Request for Approval under the "Conference, Meeting, Workshop, and Poster Session Registration Generic Clearance (OD)"

(OMB#: 0925-0740 Exp Date: 07/31/2022)

TITLE OF INFORMATION COLLECTION: Precision Probiotic Therapies—Challenges and Opportunities Workshop (NCCIH)

PURPOSE:

Traditional and next-generation probiotic interventions may potentially offer a wide range of beneficial effects, including alleviation of gastrointestinal symptoms, "strengthening" of the immune system, protection against infectious diseases, prevention of metabolic disorders, mental and behavioral augmentation, and promotion of well-being. However, one major challenge in probiotic intervention is the differential responses among individuals that has led to a lack of consistent results in clinical trials. Interpersonal contributors to the discordant outcomes from probiotic supplementations include variables such as the resident gut microbiome, diet, age, and lifestyle factors. Innovative research approaches call to understand the interrelationships between these contributing factors and to develop advanced technologies for their assessment and implication for therapeutics. There is strong interest in the medical field to develop tailored microbial therapeutics for targeted and effective interventions.

The goals of this workshop are to identify knowledge gaps from current methodologies and challenges in probiotic research and to roadmap future directions of precision probiotic therapies.

DESCRIPTION OF RESPONDENTS:

Basic/mechanistic and clinical researchers, members of the public, advocates, policymakers, journalists, NIH Employees, members of academia, non-profits, and other interested parties.

TYPE OF COLLECTION: (Check one)	
[] 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 <u>not</u> raise issues of concern to other federal agencies.

Name: Hye-Sook Kim, Ph.D., Program Director, Basic and Mechanistic Research in Complementary and Integrative Health Branch, NCCIH

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

An	noi	unt	:				

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)	500	1	10/60	83
Totals		500		83

COST TO RESPONDENT

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals	83	\$48.45	\$4,021.35
Total			\$4,021.35

^{*}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/2020/may/oes nat.htm

FEDERAL COST: The estimated annual cost to the Federal government is \$1,429.50

Staff	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Director	GS14-6	\$ 142,950	1%		\$1429.50
Contractor Cost					
Travel					

Other Cost			
Total			\$1,429.50

^{**}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

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 [X] 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 promote the meeting through the NCCIH public website, NCCIH communication channels, and third-party organizations such as professional associations and research societies who are interested in whole person research. We will contact individual researchers interested in this topic as identified through NIH databases.

Administration of the Instrument

[] Yes [X] No

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 use

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