



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-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 Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Chyren Hunter, Associate Director, Basic and Translational Research, Office of Research on Women's Health, 6707 Democracy Blvd, Room 437, Bethesda, Maryland, 20817 or call non-toll-free number (301) 496-7849 or email your request to

ORWHCourses@od.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on April 30, 2020, pages 23978-23980 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of Research on Women’s Health, National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Bench to Bedside: Integrating Sex and Gender to Improve Human Health and Sex as a Biological Variable: A Primer - 0925-New – expiration date, 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, the National Institute of General Medical Sciences, 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 4,060.

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- and post- test	Private sector	105	2	5/60	18
	Federal government	180	2	5/60	30
	Individual	15	2	5/60	3
Module completion	Private sector	105	1	1	105
	Federal government	180	1	1	180
	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
Knowledge check	Private sector	105	1	10/60	18
	Federal government	180	1	10/60	30
	Individual	15	1	10/60	3
Module evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Outcomes evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Bench to Bedside: Cardiovascular Module					
Attitude survey pre- and post- test	Private sector	105	2	5/60	18
	Federal government	180	2	5/60	30
	Individual	15	2	5/60	3
Module completion	Private sector	105	1	1	105
	Federal government	180	1	1	180
	Individual	15	1	1	15
Knowledge check	Private sector	105	1	10/60	18
	Federal government	180	1	10/60	30
	Individual	15	1	10/60	3
Module evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Outcomes evaluation	Private sector	17	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
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Bench to Bedside: Pulmonary Disease Module					
Attitude survey pre- and post- test	Private sector	105	2	5/60	18
	Federal government	180	2	5/60	30
	Individual	15	2	5/60	3
Module completion	Private sector	105	1	1	105
	Federal government	180	1	1	180
	Individual	15	1	1	15
Knowledge check	Private sector	105	1	10/60	18
	Federal government	180	1	10/60	30
	Individual	15	1	10/60	3
Module evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Outcomes evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Bench to Bedside: Neurology Module					
Attitude survey pre- and post- test	Private sector	105	2	5/60	18
	Federal government	180	2	5/60	30
	Individual	15	2	5/60	3

Form Name	Type of Respondents	Number of respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Module completion	Private sector	105	1	1	105
	Federal government	180	1	1	180
	Individual	15	1	1	15
Knowledge check	Private sector	105	1	10/60	18
	Federal government	180	1	10/60	30
	Individual	15	1	10/60	3
Module evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Outcomes evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Bench to Bedside: Endocrinology Module					
Attitude survey pre- and post- test	Private sector	105	2	5/60	18
	Federal government	180	2	5/60	30
	Individual	15	2	5/60	3
Module completion	Private sector	105	1	1	105
	Federal government	180	1	1	180
	Individual	15	1	1	15
Knowledge check	Private sector	105	1	10/60	18
	Federal government	180	1	10/60	30
	Individual	15	1	10/60	3
Module evaluation	Private sector	17	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
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Outcomes evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Bench to Bedside: Mental Health Module					
Attitude survey pre- and post- test	Private sector	105	2	5/60	18
	Federal government	180	2	5/60	30
	Individual	15	2	5/60	3
Module completion	Private sector	105	1	1	105
	Federal government	180	1	1	180
	Individual	15	1	1	15
Knowledge check	Private sector	105	1	10/60	18
	Federal government	180	1	10/60	30
	Individual	15	1	10/60	3
Module evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
Outcomes evaluation	Private sector	17	1	5/60	1
	Federal government	30	1	5/60	3
	Individual	3	1	5/60	0
SABV Primer					

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- and post- test	Private sector	105	8	5/60	70
	Federal government	180	8	5/60	120
	Individual	15	8	5/60	10
Course completion	Private sector	105	4	1	420
	Federal government	180	4	1	720
	Individual	15	4	1	60
Knowledge check	Private sector	105	4	10/60	70
	Federal government	180	4	10/60	120
	Individual	15	4	10/60	10
Total		600	12,570		4,060

Dated: September 6, 2020.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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