

## 2021 Current Fiscal Year Report: Task Force on Research Specific to Pregnant Women and Lactating Women

Report Run Date: 05/01/2024 09:55:04 PM

<b>1. Department or Agency</b>		<b>2. Fiscal Year</b>	
Department of Health and Human Services		2021	
<b>3. Committee or Subcommittee</b>		<b>3b. GSA Committee No.</b>	
Task Force on Research Specific to Pregnant Women and Lactating Women		2603	
<b>4. Is this New During Fiscal Year?</b>	<b>5. Current Charter</b>	<b>6. Expected Renewal Date</b>	<b>7. Expected Term Date</b>
No	03/13/2019	03/13/2021	03/13/2021
<b>8a. Was Terminated During FiscalYear?</b>	<b>8b. Specific Termination Authority</b>		<b>8c. Actual Term Date</b>
Yes	Section 2041 of the 21st Century Cures Act, P.L. 114-255		03/13/2021
<b>9. Agency Recommendation for Next FiscalYear</b>	<b>10a. Legislation Req to Terminate?</b>		<b>10b. Legislation Pending?</b>
Terminate	Yes		
<b>11. Establishment Authority</b> Statutory (Congress Created)			
<b>12. Specific Establishment Authority</b>	<b>13. Effective Date</b>	<b>14. Committee Type</b>	<b>14c. Presidential?</b>
Section 2041 of the 21st Century Cures Act, P.L. 114-255	12/13/2016	Continuing	No
<b>15. Description of Committee</b> Scientific Technical Program Advisory Board			
<b>16a. Total Number of Reports</b>	No Reports for this FiscalYear		
<b>17a. Open</b>	<b>17b. Closed</b>	<b>17c. Partially Closed</b>	<b>Other Activities</b>
0	0	0	0
<b>17d. Total</b> 0			

## Meetings and Dates

No Meetings

	Current FY	Next FY
<b>18a(1). Personnel Pmts to Non-Federal Members</b>	\$0.00	\$0.00
<b>18a(2). Personnel Pmts to Federal Members</b>	\$0.00	\$0.00
<b>18a(3). Personnel Pmts to Federal Staff</b>	\$0.00	\$0.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$0.00	\$0.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$0.00	\$0.00
<b>18d. Total</b>	\$0.00	\$0.00
<b>19. Federal Staff Support Years (FTE)</b>	0.00	0.00

## 20a. How does the Committee accomplish its purpose?

The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) was established under section 2041 of the 21st Century Cures Act, P.L.114-255 to provide advice and guidance to the Secretary of Department of Health and Human Services 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. The committee prepared and submitted to the HHS Secretary and Congress a report to correspond with the legislative requirements under the 21st Century Cures Act.

**20b. How does the Committee balance its membership?**

The Task Force was composed of both Federal and non-Federal members. For FY21, the committee included 16 federal members and 8 non-federal members.

**20c. How frequent and relevant are the Committee Meetings?**

The Task Force did not meet in FY 2021 and the committee terminated in March 2021. The last full Task Force meeting was held via Webinar in June 2020.

**20d. Why can't the advice or information this committee provides be obtained elsewhere?**

The 21st Century Cures Act established PRGLAC to advise the Secretary of Health and Human Services regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women. The committee is tasked with identifying these gaps and will report its findings back to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The quality, scope, and balance of advice from this committee cannot be obtained from NIH staff or from other established source because the membership of the committee is constituted to meet the specific requirements

mandated in legislation.

**20e. Why is it necessary to close and/or partially closed committee meetings?**

Not Applicable

**21. Remarks**

PRGLAC did not meet in FY 2021. Lisa Kaeser, J.D. retired on 12/31/2020 and was replaced by Laura Berkson, J.D. as the DFO and Decision Maker of the committee. The sunset date of the committee was March 13, 2021. All Special Government Employees (SGE), NIH-Federal and non-NIH Federal members retired on March 13, 2021. SGE members do not receive honoraria for service on this committee.

**Designated Federal Officer**

Laura Berkson Director, Office of Legislation, Public Policy, and Ethics

Committee Members	Start	End	Occupation	Member Designation
AVENEVOLI, SHELLI	05/04/2017	03/13/2021	DEPUTY DIRECTOR, NIMH	Regular Government Employee (RGE) Member
BIANCHI, DIANA	05/04/2017	03/13/2021	DIRECTOR, NICHD	Regular Government Employee (RGE) Member
BOK, KARIN	07/03/2017	03/13/2021	SENIOR ADVISOR, VACCINE DEVELOPMENT, NIAID	Regular Government Employee (RGE) Member
BREMER, ANDREW	05/04/2017	03/13/2021	BRANCH CHIEF, NICHD	Regular Government Employee (RGE) Member
BUCCI-RECHTWEG, CHRISTINA	02/18/2018	03/13/2021	HEAD, NOVARTIS PHARMACEUTICALS CORPORATION	Special Government Employee (SGE) Member

FABIYI, CAMILLE	05/04/2017	03/13/2021	SENIOR ADVISOR FOR WOMEN'S HEALTH AND GENDER RESEARCH, AHRQ DEPUTY ASSISTANT SECRETARY ON WOMEN'S HEALTH AND DIRECTOR, OFFICE OF WOMEN'S HEALTH MATERNAL AND CHILD HEALTH EDUCATION PLANNER, MARCH OF DIMES CLINICAL EDUCATION COORDINATOR, SHRINERS HOSPITALS FOR CHILDREN	Regular Government Employee (RGE) Member  Regular Government Employee (RGE) Member  Special Government Employee (SGE) Member  Special Government Employee (SGE) Member
FINK, DOROTHY	10/11/2019	03/13/2021		
GIVENS, SUSAN	02/18/2018	03/13/2021		
GORMAN, MELISSA	02/18/2018	03/13/2021		
GORODETSKY, ELENA	05/04/2017	03/13/2021	HEALTH SCIENTIST ADMINISTRATOR, ORWH	Regular Government Employee (RGE) Member
JONES, BRIDGETTE	02/18/2018	03/13/2021	ASSOCIATE PROFESSOR OF PEDIATRICS, CHILDREN'S MERCY HOSPITAL AND UMKC SCHOOL OF MEDICINE DIRECTOR OF PATIENT ADVOCACY AND GLOBAL HEALTHCARE SYSTEM STRATEGY, UCB, INC.	Special Government Employee (SGE) Member  Special Government Employee (SGE) Member
LENGYEL, KRISTI	02/18/2018	03/13/2021		
LIPSON, LINDA	07/03/2017	03/13/2021	SCIENTIFIC PROGRAM MANAGER (RETIRED), VA	Regular Government Employee (RGE) Member
LOPATA, AARON	12/01/2019	03/13/2021	CHIEF MEDICAL OFFICER, HRSA	Regular Government Employee (RGE) Member

NAGEL, JOAN	05/04/2017	03/13/2021	PROGRAM DIRECTOR, NCATS	Regular Government Employee (RGE) Member
OSGANIAN, VOULA	10/21/2019	03/13/2021	PROGRAM DIRECTOR, NIDDK	Regular Government Employee (RGE) Member
PEMBERTON, VICTORIA	05/04/2017	03/13/2021	CLINICAL TRIALS SPECIALIST, NHLBI	Regular Government Employee (RGE) Member
PIPER, JEANNA	05/04/2017	03/13/2021	SENIOR MEDICAL OFFICER, NIAID	Regular Government Employee (RGE) Member
REEFHUIS, JENNITA	10/16/2019	03/13/2021	BRANCH CHIEF, BIRTH DEFECTS BRANCH	Regular Government Employee (RGE) Member
SHEFFIELD, JEANNE	02/18/2018	03/13/2021	DIRECTOR, DEPARTMENT OF GYNECOLOGY AND OBSTETRICS, JOHNS HOPKINS UNIVERSITY	Special Government Employee (SGE) Member
SPATZ, DIANE	02/18/2018	03/13/2021	PROFESSOR OF PERINATAL NURSING AND THE HELEN M. SHEARER TERM CHAIR IN NUTRITION, UNIVERSITY OF PENNSYLVANIA	Special Government Employee (SGE) Member
TERNIK, ROBERT	02/18/2018	03/13/2021	SENIOR RESEARCH ADVISOR, ELI LILLY COMPANY	Special Government Employee (SGE) Member
VASISHT, KAVEETA	11/20/2019	03/13/2021	OFFICE DIRECTOR, FDA	Regular Government Employee (RGE) Member
WEBER, WENDY	10/17/2019	03/13/2021	BRANCH CHIEF, NCCIH	Regular Government Employee (RGE) Member

**Number of Committee Members Listed: 24**

## Narrative Description

NICHD conducts and supports research in the United States and throughout the world on fetal, infant and child development; maternal, child and family health; reproductive biology and population issues; and medical rehabilitation. Currently, insufficient information exists to guide the care and treatment of pregnant women in many areas. For instance, the safety, efficacy, and dosing of medications approved for the general population may not apply to pregnant or nursing women. PRGLAC reviewed current research on pregnancy and lactation, identifying ethical issues surrounding the inclusion of pregnant women and nursing mothers in clinical research, and chronicling the federal activities that focus on therapies for pregnant women and nursing mothers. This effort, resulted in a report to the HHS Secretary and to Congress, which included a focus on specific drugs, formulations, and other pharmacological factors that may affect health outcomes for pregnant women and nursing mothers and their children. PRGLAC also created an implementation plan for the recommendations listed in the report.

## What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input type="checkbox"/>
Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input checked="" type="checkbox"/>
Increased customer satisfaction	<input type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

## Outcome Comments

Outcome Major Policy Changes: PRGLAC released an implementation plan in August 2020 to provide guidance on implementing the recommendations made in the initial

report. Outcome Improved Service Delivery: Improved information relevant to therapeutics used by pregnant women and lactating women depends on implementation of the report.

**What are the cost savings associated with this committee?**

Checked if Applies

- |                            |                                     |
|----------------------------|-------------------------------------|
| None                       | <input type="checkbox"/>            |
| Unable to Determine        | <input checked="" type="checkbox"/> |
| Under \$100,000            | <input type="checkbox"/>            |
| \$100,000 - \$500,000      | <input type="checkbox"/>            |
| \$500,001 - \$1,000,000    | <input type="checkbox"/>            |
| \$1,000,001 - \$5,000,000  | <input type="checkbox"/>            |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/>            |
| Over \$10,000,000          | <input type="checkbox"/>            |
| Cost Savings Other         | <input type="checkbox"/>            |

**Cost Savings Comments**

Not Applicable

**What is the approximate Number of recommendations produced by this committee for the life of the committee?**

125

**Number of Recommendations Comments**

The implementation plan contains 110 recommendations/implementation steps for the original 15 recommendations contained in the Task Force report sent to HHS on September 13, 2018.

**What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?**

7%

**% of Recommendations Fully Implemented Comments**

The HHS Secretary extended PRGLAC's charter for two years in March 2019, requesting additional guidance on implementation of the recommendations. This action fulfilled Recommendation 14, which advised the extension of the Task Force.

**What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?**

0%



### **% of Recommendations Partially Implemented Comments**

The implementation plan will provide guidance to the HHS Secretary about what steps are needed to carry out the remaining recommendations.

### **Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☒ No ☐ Not Applicable ☐

### **Agency Feedback Comments**

NICHD led the Task Force for the NIH. Multiple federal agencies and other input incorporated into the final recommendations/report.

### **What other actions has the agency taken as a result of the committee's advice or recommendation?**

Checked if Applies

Reorganized Priorities	<input type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input type="checkbox"/>

### **Action Comments**

All of the above actions are possible; depends on the responses from the Secretary, from Congress, and internally to the guidance provided by PRGLAC implementation plan.

### **Is the Committee engaged in the review of applications for grants?**

No

### **Grant Review Comments**

Not Applicable

### **How is access provided to the information for the Committee's documentation?**

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>

Online GSA FACA Web Site



Publications



Other



**Access Comments**

IC CMO: Lisa Neal, NICHD Committee Management Officer; contact information:  
lisa.neal@nih.gov.