2025 Current Fiscal Year Report: Secretary's Advisory Committee on Human Research Protections

Report Run Date: 07/12/2025 07:48:44 AM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Secretary's Advisory Committee on Human Research Protections	9492

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/01/2022	10/01/2024	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No	Executive Order 14217	

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 USC 217a, Section 222 of the PHS Act	10/17/1962	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
0	0	0	0	0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$8,000.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$100,000.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$33,000.00	$0.00
18e. Total Costs	$141,000.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Committee is composed of members with varied expertise who provide advice on the development and management of guidance and communications between HHS and its operating and staff divisions and other pertinent elements of the federal government; the biomedical academic,

and research communities; non-governmental entities; and other organizations as necessary to further the interests of the human subjects protection enterprise. In addition, the Committee provides counsel on opportunities to improve public awareness of the function and importance of human subjects protection activities.

20b. How does the Committee balance its membership?

The Secretary's Advisory Committee on Human Research Protections (SACHRP) is authorized to have 11 voting members, including the Chair. The voting members are selected from multi-disciplinary backgrounds that are pertinent to human subjects protection and/or clinical research, including law, medicine, genetics, consumer advocacy, IRB administration, research, bioethics and the social sciences. Representatives from the following seven HHS organizational components serve on the Committee as non-voting ex-officio members: Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Office of Civil Rights (OCR).

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

The Committee meets three times per year for the purpose of providing advice on the development and management of human subjects research protections, and to further the interests of the human subjects protection enterprise. The Committee hears expert presentations from government agencies, professional organizations,

advocacy groups, pharmaceutical companies, and academic research bodies, and responds to HHS' requests for discussion and comment on specific issues. Meetings are tailored to focus on time-sensitive topics, enabling SACHRP to provide recommendations quickly to the Secretary on sensitive issues.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
The Committee uniquely addresses HHS human research subjects protection regulations and guidance, and focusing on specific regulatory issues such as provisions of the 2018 Revised Common Rule. The Committee provides advice on the development and management of guidance and harmonization between HHS and its operating and staff divisions, and other pertinent elements of the federal government. Meetings frequently include the biomedical, academic, and research communities, non-governmental entities, and other organizations as necessary to further the interest of the human subjects protection enterprise. No other Federal Advisory Committee provides this advice.

20e. Why is it necessary to close and/or partially closed committee meetings?
N/A; all committee meetings are open to the public.

21. Remarks
Per Executive Order (E.O.) 14217, "COMMENCING THE REDUCTION OF THE FEDERAL BUREAUCRACY" this FACA Committee has been terminated. SACHRP met three times in FY 2024. Please note: costs for this fiscal year reflect actual costs to the extent possible. Funds must be budgeted for payment of

members, though members may ultimately not bill for their time. The "Other" column as projected for the future fiscal year necessarily includes costs of minutes and AV. Other than ensuring that the SACHRP report posted in the FACA database is accurate and complete, there is no annual reporting requirement to which the Committee must comply.

Designated Federal Officer

Julia G. Gorey Executive Director, SACHRP, Office for Human Research Protections

Committee Members	Start	End	Occupation	Member Designation
Anthony, Elise	01/01/2024	12/31/2025	ONC	Ex Officio Member
Bass, Micah	01/01/2024	12/01/2025	CDC	Ex Officio Member
Bateman-House, Alison	08/29/2023	08/29/2026	New York University	Special Government Employee (SGE) Member
Berger, Adam	01/01/2024	12/31/2025	NIH	Ex Officio Member
Cope, James	01/01/2024	12/31/2025	CDC	Ex Officio Member
Dickert, Neal	09/08/2023	09/08/2027	Emory Health Services Research Center	Special Government Employee (SGE) Member
Diekema, Douglas	07/20/2020	10/31/2024	University of Washington School of Medicine	Special Government Employee (SGE) Member
Gordon-Nguyen, Marrissa	01/01/2024	12/31/2025	OCR	Ex Officio Member
He, Hope	01/01/2024	12/31/2025	AHRQ	Ex Officio Member
Isaac, Peyton	01/01/2024	12/31/2025	OCR	Ex Officio Member
Lee, Sandra	05/11/2021	05/11/2025	Chief, Division of Ethics, Columbia University	Special Government Employee (SGE) Member

Mah, Eric	07/05/2023	07/05/2027	University of California San Diego	Special Government Employee (SGE) Member
Marchesini, Kathryn	01/01/2024	12/31/2025	ONC	Ex Officio Member
Meeker-OConnell, Winifred	03/23/2021	03/23/2025	Food and Drug Administration	Ex Officio Member
Moore, Celine	01/01/2024	12/31/2025	NIH	Ex Officio Member
Prohaska, Kevin	01/01/2024	12/31/2025	FDA	Ex Officio Member
Reeter, Mindy	07/13/2023	07/13/2027	University of Illinois college of Medicine	Special Government Employee (SGE) Member
Roland, Joella	05/01/2022	05/01/2025	Health Resource Services Administration	Ex Officio Member
Shepherd, Lois	07/19/2021	07/19/2025	Law Professor, University of Virginia	Special Government Employee (SGE) Member
Tracy, Rachael	01/01/2024	12/31/2025	IHS	Ex Officio Member
Van Aerden, Catherine	01/01/2024	12/31/2025	HRSA	Ex Officio Member
Yearby, Ruqaiijah	07/11/2023	07/11/2027	The Ohio State University	Special Government Employee (SGE) Member

Number of Committee Members Listed: 22

Narrative Description

SACHRP supports HHS by providing recommendations, interpretations and conclusions on issues associated with HHS regulations for the protection of human subjects.

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

	Checked if Applies
Improvements to health or safety	✓

Trust in government	✓
Major policy changes	✓
Advance in scientific research	
Effective grant making	
Improved service delivery	
Increased customer satisfaction	
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	✓
Unable to Determine	
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

NA

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

727

Number of Recommendations Comments

Recommendations are provided to the Secretary of HHS in a series of letters from SACHRP to the Secretary through the Assistant Secretary for Health. These letters outline the committee's interpretation and conclusions on issues associated with HHS regulations for the protection of human subjects, including but not limited to the following: Considerations for the Inclusion of LGBTQI+ Participants in HHS Human Subjects

Research, Interpretation of the Best Interests Standard for the Retention of Subjects in Human Subjects Research that Has Been Suspended or Terminated, and recommendations on GAO-23-104721, INSTITUTIONAL REVIEW BOARDS: Actions Needed to Improve Federal Oversight and Examine Effectiveness, as well as recommendations pertaining to research with children, prisoners, pregnant women, individuals with impaired decision-making, and areas within subpart A, known as the Common Rule. Note that the majority of these topics result in many sub-recommendations, while others may generate one or two overall considerations; therefore the overall number is difficult to quantify and separate; the number provided represents a best estimate based on SACHRP letters to the Secretary.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
4%

% of Recommendations Fully Implemented Comments
Note that many SACHRP recommendations impact issues not yet resolved within the Department, such as the use of artificial intelligence in human subjects research; therefore such recommendations, while meaningful to the Department, cannot be quantified as fully or partially implemented at this time. Among the fully implemented recommendations have been recommendations pertaining to: IRB acountability, the formation of a subcommittee to examine harmonization of Federal regulations and guidance affecting human subjejcts research; the addition of ex-officio representation from the Office of Civil Rights; the 45 CFR 46.407 review process for research involving children as subjects; the accreditation of human research protection programs; the interpretation of 45 CFR subpart C (protections for prisoners involved as subjects in human subjects research); a recommendation that a workshop be convened focusing issues pertaining to central IRB review; various FAQs on parental permission, child assent, and documentation of informed consent; IRB accoutability; and continuing review.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
Note that many SACHRP recommendations impact issues not yet resolved within the Department, such as the use of artificial intelligence in human subjects research; therefore such recommendations, while meaningful, cannot be quantified as fully or partially implemented at this time. Among partially implemented recommendations are

those pertaining to: Justice as an Ethical Concept in 5 CFR 46; 45 CFR 46 subpart D, research involving children as subjects; subpart A continuing review, and expedited review categories; and recommendations calling for initial and continuing training of IRB members, IRB staff, and institutional officials.

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

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

The DFO communicates with the Chair and the full committee at open public meetings. Information about Committee-related matters is also available on the SACHRP website that is managed through the Office for Human Research Protections (OHRP).

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

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The majority of SACHRP's recommendations are under consideration by OHRP, and may result in changes to HHS guidance, regulation, or agency policy. SACHRP recommendations may also be directed towards other components of HHS such as NIH or FDA.

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

No

Grant Review Comments

NA

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

	Checked if Applies
Contact DFO	☑

Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A