

2023 Current Fiscal Year Report: Secretary's Advisory Committee on Human Research Protections

Report Run Date: 03/29/2024 06:36:28 AM

1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2023

3. Committee or Subcommittee

Secretary's Advisory Committee on Human Research Protections

3b. GSA

Committee

No.

9492

4. Is this New During Fiscal Year?

No

5. Current Charter

10/01/2022 10/01/2024

6. Expected Renewal Date

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority

42 USC 217a, Section 222 of the PHS Act

13. Effective Date

10/17/1962

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open

3

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

3

Meetings and Dates

Purpose

Start

End

This is the 1st of 3 annual open meetings to discuss matters related to HHS research and human subjects protection. 10/19/2022 - 10/20/2022

This is the 2nd of 3 yearly open SACHRP meetings to discuss matters related to HHS research and human subjects protection. 03/22/2023 - 03/23/2023

This is the 3rd of 3 annual open meetings to discuss matters related to HHS research and human subjects protection. 07/19/2023 - 07/20/2023

Number of Committee Meetings Listed: 3

| | Current FY | Next FY |
|---|-------------------|----------------|
| 18a(1). Personnel | | |
| Pmts to Non-Federal Members | \$2,100.00 | \$10,000.00 |
| 18a(2). Personnel | | |
| Pmts to Federal Members | \$10,000.00 | \$11,000.00 |
| 18a(3). Personnel | | |
| Pmts to Federal Staff | \$150,000.00 | \$155,000.00 |
| 18a(4). Personnel | | |
| Pmts to Non-Member Consultants | \$0.00 | \$0.00 |
| 18b(1). Travel and Per Diem to Non-Federal Members | \$7,110.00 | \$10,000.00 |
| 18b(2). Travel and Per Diem to Federal Members | \$0.00 | \$0.00 |
| 18b(3). Travel and Per Diem to Federal Staff | \$100.00 | \$100.00 |
| 18b(4). Travel and Per Diem to Non-member Consultants | \$0.00 | \$0.00 |
| 18c. Other(rents,user charges, graphics, printing, mail, etc.) | \$60,000.00 | \$63,000.00 |
| 18d. Total | \$229,310.00 | \$249,100.00 |
| 19. Federal Staff Support Years (FTE) | 1.00 | 1.00 |

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

SACHRP met three times in FY 2023. 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 |
|------------------------|------------|------------|--|--|
| Allen, Mary | 05/14/2019 | 05/13/2023 | Genentech, Inc. | Special Government Employee (SGE) Member |
| Bass, Micah | 09/30/2020 | 09/30/2024 | Center for Disease Control and Prevention | Ex Officio Member |
| Diekema, Douglas | 07/21/2020 | 07/21/2024 | University of Washington | Special Government Employee (SGE) Member |
| Gordon-Nguyen, Marissa | 09/30/2020 | 09/30/2024 | Office of Civil Rights | Ex Officio Member |
| He, Hope | 03/01/2020 | 03/01/2024 | Agency for Health Research Quality | Ex Officio Member |
| Kline, Lydia | 09/30/2020 | 09/30/2024 | National Institutes of Health | 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 | 03/01/2020 | 03/01/2024 | Office of the National Coordinator for Health Information Technology | Ex Officio Member |
| Meeker-OConnell, Winifred | 03/23/2021 | 03/23/2025 | Food and Drug Administration | Ex Officio Member |
| Nelson, Robert | 05/23/2019 | 05/22/2023 | Johnson & Johnson | Special Government Employee (SGE) 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 |
| Straus, Walter | 06/12/2019 | 06/11/2023 | Merck and Co. | Special Government Employee (SGE) Member |
| Tracy, Rachel | 09/30/2020 | 09/30/2024 | Indian Health Service | Ex Officio Member |
| Weinfurt, Kevin | 07/20/2020 | 07/20/2024 | Duke University | Special Government Employee (SGE) Member |
| Wilkins, Consuelo | 05/01/2019 | 04/30/2023 | Georgia State University | Special Government Employee (SGE) Member |
| Yearby, Ruqaijah | 07/11/2023 | 07/11/2027 | The Ohio State University | Special Government Employee (SGE) Member |

Number of Committee Members Listed: 19

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

Outcome Comments

NA

What are the cost savings associated with this committee?

| | Checked if Applies |
|----------------------------|-------------------------------------|
| None | <input checked="" type="checkbox"/> |
| Unable to Determine | <input 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

NA

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

662

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: OHRP draft guidance on limited IRB review and related exemptions, FDA draft guidance on decentralized clinical trials for drugs, biological products and devices, and ethical considerations for clinical investigations of medical products involving children, recommendations on the use of artificial intelligence in research, and topics 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?

5%

% 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 accountability, the formation of a subcommittee to examine harmonization of Federal regulations and guidance affecting human subjects 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 accountability; 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 | <input checked="" 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 checked="" type="checkbox"/> |

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 | <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 | <input checked="" type="checkbox"/> |
| Publications | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

N/A