

## GEN IC REQUEST TEMPLATE FOR

Generic Clearance: Quantitative Data on Tobacco Products and Communications  
OMB Control Number 0910-0810

### BEFORE SUBMISSION

Ensure that your Gen IC meets the requirements of the umbrella generic. This generic facilitates FDA's ability to assess the need for communications on specific topics and to assist in the development and modification of communication messages.

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

Delete all italicized instructions.

### 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  
Center for Tobacco Products  
Generic Clearance: Quantitative Data on Tobacco Products and Communications  
OMB Control Number 0910-0810  
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. How the Information is Collected

Experimental Study       Survey       Other (Describe):

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

5. Confidentiality of Respondents

Describe any assurance of confidentiality provided to respondents and the basis for the assurance.

*[For example, methods of assuring confidentiality may include not linking Personally Identifiable Information (PII; e.g., names and contact information) with respondents' data from the information collection, and storing the data in a password-protected folder accessible only to staff working on the project.]*

Cite and describe Privacy Impact Assessment (PIA), # XXXXX.

*[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."]*

6. 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.

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) 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.***

*Round up to whole numbers for the total burden hours.*

Type of Information Collection/Category of Respondent/Activity	Number of Respondents	Participation Time (choose hours or minutes)	Total Burden (hours)
Youth aged 13–17 (Youth Recruiting and Screening)	200	.25 hour (15 minutes)	50
Youth aged 13–17 (Self-administered Online Survey)	120	1 hour	120
Totals	200		170

10. Date(s) to be Conducted

Insert date(s) and locations, if applicable.

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, email Enter program office Center for Tobacco Products	Insert name, email Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations