

Supporting Statement A for

**Bench to Bedside: Integrating Sex and Gender to Improve Human Health & Sex as
a Biological Variable: A Primer (Office of the Director)**

0925-New – expiration date

Date: November 17, 2020

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing w/o OMB approval

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A. Justification

Abstract

“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 courses, ORWH will collect information through knowledge checks, pre-/post-attitude assessments, and course/module evaluations. The information collected will be used in the following ways: 1. To assess uptake and learning of concepts in each module; 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. The information collection will provide a valuable measure of the degree to which ORWH e-learning courses are furthering the ORWH mission to promote women's health research within and beyond the NIH scientific community.

A.1 Circumstances Making the Collection of Information Necessary

ORWH serves as the focal point for women's health research at the NIH, reporting directly to the NIH Director, and working in a collaborative partnership with the Institutes, Centers, and Offices. The ORWH legislative mandate includes ensuring that research conducted and supported by NIH adequately addresses issues regarding women's health and ensuring that women are appropriately represented in biomedical and biobehavioral research studies supported

by the NIH. In partial fulfillment of that mandate, ORWH is expanding its interprofessional education efforts to include online courses.

One of these courses, “Bench to Bedside: Integrating Sex and Gender to Improve Human Health,” (“Bench to Bedside”) will provide an opportunity for learners to earn free Continuing Education (CE) credits upon successful completion of the course. The CE provider requires ORWH to collect and provide certain information from those learners, including scores on module-specific knowledge checks, an overall evaluation, and an outcomes assessment to be administered 4-6 weeks after completing a module.

A.2 Purpose and Use of the 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 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.

The Bench to Bedside course contains six modules, and the SABV course contains 4 modules. In both courses, modules can be taken in any order, and learners are not required to complete more than one module. ORWH will collect information from learners through a pre-/post- attitude assessment (Attachment 1) which will be taken before learners begin a module. Each module of the Bench to Bedside course (Attachment 2-Module/Course Completion) is self-paced and expected to take one hour to complete. After completion of each Bench to Bedside module, learners will complete a module-specific knowledge check (Attachments 5-10). Learners should be able to complete the SABV course within one hour (Attachment 2-Module/Course

Completion). Each module of the SABV course includes knowledge checks (Attachments 13-16). For both Bench to Bedside and the SABV course, learners will retake the pre-/post-attitude assessment (Attachment 1) after they've completed each module. Learners taking the Bench to Bedside course for CE credits will complete a module evaluation form after each module (Attachment 3). Continuing education learners will also receive a link to complete an outcomes assessment 4-6 weeks after successfully completing the module (Attachment 4). Together, these assessments, knowledge checks, and evaluations will provide a valuable measure of the degree to which ORWH e-learning courses are furthering the ORWH mission to promote women's health research within and beyond the NIH scientific community.

This information collection will help ORWH track progress toward achieving its strategic goals as outlined in the Trans-NIH Strategic Plan for Women's Health Research, especially Strategic Goal 4, to promote training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women. Information collected will be used to assess individual course effectiveness, to analyze user engagement, and to inform course development moving forward. Specifically, ORWH plans include:

1. To assess uptake and learning of concepts in each module;
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.

Analyses of the information collection will include: a characterization of baseline understandings of the scientific basis of sex and gender-related differences among health professionals, the general public, and health educators; measures of SABV awareness and understanding in NIH stakeholders; and an analysis of the demographic trends across learners to inform future course development and dissemination plans.

Without approval to collect information for the online training course, ORWH would be compromised in the ability to determine if the course is reaching its goal of helping learners understand the influence of sex and gender on health and disease and apply that knowledge when conducting research and interpreting evidence for clinical practice. Information collected from the module-specific knowledge checks, course/module evaluations, and the outcomes assessment are required by the CE provider.

OMB clearance is requested for three years. Necessary funds to support this information collection over that time have been identified in ORWH budget.

A.3 Use of Information Technology and Burden Reduction

The online courses will be accessible via the ORWH public website: <https://orwh.od.nih.gov/career-development-education/e-learning>. The courses are entirely online and have no cost to learners. Learners register and complete all assessments electronically, reducing the time burden for registrants. ORWH is not planning to collect information from any existing databases. All information will be collected via new user submissions.

A PIA has been completed to include this collection and the course registration form and is attached to this application (Attachment 11). Information collected will be stored on CIT and OIT databases behind the NIH firewall.

A.4 Efforts to Identify Duplication and Use of Similar Information

The pre- and post- attitude assessment (Attachment 1) and module-specific knowledge checks (Attachments 5-10; 13-16) are unique to these online courses therefore the information collected is not available in any existing database and must be collected via new request. The ORWH analysis plan includes an exploration of the course's impact on individual learners, which will require collecting data during specific time points (before and after course completion). It would not be possible to conduct these analyses without the proposed information collection.

Where possible, we have minimized duplication. Pre- and post- assessments (Attachment 1) have been synchronized and will be used across all ORWH courses. The information collected from the Bench to Bedside knowledge checks (Attachments 5-10) and module evaluation (Attachment 3) is required by the continuing education provider. ORWH is required to administer those surveys to offer CEUs.

A.5 Impact on Small Businesses or Other Small Entities

This information collection does not impact small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

ORWH would not be able to identify changes in learners' attitudes with a less frequent information collection. ORWH must assess learners' knowledge during and after each module in order to evaluate learning.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Collected information is consistent with these guidelines.

A.8.1 Comments in Response to the Federal Register Notice

The 60-Day Federal Register Notice was published on April 30, 2020 (Vol. 85, No. 84, pages 23978-23980). Comments were received (Attachment 17).

A.8.2 Efforts to Consult Outside Agency

The ORWH engaged in formal and informal consultation with representatives of those from whom information is to be obtained (Attachment 18). These consultation processes included meetings with the ORWH internal and external advisory committees: Coordinating Committee for Research on Women's Health (CCRWH) and Advisory Committee on Research on Women's Health (ACRWH). ORWH consulted with partners at FDA and discussions with external subject matter experts. Areas of discussion included identification of subject matter experts, course

authors, and expert reviewers; topics for *Bench to Bedside: Integrating Sex and Gender to Improve Human Health*; and areas for future course development.

A.9 Explanation of Any Payment of Gift to Respondents

Neither payments nor gifts will be distributed to individuals to encourage the completion and submission of registration forms, course surveys, or attitude assessments.

A.10 Assurance of Confidentiality Provided to Respondents

No assurances of confidentiality are provided to respondents. Respondents are provided with the following privacy statement when they register for the course:

“Collection of this information is authorized under 5 CFR 930.301. The primary use of the personally identifiable information (PII) you provide to enter the course portal is to allow the tracking system to record courses and trainings you take. If you do not provide this information, NIH will not have the supporting documentation to record your progress and completion. Privacy Act System of Records Notices that cover this information collection include:

OPM/GOVT-1; General Personnel Records

(<https://dpcl.d.defense.gov/Privacy/SORNsIndex/DOD-wide-SORN-Article-View/Article/570733/opmgovt-1/>),

OPM/GOVT-6, Personnel Research and Test Validation Records

(<https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-govt-6-personnel-research-and-test-validation-records.pdf>),

and #09-25-0108 Personnel: Guest Researchers, Special Volunteers, and Scientists

Emeriti (<https://www.federalregister.gov/documents/2002/09/26/02-23965/privacy-act-of-1974-annual-publication-of-systems-of-records#h-328>).”

Personally Identifiable Information (PII) is collected via the course registration form. The registration form asks for name gender, race, ethnicity, contact information, education history and employment status. The information collected via the registration form is subject to the Privacy Act. A PIA was completed for the system and approved by HHS on February 25, 2020 (Attachment 11). Records are maintained in accordance with the following NARA record retention schedules: General Records Schedule (GRS) 2.6.010, Non-mission employee training

records; DAA-GRS-2016-0014-000. Destroy when 3 years old, or 3 years after superseded or obsolete, whichever is appropriate, but longer retention is authorized if required for business use.

Information will be stored in a secure database behind the NIH firewall and will be collected and maintained in accordance to the following records system numbers: 09-25-0108, Personnel: Guest Researchers, Special Volunteers, and Scientists Emeriti, HHS/NIH/OHRM; OPM/GOVT-6, Personnel Research and Test Validation Records; OPM/GOVT-1, General Personnel Records.

The following system controls are in place:

Administrative Controls: System users are approved for access and permissions based on their functional role. Anyone with access to the system has been vetted and approved by management based on their job duties and need to have access.

Technical Controls: Access to the system is controlled by NIH log-in which authenticates the user prior to granting access. Access level and permissions are controlled by the system and based on user, role, organizational unit, and status of the report. All servers have been configured to remove all unused applications and system files and all local account access except when necessary to manage the system and maintain integrity of data.

Physical Controls: For information that is pulled from CIT, servers reside in the Center for Information Technology (CIT) Computer Room where policies and procedures are in place to restrict access to the machines. This includes guards at the front door and entrance to the machine room. Once information is transferred over to ORWH and uploaded to servers residing in the Office of Information Technology (OIT) Data Center, policies and procedures are in place to restrict access to the machines.”

A.11 Justification for Sensitive Questions

The registration form for this course contains potentially sensitive questions including learners' race, ethnicity, education, sex, and gender. The pre-/post-attitude assessment (Attachment 1) asks learners to disclose their attitudes about the role of sex and gender in research and clinical care. This potentially sensitive information is essential to ORWH's planned analyses, including describing trends in course user demographics, assessing course effectiveness, and identifying barriers and facilitators to the implementation of the SABV policy.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

Course users will complete one pre-assessment and a post-assessment after each module that is completed (Attachment 1). Each module of Bench to Bedside and the complete SABV course can be completed within one hour (Attachment 2). After completing a module of the Bench to Bedside course, learners will complete a module-specific knowledge check (Attachments 5-10). Each module of the SABV course is also followed by a knowledge check (Attachments 13-16). Learners taking the Bench to Bedside course for CE credits will also complete a Module evaluation (Attachment 3) and Outcomes Assessment (Attachment 4).

Table 12-1 below reflects the total burden hours should each learner complete every module. Based on preliminary registration information for Bench to Bedside, ORWH anticipates approximately 300 learners for the Bench to Bedside course, and 300 learners for the SABV course, for a total of 600 learners between both courses. Registration information to date indicates approximately 60% of learners will be federal employees, 35% will be from the private sector, and 5% will take the course as individuals. Based on previous ORWH courses that have been offered for CE credits, ORWH anticipates that 50 of the 300 Bench to Bedside learners will take the course for CE credit (30 federal employees, 17 private sector employees, and 3 individuals).

The six modules of Bench to Bedside and four modules of SABV can be taken independently and in any order. Learners are not required to complete multiple modules. ORWH expects that some learners with an interest in the subject matter may choose to complete multiple

modules, but doing so is not required. Two of the assessments associated with the Bench to Bedside course (Outcomes Assessment and Course Evaluation) will only be administered to learners taking the course for CE credits. The burden table reflects the maximum possible burden should a learner complete all modules of both courses. However, ORWH expects that most learners will not complete all available modules

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
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

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: 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
	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

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: 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
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

Form Name	Type of Respondents	Number of respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
	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
	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

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
SABV Primer					
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

A.12-2 ANNUAL COST TO RESPONDENT

Annualized cost to respondents was determined based on Table 12-1, which reflects annualized burden hours of 4,056. Based on registration for previous ORWH online courses and registration

information to date for Bench to Bedside, ORWH assumes 65% of course users will be health professionals, 20% will be members of the general public including medical students, and 15% will be health educators.

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
General Public	811	\$24.98	\$20,258
Health Professionals	2,634	\$39.42	\$103,832
Health Educators	608	\$28.68	\$17,437
TOTAL			\$141,527

* Hourly wage rates are based on Bureau of Labor and Statistics tables (https://www.bls.gov/oes/current/oes_nat.htm). General public occupation title “All Occupations” code 00-0000. Health professionals occupation title “Healthcare Practitioners and Technical Occupations” code 29-0000. Health educators occupation title “Health Educators” code 21-1091.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital costs, operating costs, or maintenance costs to report.

A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government, \$193,172 which includes data analysis and federal oversight. The ORWH analysis plan includes: quarterly internal progress reports, interim and final data tabulation and descriptive analysis, and interim and final publications based on the information collections. The scope of the planned analyses represents a primary responsibility of the ORWH support staff for the courses [contract scientist]. The analysis does not require additional equipment, overhead, or printing costs that would not otherwise be incurred. A summary of contract costs, federal employees, and office staff contractors are presented in the table below.

Table 14: Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Supervisory Health Scientist Administrator	GS15/6	\$166,487/year	10%		\$16,649
Health Scientist Administrator	GS14/2	\$125,360/year	2%		\$2,507
Contractor Cost					
Contract Scientist		\$122,016/year	100%		\$122,016
Software system CIT maintenance administrator – CIT (maintenance MOU)					\$52,000
Total cost					\$193,172

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB.aspx>

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Pre-/post-test data will be analyzed to assess effectiveness of course materials.

ORWH will collect data from respondents for 3 years (36 months) after OMB approval.

Data will be cleaned, coded, and tabulated by ORWH staff with contract scientist support.

ORWH plans for tabulation and publication include, but are not limited to, program evaluation, quarterly internal progress reports and assessments every 3 months after OMB approval; interim data tabulation and descriptive analysis using descriptive statistics (mean, median, range) 12 months after OMB approval; and final tabulation, analysis, and publication 36 months after OMB approval. ORWH staff will describe learners' baseline attitudes by calculating

the mean, median, and range of pre-test responses. ORWH staff will calculate the difference between learners' pre- and post-test responses and compile this data using descriptive statistics (mean, median, range).

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Data collection via survey and assessments	For 36 months after OMB approval
Completion of internal progress assessment report	Every 3 months after OMB approval
Data tabulation	12 & 36 months after OMB approval
Data analysis using descriptive statistics (mean, median, range)	12 & 36 months after OMB approval
Interim publication or presentation	18 months after OMB approval
Final publication or presentation	48 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

ORWH will display the OMB Clearance Number, Expiration Date, and Burden Disclosure Statements on our registration forms, surveys, and assessments.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None.