

Request for Approval under the Generic Clearance for the “Conference, Meeting, Workshop, and Poster Session Registration Generic Clearance (OD)” (OMB#: 0925-0740, Expiration Date: 07/31/2022)

TITLE OF INFORMATION COLLECTION: HPV Serology Standardization Meeting (NCI)

PURPOSE: The purpose of this meeting is to bring together key stakeholders to review current status of ongoing HPV serology standardization efforts, identify remaining gaps and action plans to bridge these gaps. HPV serology is increasingly important for public health decisions. A number of ongoing vaccine trials will be using HPV serology data as primary endpoints for new vaccine recommendations. This meeting will discuss currently available HPV serology assays, progress of the HPV Serology standardization work (including standards and critical reagents production, assay development and validation), and guidelines for use of available reference materials/standards in vaccine trial studies using immunoassays. Inter-assay comparisons conducted using proficiency materials will be discussed. An overview of serological assessments planned for ongoing immunobridging trials will be presented and discussed. Finally, analyses to determine clinically relevant antibody levels associated with protection from breakthrough infections will be discussed.

DESCRIPTION OF RESPONDENTS: NIH/NCI Scientists, HPV Specialists, Leidos Contractors, Researchers, PIs, postdocs, academic and institutions

TYPE OF COLLECTION: (Check all that apply)

Abstract

Application

Registration Form

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.

Name: Steven W. Cole

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

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? 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 [] No

Gifts or Payments:

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

Amount: N/A

Explanation for incentive: (include number of visits, etc)

ESTIMATED BURDEN HOURS and COSTS

Category of Respondent	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Burden Hours
Individuals - Registration	80	1	5/60	7
Totals		80		7

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals	7	\$46.95	\$ 328.65
Total			\$ 328.65

*Source of the mean Hourly Wage Rate is provided by the Bureau of Labor Statistics, Occupation title "Medical Scientists" 19-1040, https://www.bls.gov/oes/2019/May/oes_nat.htm#00-0000.

FEDERAL COST: The estimated annual cost to the Federal government is \$1,209.72.

Staff	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Analyst	13/6	\$120,972	1%		\$1,209.72
Contractor Cost					\$0
Travel					\$0
Other Cost					\$0
Total					\$1,209.72

**The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx>

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 the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

We will construct a participants list for respondents that will be electronically generated and collected in an excel sheet. This meeting is advertised through NCI Registration Website: events.cancer.gov/nci/hpvserology , and will be invite only. Will not be advertised anywhere else.

Administration of the Instrument

How will you collect the information? (Check all that apply)

- Web-based or other forms of Social Media
- Telephone
- In-person
- Mail
- Survey Form
- Chart Abstraction
- Other, Explain

Will interviewers, facilitators, or research coordinators be used? Yes No

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