

United States Food and Drug Administration
Generic Clearance: Focus Groups as Used by the FDA
OMB Control Number 0910-0497
Gen IC Approval Request

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 Gen IC: [Provide the name of the collection of information that is the subject of the request.]

1. Statement of Need:

[Provide a brief description of the purpose of this collection.]

2. Intended Use of the Information:

[Indicate how the information will be used and if this is part of a larger study or effort.]

3. Description of Respondents:

[Describe participants/respondents.]

4. How the Information is Collected:

[Provide details about how the focus group(s) will be conducted and who (e.g., contractor) will facilitate.]

5. Number of Focus Groups:

[Provide the number of focus groups to be conducted and how many participants in each.]

6. Amount and Justification for Proposed Incentive:

Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? [] Yes [] No

If yes, describe the incentive and provide a justification for the amount. If no, delete this instruction.]

7. Questions of a Sensitive Nature:

[Describe and provide justification.]

8. Description of Statistical Methods:

[Describe sample size and method of selection.]

9. **Burden:** [Complete the table below.]

Burden Hour Computation -- (Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours).

Example:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Older Adult Patients	9	60	9
Pediatric Patient Proxies	9	60	9
Pharmacists	5	60	5
Prescribers	5	60	5
Totals	28		28

10. **Date(s) to be Conducted and Locations:**

[Insert dates and corresponding locations focus groups will take place.]

11. **Requested Approval Date:** [Insert date.]

12. **FDA Contacts:**

Program Office Contact	FDA PRA Contact
[Insert name, phone number and center.]	

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

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."