DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

CHARTER

RECOMBINANT DNA ADVISORY COMMITTEE

AUTHORITY

42 U.S.C. 282(b)(16), section 402(b)(16) of the Public Health Service Act, as amended. The Recombinant DNA Advisory Committee (Committee) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Committee will provide advice to the Director, National Institutes of Health (NIH), on matters related to (1) the conduct and oversight of research involving recombinant DNA, including the content and implementation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, as amended *(NIH Guidelines)*, and (2) other NIH activities pertinent to recombinant DNA technology. There will be a continuing need for the Committee to serve these functions so long as the NIH supports activities involving recombinant DNA.

DESCRIPTION OF DUTIES

The Committee makes recommendations on research involving the use of recombinant DNA and on developments in recombinant DNA technology. More specific functions of the Committee are set forth in Section IV-C-2 of the *NIH Guidelines*. The Committee is responsible for carrying out the functions set forth in the *NIH Guidelines*, as well as any others assigned under its charter or by the Secretary of Health and Human Services (Secretary) or the Director, NIH.

As necessary, and with the approval of the Designated Federal Officer, the Committee and its subcommittees may call upon special consultants, assemble ad hoc working groups, and convene conferences, workshops and other activities.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee will advise, assist, consult with, and make recommendations to the Director, NIH.

SUPPORT

Management and support services will be provided by the Office of Biotechnology Activities (OBA).

ESTIMATED ANNUAL OPERATING COST AND STAFF YEARS

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is $394,278. The estimated annual person-years of staff support required is 3.1 at an estimated annual cost of $846,602.

DESIGNATED FEDERAL OFFICER

The Director, OBA, will assign a full-time or permanent part-time OBA employee as the Designated Federal Officer (DFO) of the Committee. In the event that the DFO cannot fulfill the assigned duties of the committee, one or more full-time or permanent part-time OBA or NIH employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the committee's and subcommittees' meetings, prepare and approve all meeting agendas, attend all committee and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH or the Director, OBA.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Committee will be held approximately four times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing. This committee is mandated with no specified end date.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the Recombinant DNA Advisory Committee will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of 21 voting members, including the Chair, appointed by the Director, NIH. A majority of the voting members must be knowledgeable in relevant scientific fields, e.g., molecular genetics, molecular biology, recombinant DNA research, including clinical gene transfer research. Of the 21 members, at least four members of the Committee must be persons knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human subjects of research, the environment, ethics, law, public attitudes or related fields. All non-Federal Members serve as Special Government Employees. Members and the Chair will be invited to serve for overlapping four-year terms. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

There may be nonvoting representatives from each of the following Federal agencies: Department of Agriculture; Department of Commerce; Department of Defense; Department of Health and Human Services--Centers for Disease Control and Prevention--National Institute for Occupational Safety and Health--Food and Drug Administration--Center for Biologics Evaluation and Research--Office for Human Research Protections; Department of Energy; Department of Interior; Department of Justice; Department of Labor; Department of State; Department of Transportation; Department of Veterans Affairs; Environmental Protection Agency; Executive Office of the President; National Aeronautics and Space Administration; National Science Foundation; Nuclear Regulatory Commission; U.S. Arms Control and Disarmament' Agency.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Committee's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. A quorum for a subcommittee will be three members. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

June 30, 2009

APPROVED

04/17/09	**/s/ Raynard S. Kington**
Date	Acting Director, NIH