



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Bench to Bedside: Integrating Sex and Gender to Improve Human Health & Sex as a Biological Variable: A Primer (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health Office of Research on Women's Health (ORWH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Chyren Hunter, Associate Director, Basic and Translational Research, 6707 Democracy Blvd, Room 437, Bethesda, Maryland, 20817 or call non-toll-free number (301) 402-1770 or email your request to ORWHinfo@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Bench to Bedside: Integrating Sex and Gender to Improve Human Health & Sex as a Biological Variable: A Primer, 0925-NEW, expiration date XX/XX/XXXX, Office of Research on Women's Health (ORWH), Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Bench to Bedside: Integrating Sex and Gender to Improve Human Health" is an online course developed by ORWH, the FDA Office of Women's Health, and other non-federal subject matter experts. "Sex as a Biological Variable: A Primer" is an online course developed by ORWH, NIGMS, and other non-federal subject matter experts. Together, these two courses will provide learners a rationale for the study of biological differences between the sexes, the impact of sex and gender difference on illness, guidance on incorporating the NIH policy on sex as a biological variable (SABV) into studies, and an exploration of sex- and gender-related

differences in key disease areas. The Bench to Bedside course will also offer free continuing medical education credits.

In conjunction with these two courses, ORWH will collect information through registration information and surveys (knowledge checks, attitude assessments, and course evaluations). The information collected will be used in the following ways: 1. To assess uptake and learning of concepts in each lesson; 2. To identify demographic trends across learners in order to inform targeted outreach 3. To assess effectiveness of course materials; and 4. To identify areas of focus for future course improvement, modifications, and expansion.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 970.

Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Bench to Bedside: Immunology Module					
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15
Knowledge check	Private sector	25	1	10/60	4
	Federal government	60	1	10/60	10
	Individual	15	1	10/60	3

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Bench to Bedside: Cardiovascular Module					
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15
Knowledge check	Private sector	25	1	10/60	4
	Federal government	60	1	10/60	10
	Individual	15	1	10/60	3
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Bench to Bedside: Pulmonary Module					

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15
Knowledge check	Private sector	25	1	10/60	4
	Federal government	60	1	10/60	10
	Individual	15	1	10/60	3
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Bench to Bedside: Neurology Module					
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15
Knowledge check	Private sector	25	1	10/60	4

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
	Federal government	60	1	10/60	10
	Individual	15	1	10/60	3
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Bench to Bedside: Endocrinology Module					
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15
Knowledge check	Private sector	25	1	10/60	4
	Federal government	60	1	10/60	10
	Individual	15	1	10/60	3
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Bench to Bedside: Mental Health Module					
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15
Knowledge check	Private sector	25	1	10/60	4
	Federal government	60	1	10/60	10
	Individual	15	1	10/60	3
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Module evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Sex as a Biological Variable: A Primer					
Attitude survey pre-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Course completion	Private sector	25	1	1	25
	Federal government	60	1	1	60
	Individual	15	1	1	15

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Attitude survey post-test	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Course evaluation	Private sector	25	1	5/60	2
	Federal government	60	1	5/60	5
	Individual	15	1	5/60	1
Total		100	3400		970

Dated: April 22, 2020.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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