III. Areas of Research Involving Human Pluripotent Stem Cells That Are Ineligible for NIH Funding

Areas of research ineligible for NIH funding include:

A. The derivation of pluripotent stem cells from early human embryos;

B. Research in which human pluripotent stem cells are utilized to create or contribute to a human embryo;

C. Research in which human pluripotent stem cells are combined with an animal embryo;

D. Research in which human pluripotent stem cells are used for reproductive cloning of a human;

E. Research in which human pluripotent stem cells are derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg;

F. Research utilizing human pluripotent stem cells that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; and

G. Research utilizing pluripotent stem cells that were derived from human embryos created for research purposes, rather than for infertility treatment.

IV. Oversight

A. Requests to the NIH for the funding of research involving human pluripotent stem cells should include documentation that the human pluripotent stem cells have been or will be derived in accordance with these Guidelines.

B. NIH will consider requests for funding for research utilizing human pluripotent stem cells from: (1) Awardees who want to use existing funds; (2) awardees requesting an administrative supplement; and (3) applicants or intramural researchers submitting applications or proposals.

C. NIH will consider funding requests for the derivation of human pluripotent stem cells from fetal tissue.

D. All applications shall be reviewed for scientific merit by: (1) An initial review group, in the case of new or competing continuation (renewal) applications; (2) by Institute or Center staff in the case of requests to use existing funds or applications for an administrative supplement; or (3) by the Scientific Director in the case of intramural proposals prior to submission to the HPSCRG.

E. The NIH will establish a Human Pluripotent Stem Cell Review Group (HPSCRG). This group will review documentation of compliance with the NIH Guidelines for Research Involving Human Pluripotent Stem Cells, and may, when warranted, seek further information in support of an application. The group will hold public review meetings when a funding request proposes the use of a newly derived line of human pluripotent stem cells that has not been reviewed previously by the HPSCRG in a public process or when an investigator proposes a protocol for the derivation of a new human pluripotent stem cell line from fetal tissue.

F. The HPSCRG will compile a yearly report that will include the number of applications and proposals reviewed and the titles of all awarded applications, supplements or administrative approvals for the use of existing funds, and intramural projects.

G. The HPSCRG will also serve as a resource for recommending to the Director, NIH any revisions to the NIH Guidelines for Research Involving Human Pluripotent Stem Cells.

Dated: November 29, 1999.

Harold Varmus,

Director, NIH.

[FR Doc. 99–31339 Filed 12–1–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences National Toxicology Program; Availability and Request for Comments on the Revised Guidance Document: Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)

Summary

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) prepared an initial version of the document, Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to the Interagency Coordinating Committee on the Validation of Alternative Method in May 1998. It has now been updated by ICCVAM to reflect experience gained with the first two test methods reviewed by ICCVAM in 1998–1999. Further modifications are anticipated as experience accrues. The document provides guidance to test method developers on the information needed by ICCVAM to evaluate the validation status of new or revised test methods at any stage of development and after the completion of validation studies. It includes a framework for organizing the information supporting the validity of a test method. The purpose of this notice is to announce the availability of the revised guidance document and to request comments and suggestions for further improvement.

Background

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was established in 1997 as a standing collaborative effort by the National Institute of Environmental Health Sciences (NIEHS) and 13 other regulatory and research agencies. ICCVAM coordinates issues within the Federal government that relate to the development, validation, acceptance, and national/international harmonization of toxicological test methods. The Committee's functions include the coordination of interagency scientific reviews of toxicological test methods and communication with outside groups throughout the process. The focus is on new and revised test methods that are applicable to multiple Federal agencies. Emphasis is given to test methods that provide for improved prediction of adverse human health or ecological effects, and that may reduce, refine, or replace animal use.

In the report, Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods *(http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/iccvam.html),* various stages were identified to move a proposed test method from concept to regulatory acceptance. One stage is the communication of a proposed test method by the sponsor to ICCVAM for consideration and review. The ICCVAM review process typically involves an assessment by an ICCVAM working group comprised of government scientists, followed by an independent peer review evaluation by an expert scientific panel. Following this review, ICCVAM forwards recommendations on the usefulness and limitations of the proposed test method to regulatory agencies. Based on their specific regulatory mandates, each Federal agency then makes a determination regarding the acceptability of the test method. If the test method is accepted, appropriate actions (e.g., revision of existing regulations, guidelines, and/or guidance documents) are taken to inform the regulated community.

The following Federal regulatory and research agencies participate in this effort:

Consumer Product Safety Commission

Department of Defense
Department of Energy
Department of Health and Human Services
  Agency for Toxic Substances and Disease Registry
  Food and Drug Administration
  National Cancer Institute
  National Institute for Occupational Safety and Health/Centers for Disease Control
  National Institute of Environmental Health Sciences
  National Institutes of Health
  National Library of Medicine
Department of the Interior
Department of Labor
  Occupational Safety and Health Administration
Department of Transportation
  Research and Special Programs Administration
Environmental Protection Agency

To support the activities of ICCVAM, NIEHS established the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). NICEATM provides a means of communication between test developers and Federal agencies during the development and validation process. NICEATM coordinates test method workshops, expert panel meetings, and independent scientific peer reviews, where appropriate and recommended by ICCVAM. Test method developers are encouraged to contact NICEATM (*http://iccvam.niehs.nih.gov*) prior to submission of proposed test methods for guidance on the submission and evaluation process.

Before a new or revised test method is used to generate information to support regulatory decisions, it must be: (a) Validated to determine its reliability and relevance for its proposed use and (b) determined to be acceptable by one or more regulatory agencies to fill a specific need. Criteria for validation and regulatory acceptance have been prepared and are described in the report, Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (*http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/iccvam.html*). Prior to the initiation of any test method development or validation efforts, sponsors are encouraged to consider the validation and acceptance criteria described in the report.

ICCVAM is issuing revised guidance for developers on organizing information needed to assess the validation status of a new or revised test method at any stage of development and/or following the completion of validation studies. The guidance document, Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM, is available online (*http://iccvam.niehs.nih.gov/doc1.htm*); additional copies can be obtained from the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM, contact information given below). The initial guidance document was first released in May of 1998. This version has been updated by ICCVAM to reflect experience gained with the first two test methods reviewed by ICCVAM in 1998–1999: the Local Lymph Node Assay (*http://iccvam.niehs.nih.gov/llnarep.htm*) and Corrositex® (*http://iccvam.niehs.nih.gov/corprrep.htm*).

The guidance document calls for the development of an ICCVAM submission for a given test method that describes the extent to which the validation and acceptance criteria have been addressed. It can also be used as a guide to prepare background review documents for methods that describe how validation criteria will be addressed in proposed studies. Background review documents serve as comprehensive compilations of all existing data for test methods. Completion of background review documents prior to the conduct of validation studies is encouraged to provide the basis for decisions on standardized protocols and design of the validation studies. In preparing test method submissions and background review documents, developers should use the outline provided to organize information. Submissions should be prepared well in advance of any peer review of the validation status of a method.

Test method developers are encouraged to consult with NICEATM and ICCVAM during submission preparation and throughout test method development, pre-validation, and validation. The objective of these interactions is to maximize the likelihood that adequate information will be generated to characterize the usefulness and limitations of a test method. If requested, ICCVAM will solicit interagency comments on proposed study designs and protocols. Validation study designs submitted to ICCVAM for comment should describe the basis for the proposed protocol and proposed validation studies. The completed submission is then used to assess the method's validation status through an independent ICCVAM peer review process. This process enhances the likelihood that agencies will be provided with sufficient information to determine a method's usefulness and limitations for meeting regulatory needs.

Request for Comments

Interested parties are encouraged to submit comments on the ICCVAM guidance document: Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM. Comments should include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any). Comments may be submitted anytime; however, those received within 60 days from the appearance of this notice will be considered by ICCVAM for a possible revision in early 2000. The document is available on the Internet at *http://iccvam.niehs.nih.gov/doc1.htm* or may be requested from NICEATM, MD–EC–17, P.O. Box 12233, Research Triangle Park, NC 27709; 919–541–3398 (phone); 919–541–0947 (FAX); and *ICCVAM@niehs.nih.gov* (e-mail). Comments should be directed to the ICCVAM Co-Chairs, Dr. William S. Stokes 919–541–7997 (phone); 919–541–0947 (fax); *stokes@niehs.nih.gov* (e-mail) or Dr. Richard Hill 202–260–2894 (phone); 202–260–1847 (fax); *Hill.Richard@epamail.epa.gov.*

Dated: November 24, 1999.

Samuel H. Wilson,

Deputy Director, NIEHS and NTP.

[FR Doc. 99–31342 Filed 12–1–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Request for Standing Review Committee Nominations

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Request for Standing Review Committee Nominations.

SUMMARY: The purpose of this notice is to invite qualified people to serve as peer reviewers for the Substance Abuse and Mental Health Services Administration's (SAMHSA's) standing committees to review competitive grant and cooperative agreement applications.

SUPPLEMENTARY INFORMATION: The Substance Abuse and Mental Health Services Administration (SAMHSA) and its three Centers, the Center for Mental Health Services (CMHS), the Center for Substance Abuse Prevention (CSAP), and the Center for Substance Abuse Treatment (CSAT), depend on the