

United States Food and Drug Administration
Generic Clearance: Quantitative Testing for the Development of FDA Communications
OMB Control Number 0910-0865
Gen IC Request for Approval

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. Type of Collection: (Check one box below. If you are requesting approval of other instruments under the generic, complete this justification for each instrument.)

Experiment

Survey

5. Confidentiality of Respondents:

[Describe any assurance of confidentiality provided to respondents.]

[You may provide this statement on your survey instrument]: “Your participation / non-participation 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.”

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 or attach a sampling plan.]

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 of information collection/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Total			

10. **Date(s) to be Conducted:** [Insert date(s).]

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

12. **FDA Contacts:**

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