

2016 Current Fiscal Year Report: NIH Advisory Board for Clinical Research

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1. Department or Agency Department of Health and Human Services
2. Fiscal Year 2016

3. Committee or Subcommittee NIH Advisory Board for Clinical Research
3b. GSA Committee No. 5122

4. Is this New During Fiscal Year? No
5. Current Charter 04/26/2016
6. Expected Renewal Date 04/26/2018
7. Expected Term Date

8a. Was Terminated During Fiscal Year? Yes
8b. Specific Termination Authority
8c. Actual Term Date 07/01/2016

9. Agency Recommendation for Next Fiscal Year Terminate
10a. Legislation Req to Terminate? No
10b. Legislation Pending? Not Applicable

11. Establishment Authority Authorized by Law
12. Specific Establishment Authority 42 USC 282(b)(16)
13. Effective Date 11/04/1988
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 0 **17b. Closed** 0 **17c. Partially Closed** 1 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
NIH Program Advisory	03/21/2016	- 03/21/2016

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$1,400.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$59,855.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$3,409.00	\$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. Other(rents,user charges, graphics, printing, mail, etc.)	\$3,837.00	\$0.00
18d. Total	\$68,501.00	\$0.00
19. Federal Staff Support Years (FTE)	0.40	0.00

20a. How does the Committee accomplish its purpose?

The full NIH Advisory Board for Clinical Research (previously the Board of Governors of the Warren Grant Magnuson Clinical Center) met once this year at the NIH Bethesda campus. The ABCR Charter stipulated that the Board advised, consulted with, and make recommendations to the NIH Director, the NIH Deputy Director for Clinical Research, and the Clinical Center Director. In addition, the Board provided guidance for the incorporation of clinical research initiatives in the intramural clinical research programs by developing an integrated strategic operating plan

for clinical research. This plan included: development of a shared vision for the intramural clinical research program, taking into account the clinical research visions of all ICs; made recommendations on strategies for integrating proposed research initiatives considering their possible effects on future intramural clinical research program; reviewed and recommended a strategic operating plan for the Clinical Center; and conducted an annual review of each NIH Institute's or Center's performance with respect to annual plans for the use of the Clinical Center's resources. Although the scope of the Board's responsibilities related only to the intramural clinical research program, the Board was also open to new opportunities for clinical research, including high-risk, high-impact research, research on rare diseases, and interactions between intramural and extramural clinical research programs. The Board reviewed the Clinical Center's annual budget and provided recommendations to the Director, NIH. The Board's recommendation was also shared with the Clinical Center Governing Board to inform their budget recommendation to the Director, NIH. The Board reviewed the process by which the Medical Executive Committee approves credential and privileging actions and continuous improvement of the quality of clinical activities in the Clinical Center. The Board also evaluated the Clinical Center's Board of Scientific Counselors' process for review of independent research conducted by the Clinical Center's investigators. Additionally, the ABCR oversaw the Clinical Center's Operational Review process used to review the efficiency and quality of the operations of Clinical Center departments with the goal of containing expenditures while maximizing productivity in support of the NIH clinical research mission.

Working groups were developed to address topics between full meetings of the Board in a more in depth fashion.

20b. How does the Committee balance its membership?

The Board consists of 18 appointed members including the Chair and Vice Chair. Of the 18 members, ten are non-NIH employees and eight are NIH employees. None of the members are Clinical Center employees or employees of the NIH Deputy Director for Intramural Research. The Deputy Director for Intramural Research, the Clinical Center Director, the chair of the Medical Executive Committee, and other senior NIH leadership as determined by the NIH Director also serve as nonvoting ex officio members of the Board. The Chair and Vice Chair must be non-NIH employees.

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

The full ABCR met once in FY16 due to government closure related to weather in January and the termination of the ABCR prior to the September meeting. Agendas were developed for each meeting to address current and relevant topics and challenges pertinent to the Clinical Center, Intramural Research Program and greater NIH. During FY16, the Board provided guidance concerning the FY16 and FY17 budgets, Clinical Center departmental operational reviews, the Clinical Center Strategic and Annual Operating Plan, long-term planning for the NIH Intramural Research Program.

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

Members of the group were chosen for their

knowledge of health care governance and management, operational aspects of large academic health care centers, clinical research, and other areas of importance to the future development of the Clinical Center. The individual expertise and broad perspective that both the outside representatives and the NIH staff brought to the Board's deliberations were invaluable to obtaining balanced advice.

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

The meetings of the Board were closed to the public for the discussion of personnel qualifications and performance. Section 552b(c)(6) of the Government in the Sunshine Act permits the closing of meetings where discussion could reveal personal information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

21. Remarks

The Designated Federal Official and Committee Decision Maker roles are both held by the same individual based on assigned duties within the Center. Reports: The committee did not produce any reports this fiscal year. Website: This committee does not have a public website. Member William Dahut appointment was extended beyond the date listed on the FY-2015 ACR. This committee was terminated 7/1/2016.

Designated Federal Officer

MAUREEN E GORMLEY CHIEF OPERATING OFFICER

Committee Members	Start	End	Occupation	Member Designation
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BALABAN, ROBERT	09/20/2011	04/22/2016	SCIENTIFIC DIRECTOR	Regular Government Employee (RGE) Member
DAHUT, WILLIAM	01/01/2013	04/22/2016	CLINICAL DIRECTOR	Regular Government Employee (RGE) Member
DIETZ, HARRY	12/27/2015	04/22/2016	PROFESSOR OF MEDICINE AND GENETICS	Special Government Employee (SGE) Member
FENWICK, SANDRA	12/27/2015	04/22/2016	PRESIDENT AND CHIEF EXECUTIVE OFFICER	Special Government Employee (SGE) Member
GALLIN, JOHN	04/26/2004	04/22/2016	DIRECTOR	Ex Officio Member
GIBBONS, GARY	07/01/2014	04/22/2016	DIRECTOR	Regular Government Employee (RGE) Member
GOTTESMAN, MICHAEL	04/26/2004	04/22/2016	DEPUTY DIRECTOR FOR INTRAMURAL RESEARCH	Ex Officio Member
HOLLAND, STEVEN	07/01/2015	04/22/2016	CHIEF	Ex Officio Member
LIANG, TSANYANG	09/21/2011	04/22/2016	TENURE CHIEF	Regular Government Employee (RGE) Member
MARKS, LILLY	09/18/2014	04/22/2016	EXECUTIVE VICE CHANCELLOR	Special Government Employee (SGE) Member
NATH, AVINDRA	01/01/2015	04/22/2016	CLINICAL DIRECTOR	Ex Officio Member
NIENHUIS, ARTHUR	01/24/2016	04/22/2016	MEMBER	Special Government Employee (SGE) Member
OFILI, ELIZABETH	10/01/2012	04/22/2016	DIRECTOR	Special Government Employee (SGE) Member

PESCOVITZ, ORA	09/22/2013	04/22/2016	EXECUTIVE VICE PRESIDENT FOR MEDICAL AFFAIRS	Special Government Employee (SGE) Member
PUCK, JENNIFER	09/22/2013	04/22/2016	PROFESSOR	Special Government Employee (SGE) Member
RADER, DANIEL	01/16/2015	04/22/2016	DIRECTOR	Special Government Employee (SGE) Member
SHEKHAR, ANANTHA	09/22/2013	04/22/2016	DIRECTOR	Special Government Employee (SGE) Member
STRATAKIS, CONSTANTINE	07/01/2015	04/22/2016	SCIENTIFIC DIRECTOR	Regular Government Employee (RGE) Member
VALANTINE, HANNAH	07/01/2015	04/22/2016	CHIEF OFFICER FOR SCIENTIFIC WORKFORCE DIVERSITY	Regular Government Employee (RGE) Member
VOLKOW, NORA	07/01/2013	04/22/2016	DIRECTOR	Regular Government Employee (RGE) Member
WALSH, KATHLEEN	07/01/2015	04/22/2016	PRESIDENT & CEO	Special Government Employee (SGE) Member
ZARATE, CARLOS	07/01/2013	04/22/2016	CHIEF	Regular Government Employee (RGE) Member

Number of Committee Members Listed: 22

Narrative Description

At the NIH Clinical Center, clinical research participants, more than 400,000 since the hospital opened in 1953, are active partners in medical discovery, a partnership that has resulted in a long list of medical milestones including development of chemotherapy for

cancer; the first use of an immunotoxin to treat a malignancy (hairy cell leukemia); identification of the genes that cause kidney cancer, leading to the development of six new, targeted treatments for advanced kidney cancer; the demonstration that lithium helps depression; the first gene therapy; the first treatment of AIDS (with AZT); and the development of tests to detect AIDS/HIV and hepatitis viruses in blood, which led to a safer blood supply.

Patients come from all 50 states and from around the world. Some 1,200 credentialed physicians, dentists, and PhD researchers; 620 nurses; and 450 allied health-care personnel work in patient care units and laboratories in numerous areas of clinical study.

Research conducted at the NIH Clinical Center include: musculoskeletal and skin diseases; cancer; dental and craniofacial disorders; eye disorders; heart, lung, and blood diseases; infectious diseases; medical genetics; mental health; and neurological disorders. The NIH Advisory Board for Clinical Research advises, consults with, and makes recommendations to the Director, NIH, the NIH Deputy Director for Intramural Research, and the Director, Clinical Center on the integration of clinical research initiatives in the intramural clinical research programs by developing an integrated operating strategic plan for clinical research. This plan includes: development of a shared vision for the intramural clinical research program taking into account the clinical research visions of all institutes and centers; making recommendations on strategies for integrating proposed research initiatives considering their possible effects on the current and future intramural clinical research program; reviewing and recommending an annual strategic operating plan for the Clinical Center; and, conducting annual review of each NIH institute's or center's performance with respect to its annual operations plan for using Clinical Center resources.

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

During FY16, the Board provided guidance concerning the FY16 and FY17 budgets, future Clinical Center departmental operational reviews, Third Party Reimbursement and opening the doors to extramural investigators.

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

81

Number of Recommendations Comments

Two action items were generated from the meeting held in FY16. The NIH Intramural Research Program and the Clinical Center consider all ABCR recommendations, delegates follow-up to appropriate individuals in the organization and reports progress back to the ABCR as needed. This fiscal year issues included: monitoring the FY16 budget and developing the FY17 budget, and endorsement of the Strategic and Operating

Plan.

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

100%

% of Recommendations Fully Implemented Comments

The percentage of recommendations implemented stated above was developed at the time the Annual Comprehensive Review report was prepared. Additional information is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at <http://report.nih.gov>.

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

NA

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

Yes No Not Applicable

Agency Feedback Comments

At the beginning of each meeting, the ABCR Chair provides a summary of the minutes prior to asking for approval. Doing so reminds Board members of the action items. The Clinical Center Director's remarks at the beginning of the meeting also include an update on the progress of the action items.

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 checked="" type="checkbox"/> |
| Issued new regulation | <input type="checkbox"/> |
| Proposed legislation | <input type="checkbox"/> |

Approved grants or other payments

Other

Action Comments

During FY16, the Board provided guidance concerning the FY16 and FY17 budgets, future Clinical Center departmental operational reviews, Third Party Reimbursement and opening the doors to extramural investigators.

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

NA