

2003 Current Fiscal Year Report: Clinical Trials Review Committee

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1. Department or Agency

Department of Health and Human
Services

2. Fiscal Year

2003

3. Committee or Subcommittee

Clinical Trials Review Committee

3b. GSA Committee

No.

830

4. Is this New During Fiscal Year?

No

5. Current Charter

07/01/1987

6. Expected Renewal Date

7. Expected Term Date

09/30/2003

8a. Was Terminated During Fiscal Year?

Yes

8b. Specific Termination Authority

Departmental
Determination

8c. Actual Term Date

09/30/2003

9. Agency Recommendation for Next Fiscal Year

Terminate

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

11. Establishment Authority

Authorized by Law

12. Specific Establishment Authority

42 U.S.C. 282(b)(6)

13. Effective Date

11/20/1985

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

Grant Review Committee

16a. Total Number of Reports

1

16b. Report Date

09/30/2003

Annual Report to the Secretary

Number of Committee Reports Listed: 1

17a.

Open

0

17b. Closed

3

17c. Partially Closed

0

Other Activities

0

17d. Total

3

Meetings and Dates

Purpose	Start	End
Grant Review	10/28/2002	- 10/28/2002
Grant Review	02/24/2003	- 02/24/2003
Grant Review	06/23/2003	- 06/23/2003

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$15,500.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$146,682.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$37,245.00	\$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.)	\$6,808.00	\$0.00
18d. Total	\$206,235.00	\$0.00
19. Federal Staff Support Years (FTE)	1.90	0.00

20a. How does the Committee accomplish its purpose?

Section 492 of the PHS Act states that The Secretary... shall by regulation require appropriate technical and scientific peer review - A) applications...; and B) biomedical and behavioral research and development contracts... This Committee is composed of recognized biomedical and/or behavioral research authorities who represent the forefront of research and technical knowledge and who provide first-level merit review of highly scientific and technical research grant applications of investigator initiated funding of

single and/or multi-center clinical trials and registries involving cardiovascular, pulmonary, and blood diseases. During this reporting period, the Committee reviewed 45 applications requesting \$113,609,519.

20b. How does the Committee balance its membership?

The members of this Committee are authorities knowledgeable in the fields of fundamental and clinical research in disciplines related to cardiovascular, lung, and blood diseases, as well as epidemiology, biostatistics, and clinical trial design.

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

The Committee met 3 times during this reporting period.

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

The Committee is composed of recognized biomedical and behavioral research authorities who represent the forefront of research and technical knowledge and who provide first-level merit review of highly scientific and technical research grant applications. These evaluations and recommendations cannot be obtained from other sources because the specialized, complex nature of the applications require a unique balance and breadth of expertise not available on the NIH staff or from other established sources.

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

The meetings of the Committee were closed to the public for the review of grant applications. Sections 552b(c)(4) and 552b(c)(6) of the

Government in the Sunshine Act permit the closing of meetings where discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

21. Remarks

Designated Federal Officer

VALERIE L. PRENGER SCIENTIFIC REVIEW
ADMINISTRATOR

Committee Members	Start	End	Occupation	Member Designation
				Special Government
ABRAIRA, CARLOS	02/24/2003	02/24/2003	CO-CHAIRMAN	Employee (SGE) Member Special Government
BALMES, JOHN	06/23/2003	06/24/2003	PROFESSOR	Employee (SGE) Member Special Government
BENJAMIN, MARSHALL	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR	Employee (SGE) Member
			PROFESSOR OF PATHOLOGY	Special Government
BOCK, JAY	10/28/2002	10/29/2002	AND DIRECTOR OF CLINICAL PATHOLOGY	Employee (SGE) Member
				Special Government
BRAITH, RANDY	06/23/2003	06/24/2003	ASSOCIATE PROFESSOR	Employee (SGE) Member Special Government
BREALL, JEFFREY	02/24/2003	02/24/2003	CLINICAL PROFESSOR	Employee (SGE) Member

BRENER, SORIN	06/23/2003	06/24/2003	DIRECTOR	Special Government Employee (SGE) Member
BULKLEY, GREGORY	06/23/2003	06/24/2003	RAVICH PROFESSOR OF SURGERY	Special Government Employee (SGE) Member
CAMARGO, CARLOS	10/28/2002	10/29/2002	ASSISTANT PROFESSOR	Special Government Employee (SGE) Member
CARTER, SHELLY	07/15/2002	09/30/2003	SENIOR STATISTICIAN AND PROJECT MANAGER	Special Government Employee (SGE) Member
CHINCHILLI, VERNON	07/01/1999	06/30/2003	PROFESSOR AND VICE CHAIR	Special Government Employee (SGE) Member
CONNETT, JOHN	06/23/2003	06/24/2003	PROFESSOR	Special Government Employee (SGE) Member
DIMARCO, ANTHONY	10/28/2002	10/29/2002	PROFESSOR	Special Government Employee (SGE) Member
DOBIE, ROBERT	02/24/2003	02/24/2003	PROFESSOR	Special Government Employee (SGE) Member
DOLLAGHAN, CHRISTINE	10/28/2002	10/29/2002	PROFESSOR	Special Government Employee (SGE) Member
ELASHOFF, ROBERT	07/30/2003	09/30/2003	PROFESSOR	Special Government Employee (SGE) Member
ENRIGHT, PAUL	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member

ERNST, PIERRE-PAUL	02/24/2003	02/24/2003	PROFESSOR	Special Government Employee (SGE) Member
FISH, JAMES	07/01/2001	06/30/2003	GLOBAL CLINICAL DIRECTOR	Special Government Employee (SGE) Member
FONTAINE, JOHN	07/01/2001	09/30/2003	ASSOCIATE PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
FRANCIS, CHARLES	06/23/2003	06/24/2003	PROFESSOR	Special Government Employee (SGE) Member
GANZ, PETER	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
GILLAM, RONALD	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
GOTTLIEB, DANIEL	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
GOTTLIEB, STEPHEN	06/23/2003	06/24/2003	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
HOCHMAN, JUDITH	07/09/2002	09/30/2003	PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
HOSKING, JAMES	07/01/1999	06/30/2003	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
JONES, ROBERT	02/24/2003	02/24/2003	PROFESSOR	Special Government Employee (SGE) Member

KACMAREK, ROBERT	10/28/2002	10/29/2002	DIRECTOR	Special Government Employee (SGE) Member
KLEINHENZ, MARY	02/24/2003	02/24/2003	ASSOCIATE PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
KORTHUIS, RONALD	06/23/2003	06/24/2003	PROFESSOR	Special Government Employee (SGE) Member
LEEPER, KENNETH	08/14/2000	09/30/2003	ASSOCIATE PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
LEHMANN, KENNETH	02/24/2003	02/24/2003	ASSOCIATE PROFESSOR OF MEDICINE AND DIRECTOR	Special Government Employee (SGE) Member
LIU, MARK	02/24/2003	02/24/2003	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
MANCO-JOHNSON, MARILYN	07/01/2001	09/30/2003	PROFESSOR OF PEDIATRICS AND PATHOLOGY	Special Government Employee (SGE) Member
MARGULIES, KENNETH	06/23/2003	06/24/2003	DIRECTOR	Special Government Employee (SGE) Member
MC CAFFREY, TIMOTHY	02/24/2003	02/24/2003	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
MCGRADY, ANGELE	06/23/2003	06/24/2003	PROFESSOR	Special Government Employee (SGE) Member
MOLINE, MARGARET	02/24/2003	02/24/2003	DIRECTOR AND HEAD	Special Government Employee (SGE) Member

O'BRIEN, KEVIN	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
OWNBY, DENNIS	06/23/2003	06/24/2003	PROFESSOR OF PEDIATRICS	Special Government Employee (SGE) Member
PEPINE, CARL	07/01/2001	06/30/2003	PROFESSOR AND CHIEF	Special Government Employee (SGE) Member
POLLARD, HARVEY	06/23/2003	06/24/2003	CHAIR	Special Government Employee (SGE) Member
POWELL, LYNDA	08/04/2003	09/30/2003	PROFESSOR	Special Government Employee (SGE) Member
RAND, CYNTHIA	07/01/1999	06/30/2003	ASSOCIATE PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
REBOUSSIN, DAVID	07/16/2002	09/30/2003	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
SCHMIDT-NOWARA, WOLFGANG	02/24/2003	02/24/2003	CLINICAL ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
SNETSELAAR, LINDA	07/01/2000	09/30/2003	ASSOCIATE PROFESSOR	Special Government Employee (SGE) Member
STEIN, CHARLES	07/01/2000	06/30/2004	ASSOCIATE PROFESSOR OF MEDICINE	Special Government Employee (SGE) Member
TELEN, MARILYN	07/01/2001	09/30/2003	CHIEF, DIVISION OF HEMATOLOGY	Special Government Employee (SGE) Member

TUCCI, DEBARA	02/24/2003	02/24/2003	ASSOCIATE PROFESSOR OF SURGERY	Special Government Employee (SGE) Member
WAKEFIELD, THOMAS	06/23/2003	06/24/2003	PROFESSOR	Special Government Employee (SGE) Member
WARREN, H.	10/28/2002	10/29/2002	ASSOCIATE PROFESSOR OF PEDIATRICS	Special Government Employee (SGE) Member
YUNIS, CARLA	07/01/2000	09/30/2003	ASSOCIATE DIRECTOR OF CLINICAL RESEARCH	Special Government Employee (SGE) Member

Number of Committee Members Listed: 54

Narrative Description

The goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold. The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad. Section 492 of the PHS Act states that The Secretary ...shall by regulation require appropriate technical and scientific peer review of -(A) applications...; (B) biomedical and behavioral research and development contracts... During this reporting period, the Committee reviewed 45 applications requesting \$113,609,519.

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 | <input checked="" 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

NIH supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

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

45

Number of Recommendations Comments

Grant Review

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

0%

% of Recommendations Fully Implemented Comments

Section 9(b) of the Federal Advisory Committee Act states that unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government. NIH does not currently track this information.

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

Section 9(b) of the Federal Advisory Committee Act states that unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government. NIH does not currently track this information.

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

Yes ☐ No ☐ Not Applicable ☒

Agency Feedback Comments

NA

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 checked="" type="checkbox"/>

Action Comments

Initial Review Groups only provide advice.

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

Yes

What is the estimated Number of grants reviewed for approval 45

What is the estimated Number of grants recommended for approval 0

What is the estimated Dollar Value of grants recommended for approval \$0

Grant Review Comments

NIH does not currently collect this data.

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 type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

NA