# FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS (0910-0360)

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

**TITLE OF INFORMATION COLLECTION:** Assessment of physician applicants' experiences with FDA's Expanded Access and Compassionate Use programs

## DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

FDA is committed to increasing awareness of and knowledge about its Expanded Access and Compassionate Use (EA/CU) programs and the procedures for obtaining access to human investigational drugs (including biologics) and medical devices, and in improving the experiences of users of these programs. FDA seeks to identify areas of improvement to strengthen these programs. Portions of these programs have been the target of a GAO report and EA/CU programs have been discussed in relation to Congressional interest in possible Right to Try legislation, and these programs are a priority for FDA.

Evaluation of the experiences of physician applicants who have used these programs is critical to understanding the impact of FDA's internal processes and practices. Evaluation of these physician applicants' "real-world" experiences is essential in identifying what is working well and which areas are ripe for improvement. Given the current environment, we chose this generic collection so the information could be collected quickly.

2. **Intended use of information:**

The information collected will be used to aid in improving FDA's EA/CU programs. These programs represent a "last chance" for patients who have no other reasonable medical options; improvements to the program that increase use is a benefit to those patients.

3. **Description of respondents:**

The pool of potential respondents will be physicians who have submitted applications for the FDA Expanded Access or Compassionate Use programs.

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

12/11/2017 – 2/11/2018. The study will continue for 2 months from the start date.

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

Surveys will be administered via an online survey tool. No Personally Identifiable Information will be collected. The surveys are expected to take no more than 20 minutes.

6. **Confidentiality of Respondents:**

Staff at a third-party research firm and the FDA will see survey responses. No Personally Identifiable Information will be collected.

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

Participants will be paid $50 for participating in the survey. The participants are highly educated physicians in demanding specialties whose time is extremely valuable. Based on an independent third party research firm's previous experience with surveying physicians, offering this compensation is essential to driving participation.

8. **Questions of a Sensitive Nature (Data will be kept private to the extent allowed by the law)**

None.

9. **Description of Statistical Methods**

An independent third party research firm will manage the recruitment process with direct oversight from FDA staff. The potential survey participants will be identified as physician applicants of EA/CU programs by FDA staff. FDA will provide names and physical mailing addresses for physician applicants. The independent third party research firm will compare their existing panels of physicians with whom they have had previous interaction (and additional contact information). The independent third party research firm will contact the physician applicants based on a sampling plan that will allow for representative evaluation of physician applicants with experience with FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiologic Health (CDRH) as well as experience across relevant specialties.

The data collected will be assessed using descriptive statistics (mean, median, mode, range, percentages).

***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) |
|---|---|---|---|
| Physician | 200 | 20 | 66.67 |

**REQUESTED APPROVAL DATE:** 12/8/2017

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