Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0920-1050)

Instruction: This form should be completed by the primary contact person from the Program sponsoring the collection.

DETERMINE IF YOUR COLLECTION IS APPROPRIATE FOR THIS GENERIC CLEARANCE MECHANISM:

Instruction: Before completing and submitting this form, determine first if the proposed collection is consistent with the scope of the Collection of Routine Customer Feedback generic clearance mechanism. To determine the appropriateness of using the Collection of Routine Customer Feedback generic clearance mechanism, complete the checklist below.

*If you select "yes" to all criteria in Column A, the Collection of Routine Customer Feedback generic clearance mechanism **can** be used. If you select "yes" to any criterion in Column B, the Collection of Routine Customer Feedback generic clearance mechanism **cannot** be used.*

Column A	**Column B**
The information gathered will only be used internally to CDC. [X] Yes [ ] No	Information gathered will be publicly released or published. [ ] Yes [X] No
Data is qualitative in nature and not generalizable to people from whom data was not collected. [X] Yes [ ] No	Employs quantitative study design (e.g. those that rely on probability design or experimental methods) [ ] Yes [X] No
There are no sensitive questions within this collection (e.g. sexual orientation, gender identity). [X] Yes [ ] No	Sensitive questions will be asked (e.g. sexual orientation, gender identity). [ ] Yes [X] No
Collection does not raise issues of concern to any other Federal agencies. [X] Yes [ ] No	Other Federal agencies may have equities or concerns regarding this collection. [ ] Yes [X] No
Data collection is focused on determining ways to improve delivery of services to customers of a current CDC program. [X] Yes [ ] No	Data will be used to inform programmatic or budgetary decisions, for the purpose of program evaluation, for surveillance, for program needs assessment, or for research. [ ] Yes [X] No
The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future. [X] Yes [ ] No	

Did you select "Yes" to all criteria in Column A?

> If yes, the *Collection of Routine Customer Feedback* generic clearance mechanism may be appropriate for your investigation. You may proceed with this form.

Did you select "Yes" to any criterion in Column B?

> If yes, the *Collection of Routine Customer Feedback* generic clearance mechanism is **NOT** appropriate for your investigation. Stop completing this form now.

TITLE OF INFORMATION COLLECTION: Pilot Evaluation for Cervical Cancer Clinical Decision Support Tools

PURPOSE:

In 2021, CDC and the MITRE corporation, a federally funded research and development center, collaborated to develop clinical decision support (CDS) tools and electronic clinical quality measures for cervical cancer screening and management. The goals of this project are to: (1) improve clinician adoption of new cervical cancer screening and management guidelines; (2) improve patient outcomes by providing timely and appropriate screening and management options tailored according to individual risk and prior history; and (3) improve health equity by developing tools that are feasible to implement in low-resource settings and that provide care for underserved populations.

The objectives for this phase of the project are to test these CDS tools in a real-world clinical setting to: (1) ensure CDS is actively triggered and data collection is occurring; (2) assist with troubleshooting and address any malfunctions that may emerge; and (3) assess usability and user acceptance of the CDS tools on clinical workflow and practice. We will employ a mixed-methods approach for routine customer feedback. The first two objectives will be addressed by collecting a selected set of data related to pre- and post-implementation of the tool, including average time spent using tool, number of screenings/follow-ups conducted, the number of times the tool was triggered, frequency of guideline recommendations presented to clinicians, and CDS logic paths exercised during use. These data will be collected by the contractor and there will be no burden to the public. Attachment A includes the full details of the usability testing.

DESCRIPTION OF RESPONDENTS:

Respondents will include 45 care providers who are participating in the cervical cancer CDS pilot study. This accounts for 15 care providers for each of three pilots being conducted. We will make an appeal for 15 care providers who are pilot participants to meet with us and participate in the usability evaluation described in Attachment B. These are care providers who perform cervical cancer screenings in various clinical settings. Respondents will be required to speak and understand English and must be 18 years or older. Respondents will receive a participant information sheet (Attachment C) before the usability testing begins (Attachment B).

The following criteria will be used to select a representative set of 15 care providers for each pilot:

- Falls into one of the following categories, in no order of priority:

  1. Primary care (Medical Doctors—MDs, Nurse Practitioners—NPs, Physician Assistants—PAs)
  2. OB/GYN (MDs, NPs, PAs)
  3. Support staff who schedule screenings and handle follow-up scheduling of care.
  4. Pediatrics/adolescent medicine (MDs, NPs, PAs)
  5. Cervical cancer clinic providers (MDs, NPs, PAs)
  6. OB/GYN Specialists (specialists who provide management care for pre-cancer and cancer)

- Respondents must be users of the electronic health record (HER) system in use at each of the pilot sites
- Years of experience (a range of experience will be represented)
- Familiarity with United States Preventive Services Taskforce (USPSTF) and American Society for Colposcopy and Cervical Pathology (ASCCP) clinical guidelines for cervical cancer.

TYPE OF COLLECTION: (Check one)
Instruction: Please sparingly use the Other category

[ ] Customer Comment Card/Complaint Form
[X] Usability Testing (e.g., Website or Software
[ ] Focus Group
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[ ] Other:_____

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.

Name:___Dr. Mona Saraiya_____

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [X] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

If Yes: Please describe the incentive. If amounts are outside of customary incentives, please also provide a justification

BURDEN HOURS

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Private Sector: Clinicians or Support Staff	45	1 hr	45 hrs
Totals	**45**	**1hr**	**45 hrs**

FEDERAL COST:
The anticipated cost to the Federal Government is approximately $12,000. These costs are comprised of an estimate of applicable contractor costs for defining usability tasks and conducting usability testing, as well as the time to collect the information and process the results approved under this generic clearance.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
   [ ] Yes [ ] No

If Yes: Please provide a description of both below (or attach the sampling plan)
If No: Please provide a description of how you plan to identify your potential group of respondents and how you will select them or ask them to self-select/volunteer

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [ ] Web-based or other forms of Social Media
   - [ ] Telephone
   - [ ] In-person
   - [ ] Mail
   - [ ] Other, Explain
2. Will interviewers or facilitators be used? [ ] Yes [ ] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

Instructions for completing Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback"

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g. Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a concise description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a concise description of the targeted group or groups for this collection of information. These groups must have experience with the program.

TYPE OF COLLECTION: Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument. The 'Other' category should be used only in the contexts in which the provided categories cannot reasonably apply.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: As a general matter, incentives are not appropriate for customer service collections; however, incentives may be appropriate for focus groups or in-depth usability studies, especially when participants must travel to a site to participate. In the latter circumstance, the incentive should include travel costs. Customary incentives for focus groups in the Federal government are $40 for a one-hour interview and $75 for a 90-minute focus group. If you answer yes to the question, please describe the incentive and provide a justification for amounts other than those cited above; justifications should be limited to Federal studies of a similar design and subpopulation.

BURDEN HOURS:
Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.
No. of Respondents: Provide an estimate of the Number of respondents.
Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g., fill out a survey or participate in a focus group)
Burden: Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g., for surveys) or facilitators (e.g., for focus groups) used.

Please make sure that all instruments, instructions, and scripts are submitted with the request.