## 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:** Defining and Targeting Molecular Pathways to Direct Personalized Value-added Treatments for Patients with Epithelial Ovarian Cancer Clinical Trials Planning Meeting

**PURPOSE:** To develop clinical trials, based on known and emerging molecular, immunologic, and clinical characteristics, to direct clinical application of new and existing therapeutics with improved focus. The focus of the CTPM will be on the identification and prioritization of novel and existing therapeutics and combinations to target scientifically defined ovarian cancer subgroups for more precision medicine towards the personal ovarian cancer of each woman.   
  
The Institute of Medicine in 2016 recommended that ovarian cancer research focus on therapies to address the unique biology and clinical course of ovarian cancer.  These include the development of directed molecularly-driven and immunologic treatments for ovarian cancer subtypes and identification of markers of therapeutic response and treatment resistance. The Gynecologic Cancer Steering Committee (GCSC) brainstormed opportunities in treatment of ovarian cancers and surveyed members to prioritize recommendations. The top priority was “Application of molecular and clinical characterization for patient treatment selection”, a topic consistent with the GCSC Strategic Priorities, the HHS Strategic Plan Goals, and the IOM recommendations.

**DESCRIPTION OF RESPONDENTS**:

Steering committee members and their colleagues; 55 members and 8 potential NCI staff (FTEs) will be invited

**TYPE OF COLLECTION:** (Check all that apply)

[ ] Abstract [ ] Application

[ X ] 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 |
| **Totals** |  | **55** |  | **5** |

|  |  |  |  |
| --- | --- | --- | --- |
| Category of Respondent | Total Burden  Hours | Hourly Wage Rate\* | Total Burden Cost |
| Individuals | 5 | $46.95 | $ 234.75 |
| **Total** |  |  | **$ 234.75** |

\*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 $8,598.06.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/Step** | **Salary\*\*** | **% of Effort** | **Fringe**  **(if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight** |  |  |  |  |  |
| Program Director | 14/6 | $141,534 | 5% |  | $7076.70 |
| **Contractor Cost** |  |  |  |  | $1521.36 |
| Travel |  |  |  |  |  |
| Other Cost |  |  |  |  |  |
| **Total** |  |  |  |  | **$8,598.06** |

\*\*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? [x] 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)

[X ] 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? [X ] Yes [] No

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