

Fishers Lane, Room 10-42, Rockville, MD 20857, (301) 443-1644.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs; 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards, National Institutes of Health, HHS)

Dated: November 2, 1998.

Anna Snouffer,

*Acting Committee Management Officer,
National Institutes of Health.*

[FR Doc. 98-29985 Filed 11-6-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-8 (J3).

Date: December 2, 1998.

Time: 3 PM to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20982 (Telephone Conference Call).

Contact Person: Roberta J. Haber, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS-37, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-8898.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 2, 1998.

Anna Snouffer,

*Acting Committee Management Officer,
National Institutes of Health.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure

AGENCY: Office for Protection from Research Risks, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: On November 10, 1997, the Office for Protection from Research Risks (OPRR), in consultation with the Food and Drug Administration (FDA), requested written comments relating to the proposed republication of the list that identifies certain research activities involving human subjects which may be reviewed by the Institutional Review Board (IRB) through the expedited review procedure authorized in 45 CFR 46.110. The comment period closed on March 10, 1998. OPRR and FDA received a combined total of 108 comments. After a review of the comments, OPRR and FDA are now simultaneously publishing identical revised lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure.

EFFECTIVE DATES: The revised list is effective as of November 9, 1998.

FOR FURTHER INFORMATION CONTACT: Michele Russell-Einhorn, Director of Regulatory Affairs, Office for Protection from Research Risks (OPRR), National Institutes of Health, 6100 Executive Blvd., Suite 3B01, Rockville, MD 20892-7507 or telephone (301) 435-5649 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the **Federal Register** on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies¹ and institutions

¹ The following agencies have adopted the Common Rule: Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Consumer Product Safety Commission,

receiving support from those agencies for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research involving human subjects by an IRB with limited exceptions, informed consent of all research subjects; and formal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (HHS) codification of the Federal Policy can be found at 45 CFR Part 46, Subpart A.

Section _____ .110 of the Federal Policy provides for expedited review procedures for certain categories of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the expedited review list as needed after consultation with the departments and agencies that are subject to the Federal Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 (46 FR 8392, 46 FR 8980). It listed categories of research that could be reviewed by the IRB through an expedited review procedure. The FDA also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists have differed slightly, in that item nine (9) on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR 56.110.

The comments received in response to the OPRR and FDA proposed revision of the 1981 expedited review list that was published on November 10, 1997 (62 FR 60607) overwhelmingly supported the proposed revision of the list. Three commenters suggested that there should be no expedited review available at all. OPRR and FDA disagree with these three comments and believe that expedited review is an appropriate part of the IRB review process. In addition, a deletion of the expedited review process would require a regulatory change to Section 110 which is beyond the scope of this revision. Several commenters suggested changing the exemptions found at Section 101(b), a topic also outside the scope of this revision.

International Development Cooperation Agency- Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Defense, Department of Health and Human Services, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, National Science Foundation, Department of Transportation, Central Intelligence Agency, Social Security Administration.

The following discussion summarizes the 108 comments received and the resulting changes. In response to over forty comments, the introductory paragraph to the 1981 list has been reformatted into five general principles. The parenthetical in the introductory sentence in the 1981 list "(carried out through standard methods)" has been deleted in response to comments that this phrase served no particular purpose.

The reformatted general principles are set forth in paragraphs (A) through (F). Paragraph (C) makes it clear that the IRB must consider, for all categories, whether identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. OPRR does not consider this to be a new or additional consideration. These concerns have always been an implicit part of the determination of whether an activity is a minimal risk activity. The words "insurability" and "be stigmatizing" have been added and are designed to serve as an aid to IRBs when genetic research is presented for review in an expedited review procedure. These changes were made in response to concerns raised in several comments that genetic testing may have consequences beyond those normally considered by the IRB.

Consistent with two comments, paragraph (D) prohibits expedited review for classified research involving human subjects. This is also in accordance with a March 27, 1997 Presidential Memorandum which proposed the elimination of an expedited review procedure for all classified research involving human subjects.

Paragraph (E) serves as a reminder to IRBs that informed consent and expedited review are two totally separate issues. This responds to concerns that allowing an increase in the scope of research eligible for expedited review would result in more waivers of informed consent. Research reviewed pursuant to an expedited review procedure is not necessarily eligible for waiver or alteration of informed consent. All research, whether reviewed by the full IRB or by way of expedited review, must conform to the applicable requirements for obtaining and documenting prospective informed consent, unless the research meets the

conditions for waiving, excepting, or otherwise altering the informed consent requirements that are set forth in 45 CFR 46.116 and 117, 21 CFR 50.23 and 24, or 21 CFR 56.109(c).

Category one (1) preserves category ten (10) on the 1981 list. It also contains a new sentence that addresses the availability of the expedited review procedure for marketed drugs in research as well as specific citations in response to five comments that raised questions about these issues.

The following changes have been made to category two (2) in response to over 45 comments which supported enhanced expedited review concerning collection of blood, but which suggested certain refinements. Collection of blood now includes finger stick, heel stick, or ear stick as well as venipuncture. The four proposed subcategories were recombined as two separate subcategories. The critical issues to be considered by the IRB include weight, physical condition, and amount of blood to be collected. The first subcategory (a) concerns healthy nonpregnant adults. The second subcategory, (b), concerns all other adults and children. For this second subcategory, the IRB will need to make certain judgments including: consideration for the age, weight, and health of the subjects in light of the amount of blood to be collected, the frequency with which it will be collected, and the collection procedure. The final sentence of subcategory (b) reads: For these individuals, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more than 2 times per week. While an expedited review of research involving pregnant women is permissible under the revised section, this last sentence makes it clear that the amount of blood that can be drawn is subject to limitations greater than those on healthy nonpregnant adults. Also, in response to public comment, the phrase "medically vulnerable adults" that was proposed in November 1997 has been deleted.

In response to more than 24 comments, category three (3) (previously category one (1) in the 1981 list) has been changed in the following manner. The words "noninvasive means" have been added to clarify the manner of collection of research materials; and, the procedures outlined are set out as examples to the IRB of the types of procedures that could fall within this category.

Categories four (4) and five (5) on the proposed list have been combined into one new category five (5) on the 1998 list. This new section is added in

response to comments that raised questions about the relationship of proposed categories four (4) and five (5) to exempt research and about separating out existing and prospectively collected materials. The term "nonresearch purposes" was maintained in new category five (5) to describe the origins of the research materials. An explanatory note has been added to categories five (5) and seven (7) to clarify that some research described in these categories may be exempt from IRB review under 45 CFR 46.101(b) of the HHS regulations for the protection of human subjects (there is no comparable exemption provision in the FDA regulations). Thus, the listing of those categories refers only to nonexempt research.

Category six (6), proposed in November 1997, is now category four (4) on the 1998 list and addresses the collection of data through noninvasive procedures. The words "noninvasive procedures" have been added and apply to all procedures that would fall within this category. Because of several comments that raised concerns about MRIs and the use of anesthesia and sedation, expedited review would not be allowed for any procedure employing either of these. In response to more than 24 comments, this category lists procedures as examples for the IRB of the types of procedures that would qualify for expedited review.

Category seven (7) on the list proposed in November 1997 is now category six (6) on the 1998 list and deals with the collection of data from voice, digital, or image recordings. The qualification that was proposed in November of 1998 requiring consideration of certain risks to subjects is now a general guiding principle. It has been incorporated into the general Applicability section in response to several comments that questioned limiting this consideration to this type of research.

Category eight (8) on the proposed list is now category seven (7) on the revised list. In response to over 30 comments, the following changes have been made. The word "stress" has been deleted; the subsections in the proposed list have been combined; research on oral history has been included in response to approximately six comments; and specific research and research techniques have been noted. As in new category six (6), the qualification that requires consideration of certain kinds of risks to subjects has been deleted as it is now a general guiding principle for the entire list.

Category nine (9) on the proposed list received more than 50 comments

explicitly applauding this additional category. It has been divided into two categories. Category eight (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by the convened IRB, could undergo subsequent continuing review by the expedited review procedure. New category nine (9) concerns continuing review of research that is not greater than minimal risk but had to undergo initial review by a convened IRB because it did not meet the criteria of categories two (2) through seven (7) on the list.

Certain other minimal changes have been made for editorial purposes or to clarify certain words that were used in the proposed list. Accordingly, the list of categories of research which may be reviewed by the IRB through the expedited review procedure is amended as set forth below.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure¹

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children,² considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e)

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social

behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Gary B. Ellis,

Director, Office for Protection from Research Risks.

[FR Doc. 98-29749 Filed 11-6-98; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-3918-N-16]

Privacy Act of 1974; Notice of a Computer Matching Program

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice of a Computer Matching Program—HUD and the Internal Revenue Service (IRS).

SUMMARY: In accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100-503), Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818 (June 19, 1989)), and OMB Bulletin 89-22, "Instructions on Reporting Computer Matching Programs to the Office of Management (OMB), Congress and the Public," the Department of Housing and Urban

Development (HUD) is issuing a public notice of its intent to conduct a computer matching program with the Internal Revenue Service (IRS). Under the terms of the agreement IRS agrees to disclose to HUD taxpayer mailing addresses as authorized by the Commissioner or her delegate pursuant to Section 6103(m)(2) of the Internal Revenue Code (IRC) for use in locating individuals to collect or compromise Federal claims in accordance with 31 United States Code (U.S.C.) 3711, 3717 and 3718. This program is called the Taxpayer Address Request Program (TAR). It was established by the IRS to facilitate the retrieval of taxpayer mailing addresses from the individual Master File on a volume basis. The volume of addresses and the method in which the IRS maintains the information make computer matching the most feasible method of extracting the data for disclosure to other agencies. Using the TAR computer matching program, current addresses can be obtained from the IRS within a one-week period, thereby avoiding the expenditure of substantial Federal resources in the manual execution of a matching process or investigations by a large workforce to ascertain the current address of individuals against whom the agency has a claim or indebtedness.

DATES: Effective date: Computer matching is expected to begin 40 days after publication of this notice in the **Federal Register** (December 21, 1998), unless comments are received which will result in a contrary determination, or 40 days from the date a computer matching agreement is signed, whichever is later.

COMMENTS DUE BY: December 9, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410.

Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR PRIVACY ACT INFORMATION AND FOR FURTHER INFORMATION FROM RECIPIENT

AGENCY CONTACT: Jeanette Smith, Departmental Privacy Act Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone number (202) 708-2374 or FAX (202) 708-3577. (These are not toll-free numbers.)

FOR FURTHER INFORMATION FROM SOURCE AGENCY CONTACT: M.R. Taylor, Internal Revenue Service, Office of FedState Relations, 1111 Constitution Avenue, NW, Washington, DC 20224, telephone number (202) 622-5145 or Fax (202) 622-3041. (These are not toll-free numbers.)

Reporting

In accordance with Pub. L. 100-503, the Computer Matching and Privacy Protection Act of 1988, as amended, and Office of Management and Budget (OMB), Bulletin 89-22, "Instructions on Reporting Computer Matching Programs to the Office of Management and Budget (OMB), Congress and the Public;" copies of this notice and report are being provided to the Committee on Government Reform and Oversight of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget.

Authority

The matching program will be conducted under the authority of section 6103(m)(2) of the Internal Revenue Code and 31 United States Code 3711, 3717 and 3718.

Objectives to be Met by the Matching Program

HUD expects that this computer matching program will enable it to quickly and effectively identify and locate individual debtors, and to obtain current mailing addresses of defaulted debtors.

Records to be Matched

HUD will utilize its system of records entitled, Accounting Records, HUD/Dept-2. HUD will submit approximately 40,000 records annually of individuals with outstanding Federal debts for matching purposes. These records are extracted from the Privacy Act system of records, HUD/Dept-2, Accounting Records, maintained in the following programs and automated systems: (1) Title I—Debt Management Collection Systems; (2) Section 312—Loan Mortgage System; and (3) Departmental Claims—Delinquent Debt Control System. The IRS will extract taxpayer address information from Privacy Act System of Records: Individual Master File, Treas/IRS 24.030, maintained at the Martinsburg Computing Center, Martinsburg, WV. This file contains approximately 20 million records of taxpayers who have filed U.S. Individual Income Tax returns.