 36 |

10. Date(s) to be Conducted: February 2023

11. Requested Approval Date: February 2023

12. FDA Contacts:

| Program Office Contact | FDA PRA Contact |
|--|---|
| Brian Lappin, (301)796-9126 Center for Devices and Radiological Health Office of Communication and Education Abigail Corbin, (301)796-9142 Center for Devices and Radiological Health Office of Policy, CDRH-PRA Team | JonnaLynn Capezzuto (301) 796-3794 Director, Paperwork Reduction Act Staff Division of Information Governance jonnalynn.capezzuto@fda.hhs.gov |

13. Certification: In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;

- c) The collections are noncontroversial;
- d) Personally identifiable information (PII) is collected only to the extent necessary¹ and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.²
- f) 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.

Bibliography

Bureau of Labor Statistics (BLS), Total Compensation: Per Hour Worked, on the Internet at <http://www.bls.gov/ncs/> (visited November 29, 2022)

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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.

Lai, H. C., & Wirasinghe, R. (2017). Applied Research for Advertising Products: Tactics for Effective Research. In *Proceedings of the 2017 CHI Conference Extended Abstracts on Human Factors in Computing Systems* (pp. 1144-1151).

Russell, M. L., Moralejo, D. G., Burgess, E. D. (2000). Paying research subjects: Participants' perspectives. *Journal of Medical Ethics*, 26(2), 126–130

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

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¹ For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

² As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."