

GEN IC REQUEST TEMPLATE
Generic Clearance for the Collection of qualitative Data on
Tobacco Products and communications (CTP)
OMB Control Number 0910-0796

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 approval expiration date and PRA Statement as provided for in the APRA document “Displaying PRA Information on Instruments”.

HOW TO USE THIS TEMPLATE

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

U.S. Food and Drug Administration
Generic Clearance for the Collection of qualitative Data on
Tobacco Products and Communications (CTP)
OMB Control Number 0910-0796
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

Provide details about how the information will be collected (e.g., individual in-depth interviews, focus group, intercept interviews, self-administered survey, omnibus survey) 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 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) 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 where indicated.

Be sure not to double count respondents. In the example below the Number of Respondents is 3,450 because this total includes screened respondents. Round up to whole numbers for the total burden hours; do not use decimals. ***Delete this italicized instruction prior to submission.***

Respondent Type/Category	Activity (if this column is not needed, please delete)	Number of Respondents	Participation Time (choose hours or minutes)	Total Burden (hours)
Parents/guardians of youth aged 13–17	Parental Consent	3,450	2	115
Youth aged 13-17	Screening	3,450	4	230
Youth aged 13–17	Assent	152	2	5
Youth aged 13-17	Focus Group	152	95	241
Young Adults aged 18-20	Screening	1,710	4	114
Young Adults aged 18-20	Consent	100	2	3
Young Adults aged 18-20	Focus Group	100	95	158
Totals		3,450	---	866

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 and include reason for expedited review. Otherwise use the month and year, only, allowing for a 15 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 [to be completed by APRA] Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations