DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Task Force on Research Specific to Pregnant Women and Lactating Women.

The meeting will be open to the public, 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.

Name of Committee: Task Force on Research Specific to Pregnant Women and Lactating Women.

Date: February 3, 2020.

Time: 8:30 a.m. to 4:45 p.m.

Agenda: The Task Force is charged with providing advice and guidance to the Secretary of HHS, regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

8:00 a.m. Registration

8:30 a.m.–4:45 p.m. Open Session

Place: NICHD Offices, Multipurpose Room 1425/1427 (1st Floor), 6710B Rockledge Drive, Bethesda, MD 20892.

Contact Person: Lisa Kaeser, Executive Secretary, Office of Legislation and Public Policy, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, Bethesda, MD 20892, (301) 496–0536, *kaeserl@mail.nih.gov*.

Public comments are welcome either by filing written comments in advance and/or providing oral comments at the meeting. Written comments to be included at the meeting should be sent to Lisa Kaeser by 5:00 p.m. on Friday, January 24, 2020. Brief oral comments from the public may occur during the discussion periods following each of the four working group presentations.

In the interest of security, NIH has instituted stringent procedures for entrance onto NIH federal property. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Details and additional information about this meeting, prior meetings, and the Task Force's 2018 Report and Recommendations can be found at the NICHD website for the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC): *https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx* Presentations made during the meeting and any written comments will be formatted to be posted on the PRGLAC website for the record.

Registration Link: http://tiny.cc/PRGLAC0220.

Please note: This meeting will be available through NIH Videocast. If you are planning on watching the videocast remotely, please select this option on the registration form.

Dated: December 23, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–28156 Filed 12–27–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request PHS Applications and Pre-Award Reporting Requirements (OD/OPERA)

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/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

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: Ms. Mikia P. Currie, Project Clearance Branch, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 803–C, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number (301) 435–0941, or email your request, including your address to: *projectclearancebranch@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on April 12, 2019, Volume 84, No.212 pages 14956–14957 and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director, NIH, 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 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: Public Health Service (PHS) Applications and Pre-award Reporting Requirements. Revision, OMB 0925–0001, Expiration Date 3/31/2020. Form numbers: PHS 398, PHS416–1, 416–5, and PHS 6031. This collection represents a consolidation of PHS applications and pre-award reporting requirements into a revised data collection under the PRA. This collection includes the proposed use of a new PHS Human Subjects and Clinical Trial Information form.

Need and Use of Information Collection: NIH has received approval to require applicants and recipients to address Human Fetal Tissue requirements within the SF–424 R&R and the Research Performance Progress Report due to Congressional ((Sections 498A and 498B of the PHS Act (42 U.S.C. 289g–1 and 289g–2)) and Department of Health and Human Services (45 CFR 46.204 and 46.206) mandates regarding human fetal tissue research. Applicants and recipients will be required to comply with Federal and state laws concerning the acquisition of human fetal tissue (including cell lines) obtained from elective abortions as well as include a description of the proposed characteristics of the human fetal cells/tissue outlining the procurement budget details, and how the applicants/recipients will document the processes for how they will use the human fetal tissues and cells. Additionally, this revision will clarify information regarding an institutional commitment to ensuring that proper policies, procedures, and oversight are in place to

prevent discriminatory harassment and other discriminatory practices.

This collection also continues to include PHS applications and pre-award reporting requirements: PHS 398 (paper) Public Health Service Grant Application forms and instructions; PHS 398 (electronic) PHS Grant Application component forms and agency specific instructions used in combination with the SF424 (R&R); PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic]; PHS 416–1 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application (paper); Instructions for a Change of Sponsoring Institution for NRSA Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships; PHS 416–5 Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice; and PHS 6031 Payback Agreement. The PHS 398 (paper and electronic), PHS 416–1, 416–5, and PHS 6031 are currently approved under 0925–0001. All forms expire 10/31/2018. Post-award reporting requirements are simultaneously consolidated under 0925–0002, and include the Research Performance Progress Report (RPPR). The PHS 398 and SF424 applications are used by applicants to request federal assistance funds for traditional investigator-initiated research projects and to request access to databases and other PHS resources. The PHS 416–1 is used only for a change of sponsoring institution application. PHS Fellowship Supplemental Form and agency specific instructions is used in combination with the SF424 (R&R) forms/instructions for Fellowships and is used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The PHS 416–5 is used by individuals to indicate the start of their NRSA awards. The PHS 6031 Payback Agreement is used by individuals at the time of activation to certify agreement to fulfill the payback provisions. The Venture Capital Operating Companies (VCOC) Certification and the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) Funding Agreement Certifications are used by small business applicants. Oversight systems and tools are critical for the NIH to ensure participant safety, data integrity, and accountability of the use of public funds. The NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information about proposed clinical trials in the PHS applications and pre-award reporting requirements will facilitate the NIH's oversight of clinical trials as well as assist in understanding where needs in the NIH research portfolio may exist. In addition, some of the data collected here will ultimately be accessible to investigators to pre-populate certain sections of forms when registering their trials with *ClinicalTrials.gov*.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,150,389.

ESTIMATED ANNUALIZED BURDEN HOURS

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
PHS 398—Paper	4,247	1	35	148,645
PHS 398/424—Electronic:				
PHS Assignment Request Form	37,120	1	30/60	18,560
PHS 398 Cover Page Supplement	74,239	1	1	74,239
PHS 398 Modular Budget	56,693	1	1	56,693
PHS 398 Training Budget	1,122	1	2	2,244
PHS 398 Training Subaward Budget Attachment(s) Form	561	1	90/60	842
PHS 398 Research Plan	70,866	1	10	708,660
PHS 398 Research Training Program Plan	1,122	1	10	11,220
Data Tables	1,515	1	4	6,060
PHS 398 Career Development Award Supplemental Form	2,251	1	10	22,510
PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report)	54,838	1	14	767,732
Biosketch (424 Electronic)	80,946	1	2	161,892
PHS Fellowship—Electronic:				
PHS Fellowship Supplemental Form (includes F reference letters)	6,707	1	12.5	83,838
PHS Assignment Request Form	3,354	1	30/60	1,677
PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report)	5,030	1	14	70,420
Biosketch (Fellowship)	6,707	1	2	13,414
416–1	29	1	10	290
PHS 416–5	6,707	1	5/60	559
PHS 6031	6,217	1	5/60	518
VCOC Certification	6	1	5/60	1
SBIR/STTR Funding Agreement Certification	1,500	1	15/60	375
Total	.....	421,777	.....	2,150,389

Dated: December 19, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–28129 Filed 12–27–19; 8:45 am]

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