

**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)**

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**TITLE OF INFORMATION COLLECTION:** TP53 Mutated Head and Neck Cancer Clinical Trials Planning Meeting (NCI)

**PURPOSE:** General Objectives of the Clinical Trials Planning Meeting (CTPM) Identify promising synthetic lethal interaction partners and therapeutic combinations for randomized phase II trials in TP53 mutant HPV-negative HNSCC that are suitable to be conducted in a cooperative group setting; Design two-three Phase II/III clinical trials for Stage III/IV HPV-negative HNSCC that employs genomic selection or stratification; Design a randomized phase II trial employing novel combination in recurrent/metastatic HNSCC; Advance infrastructure for a generalizable approach to mutation calling. The clinical trials developed will be conducted within the NCTN with the goal of improving survival in these patients. Additionally, the plan is to develop consensus on synthetic lethal therapies, patient selection, mutation calling algorithms, and correlative science, to rapidly advance recent breakthroughs to the clinic for this common and treatment-resistant form of head and neck cancer.

**DESCRIPTION OF RESPONDENTS:**

Steering committee members and their colleagues; 45 members and 15 NCI staff (5 FTEs) will be invited

**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: Annette Mitchell

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? [ X ] Yes [ ] No

**Gifts or Payments:**

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

Amount: \_\_\_\_\_

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	55	1	5/60	5
<b>Totals</b>		<b>55</b>		<b>5</b>

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals	5	\$46.95	\$ 234.75
<b>Total</b>			<b>\$ 234.75</b>

\*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](https://www.bls.gov/oes/2019/May/oes_nat.htm#00-0000).

**FEDERAL COST:** The estimated annual cost to the Federal government is \$8,598.06.

Staff	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
Program Director	14/6	\$141,534	5%		\$7,076.70
<b>Contractor Cost</b>					\$1,521.36
Travel					
Other Cost					
<b>Total</b>					<b>\$8,598.06</b>

\*\*The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB.aspx>

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

**The selection of your targeted respondents**

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?

There is a list of steering committee members and government members that we use to invite to the registration site.

**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.**