CHARTER

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

COMMITTEE'S OFFICIAL DESIGNATION

Scientific Advisory Committee on Alternative Toxicological Methods

AUTHORITY

Required by Section 3(d) of Public Law 106-545, 42 U.S.C. 285*l*-3(d), as amended. The Scientific Advisory Committee on Alternative Toxicological Methods (also known as SACATM or Committee) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014).

OBJECTIVES AND SCOPE OF ACTIVITIES

The purpose of the Committee is to advise, consult with, and make recommendations to the Director, National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP), the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding ICCVAM activities. SACATM also advises the NIEHS and NICEATM on NICEATM activities relating to ICCVAM. The purposes of the ICCVAM as defined in the law are to increase the efficiency and effectiveness of Federal agency test method review; eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies; optimize utilization of scientific expertise outside the Federal government; ensure that new and revised test methods are validated to meet the needs of Federal agencies; and reduce, refine, or replace the use of animals in testing, where feasible. NICEATM supports activities and collaborates with ICCVAM to facilitate the development, scientific review, validation, and interagency consideration of novel toxicological methods of multiagency interest that predict human health risks while reducing, refining, and/or replacing animal tests. NICEATM promotes participation and communication with stakeholders throughout the process of test method development and validation.

DESCRIPTION OF DUTIES

SACATM will provide advice on activities and directives relating to NICEATM's support of ICCVAM and communication and outreach, as well as activities regarding the following statutorily mandated ICCVAM functions: (1) Review and evaluate new or revised or

alternative test methods, including batteries of tests and test screens that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest; (2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods; (3) Facilitate and provide guidance on the development of validation criteria, validation studies, and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders; (4) Submit ICCVAM test recommendations for the test methods reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (Secretary) (or the designee of the Secretary), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for test methods, including batteries of tests and test screens for chemicals or classes of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods; (5) Consider for review and evaluation petitions received from the public that-- (A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and (B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method; (6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the response from the agencies regarding these recommendations; and (7) Prepare reports to be made available to the public on its progress under the Act.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee will advise, consult with, and make recommendations to the Director, NIEHS and NTP, ICCVAM, and NICEATM.

SUPPORT

Management and support services will be provided by the Office of Liaison, Policy and Review, Division of the NTP, NIEHS, and NICEATM.

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 $54,345. The estimate of annual person-years of staff support required is 0.6, at an estimated annual cost of $82,028.

DESIGNATED FEDERAL OFFICER

The Director, NIEHS and NTP, will assign a full-time or permanent part-time NIEHS 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 NIEHS or NIH employees will be assigned as DFO and carry out these duties on a temporary basis.

The DFO will approve 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 official to whom the committee reports.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

The SACATM will meet not less than one time within a fiscal year. Meetings will be open to the public except as determined by the Secretary of Health and Human Services (Secretary) at the request of the DFO in accordance with 5 U.S.C. 552b(c) and 41 C.F.R. 102-3.155 including specifying the specific exception(s) that justifies closure. 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, an annual report of closed or partially-closed meetings will be prepared which will contain, at 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.

DURATION

Continuing.

TERMINATION

Unless renewed by appropriate action, the charter for the Scientific Advisory Committee on Alternative Toxicological Methods will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of up to 15 members (appointed members), including the Chair, selected by the Director, NIEHS and NTP, plus non-voting *ex officio* members, as described below. The appointed members will include representatives from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories. Knowledgeable representatives from public health, environmental communities, or organizations using new or alternative test methodologies may be included as appropriate. There will be at least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of the following categories: (1) personal care, pharmaceutical, industrial chemicals, or agricultural industry; (2) any other industry that is regulated by one of the Federal agencies

on ICCVAM; and (3) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

The Chair will be selected by the Director, NIEHS and NTP, from among the appointed members. Appointed members must be eligible to serve as Special Government Employees (SGEs) and will serve as SGEs, as defined by 18 U.S.C. § 202. Appointed members will be invited to serve for overlapping four-year terms. A member may serve after the expiration of that member's term until a successor has taken office. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

In accordance with 42 U.S.C. 285*l*-3(c) and 285*l*-3(d)(2)(B), the membership of SACATM will also include, as nonvoting *ex officio* members, the agency heads or their designees from the Federal agencies represented on ICCVAM, as follows: (1) Agency for Toxic Substances and Disease Registry; (2) Consumer Product Safety Commission; (3) Department of Agriculture; (4) Department of Defense; (5) Department of Energy; (6) Department of the Interior; (7) Department of Transportation; (8) Environmental Protection Agency; (9) Food and Drug Administration; (10) National Institute for Occupational Safety and Health; (11) National Institutes of Health; (12) National Cancer Institute; (13) NIEHS; (14) National Library of Medicine; (15) Occupational Safety and Health Administration; and (16) National Institute of Standards and Technology; (17) Department of Veterans Affairs Research and Development Office, and (18) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

SUBCOMMITTEES

As necessary, subcommittees and *ad hoc* working groups may be established by the DFO within the SACATM's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee/working group 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 are not members, 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 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to any applicable exemptions under the Freedom of Information Act, 5 U.S.C. 552(b) and 41 C.F.R. 102-3.170.

FILING DATE:

December 18, 2023

APPROVED:

[redacted]

Date

Director, NIEHS and NTP