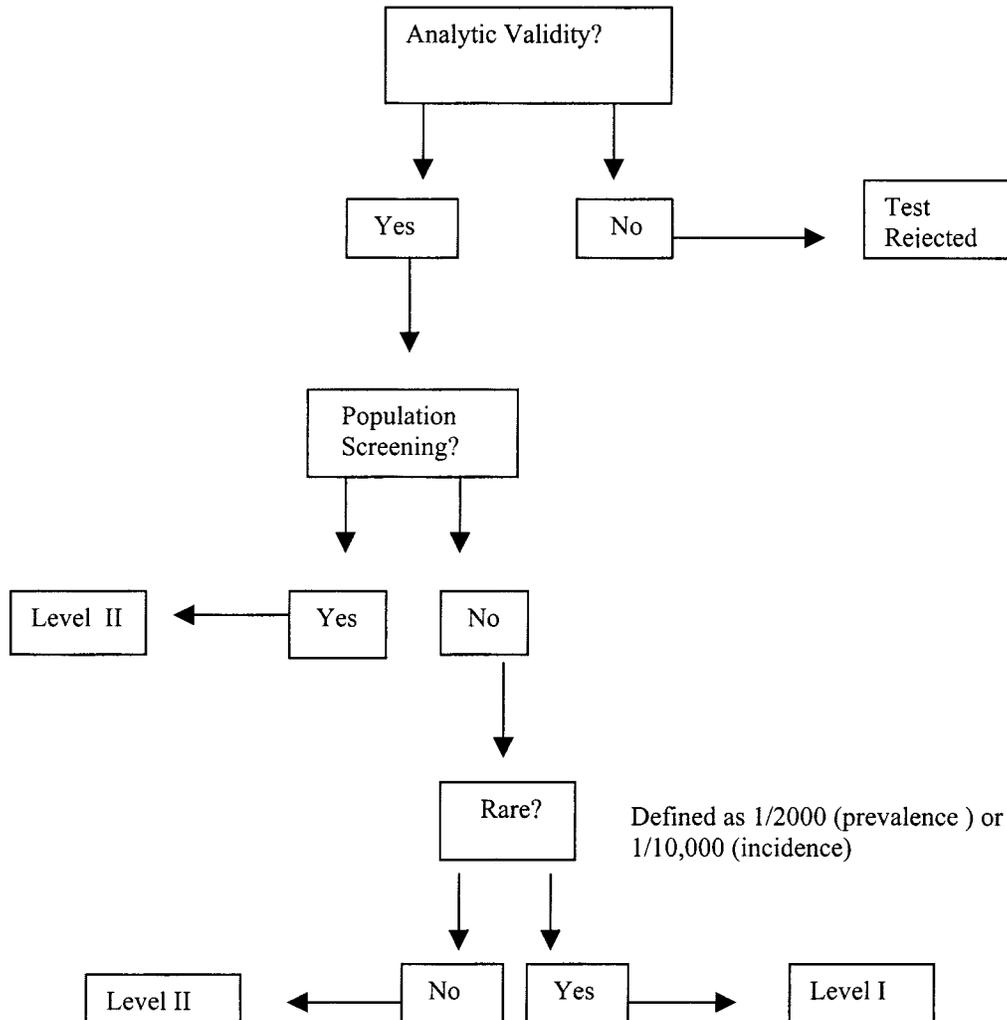


Proposed Test Classification Scheme for Determining Level of Review of Genetic Tests



[FR Doc. 00-31218 Filed 12-6-00; 8:45 am]
 BILLING CODE 4140-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Meeting of the National Human Research Protections Advisory Committee

AGENCY: Office of Public Health and Science, Office for Human Research Protections, HHS.

ACTION: Notice of first meeting.

SUMMARY: Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Human Research Protections Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below. Individuals planning on attending the meeting and who want to ask questions must submit their questions in writing in advance of the meeting to the contact person listed below.

DATES: The Committee will hold its next meeting on December 20-21, 2000. The meeting will convene from 8:30 a.m. to its recess at 4:30 p.m. on December 20th and resume at 9 a.m. to 3 p.m. EST on December 21st.

ADDRESSES: Bethesda Marriott-Pooks Hill, 515 Pooks Hill Road, Bethesda, Maryland 20814, (301) 897-9400.

FOR FURTHER INFORMATION CONTACT: Mr. Garey Rice, Administrative Officer,

Office for Human Research Protections, 6100 Executive Boulevard, Room 310B (MSC 7507), Rockville, Maryland 20892-7507, (301) 402-6003. The electronic mail address is: gr66s@nih.gov.

SUPPLEMENTARY INFORMATION: The National Human Research Protections Advisory Committee was established on June 6, 2000 to provide expert advice and recommendations to the Secretary of HHS, Assistant Secretary for Health, the Director, Office for Human Research Protections, and other departmental officials on a broad range of issues and topics pertaining to or associated with the protection of human research subjects.

Dated: November 30, 2000.

Greg Koski,

Director, Office for Human Research Protections.

[FR Doc. 00-31162 Filed 12-6-00; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Final PHS Policy for Instruction in the Responsible Conduct of Research

AGENCY: Office of the Secretary, HHS.

ACTION: Announcement of Final "PHS Policy for Instruction in the Responsible Conduct of Research."

SUMMARY: The Office of Research Integrity (ORI) in collaboration with the Agency Research Integrity Liaison Officers for each of the Public Health Service (PHS) Operating Divisions, announced on July 21, 2000, (65 FR 45381) the availability for public comment of a Draft PHS Policy for Instruction in the Responsible Conduct of Research (RCR) for extramural institutions receiving PHS funds for research or research training. The comment period closed on September 21, 2000.

In response to public comment, ORI and the PHS agencies have made substantial revisions to the draft policy and hereby announce the final "PHS Policy on Instruction in the Responsible Conduct of Research." The final policy, a summary of comments and revisions to the policy made in response thereto, a list of available resources for RCR education programs, and Frequently Asked Questions and Answers on the policy are located at <<http://ori.hhs.gov>> or may be obtained from ORI at 5515 Security Lane, Suite 700, Rockville, Maryland 20852, Phone: 301-443-5300. Public comments on the draft policy are available for public inspection on ORI's premises from Monday-Friday between 9 a.m. and 5 p.m. Please call ORI for an appointment time.

FOR FURTHER INFORMATION CONTACT: Barbara Bullman, J.D., Senior Program Analyst, Division of Education and Integrity, Office of Research Integrity, Rockwall II, Suite 700, 5515 Security Lane, Rockville, MD 20852, 301-443-5300.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 00-31152 Filed 12-6-00; 8:45 am]

BILLING CODE 4150-31-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1504]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 2000 (65 FR 57192), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0454. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-31150 Filed 12-6-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-667]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Alternate Quality Assessment Survey; *Form No.:* HCFA-667 (OMB# 0938-0650); *Use:* The HCFA-667 is used in lieu of an onsite survey for those Clinical Laboratories Improvement Amendment (CLIA) laboratories with good performance as determined by their last onsite survey. This form is designed to determine current CLIA compliance as well as prepare laboratories for future onsite surveys; *Frequency:* Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, State, Local or Tribal Government; *Number of Respondents:* 4,000; *Total Annual Responses:* 2,000; *Total Annual Hours:* 10,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.