GEN IC REQUEST TEMPLATE FOR
Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed
OMB Control Number 0910-0891

BEFORE SUBMISSION

Ensure that your Gen IC meets the requirements of the umbrella generic. This generic facilitates FDA's ability to better understand patients, consumers, and health care professionals' perceptions and behaviors regarding various issues and patient reported outcomes associated with the safety and administration of drug products overseen by the agency.

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.

Please delete all italicized instruction before submitting your gen IC.

United States Food and Drug Administration
Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed
OMB Control Number 0910-0891
Gen IC Request for Approval

Qualitative methods generally yield data that are not statistically generalizable. As such, they are useful for testing and refining ideas, and for developing hypotheses that can be further explored using quantitative methods, which is the preferred method for informing important policy and resource allocation decisions.

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

1. Type of Collection

   For this gen IC FDA will conduct

   Instruction: Please select one of the following and insert it into the sentence above:

   - In-depth, one-on-one interviews
   - Small group Discussions
   - Focus groups
   - Observations

2. Statement of Need

   Provide a brief description of the purpose of this collection.

3. Intended Use of the Information

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

4. Description of Respondents

   Describe participants/respondents.

5. How the Information is Collected

   Provide details about how the information will be collected (e.g., web-based, telephone, social media) and who (e.g., contractor) will conduct.

6. 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 have an effect on your eligibility for receipt of 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."

7. Amount and Justification for Proposed Incentive

What is the amount, if any, of the incentive offered? Provide a detailed justification as to why this group of respondents for this information collection will receive a stipend, reimbursement of expenses, token of appreciation.

8. Questions of a Sensitive Nature

Describe and provide justification.

9. Description of Statistical Methods

Describe sample size and method of selection.

10. Burden

Delete this instruction prior to submission.

Choose the appropriate collection activity in the burden chart below and delete the remaining rows.

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.

Activity	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Individual In-Depth Interviews (Screening)			
Individual In-Depth Interviews			
Focus Groups/Small Group Discussions (Screening)			
Focus Groups/Small Group Discussions			
Observation (Screening)			
Observations			
TOTALS			

11. Date(s) to be Conducted

Insert date(s) and locations, if applicable.

12. Requested Approval Date

Insert date. *Be sure to allow a maximum of 30 days review time for the PRA staff.* ***Delete this instruction before submission.***

13. FDA Contacts

Program Office Contact	FDA PRA Contact
Insert name, email Enter program office Enter center	Insert name, email Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations