United States Food and Drug Administration
Generic Clearance: FDA Focus Groups and Interviews
OMB Control Number 0910-0497
Gen IC Request for Approval

BEFORE SUBMISSION

Ensure that your Gen IC meets the requirements of the umbrella generic. This generic facilitates FDA's ability to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the agency. 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.

All documents submitted with this gen IC should indicate FDA sponsorship and display the current OMB approval expiration date.

HOW TO USE THIS TEMPLATE

This template utilizes fill-in enabled text form fields. Simply click on the shaded text and enter your narrative.

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

Title of Gen IC: (Insert center) Provide the title of the gen IC.

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

   [ ] Focus Group
   [ ] Interview

   [Provide details about how the focus groups/interviews will be conducted (how many groups/sessions, how many participants per group/session and who (e.g., contractor) will facilitate.]

5. Confidentiality of Respondents

   Describe any assurance of confidentiality provided to respondents.

   [You may provide this statement on your survey instrument]: “Your participation / nonparticipation is completely voluntary, and your responses will not affect your eligibility to receive any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.”

6. Amount and Justification for Proposed Incentive

   [If an incentive is provided to respondents, describe the incentive and provide a justification. Higher incentives need a robust justification for "hard-to-reach" populations.

7. Questions of a Sensitive Nature

   [Describe and provide justification.]

8. Description of Statistical Methods

   [Describe sample size and method of selection.]

9. Burden

   Replace the content of the example table below with the estimated burden for this gen IC.

   Participation time may be in the format of hours or minutes (use a decimal) and indicated in the heading.

   Burden Hour Computation: Number of Respondents multiplied by participation time = total burden hours. ***Data in all fields of the table must be entered, including totals****.*

   If your gen IC employs a screener be sure to not double count respondents. A screened respondent and the respondent completing the survey is counted as 1 because they are the same person. Round up to whole numbers for the total burden hours; do not use decimals. ***Delete the italicized instruction prior to submission.***

   Example:

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

10. Date(s) to be Conducted and Locations

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

11. Requested Approval Date

    Insert date if shorter than 10 day turn-around time as noted in the SSA. Otherwise use the month and year, only, allowing for a 30 day review time at APRA.

12. FDA Contacts

Program Office Contact	FDA PRA Contact
[Insert name, phone number and center.]	[PRA Staff will insert name, phone number and center.] Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations