FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: "Focus group and individual assessments of knowledge of the Expanded Access and Compassionate Use programs among stakeholders"

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.

The focus groups and individual interviews will assess knowledge of the EA/CU programs among stakeholders, including physicians who work in fields where the physician's patients are likely to benefit from these programs, manufacturers, healthcare payors, healthcare systems, patient groups, and Investigational Review Boards. They will evaluate stakeholder knowledge, interest, and use of EA/CU programs, including a self-rating of how knowledgeable they are, how they found out about them (if they have knowledge), likelihood to use them (if medically appropriate), whether or not they have used them and if they'd do so again, and what routes they would suggest FDA use to educate stakeholders about these programs. Focus groups will aim to include participants with a mix of demographic characteristics, including gender and geographic representation. Participant demographic information will not include PPI.

2. **Intended use of information:**

FDA will use the data collected during the stakeholder focus groups and individual interviews to help improve its programs, increase stakeholder understanding of the programs, and facilitate use of the programs when appropriate. The qualitative data obtained during the focus groups may also spur additional studies of the EA/CU programs by identifying previously unknown issues. Given the current environment, we chose this generic clearance so the information could be collected quickly. 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:**

Participants in these focus groups and individual interviews will have some degree of experience with EA/CU programs and belong to the following categories:

- Physicians who work in fields where the physician's patients are likely to benefit from these programs
- Members or leaders of patient advocacy groups
- Representatives of Institutional Review Boards
- Manufacturers
- Healthcare systems
- Healthcare payors

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

All focus groups will be conducted between January 8, 2018 and February 28, 2018 at the FDA campus in Silver Spring, MD or at the office of a third-party contractor in Washington, DC. When required (e.g., due to adverse weather conditions), a teleconference/webinar option will be available to participants.

Interviews will be conducted between January 11, 2018 (or immediately following approval of this application) and February 28, 2018. When possible, these interviews will take place at a location convenient to the interviewee, but most of these interviews will likely be conducted via teleconference.

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

Notes will be taken by an observer present for the focus groups. No audio or video recordings will be created.

6. **Number of focus groups and individual interviews:**

Up to 10 focus groups
Up to 40 individual interviews

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

None

8. **Questions of a Sensitive Nature:**

There will not be questions of a sensitive nature.

9. **Description of Statistical Methods (I.E. Sample Size & Method of Selection):**

- Participants will be asked a series of open-ended questions relevant to their experience with EA/CU
    - In the focus group setting, the moderator will use a moderator's guide to ensure the discussion covers topics of interest, but will also follow the group's lead to gain additional insights
    - In the interview setting, the interviewer will follow a structured interview guide
- Only qualitative data will be collected
- Efforts will be made to select a diverse and representative group of participants (e.g., gender diversity, geographic representation)
    - Up to 8 people will participate in each of up to 10 focus groups
    - Up to 40 people will participate in individual interviews
    - Up to 120 participants will be included in total
- Individuals will participate in either a focus group or an individual interview.

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)
Focus Group Participants	80	90	120
Individual Interview Participants	40	60	40
TOTAL	120	Varies	160

REQUESTED APPROVAL DATE: 12/30/2017

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