

Abstract: Currently HRSA is cleared to use the National Institutes of Health's (NIH) Biographical Sketch and Public Health Service (PHS) Inclusion Enrollment forms (0925-0001) for HRSA's SF424 Research & Related (R&R) application package research grants. However, both of these documents contain NIH-specific references. To use the forms, HRSA plans to remove the NIH-specific references and obtain its own OMB control number for the collection of this information.

The current Statement of Appointment (form PHS-2271) is also tailored to NIH programs. HRSA plans to remove references to NIH and where appropriate replace them with references to HRSA for use in the SF424 R&R application package.

Need and Proposed Use of the Information: Currently, there are two Bureaus within HRSA, the Maternal and Child Health Bureau (MCHB) and the Bureau of Health Workforce (BHW), that use the Biographical Sketch. In addition to the Biographical Sketch, MCHB also uses the PHS Inclusion Enrollment form, and BHW uses the Statement of Appointment form as required elements of the SF424 Research & Related application package. These Bureaus plan to modify these forms in slightly different ways to meet the needs of their

own research and training grant programs.

In MCHB's research grant programs, the modified Biographical Sketch form will be used by applicants to summarize the qualifications of key personnel on their proposed research team; the grant reviewers will use this information to assess the capabilities of the research team to carry out the research project. MCHB's modified PHS Inclusion Enrollment form will be used by applicants to summarize their expected population of research study participants at the time of submission of their proposal; it will also be used for Enrollment Reporting during the annual Noncompeting Continuation Award. Monitoring Inclusion Enrollment is one important component of ensuring statistically meaningful demographics (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. MCHB does not use the Statement of Appointment form, as it does not pertain to the MCHB research program.

Similarly, in BHW the modified Biographical Sketch form will be used by applicants to summarize the qualifications of key personnel proposed as project staff; the grant reviewers will use this information to assess the capabilities of the applicant organization to carry out the proposed

project. The modified Statement of Appointment form is used to document the appointment of individuals supported by the award to applicable institutional research and training programs. BHW does not use the PHS Inclusion Enrollment form, as it does not pertain to the BHW training and research programs.

Likely Respondents: Respondents are applicants to HRSA's research programs in MCHB and research and training programs in BHW.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Biographical Sketch for MCHB research grant applicants ..	200	5	1000	2	2000
PHS Inclusion Enrollment form for MCHB research grant applications	200	1	200	.5	100
Biographical Sketch for BHW training and research grant applicants	1000	5	5000	2	10,000
Statement of Appointment form for BHW training grantees	800	7	5600	.5	2,800
Total	2200	11,800	14,900

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updating the HRSA-Supported Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Effective December 20, 2016, the Health Resources and Services Administration (HRSA) updated the HRSA-supported Women's Preventive

Services Guidelines for purposes of health insurance coverage for preventive services that address health needs specific to women based on clinical recommendations from the Women's Preventive Services Initiative. This notice serves as an announcement of the decision to update the guidelines as listed below. Please see <https://www.hrsa.gov/womensguidelines2016> for additional information.

FOR FURTHER INFORMATION CONTACT:

HRSA, Maternal and Child Health Bureau at email: wellwomancare@hrsa.gov.

SUPPLEMENTARY INFORMATION:

Breast Cancer Screening for Average-Risk Women

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Breastfeeding Services and Supplies

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Screening for Cervical Cancer

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Contraception

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods,

effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) Sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), (8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Screening for Gestational Diabetes Mellitus

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Screening for Human Immunodeficiency Virus Infection

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents

and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Screening for Interpersonal and Domestic Violence

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Counseling for Sexually Transmitted Infections

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Well-Woman Preventive Visits

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services including preconception, and many services necessary for prenatal and interconception care are obtained. The primary purpose of these visits

should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, HRSA awarded a 5-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM *Clinical Practice Guidelines We Can Trust*. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

Under section 2713 of the Public Health Service Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market, policy year) that begins on or after December 20, 2017.

The guidelines concerning contraceptive methods and counseling do not apply to women who are participants or beneficiaries in group health plans sponsored by religious employers. Effective August 1, 2013, a religious employer is defined as an employer that is organized and operates as a non-profit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code. HRSA notes that, as of August 1, 2013, group health plans established or maintained by religious employers (and group health

insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services under section 2713 of the Public Health Service Act, as incorporated into the Employee Retirement Income Security Act and the Internal Revenue Code. HRSA also notes that, as of January 1, 2014, accommodations are available to group health plans established or maintained by certain eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations, with respect to the contraceptive coverage requirement. See Coverage of Certain Preventive Services Under the Affordable Care Act (78 FR 39870, July 2, 2013).

James Macrae,

Acting Administrator.

[FR Doc. 2016–31129 Filed 12–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Announcement of Updated Requirements and Registration for "The Simple Extensible Sampling Tool Challenge"

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: On September 29, 2016, OIG announced "The Simple Extensible Sampling Tool Challenge". This notice serves as an update to the original notice which stated that upon receipt of an updated submission the previous submission would be excluded in its entirety from the competition. This updated notice removes this restriction for entries from teams that have been previously identified as finalists. Any finalist may update their entry without losing their finalist designation. Updates from the finalists will be accepted until 5:00 p.m. EST on the fourteenth day after the fifth finalist has been identified or May 15, 2017, 5:00 p.m. EST, whichever comes first. The newest entry from each team will be used for all judging purposes unless otherwise requested by the team. Other than the above change, all rules and requirements outlined in the September 29, 2016, **Federal Register** notice remain in effect.

Dated: December 21, 2016.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2016–31182 Filed 12–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (<http://videocast.nih.gov>).

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Council of Councils.

Open: January 27, 2017.

Time: 8:15 a.m. to 11:30 a.m.

Agenda: Call to Order and Introductions; Announcements and Updates; Tracking Utility of Common Fund Data Sets; Small Molecules from the Human Microbiota; Invited Speaker; NIH Update; Discussion; 2017 Biennial Advisory Council Report—Compliance with the NIH Policy on the Inclusion of Women and Minorities in Clinical Research.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: January 27, 2017.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Open: January 27, 2017.